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Improving Maintenance of Physical Activity in Older, Knee Osteoarthritis Patients Trial-Pilot (IMPACT-P): Design and Methods

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Abstract

Promoting increased physical activity participation is now consistently advocated in the medical management of knee osteoarthritis (OA). Unfortunately, physical activity interventions targeting older knee OA patients are plagued by high attrition rates and poor long-term adherence. Consequently, identifying effective approaches for promoting maintenance of physical activity participation is integral for the successful behavioral management of knee OA. The present study, the Improving Maintenance of Physical Activity in Knee Osteoarthritis Pilot Trial (IMPACT-P), was a single-blind two-arm, randomized controlled pilot study designed to contrast the effects of a group-mediated cognitive behavioral (GMCB) exercise intervention with those of traditional center-based exercise therapy approach (TRAD) in older, knee OA patients. A total of 80 older adults with symptomatic knee OA were randomly assigned to GMCB or TRAD interventions. The primary outcome of the IMPACT-P study was change in self-reported (CHAMPS questionnaire) and objectively assessed (LIFECORDER EX Plus) physical activity participation of moderate intensity or greater. Secondary outcomes include physical function, quality of life, and social cognitive variables. Outcomes were obtained at baseline, 3 month, and 12 month assessments by trial personnel blinded to participants' randomization assignment.

Discussion—Determining the comparable efficacy of the GMCB and TRAD exercise interventions in producing meaningful improvements in physical activity and OA outcomes could enhance the efficacy of implementing physical activity participation in the behavioral management of symptomatic knee OA.

Keywords

Physical activity; functional limitations; arthritis; exercise; disability

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1. Introduction/Background

Symptomatic knee osteoarthritis (OA) is a prevalent chronic degenerative disease that acts as a primary cause of activity restriction and physical disability among older adults. [1]. There is considerable evidence that inactivity, secondary to the primary OA symptoms, exacerbates pain symptoms and accelerates progression towards disability in older knee OA patients [2, 3]. Given that traditional surgical and pharmacologic treatments are associated with mixed success and adverse long-term side effects, current approaches to treatment increasingly focus upon lifestyle interventions designed to manage adverse OA symptoms. In this regard, findings from randomized controlled intervention trials demonstrate that exercise produces meaningful improvements in OA outcomes [4–8] and exercise is now advocated as an essential portion of the medical management of knee OA [9–11].

Although exercise represents a promising lifestyle intervention, most OA patients fail to obtain recommended daily amounts of physical activity [12]. Additionally, physical activity interventions targeting knee OA patients are plagued by high attrition rates and poor post-intervention maintenance of treatment benefits [13–17]. Recent evidence suggests the deterioration of exercise-induced benefits in OA outcomes is directly related to declining rates of post-intervention physical activity adherence [14, 18]. These findings suggest that many older knee OA patients quickly return to sedentary lifestyles following the end of structured exercise interventions and that the lack of adherence results in the erosion of the clinically meaningful benefits obtained from exercise. Consequently, promoting maintenance of regular physical activity is integral to sustaining the benefits of exercise interventions for knee OA patients.

Although Hughes et al. (19) have demonstrated the benefits of a combined exercise and cognitive behavioral education intervention, the efficacy of theory-based, cognitive behavioral interventions for promoting PA maintenance in knee OA has yet to be systematically investigated. Indeed, one explanation for poor exercise adherence rates is that traditional interventions fail to provide OA patients with the self-regulatory skills necessary to facilitate the transition from center-based exercise therapy to the maintenance of independent physical activity participation [20]. One new approach, the social cognitive theory-based (21) group-mediated cognitive behavioral (GMCB) physical activity intervention, has recently yielded significant improvements in physical activity and quality of life in randomized trials targeting older adults with chronic disease [22–24]. Although this approach holds promise for improving physical activity adherence and quality of life for arthritis patients, the efficacy of the GMCB intervention for older knee OA patients has yet to be evaluated. The primary aims of this study were to determine the comparable efficacy of the GMCB and traditional exercise interventions for increasing moderate intensity or greater physical activity participation in older knee OA patients. Secondary aims were to compare the effects of the GMCB and traditional exercise interventions on change in physical function, pain, and quality of life outcomes. It was hypothesized that the GMCB intervention would result in significantly greater physical activity participation and more favorable improvements in OA outcomes when compared to the TRAD intervention

