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Promoting Physical Activity in Older Adults with Knee Osteoarthritis and Hypertension: A Randomized Controlled Trial

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Abstract

A 6-month self-efficacy intervention was compared with attention-control intervention on physical activity, clinical outcomes, and mediators immediate postintervention and 6-month postintervention in 182 older adults with knee osteoarthritis and hypertension using a randomized controlled trial design. The intervention group received six weekly individual physical therapy sessions for lower-extremity exercise and fitness walking and nine biweekly nurse telephone counseling sessions. The attention-control group received six weekly and nine biweekly nurse telephone sessions on health topics. Lower-extremity exercise was assessed by e-diary; fitness walking was assessed by accelerometer and e-diary; blood pressure was assessed by automated monitor; function was assessed by performance-based tests and questionnaires; and pain, self-efficacy, and outcome expectancy were assessed by questionnaires. Self-reported lower-extremity exercise and fitness walking, function, pain, self-efficacy, and outcome expectancy showed significant group or group by time effects favoring intervention. The intervention did not improve physical activity by accelerometer and blood pressure. Mean minutes of fitness walking fell short of the 150 min/week goal.

Keywords

comorbidity; function; outcome expectancy; pain; self-efficacy

Over nine million Americans have knee osteoarthritis (KOA), a chronic disorder associated with frequent knee pain and functional limitations that intrude upon everyday life. About half of those with KOA have hypertension (HBP), one of the most prevalent risk factors

for cardiovascular disease (Eymard et al., 2015). Systematic reviews and meta-analyses reported the benefits of aerobic exercise interventions on resting blood pressure (BP). For example, significant BP reductions were observed across HBP status with greater reductions in those with hypertension ($-8.3/-5.2$ mmHg) compared with pre-HBP ($-2.1/-1.7$ mmHg), and normal BP ($-0.75/-1.1$ mmHg) (Cornelissen & Smart., 2013). Sedentary older adults participating in aerobic exercise have reductions in resting BP of $-5.39/-3.68$ mmHg (Huang et al., 2013). Significant BP reductions occur with walking interventions ($-3.58/-1.54$ mmHg) (Murtagh et al., 2015).

The 2018 Physical Activity Guidelines Advisory Committee (2018) summarized systematic reviews and meta-analyses reporting positive effects of physical activity interventions on BP. While a range of physical activity doses was seen in studies that shared this information, in general frequency of physical activity was 3 days/week (range 1–7), intensity was low to moderate (levels included low, moderate, or vigorous), time was 30–60 min/session (range 8–63), and study duration was 16–20 weeks (range 4–52). A study of older women with HBP found reductions in systolic BP (SBP) of -1.0 mmHG and -3.3 mmHG in those exercising for an average of 136 ± 20 and 192 ± 34 min/week, respectively, but not in those exercising 72 ± 12 min/week who had $+0.8$ mmHG increase in SBP (Church, Earnest, Skinner, & Blair, 2007). These studies approximate the national goal of 150 to 300 min/week of moderate intensity physical activity (2018 Physical Activity Guidelines Advisory Committee, 2018).

Only 13% with KOA (Wallis, Webster, Levinger, & Taylor, 2013) and 28% with HBP (U.S. Department of Health and Human Services, Office of Disease Prevention and Health Promotion, 2020) meet recommended guidelines for physical activity. Although physical activity is recommended for KOA (Hochberg et al., 2012) and HBP (Eckel et al., 2014), the knee pain and functional limitations associated with osteoarthritis (OA) hinder physical activity and prevent adoption and maintenance of regular physical activity. Physical activity interventions can promote physical activity and improve outcomes in adults with KOA. For example, a recent meta-analysis of four randomized controlled trials in adults with lower-extremity OA examined the effect of counseling-based physical activity interventions following one or more American College of Sports Medicine physical activity recommendations for exercise dimension and dose on daily physical activity assessed by accelerometer and/or questionnaire. This meta-analysis showed a small effect with standardized mean difference (SMD) of 0.15 (95% confidence interval $[-0.05, 0.34]$; Rausch Osthoff et al., 2018). Three meta-analyses reported the benefits of physical activity interventions focused on lower-extremity exercise (LEE) and/or aerobic exercise in adults with lower-extremity OA with significant small to moderate effects on reducing pain (SMD = 0.20–0.50) and improving function (SMD = 0.27–.52; Fransen et al., 2015; Hurley et al., 2018; Juhl, Christensen, Roos, Zhang, & Lund, 2014). A meta-analysis by Brand, Nyland, Henzman, and McGinnis (2013) reported that physical activity interventions incorporating LEE and/or aerobic exercise had small effects on improving self-efficacy for arthritis pain (SMD = 0.20), function (SMD = 0.18), and symptoms (SMD = 0.29).

Few studies combining LEE and aerobic exercise have been tailored to those with KOA and comorbidities. One randomized controlled trial examined a 20-week individualized exercise

therapy intervention for persons with KOA and one or more of the following comorbidities: coronary disease, heart failure, Type 2 diabetes mellitus, chronic obstructive pulmonary disease, or obesity. Results showed significant improvements over time in self-reported physical functioning, pain, and 6-min walk favoring the intervention group versus. usual care. No serious adverse events were reported (de Rooij et al., 2017).

Self-efficacy interventions have been used successfully to promote exercise in healthy persons (Papandonatos et al., 2012) and those with any of several chronic conditions including arthritis (Hughes et al., 2004) and HBP (Burke et al., 2008; Lee, Arthur, & Avis, 2007). Self-efficacy theory (Bandura, 1977, 1997) includes two mediators of behavior change, self-efficacy and outcome expectancy, and four strategies to alter self-efficacy and to change behavior: mastery (e.g., gradually increasing fitness walking goals); vicarious experiences or modeling (e.g., observing the interventionist performing LEE); social persuasion (e.g., coaching that continuation with exercise therapy despite difficulties shows persistence); and physiological feedback (e.g., labeling brief minor muscle soreness after LEE as normal).

