Falls in older people and the effects of Tai Chi

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Falls in Older People and the Effects of Tai Chi

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1

General introduction

De kunst van de ouderdom

Vallen en opstaan, dat is mijn leven.
Ach, was ik maar weer jong ik zal er alles voor geven.
Elke dag buiten in de frisse lucht. Ik denk eraan en slaak een zucht.
De telefoon gaat wie zou het zijn? Ik neem op en hoor een stemmetje zo fijn.
Dag oma, ik mis je hoor.
Glimlachend luister ik naar de stem, die klinkt in mijn oor.
Wat zat ik nou te klagen. Wat was dat dom.
Ik glimlach en leg de hoorn neer.
Dat is de kunst van de ouderdom.

Verena de Lange

GENERAL INTRODUCTION

"You can't help getting older, but you don't have to get old."
(George Burns, aged 100).

This one-liner might show the picture of "getting old" as undesirable and negative but also amenable. Worldwide, one of the major health concerns in older people is falling. For people aged 65 years and older, falls are the cause of conditions that reduce mobility, independence and therefore quality of life. In 2000, the estimated costs of falls ranged from almost one billion pounds in the UK to 19.2 billion dollars in the USA.[1,2]

Nowadays, falling is no longer regarded as a common, inevitable adverse consequence of aging but classified as one of the geriatric syndromes. The concept of a geriatric syndrome is not clearly defined yet, but all geriatric syndromes (e.g. falls, incontinence, frailty) have the same clinical conditions in common: high prevalence, multiple underlying factors and an association with substantial morbidity and poor outcome.[3] Moreover, falling is increasingly regarded as a marker or sign of an underlying health problem amenable to treatment. In community-living older people, extensive research has shown that fall prevention strategies including exercises can be effective.[4-8] However, some multifactorial interventions that were proven effective were not (cost-) effective in the Netherlands.[9,10] Due to the variability among older community-living persons and in the aetiology of falls more research is needed to develop and implement (cost-) effective strategies in fall prevention.

This thesis addresses several aspects regarding the effectiveness of Tai Chi - traditional Chinese exercises - in fall prevention and discusses various options concerning the prediction of falls. In this general introduction we describe the incidence and consequences of falls, risk factors and predictors for falls, Tai Chi and the aims and outline of this thesis.

INCIDENCE AND CONSEQUENCES OF FALLS

In the Netherlands, the proportion of people aged 65 years and older increased from 13.5% in 2000 to 15.3% in 2010 and is expected to rise to 25.6% in the next three decades. As both the number of older person's increases and life expectancy at birth is increasing it is to be expected that health concerns related to older populations will increase and challenge our health care system.

In developed countries, each year approximately 30% of community-living persons aged 65 years and older experiences a fall.[6,11-14] Of these falls, 55-70% results in physi-

cal injury of which 20% requires medical attention.[6,12,15] The most serious fall related injuries are fractures, which occur in 5% of the falls.[15-17] Of the fall-related injuries, fractures account for the majority of costs, morbidity and mortality.[1,2,18] The insight in negative consequences due to fall related minor injuries like bruises, contusions and wounds is less well registered. Often, minor injuries are not reported and no medical attention is needed or sought.[19-21]

Although most falls do not result in serious injuries, they may have severe consequences for the independence and quality of life of the faller. A fall can lead to functional decline,[11,22-27] restriction in activities[11,15,28-30] and fear of falling.[11,13,23,25,31,32] Given the individual burden of both injurious and non-injurious falls and the societal costs, prevention of falls is desirable.

RISK FACTORS AND PREDICTORS FOR FALLS

Since the late eighties, multiple epidemiologic studies have investigated risk factors for falling and over 400 potential risk factors were identified.[33] Although no agreed classification has been used, risk factors are generally categorised as intrinsic and extrinsic.[14,34]

Intrinsic risk factors are individual specific include for example age, sex, a history of falls, general health and functioning, visual impairments, living situation, disturbed balance, decreased muscular strength, mobility problems and dizziness.[12-15,34-43] Extrinsic factors generally include medication use (e.g. sedative use), environmental hazards (e.g. loose carpets, foot wear, snow and ice) and hazardous activities (e.g. climbing on chairs).[13,34,37,38,41] Sometimes, behaviours, activities and medication use are regarded as intrinsic risk factors.[14,38] A complex interaction between these intrinsic and extrinsic risk factors might result in falls.

Mostly, risk factors for falls are identified by single factor studies or explanatory risk factors studies wherein correction for different potential confounders is made and causal relationships between risk factors and outcome are explored.[34,44] Recently, a meta-analysis investigated risk factors for falls among community-dwelling older people and identified six (out of 31) risk factors as most strongly associated with falls: history of falls, gait problems, walking aids use, vertigo, Parkinson disease and antiepileptic drug use. The pooled odds ratios for these risk factors ranged from 1.8 to 3.5. However, for most risk factors the odds ratios were moderately above 1 and for some risk factors (e.g. balance, footwear and environmental hazards) no pooled odds ratios could be calculated because of heterogeneity.[34] Thus, meaning only a few strong risk factors for falls are identified. Risk factors are defined and measured in various ways and/or investigated in heterogeneous populations.

