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Early View

Original article

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Long-term Exercise After Pulmonary Rehabilitation (LEAP): A Pilot Randomized Controlled Trial of Tai Chi in COPD

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Take Home Message

Tai Chi, a mind-body modality, may be a feasible option to maintain the benefits gained in exercise capacity and health-related quality of life after completion of outpatient conventional pulmonary rehabilitation.

Word Count 2,981

ABSTRACT

Mind-body modalities are promising strategies to maintain the benefits gained after completion of conventional pulmonary rehabilitation (PR) in persons with COPD.

In this pilot randomized controlled study, we examined Tai Chi in persons with COPD after completing PR. Participants were randomized 2:2:1 to Tai Chi (TC), usual care (UC), or group walking (GW) for 24 weeks. We assessed feasibility; primary outcome was exercise capacity measured by 6-minute walk test (6MWT) distance at 24 weeks. Secondary outcomes included health-related quality of life measured by Chronic Respiratory Questionnaire (CRQ), dyspnea, mood, stress, social support, self-efficacy, physical activity, and exercise engagement. Effect size estimates and estimates from generalized estimating equations were calculated.

Ninety-one persons (36 TC, 37 UC, 18 GW) were enrolled, with age 69±6 years, 59% male, and FEV_1 % predicted 48±19. There was no difference in adherence and adverse events between groups. There was a small between-group effect size (ES=0.25) in change in 6MWT distance favoring TC compared to UC; 24-week comparison was nonsignificant (p=0.10). There were no differences in secondary outcomes. In exploratory analyses, there was a greater percentage of participants in TC who improved 6MWT distance at 24 weeks, compared to UC, 64% versus 39%, p=0.05. There were higher percentages of participants in TC who improved CRQ Fatigue (59% vs. 31%, p=0.02) and CRQ Mastery (47% vs. 20%, p=0.01) domain scores, compared to UC. For GW, there were no differences compared with TC.

Tai Chi may be a feasible option to maintain the benefits gained after completing conventional PR.

Trial Registration
This trial is registered in Clinical Trials.gov, with the ID number NCT01998724.

Data Sharing Statement
Data sharing will be granted upon reasonable request directly to the authors.

Key Words
Pulmonary rehabilitation, exercise, physical activity, mind-body therapies, chronic obstructive pulmonary disease

INTRODUCTION

The Global Initiative for Chronic Obstructive Lung Disease (GOLD) guidelines recommend regular physical activity (PA) for all patients with stable COPD[1]**.** Conventional pulmonary rehabilitation (PR) programs clearly improve exercise capacity, decrease breathlessness, and improve health-related quality of life (HRQL) in COPD[2]. Despite the short-term improvements, the benefits diminish to pre-intervention levels within 6-12 months of program completion without a maintenance exercise regimen[3-6].

A key goal of conventional PR is to effect behavior change so patients will engage in long-term exercise[2]. Maintenance strategies to continue exercise after PR program completion can decrease risk for acute exacerbations (AEs) and AE-related hospitalizations[7,8]. However, there is currently no commonly accepted strategy to maintain exercise in the post-rehabilitation period. Studies of exercise maintenance programs, with various combinations of supervised exercise classes, unsupervised home exercise, support groups, and/or telephone contacts with healthcare professionals, have shown mixed results in persons with COPD[9-13]. Non-adherence to maintenance exercise has been attributed to the occurrence of AEs, depression, lack of exercise opportunities, and low self-efficacy[14-16]. Novel exercise options that integrate both physical and psychosocial components are needed to maintain the benefits of PR.

With origins in traditional Chinese martial arts, Tai Chi (TC) is a gentle, conditioning exercise that coordinates physical movements with meditative attention and breathing[17,18]. TC integrates 3 important components of PR--aerobic exercise, dyspnea management, and stress/anxiety management. TC is relatively low-cost, uses no special equipment, and requires minimal space[19], all characteristics that foster long-term adherence. We have developed a protocol of TC movements specifically for persons with COPD[20].

In this study, Long-term Exercise After Pulmonary Rehabilitation (LEAP), we examine the role of TC to maintain the expected benefits gained after completion of conventional PR in persons with COPD. In addition to measures of feasibility, the primary outcome was 6-minute walk test (6MWT) distance, compared to usual care at 24 weeks. We further explore and describe changes with TC compared to group walking.

METHODS

Study Design

Details on study design and intervention groups have been previously described[21]. In this pilot randomized controlled study, participants were randomized 2:2:1 to either Tai Chi (TC), usual care (UC), or group walking (GW) for 24 weeks. The cohort was characterized with demographic information and clinical history including cigarette smoking (pack-years), supplemental oxygen use, the Charlson Comorbidity Index, and median days since completion of PR at the time of study enrollment[21]. All outcomes were assessed at entry to the research study (i.e. baseline testing which occurred after the completion of the PR program), 12, and 24 weeks. Participants were followed post-intervention for an additional 6 months by telephone to assess for the occurrence of AEs at 9 months and secondary outcomes at 1 year.

Study Population and Recruitment

Participants with COPD were enrolled from the outpatient PR programs at 5 institutions in Massachusetts, United States: Beth Israel Deaconess Medical Center, VA Boston Healthcare System, Brigham and Women's Hospital, Boston Medical Center, and South Shore Hospital. All PR programs contained the core components of aerobic exercise (treadmill, stationary bicycle, arm ergometer), strength training (resistance bands, free weights), and education delivered by a multidisciplinary staff. To be pragmatic and mirror real-world community PR programs, we did not require sites to convert to a standardized frequency or duration of classes.