The staying active with arthritis (STAR) intervention, based on self-efficacy theory, was designed and pilot tested to address the barrier to physical activity imposed by KOA (Schlenk et al., 2006; Schlenk, Lias, Sereika, Dunbar-Jacob, & Kwoh, 2011; Schlenk, Sereika, Starz, & Kwoh, 2004). The STAR intervention was an individually delivered, home-based, 6-month LEE and fitness walking intervention. The STAR pilot intervention demonstrated feasibility and acceptability in engaging older adults and yielded statistically and clinically significant improvements in LEE, fitness walking, BP, functional status, and quadriceps strength without adverse effects on pain or health-related quality of life. Also, there was a trend to improve exercise self-efficacy. Because of the high prevalence of HBP among persons with KOA and hypertension-related physical activity concerns, the STAR pilot intervention was modified to focus on persons with these two comorbid conditions (hereafter called STAR). Modifications included education about HBP and its management by pharmacologic therapy and physical activity, interactions between anti-hypertensive medications and physical activity responses, and beliefs related to HBP and physical activity.

The primary aim was to evaluate the impact of the STAR intervention, compared with attention-control intervention, on LEE, fitness walking, BP, and performance-based functional status at immediate postintervention and 6-month postintervention. The hypothesis was that at both time points the STAR group would be more likely to perform LEE, participate in fitness walking, demonstrate reductions in BP, and show improvements in performance-based functional status than the attention-control group.

The two secondary aims were (a) to evaluate the impact of the STAR intervention, compared with attention-control intervention, on self-reported functional status and pain at immediate postintervention and 6-month postintervention. The hypothesis was that at both time points the STAR group would be more likely to show improvements in self-reported functional status and pain than the attention-control group and (b) to explore the impact of the STAR intervention, compared with attention-control intervention, on mediators (self-efficacy and outcome expectancy) at immediate postintervention and 6-month postintervention. The

Consolidated Standards of Reporting Trials and Template for Intervention Description and Replication checklists were followed to report this study.

Patients and Methods

Design

The STAR study was a randomized, controlled, parallel two-group trial. Recruitment occurred January 2012 to November 2013 with follow-up ending November 2014. Assessments by a trained blinded assessor were performed at baseline (screening and enrollment visits), immediate postintervention, and 6-month postintervention at the principal investigator's dedicated research space.

Sample

A convenience sample was recruited using registries, public domain mailing lists, and self-referral. Inclusion criteria included (a) community-dwelling adults age 50 years and older with KOA and HBP treated with anti-hypertensive medication; (b) completion of a run-in consisting of completing questionnaires, using the e-diary for 7 consecutive days, and wearing an accelerometer on the waist for 7 consecutive days; and (c) written permission from physician.

Exclusion criteria included (a) currently doing LEE 2 times/week; (b) currently fitness walking 90 min/week; (c) not managing own treatment regimen; (d) no telephone; (e) cortisone or hylan G-F 20 injections in the past 6 months; (f) unstable cardiovascular, pulmonary, or metabolic disease or signs and symptoms of these conditions that restrict activity; (g) resting BP 160/100 (could be re-screened, if treated); (h) OA of the hip, spinal stenosis, inflammatory arthritis, foot drop, diabetes treated with insulin, or diabetic complications; (i) current knee conditions (meniscus tears and knee ligament ruptures); (j) major depression; (k) major surgical procedure anticipated in the next 13 months; and (l) currently participating in a drug or psychoeducational trial that could cause bias.

Procedures

This study was approved by the University of Pittsburgh Institutional Review Board and was registered on [ClinicalTrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT01280903) (NCT01280903). Potential participants who called the Recruitment Office underwent telephone screening. Those who met preliminary eligibility criteria were invited to a screening visit and asked to obtain written permission from their physician to insure they were medically stable.

At the screening visit, project staff described the study; obtained written informed consent; measured BP for possible exclusion; conducted a clinical exam to determine evidence of KOA; gave questionnaires (functional status, pain, self-efficacy, outcome expectancy, and demographic and clinical characteristics) to complete at home; and provided a cell phone with the 7-day e-diary and accelerometer to wear for 7 consecutive days. The clinical exam was based on American College of Rheumatology clinical criteria for KOA with 95% sensitivity and 69% specificity (Altman et al., 1986) and was conducted by a blinded assessor trained in this procedure by a board certified rheumatologist. If this run-in was

completed, participants were invited to an enrollment visit the following week at which project staff collected test materials (questionnaires, cell phone, and accelerometer) and performed clinical testing (BP and functional status).

Following the enrollment visit, participants were randomly assigned to the STAR group or attention-control group in a 1:1 allocation ratio and contacted to arrange the first session. An adaptive randomization procedure of minimization was used to ensure that the two groups were balanced in terms of age (50–64 years, 65–74 years, 75 years); gender and race (White and non-White). The study data manager used a computer program to generate the random allocation sequence and then notified the appropriate interventionist of the group assignment for the participant. The outcome assessor and investigators were blinded to treatment allocation.

At immediate postintervention, participants underwent clinical testing, wore an accelerometer for 7 consecutive days, and completed questionnaires and the 7-day e-diary. During the 6-month follow-up period, participants were contacted briefly by telephone at Weeks 30, 36, and 48 to thank them for participation, confirm contact information, and remind them of the 6-month postintervention study visit. At 6-month postintervention, participants underwent clinical testing, wore an accelerometer for 7 consecutive days, and completed questionnaires and the 7-day e-diary.

