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Authors

Kohn, Jordan N
Lobo, Judith D
Troyer, Emily A
[et al.](#)

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Tai Chi versus Health Education as a Frailty Intervention for Community-Dwelling Older Adults with Hypertension.

Jordan N. Kohn, Ph.D.^{1,2,*}, Judith D. Lobo, Ph.D.^{3,*}, Emily A. Troyer, M.D.³, Gavrilang, B.S.¹, Kathleen L. Wilson, M.S.¹, Amanda L. Walker, M.S.¹, Chad Spoon, M.R.P.¹, Christopher Pruitt, B.S.¹, Lize Tibiriçá, Psy.D.^{2,3}, Meredith A. Pung, Ph.D.¹, Laura S. Redwine, Ph.D.⁴, Suzi Hong, Ph.D.^{1,3}

¹Herbert Wertheim School of Public Health and Human Longevity Science, University of California San Diego, La Jolla, CA 92093

²Sam and Rose Stein Institute for Research on Aging, University of California San Diego, La Jolla, CA 92093

³Department of Psychiatry, University of California San Diego, La Jolla, CA 92093

⁴Family Medicine and Community Health, Osher Center for Integrative Health, University of Miami, Miller School of Medicine, Miami, FL 33136

Abstract

Background—Frailty is associated with poor outcomes among older adults with hypertension and complicates its pharmacological management. Here, we assessed whether 12-weeks of instructor-guided, group Tai Chi (TC) practice improved frailty relative to Healthy Aging Practice-centered Education (HAP-E) classes in older adults with hypertension.

Methods—Secondary analysis of a randomized controlled trial in San Diego County, USA, of 167 community-dwelling individuals aged 60 yrs (70% female; 72.1±7.5 yrs), defined as non-frail (66%) or frail (34%) based on 53-item deficit accumulation frailty index (FI). Linear mixed-effects models were used to assess pre-to-post intervention differences in FI and logistic regression to explore differential odds of clinically meaningful FI change.

Corresponding Author: Jordan N. Kohn, Ph.D. 9500 Gilman Dr., #0804, La Jolla, CA 92023, Telephone: (619) 543-5832, jokohn@health.ucsd.edu.

* Authors contributed equally to this work.

Author Contributions:

All authors have read and approved of the submission of this manuscript. SH and LSR designed and obtained funding for the study. JNK, JDL, and SH contributed to the analytical concept; JNK, JDL, and EAT drafted the manuscript. JNK was responsible for statistical analysis. All authors contributed to the acquisition of the data and interpretation of the findings and all authors contributed critical revisions of the manuscript.

DECLARATIONS

Compliance with Ethical Standards: All procedures performed involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

Ethical approval: The study was approved by the University of California, San Diego (UCSD) Human Research Protections Program (HRPP).

Informed Consent: Upon initial recruitment, all participants gave written informed consent to the protocol, as approved by the UCSD HRPP, and demonstrated sufficient understanding of the study via the UCSD Brief Assessment of Capacity to Consent.

Conflicts of Interest: The authors have no conflicts of interest to disclose.

Results—One hundred thirty-one participants completed post-intervention assessments. Frailty decreased pre-to-post intervention in the TC ($FI=-0.016$, $d=-0.39$, $-0.75-0.03$), but not the HAP-E arm ($FI=-0.009$, $d=-0.13$, $-0.52-0.27$), despite no significant group differences between the TC and HAP-E arms ($d=-0.11$, $-0.46-0.23$). Furthermore, greater odds of improved FI were observed for frail participants in the TC (OR=3.84, 1.14–14.9), but not the HAP-E (OR=1.34, 0.39–4.56) arm. Subgroup analysis indicated treatment effects in TC were attributed to frail participants (frail: $FI=-0.035$, $d=-0.68$, $-1.26-0.08$; non-frail: $FI=-0.005$, $d=-0.19$, $-0.59-0.22$), which was not the case in the HAP-E arm (frail: $FI=-0.017$, $d=-0.23$, $-0.81-0.35$; non-frail: $FI=-0.003$, $d=-0.07$, $-0.47-0.33$). Frail participants were no more likely to drop-out of the study than non-frail (71% vs. 69% retained).

Conclusions—Twelve weeks of twice-weekly guided TC practice was well-tolerated, associated with decreases in frailty, and increased odds of clinically meaningful FI improvement at post-intervention.

Keywords

Tai Chi; hypertension; frailty; randomized controlled trial

1. INTRODUCTION

Frailty is a multisystem aging syndrome characterized by decreased biological and functional reserve and diminished resistance to stressors. Frail individuals generally manifest cumulative decline across multiple physiological systems (e.g., neurological, musculoskeletal, immunological) and have increased risk of adverse outcomes including falls [1], cardiovascular disease (CVD) [2], neurocognitive disorders [3], and all-cause mortality [4]. Hypertension, a key risk factor for CVD, affects nearly 75% of frail adults [5], and older adults with hypertension and other CVD risk factors (e.g., hyperlipidemia, adiposity, diabetes) tend to be frailer than the general population, highlighting the bidirectional relationship between frailty and CVD [6]. Pharmacologic management of hypertension is complex in frail adults [7], in part due to increased risks of falls, hypotension, and syncope [8]. Frail adults may also benefit less from antihypertensive drug treatment than non-frail adults [9]. It remains unclear whether elevated [10] or lower [11] blood pressure (BP) protects against mortality in frail adults, suggesting that frailty may modify the relationship between BP and health outcomes and highlighting the challenging risk-benefit ratio of hypertension management in frailty. Thus, reducing frailty through non-pharmacologic, movement-based interventions indicated for hypertension in older adults, such as Tai Chi (TC), may be a worthwhile strategy for these patients.

