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Group physical therapy for veterans with knee osteoarthritis: Study design and methodology

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Abstract

Physical therapy (PT) is a key component of treatment for knee osteoarthritis (OA) and can decrease pain and improve function. Given the expected rise in prevalence of knee OA and the associated demand for treatment, there is a need for models of care that cost-effectively extend PT services for patients with this condition. This manuscript describes a randomized clinical trial of a group-based physical therapy program that can potentially extend services to more patients with knee OA, providing a greater number of sessions per patient, at lower staffing costs compared to traditional individual PT. Participants with symptomatic knee OA ($n=376$) are randomized to either a 12-week group-based PT program (six 1 h sessions, eight patients per group, led by a physical therapist and physical therapist assistant) or usual PT care (two individual visits with a physical therapist). Participants in both PT arms receive instruction in an exercise program, information on joint care and protection, and individual consultations with a physical therapist to address specific functional and therapeutic needs. The primary outcome is the Western Ontario and McMaster Universities Osteoarthritis Index (self-reported pain, stiffness, and function), and the secondary outcome is the Short Physical Performance Test Protocol (objective physical

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function). Outcomes are assessed at baseline and 12-week follow-up, and the primary outcome is also assessed via telephone at 24-week follow-up to examine sustainability of effects. Linear mixed models will be used to compare outcomes for the two study arms. An economic cost analysis of the PT interventions will also be conducted.

Keywords

Osteoarthritis; Physical therapy; Health Services Research; Pain; Function

1. Introduction

Knee osteoarthritis (OA) is one of the most common chronic health problems and a leading cause of disability [1–4]. U.S. military veterans have a higher prevalence of OA and more pain and functional limitations compared to the general population of adults, and Department of Veterans Affairs (VA) health care users are the most severely affected [5]. Physical therapy (PT) is associated with decreased pain and improved function in patients with knee OA [6–10], and it is considered a key component of OA care in the treatment guidelines of major professional organizations [11–14]. However, the demand for PT services is extensive within the Department of Veterans Affairs health care system, as well as other health care organizations. The American Physical Therapy Association recently projected that by 2020 there will be a shortage of physical therapists in the range of about 9,000–40,000 nationally (depending on the rate of therapist attrition) [15]. There is a need for evidence-based models for delivering PT to patients with knee OA and other common conditions in an efficient and cost-effective manner.

A group-based approach to delivering PT for patients with knee OA mirrors that of cardiac rehabilitation programs, as well as group medical clinics. Small studies have also shown promise for the strategy of group-based physical therapy following joint replacement surgery, as well as for women with urinary incontinence [16–18]. However, there is only limited evidence regarding the efficacy of group PT for patients with knee OA [9]. Group-based PT may be particularly appropriate and effective for patients with knee OA for several reasons. First, group visits are most useful in the context of chronic conditions, such as OA, that require education and support for a variety of self-care strategies and health behaviors[19]. In this case of knee OA, this involves education and support not only for a variety of exercise and functional skills, but also for other aspects of joint care and pain management [11,20]. Second, many of the components of usual PT care for knee OA, such as instruction in appropriate exercises, activity pacing, and joint protection, can feasibly be delivered in a group-based setting. Third, group-based PT can provide peer social support that is an important factor in promoting adherence to exercise based interventions, particularly among patients who have a shared health condition such as knee OA [21–23].

This manuscript describes the protocol for a randomized controlled trial comparing group vs. individual approaches to delivering PT for knee OA in the VA healthcare system. The group-based program was designed so that it could to extend services to more veterans, for a greater number of sessions per veteran, and at lower staffing costs, compared to

individual PT for knee OA. Results of this trial will make an important contribution to the evidence base regarding group-based delivery of PT for knee OA and potentially other health conditions. In particular, if a group-based model is effective, it could provide a cost-saving approach to delivering this highly common health service.

2. Material and methods

2.1. Hypotheses

This study tests the following hypotheses:

Primary:

- A 12-week group-based PT program will result in a significantly greater improvement in self-reported pain, stiffness, and function, as measured by the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) total score [24,25], when compared to usual PT care (defined as two individual PT visits).