Recruitment occurred between October 2013 and July 2017; participants were enrolled in cohorts. See Online Supplement for eligibility criteria. Study staff approached patients during PR classes or at their PR discharge visit. Usual procedures of each PR program were maintained to educate participants on transitioning to post-rehabilitation exercise. Participants were asked not to start Tai Chi on their own or another course of PR program while enrolled in the study. Ethics approval was obtained at each institution, and written informed consent obtained from each participant.

Randomization and Allocation Concealment

Group assignments were generated by a permuted blocks method with randomly varying block size to ensure balanced but unpredictable assignments. Assignments were sealed in numbered, opaque envelopes. All outcomes testing was conducted by study staff blinded to treatment assignment.

Intervention Groups

Participants in all 3 groups received written instructions on exercising at home and disease self-management. Both TC and GW classes were conducted at a local university fitness facility. TC instructors led the TC classes and trained study staff led the GW classes.

Tai Chi

TC included 36 classes of 1-hour duration with 2 classes per week for 12 weeks, then weekly for 12 additional weeks. The TC intervention was designed specifically for an older, physically limited population[20,22-24]. A guided audio CD of TC exercises and an instructional TC DVD facilitated home practice. Participants were encouraged to practice TC outside of class at least 3 times a week for 30 minutes each time.

Usual Care

As part of usual procedures of each PR program, upon completion of the supervised, facility-based PR program, all participants met with PR staff to formulate an unsupervised exercise plan to follow at home[2]. Participants were also allowed to continue in the maintenance programs of their usual PR program.

Group Walking

The supervised GW classes were identical to the TC classes in terms of class duration, number and frequency, and type of PA (low-moderate aerobic exercise with gentle stretching). Participants walked at their own pace around an indoor gym, targeting the intensity of exercise to reach approximately 60% of their maximum heart rate and to keep breathlessness within the 3-5 range on the Borg scale[25]. Like TC, participants were instructed to walk and perform stretches at least 3 times per week for 30 minutes outside of group classes. GW received written handout instructions for stretches that they performed in GW classes.

Outcome Measures

Exercise capacity was assessed with the 6MWT which was conducted at all sites using scripted instructions according to ATS guidelines, except that a practice walk was not administered[26]. The minimal clinically important change in 6MWT distance is 30-54 meters in stable COPD[27,28]. See Online Supplement for details about secondary outcomes and other testing. Outcomes were assessed by the Chronic Respiratory Disease Questionnaire (CRQ) and its four domains of dyspnea, fatigue, emotional function and mastery; University of California, San Diego Shortness of Breath (UCSD SOB) Questionnaire; Center of Epidemiology Studies-Depression Scale (CES-D); Perceived Stress Scale (PSS); Multidimensional Scale of Perceived Social Support (MSPSS); COPD self-efficacy scale (CSES); Resnick Exercise Self-Efficacy; and Community Health Activities Model Program for Seniors (CHAMPS) Physical Activity Questionnaire for Older Adults. The Omron HJ-720ITC pedometer objectively measured PA as daily step counts. Exercise logs captured exercise engagement. A composite measure of exercise engagement was calculated using total minutes of class time, home practice time, and other PA on the exercise logs.

Other Data Collection

Study Adherence

Participants with attendance of greater than 70% of TC or GW classes were defined *a priori* as being adherent. We also compared self-reported home practice time of TC or walking to the expected time as provided in study instructions, and the number of study visits at each timepoint completed by each participant.

Adverse Events

At each visit every 3 months, participants were queried about new or worsening symptoms and medical conditions, change in medications, or urgent care visits, emergency room visits, or hospitalizations. Participants enrolled in TC and GW also completed logs asking about adverse events, which were collected at every class attended.

Statistical Analysis

While an initial primary aim was feasibility, the study was also powered on the 6MWT distance and between-group comparisons were proposed. We recognize that sample size estimates, largely based on one small study[29,30], may be misleading. Thus, we have chosen to primarily present effect size (ES) estimates and calculation of Cohen's d. Hedges and Olkin's formula calculated 95% confidence intervals for Cohen's d[31]. The magnitude of effect sizes of 0.2, 0.5, and 0.8 represent small, medium, and large effect sizes, respectively[32]. We primarily focused on comparisons at 24 weeks between TC and UC.

Generalized estimating equations methods accounting for repeated measures also provided estimates of the difference in mean changes in outcomes between groups. Models adjusted for baseline values that were imbalanced despite randomization: sex, time since pulmonary rehabilitation, oxygen use, and Charlson Comorbidity Index.

Improvement in all outcomes was defined by any change that was better than the baseline value. Changes in the primary outcome of 6MWT distance at 24 weeks were analyzed using a non-parametric Wilcoxon-Mann-Whitney test. In addition, as further exploratory analyses, we examined outcomes as dichotomized variables: those who had any improvement versus those with no change or worsened. Chi-squared tests compared the dichotomized variables between groups. Analyses were performed using SAS, version 9.4 (SAS Institute Inc., Cary, NC).

