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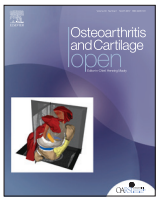

Physical activity and symmetry following total knee arthroplasty: Results of a pilot randomized trial

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ABSTRACT

Objective: This pilot trial examined a Physical Activity and Symmetry (PAS) intervention focused on common deficits of physical inactivity and joint loading asymmetry following total knee arthroplasty (TKA).
Design: Participants (n = 60) were enrolled during routine physical therapy (PT) following TKA and randomized to the PAS intervention or an attention (ATT) control group. The PAS intervention included physical activity counseling and balance exercise to address joint loading symmetry; content was delivered during 2 sessions at the end of routine PT plus supplemental sessions 4-weeks and 8-weeks following PT. The ATT control condition included supplemental sessions at 4-weeks and 8-weeks focused on general evaluation of surgical recovery benchmarks. Primary outcomes were weekly minutes of moderate to vigorous physical activity (MVPA), measured with an accelerometer, and peak force loading symmetry (limb symmetry index; LSI) during a 10 m walk, measured with a 3-sensor in-shoe device. General linear mixed models compared changes in outcomes between randomized groups at 3-month and 6-month follow-up.
Results: Both PAS and ATT groups increased MVPA, but there were no clinically meaningful between-group differences at 3- or 6-month follow-up ($p > 0.05$). There were also no clinically meaningful between-group differences LSI at 3- or 6-month follow-up ($p > 0.05$).
Conclusion: The PAS intervention did not yield improvements beyond ATT control. It is possible that PAS components were being delivered as part of routine PT, and a more intensive intervention (e.g., more visits, guidance for exercise progression) or targeted approach (e.g., those with deficits at end of routine care) may be needed to further improve outcomes.

1. Introduction

Total knee arthroplasty (TKA) is one of the most common surgical procedures in the US, and rates are rising substantially, leading to high health care costs and concerns about demand exceeding supply based on the surgeon workforce [1–5]. About 40 % of patients with unilateral TKA will progress to a TKA on the contralateral side within 10 years [6,7]. Given the high surgical volume and the common progression of disease in the contralateral limb, it is imperative that post-TKA outcomes are optimized through effective rehabilitation strategies.

Studies have identified two key deficits in individuals' activity-related trajectories following TKA. First, despite major improvements

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in joint pain for most patients, overall physical activity (PA) levels remain very low [8,9]. Specifically, accelerometer-based studies demonstrate that PA levels do not increase meaningfully following TKA and remain well below Department of Health and Human Services guidelines [10], as well as PA levels of healthy individuals [8,11–17]. The second post-TKA deficit highlighted in prior studies involves joint loading asymmetries. Although patients show improvements in pain and some aspects of physical performance following TKA and outpatient rehabilitation [18,19], many patients continue to demonstrate movement asymmetries that result in greater load on the non-surgical limb [20]. This likely contributes to the increased risk for TKA on the contralateral limb [18]. Research indicates that joint loading asymmetries are adopted as a result of pre-operative pain and weakness, and the compensatory movement mechanics persist following surgery despite resolution of pain and completion of traditional rehabilitation programs [21].

Although outpatient physical therapy (PT) is a standard practice following TKA, there is very little guidance regarding the most appropriate post-TKA rehabilitation regimen [18,22], and as a result, there is substantial variability in post-TKA PT [23–25]. Importantly, neither deficit described above – overall PA and joint loading asymmetry – is adequately addressed in current post-TKA rehabilitation paradigms [23,24]. Specifically, studies show lack of attention to general aerobic activity, guidance in exercise progression, and balance interventions that can address loading asymmetries [23,24]. This highlights the need to optimize the post-TKA rehabilitation process so that these key outcomes are adequately addressed.

To address these gaps, this pilot randomized trial examined a novel PA and Symmetry (PAS) intervention focused on the persistent deficits of physical inactivity and joint loading asymmetry following TKA. PAS intervention components were implemented in the context of routine PT following TKA, and this intervention was compared with an attention control condition.

2. Methods

This study was approved by the Institutional Review Boards of the University of North Carolina at Chapel Hill (UNC) and Virginia Polytechnic Institute and State University (Virginia Tech). Recruitment occurred from October 2019 to November 2022, with a COVID-19 related recruiting pause March–December 2020; follow-up assessments were completed in July 2023.

2.1. Study aims and procedure

This pragmatic randomized pilot trial aimed to obtain preliminary data on the efficacy of the PAS program with respect to change in objectively assessed physical activity (Aim 1) and peak load symmetry during walking (Aim 2), as well as to assess the feasibility and acceptability of the PAS program. Participants (n = 60) were randomized to the PAS intervention or an attention (ATT) control group. Randomization was stratified according to gender and presence of self-reported pain (≥3 on a 10-point scale) in any lower extremity joint (hip, knee or ankle) in addition to the surgical knee. Participants were enrolled between four and eight weeks after initiating outpatient PT, allowing time for randomization and notification of the treating therapist to begin the intervention before routine post-TKA PT was complete (since intervention content was integrated into PT visits near the end of routine care, as described below). Routine outpatient PT following TKA typically begins within about a week after surgery, and although the duration of therapy varies, visits are usually completed within 8–12 weeks. All physical therapists were trained by the study team prior to delivering the interventions. Follow-up assessments were conducted after approximately 3-months (shortly following completion of the intervention period) and 6-months.

