Lack of Effect of Tai Chi Chuan in Preventing Falls in Elderly People Living at Home: A Randomized Clinical Trial

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OBJECTIVES: To evaluate the effectiveness of Tai Chi Chuan in fall prevention in elderly people living at home with a high risk of falling.

DESIGN: Randomized controlled trial.

SETTING: Two industrial towns in the western part of the Netherlands.

PARTICIPANTS: Two hundred sixty-nine elderly people (average age 77) living at home with a high risk of falling.

INTERVENTIONS: The intervention group received Tai Chi Chuan training for 1 hour twice a week for 13 weeks; the control group received usual care. Both groups received a brochure containing general information on how to prevent fall incidents.

MEASUREMENTS: Primary outcome was the number of falls over 12 months. Secondary outcomes were balance, fear of falling, blood pressure, heart rate at rest, forced expiratory volume during the first second, peak expiratory flow, physical activity, and functional status.

RESULTS: After 12 months, no lower fall risk in the Tai Chi Chuan group was observed than in the control group (adjusted hazard ratio = 1.16; 95% confidence interval = 0.84–1.60), and there were no significant intervention effects on the secondary outcome measures.

CONCLUSION: These results suggest that Tai Chi Chuan may not be effective in elderly people at a high risk of falling who live at home. **J Am Geriatr Soc 57:70–75, 2009.**

Key words: fall prevention; Tai Chi Chuan; RCT

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Falls are a common problem for older people. Approximately 30% of community-dwelling people aged 65 and older fall at least once each year.[1,2] The incidence of falls in the Netherlands follows the same pattern.[3] Several risk factors have been identified for falls and injurious falls.[3–7] The risk is strongly related to previous fall incidents, disturbed balance, dizziness, decreased muscular strength, use of benzodiazepines and diuretics, changes in walking pattern, and age.[1,3,4,6,7] The consequences of fall incidents vary; 55% to 70% of fall incidents result in physical injury[1,5] and 5% to 6% in serious physical injury (such as hip fractures).[5] Other consequences of falls are greater fear of falling,[3] decline in functional status and physical activities, and greater use of health services.[8] It has been reported that exercise training (including balance training) may help to prevent falls, although the evidence is inconclusive.[2,9–11] A promising exercise intervention is Tai Chi Chuan,[2,12–17] a traditional Chinese exercise, practiced for centuries, that is highly suitable for elderly persons with limitations in balance and mobility. It is an integral part of traditional Chinese medicine and consists of a series of movements (positions) that are performed in a slow and flowing manner; the focused interaction between mind and body is an important aspect of Tai Chi. In addition to fall risk reduction and balance improvement, other beneficial effects of Tai Chi Chuan are reported in physical (e.g., reduced blood pressure) and psychological (e.g., enhanced mental wellbeing) functioning.[16–20]

Although Tai Chi Chuan seems to be a promising intervention to achieve improvement in a range of health-related outcomes, its effectiveness in fall prevention is inconclusive. Three trials reported significantly lower multiple falls risk for Tai Chi participants;[12,14,21] two other trials reported a decline in fall incidents but not significantly different from controls.[13,22] Reviews show that the promising effects on fall prevention is based on limited research findings.[15–17]

The present trial aimed to provide more evidence on the effects of Tai Chi Chuan on fall prevention and is the first to be conducted in Europe. The main goal was to evaluate the

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effectiveness of Tai Chi Chuan on fall prevention in elderly people living at home with a high risk of falling. It was hypothesized that balance, physical activity, and functional status would also improve and that blood pressure, heart rate at rest, and fear of falling would be lower in the intervention group than in controls.

METHODS

Study Design

A randomized, partially blinded clinical trial was conducted to assess the effectiveness of Tai Chi Chuan on fall prevention in elderly people living at home with a high risk of falling. Outcome data were collected at baseline and after 3, 6, and 12 months.

The institutional medical ethics review committee approved the study. Detailed information on the methods has been published earlier.[23]

Study Population

Eligibility criteria were age 70 and older, living at home, and having a high fall risk. High fall risk was defined as one or more self-reported fall incidents in the year preceding the study or at least two of the following self-reported risk factors for falling: disturbed balance, mobility problems, dizziness, and the use of benzodiazepines or diuretics.

