

## Clinical Study Protocol

# Novel uses of healthcare technology for individuals with mild to moderate hip or knee osteoarthritis: The technology, exercise and activity prescription for enhanced mobility (TEAM) study randomized controlled trial protocol



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## ABSTRACT

**Objectives:** Patient education, physical activity, and exercise are recommended as first-line treatments for mild to moderate hip and knee osteoarthritis (OA). We developed two novel healthcare interventions: an electronic medical record-embedded physical activity prescription tool (PARx) for physicians, and a free, online educational platform (Joint Management (JM)) with exercise programming and optional telerehabilitation with a physiotherapist for patients. **Objectives:** 1) Determine the effectiveness of PARx ± JM on patient-reported outcomes, physical activity levels, and performance-based functional outcomes in individuals with mild to moderate hip or knee OA, versus usual care; 2) evaluate engagement and adherence to PARx + JM; and 3) explore the feasibility of PARx and PARx + JM.

**Registration:** NCT04544904.

**Methods:** Randomized controlled trial (type 1 hybrid implementation effectiveness). We will recruit 339 (113/group) participants ≥40 years old with mild to moderate hip or knee OA and randomize them into three groups: PARx, PARx + JM, or control (usual care). Follow-up appointments will be completed at 2-, 6-, and 12-months. **Primary outcome:** Knee Injury/Hip Disability and OA Outcome Score. **Secondary outcomes:** physical activity levels, anthropometric measurements, physical function, and other patient-reported outcomes. We will assess intervention feasibility and hold focus groups with patients and providers to explore perceptions of the interventions.

**Conclusion:** Two novel healthcare interventions will be used to provide physical activity and exercise programming for individuals with mild-moderate knee and hip OA. This study will allow us to determine the effectiveness of these interventions on patient-reported outcomes, physical activity levels, and performance-based functional outcomes.

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## 1. Introduction

Osteoarthritis (OA) is the leading cause of disability worldwide and affects more than 4.4 million Canadians [1]. Current evidence-based guidelines for OA management recommend education, physical activity, and exercise, in addition to weight loss (where appropriate) as first-line treatments. Unfortunately, practice trends are not consistent with these guidelines. Nearly half of the patients referred for total knee arthroplasty were found to be best suited for non-operative treatments, many of whom had not tried recommended first-line treatments before being referred to orthopaedic surgeons [2,3]. Long waitlists to access total joint arthroplasty (including hip and knee arthroplasty) are already a longstanding issue in Canada, further exacerbated by backlogs due to COVID-19 [4,5]. It is therefore essential to optimize the implementation of evidence-based guidelines at the primary care level before considering surgical referrals.

As one of the evidence-based first-line treatments, physical activity can reverse or help manage the symptoms of many chronic diseases, including OA [6]. Despite proven benefits, 80 % of Canadian adults do not meet the national physical activity guidelines for health [7], and aerobic exercise interventions in knee OA may not meet recommended dosages [8]. Physicians can play a cost-effective role in addressing the global physical inactivity ‘pandemic’ [9], but only 25 % of physicians counsel their patients on physical activity [10]. Interestingly, 93 % of patients agree that, “If my doctor advised me to exercise, I would follow their advice” [11]. Systematic barriers to physician-prescribed physical activity include lack of time, limited training in physical activity counselling, and a perceived inability to change patient behaviour [12]. Health screening and monitoring via digital health tools can improve physical activity levels [13] and is highly accepted by patients [14]. Additionally, digitally delivered exercise and education can improve pain and physical function in people with knee OA [15]. While an e-health tool has been developed and tested for feasibility to support general physical activity counselling by physicians during patients’ periodic health review [16], it unknown whether digitally assisted physical activity counselling by physicians can influence clinical outcomes and objectively measured physical activity in patients with OA.

Education and exercise programs, delivered by a physiotherapist, are effective in improving pain and physical function among individuals with knee [17–19] and hip [20,21] OA, and patients presenting with knee and hip OA are more alike than different, with improvements seen in both groups after an exercise intervention [22]. However, two of the most significant barriers to accessing these programs are the associated costs and accessibility to attend the exercise sessions (proximity to facility, remote/rural communities, etc.) [23]. Online platforms that link patients with appropriate education, self-management strategies, and exercise programming may represent additional benefits to prescribed physical activity [14]. However, more research is required to understand the full impact of these types of delivery models.

We developed two interventions to address these gaps in knowledge. The first is a customized physical activity prescription tool (PARx) for individuals with OA based on our previously developed and evaluated e-health tool [24]. This supports physical activity counselling by physicians through embedding a personalized prescription and resources into patients’ electronic medical records (EMR) to be administered by the physician. This tool will be applied for the first time in a population with a specific chronic condition, with or without access to a free online platform (web/mobile enabled) for patients with hip and knee OA. The second is a virtual, educational resource, Joint Management (JM), which provides information on evidence-based treatment options, self-management, and online access to exercise programming and may yield additional benefits.