2.2. Participants and recruitment

All participants were receiving post-TKA PT from a study clinic within the UNC Healthcare System. Exclusion criteria were: significant cognitive impairment, neurological disorders affecting gait, systemic rheumatic disease; hospitalization for a cardiovascular condition in the past six months; psychosis; substance abuse disorder; lower extremity surgery in the past year (other than TKA); planning total joint replacement in next 6 months; other health conditions determined by the study team to be contraindications to a home exercise program.

Potential participants were identified though regular UNC medical record searches of patients initiating outpatient post-TKA PT. Potentially eligible patients were mailed a recruitment letter, followed by a telephone call from a study team member to assess eligibility and interest. UNC heath care providers could also discuss the study with a patient and notify a study team member if the patient agreed to be contacted. Eligible patients met with a study team member to complete a baseline visit including instructions for wearing an accelerometer for a week and returning it by mail. Following receipt of the accelerometer, participants were called by an un-blinded study team member with their randomization assignment, and the treating therapist was notified accordingly.

2.3. PAS intervention

The PAS intervention, summarized in Fig. 1, was designed to augment routine post-TKA PT through two main components: 1) counseling to increase PA and 2) balance exercises to improve joint loading symmetry. Table 1 summarizes the PAS intervention content and timing. PAS components were delivered across 4 sessions, with the first two occurring in the context of routine post-TKA PT visits (optimally during the last two visits). The third and fourth PAS intervention sessions, both delivered by a study physical therapist, occurred via phone after 4 weeks and in person (or via video or phone if needed) after 8 weeks. Details of session content were as follows.

2.3.1. PA counseling content

Session 1: The physical therapist discussed the importance of PA in TKA recovery worked with participants to establish a SMART (Specific, Measurable, Attainable, Relevant, Time-bound) goal regarding overall PA, incorporated motivational interviewing principles [26–28] and provided a list of resources to support PA.

Session 2 did not include any PA counseling content.

Session 3: The physical therapist assessed progress with overall PA, helped participants develop strategies to address barriers to PA, applied motivational interviewing principles, worked with participants to establish a new SMART PA goal for the next four weeks, and facilitated connection of participants to PA resources.

Session 4. Activities mirrored those for Session 3 with two modifications. First, SMART goal setting was more long term in nature, focusing on the next six months. Second, the physical therapist also discussed strategies for dealing with setbacks in maintenance of PA.

2.3.2. Balance exercises to improve joint loading symmetry

Session 1 did not include any joint loading symmetry content.

Session 2: Weight bearing symmetry awareness was assessed and specific balance exercises were introduced. Participants underwent a process enabling them to detect when 50 % weight bearing on each leg. The foot of the post-surgical limb was placed on an analog bathroom scale, and the contralateral foot on a small step of equivalent height. The participant then shifted weight between legs so that it felt as if 50 % of weight was on each foot. The therapist then informed the participant of the actual weight distribution and assisted the participant with achieving 50 % weight bearing stance through verbal and tactile cues. The participant then performed a series of 10 wt shifts. Participants who could not successfully assume equal weight bearing within 5 % of body weight for 8 of 10 trials were given a scale and a step of equal height to continue

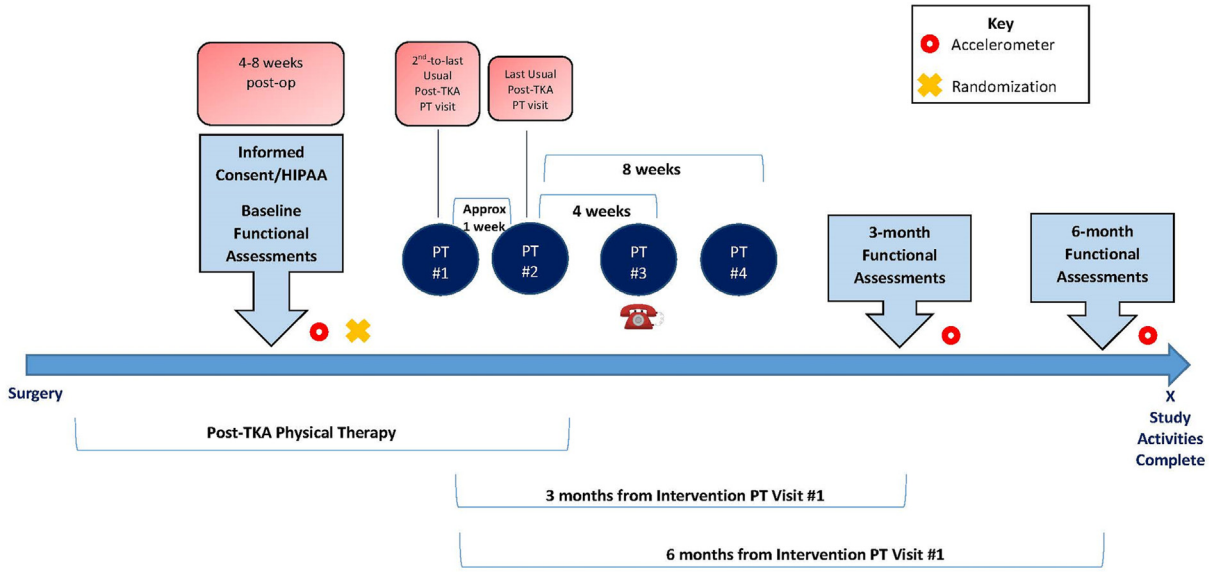

Fig. 1. PAS-TAK intervention and outcome assessment overview.