Interventions

The STAR group received usual care; 6 weekly 60–65 min individual face-to-face sessions with the licensed physical therapist for evaluation, graduated LEE, and progressive fitness walking, which were conducted in the principal investigator's dedicated research space with a waiting area, clinical examination room, ankle weights, walking track, and emergency devices; nine biweekly 15–20 min telephone sessions with the licensed registered nurse for ongoing goal setting and support, which were conducted in the project office; and daily e-diary for self-monitoring physical activity during the 6-month intervention, but not during the 6-month follow-up period. The interventionists had experience in management of older adults and were trained in the theoretical principles and intervention procedures by the principal investigator using a teach back/show back method. The interventionists followed the interactive-style STAR intervention manual (available from the principal investigator), tailoring information about KOA, HBP, and physical activity in the intervention sessions to each participant based on their exercise tolerance in terms of frequency, intensity, time, and type of exercise; adherence to goals via daily e-diary review; and personal situation. Participants received a one-page written summary of each intervention session and diagrams of the exercises with space to record LEE and fitness walking goals. If an intervention session was missed, the content was delivered at the next session to ensure that the dose was received.

Self-efficacy strategies (mastery, modeling, social persuasion, and physiological feedback) were threaded throughout the 15 sessions that covered (a) learning about OA and HBP, (b) getting started with LEE, (c) getting started with fitness walking, (d) being physically active when having pain, (e) using heat and cold, (f) telling the difference between normal body signals and warning signs, (g) scheduling physical activity, (h) dealing with

unpleasant sensations, (i) managing setbacks, (j) avoiding risks of physical activity, (k) using support from others, (l) using self-talk to motivate and persist, (m) building self-confidence through persuasion, (n) trying other types of physical activity, and (o) review and closure. Participants were instructed to continue engaging in their regular activities as able while progressing with LEE and fitness walking. LEE was based, in part, on the guidelines developed by the American College of Rheumatology for nonpharmacological treatments of KOA (Hochberg et al., 2012). LEE was performed two to three times per week with repetitions, sets, hold times, and ankle weights prescribed and personalized weekly as tolerated, and included flexibility (hamstring stretch, calf stretch, and heel slide); strengthening (quadriceps set, standing heel raise, standing wall slide, straight leg raise, hip abduction, and short arc quad); and standing balance (side-by-side, semi-tandem, tandem, and one legged). Fitness walking was brisk walking for at least 10 min that was prescribed and personalized weekly as tolerated with a goal of 150 min/week, which was consistent with guidelines at the time of the study (Physical Activity Guidelines Advisory Committee, 2008). Adherence was set at 75% of the LEE and fitness walking goals (Ettinger et al., 1997); if the adherence goals were met, LEE and fitness walking were increased as tolerated to gradually reach recommended levels.

The attention-control group received usual care and six weekly and nine biweekly 15–20 min telephone sessions, which were conducted in the project office, with the licensed registered nurse. The interventionists had experience in management of older adults and were trained in the intervention procedures by the principal investigator using a teach back/show back method. The interventionists followed the interactive-style attention-control intervention manual (available from the principal investigator) tailoring the intervention sessions to each participant based on their personal situation without recommendations for LEE and fitness walking, use of the daily e-diary, and self-efficacy-based counseling. Participants received a one-page written summary of each intervention session. If an intervention session was missed, the content was delivered at the next session to ensure that the dose was received. The 15 sessions covered health topics from the National Institute on Aging website that avoided any mention of KOA and HBP and their management, including physical activity, to prevent cointerventions (National Institute on Aging, 2019): (a) talking with your primary care provider; (b) sleep and aging; (c) eating well, Part 1; (d) eating well, Part 2; (e) preventing influenza, pneumonia, and shingles; (f) cancer screening and prevention; (g) injury prevention: balance problem; (h) injury prevention: falls; (i) osteoporosis; (j) hearing loss; (k) low vision; (l) taking care of your teeth and gums; (m) taking care of your feet; (n) taking care of your mental health; and (o) review and closure.

During the period of intervention delivery, an independent research assistant trained by the principal investigator regularly determined adherence to the intervention protocols and overall quality of the interactions by randomly auditing 10% of the audiotaped sessions. The principal investigator regularly provided feedback to the interventionists to maintain intervention fidelity; retraining was planned if fidelity was less than 90%, which did not occur. Overall intervention fidelity was 99% for the STAR intervention and 99% for the attention-control intervention. Quality of the interactions was assessed (Wickersham et al., 2011). Interventionists and participants in the STAR group were rated as 4.99 and 4.97, whereas interventionists and participants in the attention-control group were rated as 4.93

and 4.89, respectively (possible range 0–5 with 5 indicating *high quality*). No modifications were made to the interventions based on therapeutic developments or results of related studies during the study.

Measures

Measures for the primary outcomes (LEE, fitness walking, BP, and performance-based functional status); secondary outcomes (self-reported functional status and pain); and intermediate outcomes or mediators (self-efficacy and outcome expectancy) are described below and were assessed without modifications during the study.

LEE—LEE was measured by the e-diary in terms of (a) total volume of LEE, that is, number of days the participant reports completing a LEE session, and total number of LEE per day performed (Repetitions $\times$ Sets) over a 7-day period and (b) mean daily minutes of LEE.

Fitness walking—Fitness walking was measured by the GT3X ActiGraph accelerometer (ActiGraph, Pensacola, FL), which was worn on the waist, collected activity counts per minute, and produced minutes of none to very low (0–99), light (100–2,019), moderate (2,020–5,998), and vigorous ($> 5,999$) physical activity over a 7-day period (Dunlop et al., 2011). Moderate and vigorous levels were collapsed ($> 2,020$) due to the low frequency of vigorous physical activity in the sample. Mean daily minutes at each level were computed. In addition, fitness walking was measured by the e-diary in terms of mean daily minutes of fitness walking.

BP—BP was measured by the OMRON[®] HEM-907XL automatic professional digital BP monitor (Omron, Kyoto, Japan), which assessed SBP and diastolic BP (DBP) in millimeters Hg using a standardized protocol.