RESULTS

Study Population and Baseline Characteristics

Ninety-one persons with COPD who had completed PR were enrolled (N=36 TC, N=37 UC, N=18 GW) (Figure 1). Mean age was 69±6 years, 59% were male, mean FEV_1 % predicted was 48±19, and 58% were GOLD stage 3-4[1]. Mean pack years was 51±29, and 37% were on supplemental oxygen. In terms of self-reported comorbidities, 25% had cardiovascular disease, 31% cancer, and 53% chronic musculoskeletal issues or back pain.

There were slight imbalances between groups at baseline with respect to sex, Charlson Comorbidity Index, supplemental oxygen use, and time since completion of PR. There were more men randomized to UC, compared to TC and GW (73% vs. 50% vs. 47%, respectively). There was also a trend towards more participants regularly using supplemental oxygen in TC, compared to GW and UC (47% vs. 39% vs. 27%) (Table 1).

Table 1. Baseline Characteristics

Characteristic	Tai Chi (N=36)*	Group Walking (N=18)*	Usual Care (N=37)*
Age (mean, SD)	69.6 (7.5)	66.9 (6.7)	70.5 (9.2)
Male sex	17 (47)	9 (50)	27 (73)
Race			
White	28 (78)	12 (67)	27 (73)
Black	6 (17)	3 (17)	8 (22)
Other/Unknown	2 (6)	2 (11)	2 (6)
Annual income < $35K	16 (44)	7 (39)	15 (41)
Married/living with partner	13 (36)	8 (44)	18 (49)
Unemployed/retired/disabled	32 (89)	16 (89)	35 (95)
FEV_1 % predicted (mean, SD)	48.1 (17.9)	50.8 (24.6)	45.7 (17.7)
GOLD stage			
Stage I-II	16 (44)	10 (56)	13 (35)
Stage III-IV	20 (56)	8 (44)	24 (65)
BODE index			
0-2	13 (36)	7 (39)	14 (38)
3-4	16 (44)	4 (22)	14 (38)
5 or greater	7 (19)	7 (39)	9 (24)

Regular oxygen use	17 (47)	7 (39)	10 (27)
Smoking pack years (mean, SD)	52 (33.7)	44.9 (24.8)	54 (26.5)
Days Since Completing PR (median, IQR)	35 (99)	62 (120)	72 (126)
Charlson Comorbidity Index (mean, SD)	7.3 (2.5)	6.7 (2.8)	6.4 (2.4)
Comorbidities			
Cardiovascular Disease	8 (22)	4 (22)	10 (27)
Heart Failure	6 (17)	2 (11)	7 (19)
Cancer	13 (36)	6 (33)	9 (24)
Hypertension	24 (67)	10 (56)	25 (68)
Limitation of limb (paralysis, weakness)	2 (6)	3 (17)	3 (8)
Osteoarthritis, Sciatica, Chronic Back Pain	19 (53)	11 (61)	18 (49)
Peripheral vascular disease	4 (11)	4 (22)	4 (11)
Stroke or cerebrovascular disease	6 (17)	0	4 (11)
6-Minute Walk Test Distance (m)	324.7 (123.4)	365.3 (105.6)	369.7 (104.7)
CES-D (mean, SD)	12.2 (9.2)	11.1 (8.1)	11.3 (9.3)
* N(%) unless otherwise noted			

Study Adherence

Average class attendance was 81% in TC and 64% in GW. According to our definition of adherence, 83% in TC and 50% in GW attended ≥70% of classes. In the first 12 weeks, participants in TC reported 80±55 min/week of home practice, and those in GW 73±48 min/week. In the second 12 weeks, participants reported 46±48 and 41±39 min/week in TC and GW, respectively.

At 12 weeks N=86 and 24 weeks N=85, participants completed the follow-up visits. In total, 84 subjects (93%) completed outcome testing at one year; 7% were lost to follow-up (3 in TC, 2 in UC, and 2 in GW). There were no significant differences in baseline characteristics between those lost to follow-up versus those who completed the study.

Safety

Thirty-one adverse events occurred during the 24-week intervention period (19 in TC, 6 in GW, 6 in UC). In the subsequent 24-week follow-up period, there were 27 adverse events (8 in TC, 7 in GW, 12 in UC). Over the one-year study, there were 22 respiratory-related events (15 in TC, 7 in GW, 10 in UC). One participant in GW experienced musculoskeletal knee pain which was related to the study.

COPD acute exacerbations during the 24-week intervention period included 19 in TC, 8 in GW, and 20 in UC. The percentage of subjects with at least one AE who required a course of antibiotics or corticosteroids was 9% in TC, 19% in GW, and 20% in UC. There were no significant differences between groups with respect to total number of AEs or number of participants with an AE at 3, 6, 9, or 12 months.

Exercise Capacity

There was a small between-group effect size (ES=0.25) describing change in 6MWT distance favoring an increase in TC compared to UC at 24 weeks, although a Wilcoxon-Mann-Whitney test was not significant (p=0.10) (Table 2). There was a significantly greater percentage of participants in TC who improved 6MWT distance at 24 weeks, compared to UC, 64% versus 39%, p=0.05. Within TC, there was a 43-meter increase in 6MWT distance at 12 weeks, compared to baseline (p=0.07), which decreased to 22 meters at 24 weeks, p=0.17. In contrast, GW and UC had non-significant decreases from baseline to 24 weeks (27 m in GW, p=0.50, and 17 m in UC, p=0.17).

