

Intense Tai Chi Exercise Training and Fall Occurrences in Older, Transitionally Frail Adults: A Randomized, Controlled Trial

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See Editorial Comments by Drs. Laurie Lavery and Stephanie Studenski on pp 1804–1805.

OBJECTIVES: To determine whether an intense tai chi (TC) exercise program could reduce the risk of falls more than a wellness education (WE) program in older adults meeting criteria for transitioning to frailty.

DESIGN: Randomized, controlled trial of 48 weeks duration.

SETTING: Twenty congregate living facilities in the greater Atlanta area.

PARTICIPANTS: Sample of 291 women and 20 men aged 70 to 97.

MEASUREMENTS: Demographics, time to first fall and all subsequent falls, functional measures, Sickness Impact Profile, Centers for Epidemiologic Studies—Depression Scale, Activities-specific Balance Confidence Scale, Falls Efficacy Scales, and adherence to interventions.

RESULTS: The risk ratio (RR) of falling was not statistically different in the TC group and the WE group (RR = 0.75, 95% confidence interval (CI) = 0.52–1.08), $P = .13$. Over the 48 weeks of intervention, 46% ($n = 132$) of the participants did not fall; the percentage of participants that fell at least once was 47.6% for the TC group and 60.3% for the WE group.

CONCLUSION: TC did not reduce the RR of falling in transitionally frail, older adults, but the direction of effect observed in this study, together with positive findings seen

previously in more-robust older adults, suggests that TC may be clinically important and should be evaluated further in this high-risk population. *J Am Geriatr Soc* 51:1693–1701, 2003.

Key words: exercise; falls; balance; aging; tai chi

Falls by older persons are a major public health problem resulting in significant consequences for individuals, their families, and healthcare delivery systems.^{1–3} Falls may augment fear in elderly individuals while also tending to adversely affect efforts to socialize and engage in physical activity.^{4–7} Innovative approaches designed to minimize falling are therefore warranted.

Recently, there has been an increased interest in providing exercise interventions to delay or reduce the risk of falling in older adults. A group of investigators reviewed exercise programs and their effect upon risk for falls and fractures and concluded that exercises designed to improve balance and strengthen lower extremities may reduce the risk of falling and that physical activity was associated with a 20% to 40% reduction in risk of hip fractures.⁸ Through a preplanned meta-analysis, the Frailty and Injuries: Cooperative Studies of Intervention Techniques (FICSIT) trials examined the effect of balance, flexibility, endurance, resistance training, and physical therapy exercise interventions in reducing the risk of falling in older adults at eight sites. This meta-analysis did not show a significant effect of endurance, resistance, or flexibility exercises on falls risk, but there was a 10% reduction in falls risk with general exercise programs and a 17% reduction with balance-oriented exercises.⁹ Of the balance interventions, the 16-week tai chi (TC) intervention trial resulted in an adjusted risk ratio for falls of 0.525 compared with a 16-week wellness education (WE) program.¹⁰

Results from more-recent studies have suggested that TC training may improve strength and flexibility,^{11,12} balance,¹³ blood pressure,¹⁴ and cardiorespiratory function¹⁵

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in older adults. Although these findings support the benefits of TC as an exercise form, participants in all these studies were robust elderly. An unresolved question therefore is whether TC benefits older individuals who are less robust, that is, who are transitioning to frailty.

Herein, the authors report the first prospective, single-blinded, randomized clinical trial to compare an intense TC exercise program of 48 weeks duration with a WE program of similar duration on falls occurrences in elderly participants who met the criteria for transitional frailty.¹⁶ The authors hypothesized that a TC program of this intensity would be necessary to produce an effect size comparable to that demonstrated in a 16-week program with more-robust, older participants.¹⁰

METHODS

Facilities

This study was conducted in 20 congregate living facilities located in the greater Atlanta metropolitan area between September 1997 and August 2001. The target recruitment goal was to enroll at least 15 participants from each facility. Twelve facilities had more than 15 participants (maximum of 19), and all participants were allowed to enroll. Facilities were recruited in pairs by whether they were Housing and Urban Development ($n = 14$) or private ($n = 6$) sites and then randomized to the TC or WE intervention group. A total capacity of 4,032 older adults could reside in the 20 congregate living facilities; the number per facility ranged from 98 to 349. Evaluators were blinded to intervention allocation, instructors were blinded to outcome measures, and participants were instructed not to disclose the intervention they received. The Emory University human investigation committee approved this study. Written informed consent was obtained from all participants before their enrollment.