Secondary:

- The 12-week group-based PT program will result in a significantly greater improvement in objectively assessed physical function, measured by the Short Physical Performance Test Protocol [26], when compared to usual PT care.
- The group-based PT program will result in a significantly greater improvements in WOMAC scores at 24-week follow-up (12 weeks after the end of the group program) when compared to usual PT care.

2.2. Study design

This study is a randomized controlled trial of a 12-week, group-based PT program for veterans with knee OA at the Durham VA Medical Center. Following consent and baseline assessments participants are randomly assigned with equal allocation to one of two groups: group-based PT or individual PT (usual PT care). Because there are known gender and racial differences in pain, and there may also be differences in responses to the interventions, randomization is stratified by both gender and race. Race stratification is white vs. non-white, the latter of which will include primarily African Americans since other racial and ethnic minority groups are not well represented at the Durham VA Medical Center. We chose to compare group-based PT to usual (individual) PT care because the objective of this study is to examine whether an alternative delivery model of PT for knee OA is more effective (or more cost-effective) than the individual model typically used in the VA and most other clinical settings. All participants continue with their other OA-related care, including physician visits and pain medications. Assessments are completed in person at baseline and 12-week follow-up, with allowance for telephone-based follow-up assessments if participants cannot come to the Durham VAMC during that time period. We also assess a limited set of outcomes via telephone at 24-week follow-up, to examine whether any observed intervention effects are maintained.

2.3. Participant eligibility criteria

The target sample for this study includes veterans with symptomatic knee OA who have not recently received PT for that condition. Specific eligibility criteria are as follows:

- Prior diagnosis of knee OA. We examine potential participants' electronic medical records for a physician's diagnosis of knee OA.
- Current Joint Symptoms. We use the CDC definition for persistent joint symptoms, adapted to ensure that participants are experiencing joint symptoms currently [27]. Participants must answer, "yes" to two questions regarding a knee with OA: 1.) "During the past month, have you had pain, aching, stiffness, or swelling in or around a knee joint that has arthritis?" 2.) "Were these symptoms present on most days of the past month?"
- No Recent PT Care. We include only patients who have not received any PT care for knee OA in the past six months. We have included this criterion because it will allow our study to more closely replicate a sample that would be referred for PT services for knee OA in a typical clinical setting.

Patients who have any of the following conditions are excluded from the study because these conditions may prohibit safe participation in the strength training component of a PT program and/or may influence study outcomes:

- Diagnosis of systemic rheumatic diseases, including rheumatoid arthritis and other inflammatory polyarthropathies, systemic lupus erythematosus and other diffuse connective tissue diseases, polymyalgia rheumatica, and fibromyalgia
- Both knees replaced
- Hip and/or knee replacement in the prior 6 months
- On waiting list for/planning arthroplasty within next 3 months
- Knee ligament or meniscus injury in the prior 1 year
- Gout in the knees
- Hospitalized for a stroke, transient ischemic attack, aneurysm, myocardial infarction, coronary artery revascularization, or mental health condition in the past 3 months
- Current chest pain
- Multiple sclerosis
- Parkinson's disease
- Diagnosis of psychosis or suicidal ideation
- Diagnosis of dementia
- Current significant alcohol and/or drug abuse
- Other serious health problems
- Resident in nursing home

- Currently participating in another OA-related or lifestyle interventional study

2.4. Recruitment and enrollment procedures

We have three sources for recruitment:

1. **Search of Electronic Medical Records.** Using Durham VA electronic medical records, we identify potential participants who have an ICD-9 code for OA and no exclusionary diagnoses (listed above). Because the study involves multiple in-person sessions, we also restrict this data pull to patients who live within 50 miles of the Durham VAMC. Next, we further review electronic medical records to confirm a diagnosis of OA and assess exclusion criteria. These reviews are completed by the study research assistants and project coordinator, with oversight by the principal investigator and clinical co-investigators. A diagnosis of OA can be based on radiograph results, MRI results, or a clinician diagnosis. We do not require radiograph/MRI evidence for all participants because these tests are sometimes conducted outside the VA and not available within electronic records. We then mail introductory letters to patients who appear to be eligible based on their medical record. This is followed by a screening telephone call, unless patients contact us to “opt out.” The purpose of the screening call is to confirm inclusion criteria (e.g., current joint symptoms, no recent PT for knee OA), as well as some exclusion criteria that may not be adequately captured in the electronic medical record. If veterans meet screening criteria, are interested in participating in the study, and indicate being available for PT sessions during the times offered, they are asked to meet a study team member at the Durham VAMC for a baseline study visit.
2. **Provider Consults.** We have set up a consult option within the Durham VA electronic medical record system. This allows providers to send a notice to the study team regarding patients who may be eligible to participate in the study. We periodically send reminders to providers in primary care, orthopedics, rheumatology, rehabilitation, geriatrics, and the emergency department regarding the study and consult. When providers send consults to the study team, we review the medical record for the indicated patient and proceed with the recruitment process as described above.
3. **Self-Referrals.** We place advertisements about the study at various clinics and common areas at the Durham VAMC and its associated community-based outpatient clinics in Durham and Raleigh, NC. When participants call about the study, we use a standard script to provide basic information about the study and ask participants whether they are interested in determining whether they may be eligible. If they are interested, we proceed with medical record review and other recruitment processes as described above.

Following completion of the baseline study visit (which involves informed consent, HIPAA authorization, and administration of study measures), participants are randomly assigned to an intervention arm via a computer generated randomization sequence created by the study statistician. The project coordinator gives the group assignment to participants via

telephone, and the research assistant who administers study measures remains blinded to group assignments. During this telephone call, the project coordinator schedules the first PT appointment for participants randomized to the individual PT arm. For individuals in the group PT arm, the project coordinator describes an attendance contract that will be mailed to them and ask that it be signed and returned in a pre-addressed and stamped envelope. If the contract has not been signed by the first group session, a study team member asks the participant to sign the contract at that session. The attendance contract is used in the group PT arm to help facilitate commitment of participants to attend six sessions over a 12 week period; however, we inform patients that we understand there are unavoidable reasons for missed sessions, and the contract is non-binding—participants do not need to discontinue the program if they miss visits. Attendance contracts have been used successfully in other multi-session group health programs[28]. The attendance contract is not used in the individual PT arm because this mirrors usual care and only includes two sessions. Once there are eight individuals available for a specific group PT session time, the group begins.

2.5. Overview of PT interventions

We modeled the components of both group-based and individual PT interventions after typical elements of care provided to patients with knee OA [29] which include instruction in an appropriate home exercise program (focusing on strengthening and stretching exercises), instruction in strategies for pacing daily activities and protecting joints, evaluation of specific areas of weakness or inflexibility (which can then be used to tailor an exercise program), evaluation of mobility, stability, function, knee alignment, and possible limb length inequalities, and evaluation of the need for mobility aids, knee braces, and shoe orthotics. Multiple physical therapists deliver the interventions, in order to enhance generalizability. We regularly monitor both intervention arms to evaluate whether each component of the interventions is being delivered appropriately by the individual PTs and PT assistants. Although we have detailed guidelines for the content of each PT session (described below), the physical therapists have flexibility to make adaptations according to patient needs.