Table 1
Overview of PAS intervention content.

Session #	PA Counseling Content	Balance Exercise (Loading Symmetry) Content
1[a]	Overview of PA post-TKA, goal-setting, MI	–
2[a]	–	50 % weight-bearing exercise, assign home exercises
3 (phone) 4-weeks	Assess PA, address barriers, goal-setting, MI, community resources	Assess progress with exercises, advise on progression
4[a] 8-Weeks	Assess PA, dealing with setbacks, MI long-term goal setting	Demonstration of exercises, advise on progression

[a] In person session; video or phone visit if needed.

practice at home. Next, the therapist prescribed balance exercises, one static and two dynamic (see Table 2), which supplemented the general strengthening exercises assigned as part of routine PT. The initial balance exercises prescribed were the highest level at which the participant could perform at a minimal standard (defined in Table 2). Participants were provided with handouts and/or access to a website that displayed proper exercise form and instructed to perform balance exercises once daily. *Static balance exercises* were performed bilaterally in an alternating leg manner for three repetitions, 30-s each, with use of hand support as needed to recover loss of balance. *Dynamic balance exercises* were performed bilaterally for 10 repetitions per set for three sets. Participants were instructed to monitor performance in order to progress or regress each exercise per criteria.

Table 2
PAS intervention balance and functional strength exercises.

STATIC BALANCE		DYNAMIC BALANCE[a]
Initial exercise: Most challenging position that can be held for 3 repetitions, 10 s		**Initial exercise:** Most challenging activity that can be performed for 10 consecutive repetitions without a loss of balance
Progression criterion: Hold for 30 s, 3 repetitions		**Progression criterion:** Perform 3 sets of 10 repetitions without a loss of balance
***Exercises** (in order of difficulty)*		
Staggered stance	Weight shift in staggered stance	Forward lunge to 45° knee flexion and return
Narrow staggered stance	Weight shift in tandem stance	Walking forward lunge
Tandem stance	Tandem walk with arms outstretched	March with single leg hold for 3 s
Single leg stance	Tandem walk with arms crossed over chest	Walking forward lunge with 3 s hold during transition

[a] Physical therapist will assign 1 exercise from each column.

Session 3: The physical therapist and participant discussed recent performance of balance exercises. The therapist encouraged the participant to advance to the next level if an exercise had become too easy, based on criteria in Table 2.

Session 4: The physical therapist and participant discussed performance of balance exercises. Participants demonstrated current exercises if the session was conducted in-person or via video platform, and the therapist corrected form if needed. If the session was delivered in-person, the therapist also reassessed the participant's ability to stand with equal weight bearing as described for Session 2.

2.4. Attention control intervention

The ATT control group received routine post-TKA PT care, without the additional PAS components described for Sessions 1 and 2 above. To account for non-specific effects of the PAS intervention (e.g., therapist's "attention") of the two additional visits in the PAS intervention (4-week and 8-week session), the ATT control group received visits at the same intervals but differing in content. Specifically, the 4-week phone call included: information on typical recovery benchmarks for this time point, recording of participants' daily activities, and reminders about symptoms that should trigger contacting a medical professional. The 8-week visit (conducted in-person if possible or remotely via video platform or phone if needed) was consistent with a usual PT discharge exam, including assessment of range of motion, strength, and function. Participants were given a report summarizing these assessments and instructed to continue the home exercise program prescribed by their physical therapist at the end of routine care.

2.5. Measures

Measures were collected at baseline, 3- and 6-months by a trained study team member blinded to group assignment. Due to COVID-related precautions, follow-up assessments were transitioned to telephone (functional measures were not collected) for a period of time, and balance tests were discontinued for a longer period because close contact with study participants was required for administration. As a result, only 10 participants completed balance tests at all three time points, and we were therefore unable to conduct analyses for these outcomes.

2.5.1. Co-primary efficacy outcomes

We selected co-primary outcomes related to PA and joint load symmetry since the intervention addressed both of these components, and they were considered of equal importance in terms of intervention efficacy.

Objectively Assessed Physical Activity (Accelerometer). Participants wore an Actigraph GT3X+ (Pensacola, FL) at the waist for 7 days [29]. Following previously established thresholds, outcomes were only computed for participants who wore the accelerometer for ≥3 days with ≥8 h of waking wear. Accelerometer data were processed using standard procedures [30–33]. Our specific co-primary outcome of interest was minutes of moderate to vigorous physical activity (MVPA) per week, since this corresponds to Department of Health and Human Services recommendations and is a known predictor of outcomes in patients with OA [10]. Where appropriate, outcomes were standardized to a 16-h wear day to account for variations in non-wear time. We also examined step counts, minutes of any PA and sedentary minutes as secondary outcomes [34,35].