## 2. Objectives

Our primary objective is to determine the effectiveness of PARx ± Joint Management (JM) on patient-reported outcomes (PROs) of physical

function (i.e., Knee Injury/Hip Disability OA Outcome Score (KOOS/HOOS)), and measures of pain, joint stiffness, disability, quality of life, disease knowledge, self-efficacy, depression, fatigue, and physical activity levels in individuals with mild to moderate hip or knee OA at 12 months versus usual care. Our primary KOOS/HOOS subscale will be Activities of Daily Living (ADL) Function. Our secondary objectives are: 1) to evaluate engagement and adherence of PARx and JM in individuals with mild to moderate hip or knee OA, and 2) to understand the feasibility of PARx and JM for application in a broader range of primary care settings by evaluating perceptions of and experience with the technologies using qualitative focus groups. We hypothesize that access to technology-facilitated physical activity prescription and access to JM will 1) improve patient-reported outcomes (pain, joint stiffness, disability, quality of life, disease knowledge, self-efficacy, depression, and fatigue), 2) increase PA levels, and 3) improve performance-based functional outcomes (30-s chair stand test and the 40-m fast-paced walk test) in individuals with mild to moderate hip or knee OA compared to usual care. Furthermore, JM will 4) improve engagement, adherence, and implementation feasibility compared to PARx alone. Overall, we hypothesize that 5) access to JM will result in a greater improvement than PARx alone.

## 3. Materials and methods

We designed a randomized controlled superiority trial to determine the effectiveness of PARx ± JM on PROs, physical activity levels, and performance-based functional outcomes in individuals with mild to moderate hip or knee OA versus usual care at 2-, 6-, and 12-months. This study was registered with [ClinicalTrials.gov](https://clinicaltrials.gov) (NCT04544904) and received ethical approval from Western University’s Research Ethics Board (ID# 116604, Protocol Version 8, December 9, 2021) and Lawson Health Research Institute (ID# 10428). The section below details the items on the CONSolidated Standards of Reporting Trials (CONSORT) checklist [25]. A visual of study flow can be seen in Fig. 1.