2.6. Group-based PT intervention

2.6.1. Organization of group sessions—The group PT program involves six 1-h sessions, held every other week for 12 weeks. A 12-week duration was chosen for two reasons. First, prior studies of exercise for knee OA have shown that this duration is sufficient to yield improvements in pain [30–32]; therefore this amount of time may allow patients to experience beneficial effects, which may in turn foster continued adherence. Second, we believe this duration allows adequate time for participants to be guided through progression of exercise and trouble-shooting of problems they may encounter with specific activities. We chose to conduct sessions every other week based on our feasibility pilot study, which indicated that this interval was desirable for patients. Groups consist of about eight participants and are jointly led by a physical therapist and PT assistant. The PT assistant is primarily responsible for teaching and leading group exercises, as well as answering questions about the exercise program. The physical therapist is responsible for general oversight of the sessions and providing individual evaluation and consultation to

patients. An overview of activities for each group PT session is shown in Table 1. These sessions involve four types of activities:

1. Group instruction (sessions 1, 3, and 5)
2. Group discussion of exercise barriers and successes (sessions 2, 4, and 6)
3. Group exercise (all sessions)
4. Individual consultations with a physical therapist (two per participant; typically one during session 1 or 2, and one during session 3, 4, 5, or 6).

Group instruction or discussion takes place at the beginning of the session (5–10 min), followed by group exercise for the remaining time. Participants meet individually with the physical therapist during group exercise time. While this scheduling plan requires that participants miss some of the group exercise time during their individual physical therapist consultations, because there are six sessions overall, there is still ample time for each person to participate in the group exercise time and receive instruction from the PT assistant.

2.6.2. Group instruction—We provide instruction on three topics to participants as a group, as these are core issues applicable for all patients with knee OA and can be delivered efficiently in a group setting. During the first session, the PT assistant instructs the group in basic principles of exercise for knee OA, as well as a set of specific exercises (described below). During the third session, participants are instructed in activity pacing. Key points for this discussion include recognizing typical pain patterns and activities that exacerbate pain, planning for exercise and other activities during typical periods of low pain, planning for rest during typical periods of high pain, and taking rest periods when pain and soreness begin to occur. During the fifth session, participants are instructed in joint protection strategies. Key points for this discussion include specific strategies for decreasing the load on the knee joints during common activities such as walking, stair ascent/descent, rising from a chair, and doing other household activities.

2.6.3. Group discussion of exercises barriers and successes—At the beginning of the second, fourth, and sixth sessions, the PT assistant leads the group in a discussion about barriers and successes they have experienced related to their home exercises. Because there are many common barriers to exercise participation, particularly among individuals with a chronic pain condition [33], this discussion allows an opportunity to address strategies for dealing with these barriers. The PT assistant provides suggestions for dealing with specific barriers (for example, planning ahead to do exercises at a time of day when pain is typically at a low point), but we also encourage participants to suggest strategies they have used to deal with any barriers being discussed.

2.6.4. Group exercise—During each session, the PT assistant leads the group in a series of stretching and strengthening exercises. During the group exercise time, the PT assistant: 1.) observes participants' performance of the exercises to ensure they are completing them properly and safely; 2.) ask participants if they are having any difficulties with any of the exercises and recommends alternate positions or exercises accordingly; 3.) provides advisement to participants about increasing (or decreasing) weight/resistance level and/or

number of repetitions, as appropriate; 4.) answers other questions participants have about their exercise program.

We have chosen a group of 4 stretching and 6 strengthening exercises for this program, based on common exercises recommended in routine PT care and an overall approach to enhancing lower extremity strength and flexibility [34]. Stretching exercises include quadriceps stretch, calf stretch, hamstring stretch, and lower back and hip stretch. Strengthening exercises include mini-squats, single-leg stand, partial chair stands, heel raises, hip abduction, and step ups. Participants are instructed to begin with this initial set of exercises, and as the program progresses, some specific exercises may be modified, substituted, or added, according to participant needs. Participants are instructed to perform stretching exercises daily and strengthening exercises three times weekly (including the group sessions on weeks those occur) on non-consecutive days. Participants are given written instructions, including photographs, for each stretching and strengthening exercise, as well as logs to record their home exercise. Exercise logs are for participants' own use and not routinely brought to physical therapy sessions. Participants are also given therapy bands to assist with completion of some strengthening exercises.