Eligible subjects were identified using the patient registration files of participating general practitioners (GPs). Medication codes according to the Anatomical Therapeutic Chemical Classification System with Defined Daily Doses were used as keywords (e.g., fall and dizziness). GPs invited patients by mail, and subjects were subsequently screened for eligibility using a short telephone survey. An independent research assistant performed a prestratified block randomization using a computer-generated randomization list.[23] Strata were based on sex and fall incidents in the year preceding the study (yes/no),[23] which provided the opportunity to distinguish between primary and secondary prevention. GPs were not told which group their patients were allocated to.

Baseline Measurements

A blinded research assistant confirmed the eligibility, completed informed consent, and performed the baseline measurements. Baseline measurements covered sociodemographic factors, environmental factors, medication, use of walking devices, and healthcare service utilization. Secondary outcomes assessed at baseline were balance, fear of falling, blood pressure, heart rate at rest, forced expiratory volume during the first second (FEV_1), peak expiratory flow (PEF), physical activity, and functional status.

Interventions

At baseline, both groups received a brochure explaining how to prevent fall incidents in and around the house. The control group received usual care; they could use or apply for available services in the area as before. The intervention group received 1 hour of Tai Chi Chuan training twice a week for 13 weeks.

Four professional Tai Chi Chuan instructors (experienced with older persons) gave the lessons using a predefined protocol. The core of the lessons consisted of 10 positions derived from the Yang style. In the Frailty and Injuries: Cooperative Studies of Intervention Techniques Trials, these positions appeared to be successful in preventing falls.[12] Chi Kung exercises were used during the warm-up and cool-down periods.The group size ranged from seven to 14 persons. The instructors asked participants to practice the Tai Chi Chuan positions at home at least twice a week for approximately 15 minutes.

Outcome Measures

The primary outcome measure was fall incidents. At baseline, the participants received a falls calendar and the instruction to fill it out on a daily basis for 1 year. The response options were "fallen," "nearly fallen," and not "fallen." A fall was defined as "*unintentionally coming to rest on the ground, floor, or other lower level*."[24] A near fall was defined as "*the person seems to fall, but can prevent it by catching or leaning on a person or a thing (e.g., chair, a drawer or a table)*."[24] The fall calendars were collected monthly by mail. The blinded research assistant contacted the participant when forms were missing or incomplete, and they then completed the forms together over the telephone.

The secondary outcome measures were well validated for the population and included the Berg Balance Scale to measure balance,[25] the Falls Efficacy Scale for fear of falling,[26] the Physical Activity Scale for the Elderly for physical activities,[27] and the Groningen Activity Restriction Scale for functional status.[28] During the physical examination, blood pressure and heart rate at rest were measured, and FEV_1 and PEF were measured using a spirometer. Finally, a standardized questionnaire was used to register the use of walking devices, medication, use of healthcare services (e.g., GP, specialist, physiotherapist, home care or district nurse), and modifications to the home.

At the end of the intervention period (after 3 months) and after 12 months, a blinded research assistant performed the balance measurements and the physical examination and registered the Falls Efficacy Scale with the participants at the research center. All other questionnaires were self-administered. After 6 months, only the mailed questionnaires were sent to the participants.

Statistical Analysis

Baseline characteristics are reported as means and standard deviations for continuous variables and as numbers and percentages for categorical data. The primary outcome was dichotomized as fallen or not fallen (not fallen included nearly fallen). The Andersen-Gill model (also referred to as a standard and a semiparametric Poisson model) was used to calculate the hazard ratio (HR) comparing fall rates between the two groups during 12-month follow-up. This models the hazard of falls in terms of the intervention group and relevant covariates. The robust (sandwich type) standard error was used to account for dependency between multiple falls by the same person. When using the standard Poisson model, the influence of periods was taken into account (4 periods of 3 months). Age, sex, fell in the year preceding the study, and mean balance score at baseline were redefined as relevant covariates, according to the identified risk factors in literature. Variables with a clinically relevant difference (10%) at baseline were also regarded as relevant covariates. A subgroup analysis was

performed based on fall incidents in the year preceding the study (yes/no).

