Group-mediated Physical Activity Promotion and Mobility in Sedentary Patients with Knee Osteoarthritis: Results from the IMPACT-Pilot Trial

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ABSTRACT. ***Objective.*** To compare the effects of a group-mediated cognitive behavioral exercise intervention (GMCB) with traditional center-based exercise therapy (TRAD) on objectively assessed levels of physical activity (PA) and mobility in sedentary patients with knee osteoarthritis (OA).

Methods. The Improving Maintenance of Physical Activity in Knee Osteoarthritis Trial-Pilot (IMPACT-P) was a 12-month, 2-arm, single-blind, randomized controlled pilot study designed to compare the effects of GMCB and TRAD on 80 sedentary patients with knee OA with self-reported difficulty in daily activities [mean age 63.5 yrs, 84% women, mean body mass index (BMI) 32.7 kg/m^2]. Objective assessments of PA (LIFECORDER Plus Accelerometer) and mobility (400-m walk) were obtained at baseline, 3 months, and 12 months by study personnel blinded to participants' treatment assignment.

Results. Intent to treat 2 (treatment: GMCB and TRAD) × 2 (time: 3 mos and 12 mos) analyses of covariance of controlling for baseline, age, sex, and BMI-adjusted change in the outcomes demonstrated that the GMCB intervention yielded significantly greater increases in PA ($p < 0.01$) and a nonsignificant yet more favorable improvement in mobility ($p = 0.09$) relative to TRAD. Partial correlation analyses also revealed that change in PA was significantly correlated with the 400-m walk performance at 3-month ($r = -0.51$, $p < 0.01$) and 12-month ($r = -0.40$, $p < 0.01$) followup assessments.

Conclusion. Findings from the IMPACT-P trial suggest that the GMCB treatment resulted in significantly greater improvement in PA and nonsignificant yet more favorable change in mobility relative to TRAD. (First Release Sept 1 2014; J Rheumatol 2014;41:2068–77; doi:10.3899/jrheum.140054)

Key Indexing Terms:
AGING PHYSICAL ACTIVITY OSTEOARTHRITIS EXERCISE MOBILITY

Knee osteoarthritis (OA) is a progressive, chronic degenerative disease that is cited as one of the primary causes of activity restriction, functional limitations, and physical disability with advancing age[1]. Contemporary approaches to treatment of knee OA have increasingly focused on the promotion of lifestyle change to preserve or remediate function, and to manage physical symptoms. Mounting evidence suggests that inactivity, secondary to primary OA symptoms, exacerbates knee pain and accelerates progression toward functional limitations and disability in older patients with knee OA[2,3]. Findings from randomized controlled trials demonstrate that exercise produces meaningful improvements in OA outcomes[4,5,6,7,8], and exercise and/or physical activity (PA) is now advocated as an integral component to the self-management of knee OA[9,10,11].

Despite considerable evidence supporting the benefits of PA, most patients with OA fail to obtain recommended daily amounts of PA[12], and PA interventions targeting patients with knee OA are plagued by high attrition rates and poor postintervention maintenance of treatment benefits[13,14,15,16,17]. Evidence also suggests that poor postintervention adherence to PA is directly related to the deterioration of exercise-induced benefits observed in patients with knee OA[14,18]. Collectively, these findings suggest that many patients with knee OA quickly return to sedentary lifestyles following the termination of structured exercise and/or PA interventions, and that the lack of adherence contributes to the loss of clinically relevant benefits derived from exercise therapy.

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Although behavioral strategies intended to enhance the adoption and maintenance of PA have been incorporated in prior PA intervention trials targeting patients with knee OA[19], relatively little attention has been allocated to the systematic development of motives and behavioral skills that aid in promoting adherence as patients with knee OA attempt to transition from supervised to independent, self-managed PA behavior. Indeed, 1 explanation for poor exercise adherence is that traditional interventions fail to provide the self-regulatory skills necessary to facilitate the transition from center-based exercise therapy to the maintenance of independent PA participation[20]. One recent approach based on social cognitive theory and the group dynamics literature[21], a group-mediated cognitive behavioral (GMCB) intervention, has yielded significant improvements in clinically relevant behavioral and functional outcomes in patients with chronic diseases with compromised physical function[22,23,24]. While these findings suggest that this approach holds promise for the treatment of arthritis, its efficacy in patients with knee OA has yet to be evaluated.

The GMCB intervention couples exercise with counseling around the theme of self-regulatory skills to promote independent maintenance of PA and prevent progression toward mobility disability. The GMCB intervention is designed to promote the systematic development of 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 to maintain longterm, independent exercise and PA participation. Given the established challenges of adherence and erosion of treatment benefits, these features could make the GMCB approach particularly beneficial in the treatment of patients with knee OA. Consequently, the primary aim of our present study was to determine the comparative efficacy of the GMCB approach with a traditional center-based, supervised exercise intervention (TRAD) for improving moderate to vigorous PA (MVPA) participation and mobility in knee OA in sedentary, symptomatic patients having difficulty performing daily activities. It was hypothesized that the GMCB intervention would result in significantly greater weekly volume of MVPA and superior improvement in an objective measure of mobility (400-m walk time) as compared to TRAD.