## 4. Participants and interventions

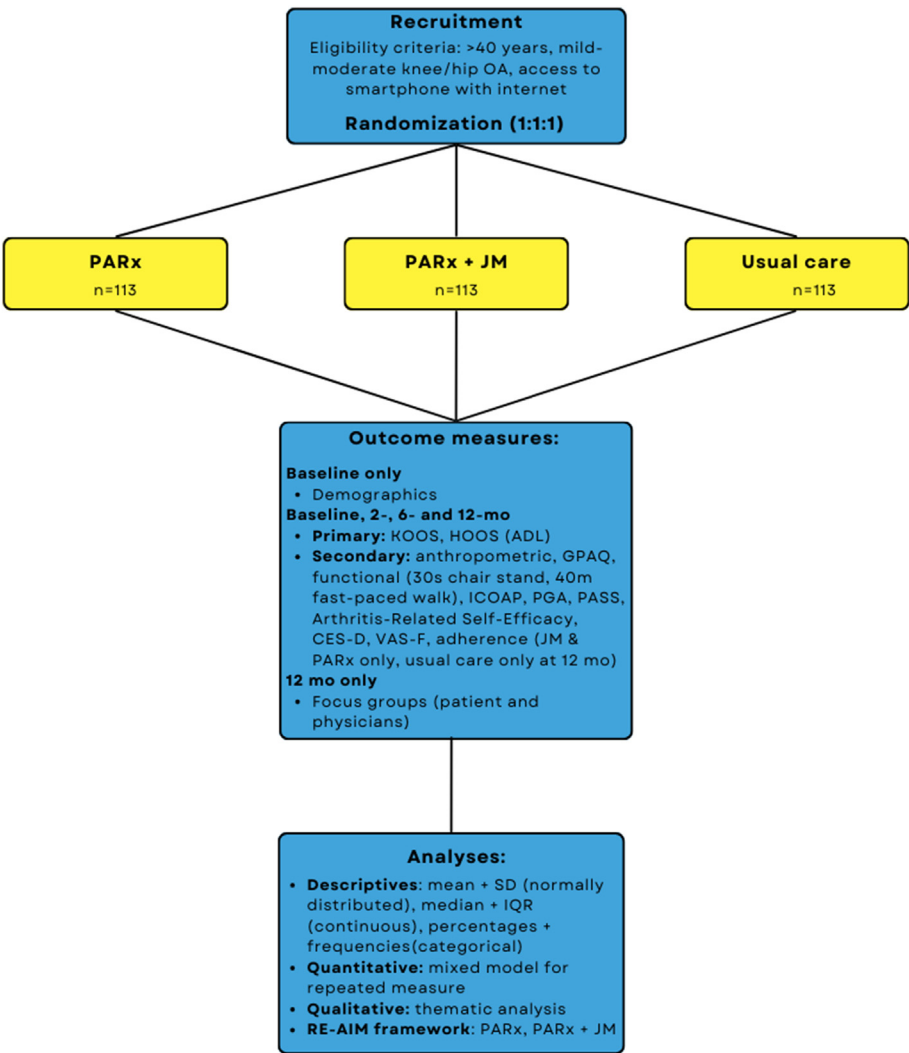
### 4.1. Study setting

The study will be conducted in a research-intensive sport medicine centre (Fowler Kennedy Sport Medicine Clinic) staffed by primary care sport and exercise medicine physicians, orthopaedic surgeons, and physiotherapists on the Western University campus in the medium-sized city of London, Ontario, Canada. Clinical research staff will oversee recruitment and all study-related activities.

All physicians administering the PARx intervention are practicing sport and exercise medicine physicians at the same clinic. Once recruited, they will be trained by the study coordinator and principal investigator (JT) on the delivery of the PARx intervention and study protocol.

### 4.2. Eligibility criteria

Individuals will be eligible for the study if they: (1) are aged 40 years or older; (2) have mild to moderate knee or hip OA based on clinical or radiographic criteria [26] as diagnosed by a physician; and (3) have access to a smartphone with internet access. Patients with a total or partial joint replacement on the contralateral side may be eligible for participation if that joint is deemed to be stable (at least one-year post-operation without complications). Furthermore, for individuals with bilateral OA, the most symptomatic joint (as determined by participant-reported pain and clinician assessment) will be designated as the index joint for analysis. Individuals will be excluded from the study if they: (1) are deemed a surgical candidate for joint replacement surgery within one year or the study period by an orthopaedic surgeon; (2) have inflammatory arthritis (rheumatoid, psoriatic, or disease-modifying anti-rheumatic drug exposure); (3) have unstable medical conditions



**Fig. 1.** TEAM recruitment, assessment and analyses plan. osteoarthritis (OA); physical activity prescription tool (PARx); Joint Management (JM); month (mo); Knee Injury and Osteoarthritis Outcome Score (KOOS); Hip Injury and Osteoarthritis Outcome Score (HOOS); activities of daily living (ADL); Global Physical Activity Questionnaire (GPAQ); second (s); meter (m); Intermittent and Constant Osteoarthritis Pain (ICOAP); Patient Global Assessment of Health Status (PGA); Patient Acceptable Symptom State (PASS); Center for Epidemiological Studies Depression Scale (CES-D); Visual Analog Scale to evaluate Fatigue (VAS-F); standard deviation (SD); inter-quartile range (IQR).

that might preclude physical activity prescription (i.e., new or uncontrolled arrhythmia, resting or uncontrolled tachycardia, resting systolic blood pressure >180 mmHg or diastolic blood pressure >100 mmHg, symptomatic hypotension, unstable/crescendo angina, acute or unstable heart failure, unstable or uncontrolled diabetes, acute febrile illness); (4) are not able/willing to be followed up for the study period; or (5) cannot communicate (read and write) in English.

4.3. Interventions

4.3.1. The PARx intervention

The PARx intervention involves an automated algorithm that considers patients' current physical activity level, risk factors/comorbidities, and readiness for change and embeds a personalized prescription and resources into participants' electronic medical records (EMR) (PS Suite EMR version 5.22.505, [27]). The current activity level is determined by the participant's total moderate-to-vigorous physical activity (MVPA) minutes per week using the Global Physical Activity Questionnaire [28] (GPAQ). Activity levels are categorized as low (<20 min), moderate (20–149 min), or high (≥150 min). Readiness for change categories is based on the Health Action Process Approach: pre-intender, intender, and actor [29]. Individuals engaging in 150 min of MVPA or more per week by default are defined as actors. Those acquiring fewer than 150 min of MVPA are categorized as an intender or pre-intender by answering yes or no, respectively, to the following question: “I have made the

decision to take part in a new kind of physical activity or increase my amount or intensity of physical activity soon”. Based on their responses, participants are allocated to a specific toolkit as pre-intender, intender, or actor (see Table 1).

Each toolkit contains the prescription as well as tailored information (e.g., activity planning, overcoming obstacles, resources, participant handout) to help participants either plan, initiate, and/or maintain physical activity (Additional file 1). The prescription page contains auto-populated information about the participant including their name, current activity levels, motivation for engaging in physical activity, and perceived barriers to physical activity.