HRQL, Dyspnea, Mood, Stress, Social Support, and Self-Efficacy

At 24 weeks and one year, there were small effect sizes favoring TC over UC in CRQ Total, CRQ-Fatigue, CRQ-Mastery, and COPD Self-Efficacy (ES=0.2-0.46) (Table 2). Examining CRQ scores as dichotomized outcomes, there were higher percentages of participants in TC who improved their CRQ Fatigue (59% vs. 31%, p=0.02) and CRQ Mastery (47% vs. 20%, p=0.01) domain scores, compared to UC, at 24 weeks.

Within TC, there were improvements in CRQ Total at 12 weeks compared to baseline (+0.22±0.70, p=0.04) but no change at 24 weeks or 1 year. At 24 weeks, there were also within group improvements in TC in COPD self-efficacy (+0.22±0.64), p=0.05), social support (+0.22 ±1.26 p=0.04), and perceived stress (-2.47 ±4.76, p=0.01). No changes in TC were seen in UCSD SOB score or CES-D score at 12 and 24 weeks, and at 1 year. In GW or UC, there were no significant changes in secondary outcomes at any follow-up time compared to baseline.

Examining social support as a dichotomized outcome, there were significantly higher percentages of participants in TC who improved their MSPSS score (62% vs. 25%, p=0.02), compared to GW, at 24 weeks.

Table 2. Mean Changes in 6MWT Distance and Secondary Outcomes

	Baseline Values		Mean Change (Baseline-24 weeks)			Adjusted Mean Difference at Week 24	Mean Change (Baseline-1 year)			Adjusted Mean Difference at 1 Year
Outcome Measure	**Tai Chi***	**UC***	**Tai Chi***	**UC***	**Effect Size****		**Tai Chi***	**UC***	**Effect Size****	
6-Minute Walk Test Distance (m)	324.7 (123.4)	369.7 (104.7)	6.8 (53.3)	-5.1 (41.2)	0.25 (-0.24, 0.73)	3.2 (-21.1, 27.4)	-	-	-	-
CRQ Dyspnea	4.97 (1.38)	5.67 (1.01)	0.06 (1.1)	-0.12 (1.06)	0.17 (-0.31, 0.64)	-0.17 (-0.66, 0.32)	-0.16 (1.13)	-0.31 (1.12)	0.14 (-0.34, 0.61)	-0.20 (-0.75, 0.35)
CRQ Fatigue	4.30 (1.06)	4.91 (0.96)	0.21 (1.03)	-0.16 (0.83)	0.40 (-0.08, 0.87)	0.17 (-0.28, 0.62)	0.08 (0.96)	-0.23 (0.88)	0.33 (-0.15, 0.81)	0.10 (-0.31, 0.5)
CRQ Emotion	5.24 (1.05)	5.51 (1.14)	-0.06 (0.69)	0.05 (0.63)	-0.18 (-0.65, 0.3)	-0.24 (-0.57, 0.1)	0.01 (0.91)	-0.25 (0.78)	0.3 (-0.17, 0.78)	0.17 (-0.21, 0.56)
CRQ Mastery	5.36 (1.44)	5.66 (1.22)	0.14 (1.05)	-0.14 (0.77)	0.30 (-0.18, 0.77)	-0.11 (-0.51, 0.3)	0.06 (1.29)	-0.24 (1.04)	0.26 (-0.22, 0.74)	0.06 (-0.39, 0.51)
CRQ Total	5.01 (0.98)	5.46 (0.93)	0.06 (0.73)	-0.07 (0.62)	0.20 (-0.27, 0.67)	-0.08 (-0.42, 0.27)	-0.01 (0.81)	-0.26 (0.72)	0.33 (-0.15, 0.81)	0.08 (-0.29, 0.45)
UCSD Shortness of Breath	39.54 (19.42)	29.58 (14.7)	-0.22 (11.24)	-0.09 (11.78)	-0.01 (-0.48, 0.46)	2.05 (-4.26, 8.37)	2.53 (12.65)	0.7 (14.09)	0.14 (-0.34, 0.61)	3.79 (-3.27, 10.85)
COPD Self-Efficacy	3.38 (0.83)	3.64 (0.78)	0.22 (0.64)	0.02 (0.57)	0.34 (-0.14,	0.14 (-0.11,	0.29 (0.6)	0.01 (0.65)	0.46 (-0.02,	0.21 (-0.06,