Secondary outcome measures were analyzed using the Mann-Whitney or Student *t*-test depending on the distribution of the variable. Missing values were replaced as described in the instrument validation studies or with multiple imputation techniques.[28] Participants who missed more than 20% of the lessons were defined as nonadherers.

Analyses were performed according to the intention-to-treat principle. If dropout was higher than 15% or the average adherence was lower than 80% an additional per-protocol analysis for the primary outcome was performed. This analysis was restricted to the participants who adhered sufficiently to the intervention protocol and outcome measurements. $P = .05$ was considered significant, and all hypotheses were tested as two-tailed. Analyses were performed with SPSS (SPSS, Inc., Chicago, IL) and SAS System for Windows (SAS Institute, Inc., Cary, NC). Multiple imputation was performed using Mice (http://web.inter.nl.net/users/S.van.Buuren/mi/hmtl/mice.htm) implemented in R (http://cran.r-project.org/). The allocation of participants was disclosed at the end of the initial analyses.

RESULTS

Participants

A pool of 5,931 patient files was screened from the database of the 23 participating GPs; 138 participants were allocated to the intervention group and 131 to the control group (Figure 1).

Baseline Characteristics

The two groups were comparable at baseline (Table 1); mean age was 77, and 71% was female. Sixty-two percent of the participants had experienced a fall incident in the previous year. Only "living alone" reached a clinically relevant difference at baseline.

Adherence and Dropout

Of the 138 Tai Chi Chuan participants, 25 withdrew before the first lesson, and 65 (47%) attended at least 21 lessons (80% of the lessons). The main reasons for nonadherence were health problems (31%), various other reasons such as partner's health problems or transportation problems (34%), and a combination of factors such as inconvenient