MATERIALS AND METHODS

Design. IMPACT-P was a 12-month, 2-arm, single-blind, randomized controlled pilot trial designed to compare TRAD and GMCB exercise interventions among sedentary patients with knee OA. A total of 80 adults with radiographically confirmed, symptomatic knee OA were randomly assigned to either the GMCB (n = 40) or TRAD (n = 40) interventions. Outcome assessments were obtained at baseline, 3-month, and 12-month followup visits by staff blinded to group assignment. Our current paper focuses upon the primary outcomes of MVPA and mobility. All analyses were conducted using the intent-to-treat principle. Complete details of the study design have been published[25].

Participants. The inclusion criteria were (1) age > 55 years; (2) knee pain on most days of the month; (3) less than 20 min/week of structured exercise during the prior 6 months; (4) self-reported difficulty with at least 1 of the following activities because of knee pain: walking 0.25 miles, climbing stairs, bending, stooping, kneeling, shopping, housecleaning, or 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; (5) radiographic evidence of Kellgren-Lawrence scale stage II or III (mild to moderate) tibiofemoral OA; and (6) willingness to participate in our study protocol.

Exclusion criteria included (1) serious medical conditions such as active cardiovascular disease, cancer, or pulmonary disease; (2) inability to walk without a cane or other assistive device; (3) physician-documented radiographic evidence of knee joint varus or valgus malalignment[26]; (4) participation in another research study; (5) ≥ 21 alcoholic drinks per week; (6) OA severity > 3 on the Kellgren-Lawrence scale; (7) inability to complete our 12-month study or unlikely to be compliant because of conflicts; and (8) other safety/adherence concerns noted by the clinical staff.

Our study spanned from September 28, 2009, to October 19, 2011. Recruitment strategies have been described previously[25]. Potential participants first had to pass inclusion/exclusion criteria through a telephone screening. Participants who passed this phase were scheduled for the baseline in-person screening visit. Eligible participants were then randomly assigned to each of the 2 treatments, with the stipulation that there were an equal number in each group. Assessment staff were blind to treatment assignment.

Measures: MVPA and total PA. Assessment of MVPA and total PA were obtained using the LIFECORDER Plus accelerometer (Suzuken Kenz Inc. Ltd.), with the primary outcome being total weekly volume of MVPA. Participants wore the LIFECORDER 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 Plus on a self-monitoring log. The LIFECORDER Plus records minutes of light, moderate, and vigorous PA participation, as well as calculates total daily steps taken. Consistent with the metabolic capacities for the targeted age group[22], PA < 3 metabolic equivalence units (METS) was light, 3–6 METS was moderate, and > 6 METS was vigorous. All participants recorded wear time on a weekly log that was checked against movement data recorded by the activity monitor. The LIFECORDER Plus accelerometer has previously established validity and reliability[27], and has been used in other trials[22,23]. Data processing was consistent with established protocols[22,23,26]; over 95% of the MVPA recorded was of moderate intensity.

Mobility. The 400-m walk test was used as an objective test of mobility. The 400-m walk test was completed in a corridor with 2 cones spaced 20 m 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 outcome. Performance was measured as the total time (in s) necessary to complete the task. The 400-m walk test is a well-established, valid, reliable, objective measure of mobility performance that has been used in multiple large-scale, randomized, controlled PA intervention trials targeting older adults[22,23].

Self-regulatory efficacy. Participants' efficacy to organize, plan, and schedule regular exercise and/or PA was assessed using the self-regulatory self-efficacy scale developed by Rejeski, *et al*[24]. Participants rate their ability to schedule and plan PA into their weekly routine on a scale ranging from 0 (not at all certain) to 100 (completely certain). It was used in our present study to evaluate the efficacy of the GMCB approach for increasing participants' confidence in their ability to plan and participate in independent PA at the 3-month followup assessment.

Procedures. Prior to randomization, participants completed an in-person baseline screening visit during which assessments of mobility and MVPA were obtained. The inclusion criteria were verified at this time, informed consent and the Health Insurance Portability and Accountability Act waiver documents were completed, and information was obtained on medical history. Subsequently, participants were provided verbal and written instructions on how to wear the accelerometer. Participants wore the accelerometer for the 7 consecutive days following the baseline screening visit and monitors were returned to trial staff by mail. Upon completion of this visit, participants were randomly assigned to treatment arms GMCB or TRAD. Outcomes assessments were obtained using the exact same procedures at both the 3-month and 12-month followup screening visits.

TRAD exercise arm intervention. The TRAD exercise intervention involved 3 center-based exercise sessions per week over a period of 3 months for a total of 36 contact h with study staff (3 weekly 1-h sessions × 12 weeks = 36 contact h). Each exercise session consisted of 30–40 min of moderate intensity aerobic exercise and 20 min 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 used on a limited basis (only 3 total exercise sessions during the entire trial) when walking was contraindicated for any reason. Exercise intensity was monitored using Borg's 6–20 perceived exertion scale[28]. Participants were asked to walk at 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 goals. Leg strengthening exercises (leg extension, leg curl, step-up, and calf raise) were performed for 1–3 sets of 8–12 repetitions. Participants complete 3 exercise sessions per week for 3 months and no further formal staff intervention contact was provided in months 4 to 12. TRAD intervention participants were also encouraged to increase independent exercise and PA participation to accrue weekly PA levels ≥ 150 min of moderate intensity PA and were provided with standard OA self-management advice (through Arthritis Foundation educational pamphlets) to facilitate exercise motivation and participation.