Peak Load Symmetry During Walking. We used a 3-sensor in-shoe load measurement device (*loadsol, Novel Electronics, Pittsburg, PA, USA*) to measure limb load symmetry. Participants completed a 10 m walking test (three trials averaged) [36], while load beneath each foot was recorded. Walking speed was also recorded and used as a covariate since gait speed may impact the loading metrics. Loading symmetry (peak force) was assessed using the limb symmetry index (LSI (|Surgical/-Non-Surgical|*100), with values lower than 100 % indicating less loading of the surgical limb [37–40]. An Limb Symmetry Index of less than 90 % or greater than 110 % is considered to be clinically meaningful and indicative of asymmetric loading. The peak force during the weight acceptance (first peak) and the push-off (second peak) phases of gait both extracted from the 10 m walking data and the corresponding Limb Symmetry Index metrics (weight acceptance and propulsive) were determined for each 10 m walking trial.

2.5.2. Secondary efficacy outcomes

Self-reported Physical Activity: Modified version of the CHAMPS (Community Health Activities Model Program for Seniors) Physical Activity Measure [41]. The modified version of the Community Health Activities Model Program for Seniors included 22 items tailored for this participant group. For each item, participants first indicated whether they had done the activity for 10 or more minutes during the past week. If they respond "yes," they were asked to report number of days and minutes per day. Minutes of self-reported MVPA per week was computed by summing minutes for each of the moderate or vigorous activities.

Physical Performance Tests. We administered tests recommended by Osteoarthritis Research Society International for clinical trials of knee OA: 30-s stair stand test, 40 m fast-paced walk, stair climb test, and Timed Up-and-Go (TUG) test; all tests were administered using standard protocols [42].

Knee injury and Osteoarthritis Outcome Score (KOOS). The KOOS is a validated patient-reported outcome that includes five separately scored subscales: pain (9 items), symptoms (7 items), activities of daily living (17 items), sports and recreation (5 items), and knee-related quality of life (4 items) [43]. All items are assessed via a 5-point Likert scale, and each subscale is transformed to a 0–100 scale, with lower scores indicating worse knee problems.

Tampa Scale for Kinesiophobia. Fear of movement (kinesiophobia) is a key concern for patients following TKA, associated with poorer clinical outcomes [44,45]. This is a 17-item measure of multiple aspects of fear of movement [46]. All items are assessed via a 4-point Likert scale, with a total range of 17–68 and higher scores indicating greater kinesiophobia.

2.5.3. Feasibility and acceptability metrics

We collected data on the number of eligible participants who were enrolled, number of participants who completed follow-up assessments, and number of outcome participants who completed intervention visits. At 6-month follow-up, participants in the PAS group were asked about the helpfulness the in-person and telephone-based PT sessions (focused on PA goal setting and balance exercises); these were rated on a scale of 0 (not at all helpful) to 10 (very helpful).

2.5.4. Participant characteristics

We collected information on participant sex, age, race/ethnicity, education, work and marital status, body mass index, joints with arthritis symptoms, and duration of knee symptoms.

2.6. Sample size considerations

As a pilot study, this trial was not intended to be fully powered for significance testing; rather, the goal was to allow sufficient experience with intervention delivery to inform a potential larger trial, as well as to gather preliminary data on intervention efficacy. The original proposed sample size was n = 72. Due to challenges related to COVID-19 (e.g. shutdown of research activities and TKAs for extended periods), the sample size was modified to n = 60 with approval from the funding agency. We projected statistical power based on expected attrition rate of 10 %, yielding a final sample of n = 54. For a two-sided 0.05 significance level, this sample size yields statistical power of 0.44–0.95 for between-group effect sizes ranging from 0.5 to 1.0 standard deviation for both primary outcomes.

2.7. Statistical analyses

Descriptive statistics are provided for participant demographic and clinical characteristics. Analyses were conducted on an intent-to-treat basis. The general linear mixed model with changes from baseline in each outcome variable as separate dependent variables was used to compare randomized groups at each follow-up time point. Fixed effects included randomized group, time, the group by time interaction, the corresponding baseline value, and two stratification variables, gender and presence of self-reported pain (≥3 on a 10-point scale) in any lower extremity joint in addition to the surgical knee. A random effect for patient accounted for the within-patient correlation induced by the repeated measures design. Estimates of the effect of PAS versus ATT were computed separately for 3- and 6- months as least squares means and their corresponding 95 % confidence intervals. For peak load symmetry during gait, the additional covariate of walking speed was included as a fixed effect. An appropriate transformation was applied to the outcomes if distribution of residuals was markedly deviated from normality. A nominal two-sided 0.05 significance level was applied to each outcome; no adjustment for multiple comparisons was applied due to the pilot nature of this trial. SAS software (Cary, NC) was used for these data analyses.