FALL RISK ASSESSMENT

Fall prevention preferably aims at identifying people with high fall risk (i.c. case-finding) and tailors the fall preventive strategy for a specific person. Due to the multifactorial origin of falling, the variability in community-living older persons and interactions between fall risk factors, the risk of independent risk factors cannot simple be summed up. To assess the absolute risk of an individual risk prediction models are needed. Risk prediction models estimate the probability that a fall will occur in a person using combinations of predictor values. Unlike risk factors, predictors do not necessarily have a causal relationship with the outcome measure (i.c. falls). Preferably, internal and external validation must be performed before the prognostic model is to be used in clinical practice.[45,46] Nowadays, several models for identifying community-living older people with (high) fall risk have been developed but few risk prediction models are validated in primary care.[47-54]

Because of the multifactorial origin of falling, individual tailoring fall preventive strategies to persons with high fall risk has to be preceded by a comprehensive assessment including history taking, physical examination, functional assessment and environmental assessment (e.g. home visits). Preferably, this assessment is performed by trained professionals in specific settings (for example fall clinics).[55-57] The case-finding process could be performed by different health care providers in primary care. Given the strict time constraints in a primary care consult, the risk prediction model used for case-finding needs to include easily and quickly measurable predictors, without the need for specialised equipment.

FALL PREVENTIVE STRATEGIES

In the development of appropriate targeted fall preventive strategies a distinction between primary and secondary prevention has to be made. Primary prevention concerns prevention of falls in those who did not fell earlier (non-fallers), while secondary prevention concerns prevention of falls in those who have fallen before (fallers). Furthermore, fallers can be divided in single fallers and recurrent fallers. Mostly, recurrent falling is defined as two or more falls in a specific period (e.g. a half year) whereas falling is defined broader including both recurrent and single falls. Recurrent fallers may be more in need of preventive measures as recurrent falls usually are caused by physical, cognitive and behavioural factors within the person. Single falls are more often coincidental and more difficult to prevent.[33] Research has indicated that single fallers and recurrent fallers are two distinct groups, but risk factors based on fall status

(single or recurrent) are less well studied compared to risk factors based on fall history in general.[55]

TAI CHI AND FALL PREVENTION

Tai Chi, also referred to as Tai Chi Chuan, Taiji or Taijiquan is a traditional Chinese exercise that has been practiced for many centuries. Tai Chi originally is a martial art but nowadays taught and practised as an integral part of the Traditional Chinese Medicine and more often practised as a healing art.[58] Besides principles of health and longevity Tai Chi commonly integrates meditative and spiritual principles and Taoist philosophy.[59] Tai Chi is also an evolving art and since the 13th -century it has been devised and modified by martial artists who created their own style.[60] Within Tai Chi there are various styles for example the Sun style, the Chen style, the Wu style and the Yang style. Although external movements appear to be different within the different styles the principles are the same. At the heart of Tai Chi is a sequence of movements (positions) known as the "Form" and energy exercises called chi kung (Qi Gong). The Form is performed in a graceful and flowing manner. Chi kung consists of static and moving exercises to gather balance and direct energy.[61] The Tai Chi positions operate on three basic principles. First, the body should be extended and relaxed. Second, the mind must be alert and calm. Last, all body movements require well-coordinated sequencing of segments.[62] Therefore, Tai Chi incorporates harmony (balance and synchrony of breathing and movement) with slow movements originating from the spine in supreme focus and concentration.

Reviews, meta-analyses and guidelines report exercise training including balance training are likely to be beneficial to prevent falls.[4-8,63-66] One of the most promising exercise interventions is Tai Chi and since the first published English paper that presented an experimental study on Tai Chi in the 1980s the body of evidence regarding the effectiveness of Tai Chi has grown substantially.[67] Although the merits of Tai Chi as fall prevention intervention remain inconclusive[4,6,8,67-77] numerous other beneficial effects of Tai Chi are reported besides fall risk reduction and balance improvement. These include reduced blood pressure,[74] enhanced muscle strength and endurance, improved flexibility, improved cardio respiratory fitness[78] and maintained bone mineral density in postmenopausal women.[79] Reported effects on psychological functioning are increase in 'self-awareness of balance' and thereby decrease of fear of falling[32,80-83] improved self-perceived physical health in the areas of ambulation and self-care,[84,85] and enhanced mental well-being.[78,86] Until recently, the existing body of evidence on the effects of Tai Chi on fall prevention in community-living older people was gathered outside Europe, mainly in the United States of America.