GMCB exercise intervention arm. Although the GMCB intervention arm also received 36 total contact h, 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, 80-min center-based sessions for a total of 36 total contact h. Each center-based session included 60 min of exercise (the same exercise prescription as in TRAD) that was followed by 20 min of group-based cognitive behavioral activity counseling that focused on the use of key self-regulatory skills (self-monitoring, group and individual goal setting, barrier problem solving, action planning, relaxation/pain management strategies) to promote independent self-regulation of PA and prevent knee OA-related disability. The GMCB counseling component is based on the group dynamics literature and social cognitive theory[21]. It emphasizes the development of motivation and key activity-related, self-regulatory skills, while using group dynamics as an agent supporting behavior change, promoting exercise adherence, and increasing all forms of PA such as participation in purposeful activity and reengagement in challenging activities of daily life.

Whereas the 36 contacts in the TRAD exercise arm were delivered in 3 months, the 36 GMCB intervention contacts were delivered across a period of 9 months. Participants transitioned from 2 center-based exercise sessions per week in the first month to 1 center-based exercise session per week in months 2 to 4, biweekly sessions in months 5 to 6, and to monthly center-based booster sessions in months 7 to 9. No formal staff intervention contact was provided to GMCB participants in months 10 to 12. In contrast to the TRAD intervention that focused upon center-based, supervised exercise, the GMCB approach places an emphasis on the regulation of behavior in, and social problem solving barriers common to, one's home and/or community environment. The self-regulatory counseling portion of the GMCB arm was led by the principal investigator (BCF), who was trained in delivering the intervention by coinvestigator (WJR), who developed this approach[22,23,24]. Description of the timing of the contacts provided in the GMCB and TRAD intervention arms is provided in Table 1.

Statistical analysis. The effects of the GMCB and TRAD interventions on changes in total PA, MVPA, and mobility were analyzed using separate 2 (treatment: GMCB and TRAD) × 2 (time: 3 mos and 12 mos) analysis of covariance (ANCOVA). Baseline adjusted changes in total PA, MVPA, and 400-m walk time were used as the outcomes with age, sex, body mass index (BMI), and baseline values of each measure included in the models as covariates. ANCOVA analyses were conducted using the intention-to-treat principle, with the last value carried forward approach used to account for missing data. One participant randomized to the TRAD intervention did not return the accelerometer at the baseline assessment. Consequently, ANCOVA analyses of total PA and MVPA was conducted with a total of 79 participants (GMCB = 40 and TRAD = 39). T tests were conducted to explore differences in adherence to the supervised exercise sessions and self-regulatory self-efficacy at the 3-month followup assessment between the GMCB and TRAD treatment arms. Partial correlation analyses controlling for age were conducted to examine (1) the relationship between MVPA and mobility at the 3-month and 12-month followup assessments, and (2) the relationship between self-regulatory self-efficacy and MVPA at 3-month followup. Additionally, effect sizes (Cohen d) were calculated by taking the mean difference and dividing by the pooled SD to determine the magnitude of differences observed for each outcome.

RESULTS

Participant characteristics and flow through the trial. A total of 174 participants were prescreened in telephone interviews. Of these, 94 prescreened individuals (55%) were excluded (Figure 1). A total of 80 participants (45% of prescreened individuals) were randomized into our study with 40 in the GMCB arm and 40 in the TRAD arm. The Consolidated Standards of Reporting Trials (CONSORT) flow diagram illustrating the recruitment and retention of participants throughout the trial is provided in Figure 1. Select demographic characteristics of the participants at baseline are summarized in Table 2, partitioned by treatment arm. No significant baseline differences in age ($p = 0.92$) or BMI ($p = 0.69$) were observed. Inspection of the data presented in Table 2 reveals that there were similar distributions of ethnicity, education, and income in each treatment arm. It should be noted, however, that there were 5 more men in the TRAD arm relative to the GMCB arm. Collectively, the sample was composed of primarily older women who were overweight or obese, and heterogeneous with regard to ethnicity and educational/income status. The CONSORT diagram summarizes the flow of participants through the IMPACT-P trials (Figure 1). A total of 80 of the 174 participants (45%) who completed the telephone prescreening interview were randomized into our study. This recruitment rate is similar to that observed in prior randomized, controlled PA intervention trials targeting older adults[22,24].

Of the 80 participants randomized, 72 (90%) completed the baseline assessment and at least 1 followup assessment. As illustrated in Figure 1, 64 participants (80%) completed the 3-month followup and 66 (82%) completed the 12-month followup assessments. Of the 8 participants (10%) who did not complete at least 1 followup assessment, 3 (4%) were from the GMCB treatment arm and 5 (6%) were from the TRAD arm. Additionally, of the 14 partici-

Table 1. Contact sequencing and content in the GMCB and TRAD interventions.