Frailty is conceptualized and assessed in two ways: (i) phenotypic criteria that include unintentional weight loss, exhaustion, low physical activity, weakness, and slowness, or (ii) an accumulation of functional and biological deficits, measured by frailty index (FI) [12]. FI is calculated as a ratio of deficits present to all deficits considered (i.e., 0.00 to 1.00), which can include clinical diagnoses, laboratory values, cognitive or psychosocial characteristics, and has been proposed as a translational measure of health in aging [13]. While operationalization of FI varies across studies, the FI uses standard criteria [12], is robust to floor and ceiling effects, and performs similarly to the frailty phenotype measure in

predicting adverse clinical outcomes [14]. FI generally increases year-to-year in older adults, but can be delayed or reversed through physical exercise, health education, or nutrition interventions [15]; however, the extent to which deficit frailty can be improved in older adults with CVD or elevated CVD risk is less clear [16]. Randomized controlled trials (RCT) of Tai Chi (TC) in older adults with hypertension have demonstrated positive effects on frailty-associated biomarkers [17], such as blood lipids and glucose, and TC studies in frail older adults suggest adequate tolerability, improved mental health, and reductions in frailty-associated outcomes such as falls [18]. However, to our knowledge, RCTs directly assessing the effect of TC on deficit frailty in older adults with hypertension have not been conducted.

Here, we conducted a secondary analysis of the effects of a 12-week randomized, single-blind TC intervention on deficit frailty in community-dwelling older adults with hypertension. Because our sample included both frail and non-frail adults living independently, we evaluated tolerability in frail adults. We hypothesized that: (i) 12 weeks of instructor-guided, group TC practice would decrease FI in older adults compared to a Healthy Aging Practice-centered Education (HAP-E) course; (ii) improvements in FI would be driven by participants who were frail at baseline; and (iii) the odds of clinically meaningful change in FI would be greater in TC and among participants with baseline frailty.

2. MATERIALS AND METHODS

2.1. Study Design and Participants

This cluster-randomized, controlled clinical trial allocated intervention sites (e.g., community centers, independent living retirement centers) to receive either TC or HAP-E in a 1:1 ratio throughout the San Diego metropolitan area between 2016 and 2019. Older adults (>60 years) with hypertension (130 mmHg > systolic BP but SBP/diastolic BP < 170/110 mmHg) were recruited through newspaper advertisements, local online forums, community centers, and wellness fairs with the stated aim of examining “healthy aging and blood pressure” by participation in “Tai Chi or Healthy Aging classes.” Subjects received compensation for participation and completion of study visits. The trial was registered with [ClinicalTrials.gov \(NCT02761603\)](https://clinicaltrials.gov/ct2/show/study/NCT02761603) on May 4, 2016. Upon initial recruitment, all participants gave written informed consent to the protocol, approved by the University of California, San Diego (UCSD) Human Research Protections Program (HRPP), and demonstrated sufficient understanding of the study via the UCSD Brief Assessment of Capacity to Consent [19]. Individuals who already engaged in regular planned moderate exercise or meditation practice (≥ 2 x week and ≥ 30 min per episode) were excluded from participation. See Supplemental Figures and Methods for CONSORT diagram and complete study inclusion and exclusion criteria.

2.2. Behavioral Interventions

Participants attended either 12-week, 120-min/week of TC or HAP-E classes as a comparator, administered in groups of 5 to 12 persons. TC sessions were two, 60-min per week whereas HAP-E was one, 120-min weekly session. Individual attendance was

calculated as a proportion of total sessions attended (out of 24 for TC, 12 for HAP-E). Drop-out was defined as failure to return for a post-intervention (T2) assessment.

2.2.1. Tai Chi (TC)—In-person TC sessions were facilitated by a certified instructor, wherein eight forms (i.e., controlled movements) in the Yang-style of Tai Chi Chuan were taught twice a week for an hour. Sessions were based on the *Tai Chi: Moving for Better Balance (TCMBB)* curriculum, a 12-week functional therapy and evidence-based fall prevention exercise program designed for community-dwelling older adults 60 years and can accommodate people with a history of falls, balance disorders, leg muscle weakness, abnormal gait, or walking difficulty, as well as individuals with mild mobility difficulty [20,21]. As designed, TCMBB aims to improve postural stability, mindfulness and control of body positioning, movement symmetry and coordination, functional walking, and range of motion. Instructional progression of exercise activities and intensity was standardized to each group, as they are pre-defined form-based movements, but modified for participants with physical limitations or who had missed multiple class sessions. Participants were permitted to practice TC while seated and encouraged to practice TC at home between in-person sessions. Each class included 10-min warm-up and cool-down periods plus 40-min TC instruction and practice, for a total 24 hrs of in-class instruction, a TC intervention format previously demonstrated to improve health-related QoL, physical, and mental health in older adults with CVD [22,23]. Individual attendance was recorded by the TC instructor at each in-person session and reported to study staff at the conclusion of the final session.