AIMS AND OUTLINE OF THIS THESIS

The main objective of this thesis is to explore the effectiveness of Tai Chi in the prevention of falling in community-living older persons in The Netherlands and to explore various options concerning the prediction of falls in primary care.

In Chapter 2, the results of a randomised clinical trial evaluating the effectiveness of a Tai Chi intervention are described. The Tai Chi intervention was based on an successful American intervention wherein the fall rate of Tai Chi participants was highly effectively reduced by 47.5 % compared to an educational control group after a 15-week Tai Chi program.[87] To gain more insight in process related factors that could explain the results of the Dutch intervention Chapter 3 describes the process evaluation that was carried out alongside the trial. In Chapter 4, the international evidence regarding the effects of Tai Chi on falls, balance and fear of falling is summarised in a meta-analysis. In the Chapters 5 and 6 two different studies related to the prediction of falls are described. Chapter 5 reports on the relationship between circumstances of falls and fall related injuries and explores the development of a predictive model for falls related to minor soft tissue injuries in community-living older people. Chapter 6 reports on an external validation study of a simple risk prediction model for recurrent falling in older people in primary care. Chapter 7 is the general discussion and reflects on the main findings presented in this thesis.

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2

Lack of effect of Tai Chi Chuan in preventing falls in elderly people living at home: a randomised clinical trial

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ABSTRACT

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

Design. Randomised, controlled trial.

Setting. Two industrial towns in the western part of the Netherlands.

Participants. Two hundred sixty-nine elderly people (average age 77 years) 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 ratio1.16; 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.

INTRODUCTION

Falls are a common problem among older people. Approximately 30% of community-dwelling elderly aged 65 years 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 are 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; 55-70% of fall incidents result in physical injury[1,5] and 5% to 6% in serious physical injuries (such as hip fractures).[5] Other consequences of falls are increased fear of falling[3], decline in functional status and physical activities, and increased 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 accent has become 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 on fall prevention is inconclusive. Three trials reported significantly reduced 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 effectiveness of Tai Chi Chuan on fall prevention in elderly people living at home with a high risk of falling. It was hypothesised 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 randomised, 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 or the use of benzodiazepines or diuretics.

Eligible persons 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 persons were subsequently screened for eligibility using a short telephone survey. An independent research assistant performed a pre-stratified block randomisation using a computer-generated randomisation list.[23] Strata were based on gender 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 utilisation. 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 (FICSIT Trials), these positions appeared successful in preventing falls.[12] Chi Kung exercises were used during the warming-up and cool-down periods.The group size ranged from seven to 14 persons. The instructors asked participants to practise 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 one year. The response options were 'fallen', 'nearly fallen' and not 'fallen'. A fall was defined as *"an 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 (BBS) to measure balance[25], the Falls Efficacy Scale (FES) for fear of falling[26], the Physical Activity Scale for the Elderly (PASE) for physical activities[27] and the Groningen Activity Restriction Scale (GARS) 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 standardised 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 FES with the participants at the research centre. 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 dichotomised 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, gender, 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 analysed with 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 non-compliers.

Analyses were performed according to the intention-to-treat principle. If dropout was higher than 15% and/or the average compliance was lower than 80% an additional per-protocol analysis for the primary outcome was performed. This analysis was restricted to the participants who complied sufficiently with the intervention protocol and outcome measurements. $P = .05$ was considered significant, and all hypotheses were tested as two-tailed. Analyses were performed with SPSS and SAS System for Windows. Multiple imputation was done using Mice implemented in R. The allocation of participants was disclosed at the end of the initial analyses.

RESULTS

Participants

A pool of 5931 patient files was screened from the database of the 23 participating GPs; finally, 138 participants were allocated to the intervention group and 131 to the control group (see 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.