3. Results

3.1. Participants and retention

We identified 301 potential patients from the electronic medical record; 203 were sent recruitment letters (Fig. 2). Of the 60 patients who screened eligible and enrolled in the study, 44 completed the final (6-month) follow-up assessments, 8 were lost to follow-up, and 8 withdrew

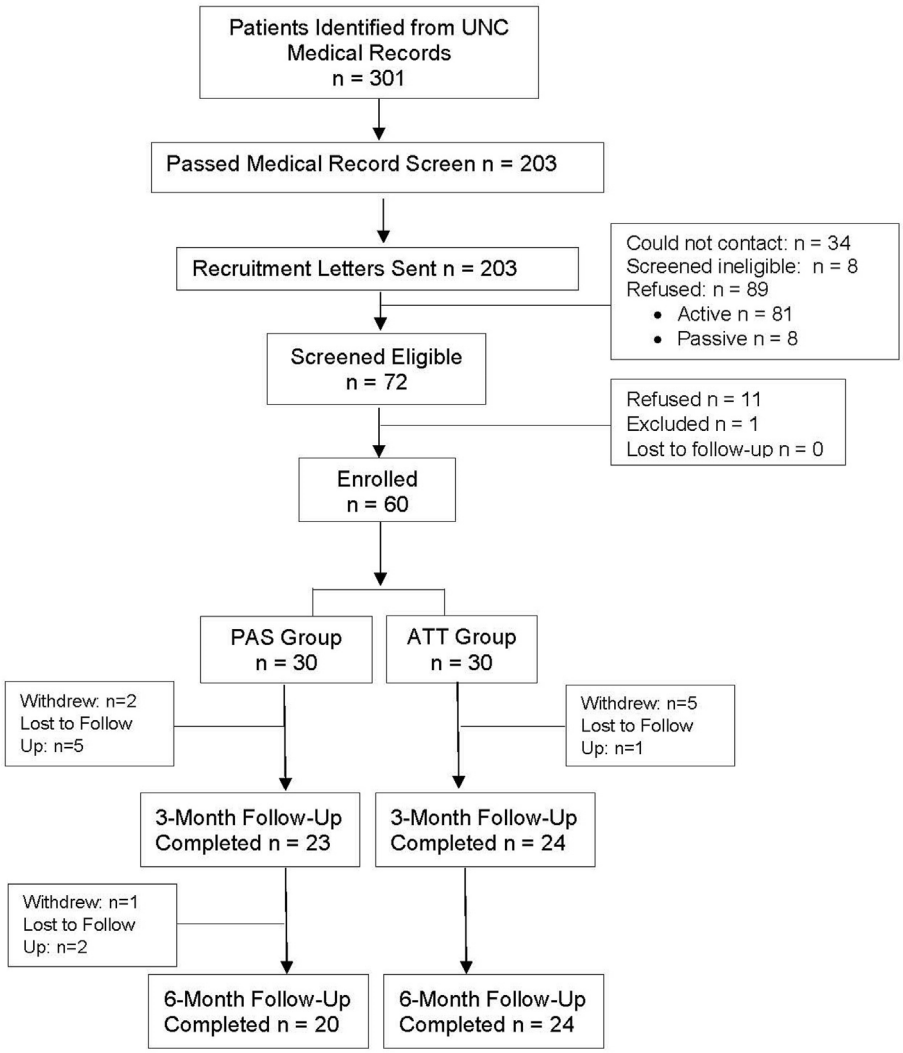

Fig. 2. CONSORT diagram.

or were withdrawn from the study; 47 participants completed 3-month follow-up assessments (Fig. 1). Baseline characteristics of participants are shown in Table 3.

3.2. Intervention delivery and acceptability

Of the 30 participants randomized to PAS the numbers of participants completing sessions 1–4 were 28, 27, 26 and 25, respectively. Of the 30 participants randomized to ATT the numbers of participants completing sessions 1–4 were 29, 22, 24 and 23, respectively. Among participants in the PAS group, the mean rating of helpfulness of the in-person PAS PT sessions was 8.4 (SD = 1.7), and the mean rating of helpfulness of the telephone-based PT sessions was 5.3 (SD = 3.9).

3.3. Adverse events

There were no serious adverse events or study-related adverse events.

3.4. Primary and secondary outcomes

3.4.1. Primary outcomes

As shown in Supplemental Table 1, both PAS and ATT groups increased minutes of MVPA per week from baseline to follow-up. Most of this change occurred between baseline and 3-month follow-up, with an increase from 65.95 min (SD = 165.25) to 119.72 (SD = 165.60) in the PAS group and from 61.38 (66.22) to 113.75 (112.93) in the ATT group. The mixed effects model did not reveal clinically meaningful between-group differences at either 3-months ($p = 0.485$) or 6-months ($p = 0.089$) (Table 4). The load symmetry measures assessed during the 10 m walk were also not different between groups at the 3-month or 6-month assessment (Table 4). The first (weight acceptance, $p = 0.094$) and second (push-off, $p = 0.418$) peak of vertical ground reaction force symmetry were unchanged across sessions, indicating that the intervention did not have an impact of peak force symmetry.

3.4.2. Secondary outcomes

Secondary PA metrics improved over time in both groups (Supplemental Table 1), but there were no significant between-group differences at either follow-up time point (Table 4). KOOS subscale scores improved substantially over time, but there were no between-group differences at either follow-up time point. Both groups reported less kinesiophobia at each follow-up time point; at 6-month follow-up, there was significantly greater improvement in the PAS group compared with the ATT group (estimate = −5.45, 95 % CI = −8.28, −2.62; $p < 0.001$). Both groups also improved in the number of chair stands completed in 30 s, time to complete the 10 m and 40 m walks, time to complete the stair-climb task, and time to complete the Timed-Up-and-Go task. However, there were no between-group differences at either time point for any of the functional tests (Table 4).

Table 3
Participant characteristics – N (%) or mean (SD).