2. Study Design/Methods

2.1 Overview

The Improving Maintenance of Physical Activity in Osteoarthritis Trial-Pilot (IMPACT-P) was a two-arm, single-blind randomized controlled pilot trial designed to investigate the comparable efficacy of two exercise interventions (TRAD and GMCB exercise interventions). A total of 80 older adults with radiographic evidence of symptomatic knee OA were randomly assigned to either the GMCB (n = 40) or traditional exercise intervention

(n = 40) arms. Assessments of the primary and secondary outcomes were obtained by study staff blinded to treatment arm assignment at baseline, 3 month, and 12 month follow-up screening visits (see Figure 1).

2.2 Eligibility

The principles guiding the selection of the inclusion and exclusion criteria were designed to ensure the recruitment of a representative sample of older, community dwelling adults with symptomatic knee OA who had self-reported functional limitations but no medical contraindications precluding the participation in moderate intensity supervised center-based exercise or unsupervised home-based physical activity participation. To be eligible to participate in the IMPACT-P trial, volunteers had to meet the following inclusion criteria: (a) age > 55 years; (b) self-reported knee pain on most days of the month; (c) sedentary activity pattern with less than 20 min of structured exercise participation per week during the past 6 months; (d) self-reported difficulty with at least one of the following activities due to knee pain: walking 0.25 miles (3–4 city blocks), climbing stairs, bending, stooping, kneeling, shopping, housecleaning; or other self-care activities such as getting in or out of bed, standing up from a chair, lifting and carrying groceries, or getting in or out of a bathtub; (e) physician documented radiographic evidence of Kellgren-Lawrence scale stage I or II (mild to moderate) tibio-femoral OA; and (f) willingness to undergo testing and intervention procedure.

Participants were ineligible to participate in IMPACT-P if they met any of the following exclusion criteria: (a) a serious medical condition that precluded safe participation in an exercise program such as coronary artery disease, severe hypertension, peripheral vascular disease, stroke, congestive heart failure, chronic obstructive pulmonary disease, insulin-dependent diabetes, psychiatric disease, renal disease, liver disease, active cancer other than skin cancer, and anemia; (b) inability to walk without a cane or other assistive device; (c) physician documented radiographic evidence of knee joint varus or valgus malalignment that, in the opinion of the physician, would make regular physical activity participation unsafe; (d) participation in another research study; (e) excessive alcohol consumption of 21 drinks per week; or (f) OA severity greater than II on the Kellgren-Lawrence Scale; (g) an inability to complete the 12-month study or unlikely to be compliant due to work, home, or personal demands; (h) an inability to complete the trial protocol, in the opinion of the clinical staff, because of frailty or illness.

2.3 Recruitment and Randomization

Recruitment of study participants began in August 2009 and concluded in September 2010. Recruitment strategies included direct referral to study investigators from Ohio State Medical Center Rheumatologists, placement of study-related advertisements and informational brochures in Columbus area physicians' offices and Arthritis Foundation newsletters, and in person presentations to Central Ohio Arthritis Foundation support groups and arthritis self-management classes. Volunteers interested in participating in the study completed a telephone screening to verify eligibility. Participants that were determined to be eligible following the completion of the phone screening interview were scheduled for the baseline screening visit. Eligible participants were randomly assigned with equal probability to each of the 2 treatment arms using a 1:1 ratio following the completion of the baseline screening visit. The computer generated randomization allocation sequence was sequentially numbered and sealed in opaque envelopes. The randomization allocation sequence was concealed from study staff responsible for conducting the baseline assessments.