2.2.2. Healthy Aging Practice-Centered Education (HAP-E)—The HAP-E arm was designed as a comparison condition with the same total group contact time of two hours per week. In-person HAP-E sessions were facilitated by a master's level study staff member (K.W.) and included interactive activities derived from the Centers for Disease Control (CDC) Program to Encourage Active and Rewarding LiveS (PEARLS) involving multidimensional health topics, including pre-recorded public lectures by researchers and clinical experts from the UCSD Stein Center for Research on Aging. Weekly sessions discussed the importance of the following topics in the context of health aging: sleep, nutrition, cardiovascular and musculoskeletal health, diabetes prevention, mental health and wellbeing, socialization, and resilience. Each session was composed of a lecture video (60 min), a group discussion (30 min), and identifying individual problem-solving strategies (e.g., clarify and define a health-related problem, set a realistic goal, brainstorm solutions, evaluate and compare solutions, select and implement solution throughout the week, and evaluate the outcome at the beginning of the next class) (30 min). Individual attendance was recorded by study staff at each in-person session.

2.3. Sociodemographic and clinical assessments

Average basal systolic (SBP) and diastolic (DBP) blood pressures were calculated from 3 consecutive seated measurements on the left arm at 5-min intervals following 15-min seated rest using an automated oscillometric sphygmomanometer (Colin Press-Mat, model BP-8800, Komaki City, JP) during in-person lab visits, which were conducted within 4 weeks of intervention initiation and/or completion. Participants self-reported their medical history and brought all currently prescribed medications to study visits, which were

reviewed and recorded by study personnel. Educational attainment (college graduate or not) and marital status (partnered or non-partnered) were self-reported. Race and ethnicity were self-reported separately and operationalized into a single two-level factor (e.g., Non-Hispanic White or Latino/Black/Asian/Asian American, Native Hawaiian or Pacific Islander/Mixed).

2.4. Frailty Index

The Frailty Index (FI) operationalizes frailty by summing the number of deficits within an individual and dividing by the total number of deficits included in the index, yielding a total FI score ranging between 0.00–1.00 [24]. A score of 1.00 represents a theoretical state of complete frailty, while a score of 0.00 reflects complete robustness or non-frailty. In accord with standardized procedures for selecting candidate health deficits for the FI [24], we selected variables that satisfied the following criteria: (i) a known health status association; (ii) age dependency; (iii) not saturating at too early age; (iv) multidimensionality (e.g., physical and psychosocial health domains); and (v) serial measurements within individuals. Thus, the present analysis considered 53 deficit variables in following categories (See Supplemental Table 1 for the complete list): 2 neuropsychiatric assessments, 14 self-assessments of fall risk in performing activities of daily living, 5 self-assessments of health, and 1 cognitive assessment (see Section 2.4.1); 14 biomarkers of organ function and 8 biomarkers of inflammation and vascular function (see Section 2.4.2); 2 physical performance measures (see Section 2.4.3); 6 self-reported comorbidities or recent medical interventions; and 1 hypertension severity measure (i.e., anti-hypertensive medications). Age- and sex-specific reference ranges were used where applicable, and empirical thresholds were derived for variables without established norms (Supplemental Methods). Notably, SBP and DBP were omitted from the FI because the directionality of BP associations with health status are unclear (see FI criteria above) in older adults, with studies reporting positive and negative relationships [25,26]. Nonetheless, BP was examined for its association with frailty. For exploratory subgroup analysis, participants were grouped into FI strata (not frail vs. frail) based on a previously validated cutoff of 0.25 [27]. Of all variables used in the FI, 75% had <2% missingness, all but 4 variables had <10% missingness, and no variable had >20% missingness.

2.4.1. Self-report and cognitive assessments—Participants completed at-home paper questionnaires within 4 weeks prior to and after completing the intervention to assess depressive symptoms (Beck Depression Inventory, BDI-II [28]), sleep (Patient-Reported Outcome Measurement Information System Sleep Disturbance Short Form 8a [29], PROMIS-SD), fear of falling while completing activities of daily life (Modified Falls Self-Efficacy Scale [30], MFSE), and self-rated health (Medical Outcomes Study 20-item Short Form Survey Instrument [31], SF-20). The 30-item Montreal Cognitive Assessment (MoCA, version 7.1–7.3) was administered by study staff at each visit, with alternate versions administered in counterbalanced order at each visit to minimize practice effects. See Supplemental Methods and Supplemental Table 1 for FI operationalization.

2.4.2. Blood collection and biomarker measurements—Blood samples were collected into sterile EDTA tubes at pre- and post-intervention laboratory assessments after

12 hours of abstinence from anti-inflammatory medications (e.g., NSAIDs), caffeine, nicotine, and strenuous exercise. Plasma was collected using a refrigerated centrifuge and stored at -80°C for biomarker quantification. Whole blood samples were sent to a CLIA-certified laboratory (LabCorp, San Diego, CA) for evaluation of complete blood counts (CBC), metabolic profile, and to rule out acute infection. Age- and sex-adjusted reference ranges defined by LabCorp were applied as thresholds for FI index calculation (Supplemental Table 1). Fourteen biomarkers of organ function were analyzed, including white blood cell count, monocyte, lymphocyte, and neutrophil proportions, hemoglobin, platelets, serum creatinine, aspartate aminotransferase, blood urea nitrogen, glycosylated hemoglobin, sodium, albumin, alkaline phosphatase, and calcium. Eight plasma inflammatory and vascular injury markers, including C-reactive protein (CRP), serum amyloid A (SAA), soluble vascular cell adhesion molecule-1 (sVCAM-1), soluble intercellular adhesion molecule-1 (sICAM-1), interleukin-(IL)-6, IL-1 β , interferon-(IFN)- γ , and tumor necrosis factor (TNF)- α , were assessed and empirical distributions (i.e., quartiles) were used to establish FI thresholds (see Supplemental Methods; Supplemental Table 1).