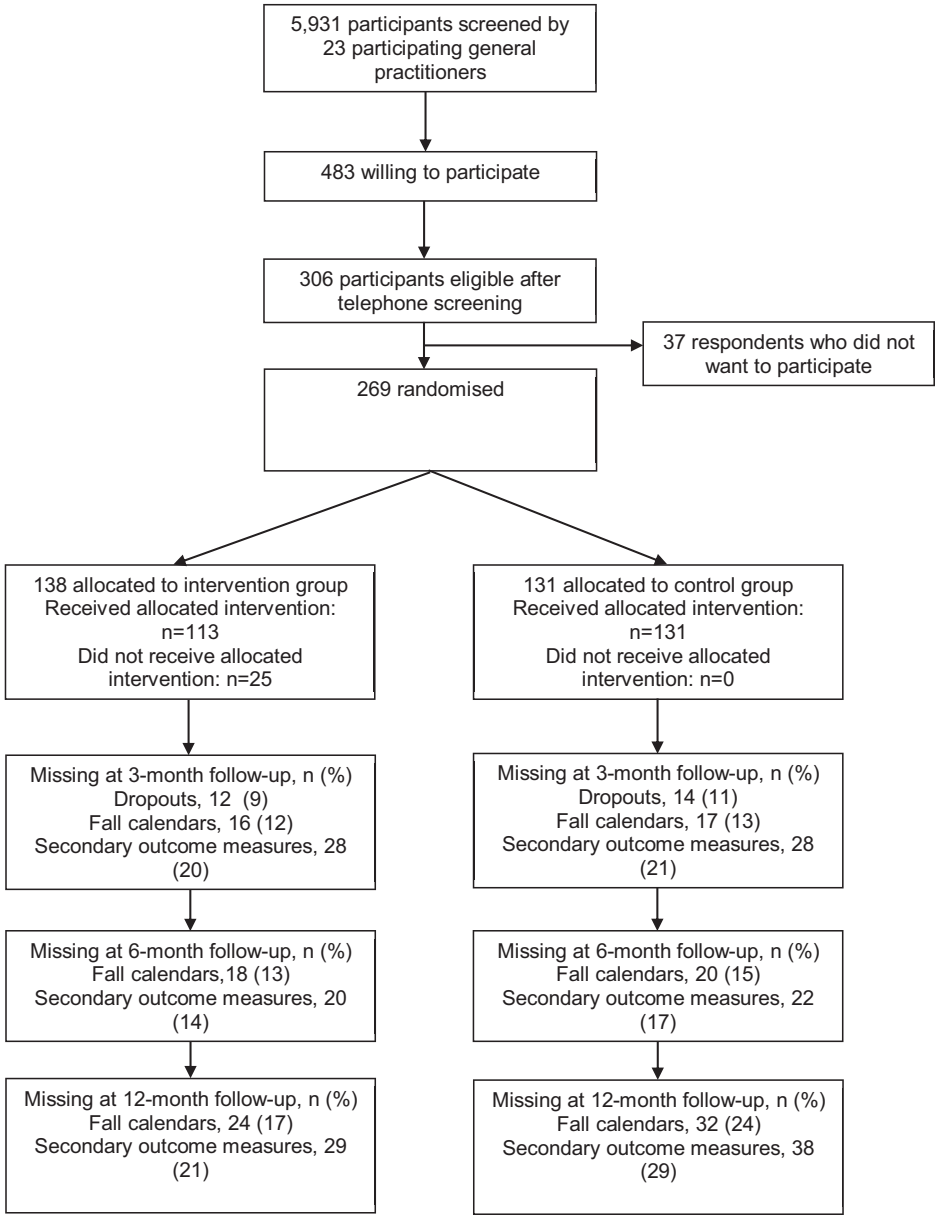

Figure 1 Flow of participants

Compliance and dropout

Of the 138 Tai Chi Chuan participants, 25 withdrew before the first lesson, and 65 (47%) attended at least 21 lessons (i.e. 80% of the lessons). The main reasons for non-compliance were health problems (31%), various other reasons such as partner's

Table 1 Baseline Characteristics

Variable	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 (yes), n (%)	75 (54,3)	58 (44,3)
High school education or higher, n (%)	93 (71,0)	93 (65,5)
Ethnicity: place of birth Netherlands (yes), n (%)	126 (96,2)	126 (91,3)
Visual problems		
Difficulty reading, n (%)	48 (34,0)	42 (32,3)
General visual problems, n (%)	27 (19,6)	26 (19,8)
Use of walking aids, n (%)	52 (37,4)	42 (32,5)
Alcohol use (yes), n (%)	79 (57,2)	77(58,8)
Glasses weekly, mean (SD)	7,0 (6,8)	6,3 (7,1)
Use of healthcare services		
General practitioner	82 (59,4)	77 (58,8)
Specialist	53 (38,4)	58 (44,3)
Physiotherapist	25 (18,1)	26 (19,8)
Home care/district nurse	64 (46,4)	58 (44,3)
Co-morbidity		
COPD, n (%)	19 (14,2)	13 (10,0)
Cardiological problems, n (%)	14 (10,5)	10 (7,7)
Diabetes, n (%)	30 (22,4)	25 (19,2)
Arthritis, n (%)	62 (46,2)	51 (39,2)
Cancer, n (%)	9 (6,7)	6 (4,6)
None, n (%)	18 (13,4)	20 (15,4)
Balance: BBS (0-56), mean (SD)	52 (4,3)	51 (5,0)
Fear of falling: FES (0-30), mean (SD)	6 (5,0)	6 (5,0)
Blood pressure (systolic/diastolic), mean (SD)	156/85 (25/11)	158/87 (21/12)
Heart rate at rest, mean (SD)	71 (11)	71 (13)
Physical activity: PASE (0-356)†, mean (SD)	75 (47,3)	73 (40,6)
Functional status: GARS (18-72), mean (SD)	25 (7,0)	25 (7,5)

† range in this population: a higher score means more physical activity.

health problems or transportation problems (34%), and a combination of factors such as inconvenient timing, and motivational or health problems (35%). Self-reported practise at home was completed by 85 participants; 52 participants practised twice a week or more, but only 18 participants practised 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 one person died. 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%) (see 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 semiparametric Poisson model, an unadjusted HR of 1.17 (95% CI = 0.84-1.63) was found. After correction for age, gender, 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 (BBS), fear of falling (FES), physical activities (PASE) or functional status (GARS), and no differences in blood pressure and heart rate.