Performance-based functional status—Performance-based functional status was measured by the total score for the Short Physical Performance Battery (SPPB: 4-m walk, repeated chair stands, and standing balance) and 6-min walk. These tests have acceptable reliability and validity in older adults (Guralnik et al., 1994, 2000; Rikli & Jones, 1999a; Rossiter-Fornoff, Wolf, Wolfson, Buchner, & for the FICSIT Group, 1995) with normative scores reported (Rikli & Jones, 1999b).

Self-reported functional status—Self-reported functional status was measured with the 17-item, 5-point Likert function subscale of the Western Ontario and McMaster Universities (WOMAC) OA Index, which assessed knee function over the past 48 hr. It has high internal consistency ($\alpha = .95$), adequate 1-week test-retest reliability ($r = .68$), and evidence of construct validity (Bellamy, 2002; Bellamy, Buchanan, Goldsmith, Campbell, & Stitt, 1988). Its internal consistency in this study was excellent (right knee $\alpha = .957$, left knee $\alpha = .962$).

Pain—Pain was measured with the five-item, 5-point Likert pain subscale of the WOMAC OA Index, which assessed knee pain over the past 48 hr. It has high internal consistency ($\alpha = .86$), adequate 1-week test-retest reliability ($r = .68$), and evidence of construct validity

(Bellamy, 2002; Bellamy et al., 1988). In this study, internal consistency was very good (both knees $\alpha = .885$).

Self-efficacy—Self-efficacy was measured with two scales. The 20-item, 10-point Likert Arthritis Self-efficacy Scale assessed self-efficacy to perform behaviors to self-manage pain (five items), function (nine items), and symptoms (six items). The three subscales have moderately high internal consistency ($\alpha = .76, .89$, and $.87$, respectively). The subscales significantly correlated with present and future health status. Test-retest reliabilities were $0.87, 0.85$, and 0.90 , respectively, with a mean of 9.4 days (range 2–29 days; Lorig, Chastain, Ung, Shoor, & Holman, 1989). The three subscales had very good internal consistency in this study ($\alpha = .861, .877$, and $.922$, respectively). The 21-item, 11-point Likert self-efficacy scale assessed self-efficacy for continuing to exercise (self-efficacy exercise subscale) and overcoming setbacks to exercise (self-efficacy exercise barriers subscale) and has been used with older adults. Internal consistency was reported as $.85$, and predictive validity was established by predicting exercise behavior (McAuley, 1992, 1993). The two subscales had excellent internal consistency in this study ($\alpha = .993$ and $.947$, respectively).

Outcome expectancy—Outcome expectancy was measured by the 10-item, 11-point Likert Perceived Therapeutic Efficacy (PTE) Scale, which assessed outcome expectancy for exercise and (a) arthritis and (b) HBP. In a previous study, the PTE had excellent internal consistency ($\alpha = .94$), was stable over 16 weeks ($r = .90, p < .01$), and predicted exercise behavior ($r = .42-.55, p < .05$) (Dunbar-Jacob, Burke, Schlenk, & Sereika, 2006). The two scales had excellent internal consistency in this study ($\alpha = .961$ and $.954$, respectively).

Statistical Analyses

The effect size f , defined as $\sigma_{\text{effect}}/\sigma$, which is a generalization of the standardized difference of means, was derived for the four primary endpoints from a preliminary study. Fitness walking required the largest number of participants so $f = 0.198$ was selected for the power analysis. Based on power of 0.80 between the STAR and attention-control groups at immediate postintervention and 6-month postintervention within the context of linear mixed modeling and p of $.01$ (two-tailed), 180 participants (90 per group) were needed to complete the study. Although an attrition rate of 20% was anticipated, additional participants were not able to be recruited in time to complete the study by the planned completion date.

Exploratory data analyses were first performed to describe the total sample and each group and to identify any data anomalies (e.g., outliers, missing data, group imbalances, etc.). Missing data were largely due to participant attrition and appeared to be either missing completely at random (not related to missing or observed data) or missing at random (not related to missing data). Outliers were identified for fitness walking. Based on a sensitivity analysis, the results for fitness walking did not change with the omission of these participants; therefore, the outliers were retained in the analysis. Group imbalances were found for mean daily minutes in the moderate/vigorous level based on the accelerometer and self-efficacy exercise barriers. As covariate adjustment did not yield markedly different findings, the results with no covariate adjustment are reported.

Efficacy analyses were performed following the intention-to-treat principle. As the response variables for the primary aim and two secondary aims were approximately normally distributed, linear mixed modeling was used to investigate the relationship of randomized group assignment with the primary outcomes, secondary outcomes, and intermediate outcomes or mediators, respectively, over time. In these analyses, time was treated as a categorical, fixed effect. Using linear contrasts, group comparisons were also performed at immediate postintervention and 6-month postintervention. The level of significance was set to .050 for omnibus F-testing and .010 for the time-point specific group comparisons.

Three ancillary analyses were performed to examine (1) the association of changes in BP medication prescriptions by group using χ^2 tests, (2) the association of changes in KOA treatments during the intervention and for 6-month postintervention by group using χ^2 tests, and (3) the relationship between mean daily minutes of moderate/vigorous activity by accelerometer and mean daily minutes of fitness walking by e-diary at baseline using the paired *t* test and Pearson *r* correlation.

Results

Participants

Figure 1 shows the participant flow through the study; 1,363 were screened for eligibility with 1,181 (88.6%) excluded primarily for currently exercising; no KOA; no antihypertensive medication; unstable cardiovascular, pulmonary, or metabolic disease; and recent knee injections. A total of 182 participants were randomized to the STAR group ($n=91$) or the attention-control group ($n=91$) with 88 (96.7%) and 84 (92.3%) receiving their allocated intervention, respectively. Numbers of participants who discontinued intervention or were lost to follow-up at immediate postintervention and 6-month postintervention are shown. Some participants who discontinued intervention returned for assessments. Numbers of STAR group and attention-control group participants completing assessments were 71 (78.0%) and 78 (85.7%) at immediate postintervention and 68 (74.7%) and 75 (82.4%) at 6-month postintervention, respectively, for a total attrition rate of 21.4%. All 182 randomized participants were analyzed.