2.4.3. Fall risk and mobility assessment—Fall risk was assessed with the BTrackS Balance Test protocol [Balance Tracking Systems (BBT), San Diego, CA, USA], which measures postural sway, a widely validated indicator of balance. The BBT uses a database of >20,000 individuals to generate age- and sex-adjusted percentile scores and has strong predictive validity for falls [32]. Mobility was assessed using the Centers for Disease Control Timed Up & Go (TUG) protocol.

2.5. Statistical Analysis

Study data were collected and managed using REDCap electronic data capture tools. Analyses were conducted using R v4.2.0. An alpha level of 0.05 was used to determine statistical significance, and 95% confidence intervals (CI) are reported. Fisher's Exact Test were used to compare frequencies between intervention arms for non-continuous variables, and *t*-tests for continuous variables.

Linear regression was implemented to test for associations between covariates and FI at baseline/T1, and linear mixed-effects models (LMM) for longitudinal relationships between BP and FI at T1 and T2. Multiple imputation by chained equations [33] was performed by classification and regression trees ($N=5$ imputed datasets) for missing variables, which were presumed missing at random. Each participant's FI was then computed as their mean FI across imputed datasets. LMM was implemented in intent-to-treat analyses to test the null hypothesis that pre-to-post-intervention FI did not differ by intervention arm, with log-transformed FI score as the outcome variable, the main effect of visit-by-intervention interaction, with covariates of age, sex, race, education, and marital status. Nested random effects (i.e., participant within site) were included in LMMs to reflect the study design and adjust for potential site effects. A priori Tukey-adjusted post hoc tests of conditional means were conducted to assess FI within each intervention arm across pre-to-post intervention using *lsmeans* [34], regardless of interaction term significance. Regression diagnostics were performed to assess predictor multicollinearity and model heteroskedasticity, including

variance inflation factor and quantile-quantile residual plots. Standardized betas (β) and Cohen's d effect sizes (small: $d \approx 0.20$, medium: $d \approx 0.50$, large: $d \approx 0.80$) are reported.

Exploratory subgroup analyses were conducted to test the hypothesis that individuals with greater baseline frailty (FI ≥ 0.25) would yield greater improvements in FI compared to non-frail individuals. To accomplish this, a LMM was implemented within frailty groups (frail or non-frail at baseline) as described above, with a main effect of visit-by-study arm and post hoc testing of conditional mean differences using *lsmeans*. An additional analysis was performed to determine whether odds of clinically meaningful changes in FI between T1 and T2 differed between intervention arms. Four logistic regression models were implemented using FI thresholds of (i) FI ≥ -0.03 (0.50 SD) and (ii) FI ≥ -0.02 (0.33 SD), indicating improvement in FI; (iii) FI ≥ 0.03 and (iv) FI ≥ 0.02 , indicating worsening in FI. These thresholds have been proposed as minimum clinically important difference (MCID) for FI using anchor-based [35] and distribution-based methods [36]. Class attendance (% attended of total) was also included in the logistic models to assess associations with MCID.

3. RESULTS

3.1. Participant characteristics and intervention attendance

Baseline sociodemographic and clinical characteristics of the study population are summarized in Table 1. A total of 182 adults aged 60–93 were randomly assigned to 12 weeks of either TC or HAP-E (Supplemental Figure 1). Altogether, 167 participants (70% female; age: 72.1 ± 7.5 yrs) completed pre-intervention (T1) assessments (see Methods). All but eleven participants who completed T1 assessments attended at least 1 class ($N=156$; HAP-E: $N=75$; TC: $N=81$), and 131 participants completed post-intervention (T2) assessments sufficient to compute FI at T2 (HAP-E: $N=62$; TC: $N=69$). Participants who attended ≥ 1 class but did not complete T2 assessments (HAP-E: $N=13$; TC: $N=12$) did not differ from those who completed T2 by FI, or by age, sex, race, marital status, education, MoCA score, SBP, DBP, or BMI. Attendance in the TC arm ($75.3 \pm 21.6\%$) was higher than the HAP-E arm ($42.4 \pm 6.8\%$; $d=2.06$, 1.59–2.53), corresponding to 18.1 and 10.2 hours of in-class time on average, respectively, although T2 assessment completion did not differ between intervention arms (HAP-E=77%; TC=71%; OR=0.79, 0.38–1.67). No intervention-related injuries or falls were observed during the study.

3.2. Associations between baseline FI, sociodemographics, and follow-up assessments

At baseline, the two intervention arms did not differ by sociodemographic or clinical factors, nor by FI or the proportion of participants who were frail (FI ≥ 0.25 : HAP-E: $N=29$, 36% frail, TC: $N=27$, 31% frail; OR=1.26, 0.63–2.53; Table 1). Age was positively associated with baseline FI ($\beta=0.21$, 0.06–0.36) (Supplemental Figure 2), and a larger proportion of participants >80 years old were frail (58%) compared to those aged 60–70 (30%) or 70–80 years (25%; $\chi^2=10.6$, $p=0.005$). Univariate analysis indicated that apart from age, FI did not differ by gender ($d=0.14$, -0.19 – 0.48), race/ethnicity ($d=0.12$, -0.33 – 0.57), education ($d=-0.04$, -0.35 – 0.27), SBP ($d=0.09$, -0.21 – 0.40), or DBP ($d=-0.15$, -0.46 – 0.16), and was unrelated to class attendance ($d=-0.16$, -0.47 – 0.14). Higher baseline FI was associated with being single ($d=0.34$, 0.02–0.66). Frail participants were similarly likely to have completed

a T2 assessment (71%) as non-frail (69%; OR=0.98, 0.57–1.69). The rate of non-completion of T2 assessments by frail participants did not differ between the TC (33%) and HAP-E arms (25%; OR=1.49, 0.40–5.77).