Eligibility Criteria

Details regarding the design and methodology of this trial have been reported elsewhere.¹⁷ Briefly, to be eligible for inclusion, all persons had to be aged 70 and older and transitioning to frailty. Ten attributes based upon age, gait/balance, walking activity for exercise, other physical activity for exercise, presence or absence of depression, use of sedatives, near-vision status, upper and lower extremity strength, and lower extremity disability are used to define this transition.¹⁶ Older adults are considered "vigorous" persons if they possess at least three vigorous and no more than two frail attributes. Frail elderly adults have at least four frail and no more than one vigorous attribute. Elderly adults were defined as transitionally frail if they did not meet the frail or vigorous criteria. Also, all potential participants had to have fallen at least once in the past year. Potential participants at each congregate living facility were excluded if the health survey or physical examination revealed any symptoms or signs consistent with major unstable cardiopulmonary diseases (ischemic chest pain, unaccustomed shortness of breath, shortness of breath with mild exertion, recurrent syncopal episodes, orthopnea, paroxysmal nocturnal dyspnea, palpitations, tachycardia, claudication, or severe pitting ankle edema);

cognitive impairment defined as a Mini-Mental State Examination (MMSE) score of less than 24; contraindications to physical exercise, such as major orthopedic conditions (e.g., severe lumbar spine, hip, knee, or ankle arthritis that limits exercise capability); restricted to a wheelchair; terminal cancer; or evidence of any other progressive or unstable neurological or medical condition.

Interventions

TC consists of slow, rhythmic movements that emphasize trunk rotation, weight shifting, coordination, and a gradual narrowing of lower extremity stance. Six of the 24 simplified TC forms that best exemplified these movements and could be combined into a final product (2 continuous minutes of unassisted TC exercise) were used.¹⁸ All TC exercise was standardized by having the two instructors practice with one another until their execution of the movement forms to be taught in each class were identical. One instructor was a TC grand master, and the other was his student, who had studied with him for more than 5 years. Participants progressed from often being dependent on assistive devices for upright support to performing 2 continuous minutes of TC without support. TC was taught at each facility randomized to that intervention. "Intense" TC was defined as two sessions a week at increasing durations starting at 60 minutes contact time and progressing to 90 minutes over the course of 48 weeks. The actual "work" time, exclusive of warm up and cool down, progressed from approximately 10 minutes to 50 minutes over the course of the 48 weeks. Intensity must also be considered within the context of the capability of the participants and the physiological effort they were required to exert.

The WE program was given at participating facilities for an hour each week and consisted of instruction about falls prevention; exercise and balance; diet and nutrition; pharmacological management; legal issues relevant to health; changes in body function; and mental health issues such as stress, depression, and life changes. Interactive handout materials were provided, but there was no formal instruction in exercise. The total time for individual attention from each instructor to participants in each group was comparable.

Quantification of Fall Events

Fall events represent the primary outcome measure for this study and were defined as events in which the participant unintentionally came to rest on an object (e.g., person, table, chest of drawers) that prevented center of mass from exceeding the base of support or came to rest on the floor or a lower object because the center of mass exceeded the base of support. This definition of a fall event is consistent with the definition used in the Atlanta FICSIT site study.¹⁰ Participants were asked to complete two forms. The first form required identifying the day in which one or more falls occurred, and the second form provided a checklist for the type(s) of fall(s) and circumstances surrounding each fall. The second form allowed the participant to check the type of fall, the reason for the fall, the extent of injury if any occurred, and the need for any medical intervention. Injurious falls were defined as falls resulting in hospital

visits or admission for the treatment of a fracture or suspected fracture. Participants were requested to submit their forms to the instructor weekly. Fall reports were reviewed monthly. After the first month of the study, only sporadic omissions or mistakes were made. These mistakes were followed up with a phone call to obtain the correct information.

Participants who reported a fall were called within 1 week after the report was reviewed to confirm the fall, obtain more-detailed information regarding its nature, and ascertain the extent of injury and use of healthcare services. Participants who did not turn in their forms, provided incomplete forms, or filled out forms incorrectly were called within 1 to 2 weeks after the regularly scheduled review.