Intervention Criteria	GMCB	TRAD
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/mo	No sessions
Supervised exercise months 7–9	1 session/mo	No sessions

GMCB: group-mediated cognitive behavioral exercise; TRAD: traditional center-based exercise therapy.

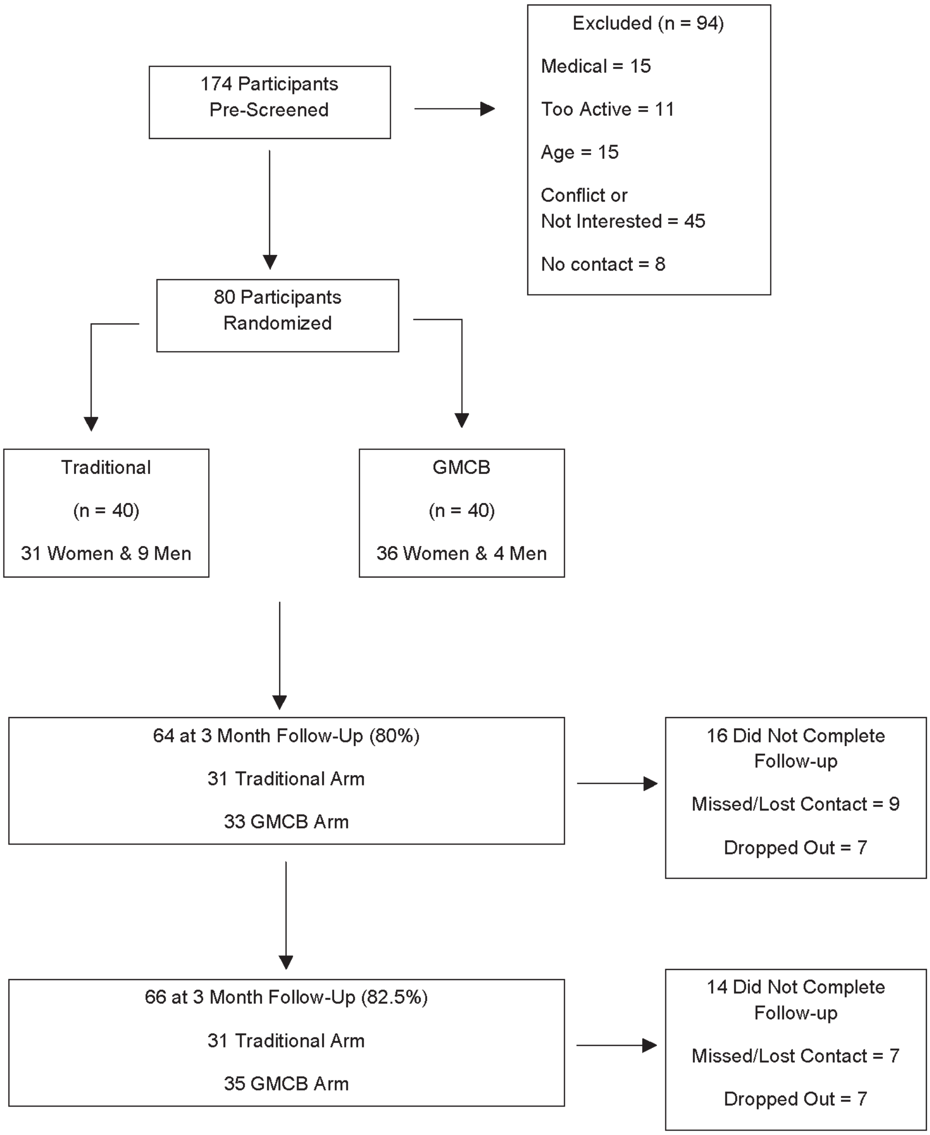

Figure 1. CONSORT diagram for the IMPACT-P trial. CONSORT: Consolidated Standards of Reporting Trials; IMPACT-P: Improving Maintenance of Physical Activity in Knee Osteoarthritis Trial-Pilot; GMCB: group-mediated cognitive behavioral exercise intervention.

Table 2. Characteristics of the participants.

Characteristic	Intervention Arms, n (%) GMCB, n = 40	TRAD, n = 40
Age, mean (SD)	63.4 (7.2)	63.6 (6.6)
Sex		
Male	4 (10)	9 (23)
Female	36 (90)	31 (77)
Ethnicity		
White	29 (73)	26 (65)
African American	8 (20)	12 (30)
Asian	1 (2)	1 (2)
Latino	2 (5)	1 (2)
Education		
High school or less	16 (40)	18 (45)
More than high school	24 (60)	22 (55)
Income, US		
< $15 K	4 (10)	9 (23)
$15–$35 K	9 (23)	7 (17)
$35–$50 K	3 (8)	6 (15)
> $50 K	24 (60)	18 (45)
BMI, kg/m^2, m (SD)	32.4 (7.1)	33.0 (7.1)
BMI classification		
Normal/underweight	6 (15)	3 (7)
Overweight	10 (25)	12 (30)
Obese	24 (60)	25 (63)

GMCB: group-mediated cognitive behavioral exercise; TRAD: traditional center-based exercise therapy; BMI: body mass index.