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 our hypotheses 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.

Table 2 Intervention effects on secondary outcome measurements

Variable	Tai Chi Chuan	Control	p-value
Balance: BBS, mean (SD)			
0 months	51,8 (4,3)	51,2 (5,0)	0,45†
3 months	51,9 (4,0)	51,4 (4,4)	0,30†
12 months	50,4 (5,1)	50,2 (5,1)	0,90†
Fear of falling: FES, mean (SD)			
0 months	6,0 (5,0)	5,7 (5,0)	0,47†
3 months	4,9 (4,4)	5,8 (5,3)	0,38†
12 months	5,2 (4,8)	5,7 (4,7)	1,00†
Physical activity: PASE, mean (SD)			
0 months	74,8 47,3)	73,2 (40,6)	0,81†
3 months	76,3 (49,0)	69,7 (42,4)	0,28†
6 months	72,9 (51,0)	72,3 (48,8)	0,95†
12 months	67,9 (37,2)	72,7 (43,5)	0,59†
Functional status: GARS, mean (SD)			
0 months	25,2 (7,0)	24,6 (7,5)	0,27†
3 months	24,7 (6,8)	25,0 (7,8)	0,97†
6 months	26,3 (8,8)	25,8 (8,1)	1,00†
12 months	25,8 (7,9)	26,1 (8,7)	0,99†
Blood pressure: mean systolic (SD)			
0 months	156,1(24,6)	158,1 (21,4)	0,48‡
3 months	149,7(21,5)	149,6 (19,8)	0,96‡
12 months	148,3 (21,6)	148,2 (23,3)	0,97‡
Blood pressure: mean diastolic (SD)			
0 months	85,3 (11,2)	86,8 (11,5)	0,28‡
3 months	83,0 (10,1)	83,6 (9,9)	0,67‡
12 months	82,0 (10,7)	83,1 (11,1)	0,48‡
Heart rate at rest: mean (SD)			
0 months	71,0 (11,4)	70,6 (12,7)	0,82‡
3 months	68,5 (11,1)	69,4 (11,9)	0,61‡
12 months	68,3 (10,0)	67,8 (13,3)	0,77‡

† = p-value Mann-Whitney test ‡ = p-value Student's t-test

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, and 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 study was comparable with that of one of the previous trials[12] (45 minutes, 2 times/wk., for 15 weeks) but less than one 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 their 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 cut-off point of 45 on the BBS, [25] indicating that the participants 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 favourable 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 increased fall risk based on other relevant risk factors. During the study period, because the percentages of fallers in the total population is 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 future 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 randomised 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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3

Explaining the ineffectiveness of a Tai Chi fall prevention training for community-living older people: A process evaluation alongside a randomised clinical trial (RCT)

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ABSTRACT

The results of a randomised clinical trial on the effects of a Tai Chi fall prevention program in community-living older people with a high risk of falling in the Netherlands showed no beneficial effects on falls and secondary outcomes (e.g. balance, fear of falling). The aim of this study is to provide insight in process-related factors that may have influenced the effectiveness of the intervention. The intervention consisted of Tai Chi Chuan (TCC) training for 1 hour twice a week for 13 weeks. We used self-administered questionnaires and registration forms to collect data from participants and instructors. We analysed quantitative data by means of descriptive statistics and categorized qualitative data based on the content of the answers given. Of the participants that started the programme 89 (79%) completed the intervention, but a minority of 47 % attended 80% of more of the lessons. All participants and instructors were positive about the programme and most participants reported benefits from the intervention. Suggestions for improvements mainly relate to adjustments of training aspects. The main process-related factors that may be have influenced the lack of beneficial effects on falls and secondary outcomes are the relatively high withdrawal and the low adherence rates.

INTRODUCTION

Falls remain an important threat to the health and independence of many older people despite extensive preventive efforts. Approximately one third of community dwelling older people of 65 years and over fall at least once each year. Up to 70% of the fall incidents result in physical injury[1-3] of which five percent is serious (e.g. hip fractures).[1,4] Besides these physical injuries, falls may have other negative consequences in terms of increased fear of falling, functional decline and increased use of health services.[5-7]

Tai Chi is an exercise intervention with promising effects on fall prevention in both American and Australian studies.[8-10] Because the generalizability of effects of Tai Chi across culture and patient characteristics is not evident we conducted a randomised clinical trial (RCT) in the Netherlands wherein we evaluated a Tai Chi intervention (based on a successful American intervention) in older community-living people with a high fall risk.[8,11] The results of our trial showed no beneficial effects of Tai Chi on falls and secondary outcomes: balance, fear of falling, physical activity, functional status and biological variables (e.g. blood pressure).[11]

In this paper we present and discuss the results of the process evaluation we carried out alongside the trial. The aim of this process evaluation is to provide insight in process-related factors that may have influenced the effectiveness of the Tai Chi intervention by assessing: 1) to what extent the intervention was performed according protocol; 2) participants' attendance and self-reported adherence; and 3) participants' and instructors' opinions of the intervention.