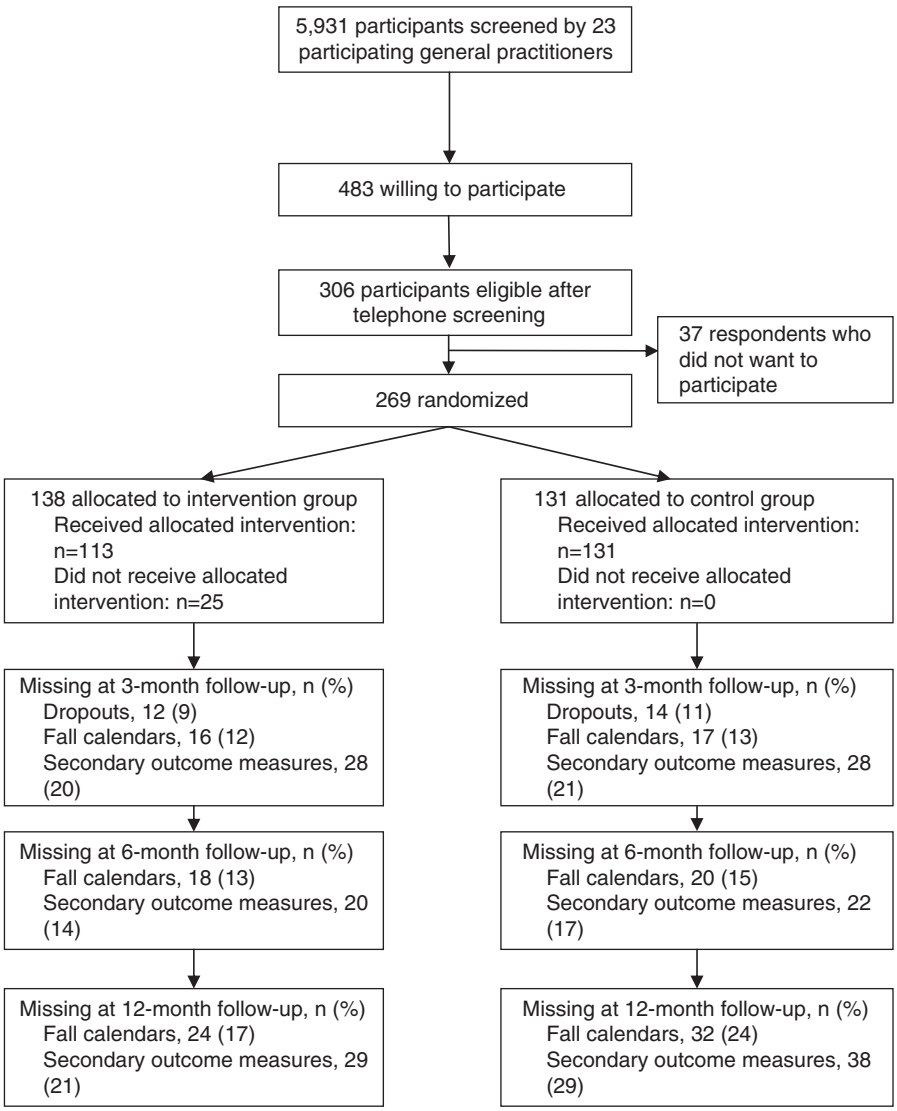

Figure 1. Flow of participants.

timing and motivational or health problems (35%). Eighty-five participants completed self-reported practice at home; 62 participants practiced twice a week or more, but only 18 practiced for 10 minutes or longer per session. There were 26 dropouts: 12 (9%) in the intervention group and 14 (11%) in the control group. Reasons for dropout in the intervention group were health problems of participant or spouse (n = 7), "not interested anymore" (n = 4), and death (n = 1). The main reason for dropout in the control group was "not interested anymore" (n = 11).

The intervention group filled out on average 332 fall calendar days (89%) and the control group 322 fall calendar days (86%) (Figure 1). The baseline characteristics of participants lost to follow-up were comparable with those of participants who completed the study.

Effects on Primary Outcome: Fall Incidents

During the 12-month follow-up, more falls occurred in the intervention group than in the control group (115 vs 90). In the intervention group, 58 of 138 (42%) participants fell, and in the control group, 59 of 131 (45%) fell. Over the 12 months, the number of falls per participant ranged from 0 to 6. The unadjusted hazard ratio (HR; using the standard Poisson model and taking four periods into account) was 1.16 (95% confidence interval (CI) = 0.86–1.56). When comparing the Tai Chi group with the control group using the semi-parametric Poisson model, an unadjusted HR of 1.17 (95% CI = 0.84–1.63) was found. After correction for age, sex, living alone, fell in the year preceding the study (yes/no), and mean balance score at baseline, the effect estimate hardly changed (adjusted HR 1.16, 95% CI = 0.84–1.60).

In the additional per-protocol analysis, the intervention again showed no positive effect on the primary outcome compared with controls (adjusted HR = 1.08, 95% CI = 0.72–1.63).

Subgroup Analysis

In the year preceding the study, 167 participants fell (Table 1). In this predefined subgroup, more falls occurred (during the 12-month follow-up) in the Tai Chi Chuan group (95 falls) than in the controls (59 falls), but the difference was not significant (adjusted HR = 1.38, 95% CI = 0.98–1.95). In the Tai Chi Chuan group, 44 of 88 (50%) participants fell, and in the control group, 40 of 79 (51%) participants fell.

Effects on Secondary Outcome Measures

No significant intervention effects were found on the secondary outcome measures (Table 2). There were no significant differences between groups in mean scores on balance (Berg Balance Scale), fear of falling (Falls Efficacy Scale), physical activities (Physical Activity Scale for the Elderly), or functional status (Groningen Activity Restriction Scale) and no differences in blood pressure and heart rate.