As shown in Table 1, participants were on average aged 65 years ($SD=8$, range 50–90); 73% ($n=133$) White; 73% ($n=133$) female; 46% ($n=84$) married; 50% ($n=88$) employed, with greater than high school education (79%, $n=143$); and a household income <\$50,000 (49%, $n=75$). Participants were obese with mean BMI of 34.1 ($SD=7.0$), had on average 6.6 ($SD=2.8$) comorbidities, and had OA and HBP for 11.5 ($SD=9.5$) years and 13.8 ($SD=9.3$) years, respectively. There were no group differences in sociodemographic or clinical characteristics at baseline. Table 2 provides the baseline values for the primary, secondary, and intermediate outcomes with group differences seen in two measures. The STAR group had significantly lower mean daily minutes in the moderate/vigorous level ($p=.006$) and significantly lower self-efficacy exercise barriers ($p=.021$).

Results for Primary Aim

Since results were comparable for the two measures of LEE, only the results for mean daily minutes of LEE are reported. As shown in Table 3, a significant group by time interaction was found for mean daily minutes of LEE based on the e-diary ($p < .0001$). The STAR group improved in LEE at immediate postintervention and 6-month postintervention compared with baseline, whereas the attention-control group was unchanged from baseline. Among the 89 STAR group participants who completed at least one of 23 weekly LEE goals, mean adherence to LEE goals was 77.4% ($SD = 25.6\%$) with 61 of these 89 participants achieving 75% adherence based on their observed sessions. When examining the 71 STAR group participants who completed all 23 weekly LEE goals, mean adherence to LEE goals was 81.1% ($SD = 24.1\%$) with 54 of these 71 participants achieving 75% adherence based on their observed sessions.

No significant group by time interactions in physical activity were found for the three levels (none to very low, light, and moderate/vigorous) based on the accelerometer; however, as shown in Table 3, a significant group by time interaction was found for mean daily minutes of fitness walking based on the e-diary ($p < .0001$). The STAR group improved in self-reported fitness walking at immediate postintervention and 6-month postintervention compared with baseline, whereas the attention-control group increased slightly at immediate postintervention and returned to baseline at 6-month postintervention. Among the 88 STAR group participants who completed at least one of 22 weekly fitness walking goals, mean adherence to fitness walking goals was 74.9% ($SD = 25.1\%$) with 55 of these 88 participants achieving 75% adherence based on their observed sessions. When examining the 71 STAR group participants who completed all 22 weekly fitness walking goals, mean adherence to fitness walking goals was 76.8% ($SD = 24.8\%$) with 47 of these 71 participants achieving 75% adherence based on their observed sessions.

Regarding performance-based functional status, a significant group by time interaction was found for the SPPB total score ($p = .032$), but not the 6-min walk (Table 3). The attention-control group had improved SPPB scores at 6-month postintervention compared with both baseline and immediate postintervention, whereas the STAR group remained unchanged from baseline. Also, no significant group by time interactions were found for SBP and DBP (Table 3).

Results for Secondary Aims

Concerning self-reported functional status, a significant group by time interaction was found for WOMAC Function ($p = .016$; Table 4). The STAR group had better knee function at immediate postintervention and 6-month postintervention compared with baseline, whereas the attention-control group was unchanged from baseline. A significant group by time interaction was found for WOMAC Pain ($p = .015$; Table 4). The STAR group had less knee pain at immediate postintervention and 6-month postintervention compared with baseline, whereas the attention-control group remained unchanged from baseline.

Pertaining to self-efficacy, as shown in Table 5, significant group by time interactions were seen for self-efficacy arthritis pain ($p = .002$) and self-efficacy exercise barriers ($p = .029$).

The attention-control group's self-efficacy arthritis pain scores decreased at immediate postintervention compared with baseline and remained low, whereas the STAR group's scores remained stable over time. The attention-control group's self-efficacy exercise barriers scores were worse at both immediate postintervention and 6-month postintervention compared with baseline, whereas the STAR group's scores at immediate postintervention were stable compared with baseline and declined at 6-month postintervention compared with baseline and immediate postintervention. No significant group by time interactions were seen for self-efficacy arthritis function, self-efficacy arthritis symptoms, and self-efficacy exercise.

As regards to outcome expectancy, as shown in Table 5, significant group by time interactions were seen for PTE-arthritis ($p < .0001$) and PTE-HBP ($p = .042$). The attention-control group's PTE-arthritis scores were worse at both immediate postintervention and 6-month postintervention compared with baseline, whereas the STAR group's score at immediate postintervention was stable compared with baseline and declined at 6-month postintervention compared with immediate postintervention. The attention-control group's PTE-HBP scores were worse at both immediate postintervention and 6-month postintervention compared with baseline, whereas the STAR group's scores remained stable over time.

Results for Ancillary Analyses

No adverse events were reported during the study. Self-reported data on BP medication prescriptions collected at baseline, immediate postintervention, and 6-month postintervention were examined to determine if there were no changes, increases, or decreases in the groups at immediate postintervention, and 6-month postintervention. All participants were prescribed BP medication at baseline. The majority of participants had no changes in BP medication prescriptions at immediate postintervention (84%) and 6-month postintervention (89%). A 3×2 χ^2 test found no statistically significant association between changes in BP medication prescriptions and group assignment at immediate postintervention ($p = 0.581$) and 6-month postintervention ($p = 0.669$).