2.4 Informed Consent

Approval of trial protocol and informed consent documents were obtained prior to the initiation of recruitment procedures. All participants completed informed consent and Health Insurance Portability and Accountability Act (HIPAA) authorization forms prior to beginning participation in the trial.

2.5 Measures

Assessments of all study measures were obtained at baseline, 3-month, and 12-month post-treatment screening visits using measures with well established validity and reliability demonstrated in prior exercise intervention studies in older adults [20–23]. Outcome assessments were obtained by trained study personnel that were blinded to participants' treatment assignment.

2.5.1 Primary Outcome: Physical activity participation—Assessments of physical activity were obtained using objective and self-report measures. The LIFECORDER EX-Plus accelerometer (Suzuken Kenz Inc Limited, Japan) was used to obtain an objective assessment of physical activity participation. Participants wore the LIFECORDER EX-Plus on their right hip attached to either the waistband or belt during all waking hours, except when showering, bathing, or swimming, for 7 consecutive days following the completion of the baseline screening visit. Participants recorded the times they put on and took off the LIFECORDER EX Plus on a self-monitoring log. The LIFECORDER Plus EX provides assessment of minutes of light, moderate, and vigorous physical activity participation as well as calculating total daily steps taken. Consistent with the metabolic demands for the targeted age group [22], the accelerometer was set for intensity levels of 3–6 METS corresponding to moderate intensity physical activity and > 6 METS corresponding to vigorous intensity physical activity. Self-reported physical activity was assessed using the CHAMPS Questionnaire [25]. The CHAMPS is a 41-item measure developed specifically for the assessment of physical activity in adults 50 years and older. The CHAMPS measure yields estimates of total minutes of physical activity and energy expended per week in all physical activities of moderate or higher intensity.

2.5.2 Secondary Outcomes

2.5.3 Mobility Performance—The 400 Meter Walk and Timed Stair Climb tests were used as objective assessments of participants' mobility performance. The 400 Meter Walk test was completed in a corridor with 2 cones spaced 20 meters apart. Individuals were instructed to walk as quickly as they could and the time to complete 10 laps around the cones was recorded as the performance measure. The stair-climb task involved ascending a set of 8 stairs, turning around on the top of the platform, and then descending. Participants were instructed to complete the task as quickly as they could and performance was measured as the total time (in seconds) necessary to complete the task.

2.5.4 Mobility-Related Self-Efficacy—Mobility-related self-efficacy was assessed by asking participants to rate their confidence in successfully completing incrementally more challenging amounts of the 400 Meter Walk and Stair Climb tasks. For walking self-efficacy, participants were asked to rate their confidence on a 0 (no confidence at all) to 10 (completely confident) scale in completing 2, 4, 6, 8, and 10 laps around the cones without stopping. For stair climb self-efficacy participants were asked to rate their confidence in successfully completing 2, 4, 6, 8, and 10 trips on the stairs without stopping. Mobility-related self-efficacy scores were calculated for each task by summing the total, dividing by the total number of ratings, and multiplying by 10 to yield a score ranging from 0 to 100. This hierarchical procedure for assessing mobility-related self-efficacy is consistent with

Bandura's recommendations (21) and has been shown to be valid and reliable in prior exercise intervention trials targeting older knee OA patients (26)

2.5.6 Leg Extension Strength—Consistent with procedures recently described by Rejeski et al [27], participants' leg strength was assessed by performing as many leg extension repetitions as possible to volitional fatigue using a weight self-rated as being moderately difficult to lift. The strength score at each assessment was calculated by multiplying the weight lifted by the number of repetitions completed.