METHODS

Study design and population

This process evaluation was performed alongside a RCT on the effectiveness of a Tai Chi intervention and had a cross-sectional design. The study population consisted of 138 community-living older people with high fall risk allocated to the Tai Chi intervention group and four professional Tai Chi instructors experienced in teaching Tai Chi in older people. 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 or the use of benzodiazepines or diuretics. The general practitioner invited patients of 70 years and older with high fall risk by mail, and patients were subsequently screened for eligibility and asked if they preferred to be enrolled in a specific group (allocation preference) using a short telephone survey.[12]

Intervention

The intervention consisted of 1 hour Tai Chi Chuan (TCC) training twice a week for 13 weeks. Four professional Tai Chi instructors experienced in working with older people gave the lessons using a predefined protocol. Each lesson consisted of 20 minutes warming-up, 30 minutes TCC and 10 minutes cooling down. Chi Kung exercises were used with emphasis on relaxation and contemplation of breath during warming-up and cooling down.[13] The TCC form during the heart of the lessons is derived from the Yang style and consisted of a form with ten positions: 1. Opening; 2 Grasping the Sparrow's tail, Left; 3. Grasping the Sparrow's tail, Right; 4. Cloud hands; 5. Repulse Monkey; 6. Part Wild Horse's Mane; 7. Brush Knee Twist Step; 8. Lift Kick Left; 9. Lift Kick Right; 10. Closing. In the intervention of Wolf et al. (1996) these positions appeared successful to prevent falls.[8] The forms were linked together in a continuous, smooth-flowing sequence. The instructors asked the participants to practice the learned TCC positions at home at least twice a week for about fifteen minutes per session. We organised the lessons at a location close to where the older people lived and refunded travel costs. Between February 2004 and July 2005, 11 groups of seven to 14 older persons received the TCC training provided by the four instructors.

Data collection

During the short telephone survey we registered if participants preferred to be enrolled in a specific group (allocation preference). Then we assessed the following aspects of the intervention process: 1) the extent to which the Tai Chi intervention was performed according protocol as reported by the instructors, 2) participants' attendance and adherence and 3) participants' and instructors' opinions of the intervention including self-reported effects of the intervention. Table 1 presents an overview of the measurements and timing of the measurements. We collected data from participants by means of self-administered questionnaires and short telephone interviews. All participants filled out a questionnaire covering general information (e.g. sociodemographic factors, medication) at baseline and participants that completed the intervention (i.e. persons who had not withdrawn during the 26 training lessons) received a questionnaire covering process-related factors directly after the last TCC training. To avoid social desirable answers we asked the participants to administer the latter questionnaire at home and assured that the data was handled strictly confidential. An independent researcher contacted participants who withdrew from the intervention by phone immediately after withdrawal. Instructors filled out an attendance list per session and a questionnaire after the last TCC training of each group.

Table 1 Outcome measures and instruments of the process evaluation

Variables	During Intervention	After last Tai Chi training
Performance intervention according to protocol		
Deviations from protocol		Q^I
Participants attendance		
Number of training sessions visited by each participant	A^I	
Reason for stopping before/ during intervention	T	
Participants adherence		
Effort during tai chi training sessions		Q^I
Adherence to home practice		Q^P/ Q^I
Opinion about intervention		
Overall opinion of the intervention (mark)		Q^P/ Q^I or T
Quantity and Quality intervention		Q^P/ Q^I or T
Opinion of the instructors		Q^P/ Q^I or T
Experienced benefits		Q^P/ Q^I
Suggestions for improvement		Q^P/ Q^I

Q^I = Questionnaire instructor; A^I= Attendance list filled out by instructor; T= Telephone interview; Q^P = Questionnaire participant

Data analysis

We analysed quantitative data by means of descriptive statistics and used chi square statistics to evaluate if self-reported benefits by participants differed according to allocation preference (preference for TCC training/no preference). Qualitative data were categorised based on the content of the answers given. We defined protocol deviations as deviations from protocol during 20% or more of the lessons; additional exercises during warming-up or cooling down were considered as minor deviations and changes in TCC forms as major. Participants that attended 80% or more of the lessons were considered as adherent.[12] The institutional medical ethics review committee approved the study.