					0.81)	0.39)			0.94)	0.49)
CES-D Score	12.18 (9.22)	11.31 (9.28)	-1.21 (4.48)	-1.54 (4.91)	0.07 (-0.4, 0.54)	0.83 (-1.23, 2.89)	-0.82 (5.72)	-0.37 (6.93)	-0.07 (-0.55, 0.41)	0.13 (-2.51, 2.78)
MSPSS Social Support	5.64 (1.33)	5.72 (1.14)	0.22 (1.26)	0.17 (1.04)	0.04 (-0.43, 0.51)	-0.06 (-0.44, 0.31)	0.33 (0.84)	0.22 (1.03)	0.12 (-0.35, 0.6)	0 (-0.29, 0.3)
PSS Perceived Stress	11.73 (6.32)	11.1 (5.75)	-2.47 (4.76)	-0.27 (4.56)	-0.47 (-0.95, 0.01)	-1.40 (-3.51, 0.71)	-0.10 (5.41)	0.83 (4.97)	-0.18 (-0.66, 0.3)	-0.37 (-2.66, 1.92)
Resnick Exercise Self-Efficacy	57.59 (19.28)	66.23 (23.56)	-10.69 (21.52)	-2.97 (18.62)	-0.38 (-0.86, 0.09)	-11.64 (-21.44, -1.83)	-12.2 (21.81)	-9.34 (23.89)	-0.13 (-0.6, 0.35)	-7.05 (-17.01, 2.91)
Calorie Expenditure-Moderate Intensity	1561 (3390)	1317 (1969)	65 (2276)	614 (2636)	-0.22 (-0.79, 0.35)	-242 (-1789, 1305)	634 (3940)	-558 (1321)	0.41 (-0.18, 0.99)	1546 (-20, 3111)
Daily Step Count	2623 (1597)	3205 (2265)	-404 (749)	146 (1667)	-0.43 (-1.01, 0.16)	-560 (1190, 70)	-401 (788)	-206 (1819)	-0.14 (-0.72, 0.44)	-225 (-863, 414)

*mean change (±SD)
**standardized difference (95%CI)

Each row represents one model that incorporates all time points. Models adjust for time since pulmonary rehab, oxygen use, sex, and Charlson Comorbidity Index.
For measures where higher score means better status, positive values reflect improvement, while negative values indicate deterioration.
For measures where higher score reflects worse status, positive values reflect deterioration while negative values indicate improvement.

Physical Activity and Exercise Engagement

At 24 weeks, the mean daily step count (±SD) in TC was 2,431(±1,357), 2,839(±2,376) in GW, and 3,294(±2,461) in UC (Table 3). At 1 year, the mean daily step count was 2,264(±1,255) in TC, 2,983(±3,549) in GW, and 3,402(±2,884) in UC. In the subgroup of participants who wore the Omron pedometer at both follow-up timepoints, there was no difference in PA directly measured as daily step counts between the 3 groups.

Although TC did not increase daily step counts during the 24 weeks, they appeared to be doing other physical activities and engaging in TC as demonstrated by the class attendance and exercise engagement data (Table 3). There was reasonable home practice in TC; they were encouraged to engage in TC 3 times/week for 30 minutes each session, and the data showed an average of 80 minutes/week and 3.9 times/week. UC did more walking, strength training, and cardiovascular exercise (i.e. what they had learned in PR) while TC performed more everyday activities (i.e. housework) and sports. Overall, there were no differences between TC and UC with respect to total self-reported minutes of PA at 12 and 24 weeks, and at 12 months (Table 3). Composite exercise engagement, including intervention, home practice, and other self-reported PA was higher in the first 12 weeks in TC, but similar to the other 2 groups in the follow-up periods.

Table 3. Adherence, Physical Activity, and Exercise Engagement

	(Baseline-12 weeks)			(12 weeks-24 weeks)			(24 Weeks-1 Year)		
	Tai Chi	Group Walking	Usual Care	Tai Chi	Group Walking	Usual Care	Tai Chi	Group Walking	Usual Care
Adherence - Class Time (mins/wk)	105.3 (33.2)	82.5 (43.4)	-	40.6 (16.3)	33.1 (17.2)	-	-	-	-
Adherence - Home Practice Time (mins/wk)	80.2 (55.2)	73.3 (48.3)	-	45.7 (48.5)	40.5 (39.8)	-	-	-	-
Physical Activity Logs - Total (mins/wk)	414.9 (365.6)	249.6 (203.0)	402.9 (295.5)	368.3 (386.5)	240.6 (200.3)	382.2 (372.9)	351.8 (418.0)	319.8 (312.2)	376.0 (329.2)
Walking	125.3 (141.6)	126.2 (139.5)	173.5 (191.9)	115.3 (159.6)	117.0 (126.6)	183.7 (310.8)	107.0 (131.4)	136.0 (180.4)	160.1 (208.5)
Stretching Exercises	17.6 (22.4)	21.4 (22.9)	27.9 (38.9)	15.2 (24.1)	16.2 (16.7)	27.2 (35.3)	11.9 (15.7)	26.5 (27.5)	29.9 (41.0)
Cardiovascular Exercise*	9.3 (19.0)	2.7 (5.3)	37.2 (51.1)	4.9 (11.9)	1.4 (2.6)	35.0 (66.2)	10.3 (25.3)	7.0 (15.0)	26.1 (38.8)
Strength Training**	20.9 (37.0)	10.0 (15.2)	37.5 (60.0)	18.0 (28.5)	10.0 (18.6)	28.1 (40.5)	19.8 (33.0)	19.8 (26.7)	35.0 (57.4)
Playing Sports***	17.0 (62.6)	0.2 (0.6)	4.3 (23.0)	11.0 (32.8)	0	1.3 (5.0)	5.4 (13.3)	3.2 (10.3)	1.0 (4.7)
Heavy Housework†	33.2 (69.7)	9.2 (20.2)	22.4 (38.6)	57.8 (172.1)	5.6 (9.7)	19.4 (30.6)	65.9 (231.2)	27.3 (29.8)	22.6 (57.5)
Light Housework††	132.6 (174.3)	69.8 (63.9)	88.2 (14.2)	95.0 (121.3)	70.9 (73.7)	78.6 (93.7)	96.3 (123.9)	92.6 (108.4)	90.7 (150.4)
Composite Exercise Engagement (mins/wk)	**538.7 (366.9)**	**396.3 (220.7)**	**402.9 (295.5)**	**404.7 (397.7)**	**306.3 (193.2)**	**382.1 (373.0)**	**322.2 (419.5)**	**319.8 (312.2)**	**376.0 (329.2)**