	Total (N = 60)	Attention Control (N = 30)	PAS Intervention (N = 30)
DEMOGRAPHIC AND CLINICAL CHARACTERISTICS			
Age (years)	66.2 (7.5)	66.1 (7.2)	66.2 (7.8)
Body Mass index (kg/m^2)	30.7 (5.5)	29.7 (4.4)	31.7 (6.2)
Male sex	23 (38.3 %)	12 (40 %)	11 (36.7 %)
Married or living with partner as married	45 (75 %)	26 (86.7 %)	19 (63.3 %)
Education: High school or less	6 (10 %)	2 (6.7 %)	4 (13.3 %)
Currently working	24 (40 %)	14 (46.7 %)	10 (33.3 %)
Race:			
Caucasian/White	46 (76.7 %)	23 (76.7 %)	23 (76.7 %)
Black or African American	10 (16.7 %)	4 (13.3 %)	6 (20.0 %)
American Indian/Native Alaskan	1 (1.7 %)	0 (0 %)	1 (3.3 %)
Asian	2 (3.3 %)	2 (6.7 %)	0 (0 %)
Multiple selected	0 (0 %)	0 (0 %)	0 (0 %)
Refused	1 (1.7 %)	1 (3.3 %)	0 (0 %)
Hispanic	0 (0 %)	0 (0 %)	0 (0 %)
Duration of arthritis symptoms (years)	13 (10.4)	15.4 (10.9)	10.6 (9.5)
Knee injury and osteoarthritis outcome sale (KOOS) – Pain	60.1 (16.3)	61.7 (16.7)	58.4 (16.1)
KOOS - symptoms	55.4 (15.8)	55.2 (14.7)	55.5 (17.1)
KOOS - ADL	71.7 (14.9)	72.8 (14.6)	70.6 (15.3)
KOOS - QOL	38.3 (18.9)	36.3 (17.2)	40.4 (20.4)
Tampa kinesiophobia scale	36.8 (5.5)	36.4 (6.2)	37.1 (4.9)
BASELINE PHYSICAL ACTIVITY DATA			
Minutes of moderate-to-vigorous physical activity (MVPA) per week	63.7 (124.8)	61.4 (66.2)	65.9 (165.2)
Steps per day[a]	4498.8 (2703.0)	4310.1 (1782.7)	4687.5 (3407.7)
Minutes per day sedentary[a]	693.4 (77.3)	701.3 (68.7)	685.4 (85.4)
Minutes per day light activity[a]	255.7 (77.9)	248.3 (66.7)	263 (88.2)
Minutes per day of MVPA[a]	11.0 (21.3)	10.4 (10.8)	11.6 (28.3)
Self-report minutes of MVPA per week (CHAMPS)	154.3 (170.4)	169.2 (184.2)	139.5 (157.1)
BASELINE PHYSICAL FUNCTION TESTS			
30-s chair stand test (# stands)	8.2 (2.5)	8 (2.3)	8.4 (2.6)
Stair climb test (seconds)	27.8 (13.2)	27.6 (11.7)	28 (14.9)
40m Fast-paced walk (seconds)	35.3 (11.8)	35.8 (12.9)	34.8 (10.8)
10m Fast-paced walk (seconds)	12.9 (4.4)	12.8 (4.9)	13 (3.9)
Timed up and Go (seconds)	10.6 (3.1)	10.8 (2.9)	10.3 (3.3)
BASELINE LOADSOL DATA (10m walk, averaged across steps)			
Peak impact force limb symmetry index (LSI)	98.8 (14.4)	99.1 (12.9)	98.5 (16.0)
Peak push-off force LSI	101.4 (11.6)	100.3 (10.1)	102.5 (13.0)

Percents may not add to 100 due to rounding.
[a] Standardized to a 16 h day.

4. Discussion

Participants in both the PAS and ATT groups improved over time in many study outcomes, including PA metrics, limb loading symmetry and physical function tests. However, there were not clinically meaningful between-group differences in most study outcomes at either 3-month or 6-month time follow-up. There was a statistically significant between-group difference in one secondary outcome, Tampa Scale for Kinesiophobia, at 6-month follow-up, with participants in the PAS group reporting less fear of movement than those in the ATT group. Due to COVID-19 impacts, we were unable to assess balance outcomes, which was a key intervention target. Participants rated the in-person PAS PT intervention sessions as helpful (mean of 8.5) but perceived the telephone-based sessions to be less helpful (mean of 5.3); this indicates a need to modify the content of Session 3.

Prior systematic reviews indicate there are negligible changes in PA 6 months following TKA, with small to moderate improvements by 12 months but variability across studies [9,12]We observed improvements in accelerometer-based measures at both 3 and 6 months following surgery. For example, participants increased steps per day by about 1500. It is possible that increases in PA in this study were somewhat greater than some prior studies because all participants in the clinical trial were receiving some type of intervention (PAS or ATT), whereas prior reports have been based primarily on observational data [9,12]. However, PA levels were still below recommendations [10], and t a more intensive approach may be needed to support patients in increasing their post-TKA PA.