3.3. Pre-to-post intervention changes in FI by study arm and frailty status

At the post-intervention visit, FI did not differ significantly between HAP-E (mean FI=0.227, SD=0.099) and TC intervention arms (mean FI=0.209, SD=0.093; $d=-0.11$, $-1.03-0.81$), consistent with a lack of visit-by-intervention effect ($d=-0.11$, $-0.46-0.23$). However, post hoc contrasts revealed decreases in FI from pre-to-post intervention in the TC arm (FI=-0.016, $d=-0.36$, $-0.71-0.02$), but not in the HAP-E arm (FI=-0.009, $d=-0.13$, $-0.47-0.21$). Adjustment for age, gender, race, marital status, and education did not change post hoc test results (TC: $d=-0.38$, $-0.73-0.04$; HAP-E: $d=-0.15$, $-0.49-0.27$; Table S2). Subgroup analyses stratified by baseline frailty did not indicate a visit-by-intervention effect for frail participants ($\beta=-0.15$, $-0.38-0.07$), but post hoc contrasts (both unadjusted and covariate-adjusted) revealed decreases in FI for frail participants within the TC arm (frail: FI=-0.035, $d=-0.68$, $-1.26-0.08$; non-frail: FI=-0.005, $d=-0.19$, $-0.59-0.22$; Fig. 1), but not in the HAP-E arm (frail: FI=-0.017, $d=-0.23$, $-0.81-0.35$; non-frail: FI=-0.003, $d=-0.07$, $-0.47-0.33$; Table S3). Across both T1 and T2 assessments, FI was not associated with DBP ($d=-0.14$, $-0.38-0.10$) or SBP ($d=-0.04$, $-0.29-0.21$).

3.4. Clinically meaningful changes in FI by study arm

Participation in TC did not confer increased odds of clinically meaningful improvement in FI relative to HAP-E (FI -0.02: HAP-E: $N=26$, 43% improved; TC: $N=31$, 45% improved; OR=1.09, 0.52–2.33) or *decreased* odds of worsening FI (FI 0.02: HAP-E: $N=15$, 25% worsened; TC: $N=19$, 28% worsened; OR=1.16, 0.49–2.78). Similar results were observed at the more stringent MCID thresholds (FI -0.03: OR=0.88, 0.40–1.92; FI 0.03: OR=0.94, 0.37–2.41). However, subgroup analyses stratified by treatment arm revealed that being frail at baseline was associated with increased odds of improved FI in TC (OR=3.84, 1.14–14.9), but not in HAP-E (OR=1.34, 0.39–4.56). In addition, greater class attendance was associated with decreased odds of worsening FI in TC (OR=0.44, 0.22–0.79), but not HAP-E (OR=1.05, 0.57–2.07). Lastly, older age was associated with decreased odds of improved FI in TC (OR=0.49, 0.22–0.93), and women in the HAP-E arm had decreased odds of improved FI relative to men (OR=0.16, 0.04–0.57).

4. DISCUSSION

Our findings provide initial evidence that a 12-week TC intervention was associated with moderate improvements in multidimensional deficit frailty in community-dwelling older adults with hypertension. Subgroup analyses stratified by baseline frailty indicated that observed treatment effects were attributable to frail participants, supporting the hypothesis that TC may be an effective frailty intervention for frail older adults. Furthermore, analyses of clinically meaningful changes in FI indicated that frail participants had increased odds of improved frailty in the TC arm, but not the HAP-E, which was also associated with in-class TC participation. Notably, drop-out rates of frail participants were not higher than non-frail

participants, suggesting that TC is well-tolerated in frail older adults and highlighting its potential benefit in secondary and tertiary prevention of frailty.

The efficacy of TC compared to the health education control arm in the present study ($d=-0.68$) parallels the reported effect sizes of exercise interventions in community- and care home-dwelling older adults to mitigate frailty ($d=-0.63$ [37]; $d=-0.57$ [38]). Compared to non-exercise control cohorts, TC has been shown to improve components of frailty, including deficits in balance and mobility, cognitive function, psychosocial wellbeing, and cardiovascular parameters [39], and the TCMBB protocol used in this study, specifically, has demonstrated efficacy in improving frailty-related deficits over a relatively brief 12-week intervention period [40]. TCMBB involves relaxation and deep breathing, can be performed while sitting, and compared to conventional exercise programs, such as strength or aerobic training, may therefore be ideally suited for older adults with greater degrees of frailty [41]. Indeed, our findings support the notion that TC may improve deficit frailty markers, specifically among those meeting criteria for frailty. Similarly, a large-scale multicomponent RCT in frail older adults [42] recently reported that individuals with the lowest physical performance battery scores at baseline (i.e., most frail) had greater mobility improvements than a health education control group, with no improvements observed in those with high baseline performance (i.e., least frail). Notably, we observed that older participants had lower odds of FI improvement in TC. This may have been due to age-related loss of plasticity in biological or psychosocial factors that comprised our FI in the oldest-old, or a reduced capacity to execute the TC protocol as prescribed.