2.6.5. Individual physical therapist consultations—Prior to beginning the group sessions, participants complete a questionnaire that includes information about prior injuries, recent joint injections, pain level, specific functional and activity limitations, use of assistive devices, and other health problems that could affect exercise. Information on this form facilitates the physical therapists' evaluations and discussions with participants. The primary purpose of the first individual physical therapist consultation is to discuss health issues that may affect exercise prescription and goals. During this consultation the physical therapist

1. Examines affected knee(s) for edema and provide appropriate recommendations for the use of heat, cold, elevation, and/or self-massage, particularly to be used before or after exercises.
2. Discusses with the participant any health issues (from the questionnaire) that may affect their exercise and provides recommendations as appropriate.

During this second individual consultation, the physical therapist

1. Completes several brief, standard assessments including range of motion, knee alignment, limb length equality, balance, and gait. These assessments are used to make recommendations for additional referrals (see #3) and tailoring of exercises to address specific deficits.
2. Discusses participants' progress with home exercise and provides recommendations for any appropriate modifications.
3. Based on assessments listed in #1, provides recommendations for referrals for
 - a. Assistive devices
 - b. Knee braces
 - c. Shoe orthotics

2.7. Individual PT intervention (usual PT care)

2.7.1. Overview of individual PT intervention—This intervention is modeled after typical PT for knee OA at the Durham VA Medical Center. Participants receive two individual 1-h visits with a physical therapist, approximately 2–3 weeks apart, for evaluation and instruction in an independently performed home exercise program. These visits include the same evaluation, education, and exercise prescription components as described above for the Group-Based PT Intervention, though these components are organized differently to accommodate the 2-visit structure. Prior to the first visit, participants complete the same questionnaire as described above for the Group-Based PT Intervention. Participants also receive the same written exercise instructions, exercise logs, and therapy bands.

2.7.2. Activities for individual PT sessions—Activities to be conducted in each physical therapy session are summarized in Table 1. During the first session, the physical therapist:

1. Instructs the participant in the same exercise program as described above for the group-based PT Intervention, including instructions for home exercise, progression, and continuing after the final physical therapy visit.
2. Examines participants' affected knee(s) for edema and provides appropriate recommendations for the use of heat, cold, elevation, and/or self-massage, particularly to be used before or after exercises.
3. Discusses any health issues (from the questionnaire) that may affect exercise and provide recommendations as appropriate.

During the second session, the physical therapist

1. Completes several brief, standard assessments including range of motion, knee alignment, limb length equality, balance, and gait. These assessments are used to make recommendations for additional referrals (see #3) and tailoring of exercises to address specific deficits.
2. Discusses participants' progress with home exercise and provide recommendations for any appropriate modifications.
3. Asks participants to perform the strengthening and stretching exercises and
 - a. Ensure they are completing exercises properly and safely
 - b. Ask participants if they are having any difficulties with any of the exercises and recommend alternate positions or exercises accordingly
 - c. Provide advisement about increasing (or decreasing) weight/resistance level and/or number of repetitions,
4. Based on assessments listed in #1, provides recommendations for
 - a. Assistive devices
 - b. Knee braces
 - c. Shoe orthotics

5. Instructs participants in activity pacing and joint protection, using the same information as described above.

2.8. Measures

Measures are administered by a trained research assistant, blinded to participants' randomization. Table 2 describes study measures and time points at which they are assessed.

2.8.1. Primary outcome—The primary outcome measure for this study is the WOMAC, a measure of lower extremity pain (5 items), stiffness (2 items), and function (17 items). All items are rated on a Likert scale of 0 (no symptoms) to 4 (extreme symptoms). The reliability and validity of the WOMAC total score and subscales have been confirmed [24,25]. In patients with hip or knee OA, Bellamy et al. reported internal consistency coefficients (Cronbach's alpha) between 0.86 and 0.95 on WOMAC pain, stiffness, and function subscales [25]. Construct validity has been confirmed by a significant association with the Lequesne Algofunctional Index for Knees [25]. The WOMAC scale has been widely used in trials of various exercise and rehabilitation programs, confirming its sensitivity to change in the context of this type of intervention [35,36].