There were no clinically meaningful changes in peak load symmetry between groups or across time. For example, the change between the initial assessment and the immediate post-intervention assessment (3 months) was a decrease in load symmetry of 2.53 % for the ATT group, while in the PAS group there was a 4.26 % increase in loading symmetry (See Supplemental Table). It is important to note that the average limb symmetry prior to the intervention for the ATT group was 99.09 % ± 12.86 %, and for the PAS group it was 98.46 % ± 16.01 %. Prior research has indicated that following TKA patients demonstrate significant load asymmetries in the early recovery phase following TKA [47–49]. The lack of substantial loading asymmetry at baseline in this cohort is likely a reason for the limited changes in response to the intervention.

There are several possible reasons for the lack of between-group differences in most study outcomes. First, the PAS intervention may not be intense enough to elicit change beyond routine PT following TKA. We endeavored to develop an intervention that would be feasible to implement in the context of routine care. However, a more intensive approach with a greater therapeutic dose may be needed to markedly increase PA and limb loading patterns. Second, study physical therapists may have incorporated elements of the PAS intervention as part of their routine care. Although they were not trained to incorporate these elements, and we conducted fidelity assessments to check for purposeful inclusion of PAS intervention components for control group patients, it is still possible that some of these activities were included in routine PT visits. Third, it is possible that the PAS intervention occurred too early during post-TKA rehabilitation. Changes in KOOS scores show that participants in both groups made substantial improvements in pain and function during the course of the study [50]. Because participants were likely still experiencing substantial changes during this fairly early post-TKA period, this may have overshadowed specific effects of the PAS intervention. Fourth, as noted above, participants exhibited, on average, healthy joint loading symmetry at the time of study enrollment. An alternative strategy for addressing load symmetry in this patient group may be to wait until a later time point post-surgery evaluate patients' load symmetry using a field-based measure (such as the one we utilized in this study) and target the intervention to patients who have persistent joint loading asymmetry.

There were several limitations to this study. First, this was an exploratory study with a relatively small sample size and single study site. Second, study physical therapists delivered both PAS and ATT interventions. We conducted fidelity checks to monitor for contamination, but it is possible that physical therapists incorporated some aspects of the PAS intervention into their practice for ATT patients. Third, our evaluation of the PAS intervention was incomplete because we were unable to adequately assess balance outcomes due to COVID-19. Fourth, we did not

Table 4
Within- and between-group mean changes in outcomes and 95 % confidence intervals: Results of intent-to-treat analyses.