Frail participants had similar rates of class attendance to non-frail participants and were no less likely to have dropped out of the study altogether. Frail participants generally have reduced mobility, greater medical comorbidities, and cognitive deficits that may impede attendance, particularly among community-dwelling individuals for whom transportation barriers may exist, though these factors were not significant barriers to participation in the present study. Notably, drop-outs among frail participants also did not differ between the TC and HAP-E intervention arms, suggesting that the physical demands of TC practice were unlikely to have caused drop-out. Interestingly, women in HAP-E had decreased odds of improved FI relative to men, which has been previously reported in other lecture-based health education programs for CVD [43], and may be due to sex differences in the components that comprise deficit frailty [44]. Future studies should directly compare efficacy of TC to other non-pharmacologic interventions in reducing or preventing worsening of frailty considering participant characteristics that may explain differential acceptability or intervention responses.

There is a lack of consensus regarding the measurement and definition of frailty, which has resulted in heterogeneity of research findings and challenges in translating such findings into clinical recommendations. For example, a 2022 review of frailty interventions in CVD patients [16] noted at least twenty-five unique instruments used to measure frailty. For FI, a threshold of 0.25 is commonly applied to define frailty [27], as in the present study; however, an analysis of associations between FI and hospital-related event risk in Canadian community-dwelling older adults suggested 0.21 as an optimum [45], while others have applied lesser, greater, or age-adjusted thresholds [46] based on all-cause mortality risk,

morbidity, and other adverse clinical outcomes. Thus, establishing the optimal frailty instrument and its associated thresholds remain a challenge to translating frailty-focused RCTs outcomes into patient-specific clinical recommendations.

A related challenge in RCTs in frail adults is in estimating clinically meaningful changes (i.e., MCID). Our study is one of the first RCTs to evaluate MCID in frailty between pre- and post-intervention assessments [47]. Mean annual changes in FI in older adults were recently estimated to be ± 0.02 [48], with larger variability and greater mortality risk for FI increases reported in frail individuals compared to the less frail. This suggests that limiting further increases in frailty among already-frail older adults may reduce mortality risk, though longer-term follow-up studies are needed. MCID for FI has been approximated to be 0.03 using the Clinical Frailty Scale as anchoring measurement [35], 0.028 based on quality of life anchoring, or 0.023 using distribution-based methods in community-dwelling older adults [49], though the underlying biological mechanisms remain unclear. It was recently demonstrated that a 0.02 improvement in FI corresponded to 1 SD decrease in GrimAge, a phenotype- and mortality-trained epigenetic clock [50], which is consistent with the magnitude of FI change observed in TC in our study. Interestingly, FI and GrimAge have been reported to be complementary in their predictive capacity of increased mortality risk [51], though the extent to which intervention-associated improvements in FI correspond to decreased biological age and mortality risk warrants further examination.

There were a handful of limitations of the current study. First, the study excluded individuals who had a hospital admission resulting from a fall within the preceding 12 months, potentially introducing a sampling bias of individuals with better health. However, the mean FI of study participants ($FI \approx 0.22$) and the proportion classified as frail at baseline ($TC=31\%$; $HAP-E=36\%$) were within range of large epidemiologic surveys [52], suggesting that study participants were no more or less frail than the general population. Second, the use of FI, rather than phenotype criteria to measure frailty, has certain disadvantages, such as the invariance of medical diagnoses, rendering them 'resistant' to intervention effects. However, FI has been demonstrated to perform as well (or better) than phenotype criteria in predicting adverse outcomes. Third, while the 12-week intervention period was sufficient to detect meaningful changes in FI, longer-term follow-up assessment is needed to determine the durability of such effects, in particular comparing participants who continued TC practice beyond the formal study period to those who did not, and whether health behaviors or medication utilization changed over the long term. We also note that while study assessments were mostly administered within 2 weeks post-intervention, some participants completed follow-up at up to 4 weeks, which may have introduced detraining effects. Fourth, we did not include BP in the FI, as its directional association with frailty is not well-established [26,53], and we did not observe associations between FI and BP in our sample of older adults with well-controlled hypertension. While direct causal associations between frailty and BP have yet to be elucidated, interventions actively targeting frailty will likely be necessary to improve CVD-related outcomes. To that end, future frailty interventions should recruit frail individuals with poorly-controlled hypertension [54] ($SBP > 150$ mmHg), and patients with CVD, such as heart failure. Fifth, changes in medication use, diet, and physical activity associated with the intervention were not considered, which may have confounded our findings. At-home TC participation was not quantified; however,

our analyses accounted for differential class attendance, which captures the primary factor underlying intervention ‘dosage.’ Sixth, frailty improvements within TC were quantified by *post hoc* testing, despite absence of a formal interaction effect (i.e., visit x study arm) in the LMMs. Thus, our findings should be interpreted as preliminary and necessitate replication in larger trials with greater power to detect treatment effect differences between TC and health education interventions. Lastly, our sample was demographically homogenous, with the majority being female, college-educated, and more non-Latino White than San Diego County as a whole (65–74 yrs: 65.9%; 75–84 yrs: 66.3%). Thus, our results may not apply to other geographic locations or more ethnically diverse populations.

5. CONCLUSION

Twice-weekly TC practice over 12 weeks was well-tolerated in older adults with hypertension and was associated with moderate improvements in frailty, specifically among participants who were frail at baseline. TC was also associated with increased odds of improved frailty at post-intervention compared to a healthy aging educational course, altogether suggesting that TC may be an effective frailty intervention for frail older adults with hypertension.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Impact Statement:

We certify that this work is novel. This study is, to our knowledge, the first of its kind to provide evidence from a randomized controlled trial that 12 weeks of group Tai Chi practice was associated with decreased frailty in community-dwelling older adults with hypertension relative to a healthy aging education course and suggests that Tai Chi may be an effective frailty intervention for older adults at increased risk for cardiovascular disease.