Measurement of Function

Functional measurements were performed every 4 months and were selected based upon their proven reliability and validity, simplicity to administer, minimal expense, and ease of transport and assembly at each site. Interrater reliability of the evaluation team was assessed during prestudy training and reassessed every month for the first 18 months of the trial by having all evaluators perform functional measures concurrently on participants; reliability was maintained at kappa of 0.98 or greater. Measures included the distance participants could reach the arm forward at 90° shoulder flexion without moving their feet (functional reach test¹⁹), elements from the Berg balance test²⁰ (360° turn and picking up an object from the floor), single limb support with eyes open and closed,^{21,22} three consecutive chair stands,²³ and time to complete a 10-meter walk.²³

Measurement of Behavior

Fear of falling was assessed quarterly using the Falls Efficacy Scale²⁴ and the Activities-specific Balance Confidence Scale.²⁵ Health-related quality of life was assessed at baseline and after 1 year using the Sickness Impact Profile (SIP).²⁶ This 136-item test is divided into 12 categories. Categories can be scored independently or combined to produce an overall summary score. Three of the 12 categories were summed to form a physical score, and four categories were grouped to provide a psychosocial score. Depression was evaluated quarterly using the Centers for Epidemiologic Studies—Depression Scale.²⁷ This test for depression consists of 20 items measuring four domains of depressive symptoms, including depressive affect, positive affect, somatic symptoms, and interpersonal relationships. Scores of 16 or greater are indicative of depression. Cognitive impairment was evaluated at baseline and after 1 year using the MMSE.²⁸

Additional Measurements and Definitions

The evaluating physician assessed height, weight, muscle strength through manual muscle testing, range of active joint motion in all limbs, and vital signs. Sensation and visual acuity were also recorded every 4 months. Grip strength was measured using handheld dynamometry. Changes in pharmacological intake, health status, and exercise activities were also recorded. Previous fall-related fractures were defined as self-reported fractures of long bones in the extremities at age 65 or older.

Besides injurious falls, other adverse events followed throughout this study were deaths and hospitalizations caused by medical or surgical problems probably unrelated to participation.

DROPOUTS

Dropouts were defined as participants who were noncompliant or missed more than 8 consecutive weeks of the intervention, usually due to declining health. Beyond this interval, learning TC movement forms or WE materials already covered by the classes would have impeded the progress of those classes. Every effort was made to secure quarterly follow-up data from all randomized participants.

Sample Size and Study Power

The main hypothesis for this study was that TC would reduce falls risk by 50% more than WE. The estimates of the required sample size were based on the adjusted risk of 0.525 from the Atlanta FICSIT study,¹⁰ on the risk of falling within 48 weeks for a WE participant of 0.22,¹⁰ and a two-sided log-rank test for the time to first fall. An overall sample size of 392 participants (196 participants per group) would achieve an 80% power at a two-sided 0.05 significance level to detect a risk ratio (RR) of 0.50 when comparing the TC and WE groups after the 48-week intervention period. The original power calculation assumed that sufficient facilities could participate to fulfill recruitment requirements. Because 311 persons at 20 facilities were recruited, rather than the originally estimated 392, a reestimated power analysis showed a greater than 70% power to detect a RR of 0.50. These power calculations allow for a 15% dropout rate for each of the intervention groups across the entire trial (approximately the same dropout rate as the Atlanta FICSIT trial that assessed more-robust, older adults).¹⁰ The sample size estimate and statistical power for this trial assume a weak but negligible effect for randomization by center. This assumption is based in part on the primary outcome being falls.

Statistical Analyses

Univariate and multivariate statistical methods were used to estimate the RR for falling for TC compared with WE participants. Baseline measurements of TC and WE participants were compared using a permutation test²⁹ in which the unit of randomization is the center pair. The primary analyses compared the frequency of falls in the two groups using the Wei, Lin, and Weissfeld (WLW)³⁰ extension of the Cox proportional hazards model. Like the Cox model, the WLW method models the hazard of falls (the risk of a fall during a brief time interval) in terms of the intervention group and relevant covariates. Unlike the Cox method, the WLW method allows for the event of interest to occur more than once. The RR was used as the measure of association. Moreover, using the WLW method, data were analyzed adjusting for site (center); that is, it was assumed that each center had a separate baseline hazard function. All statistical analyses were based on the intention-to-treat principal, that is, all participants were analyzed as randomized.

A priori, the authors included selected demographic characteristics (age, sex, ethnicity, education, and marital status) and risk factors for falls (fear of falling, depression, gait speed, use of walking aids, exercise, history of previous fractures, health status, and strength) as covariates based upon previous literature.^{1,5} To assess whether subgroup variation in risk ratios was significant, the relevant interaction terms between the intervention group and the covariate were entered into the WLW model using the .05 level of significance. For a covariate to be a confounder and included in the final WLW model, it had to lead to a 10% change in the RR. Ninety-five percent confidence intervals (CIs) were calculated for the RRs comparing the TC group with the WE group.