RESULTS

Participants

Of the 138 participants allocated to the intervention group, 89 persons completed the programme and received an evaluation questionnaire after the last TCC training (Figure 1). Only one questionnaire was not returned resulting in a response rate of 99% (n= 88). All 49 participants that withdrew (before or during the intervention) participated in the telephone interview. Table 2 shows the characteristics of the 89 participants that completed the intervention and the 49 participants who did not complete the intervention. The mean age of the participants was 77.5 years and more than half was female, lived alone and reported balance problems, mobility problems and a fall incident in the previous year.

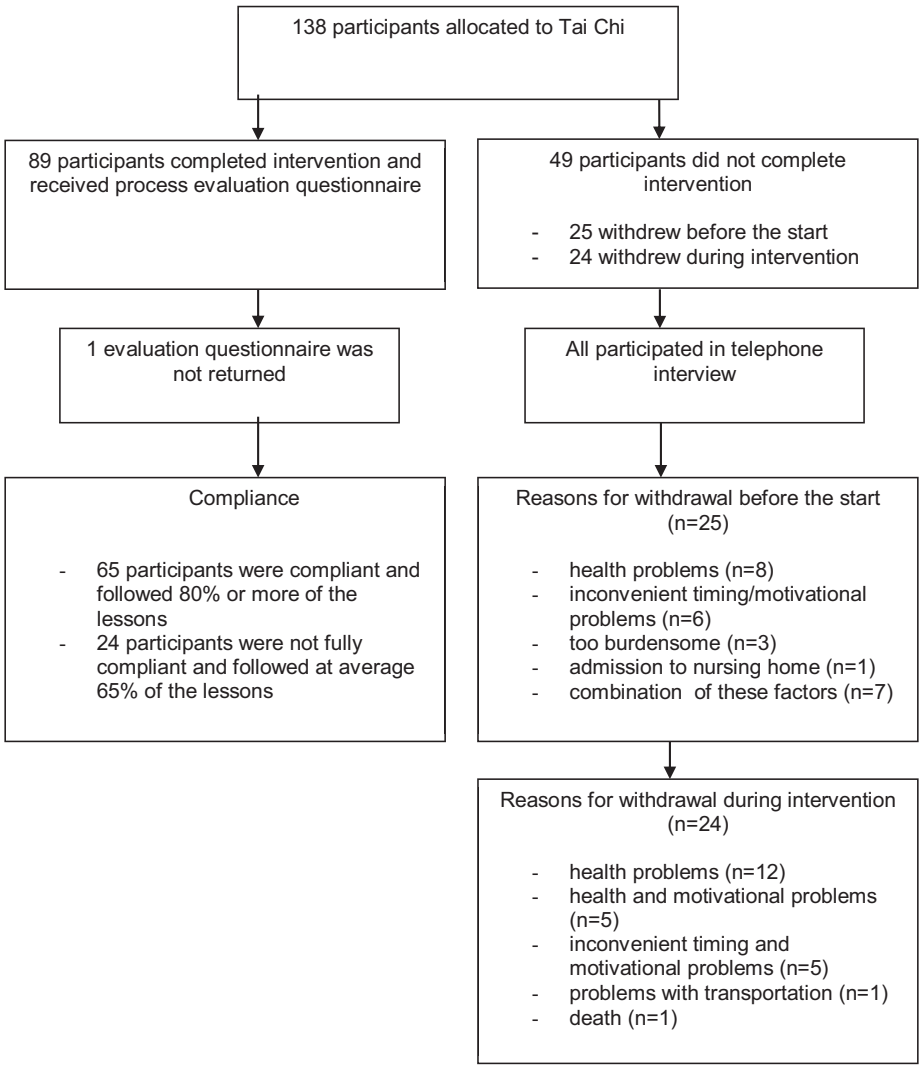

Figure 1 Flow of participants

Performance of Tai Chi intervention according to protocol

The four instructors filled out attendance lists for all 286 training sessions (11 groups x 26 sessions) and a questionnaire at the end of the TCC training per group (n=11). They reported for four out of eleven groups' protocol deviations. For three of the groups the adjustments to the protocol involved additional exercises to the 10 Tai Chi positions (e.g. knee massage and other breath control exercises) during warming-up and/or cooling down. For one group there was need for an extra break of 10 minutes, as the participants could not stand one hour successively. All protocol deviations were considered as minor.