To control for participants seeking out information or receiving KOA treatments as part of usual care, at immediate postintervention and 6-month postintervention, participants self-reported if they had seen a physical therapist or occupational therapist, received a cortisone or hylan G-F 20 knee injection, or had knee surgery since their STAR study visit 6 months ago. There were no group differences in these KOA treatments at either time point ($p > .05$).

As shown in Table 2, at baseline mean daily minutes of moderate/vigorous activity by accelerometer was 44.7 ($SD = 31.6$) and mean daily minutes of fitness walking by e-diary was 2.42 ($SD = 6.12$). There was a significant difference between mean daily minutes of moderate/vigorous activity by accelerometer and mean daily minutes of fitness walking by e-diary, $t(181) = -17.94$, $p < .0001$, and no significant relationship between the two measures ($r = .058$, $p = .438$).

Discussion

The study hypotheses were partially supported. The STAR group had significant improvements in self-reported LEE and fitness walking at immediate postintervention with slight declines at 6-month postintervention. LEE increased from 1 to 9 mean daily minutes and fitness walking increased from 3 to 12 mean daily minutes in the STAR group from baseline to immediate postintervention, whereas the attention-control group remained stable. Twelve mean daily minutes (about 84 min/week) of fitness walking in the STAR group is greater than the minimum threshold of 45 min/week found to improve functional status (Dunlop et al., 2017), which in conjunction with LEE, may have contributed to improvements in functional status and knee pain seen in the STAR group, whereas the attention-control group remained stable. Furthermore, the improvements in functional status and knee pain at immediate postintervention in the STAR group were generally maintained at 6-month postintervention.

When comparing SMDs between the groups in this study to those reported in a systematic review of exercise interventions for KOA (Fransen et al., 2015), STAR effects on functional status were lower at immediate postintervention (0.24 vs. 0.52, respectively) and slightly higher at 6-month postintervention (0.21 vs. 0.15, respectively). Similarly, STAR effects on pain were lower at immediate postintervention (0.21 vs. 0.49, respectively) and slightly lower at 6-month postintervention (0.18 vs. 0.24, respectively).

The STAR group did not have improvements in fitness walking assessed by accelerometer. There were decreases in none to very low and light activity and an increase in moderate/vigorous activity from baseline to immediate postintervention in the STAR group, but these changes were not significant. A few possible reasons may account for the discrepancy between performance-based and self-reported measures of fitness walking. The e-diary may be unreliable as shown by the significant difference in means of the e-diary and accelerometer and the nonsignificant correlation between these two measures. Also, although instructed to continue engaging in their regular activities as able, participants may have reduced other physical activity when LEE and fitness walking were added, so moderate activity did not significantly change. Given the growing attention on reducing the amount of none to very low activity (Keadle, Conroy, Buman, Dunstan, & Matthews, 2017), research on strategies to both decrease sitting time and increase fitness walking are needed.

The STAR group did not have improvements in BP. Participant reports of changes in BP medication prescriptions at immediate postintervention and 6-month postintervention were not significantly different between the groups. The amount of fitness walking fell short of the goal of 21 mean daily minutes (150 min/week), which may have contributed to lack of group differences in BP. Other factors such as medication adherence, diet, alcohol intake, and stress that were not measured may counter any benefits from physical activity and help explain the lack of effect on BP.

Somewhat surprisingly, the STAR group did not improve in performance-based functional status, contrary to the pilot study (Schlenk et al., 2011). However, the baseline average SPPB total score and yards walked in the 6-min walk were 0.2 points and 43.8 yards higher,

respectively, in the current study compared with the pilot study, which may have contributed to these mixed results. The SPPB total score was near the upper end of the possible range at baseline, so it may not be the most appropriate test for a generally healthy community-based sample. The 6-min walk measures walking speed; however, the intervention was focused on improving the amount, not the intensity, of fitness walking, which may explain this non-significant group difference.

Changes in self-efficacy were found, specifically self-efficacy arthritis pain and self-efficacy exercise barriers, similar to other self-efficacy based interventions (Callahan et al., 2011; Higgins, Middleton, Winner, & Janelle, 2014). Future studies could explore the extent to which self-efficacy mediates the relationship between the STAR intervention and physical activity. In addition, changes in outcome expectancy were found suggesting that the STAR intervention positively affected the belief that being physically active improves BP, function, and pain. The role of outcome expectancy in physical activity has produced mixed results (Williams, Anderson, & Winett, 2005), so further investigation of the extent to which outcome expectancy mediates the relationship between the STAR intervention and physical activity as well as the relationship between self-efficacy and outcome expectancy are indicated.

This study had a few limitations. First, there was insufficient time to over-recruit so 143 rather than 180 participants completed the study, which may have affected some of the results. Second, the attrition rate was 21%; however, this rate is comparable with many physical activity studies with older adults. The STAR group had somewhat greater attrition than the attention-control group, perhaps due to greater intervention demands of adoption and maintenance of physical activity and a daily e-diary. Third, although the two groups received 15 intervention sessions on the same schedule with handouts about their respective topics, the STAR group received more attention than the attention-control group since the STAR group had six physical therapy sessions; thus, the Hawthorne effect may have influenced STAR group responses. Furthermore, since participants were not blinded to group assignment, it is possible that those in the attention-control group performed less well than they normally would. Fourth, convenience sampling was used, so sampling bias may have been present. While the racial composition of the sample exceeded expectations for the proportion of non-Whites, generalizability of the findings are limited to primarily highly functioning but sedentary, older, White, educated women with KOA and HBP prescribed antihypertensive medication with BP generally controlled. Fifth, despite randomization, baseline differences were seen on two measures, although results were similar with and without covariate adjustment. It is possible that the threat of instrumentation affected the results of this study; however, only one trained blinded outcome assessor was used during this study. Seventh, improvements were seen in some self-report measures, which can be influenced by recall and social desirability biases. Finally, the study period was 1 year, so participants could change over time. While changes in BP medications and KOA treatments were tracked, other changes that were not measured could have affected the results.