RESULTS

From December 1997 to September 1999, 311 persons were enrolled in this trial. A recruitment and randomization flow chart is shown in Figure 1. Twenty-four participants randomized to TC ($n = 12$) and WE ($n = 12$) withdrew immediately after randomization because they were no longer interested ($n = 7$), perceived their health to be too poor ($n = 5$), were denied physician approval to participate ($n = 7$), experienced catastrophic health events ($n = 3$), or died ($n = 2$). One additional participant was later excluded from the analysis because of the previously undetected diagnosis of Parkinson's disease.

Most clinical characteristics of the two groups were similar at baseline (Table 1), including all attributes.¹⁶ The 24 persons who dropped out after randomization assignment had similar baseline characteristics as those in their respective treatment groups. Of the remaining 286 participants, 69 (24%) did not complete the intervention: 37 in the TC group and 32 in the WE group. The number of persons who dropped out of the trial did not differ significantly between groups.

At baseline, persons in the TC group used a walking aid less often ($P = .02$) and had a better total SIP ($P = .04$) and SIP physical dimension ($P = .001$) score than those in the WE group.

The number of participants who fell at least once during each month for the 48 weeks of evaluation is plotted in Figure 2. Individual rates were not determined because some participants fell multiple times. For the TC participants, the greatest number of falls occurred during Month 1, whereas for the WE participants, the greatest number of falls occurred during Month 4. During the early learning phase of TC training (Months 1–3), the number of injurious falls was similar in the TC ($n = 3$) and WE ($n = 4$) groups. There were no differences between groups for other adverse events.

The RR for falls adjusted for center over the entire 48 weeks of evaluation for the TC compared with the WE group was 0.75 (95% CI = 0.52–1.08). Over the 48 weeks of evaluation, 46% ($n = 132$) of the participants did not fall, and the percentage of participants that fell at least once was 47.6% in the TC group and 60.3% for the WE group (Table 2).

Each baseline variable in Table 1 was assessed in the WLW model for interaction (effect modification)-by-treatment group. Previous fall-related fractures ($P = .02$) and

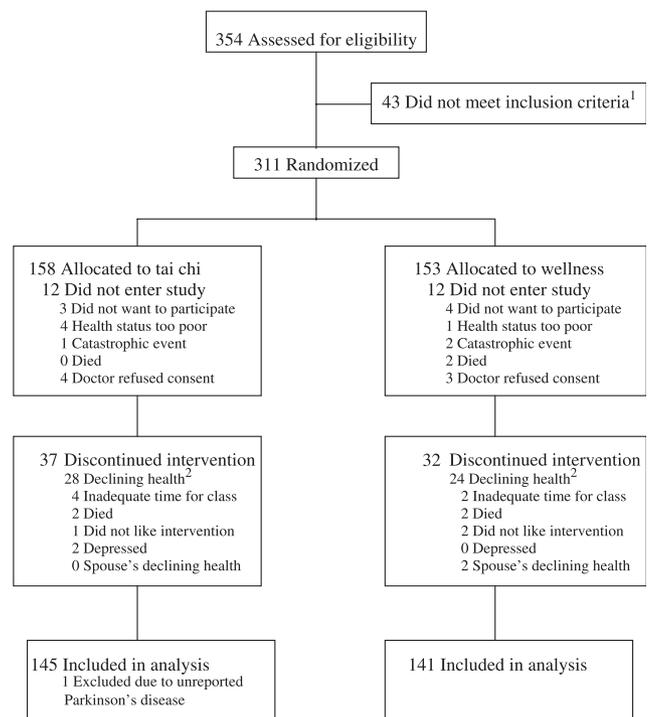


Figure 1. Progress through the stages of the tai chi (TC) and wellness education (WE) study, including flow of participants, withdrawals, and inclusion in analyses.¹ Not meeting inclusion criteria reasons: too frail ($n = 7$); chose to stop screening procedure ($n = 7$); progressive neurological disease ($n = 6$); too robust ($n = 5$); unstable coronary status ($n = 5$); Mini-Mental State Examination score < 24 ($n = 4$); orthopedic problems ($n = 3$); emotionally unstable/early dementia ($n = 2$); recent cerebrovascular accident ($n = 2$); untreated abdominal aneurysm ($n = 1$); severely compromised vision ($n = 1$).² Declining health reasons: injuries/fractures ($n = 4$, TC; $n = 5$, WE); deteriorating vision ($n = 3$, TC); cardiac ($n = 3$, TC; $n = 3$, WE); musculoskeletal/neurological impairment ($n = 10$, TC; $n = 4$, WE); loss of independence ($n = 1$, TC; $n = 6$, WE); stroke ($n = 1$, TC; $n = 2$, WE); cancer ($n = 1$, TC; $n = 2$, WE); diabetes mellitus ($n = 1$, TC; $n = 1$, WE); diverticulitis ($n = 1$, TC); major surgery ($n = 1$, TC); asthma ($n = 1$, TC); hospitalized at time of post intervention interview (subject later died) ($n = 1$, TC); prolonged illness ($n = 1$, WE).