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Highlights

- A 12-week, group Tai Chi course improved deficit frailty in older adults with hypertension
- Tai Chi conferred increased odds of improved frailty
- Beneficial effects were attributable to individuals who were frail at baseline
- Tai Chi may be effective for frailty in older adults with hypertension.

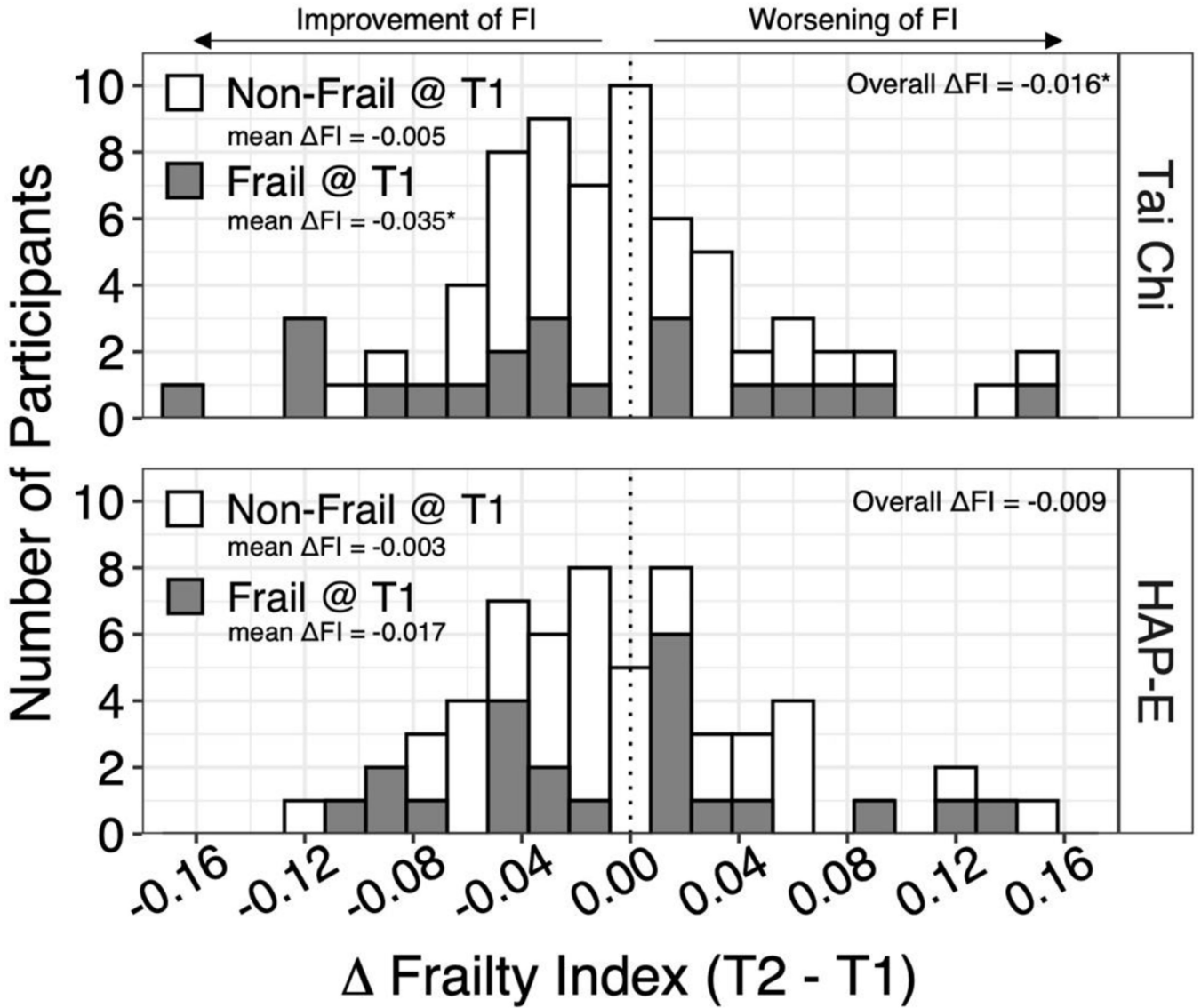


Figure 1. Change in Frailty Index from pre- to post-intervention follow-up at 12 weeks in Healthy Aging Practice Centered Education (HAP-E; n=62) and Tai Chi (n=69) arms. Change in Frailty Index (FI) was calculated as the arithmetic difference in FI (i.e., T2 minus T1) for all participants who provided sufficient data at T2 (N= 131). Dotted vertical line indicates no change (FI = 0.00), with bars to the right and left of the line indicating increased and decreased FI, respectively. Shaded bars indicate study participants with T1 frailty. Mean change in FI within each study arm stratified by T1 frailty status shown in top left corner of both plots. **p*<0.05, based on post hoc testing of linear mixed-effects models within intervention arm subgroups (see Section 2.5).