Table 1. Baseline Characteristics

Characteristic	Tai Chi Chuan (n = 138)	Control (n = 131)
Age in years, mean ± SD (range)	77.5 ± 4.7 (69–90)	76.8 ± 4.6 (70–93)
Female sex, n (%)	96 (69.6)	95 (72.5)
Previous falls, n (%)	88 (63.8)	79 (60.3)
Number of falls, median (range)	2 (1–11)	2 (1–10)
Medication use (yes), n (%)	136 (98.6)	129 (98.5)
Living alone, n (%)	75 (54.3)	58 (44.3)
≥High school education, n (%)	93 (71.0)	93 (65.5)
Place of birth Netherlands (yes), n (%)	126 (96.2)	126 (91.3)
Visual problems, n (%)		
Difficulty reading	48 (34.0)	42 (32.3)
General visual problems	27 (19.6)	26 (19.8)
Use of walking aids, n (%)	52 (37.4)	42 (32.5)
Alcohol use, n (%)	79 (57.2)	77(58.8)
Glasses weekly, mean ± SD	7.0 ± 6.8	6.3 ± 7.1
Use of healthcare services, n (%)		
General practitioner	82 (59.4)	77 (58.8)
Specialist	53 (38.4)	58 (44.3)
Physiotherapist	25 (18.1)	26 (19.8)
Home care or district nurse	64 (46.4)	58 (44.3)
Comorbidity, n (%)		
Chronic obstructive pulmonary disease	19 (14.2)	13 (10.0)
Cardiological problems	14 (10.5)	10 (7.7)
Diabetes mellitus	30 (22.4)	25 (19.2)
Arthritis	62 (46.2)	51 (39.2)
Cancer	9 (6.7)	6 (4.6)
None	18 (13.4)	20 (15.4)
Berg Balance Scale score, mean ± SD (range 0–56)	51.8 ± 4.3	51.2 ± 5.0
Falls Efficacy Scale score, mean ± SD (range 0–30)	6.0 ± 5.0	5.7 ± 5.0
Blood pressure (systolic/diastolic), mean ± SD	156.1/ 85.3 ± 24.6/ 11.2	158.1/ 86.8 ± 21.4/ 11.5
Heart rate at rest, mean ± SD	71.0 ± 11.4	70.6 ± 12.7
Physical Activity Scale for the Elderly score, mean ± SD (range 0–356)*	74.8 ± 47.3	73.2 ± 40.6
Groningen Activity Restriction Scale score, mean ± SD (range 18–72)	25.2 ± 7.0	24.6 ± 7.5

*Higher score means more physical activity.
SD = standard deviation.

DISCUSSION

In this study, fall risk was no lower in the Tai Chi Chuan group than in the control group receiving usual care. Moreover, no support was found for the hypothesis that Tai Chi Chuan would improve balance, physical activity and functional status and reduce blood pressure, heart rate at rest, and fear of falling in elderly people living at home.

This European study is the sixth trial to include a direct measure of the number of fall incidents. Of the five earlier studies, two found no beneficial effect of Tai Chi Chuan in fall reduction,[13,22] whereas three reported significant fall reduction.[12,14,21] The two studies that found no beneficial effects used a narrow definition of "fall" (e.g., injurious falls)[13] or included an older, less-healthy population.[22]

The current study used the same (Yang) style and positions as one of the trials that found a beneficial effect,[12] but fewer positions (10 vs 24) than one of the others.[14] The frequency and duration of the intervention in the current

Table 2. Intervention Effects on Secondary Outcome Measurements

Variable	Tai Chi Chuan	Control	*P*-Value
	Mean ± Standard Deviation		
Berg Balance Scale score			
0 months	51.8 (4.3)	51.2 (5.0)	.45*
3 months	51.9 (4.0)	51.4 (4.4)	.30*
12 months	50.4 (5.1)	50.2 (5.1)	.90*
Falls Efficacy Scale score			
0 months	6.0 (5.0)	5.7 (5.0)	.47*
3 months	4.9 (4.4)	5.8 (5.3)	.38*
12 months	5.2 (4.8)	5.7 (4.7)	1.00*
Physical Activity Scale for the Elderly score			
0 months	74.8 (47.3)	73.2 (40.6)	.81*
3 months	76.3 (49.0)	69.7 (42.4)	.28*
6 months	72.9 (51.0)	72.3 (48.8)	.95*
12 months	67.9 (37.2)	72.7 (43.5)	.59*
Groningen Activity Restriction Scale score			
0 months	25.2 (7.0)	24.6 (7.5)	.27*
3 months	24.7 (6.8)	25.0 (7.8)	.97*
6 months	26.3 (8.8)	25.8 (8.1)	1.00*
12 months	25.8 (7.9)	26.1 (8.7)	.99*
Systolic blood pressure			
0 months	156.1 (24.6)	158.1 (21.4)	.48†
3 months	149.7 (21.5)	149.6 (19.8)	.96†
12 months	148.3 (21.6)	148.2 (23.3)	.97†
Diastolic blood pressure			
0 months	85.3 (11.2)	86.8 (11.5)	.28†
3 months	83.0 (10.1)	83.6 (9.9)	.67†
12 months	82.0 (10.7)	83.1 (11.1)	.48†
Heart rate at rest			
0 months	71.0 (11.4)	70.6 (12.7)	.82†
3 months	68.5 (11.1)	69.4 (11.9)	.61†
12 months	68.3 (10.0)	67.8 (13.3)	.77†