Table 3. Unadjusted descriptive statistics (m/SD) for weekly minutes of total PA and MVPA, and 400-m walk time.

Variable	Intervention Arms GMCB	TRAD
Weekly mins total PA		
Baseline	351.0 (196.8)	352.5 (229.5)
3 mos	410.3 (246.4)	299.1 (179.2)
12 mos	404.5 (251.8)	278.3 (179.2)
Weekly mins MVPA		
Baseline	52.4 (63.3)	51.7 (70.0)
3 mos	83.4 (77.0)	44.8 (62.3)
12 mos	81.1 (82.0)	33.0 (48.9)
400-m walk time, s		
Baseline	357.6 (98.5)	385.8 (120.4)
3 mos	347.0 (95.6)	382.3 (112.2)
12 mos	351.3 (95.5)	419.4 (196.9)

PA: physical activity; MVPA: moderate to vigorous physical activity; GMCB: group-mediated cognitive behavioral exercise; TRAD: traditional center-based exercise therapy.

pants (18%) who did not complete the 12-month assessment, 5 were from the GMCB intervention (6%) and 9 were from TRAD (11%). The primary reasons for loss to followup were lost contact (11%), time conflict (4%), and difficulty in traveling to the center-based sessions and/or assessments (3%). It should also be noted that 7 participants who did not complete all followup assessments dropped out of our study after randomization, but prior to the start of the intervention. Only 2 adverse events were reported during the trial, with 1 participant in each intervention arm reporting injuries they experienced while involved in activities not related to the study. Consequently, no adverse events directly related to the interventions were observed during the IMPACT-P trial.

Effects of the interventions on MVPA and total PA. Evaluation of the logs and the movement data revealed participants averaged daily wear time of about 13 and a half h at baseline, 13 h at 3-month followup, and 13 h at 12-month followup. The unadjusted descriptive statistics for MVPA and total PA are summarized in Table 3. ANCOVA analysis of MVPA yielded a significant treatment main effect ($F[1,74] = 18.77$, $p < 0.001$). Inspection of the group means provided in Table 3 demonstrates that the GMCB intervention resulted in superior increases in weekly minutes of MVPA at 3 months (GMCB = 83.4 min, TRAD = 44.8 min, $d = 0.54$) and 12 months (GMCB = 81.1 min, TRAD = 33.0 min, $d = 0.70$) relative to the TRAD intervention (Figure 2 and 3). Baseline MVPA was also a strong predictor of change in MVPA ($F[1,74] = 13.56$, $p < 0.001$), with those participating in the least MVPA at baseline demonstrating the greatest increase in MVPA at the 3-month and 12-month followup assessments. ANCOVA analysis of baseline-adjusted change in weekly minutes of total PA yielded a significant treatment main effect ($F[1,74] = 20.70$, $p < 0.001$). Inspection of the group means provided in Table 1 demonstrates that the GMCB intervention resulted in superior increases in total weekly minutes of PA at 3 months ($d = 0.51$) and 12 months ($d = 0.58$) relative to the TRAD intervention. Consistent with the findings for total minutes of PA, baseline minutes of PA ($F[1,74] = 7.38$, $p < 0.01$) was a strong predictor of change in total minutes of PA with those participants accruing the least PA at baseline demonstrating the greatest increase in total minutes of PA at the 3-month and 12-month followup assessments (Figure 2 and 3).

Effects of the interventions on mobility. The unadjusted descriptive statistics for 400-m walk time are summarized in Table 3. Although ANCOVA analysis of baseline-adjusted change in 400-m walk time revealed the treatment main effect did not reach significance ($F[1,74] = 2.89$, $p = 0.09$), inspection of the group means provided in Table 3 demonstrates that the GMCB intervention resulted in more favorable improvements in 400-m walk time at 3 months (GMCB = 347 s, TRAD = 382 s, $d = 0.34$) and 12 months (GMCB = 351 s, TRAD = 419 s, $d = 0.44$) relative to the TRAD intervention (Figure 4).

Adherence to supervised exercise. Adherence to supervised exercise sessions was 71% in the GMCB intervention and 63% in the TRAD intervention. T test analysis of differences in adherence approached significance ($t[62] = 1.61$, $p = 0.10$) with more favorable exercise adherence to the center-based, supervised exercise sessions being observed in the GMCB intervention arm ($d = 0.40$).