*E.g. jog, run, bike, row
**E.g. general conditioning, chair exercises, using weights, resistance bands
***E.g. golf, tennis, racquetball, basketball, soccer, swimming

†E.g. washing windows, cleaning gutters, home repairs, mowing lawn, raking leaves, shoveling snow
††E.g. sweeping, vacuuming, cleaning, watering plants, weeding, planting

DISCUSSION

The Long-term Exercise After Pulmonary Rehabilitation (LEAP) study examined TC to maintain benefits after completion of outpatient conventional PR in persons with COPD. There was a small between-group effect size in change in 6MWT distance favoring TC compared to UC although the comparison was nonsignificant. In exploratory analyses, there was a significantly greater percentage of persons in TC who had an improvement in exercise capacity, compared to UC. There were also significantly higher percentages of participants in TC who improved HRQL domains, such as fatigue and mastery, compared to UC at 24 weeks. TC was safe, without increased numbers of adverse events, compared to UC. In terms of adherence, class attendance was better in TC compared to GW, but home practice was similar.

Maintenance exercise regimens have typically focused on supervised exercise training with walking drills or cycle ergometers for leg training, and free weights for arm training[3-9,11-13]. Unlike these previous maintenance regimens that have improved exercise capacity but not HRQL, TC also improved HRQL over 24 weeks. These findings are not surprising since TC also incorporates cognitive components, including heightened somatic awareness, focused mental attention, and stress management that can positively impact HRQL.

The significant between-group differences were not observed when change in 6MWT distance or CRQ domains were examined as continuous variables. Nevertheless, given the pilot nature of the study, we noted positive effect sizes for change scores as well as within-group changes in TC, which were not observed in UC or GW, that might inform future studies. Because the elderly commonly choose walking as a convenient and familiar exercise, we explored whether GW, with its added social support, could maintain benefits more effectively than UC. However, these results did not show effect sizes in favor of UC or GW.

Like previous studies, improvements at 24 weeks were no longer evident at one year following completion of PR. We also observed a decrease in exercise time in both TC and GW during the second 12 weeks compared to the first 12 weeks, suggesting that long-term sustained behavior change is also a challenge for mind-body exercise interventions. Diaries, phone calls, pedometers, and a web-based app have been previously used to improve adherence[33,34]. Our data suggest that continued TC classes may be important. As observed in other PR studies, our participants with COPD referred to PR had moderate-severe obstructive lung disease and multiple co-morbidities[13].

We note that the study was powered for between-group difference in change in 6MWT distance at 24 weeks compared to baseline (when PR was completed). We hypothesized that the change in 6MWT distance would be greater in the TC group compared to UC. We did not specify which direction of change would occur within each group, but based on the literature about the natural course of exercise capacity after completion of PR, we expected that the UC group would decline, while the TC group would maintain or improve 6MWT distance. Thus, maintenance rather than continued improvement of benefits in the TC group, leading to a significant change compared to UC, can also be viewed as a meaningful outcome.

Given limited exercise options for PR maintenance, these data on TC are very encouraging. It is likely that no one model of exercise maintenance is ideal for all patients with COPD and that personalized maintenance exercise programs are needed. A broad repertoire of exercise opportunities would optimize maintenance of PA and exercise in persons with COPD who have completed PR[16,33]. Previous studies in persons with COPD, who had not already engaged in PR, support TC's feasibility, safety, and efficacy[35,36]. The low impact, adaptable movements and postures make TC particularly attractive for persons with COPD[37,38]. In a separate pilot RCT in patients with moderate-severe COPD, we demonsrated trends toward improvement in HRQL, depression, and dyspnea after 3 months of TC versus an education control group[20]. The current results extend these previous studies by showing that TC may be a feasible option to maintain the benefits gained after completion of supervised PR.

The type, frequency, intensity, and duration of exercise needed for optimal maintenance and outcomes are unknown. It appears that longer duration programs are more beneficial. Supervised maintenance exercise programs that lasted 9-12 months were associated with risk reduction of pulmonary-related hospitalizations[8]. Improvements in 6MWT distance, CAT score, and mMRC dyspnea score were demonstrated with a 12-month maintenance program of home-visits and telephone contacts[39]. Clearer benefits may have been observed if we had continued our TC intervention to 9-12 months. Based on our findings that UC did more walking, strength training, and cardiovascular exercise while TC performed more everyday activities and sports, we acknowledge that more UC participants may have engaged in maintenance PR since they were enrolled in our research study compared to rates typically seen in the clinical setting.