The STAR intervention is novel in concurrently addressing two comorbid conditions, KOA and HBP, jointly prevalent in many older adults to improve physical activity and clinical outcomes. While some improvements were seen, mean physical activity fell short of the 150

min/week goal and BP did not change indicating that the current STAR format is not ready for a demonstration project. A future study could investigate enhancements to the STAR intervention, such as the addition of companion support (Kahn et al., 2002; Lindsay-Smith, Banting, Eime, O'Sullivan, & van Uffelen, 2017), to further improve physical activity to the minimum threshold of 150 min/week and to evaluate its effect on BP.

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Figure 1 –
Participant Flow Diagram. STAR = staying active with arthritis.

Table 1Baseline Demographic and Clinical Characteristics ($N = 182$)

Baseline characteristic	Total ($N = 182$)	STAR group ($n = 91$)	Attention-control group ($n = 91$)	p
Age (years), mean (SD)	64.71 (8.10)	64.47 (8.46)	64.96 (7.76)	.688
White, n (%)	133 (73.1)	66 (72.5)	67 (73.6)	.999
Female, n (%)	133 (73.1)	67 (73.6)	66 (72.5)	.999
Married, n (%)	84 (46.2)	38 (41.8)	46 (50.5)	.407
Education, > HS, n (%) ($n=181$)	143 (79.0)	72 (79.1)	71 (78.9)	.547
Employed, n (%)	88 (49.7)	45 (50.6)	43 (48.9)	.881
Household income, < \$50,000, n (%) ($n=152$)	75 (49.3)	37 (48.7)	38 (50.0)	.677
Body mass index, mean (SD)	34.07 (6.97)	34.50 (7.48)	33.64 (6.43)	.408
Number of comorbidities, mean (SD)	6.6 (2.8)	6.8 (2.9)	6.5 (2.7)	.447
Duration of OA (years), mean (SD)	11.49 (9.52)	11.71 (9.91)	11.26 (9.16)	.750
Duration of HBP (years), mean (SD)	13.78 (9.34)	14.71 (9.69)	12.87 (8.94)	.185

Note. HBP = hypertension; HS = high school; OA = osteoarthritis; STAR = staying active with arthritis.

Table 2Baseline Values for Primary, Secondary, and Intermediate Outcomes ($N = 182$)

Baseline outcome	Total ($N = 182$) Mean (SD)	STAR group ($n = 91$) Mean (SD)	Attention-control group ($n = 91$) Mean (SD)	p
LEE, mean daily minutes	1.07 (3.50)	1.09 (3.55)	1.06 (3.47)	.962
Accelerometer, mean daily minutes				
None to very low	425.2 (104.9)	440.1 (96.5)	410.3 (111.1)	.054
Light	333.4 (81.7)	327.5 (76.8)	339.3 (86.4)	.330
Moderate/vigorous	44.7 (31.6)	38.3 (20.7)	51.2 (38.7)	.006
Fitness walking, mean daily minutes	2.42 (6.12)	2.65 (6.78)	2.19 (5.40)	.615
Systolic BP, mmHg	121.96 (14.37)	122.09 (15.01)	121.82 (13.78)	.898
Diastolic BP, mmHg	73.01 (10.33)	72.86 (11.18)	73.15 (9.47)	.853
SPPB	10.8 (1.6)	11.0 (1.7)	10.6 (1.6)	.119
6-min walk, yards	485.5 (97.1)	486.2 (105.9)	484.7 (88.1)	.918
WOMAC Function	20.9 (12.8)	22.5 (13.4)	19.3 (11.9)	.087
WOMAC Pain	5.3 (3.5)	5.8 (3.9)	4.8 (3.0)	.073
SE arthritis pain	74.1 (17.6)	73.7 (17.0)	74.4 (18.2)	.775
SE arthritis function	84.2 (15.6)	83.1 (15.5)	85.2 (15.6)	.361
SE arthritis symptoms	77.3 (17.2)	76.8 (17.4)	77.8 (17.2)	.694
SE exercise	73.6 (27.5)	72.8 (28.0)	74.4 (27.2)	.704
SE exercise barriers	64.3 (23.9)	60.3 (25.6)	68.3 (21.4)	.021
PTE-arthritis	70.0 (23.1)	67.8 (24.5)	72.1 (21.7)	.208
PTE-HBP	74.5 (22.3)	74.2 (21.2)	74.7 (23.4)	.876

Note. BP = blood pressure; HBP = hypertension; LEE= lower-extremity exercise; PTE = perceived therapeutic efficacy; SE = self-efficacy; SPPB = short physical performance battery; STAR = staying active with arthritis; WOMAC = Western Ontario and McMaster Universities. Statistically significant p values are in bold.

Table 3Group by Time Interactions in Primary Outcomes ($N = 182$)