2.5.7 Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC)—Self-reported physical function and pain symptoms was assessed using the WOMAC [28]. Participants will indicate on a scale of 0 (none) to 4 (extreme) the amount of difficulty they have experienced performing basic physical function tasks in the past 48 hours due to knee OA. The physical function subscale consists of 17 items that will be summed to produce a physical function score ranging from 0 to 68 with higher scores indicating poorer function. Participants will also indicate the pain severity they had experienced during the past 48 hours due to knee OA on a scale ranging from 0 (none) to 4 (extreme). The WOMAC pain subscale consists of 5 items and total scores range from 0 to 20 with higher scores indicating greater pain.

2.5.8 Health-Related Quality of Life (HRQL)—Generic HRQL was obtained using the Rand Medical Outcomes Study 36-item Short Form Health Survey (SF-36) [29]. The SF-36 is a generic measure of HRQL which consists of 2 norm-based composite scales (mental health and physical health) and 8 subscales (physical functioning, mental health, role-physical, role-emotional, bodily pain, general health, vitality, and social functioning).

2.5.9 Late Life Function and Disability Inventory—Self-reported functional limitations and disability were assessed using the abbreviated LL-FDI [30]. The 15 item functional limitations component of the LL-FDI is composed of three 5-item subscales assessing advanced lower extremity function, basic lower extremity function, and upper extremity function. The disability component of the LL-FDI is composed of 8 item disability frequency and 8 item disability limitation subscales.

2.5.10 Social Cognitive Process Measures—A series of social cognitive theory-based processes measures were assessed using the physical activity barriers self-efficacy scale [31], satisfaction with function and appearance scale [32], and self-regulatory self-efficacy scale [33].

2.5.11 Feasibility Measures—Descriptive statistics for assessments of select indicators of trial feasibility including recruitment rates, intervention adherence, adverse events, and retention rates will be calculated prospectively throughout the trial.

2.6 Procedures

Volunteers expressing an interest in participating in IMPACT-P completed a phone screening to determine their eligibility for the study. Prior to participation in the interventions, participants completed a baseline screening visit during which assessments of the primary and secondary outcomes were obtained. At the beginning of the baseline screening visit, inclusion criteria were verified and medical history, informed consent, and HIPPA waiver documents were completed. Participants then completed the mobility performance tasks and the leg strength assessment followed by the questionnaire assessments. Following completion of the questionnaires, participants were provided verbal and written instructions on how to wear the accelerometer. Participants wore the

accelerometer for the next 7 consecutive days and monitors were returned to trial staff via U.S. postal service. Upon completion of the baseline screening visit, participants were randomly assigned into one of the two treatment arms (TRAD or GMCB exercise intervention). Physician clearance to exercise and physician documentation of knee OA diagnosis were obtained prior to participation in the interventions. Assessments of the primary and secondary outcomes were obtained using the exact same procedures at 3 month and 12 month follow-up screening visits conducted by study staff blinded to participants' treatment group assignment.

2.6.1 Interventions

2.6.2 Traditional Arm (TRAD)—The traditional exercise intervention involved 3 center-based exercise sessions per week over a period of 3-months for a total of 36 contact hours with study staff (3 weekly 1 hour sessions $\times$ 12 weeks = 36 contact hours). Each exercise session consisted of 30–40 minutes of moderate intensity aerobic exercise and 20 minutes of lower body strength training. Moderate intensity walking was the primary mode of aerobic exercise. However, other modes of aerobic activity (e.g., stationary cycling) were utilized on a limited basis when walking was contraindicated for any reason. Moderate intensity was assessed by Borg's 6–20 perceived exertion scale [34]. Participants are asked to walk at an intensity 13 (Somewhat Hard) and were discouraged from exercising at levels > 15 (Hard) or < 11 (Light). The exercise prescription was tailored to each individual's abilities and exercise tolerance/capacity and exercise duration and intensity were gradually increased across the intervention to reach targeted prescription ranges. Leg strengthening exercises (leg extension, leg curl, step-up, and calf raise) were performed for 1–3 sets of 8–12 repetitions. Consistent with standard models of exercise therapy, participants complete 3 exercise sessions per week for 3 months and no further formal staff intervention contact is provided in months 4 to 12. Traditional intervention participants were also encouraged to increase independent exercise and physical activity participation to accrue weekly physical activity levels consistent current national recommendations (i.e., 150 minutes of moderate intensity physical activity) and provided standard OA self-management advice to facilitate exercise motivation and participation. An overall objective of the TRAD exercise intervention is to focus upon maintaining attendance and exercise behavior to highly controlled environments within a time-limited framework with the assumption that patients will subsequently generalize this behavior to a program of independent exercise at home once the supervised intervention ends.