education ($P = .02$) were the only two variables that modified the effect of treatment group significantly. For those persons with previous fall-related fractures, the fall rate in the TC group was higher but not statistically significantly different from that in the WE group (RR = 1.76, 95% CI = 0.78–3.96). Participants in the TC group without previous fall fractures had significantly lower fall rates than those in the WE group (RR = 0.58, 95% CI = 0.38–0.90). Participants in the TC group with no high school degree had significantly lower fall rates than those in the WE group (RR = 0.41, 95% CI = 0.23–0.72), whereas participants in the TC group with a high school degree or higher had a similar fall rate to that of those in the WE group (RR = 1.06, 95% CI = 0.64–1.76). Participants with no high school degree were significantly less physically active at baseline than participants with a high school education or greater ($P = .014$).

Table 1. Baseline Characteristics of Study Subjects (N = 286)

| Characteristic | Tai Chi (n = 145) | Wellness (n = 141) | P-value |
|---|-------------------|--------------------|---------|
| Age | | | |
| Mean \pm SD | 80.9 \pm 6.6 | 80.8 \pm 5.8 | |
| Median | 82 | 81 | |
| Range | 70–95 | 70–97 | .80 |
| Ethnicity, n (%) | | | |
| Caucasian | 116 (80.0) | 115 (81.6) | |
| Non-Caucasian | 29 (20.0) | 26 (19.4) | .62 |
| Education, n (%) | | | |
| Did not complete high school | 29 (20.0) | 31 (22.0) | |
| High school and beyond | 116 (80.0) | 110 (78.0) | .97 |
| Sex, n (%) | | | |
| Male | 8 (5.5) | 9 (6.4) | |
| Female | 137 (94.5) | 132 (93.6) | .72 |
| Marital status, n (%) | | | |
| Widowed | 108 (74.5) | 105 (74.5) | |
| Other | 37 (25.5) | 36 (25.5) | .99 |
| Fear of falling by falls efficacy scale | | | |
| Mean \pm SD* | 19.9 \pm 6.2 | 20.4 \pm 6.1 | |
| Median | 20.0 | 19.0 | |
| Range | 10–38 | 10–40 | .54 |
| Fear of falling by Activities-specific Balance and Confidence Scale, %† | | | |
| Mean \pm SD | 53.2 \pm 19.4 | 50.4 \pm 21.1 | |
| Median | 52.5 | 48.1 | |
| Range | 10.6–99.4 | 0–96.6 | .27 |
| Depression by Centers for Epidemiologic Studies Depression Scale (CES-D), n (%) | | | |
| Absent (CES-D = 0–15) | 104 (75.9) | 101 (74.3) | |
| Present (CES-D = 16–60) | 33 (24.1) | 35 (25.7) | .80 |
| Functional reach, inches | | | |
| Mean \pm SD | 11.68 \pm 3.00 | 10.52 \pm 3.09 | |
| Median | 12.13 | 10.71 | |
| Range | 2.35–17.33 | 0.05–17.83 | .04 |
| Gait speed, m/s | | | |
| Mean \pm SD | 1.02 \pm 0.34 | 0.94 \pm 0.30 | |
| Median | 1.03 | 0.92 | |
| Range | 0.26–2.28 | 0.28–1.73 | .13 |
| Three chair stand, seconds | | | |
| Mean \pm SD | 10.95 \pm 4.37 | 10.37 \pm 4.01 | |
| Median | 9.80 | 9.65 | |
| Range | 5.45–24.93 | 1.24–24.05 | .33 |
| 360° turn | | | |
| Mean \pm SD | 4.54 \pm 2.85 | 4.95 \pm 2.79 | |
| Median | 3.99 | 4.35 | .50 |
| Range | 1.70–28.74 | 1.76–19.78 | |
| Single limb support | | | |
| Eyes open - right | | | |
| Mean \pm SD | 2.69 \pm 2.61 | 2.15 \pm 1.91 | |
| Median | 1.88 | 1.67 | .03 |
| Range | 0.44–16.83 | 0.12–16.22 | |
| Eyes open - left | | | |
| Mean \pm SD | 2.70 \pm 2.60 | 2.16 \pm 1.90 | |
| Median | 1.79 | 1.58 | .16 |
| Range | 0.32–12.21 | 0.35–14.68 | |
| Eyes closed - right | | | |
| Mean \pm SD | 1.35 \pm 0.84 | 1.30 \pm 0.78 | |
| Median | 1.22 | 1.12 | .56 |
| Range | 0.32–8.13 | 0.34–5.74 | |