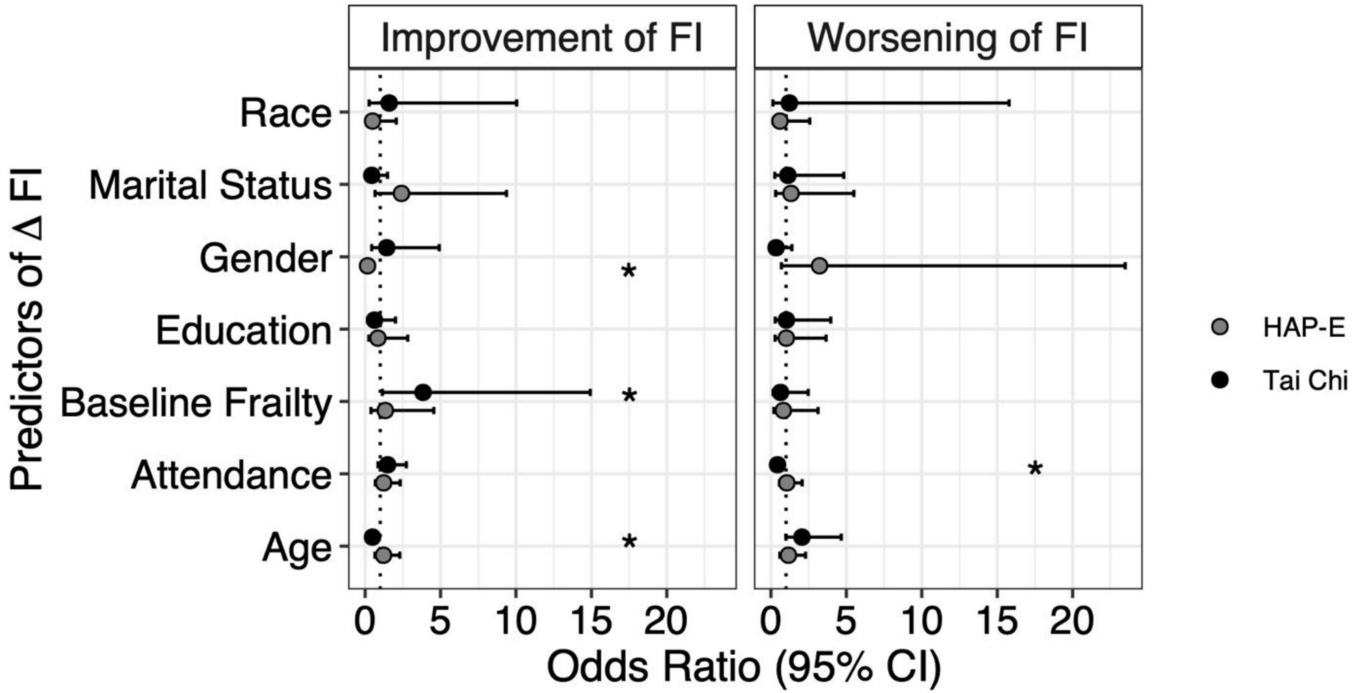


Figure 2. Differential odds of minimum clinically important difference (MCID) in Frailty Index (FI) across 12-weeks between Tai Chi (TC) and Healthy Aging Practice Centered Education (HAP-E) intervention arms.

Results from four logistic regression models, implemented based on thresholds for worsening of FI ($FI \geq 0.02$; right panel) and improvement of FI ($FI \leq -0.02$; left panel) to assess differential odds of ΔFI by intervention arm (HAP-E: grey points; Tai Chi: black points). Model predictors shown on left, with respective odds ratios and 95% confidence intervals. Asterisks denote statistical significance at $p < 0.05$, uncorrected, for each respective predictor.

Table 1.

Comparison of Baseline Sociodemographic, Clinical, and Frailty between Intervention Arms

Variable	HAP-E (N=80)	TC (N=87)	Test Statistic (95% CI)
<i>Sociodemographics</i>			
Age	73.2 (7.7)	71.6 (7.5)	$d = 0.22$ (-0.09, 0.52)
% Female	68%	72%	OR = 1.21 (0.59, 2.50)
Race (% White)	82%	90%	OR = 2.01 (0.73, 5.92)
% Married/Partnered	33%	36%	OR = 1.14 (0.58, 2.30)
% College Educated	50%	60%	OR = 1.57 (0.81, 3.08)
<i>Clinical</i>			
SBP (mmHg)	135.7 (20.2)	134.1 (16.3)	$d = 0.09$ (-0.23, 0.41)
DBP (mmHg)	69.3 (10.0)	69.5 (9.6)	$d = -0.02$ (-0.33, 0.29)
BMI (kg/m ²)	28.8 (6.1)	29.9 (6.9)	$d = -0.18$ (-0.48, 0.13)
MoCA	25.2 (3.2)	25.4 (3.7)	$d = -0.06$ (-0.37, 0.25)
% Frail (FI 0.25)	36%	31%	OR = 1.26 (0.63, 2.53)
Frailty Index (FI)	0.224 (0.10)	0.224 (0.09)	$d = 0.00$ (-0.31, 0.31)

Means (SD) and proportions (%) for sociodemographic and clinical variables at baseline between two intervention arms. Effect size estimates for continuous (Cohen's d) and categorical (Odds Ratio; OR) predictors and 95% Confidence Intervals (CI) derived from two-tailed, independent samples t -tests or Fisher's Exact Test, respectively. SBP: Systolic Blood Pressure. DBP: Diastolic Blood Pressure. BMI: Body Mass Index. MoCA: Montreal Cognitive Assessment. FI: Frailty Index, computed from 53-item deficit accumulation model. TC: Tai Chi intervention arm. HAP-E: Health Education intervention arm.