2.8.2. Secondary outcome—Because functional limitations are a key outcome of OA, particularly in the context of PT care, we also objectively assess physical function using the Short Physical Performance Test Protocol [26]. This series of functional tests has been shown to predict hospitalization, disability, nursing home placement, and declines in health and function [26,37]. This test battery is relevant to the proposed study because it assesses aspects of daily function that require lower extremity strength and are often impacted by knee OA. Specifically, this battery examines participants' balance (3 tests), gait speed (8-ft walk), and time to rise from a chair and return to the seated position five times. We will follow previously established protocols for administering and scoring each of these tests [38]. For each test, the possible range of scores is 0–4, for a total range of 0–20 for all five tests.

2.8.3. Process/adherence measures—We assess physical activity levels using the CHAMPS physical activity questionnaire, which assesses both light and more vigorous activities and yields four separate scores: estimated kilocalories per week and frequency per week of moderate (or higher) intensity activities, and estimated kilocalories per week and frequency per week of all activities [39,40]. The CHAMPS also includes items specifically addressing the frequency of use of stretching and strengthening exercises, which are directly relevant to this study. For a subset of participants in this study, we are also objectively assessing physical activity with the ActiGraph accelerometer (model GT3X) [41,42]. We estimate these data will be collected on about 50% of participants, based on availability of accelerometers. Minute-by-minute activity data are collected over a period of seven consecutive days. The accelerometer assesses ambulatory activity and yields time spent in activities of varying intensities (i.e., light, moderate, and vigorous). The ActiGraph data will help to assess the validity of the CHAMPS in this particular patient group and study context.

For participants in the group PT arm, we calculate the total number of sessions attended during the intervention period; for participants in the individual therapy arm, we also document the number of sessions completed (of the two scheduled appointments).

2.8.4. Participant feedback on intervention—We ask participants open-ended questions regarding their experience with the program and ways we can improve the program for future use.

2.8.5. Participant demographic and clinical characteristics—These characteristics will be used to describe the study sample, as well as to conduct exploratory analyses of effect modification. Demographic characteristics include self-reported age, gender, race/ethnicity, education level, income level, working status, and marital status. Clinical and health-related variables include American College of Rheumatology clinical criteria for knee OA [43], body mass index (calculated based on measured height and weight), joint involvement (i.e., report of all joints affected by OA), duration of OA symptoms, general self-rated health, comorbid medical conditions, smoking, and alcohol use. Comorbid medical conditions are assessed using the Self-Administered Comorbidity Questionnaire [44].

2.8.6. Additional measures—We also collect additional measures, shown in Table 2, that add important information about the efficacy of the PT interventions.

2.9. Power and sample size considerations

The sample size estimate for the study, $n=188$ subjects per group (total $n=376$), is based on the primary hypothesis that the group-based PT program will result in a significantly greater improvement in WOMAC scores, when compared to the individual PT program. Our goal was to have sufficient sample size to detect a medium effect size of approximately 0.27 for the primary hypothesis with 80% power and a type-I error rate (α) of 0.05. This effect size translates to detecting as small as a 4 point differential in WOMAC scores at 12 weeks between the two intervention groups. Sample size calculations were based on methods appropriate for ANCOVA type analyses [45] adjusted to reflect the small group clustering within the intervention arm using the method of Donner & Klar [46]. A correlation of 0.64 between time points was estimated based on our pilot data, and we accounted for a 25% attrition rate.

2.10. Data analyses

The main conclusions drawn from this trial will be based on the pre-specified primary and secondary hypotheses and will be tested with two-sided p -values at the standard 0.05 level. The primary and secondary analyses will be conducted on an intent-to-treat basis [47]. Statistical analyses will be performed using SAS for Windows (Version 9.2: SAS Institute, Cary, NC) and R (<http://www.R-project.org>).