(continued)

Table 1. (Continued)

| Characteristic | Tai Chi (n = 145) | Wellness (n = 141) | P-value |
|---|-------------------|--------------------|---------|
| Eyes closed - left | | | |
| Mean \pm SD | 1.28 \pm 0.58 | 1.15 \pm 0.59 | .16 |
| Median | 1.24 | 1.06 | |
| Range | 0.03-1.24 | 0.34-1.06 | |
| Speechley et al. frailty characteristics, n (%) | | | |
| Age \geq 80 | 80 (55.2) | 83 (58.9) | .51 |
| Impaired gait/balance ^{46,47} | 134 (92.4) | 134 (95.0) | .36 |
| Walking for exercise [‡] | 50 (34.5) | 39 (27.7) | .48 |
| Other physical exercise [‡] | 57 (39.3) | 55 (39.0) | .98 |
| Depression [§] | 51 (35.2) | 53 (37.6) | .61 |
| Use of sedatives | 36 (24.8) | 34 (24.1) | .86 |
| Near vision | 142 (97.9) | 139 (98.6) | .62 |
| Impaired upper extremity strength | 23 (15.9) | 25 (17.7) | .70 |
| Impaired lower extremity strength | 36 (24.8) | 40 (28.4) | .59 |
| Lower extremity disability [¶] | 53 (36.6) | 55 (39.0) | .73 |
| Use of walking aid, n (%) | 62 (42.8) | 80 (56.7) | .02 |
| Any regular physical activity, n (%) | 88 (53.7) | 76 (46.3) | .54 |
| History of previous fractures, n (%) | 35 (24.1) | 29 (20.6) | .61 |
| Sickness impact profile | | | |
| Mean \pm SD | 12.1 \pm 8.8 | 15.7 \pm 10.7 | .04 |
| Median | 9.7 | 13.3 | |
| Range | 0-47 | 0-45 | |
| Psychosocial dimension | | | |
| Mean \pm SD | 10.0 \pm 10.3 | 13.5 \pm 14.1 | .18 |
| Median | 6.5 | 8.1 | |
| Range | 0-42 | 0-76 | |
| Physical dimension | | | |
| Mean \pm SD | 12.9 \pm 9.0 | 16.6 \pm 10.6 | .001 |
| Median | 11.6 | 14.7 | |
| Range | 0-51 | 0-43 | |
| Grip strength | | | |
| Right | | | |
| Mean \pm SD | 17.3 \pm 6.0 | 16.9 \pm 5.3 | .35 |
| Median | 17.7 | 16.3 | |
| Range | 0.0-36.0 | 5.0-38.7 | |
| Left | | | |
| Mean \pm SD | 16.0 \pm 5.2 | 15.5 \pm 5.4 | .34 |
| Median | 15.7 | 15.0 | |
| Range | 2.3-33.3 | 4.3-34.3 | |

* 10 = not at all concerned about falling; 40 = very concerned about falling.

† Confidence in percentage not to lose balance.

‡ Exercise: moderate intensity (\geq 12 rating on Borg Scale) and accumulation of \geq 60 minutes per week and duration of \geq 6 months during past year.

§ Use of antidepressants or \geq 16 on CES-D scale.

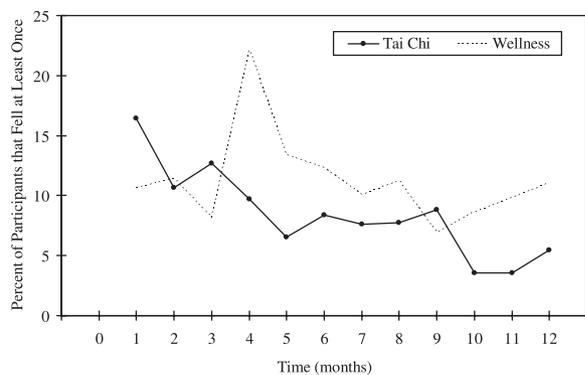
|| Sedatives = narcotics, benzodiazepines, antidepressants, or phenothiazines.