When the participant arrives for their appointment, the physician will open the assigned toolkit to review with the participant. In a 15-min

**Table 1**  
PARx toolkit status rating.

Toolkit	Weekly minutes of MVPA	Participant's response to: “I have made the decision to take part in a new kind of physical activity or increase my amount or intensity of physical activity soon.”	Status
A	<20 min	No	Pre-intender
B	20–149 min	No	Pre-intender
C	>20 min	Yes	Intender
D	20–149 min	Yes	Intender
E	≥150 min	Yes or No	Actor

appointment and through a shared decision-making approach, the physician will counsel the participant on OA and physical activity and provide the physical activity prescription with an agreed-upon goal regarding the number of minutes of physical activity per day, the type(s) of activity (e.g., walking, swimming), and the frequency per week that the participant will engage in until the next visit, along with any other special considerations. The physician will sign and print a hard copy of the prescription and PARx toolkit for the participant to keep. A copy of the PARx will also be uploaded to the participant's EMR. Following the PARx, the research team will provide participants access to the smartphone application (*myrecovery app*, [www.msk.ai/patients](http://www.msk.ai/patients)) [30], which will capture participants' step count information.

Participants receiving the PARx intervention will be immediately scheduled for three follow-up appointments at 2-, 6-, and 12 months following the baseline visit. At each visit, participants will respond to the same questions to identify the appropriate PARx toolkit and receive 15 min of physical activity counselling from their physician.

#### 4.3.2. The JM intervention

Participants randomized to the PARx + JM intervention arm will receive the PARx intervention as described above as well as access to JM ([www.jointmanagement.ca](http://www.jointmanagement.ca)) [31], a free, web-based platform, which includes evidence-based resources focusing on non-operative management strategies for individuals with mild to moderate hip and/or knee OA. The platform includes exercise programming (e.g., videos, pictures, and descriptions of the exercises), written education, and infographics to promote self-management and evidence-based therapies for OA (e.g., benefits of exercise, lifestyle modifications, nutrition, injections). JM was developed by OA researchers, orthopaedic surgeons, sports medicine physicians, and physiotherapists. JM also provides an optional component including virtual appointments with a registered physiotherapist for further individualized support, recommendations, and exercise programming for a fee (approximately 92 USD for initial assessment, 68 USD for follow-up). Participants in this arm will receive a unique login and password for the JM website following their baseline visit. This group will have unlimited access to JM for the duration of the study. Participants in this group will respond to additional questionnaires related to their engagement with (biweekly for the first two months, then monthly for 10 months) and perceptions of (2-, 6-, 12-month follow-ups) the JM website (see below for further details).

#### 4.3.3. Usual care

All participants, including the group of participants randomized to the control arm, will continue to receive usual clinical care which includes generic advice regarding non-surgical options. Participants will visit the clinic to complete the clinical evaluation and functional assessments with the research team and receive access to the *myrecovery app* to track their step count information. Participants will have the option of completing study questionnaires prior to their appointment using a unique link sent to their email or during their clinic visit. Participants in the control group can seek treatment during the study period at their discretion (i.e., physical therapy, exercise programs, etc.). After the 12-month follow-up, participants in the control arm will be offered physical activity counselling by a physician, and all groups will receive access to JM.

Participants in all treatment arms may pursue any nonsurgical concomitant care for OA (i.e., topical creams, braces, injections, or pain/anti-inflammatory medications). Research staff will record all reported co-interventions and total physical activity minutes during study visits, which may be controlled with sensitivity analyses as appropriate. To enhance participant retention and adherence, the study staff will be in regular contact with participants by phone and email with reminders about appointments and completion of online surveys. In the rare event that a physician is unable to see a participant at the time of their appointment, the physical activity counselling may occur by telephone and the PARx will be sent to the participant by email or mail depending on their preference. Study staff will also provide verbal instructions on

how to complete online surveys, download and use the *myrecovery app*, and access the JM website. If necessary, study staff will offer in-person demonstrations during study visits and follow up with written instructions. Parking fees will be waived for any study-related visit to the clinic. If a participant chooses to discontinue or withdraw from the intervention after the baseline visit, we will ask if they can continue completing the online surveys (PROs) only for the remainder of the study.

### 5. Outcome measures

Baseline demographic data will include age, sex, gender, racial/cultural group(s), occupation, education, household income, medical history (e.g., smoking status, alcohol consumption, lower body trauma/injury, family history of OA, and present or past medical conditions), status of the contralateral limb and history of competitive sport.

The following outcome measures will be collected at baseline, 2-, 6- and 12-month visits (see Table 2).