2.6.3 GMCB Intervention Arm—The GMCB intervention arm received the identical 36 total contact hours provided for the TRAD intervention. However, the structure, sequencing, and goals of the contacts in the GMCB arm differed from those provided in the TRAD arm. Participants randomized to the GMCB intervention completed 27 center-based session each lasting 80-min in duration (36 total contact hours). Each center-based session was comprised of a 60-min exercise component involving the same exercise prescription provided in the TRAD intervention that was followed by 20 minutes of group-based cognitive behavioral activity counseling that focused on the use of self-regulatory skills to promote maintenance of physical activity and prevention of knee OA-related disability. The goal of GMCB intervention was to provide participants with instruction and practice in physical activity-related self-regulation skills via the group-mediated activity counseling and gradually facilitate the transition from supervised, center-based exercise towards independent self-regulation of exercise and physical activity participation. The 27 center-based sessions (36 contact hours) provided during the GMCB intervention were delivered with systematically decreased frequency across a 9 months period the trial. The GMCB counseling component is based on the group dynamics literature and social cognitive theory [21] and emphasizes the development of motivation and key activity-related self-regulatory skills to promote exercise

adherence and an increase in all forms of physical activity such as participation in purposeful activity and reengagement in challenging ADLs. Specific content of the GMCB counseling component includes the promotion of group identity and social norms for activity; self-monitoring; goal setting; barrier problem solving; fostering social support; reducing sedentary time; and mindfulness-based relaxation and pain management strategies. The purpose of combining counseling and exercise in the GMCB approach is to instruct participants on how to use self-regulatory skills necessary to be physically active with the challenge of knee OA, and through the use of the group as an agent of behavioral change, facilitate motivation to develop and implement these behavioral skills in order to maintain long-term, independent exercise and physical activity participation.

Whereas the 36 contacts in the traditional exercise arm were delivered in 3 month, the 36 GMCB intervention contacts were delivered across a period of 9 months. Participants transition from 2 center-based exercise sessions per week in Month 1 to 1 center-based exercise session per week in Months 2 through 4, biweekly sessions in Months 5–6, and to monthly center-based booster sessions in Months 7 to 9. No formal staff intervention contact is provided to GMCB participants in months 10 to 12. In each of these months, participants are using the motivation and skills developed in the GMCB counseling to plan and participate in increasing frequency of independent, home-based exercise/physical activity. A basic principle underlying these contacts and their sequencing is one of gradually weaning participants from the dependency on staff and the group program toward independent self-regulation of physical activity. This process is one of a phased increase in the ratio of personal responsibility in conjunction with a phased decrease in staff, group and clinic dependency. Thus, in contrast to the TRAD intervention, the GMCB approach places an emphasis on the regulation of behavior in, and social problem solving barriers common to, free-living environments.

2.7 Statistical Analysis

The primary hypotheses of the IMPACT-P trial were that the GMCB intervention would result in significantly greater physical activity participation and more favorable improvements in select OA outcomes when compared to the traditional exercise intervention. Differences in the longitudinally gathered outcome data collected at 3 and 12 months will be individually standardized by baseline values and evaluated using a weighted repeated measures analysis of variance statistical model adjusting for the effects of age and gender. All analyses will be conducted according to the intention to treat principle with maximum likelihood imputation methods used to account for missing data. The sample size originally targeted for IMPACT-P (90 participants with 20% attrition rate) was selected to provide > 80% power to detect a moderate effect size ($d = .50$) difference in primary and secondary outcomes of interest.