2.10.1. Primary and secondary hypotheses—Our primary hypothesis will be tested using a hierarchical linear mixed model to estimate the mean difference in WOMAC scores between the treatment arms at the 12-week time point. A random intervention effect will be

included in the model to account for potential clustering in the intervention arm resulting from the small group format. We will apply an unstructured covariance matrix to take into account the within-patient correlation between repeated measures over time (baseline and 12-week). The predictors in the model will include a dummy coded time effect and an indicator variable for the intervention interacting with the time effect. The fixed-effect portion of the model will have the form

$$Y_{ijk} = \beta_0 + \beta_1 * (\text{time12}) + \beta_2 * (\text{intervention} * \text{time12})$$

The test of the primary hypothesis is the test of the β_2 equal to zero. We will estimate the parameters in the model using the SAS procedure MIXED (Cary, NC). This method handles dropout in a principled manner. However, depending on the type and scope of any missing data, we will also explore multiple imputation as a strategy to use in conjunction with our primary analytic tools [48]. As recommended in the Committee for Proprietary Medicinal Products guidelines, the primary (as well as secondary) analyses will include the race and sex stratification variables as fixed covariates in the main analytic models. Secondary analyses at the 12-week time point will be conducted in a similar manner, and a third time point will be added to the above model to examine differences at 24-weeks between intervention arms.

2.11. Economic evaluation

We will conduct the economic analysis from the VA's perspective as payer/provider. Our primary analysis will focus on the 12-week intervention period. A secondary analysis will involve 24-month (maintenance) assessment data.

2.11.1. Costs—The cost portion of the analysis will include the equipment (therapy bands; both study arms), travel reimbursement (for PT visits in both arms), and labor costs associated with the group PT arm and the usual care arm. Labor costs include

1. Time required for initial planning of the group sessions (included for group-based PT arm only). Although the structure and materials for the group physical therapy sessions were developed prior to initiation of the study, some additional planning time would be required to finalize logistics if this program is implemented in other PT clinics. We estimate this will take approximately 8 h and will require input from the physical therapist, PT assistant, and PT Service Chief.
2. Time required for the physical therapist and PT assistant to conduct the group and individual PT sessions. This will include all set-up and clean-up activities.
3. Time required to make reminder calls prior to group and individual PT sessions.

Salary data associated with labor costs will be based on typical VA hourly wages of these positions. To account for indirect costs (e.g., overhead, administrative, and custodial costs), we will use the VA's Decision Support System to calculate the direct-to-indirect cost ratio for PT services and apply this ratio as a multiplier to the total direct cost to derive overall total (direct+indirect) intervention cost. This total cost will be divided by the number of

participants in the group PT arm to derive average cost per participant. The EuroQoL EQ-5D and WOMAC will be used as effectiveness measures in these analyses.

2.11.2. Analysis—The type of economic analysis we will ultimately conduct will depend on the effectiveness results. First, if the results of the study indicate that the two PT interventions have equivalent effectiveness, then the factor of economic interest is cost. In this situation we will conduct a cost-minimization analysis to evaluate which treatment arm has lower average cost per patient. We designed the group intervention to cost less per patient than the individual arm (due to lower per-patient labor costs). However, patient attendance in group and individual PT sessions will affect actual per-patient costs, and this will be analyzed. Second, if the results of the study shows that either treatment arm is both more effective and costs less, then that arm is dominant and we will simply report the cost-savings and greater effectiveness of that treatment arm. Third, if, however, one treatment arm is more effective but also costs more than the other treatment arm, then we will conduct appropriate decision analytic modeling to calculate an incremental cost-effectiveness ratio, with the WOMAC scores and quality-adjusted life years derived from the utility values as the effectiveness measures.

3. Discussion

This study is one of the first clinical trials to evaluate a group-based approach to delivering PT for patients with knee OA, one of the most common musculoskeletal conditions treated in the outpatient PT setting. A prior study in Australia compared a small group PT format with individual PT and a waiting list control condition among patients with knee OA[9]. Both PT groups were 8 weeks long; group sessions were held twice weekly for 1 h, and the number of weekly visits for participants in the individual PT group was at the discretion of the therapist. Participants in both PT arms had significantly better outcomes, including self-reported pain and function, muscle strength, and walking speed, compared to participants in the control arm, but there were no significant differences in any outcomes between the two PT arms. However, the per-patient physical therapist hours were lower for the group PT program, making it a less costly approach. Therefore, that study provided support that delivering PT in a group setting may be a cost-saving approach to providing an equivalent quality of care for patients with knee OA.