#### 5.1. Primary outcomes

The primary outcome is the KOOS and HOOS, both validated and reliable PROs that are widely used and accepted in research [32,33]. Participants will report the location of their OA (knee or hip) and complete the corresponding outcome questionnaire. If they have OA in both joints, the most symptomatic will be the index joint. Participants report their perceptions of their knee/hip OA across five domains (pain, symptoms, function in ADL, function in sport and recreation, and knee/hip-related quality of life) via Likert-scale type questions [32,33], however, the ADL subscale will be the primary outcome of interest. The questionnaires take approximately 10 min to complete. The primary comparison will be the scores between treatments at 12 months.

#### 5.2. Secondary outcomes

1. Anthropometric measurements: At each clinic visit, a trained research staff member will measure mass (nearest 0.01 kg), and abdominal circumference (nearest 0.1 cm) according to World Health Organization recommended practices [34]. Height (nearest 0.1 cm) is measured at the baseline visit only. Participant's body mass index will be calculated.
2. Physical activity levels: Participant physical activity levels will be measured using the GPAQ, a validated 16-item questionnaire developed by the World Health Organization to collect information on physical activity in three domains (i.e., work, travel, and recreational activities) [28,35]. A member of the research team will discuss the Global Physical Activity Questionnaire (GPAQ) with the participants in person at each clinic visit. Answers will be checked and confirmed with the participant to ensure data is reported correctly. The analyses of GPAQ data will follow the process outlined in the GPAQ Analysis Guide. Objective physical activity levels (steps per day) will be collected using smartphone accelerometer data via the *myrecovery app* and extracted weekly. Participants will be encouraged to take their smartphone with them during physical activity. Smartphone accelerometer data is accurate and valid for step counts during various walking speeds [36].
3. Performance-based functional outcomes: Two Osteoarthritis Research Society International recommended assessments to evaluate physical function in participants' knee/hip OA will be administered: the 30-s chair stand test and the 40-m fast-paced walk test [37].
4. Patient-Reported Outcomes (PROs): A series of PROs will be assessed using valid and reliable tools via an electronic survey prior to or at each clinic visit. Pain, function, and symptoms will be assessed through the following measures: Intermittent and Constant OA Pain (ICOAP) [38,39], Patient Global Assessment of Health Status (PGA) [40], and Patient Acceptable Symptom State (PASS) [41].



**Table 2**  
Study outcomes and timeline.

	Usual care arm				PARx and PARx + JM arms			
	Baseline	2-mo	6-mo	12-mo	Baseline	2-mo	6-mo	12-mo
<b>Participants</b>								
Consent	x				x			
Demographics and medical history	x				x			
Anthropometrics	x	x	x	x	x	x	x	x
Functional testing <sup>a</sup>	x	x	x	x	x	x	x	x
KOOS/HOOS	x	x	x	x	x	x	x	x
GPAQ	x	x	x	x	x	x	x	x
ICOAP	x	x	x	x	x	x	x	x
PGA	x	x	x	x	x	x	x	x
PASS	x	x	x	x	x	x	x	x
Arthritis self- efficacy	x	x	x	x	x	x	x	x
CES-D	x	x	x	x	x	x	x	x
VAS-F	x	x	x	x	x	x	x	x
Step count	x	x	x	x	x	x	x	x
Process evaluation						x	x	x
Perceptions						x	x	x
Adherence <sup>b</sup>					x	x	x	x
Focus groups				x				x
<b>Physicians</b>								
Consent				x				x
Focus groups				x				x

Abbreviations: Center for Epidemiological Studies Depression Scale (CES-D); Global Physical Activity Questionnaire (GPAQ); Hip Osteoarthritis Outcome Score (HOOS); Intermittent and Constant Osteoarthritis Pain (ICOAP); Knee Osteoarthritis Outcome Score (KOOS); Joint Management (JM); Patient Acceptable Symptom State (PASS); Physical Activity Prescription (PARx); Patient Global Assessment of Health Status (PGA); Visual Analogue Scale to Evaluate Fatigue (VAS-F).

<sup>a</sup> 30-s chair stand test and 40-m fast-paced walk test.

<sup>b</sup> Biweekly from baseline to 2-mo, monthly from 2-mo to 12-mo for PARx + JM group only.

Additionally, participants will respond to the Arthritis-Related Self-Efficacy [42], the Center for Epidemiological Studies Depression Scale (CES-D) [43], and the Visual Analogue Scale to Evaluate Fatigue Severity (VAS-F) [44]. All PROs will be administered and analyzed by the scoring instructions.

- Participant perceptions and experiences: We will conduct qualitative focus groups with participants and physicians (separately) to understand their experiences and perceptions of PARx and JM. Additionally, we will conduct focus groups with the control group to understand their experiences and perceptions over the study period.
- Adherence: Participants in the PARx + JM intervention group will only be asked two questions about their use of the JM platform. This brief questionnaire will be administered electronically weekly for the first two months and then monthly for 10 months.