Outcome	Baseline to 3-Month Difference (95 % CI)	Difference in Baseline to 3-Month, PAS vs. ATT (95 % CI), p-value	Baseline to 6-Month Difference (95 % CI)	Difference in Baseline to 6-Month, PAS vs. ATT (95 % CI), p-value
PHYSICAL ACTIVITY OUTCOMES[a]				
Minutes MVPA per week (N = 47)[a]				
ATT	0.59 (0.12,1.07)		0.64 (0.23,1.06)	
PAS	0.36 (−0.12,0.84)	−0.23 (−0.90,0.43), 0.485	0.12 (−0.34,0.57)	−0.53 (−1.13,0.08), 0.089
Steps per day (N = 47) [c,a]				
ATT	0.33 (0.19,0.46)		0.32 (0.18,0.46)	
PAS	0.18 (0.04,0.32)	−0.15 (−0.34,0.05), 0.134	0.15 (−0.01,0.30)	−0.17 (−0.38,0.03), 0.094
Minutes of all intensity activity per day (N = 47)[c,a]				
ATT	0.09 (0.02, 0.17)		0.09 (0.00, 0.18)	
PAS	0.04 (−0.04, 0.11)	−0.06 (−0.16, 0.04), 0.252	0.00 (−0.01, 0.01)	−0.09 (−0.22, 0.04), 0.156
Minutes sedentary per day (N = 47)[c]				
ATT	−26.68 (−48.70,-4.65)		−26.52 (−52.47,-0.56)	
PAS	−5.32 (−27.52,16.89)	21.36 (−9.29,52.02), 0.167	−1.37 (−29.66,26.92)	25.15 (−12.85,63.14), 0.189
Light activity minutes per day (N = 47)[c,a]				
ATT	0.07 (−0.01,0.14)		0.06 (−0.02,0.15)	
PAS	0.01 (−0.07,0.09)	−0.06 (−0.17,0.05), 0.259	−0.02 (−0.11,0.08)	−0.08 (−0.21,0.05), 0.208
Minutes MVPA per day (N = 47)[c,a]				
ATT	0.56 (0.09,1.02)		0.60 (0.18,1.02)	
PAS	0.32 (−0.16,0.79)	−0.24 (−0.89,0.41), 0.464	0.13 (−0.34,0.59)	−0.47 (−1.09,0.14), 0.130
Self-report minutes of MVPA per week (CHAMPS) (N = 47)[b]				
ATT	−0.62 (−4.02,2.77)		−0.16 (−4.23,3.90)	
PAS	3.23 (−0.24,6.71)	3.85 (−0.91,8.62), 0.110	1.58 (−2.71,5.87)	1.74 (−4.10,7.59), 0.550
LOADSOL OUTCOMES				
PIF LSI (N = 35)[a]				
ATT	−0.02 (−0.09, 0.06)		0.02 (−0.03, 0.07)	
PAS	0.04 (−0.04, 0.13)	0.06 (−0.05, 0.17), 0.296	−0.05 (−0.11, 0.01)	−0.07 (−0.15, 0.01), 0.094
PPF LSI (N = 35)[a]				
ATT	−0.01 (−0.07, 0.04)		1.0 (−0.04, 0.05)	
PAS	0.04 (−0.02, 0.10)	0.05 (−0.03, 0.13), 0.196	−0.02 (−0.07, 0.03)	−0.03 (−0.09, 0.04), 0.418
PHYSICAL FUNCTION TESTS				
30-s chair stand test (N = 31)[a]				
ATT	0.43 (0.33,0.53)		0.50 (0.38,0.62)	
PAS	0.52 (0.42,0.62)	0.10 (−0.04,0.24), 0.173	0.55 (0.43,0.67)	0.05 (−0.12,0.22), 0.551
40m fast-paced walk (m/s) (N = 38)				
ATT	0.41 (0.31,0.51)		0.41 (0.31,0.52)	
PAS	0.37 (0.26,0.48)	−0.04 (−0.19,0.11), 0.602	0.44 (0.32,0.55)	0.02 (−0.13,0.18), 0.772
10m fast-paced walk (m/s) (N = 38)				
ATT	0.23 (0.16, 0.29)		0.28 (0.20, 0.37)	
PAS	0.24 (0.17, 0.31)	0.01 (−0.08,0.11), 0.756	0.27 (0.17, 0.37)	−0.01 (−0.14, 0.12), 0.837
Stair climb test (seconds) (N = 34)[a]				
ATT	−0.58 (−0.71,-0.45)		−0.62 (−0.75,-0.49)	
PAS	−0.70 (−0.85,-0.55)	−0.12 (−0.31,0.08), 0.229	−0.74 (−0.90,-0.58)	−0.12 (−0.32,0.08), 0.240
Timed up and Go test (seconds) (N = 38)[b]				
ATT	−0.49 (−0.60,-0.38)		−0.50 (−0.62,-0.38)	
PAS	−0.42 (−0.54,-0.29)	0.07 (−0.09,0.24), 0.371	−0.45 (−0.59,-0.31)	0.05 (−0.13,0.23), 0.5689
ADDITIONAL patient-reported OUTCOMES				
KOOS pain (N = 47)				
ATT	26.19 (21.80,30.58)		28.72 (24.26,33.19)	
PAS	28.70 (24.24,33.16)	2.51 (−3.65,8.67), 0.416	30.16 (25.43,34.89)	1.43 (−4.98,7.85), 0.654
KOOS symptoms (N = 47)				
ATT	22.02 (16.72,27.32)		25.54 (20.04,31.04)	
PAS	23.16 (17.76,28.56)	1.14 (−6.29,8.57), 0.759	29.49 (23.67,35.31)	3.95 (−3.93,11.83), 0.318
KOOS quality of life (N = 47)				
ATT	32.66 (25.77,39.54)		34.83 (27.05,42.61)	
PAS	29.12 (22.08,36.16)	−3.54 (−13.20,6.12), 0.464	36.47 (28.13,44.80)	1.64 (−9.61,12.89), 0.770
KOOS activities of daily living (N = 47)				
ATT	18.37 (15.41,21.33)		19.67 (16.29,23.04)	
PAS	20.91 (17.90,23.92)	2.54 (−1.61,6.69), 0.223	22.92 (19.26,26.57)	3.25 (−1.67,8.17), 0.189
Tampa scale for kinesiophobia (N = 47)				
ATT	−2.86 (−4.94,-0.78)		−2.86 (−4.81,-0.90)	
PAS	−4.81 (−6.98,-2.65)	−1.95 (−4.92,1.01), 0.191	−8.31 (−10.41,-6.20)	−5.45 (−8.28,-2.62), 0.0004

Abbreviations: **PAS,** Physical Activity & Symmetry; **ATT**, Attention Control; **MVPA**, Moderate to Vigorous Physical Activity; **KOOS**, Knee injury and Osteoarthritis Outcome Score; **LSI**, Limb Symmetry Index; **PIF**, Peak Impact Force (1st peak of the walking GRF) – BW; **PPF**, Peak Pushoff Force (2nd peak of the walking GRF) - BW; **ILR**, Initial Loading Rate - N/s; **ALR**, Average Loading Rate - N/s.

[a] A log transformation was applied due to superior diagnostics relative to untransformed values in statistical modeling; transformed values are presented here.

[b] A square root transformation was applied due to superior diagnostics relative to untransformed values in statistical modeling; transformed values are presented here.

[c] Standardized to a 16 h day.

have systematic documentation of participants' home exercise adherence progression, so we are unable to determine whether these were factors contributing to the lack of between-group differences.

In summary, we were able to integrate this intervention into routine PT care following TKA, but we observed no clinically meaningful impacts on outcomes other than kinesiophobia. Both groups improved over time in both PA and loading metrics. Therefore, it is likely that a more intensive intervention is needed to elicit changes in these outcomes

beyond standard PT following TKA and that this intervention should be targeted towards individuals with a persistent load asymmetry and limited PA following standard rehabilitation.

Contributions

RMQ, LA, DH, CH, TAS and KDA contributed to the conception and design of the study. RMQ, KDA, KFH, and DH contributed to acquisition of data. All authors contributed to interpretation of data. All authors contributed to drafting of the article or revising it for important intellectual content and approved of the final version to be submitted.

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Declaration of competing interest

The authors have no competing interests to declare.

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Appendix ASupplementary data

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