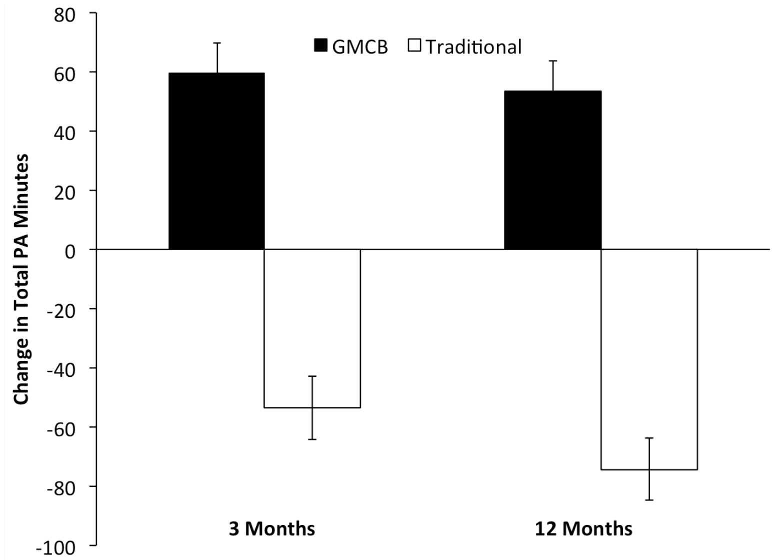

Figure 2. Adjusted means of the change in total physical activity from baseline by treatment arm. GMCB: group-mediated cognitive behavioral exercise intervention.

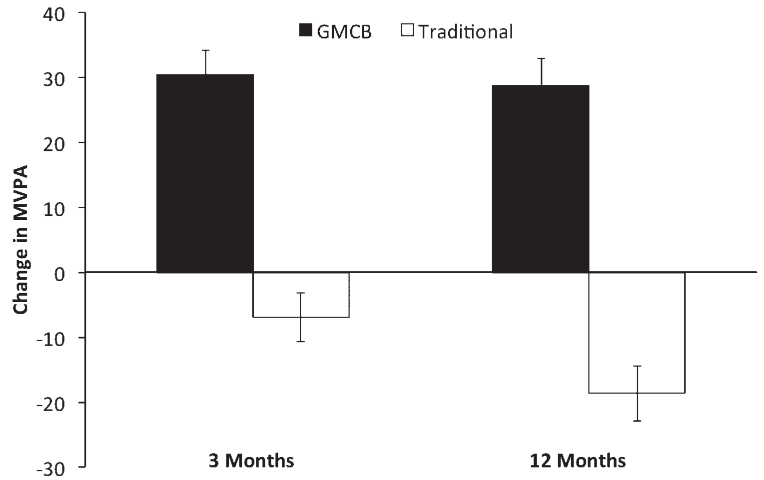

Figure 3. Adjusted means of the change in MVPA from baseline by treatment arm. MVPA: moderate to vigorous physical activity; GMCB: group-mediated cognitive behavioral exercise intervention.

Self-regulatory self-efficacy. T test analysis of differences in self-regulatory self-efficacy at 3-month followup revealed a significant difference ($t[78] = 2.54$, $p < 0.01$) with the GMCB intervention arm demonstrating superior self-regulatory self-efficacy relative to the TRAD arm ($d = 0.63$).

The relationship between PA and mobility performance. Partial correlation analysis controlling for age also revealed that weekly minutes of total PA were significantly correlated with 400-m walk time at 3 months ($r = –0.56$, $p < 0.01$) and 12 months ($r = –0.47$, $p < 0.01$). Additionally, weekly minutes of MVPA were also significantly correlated with 400-m walk time at 3 months ($r = –0.51$, $p < 0.01$) and 12 months ($r = –0.40$, $p < 0.01$).

The relationship between self-regulatory self-efficacy and MVPA. Partial correlation analysis controlling for age also revealed that self-regulatory self-efficacy was significantly correlated with weekly minutes of MVPA at 3 months ($r = 0.35$, $p < 0.01$).

DISCUSSION

Our findings from this pilot, comparative efficacy trial demonstrate that the GMCB intervention resulted in significantly greater improvements in objectively determined PA and more favorable, though nonsignificant, improvements in mobility relative to a traditional PA intervention approach emphasizing 12 weeks of center-based, supervised exercise.

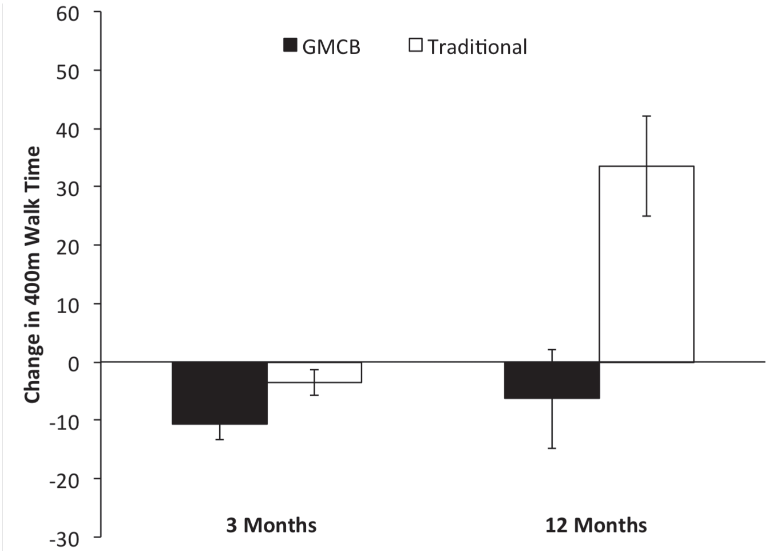

Figure 4. Adjusted means of the change in 400-m walk time from baseline by treatment arm. GMCB: group-mediated cognitive behavioral exercise intervention.