## 6. Sample size

Sample size estimation is based on the primary comparison of PARx vs usual care control in mean difference in KOOS/HOOS scores at 12-month follow-up. Since there is a lack of information on mean and standard deviation of the outcome score in populations similar to the one under study, we deem a standardized mean difference of 0.4, which is close to Cohen's moderate effect size [45], as clinically meaningful for the current study. To detect such a difference with 80 % power at a 2-sided significance level of 5 % with a 1:1:1 group ratio, a minimum size of 98 participants per group is required. Accounting for a 15 % loss to follow-up, 113 participants per group will be recruited with a total sample size of 339. We will declare the study feasible if the average recruitment rate over 6 months is 8 participants per month and the retention rate at the 1-year post-study start is >80 %. Research personnel will keep track of daily recruitment numbers and remain in close communication with clinic staff to ensure recruitment targets.

## 7. Recruitment

Individuals 40 years of age or older with mild to moderate knee or hip OA will be recruited through one of the following pathways.

- Individuals with knee or hip OA are referred to the Southwest Musculoskeletal Rapid Access Clinic (RAC) by their family physician. The recruitment poster and a short description of the study will be sent to patients via email by the RAC as part of their patient intake package. Once screened by a member of the patient's clinical care team (Advanced Practice physiotherapist at the RAC), patients will be asked if a member of the study team can contact them via telephone with more information.
- Sport medicine physicians, orthopaedic surgeons, and physiotherapists at Western University (Fowler Kennedy Sport Medicine Clinic) will introduce the study to eligible patients. If interested in participating in the study, the sport medicine physician or orthopaedic surgeon will notify a member of the research team.

All eligible sport medicine physicians at Fowler Kennedy Sport Medicine Clinic will be invited to join the study and administer the PARx to consented patients. Only those who deliver the intervention will be asked to attend the focus groups.

## 8. Randomization

If eligible to participate in the study, research staff will randomly assign participants to one of three intervention arms via a 1:1:1 allocation ratio using a web-based software program (Empower Inc.) [46]. Randomization will be stratified by sex and age (<55 years or ≥55 years). It is not possible to blind participants to the intervention arm as they will be aware of whether they receive a PARx from a physician and access to the JM website. Research staff will inform participants of their assignment once baseline questionnaires are complete. Given that physicians administer the PARx, it will not be possible to blind them from assignment to control or experimental conditions; however, physicians will remain unaware of the experimental group assignment (i.e., PARx or PARx + JM).

## 9. Data collection

Surveys will be administered electronically via Research Electronic Data Capture (REDCap), a secure web-based program for designing and

managing online surveys [47,48]. The research team will send participants a unique link to access and respond to questionnaires at baseline and each follow-up time point. Participants will be asked to complete questionnaires prior to each visit, however, they will have an opportunity to complete outstanding questionnaires upon arrival for their appointment. Surveys are administered in English only. The research team will input data from anthropometric measurements and functional assessments into REDCap. If a participant withdraws from the study, the data collected up until that point will be analyzed.

Focus groups will be organized for each study arm (PARx, PARx + JM, and usual care) and providers in the intervention groups delivering PARx at 12 months. All participants will be invited to attend a focus group. Once 5–8 participants from the same intervention group have agreed to participate, a focus group will be formed. Participant and physician focus groups will be completed separately. The focus groups will be conducted via Zoom by two members of the research team with expertise in qualitative research. A semi-structured interview guide that consists of open-ended questions with prompts meant to elicit rich information regarding participant and physician experiences with PARx and JM. For example, “tell me about your experience with the PARx tool” and “tell me about your experience with the JM website”. Recruitment for focus groups will continue through an iterative analysis process until thematic saturation [49]. Focus groups will be audio-recorded and transcribed verbatim for analysis.

## 10. Data management, monitoring, and auditing

Participants will complete PROs using a unique REDCap link sent to them by email. All other outcome measures will be entered by a member of the research team using an institutional REDCap login. Data entry checks will occur throughout the study to check for accuracy. Data will be stored on the online REDCap server. Identifiable data will be retained for 15 years. As the principal investigator is directly involved with the study and has access to all the study data a Data Safety Monitoring Board is not required. Data and safety monitoring will be conducted by the research team/principal investigator by reviewing responses to PROs and monitoring the overall progress of patients in the clinic. A formal interim analysis is not planned for this study. During each study visit, data will be reviewed by a research team member to ensure accuracy and completion. Unrealistic and impossible data will be reviewed with each patient.

## 11. Data analysis

### 11.1. Statistical analysis

We will provide a descriptive summary of participants in each treatment group and each visit using mean and standard deviation for normally distributed data, the median and interquartile range for continuous but not normally distributed data, and count and percentage for categorical data. Researchers conducting the statistical analyses will be blinded to the intervention group.