* Mann-Whitney test.
† Student *t* test.

study was comparable with that of one of the previous trials[12] (45 minutes, 2 times/wk, for 15 weeks) but less than that of another[14] (1 hour, 3 times/wk, for 26 weeks). The third trial that found a beneficial effect[21] used different styles; only 3% of those participants followed the Yang style (1 hour, 1 time/wk, for 16 weeks). These differences in intervention do not fully explain the differences in results.

There are several underlying constructs related to the supposed beneficial effect of Tai Chi on fall reduction. The most plausible explanation lies in balance improvement, but in the group in the current study, no significant or clinically relevant balance improvement was achieved. This absence of balance improvement might explain the lack of beneficial effects in fall reduction. The mean balance scores never reached the critical single cutoff point of 45 on the Berg Balance Scale,[25] indicating that the subjects had minor balance problems and little fall risk based on disturbed balance.

Similarly, fear of falling was not significantly better than for controls. Reduced fear of falling has been suggested to partly explain the positive results in fall reduction,[12,29] but these latter findings were based on only 52 patients. The current sample size was much larger and showed a low fear of falling at baseline, indicating that no large improvements could be obtained.

STRENGTH AND LIMITATIONS

This is the first Tai Chi Chuan trial to study the effect of Tai Chi Chuan on fall prevention in western Europe, which means that these results must be interpreted within this context. The participants were recruited in two small to medium-sized industrial towns (45,000 and 118,000 inhabitants) near Rotterdam. The threshold for participation was lowered as much as possible by keeping participant costs (and investment in time and travel) as small as possible. This resulted in a low dropout rate and acceptably low loss to follow-up. The general population will probably have more barriers to start and continue Tai Chi training. Neither insufficient power[23] nor unexpected positive results in fall reduction in the control group could explain the absence of favorable results of Tai Chi Chuan in fall reduction.

Although the participants did not have a higher fall risk because of disturbed balance,[25] they had greater fall risk based on other relevant risk factors. During the study period, because the percentages of fallers in the total population was higher than indicated in the literature (60% vs 30%), it was assumed that a population with high risk of falling was selected.[1–3] Risk factors for falls in this population will be investigated in further analyses, and the limitations involved with self-reported identification of risk factors for falling, for example, will be discussed.

Two minor adjustments were made regarding the study protocol. First, there were technical problems with the spirometers, leading to uncertainty about the validity and accuracy of the FEV_1 and PEF values. Therefore, it was decided not to use these outcome measures. Second, a cost-effectiveness calculation on account of the results was not performed. Nevertheless, it was felt that these adjustments did not influence the validity of the study.

CONCLUSION

In this randomized clinical trial, no beneficial effects of Tai Chi Chuan on reducing fall incidents in elderly people living at home with a high risk of falling could be demonstrated. The lack of balance improvement could in part be responsible for these results. Also, the characteristics of the study population (minor balance problems and low fear of falling) could be responsible for the absence of fall reduction. Further analysis on secondary outcome measures will provide more insight into the effects of Tai Chi Chuan on physical and psychological functioning in this population. These results suggest that Tai Chi Chuan may not be effective in elderly people with high fall risk who live at home.

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