This study will expand the evidence base regarding group-based PT for patients with knee OA in several ways. First, this study involves fewer in-person group sessions than the prior study of $n=126$ patients conducted by Fransen et al. (6 vs. 16) [9]. We chose a smaller number of sessions because this may be more feasible for many patients to attend and therefore be a more clinically practical program in some settings. Second, this study involves a PT assistant (as well as a physical therapist) in the delivery of the group-based program. This expands the capability for individual contact with patients while still keeping the total costs for the group-based program lower than individual PT visits. Specifically, this group based-program would serve eight patients, with a total of 48 patient contact hours (if all patients attended all sessions) and 12 personnel hours (six from a physical therapist and six from a PT assistant). In contrast, providing individual PT to eight patients (assuming two visits per patients) provides 16 patient contact hours and 16 physical therapist hours.

Therefore this group PT model not only provides more visits contact hours per patient, but it is also less expensive to deliver. Third, we will conduct a thorough cost analysis of the PT interventions. This will be important for administrators to evaluate the utility of implementing a group-based model. Although this study is conducted specifically within a particular Medical Center in the VA healthcare system, and “usual PT care” varies widely both within and across health care systems (e.g., multiple in-person visits rather than a home program with 1–2 in-person visits), these results will have implications for any setting in which costs and resources are constrained and need to be used efficiently. Specifically, results will compare the use of resources to provide a couple of individuals visits vs. a larger number of group visits. In summary, this study will provide important information about a care delivery strategy that could not only improve outcomes but also increase access for patients with knee OA. Given the expected rise in prevalence of knee OA [49,50] and the general need to provide efficient healthcare, a group-based approach to delivering PT for this condition could be an important tool in many healthcare settings.

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Table 1

Activities for group and individual physical therapy sessions.

	Group physical therapy arm session #	Individual physical therapy arm session #
Instruction		
Exercise Program	1	1
Activity Pacing	3	2
Joint Protection	5	2
Physical therapist evaluation/consultation components		
Evaluation for edema/instruction in use of heat, cold, etc.	1–2	1
Discussion of individual health issues affecting exercise/develop exercise goals	1–2	1
Assessment of range of motion, alignment, etc.	4–6	2
Review of progress toward exercise goals/recommend modifications	4–6	2
Recommendations for referrals for braces, orthotics, etc.	4–6	2
Group exercise	1–6	N/A
Group discussion of exercises barriers/successes	2, 4, 6	N/A

Table 2

Summary of measures and time points of administration.

Measure	Baseline	12-Week follow-up	24-Week follow-up
Primary outcome			
Western Ontario and McMasters Universities Osteoarthritis Index	X	X	X
Secondary outcome			
Short physical performance test protocol	X	X	
Process/adherence measures			
CHAMPS (physical activity)	X	X	X
Number of PT sessions attended		X	
Demographic and clinical characteristics	X		
Participant feedback on intervention		X	
Additional measures			
Measure of intermittent and constant osteoarthritis pain [51]	X	X	X
Pain visual analog scale	X	X	
Pain visual numeric scale	X	X	X
Satisfaction with physical function questionnaire [52]	X	X	
Global assessment of knee symptom change		X	
Use of assistive devices for knee OA	X	X	
Use of pain medications for knee OA	X	X	X
History of knee injuries, surgeries, and injections	X	X	X
Exercise self-efficacy scale [53]	X	X	X
Foot symptoms	X	X	
Brief fatigue inventory [54]	X	X	X
EuroQol [55]	X	X	
Six-minute walk	X	X	
Seven-day physical activity (accelerometer)	X	X	