The primary outcome data, KOOS/HOOS scores, will be analyzed using a mixed model for repeated measure approach [50]. The model will include the fixed, categorical effects of treatment, visit, and treatment-by-visit interaction, as well as the continuous, fixed covariates of baseline score and baseline score-by-visit interaction. An unstructured (co)variance structure will be used to model the within-patient errors. The Kenward-Roger approximation will estimate denominator degrees of freedom and adjust standard errors. Significance tests will be based on least-squares means using a two-sided  $p < 0.05$  (two-sided 95 % confidence intervals). Analyses will be conducted using SAS PROC MIXED [51]. The primary comparison of PARx vs Usual Care, as well as PARx + JM vs Usual Care will be the contrast obtained for the 12-month follow-up. The mixed model for repeated measure approach can be more efficient than the multiple imputation, provided that the data are normally distributed and missing at random [50,52]. Other continuous

outcomes will be analyzed using a similar approach. As a sensitivity analysis for normality assumption, the primary outcome data and PRO will be subjected to nonparametric analysis [53,54]. Results will be presented in point estimates (95 % confidence interval) of win probability that a participant in the intervention group will have a better score than a participant in control. Ordinal outcome data will also be analyzed using a similar approach. We will use a sex and gender-based approach to explore differences in response to the intervention and physical activity behaviours in men and women, using the Sex and Gender Equity in Research guidelines [55].

### 11.2. Qualitative analysis

We will use the consolidated criteria for reporting qualitative research checklist to guide our approach to data collection and analysis [56]. A thematic analysis of the focus group data will be conducted, following guidelines from Braun and Clarke (2006) [47]. Transcripts will be analyzed by two members of the research team, using an inductive approach to identify themes directly from the data. A descriptive thematic framework of key themes, categories, and codes will be developed in NVivo (Version 14, released 2023) [57], ensuring that the analysis is data-driven and reflective of the patients' experiences.

### 11.3. RE-AIM evaluation

We will evaluate PARx and PARx + JM interventions using the RE-AIM Framework, designed to evaluate five key factors (i.e., Reach, Effectiveness, Adoption, Implementation, and Maintenance) for translation and generalizability of interventions [58]. We will use a mixed methods approach incorporating quantitative and qualitative data from the research staff records, online surveys, and qualitative data to evaluate the five domains of RE-AIM (Table 3).

## 12. Ethical considerations

### 12.1. Consent

Electronic informed consent will be obtained from each participant before enrolling them in the study (see Additional file 2). A member of the research team will obtain informed consent after the study physician has introduced the study and confirmed eligibility. Participation in the study is voluntary and individuals are free to refuse participation or withdraw from the study at any time with no effect on their future care. Participants do not waive any legal rights by signing the consent form. Protocol deviations and adverse events will be reported by Western University's Health Sciences Research Ethics Board (HSREB) guidelines. Participants will be provided contact details of the study team and encouraged to report any discomfort or adverse experiences between visits. A summary of adverse events will be included.

### 12.2. Confidentiality

All study data and information will be kept in a secure and confidential location for 15 years. A list linking study identifiers with participant identifiers will be kept in a secure place, separate from participant study files. All identifiable information collected during this study will be kept confidential. Dr. Jane Thornton and necessary members of the study team will have access to the identifiable data otherwise this data will not be shared with anyone unless required by law. Participants will not be named in any reports, publications, or presentations that may come from this study. Representatives of The University of Western Ontario HSREB and Lawson Health Research Institute may require access to study-related documents to oversee the ethical conduct of this study.

**Table 3**

Overview of RE-AIM and measures to evaluate each dimension.

RE-AIM dimension and definition <sup>a</sup>	Example measures <sup>b</sup>
<b>Reach</b>	
Absolute number, proportion, and representativeness of individuals willing to participate in a given initiative, intervention, or program.	Percent individuals excluded based on eligibility criteria Percent eligible individuals who participate Characteristics of participants compared to nonparticipants Percent recruited from each pathway Reasons for not participating
<b>Effectiveness</b>	
Impact of an intervention on outcomes, including potential negative effects, quality of life, and economic outcomes.	Measure of secondary outcome(s) at 6 months Measure of robustness across subgroups Percent of participants withdrawn or lost to follow up within first 6 months Participant and physician perceptions of PARx and JM effectiveness
<b>Adoption</b>	
Absolute number, proportion, and representativeness of settings intervention agents willing to initiate a program.	Physicians excluded from participating Percent of physicians invited that participate Factors that affect physician participation
<b>Implementation</b>	
At the setting level, intervention agents' fidelity to intervention's protocol, including consistency of delivery as intended, time and cost of the intervention. At the individual level, clients' use of the intervention strategies.	Percent of PARx completed Consistency and content of PARx Percent of PARx + JM participants logging into JM Total number and frequency of JM logins Minutes physician focus on PA during appointment Participant satisfaction with PA counselling Perceived barriers and facilitators to implementation from physician and participant perspectives
<b>Maintenance/sustainment</b>	
Extent to which a program or policy becomes institutionalized or part of the routine organizational practices and policies. At the individual level, long-term effects of a program on outcomes after ≥6 months after most recent intervention contact.	Measure of secondary outcome(s) at 12 months Percent participants withdrawn and loss to follow up (after 6 months) by treatment arm and patient characteristics Percent physicians who continue to use PARx after study