We enrolled a well-characterized cohort of persons with COPD and comprehensively assessed physiological and psychosocial outcomes. Strengths of this study include the RCT design and enrollment of an ethnically diverse Western population. It is possible that only a subset of patients who complete conventional PR would benefit from TC as a maintenance regimen. In a cohort who all improved outcomes after 8 weeks of outpatient PR, mixed results of a maintenance intervention were explained by the fact that not all participants may be realistic targets for maintenance exercise given the severity of underlying lung disease and/or comorbidities[13]. It has also been suggested that the degree of improvement in exercise capacity after the initial conventional PR program may affect the ability to achieve long-term benefits with a maintenance regimen[33]. We were unable to stratify by those who improved outcomes after conventional PR, before enrolling in this study. We acknowledge that we have shown statistically significant improvements in outcomes but not necessarily clinically important improvements. Overall, TC may be a feasible option to maintain the benefits gained after completing PR and warrants further study.

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Conflict of Interest Declaration
Peter Wayne is the founder and sole owner of the Tree of Life Tai Chi Center. Peter Wayne's interests were reviewed and are managed by the Brigham and Women's Hospital and Partners HealthCare in accordance with their conflict of interest policy. No other authors have conflicts to declare.

FIGURE LEGEND

Figure 1. CONSORT

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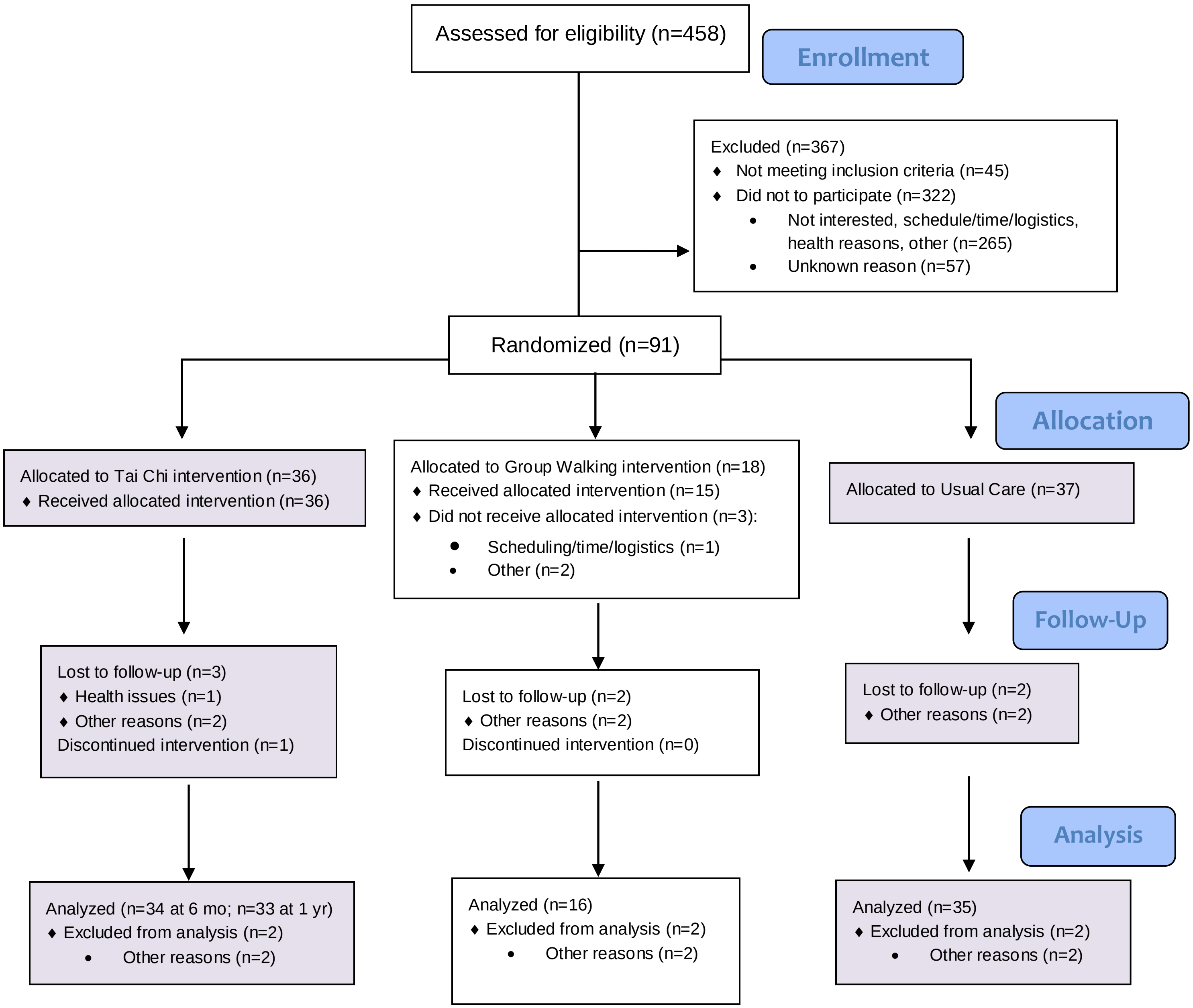
Assessed for eligibility (n=458)
Enrollment
Excluded (n=367)
♦ Not meeting inclusion criteria (n=45)
♦ Did not to participate (n=322)
• Not interested, schedule/time/logistics, health reasons, other (n=265)
• Unknown reason (n=57)
Randomized (n=91)
Allocation
Allocated to Tai Chi intervention (n=36)
♦ Received allocated intervention (n=36)
Allocated to Group Walking intervention (n=18)
♦ Received allocated intervention (n=15)
♦ Did not receive allocated intervention (n=3):
• Scheduling/time/logistics (n=1)
• Other (n=2)
Allocated to Usual Care (n=37)
Follow-Up
Lost to follow-up (n=3)
♦ Health issues (n=1)
♦ Other reasons (n=2)
Discontinued intervention (n=1)
Lost to follow-up (n=2)
♦ Other reasons (n=2)
Discontinued intervention (n=0)
Lost to follow-up (n=2)
♦ Other reasons (n=2)
Analysis
Analyzed (n=34 at 6 mo; n=33 at 1 yr)
♦ Excluded from analysis (n=2)
• Other reasons (n=2)
Analyzed (n=16)
♦ Excluded from analysis (n=2)
• Other reasons (n=2)
Analyzed (n=35)
♦ Excluded from analysis (n=2)
• Other reasons (n=2)