Weekly minutes of total PA and MVPA were also significantly correlated with change in 400-m walk time, supporting the relationship between increased PA participation and improvements in mobility. Additionally, the overall study recruitment, retention, and adherence rates were strong and compared favorably with similar PA intervention trials targeting older adults with chronic disease[7,22,23,24]. Thus, the IMPACT-P trial is one of the first studies to demonstrate the utility and preliminary efficacy of a GMCB activity counseling exercise intervention for promoting longterm maintenance of PA participation and enhancing mobility in sedentary patients with knee OA who have self-reported difficulty with daily activities.

Findings from our present trial are consistent with other randomized controlled PA intervention trials demonstrating the benefits of the GMCB approach among older adults at risk for mobility disability[22,23,24], and extend these benefits to a sample of sedentary patients with knee OA. Notably, results from the Cardiovascular Health and Activity Maintenance Program (CHAMP)[24], Lifestyle Interventions and Independence for Elders (LIFE)[22], and Comprehensive Lifestyle Intervention Program (CLIP)[23] trials have also demonstrated that the GMCB intervention leads to significant improvements in PA participation, mobility performance, and quality of life in patients at risk for cardiovascular disease[24] and those who have compromised physical function[22,23]. Further, the effect sizes accompanying the differences in PA and mobility with the GMCB intervention are similar in magnitude to those observed in the prior trials implementing this approach[22,23,24]. The favorable recruitment, retention, and adherence rates together with the absence of intervention-related adverse events support the feasibility of implementing the GMCB PA intervention in older patients with knee OA. Thus, findings from the IMPACT-P study provide initial evidence that the GMCB approach is a well-tolerated intervention that underscores the potential promise of integrating group-based cognitive behavioral counseling within exercise interventions to promote sustained PA participation for patients with symptomatic knee OA.

The GMCB treatment arm yielded significantly superior improvements in weekly minutes of objectively determined total PA and MVPA relative to TRAD at 3-month and 12-month followup. It is notable that while participants in the TRAD group systematically progressed to accruing up to 120 min of supervised walking by Week 12 of the intervention, postintervention assessment of objectively determined PA revealed a decline in total minutes of activity and MVPA relative to baseline. These results reinforce the position that inactive older adults burdened with chronic disease often rapidly return to sedentary behavior following the cessation of center-based, supervised exercise interventions[24]. Similarly, these findings may also suggest that exercise interventions focusing exclusively on center-based exercise training may not translate to an increase in PA in the home environment. Recall that a primary goal of the design and sequencing of the GMCB intervention was to gradually wean participants from dependency on staff-supervised, center-based exercise and toward independent self-regulation of PA behavior in one's home and/or community environment. Our present findings underscore the value of implementing alternative approaches that emphasize the development of behavioral skills necessary for self-regulation of PA participation to prepare patients with knee OA for the transition from supervised to independent PA maintenance.

In this regard, key self-regulatory elements of the GMCB intervention may make this approach particularly beneficial for patients with knee OA. The focal instruction, training, and practice of activity and OA symptom-related self-monitoring, implementation of a social problem-solving model to identify and overcome barriers to PA, use of peer-initiated solutions to address challenges in maintaining PA, and training in basic mindfulness-based relaxation and pain management strategies may be particularly beneficial in promoting the systematic transition from supervised exercise participation to independent home- and/or community-based PA among patients with knee OA. The superior improvements in PA accompanying the GMCB suggest this approach is superior to traditional center-based programs and provides support for the importance of targeting the development of behavioral self-regulatory skills to enhance longterm adherence to an active lifestyle. It should also be noted that baseline PA levels were also a significant predictor of change in PA across the trial. Thus, those who were least active prior to exposure to the PA interventions demonstrated the greatest improvement in PA participation.

It is important to acknowledge that while the treatment's main effect for mobility did not reach statistical significance ($p = 0.09$), the most favorable improvements in 400-m walk time were observed following the GMCB intervention. We believe this finding supports the preliminary efficacy of the GMCB approach for eliciting improvements in objective measures of mobility that represent meaningful clinical outcomes for older patients with knee OA. It is notable that differences observed for both PA and mobility appear to be primarily attributable to the divergent trajectories of change from baseline. That is, the combination of relatively modest improvements from baseline in PA and 400-m walk time accompanying the GMCB arm together with declines from baseline status in these outcomes following the traditional intervention across the 12-month followup period drove the effects favoring the GMCB intervention.

Although the improvement in mobility that emerged following the GMCB intervention did not reach the 20 s threshold proposed as the minimal clinical significant difference[29], it is similar in magnitude to change in 400-m walk performance observed following a GMCB-based PA intervention implemented in the LIFE-P trial targeting community-dwelling older adults at risk for mobility disability[22]. Additionally, when interpreting the clinical significance accompanying the change in mobility in our present trial, it is important to recognize that the proposed 20 s threshold[28] was determined using data from a sample composed of older (> 70 yrs of age), more functionally limited individuals relative to participants in IMPACT-P. Change in function is meaningfully influenced by baseline performance, with those exhibiting the poorest performance initially demonstrating the greatest improvement. Thus, the baseline status of our present sample may have influenced the magnitude of change observed in mobility. Nonetheless, taken collectively, findings from LIFE-P and our present study demonstrate that the GMCB intervention results in modest improvements in mobility performance that can persist for up to a year (3 mos following the final contact in our present trial) in patients with knee OA and older adults at risk for mobility limitations.