<sup>a</sup> RE-AIM. What is RE-AIM? <https://re-aim.org/learn/what-is-re-aim/>. Accessed October 13, 2023.

<sup>b</sup> Adapted from National Cancer Institute. *Measuring the Use of the RE-AIM Model Dimension Items Checklist*. <https://re-aim.org/learn/checklist-for-inclusion-of-re-aim-issues-by-re-aim-dimension/>. Accessed October 13, 2023.

### 12.3. Harms

Participants may experience mild muscle soreness or joint pain. The potential duration of discomfort is expected to be brief and should occur less frequently as the participant continues training or exercising. If a participant is injured or ill because of the study interventions and requires medical care, they can contact our clinic and be seen by our primary care physicians. Participants can also proceed to the emergency department or urgent care clinic depending on the severity of the injury or illness. There are no anticipated risks or harms related to participation in the JM intervention arm. The JM intervention does involve an exercise program, so it is possible to experience some level of stiffness or discomfort after exercising. However, through the website participants will be taught to monitor their exertion throughout the program, with the goal of any increase in soreness returning to the pre-exercise level by the next day. Any 'red flags' such as prolonged increases in pain that may occur will be addressed by one of the physician participants.

### 12.4. Risk of potential breach of privacy

Any identifiers will be kept separate from the participant and only approved research staff will have access to both the identifiers and the data. Security measures are in place to protect against the loss, misuse, and alteration of personal information. For example, our security and privacy policies are periodically reviewed and enhanced as necessary and only authorized personnel will have access to personal information.

## 13. Discussion

At present, individuals with hip and knee OA are not consistently provided with easily accessible evidence-based treatment options to manage their condition, which may compromise their mobility and quality of life. Providing physical activity prescriptions and access to a free web-based exercise and education platform could indirectly reduce referrals to

orthopaedic surgeons and provide superior treatment for patients with mild to moderate hip and knee OA compared to usual care. In this study, we will assess whether weaving evidence and technology into the fabric of physician consultation may enhance patient satisfaction and yield patient benefits. The results generated from this study will be published in academic papers and presented at scientific meetings across various disciplines (e.g., sport medicine, kinesiology) to reach academic and medical communities, as well as disseminated to lay and non-academic audiences through infographics and newspaper articles. All knowledge products related to this project will be housed on the Return to Health and Performance website [59].

The novel technologies (PARx and JM) are innovative tools informed by patient feedback geared towards 1) developing new and more personalized treatment approaches, 2) developing more effective self-management tools, and 3) reducing disparities in vulnerable and hard-to-reach populations. Co-designed with patient partners, the PARx tool for primary care physicians and their patients will generate effective, personalized physical activity counselling that targets patients' chronic diseases. This can inform future interventions as a model for other chronic conditions. JM will provide cost-effective education, exercise, and self-management strategies for patients while also leveraging the utility of telerehabilitation and personalized support.

### Ethics approval and consent to participate

The TEAM Study (ID #116604) received ethical approval from Lawson Health Research Institute (ID# 10428) and Western University's HSREB on March 10, 2021, after undergoing full board review. Electronic informed consent will be obtained from each participant before enrolling them in study. A member of the research team will obtain informed consent after the study physician has introduced the study and confirmed eligibility. Participation in the study is voluntary and individuals are free to refuse participation or withdraw from the study at any time with no effect on their future care. Participants do not waive any legal rights by signing the consent form.

## Consent for publication

Not applicable.

## Availability of data and materials

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

## Author contributions

JT conceived the idea regarding PARx, and KB and LC regarding JM. DB and GYZ assisted with the formal analysis. AA and SC assisted with project administration and writing (review and editing). MZ, AG, RD, SM, JS and HH assisted with the review and editing process of the manuscript. SW was involved in the funding acquisition. JT, JS, KB and LC completed the writing of the original draft as well assisted with the editing process. All authors read and approved the final manuscript.

## Authors' information

N/A.

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## Declaration of competing interest

The authors have no competing interests to declare, nor have they received financial support that may be perceived as a conflict of interest.

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## Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.ocarto.2025.100586>.

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