¶ Gross lower extremity motor impairment; disability and impairment based upon Ref 16 definitions (for original sources, see References 46 and 47).
SD = standard deviation.

After assessing each baseline variable in Table 1 (other than education and prior history of fall-related fractures) for potential confounding, only one statistically significant variable, the SIP psychosocial dimension ($P = .05$), was found. In both intervention groups, persons with better (lower) psychosocial scores had lower fall RRs than those with worse (higher) psychosocial scores. The inclusion of the psychosocial SIP scores had little effect on the overall risk ratio (RR = 0.78, 95% CI = 0.54-1.14) and thus was not considered a confounding factor.

Each participant was transitionally frail and had as many as seven frail attributes or as few as three frail attributes. When the analysis controlled for the number of frail attributes in the participants, no statistically significant differences in fall RR was observed between the TC group and the WE group (RR = 0.75, 95% CI = 0.51-1.09).

Adherence to the TC exercise and to the WE program was assessed by maintaining weekly attendance records and calculating the percentage of total sessions attended. The average \pm standard deviation attendance in the TC group



No. at risk: Tai Chi 145 140 131 126 124 122 119 118 116 113 112 110
 Wellness 141 141 140 134 131 127 122 119 116 116 116 109

Figure 2. Percentage of participants that fell at least once by intervention and month (ordinate) and participants from whom data were obtained by month (abscissa).

was 76 ± 19% (range: 6–100%), whereas the average attendance for the WE group was 81 ± 17% (range: 10–100%); this difference was marginally statistically significant (*P* = .06). When attendance was evaluated in the WLW model adjusted for center, a statistically significant effect of attendance (*P* = .006) was found; TC and WE participant groups who attended their sessions had a lower risk for falls. The RR for falls comparing TC with WE adjusted for attendance was 0.71 (95% CI = 0.49–1.03), similar to that found earlier without adjusting for attendance.

Both TC instructors, who were blinded to study outcomes, independently informed the authors after the interventions were completed that it took about 3 months for most TC participants to progress from often being dependent on assistive devices for upright support to performing TC movement forms without support and to increase the intensity of the exercise from 20 to 50 minutes. Therefore, post hoc analyses were undertaken. The TC group had a significantly lower risk of falls adjusted for center from Month 4 through Month 12 (RR = 0.54, 95% CI = 0.36–0.81) than the WE group. If Month 4 was eliminated from the analysis because of the marked increase in falls during that month for the WE group, the RR for falls for the TC group compared with the WE group was also significantly reduced from Month 5 through Month 12 (RR = 0.61, 95% CI = 0.40–0.94).

No adverse events occurred during the TC or WE intervention. One participant sustained an ankle abrasion during the medical evaluation.

DISCUSSION

The results from this study show that a 48-week TC intervention for transitionally frail older adults did not lead to a statistically significant reduction in fall risk. In the FICSIT trials, it was demonstrated that a modest TC intervention of 1 to 2 h/w for 15 weeks resulted in an adjusted RR of 0.525 compared with an education group.

There are several potential reasons why the results of this study did not achieve statistical significance, as in the FICSIT study. First, in determining the sample size requirements, the authors did not anticipate the time delay required for these transitionally frail persons to be fully performing the TC forms and overestimated the TC benefit over WE. Second, the effectiveness of intense TC in a frailer older population may not reach the magnitude seen in robust older adults undergoing a less intense TC training experience.

Third, although there were no differences in falls risk between the two groups by number of frail attributes at baseline, the definition of transitional frailty might be imprecise, leading to reduced study power. Recently, a study validated a new definition of frailty, which should allow for more precision in future studies of persons transitioning to frailty.³¹

Fourth, this present study had the power to detect a 50% but not a 25% reduction in fall rate, especially because the event rate in the WE group was higher than predicted. However, the authors based their original power calculation on the a priori premise of accruing a larger sample size and a 50% reduction in fall rate in the TC group, not on the number of actual falls that occurred in the WE group. A post hoc power analysis showed that, given the number of study participants and the fall rate in the WE group, this study would have been able to detect a 28% reduction in fall rate. Thus, the reduction in risk seen in this study is probably clinically important, although not statistically significant.

Fifth, over the 48 weeks, there appeared to be a slight decline in the number of falls per month in the WE group. Health promotion can be an effective intervention in preventing disease or injury.^{32–34} The WE activities may have motivated some participants to become more physically active, adopt healthier and safer lifestyles, and thus reduce their risk factors for falling, although the study did not measure the individual effectiveness of these potential cointerventions. Finally, the extent to which the weekly recording of fall events with active follow-up could have led to an increased awareness awaits study.