It is noteworthy that participants in the GMCB intervention maintained the improvement in weekly volume of PA whereas PA participation deteriorated across followup following the TRAD intervention. Further, results of correlation analysis revealed that higher volume of PA was also associated with more favorable mobility. Together, these findings suggest that the GMCB intervention is successful in eliciting modest increases in MVPA and total PA, and this volume of weekly PA may aid in preventing decline in mobility among older patients with knee OA. It is also important to recognize that in a prior large-scale exercise intervention study targeting patients with knee OA, the most benefit achieved in the reduction of pain with exercise therapy was among those individuals who were in the bottom 2 tertiles of time spent exercising. Those who exercised the most actually did not experience a reduction in knee pain[30]. Nonetheless, the extent to which the modest increases in PA observed following the GMCB intervention are sufficient to successfully preserve mobility should be explored in subsequent large-scale, randomized controlled PA trials.

Whereas both the GMCB and TRAD interventions received an equivalent number of contact hours, the GMCB contacts were spread across 9 months. The GMCB is purposely designed to spread contact across an extended length of time to wean participants from dependence on supervised, center-based exercise leadership and promote progressive independent self-regulation of activity behavior change. It is possible that extended contact to participants itself may contribute to the effects observed following the GMCB intervention. However, it is important to acknowledge that participants in the GMCB intervention reported significantly higher self-regulatory self-efficacy at 3-month followup, a point in the trial where they actually received less contact than that provided to the TRAD intervention. In addition, higher self-regulatory self-efficacy was significantly correlated with greater volume of MVPA. Together, these findings suggest the GMCB was more effective in producing increases in self-regulatory self-efficacy, that developing confidence in one's activity-related self-regulatory abilities may be integral to sustaining PA participation and mobility, and that the treatment differences observed for MVPA are not attributable to the extended contact alone. Nonetheless, the duration across which intervention contact is delivered may also be a key aspect of the PA behavior change process for sedentary patients with knee OA and future inquiry examining the influence of this sequencing of intervention contact is warranted.

About 90% of the IMPACT-P participants were classified as overweight or obese and participant weight may have partially contributed to the modest treatment effects observed for change in mobility. Indeed, recent findings in samples of patients with knee OA[7,31] and community-dwelling older adults[23] who were overweight or obese revealed that lifestyle interventions combining PA and dietary weight loss result in superior improvements in objective measures of mobility relative to the effects of PA alone. Consequently, combining PA with dietary weight loss may augment the effects of lifestyle interventions on mobility-related outcomes for older adults who are overweight or obese.

Although results from the IMPACT-P trial are promising, there are several limitations that should be acknowledged. Given that it is a pilot trial, the sample size did not provide optimal power to detect significant differences for all outcomes. Notably, while meaningful effect sizes for the differences between treatment arms were observed, the differences in mobility and adherence to supervised exercise sessions did not reach conventional levels of statistical significance and should be interpreted cautiously. Therefore, subsequent optimally powered, randomized controlled trials are necessary to determine the efficacy of implementing the GMCB PA intervention in the treatment of sedentary, older patients with knee OA. Prior large-scale, randomized trials suggest 75 to 100 participants per treatment arm may provide optimal statistical power to detect differences in the outcomes of interest[7,24]. While our present findings also indicate that increased PA was associated with more favorable improvement in mobility, there is no evidence that this relationship is causal. Additionally, our present sample was primarily composed of women. This precluded the ability to adequately examine potential sex differences in the effects of the 2 treatment arms and also limits the extent to which the findings can be generalized to older men with knee OA. Similarly, it should also be recognized that the fairly restrictive inclusion criteria may detract from how representative our present sample may be of the average patient with knee OA. Future community-based effectiveness trials with less selective inclusion criteria will aid in increasing the generalizability of our present findings. Finally, although a conservative intention to treat analysis using the last value carried forward approach was conducted, future large-scale, randomized trials implementing more sophisticated maximum likelihood imputation methods to account for missing data are warranted.

Findings from the IMPACT-P trial demonstrate that a PA intervention integrating group-based, self-regulatory skill counseling resulted in superior improvements in weekly volumes of PA and a trend toward more favorable mobility relative to a traditional, center-based, supervised exercise intervention. Additionally, greater PA participation was associated with more favorable mobility performance at the 3-month and 12-month followup assessments. Collectively, our present results provide initial evidence supporting the safety, feasibility, and preliminary efficacy of implementing a GMCB PA intervention among sedentary patients with knee OA with self-reported difficulty with daily activities. This approach to promoting PA and preserving mobility shows promise for adults with knee OA and should be explored further in future large-scale efficacy trials.

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