3 Discussion

The IMPACT-P trial was a single-blind, two arm randomized controlled pilot trial evaluating the comparable efficacy of traditional exercise intervention with that of a social cognitive theory-based GMCB exercise intervention for producing improvements in physical activity participation and select relevant knee OA outcomes. Although exercise is now advocated as an important component in the medical management of knee OA, challenges in successfully promoting long-term maintenance of regular exercise and physical activity participation undermine the efficacy of implementing exercise as part of the adjuvant treatment of knee OA. The GMCB physical activity intervention has been shown to produce meaningful improvements in physical activity adherence, mobility performance, and quality of life in prior randomized controlled trials targeting older adults with CVD [23], obesity [22], and risk of mobility disability [21]. Nonetheless, the feasibility

and preliminary efficacy of implementing the GMCB approach in older knee OA patients has yet to be determined.

The IMPACT-P trial is one of the few studies designed to examine the efficacy of a theory-driven, evidence-based intervention approach for improving physical activity adherence in older, knee OA patients [19, 35]. Finding from this pilot trial will provide evidence of the feasibility and preliminary efficacy of implementing the GMCB intervention approach in knee OA patients. Recall that the TRAD exercise intervention focuses upon maintaining attendance and exercise behavior to highly controlled environments within a time-limited framework with the assumption that patients will subsequently generalize this behavior to a program of independent exercise at home once the supervised intervention ends. By contrast, the GMCB approach places an emphasis on the regulation of behavior in, and social problem solving barriers common to, free-living environments. Thus, the GMCB intervention is designed to promote the development of self-regulatory skills necessary to successfully facilitate the transition from supervised, center-based exercise to the maintenance of independent, home-based exercise and physical activity participation. Although findings from the IMPACT-P trial could yield meaningful implications for the promotion of physical activity among knee OA patients, there are select study limitations that should be acknowledged. Given this is a pilot trial intended to determine, in part, feasibility and preliminary efficacy of delivering the GMCB intervention to older, knee OA patients, it is possible that the sample size does not provide sufficient power to detect meaningful differences in all relevant outcomes of interest. It is also plausible that the differential sequencing of intervention contacts which are spread across 3 months in the TRAD intervention and 9 months in the GMCB intervention could be viewed as a potential limitation. However, it should be recognized that each intervention received an identical number of contact hours and the trial design allows us to evaluate if differential timing, structure, and goals of the GMCB and TRAD intervention contacts yield meaningful differences in trial outcomes.

In summary, determining the comparable efficacy of these different approaches to promoting active lifestyles in sedentary knee OA patients could have significant implications for the behavioral management of knee OA. Findings from the present pilot trial will also provide effect size estimates necessary to inform the design of subsequent, large scale definitive efficacy trial, the results of which would fill a critical gap in knowledge addressing how to augment the efficacy of implementing exercise in the treatment of older, knee OA patients.

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Figure 1.
Design of the IMPACT-P pilot trial.

Figure 2.
Flow of participants through the IMPACT-P trial

Table 1

Contact sequencing and content in the Traditional and GMCB interventions

Intervention Criteria	GMCB	Traditional
Supervised Center-Based Exercise Sessions	60 Min of Exercise (Walking and Lower Body Strength Training) + 20 Min of GMCB counseling	60 Min of Exercise (Walking and Lower Body Strength Training)
Supervised Exercise Month 1	2 Sessions/Week	3 Sessions/Week
Supervised Exercise Month 2–3	1 Session/Week	3 Sessions/Week
Supervised Exercise Month 4	1 Session/Week	No Sessions
Supervised Exercise Month 5–6	2 Sessions/Month	No Sessions
Supervised Exercise Months 7–9	1 Session/Month	No Sessions