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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