Outcome	Group $\times$ Time		Immediate postintervention			6-month postintervention		
	interaction		STAR group	Attention-control group		STAR group	Attention-control group	
	<i>F</i>	<i>p</i>	Mean (<i>SE</i>) 95% CI	Mean (<i>SE</i>) 95% CI	<i>p</i>	Mean (<i>SE</i>) 95% CI	Mean (<i>SE</i>) 95% CI	<i>p</i>
LEE, mean daily minutes	37.45	<.0001	9.33 ^a (0.92) [8, 11]	0.79 (0.32) [0, 1]	<.0001	6.95 ^{b,c} (0.99) [5, 9]	0.94 (0.36) [0, 2]	<.0001
Accelerometer, mean daily minutes: none to very low	0.33	.723	434.89 (11.69) [412, 458]	409.98 (11.54) [387, 433]	.130	426.71 (11.97) [403, 450]	408.30 (11.70) [385, 431]	.272
Accelerometer, mean daily minutes: light	0.33	.720	314.07 (9.29) [296, 332]	321.44 ^a (9.18) [303, 340]	.573	318.04 (9.50) [299, 337]	321.01 ^b (9.30) [303, 339]	.823
Accelerometer, mean daily minutes: moderate/vigorous	1.98	.140	40.53 (2.68) [35, 46]	46.69 (3.93) [39, 54]	.197	39.37 (2.74) [34, 45]	47.97 (3.97) [40, 56]	0.076
Fitness walking, mean daily minutes	10.98	<.0001	11.91 ^a (1.11) [10, 14]	4.79 ^a (1.29) [2, 7]	<.0001	10.89 ^b (1.65) [8, 14]	3.45 (0.94) [2, 5]	.0002
Systolic BP, mmHg	1.08	.342	120.33 (1.74) [117, 124]	123.07 (1.68) [120, 126]	.258	122.54 (1.78) [119, 126]	125.14 ^b (1.71) [122, 129]	.292
Diastolic BP, mmHg	0.40	.670	71.74 (1.20) [69, 74]	73.10 (1.16) [71, 75]	.416	72.62 (1.22) [70, 75]	74.06 (1.18) [72, 76]	.396
SPPB	3.53	.032	11.29 (0.22) [11, 12]	10.86 (0.23) [10, 11]	.180	11.20 (0.24) [11, 12]	11.25 ^{b,c} (0.19) [11, 12]	.856
6-min walk, yards	1.39	.252	465.46 (18.82) [428, 503]	483.02 (14.47) [454, 512]	.461	480.29 (16.89) [447, 514]	465.36 (19.26) [427, 504]	.561

Note. BP = blood pressure; CI = confidence interval; LEE = lower-extremity exercise; SPPB = short physical performance battery; STAR = staying active with arthritis.

^aSignificant within-group differences from baseline to 6 months ($p < 0.05$).

^bSignificant within-group differences from baseline to 12 months ($p < 0.05$).

^cSignificant within-group differences from 6 months to 12 months ($p < 0.05$). Statistically significant p values are in bold.

Table 4Group by Time Interactions in Secondary Outcomes ($N = 182$)

Outcome	Group $\times$ Time		Immediate postintervention			6-month postintervention		
	interaction		STAR group	Attention-control group		STAR group	Attention-control group	
	<i>F</i>	<i>p</i>	Mean (<i>SE</i>) 95% CI	Mean (<i>SE</i>) 95% CI	<i>p</i>	Mean (<i>SE</i>) 95% CI	Mean (<i>SE</i>) 95% CI	<i>p</i>
WOMAC function	4.22	.016	16.68 ^a (1.44) [14, 20]	18.30 (1.42) [16, 21]	.424	17.02 ^b (1.49) [14, 20]	17.51 (1.44) [15, 20]	.816
WOMAC pain	4.27	.015	4.25 ^a (0.39) [3, 5]	4.54 (0.38) [4, 5]	.596	4.09 ^b (0.41) [3, 5]	4.72 (0.39) [4, 5]	.260

Note. CI = confidence interval; STAR = staying active with arthritis; WOMAC = Western Ontario and McMaster Universities.

^aSignificant within-group differences from baseline to 6 months ($p < 0.05$).

^bSignificant within-group differences from baseline to 12 months ($p < 0.05$). Statistically significant p values are in bold.

Table 5Group by Time Interactions in Intermediate Outcomes ($N = 182$)

Outcome	Group × Time		Immediate postintervention		6-month postintervention			
	interaction		STAR group	Attention-control group		STAR group	Attention-control group	
	<i>F</i>	<i>p</i>	Mean (<i>SE</i>) 95% CI	Mean (<i>SE</i>) 95% CI	<i>p</i>	Mean (<i>SE</i>) 95% CI	Mean (<i>SE</i>) 95% CI	<i>p</i>
SE arthritis pain	6.14	0.002	75.58 (1.97) [72, 79]	67.38 ^a (2.13) [63, 72]	0.005	73.15 (2.06) [69, 77]	69.44 (2.19) [65, 74]	0.219
SE arthritis function	0.53	0.590	85.74 (1.79) [82, 89]	85.90 (1.67) [83, 89]	0.948	85.38 (1.82) [82, 89]	87.75 (1.69) [84, 91]	0.340
SE arthritis symptoms	0.45	0.639	78.88 (1.99) [75, 83]	77.66 (1.95) [74, 81]	0.663	75.92 (2.03) [72, 80]	75.23 (1.96) [71, 79]	0.806
SE exercise	1.78	0.170	67.43 (3.44) [61, 74]	60.20 ^a (3.35) [54, 67]	0.133	55.49 ^{b,c} (3.56) [48, 62]	51.00 ^{b,c} (3.43) [44, 58]	0.365
SE exercise barriers	3.58	0.029	59.81 (2.77) [54, 65]	58.37 ^a (2.69) [53, 64]	0.710	53.30 ^{b,c} (2.83) [48, 59]	53.05 ^b (2.73) [48, 58]	0.950
PTE-arthritis	11.10	<.0001	72.79 (2.41) [68, 78]	59.67 ^a (2.91) [54, 65]	0.001	67.09 ^c (2.83) [61, 73]	55.86 ^b (3.07) [50, 62]	0.008
PTE-HBP	3.21	0.042	77.14 (2.48) [72, 82]	69.62 ^a (2.42) [65, 74]	0.031	73.40 (2.53) [68, 78]	67.93 ^b (2.44) [63, 73]	0.120

Note. CI = confidence interval; HBP = Hypertension; PTE = Perceived Therapeutic Efficacy; SE = Self-efficacy.

^aSignificant within-group differences from baseline to 6 months ($p < 0.05$).

^bSignificant within-group differences from baseline to 12 months ($p < 0.05$).

^cSignificant within-group differences from 6 months to 12 months ($p < 0.05$). Statistically significant p values are in bold