Long-term Exercise After Pulmonary Rehabilitation (LEAP): A Pilot Randomized Controlled Trial of Tai Chi in COPD

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ONLINE SUPPLEMENT

METHODS

Eligibility Criteria

Inclusion criteria were age > 40 years and COPD defined as either FEV_1/forced vital capacity (FEV_1/FVC) <0.70 or chest CT evidence of emphysema[1]. Participants must have completed a supervised PR program within 24 weeks prior to study entry, defined as having attended 65% of the program's sessions, with a minimum of 10 sessions and of at least 8 weeks duration.

Exclusion criteria included COPD AE requiring corticosteroids, antibiotics, emergency room visit or hospitalization within the past 2 weeks; hypoxemia on 6MWT (O_2 sat < 85% on oxygen); inability to ambulate; clinical signs of unstable cardiovascular disease (i.e. chest pain on 6MWT); severe cognitive dysfunction; non-English speaking; current regular practice of Tai Chi; lung cancer treated in the past 5 years; or unstable/untreated mental health issue that precluded informed consent or affected ability to participate in the intervention[2].

Secondary Outcome Measures

HRQL, Dyspnea, Mood, Stress, Social Support, and Self-Efficacy

The disease-specific Chronic Respiratory Disease Questionnaire (CRQ) has been validated in COPD [3]. Four domains include dyspnea, fatigue, emotional function and mastery. Items are scaled on a 7-point modified Likert Scale, with higher scores indicating better HRQL[3]. The University of California, San Diego Shortness of Breath (UCSD SOB) Questionnaire assessed overall dyspnea. The 24-item instrument assesses dyspnea during usual physical activities and has a recall period of one week. Respondents rate symptoms on a 6-point scale from "not at all" to "maximally or unable to do because of breathlessness"[4]. The minimal clinically important difference is 5 units[5].

The Center of Epidemiology Studies-Depression Scale (CES-D) is a validated measure of psychological impairment, primarily depressive symptoms[6]. Participants report how often they experienced various symptoms during the past week using a 4-point ordinal scale. A score of <15 indicates no depression. The CES-D has high internal consistency (r=0.90) and a test-retest reliability of 0.51[6]. The Perceived Stress Scale (PSS) is a measure of the degree to which situations in one's life are appraised as stressful[7]. We used the 10-item version of this instrument which has been shown to have good reliability and validity. The Multidimensional Scale of Perceived Social Support (MSPSS) is a validated 12-item instrument to assess the degree of perceived social support provided in subscale areas of the subject's existing social network (family, friends, and significant others)[8]. The COPD self-efficacy scale (CSES) is a 34-item scale that assesses self-efficacy for managing breathing difficulties in certain situations, including times of negative affect, emotional arousal, physical exertion, respiratory illness, and weather-related or environmental barriers[9]. The Exercise Self-Efficacy scale by Resnick is a brief 9-item instrument that assesses one's confidence in being able to exercise in the face of certain physical, emotional or situational barriers[10].

Physical Activity and Exercise Engagement

The Community Health Activities Model Program for Seniors (CHAMPS) Physical Activity Questionnaire for Older Adults assessed self-reported physical activity (PA)[11]. CHAMPS is a 41-item instrument validated in the elderly, which covers PA from several domains, including leisure, household, and occupational activity. The Omron HJ-720ITC, a waist-mounted pedometer with on-instrument digital data presentation, objectively measured PA as daily step counts. It has been shown to accurately measure daily step counts in most persons with COPD[12,13]. Participants, whose pedometer captured at least 90% of manual step counts assessed on an in-clinic walk, were sent home to wear the Omron during waking hours for a 14-day monitoring period. Values for days with valid step counts (> 200 steps/day) were averaged. Weekly self-report exercise logs captured engagement in the assigned home exercise (practice frequency and duration of home exercise sessions) and all other PA. A composite measure of exercise engagement was calculated using total minutes of class time, home practice time, and other PA on the exercise logs.

Other Data Collection

Pulmonary Function Test Spirometry at baseline, 12, and 24 weeks was performed following American Thoracic Society standards for quality and reproducibility[14].

Acute Exacerbations We defined AEs as "a complex of respiratory symptoms (increased or new onset) of at least two of the following: cough, sputum, wheezing, dyspnea, or chest tightness lasting 3 or more days, requiring a course of treatment (5 or more days) with antibiotics or systemic steroids"[15]. Participants were interviewed in person or by telephone every 3 months using a structured questionnaire to query symptoms, use of corticosteroids and/or antibiotics, and hospitalizations. Participant reports were verified with medical records whenever possible.

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