Table 2. Number and Frequency (Percentage) of Fall Events Per Participant By Intervention

| Intervention | Falls, n (%) | | | | | | | |
|--------------|--------------|-----------|-----------|----------|---------|---------|---------|---------|
| | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| Tai chi | 76 (52.4) | 36 (24.8) | 20 (13.8) | 7 (4.8) | 3 (2.1) | 1 (0.7) | 1 (0.7) | 1 (0.7) |
| Wellness | 56 (39.7) | 43 (30.5) | 20 (14.2) | 10 (7.1) | 5 (3.5) | 5 (3.5) | 2 (1.4) | 0 (0.0) |
| Total | 132 (46.2) | 79 (27.6) | 40 (14.0) | 17 (5.9) | 8 (2.8) | 6 (2.1) | 3 (1.0) | 1 (0.3) |

Among those participants who had not sustained a fracture since the age of 65, 42% fewer falls in the TC group than in the WE group was observed. To the authors' knowledge, there are no studies investigating the relationship between falling and exercise training in older, transitionally frail adults with previous fractures. Nevertheless, another study showed that older, postmenopausal women, all of whom had histories of upper extremity fractures and were randomized to a brisk walking program, achieved a higher cumulative risk of falls than did participants randomized to an upper extremity exercise program.³⁵ Further research is needed to determine the reasons why vigorous exercise programs, such as brisk walking or TC, may have a greater effect on delaying falls in older persons without a fracture after age 65.

This study also observed that persons with less than a high school degree had a reduced risk of falling if they were in the TC group than if they were in the WE group. Another study has shown that better educated older adults are more likely to exercise without prompting or instruction than are those with less education.³⁶ Because less-educated adults were significantly less physically active at baseline, they might have had a larger window of acceptance and involvement with a structured exercise program such as TC, have practiced the exercise forms with greater intensity and awareness, and consequently, have experienced a lower falls risk.

The finding of a latent treatment effect from TC is not surprising, given that the basic TC forms require periods of learning, of increasing intensity, and of confidence in performing these forms. Nevertheless, the result was unanticipated, because no previous study on TC interventions with older adults examined this possible effect.^{9–11} Although some physical interventions for older adults can produce noticeable results within a few weeks,³⁷ other programs may require 3 months^{38–42} or longer⁴³ before significant physiological and health status changes can be observed. For example, one study showed that achieving the effect of moderate intensity physical exercise on improvements in sleep quality took more than 8 weeks,⁴⁰ whereas another study demonstrated that cardiovascular benefits following exercise were enhanced substantially by 6 months and even more profoundly after 1 year.⁴³ Similarly, other studies using multiple interventions, including exercise, tend to produce significant improvement in more-robust older persons. For example, one study's findings suggest that the effect of the multifactorial intervention in reducing falls in older persons was greater after 2 to 3 months of the intervention.⁵ Nevertheless, because this present study's finding was unexpected, it should be interpreted with caution.

The differences in baseline physical health scores of the SIP indicate that the TC participants perceived their physical health to be better than WE participants in the areas of ambulation, mobility, and activities of daily living, even though there were no differences between the two groups in their performance test scores. Previous studies have shown that, although performance and perceived health status are related, they are separate constructs, each affected by multiple factors, such as sociodemographic characteristics, cognitive status, and emotional well-being.⁴⁴ However, a preliminary analysis of SIP outcome

data suggest that the differences in perception by the two groups did not affect the outcome measure of time to falls.

Although TC participants apparently had some functional scores at baseline that were better than those of their WE counterparts, these differences were significant only for functional reach, right single limb support with eyes open, and walking aid use. Because randomization occurred by facility and none of the participants at these locations were aware of the intervention to which they were randomized until after signing informed consent, there is no reason to place much value in these baseline differences. Furthermore, male participants were underrepresented. Greater participation by women was anticipated. Few men came to the recruitment events, and anecdotal comments from spouses indicated that greater frailty or engagement in other activities might have been the primary reasons for the lack of male participation.

TC is a relatively new concept in western culture. Performance of TC relies more on recollection of images than memorization of instruction,^{45,46} suggesting that this exercise might influence cognitive processes. This concept, as well as how TC improves certain physical attributes, such as muscle strength, balance and posture, range of motion, and function, awaits study.

The health of sedentary older persons would benefit greatly if they adopted a more physically active lifestyle. The duration of effect in this study, together with positive findings seen previously in more robust older adults,¹⁰ suggests that attempts to provide TC in the general community should form the basis for future investigations.

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