Table 2 Baseline characteristics of participants

General baseline characteristics	Participants who completed intervention (N=89)	Participants who withdrew before intervention (N=25)	Participants who withdrew during intervention (N=24)
Mean age (standard deviation)	76.9 (4.5)	78.9 (5.5)	78.1 (4.2)
Gender (% female)	64 (71.9)	17 (68)	15 (62.5)
Previous falls, n (%) Number of falls in the past year, median (range)	57 (64) 1 (11)	16 (64) 1 (6)	15 (62.5) 1 (4)
Living alone (yes), n (%)	48 (53.9)	11 (44)	16 (66.7)
Use of health care services in the previous year (yes), n (%)			
General practitioner	52 (58.4)	15 (60)	15 (62.5)
Specialist	31 (34.8)	13 (52)	9 (37.5)
Physiotherapist	18 (20.2)	3 (12)	4 (16.7)
Home care/district nurse	41 (46.1)	13 (52)	10 (41.7)
Co-morbidity			
COPD, n (%)	13 (14.9)	3 (13)	3 (12.5)
Cardio logical problems, n (%)	19 (21.8)	1 (4.5)	6 (25)
Diabetes, n (%)	18 (20.7)	6 (26.1)	6 (25)
Arthritis, n (%)	4 (4.6)	0 (0)	2 (3.8)
Cancer, n (%)	6 (6.9)	1 (4)	2 (3.8)
None, n (%)	15 (17.2)	1 (4)	2 (3.8)
Use of walking aids (yes), n (%)	30 (33.7)	12 (48)	9 (37.5)
Use of benzodiazepines or diuretics (yes), n (%)	29 (32.6) or 23 (25.8)	7 (28) or 9 (36)	7 (29.2) or 8 (33.3)
Self-reported balance problems (yes), n (%)	47 (52.8)	13 (52)	16 (66.7)
Self-reported mobility problems (yes), n (%)	42 (47.2)	14 (56)	14 (58.3)
Self-reported dizziness (yes), n (%)	35 (39.3)	11 (44)	10 (41.7)
Balance: BBS (0-56), mean (SD)	52.2 (3.7)	50 (6.1)	52.2 (3.7)
Fear of falling: FES (0-30), mean (SD)	6.2 (5.2)	5.9 (4.7)	5.6 (4.5)
Blood pressure (systolic/diastolic), mean (SD)	154.2 (24.9)/ 84.6 (10.8)	158.0 (24.6)/ 84.5 (11.8)	161.2 (23.3)/ 89.0 (12.1)
Heart rate at rest, mean (SD)	71.5 (11.7)	72.7 (10.5)	67 (11.0)
Physical activity: PASE (0-356)†, mean (SD)	80.8 (49.2)	63.5 (36.8)	64.3 (45.6)
Functional status: GARS (18-72), mean (SD)	25.1 (7.2)	25.4 (6.7)	25.5 (7.1)
Which group do you prefer?, n (%)			
Tai Chi	62 (72.9)	11 (47.8)	11 (45.8)
Control	16 (18.8)	9 (39.1)	9 (37.5)
No preference	7 (8.2)	3 (13.0)	4 (16.7)

† = range in this population: a higher score means more physical activity.

Participants' attendance and adherence

A total of 89 participants (64%) completed the course of which 65 persons (47%) attended at least 21 of 26 lessons (80%) and 24 persons (17%) attended less than 21 lessons (on average 17 lessons, 65%) (Figure 1). A total of 25 participants (18%) withdrew before the first lesson. Reasons for withdrawal before the first lesson were health problems of the participant or spouse (n=8, 32%), inconvenient timing

or motivational problems (n=6, 24%), too burdensome (n=3, 12%), admission to nursing home (n=1, 4%) or a combination of these factors (n=7, 28%). During the intervention another 24 participants (17%) withdrew after attending at average 7 lessons. Reasons for withdrawal during the intervention were mostly related to health problems (n=12, 50%) or a combination of factors such as health and motivational problems (n=5, 21%) or inconvenient timing and motivational problems (n= 5, 21%), one participant had problems with transportation and one person died (8%) (Figure 1). In the questionnaire for participants that completed the intervention (n=88) the adherence to homework exercises was evaluated. Nearly all these participants (97%) reported to have practised Tai Chi at home; 52 participants (59%) practised twice a week or more but mostly less than 10 minutes per session. The instructors were also asked to judge the adherence to homework for each group. According to the instructors, in nine groups 50% or more of the participants practised at home.

Participants' and instructors' opinion of the intervention

Participants' opinion of the intervention

We asked the participants to rate the TCC training on a Likert scale ranging from 1 (most negative) to 10 (most positive) to get an overall opinion. The participants that completed the intervention gave a mean score of 8.3 (range 6-10; n=85), indicating that the participants were overall very positive about the intervention. The participants that withdrew during the intervention scored somewhat lower (mean score 7.4, range 5-10, n=23), which also indicated that they were overall positive about the intervention. Next we asked the participants that completed the intervention whether they 'agreed' or 'disagreed' with a range of topics related to the exercises during the TCC training. Most participants enjoyed the exercises (93%) and thought they were useful (91%). However, 45% of the participants considered the exercises difficult. Finally, we asked several questions regarding the dosage of the TCC training (on a 3-point Likert scale). Most participants experienced the intensity of the TCC training as sufficiently high (82%); 14% experienced it as too high and 4% as too light and a large majority experienced the frequency (twice a week) and duration of a single session (1 hour) as sufficient (77% and 82% respectively). Two thirds of the participants found the total number of sessions sufficient (65%) and 28% assessed the number of sessions as too low. Sixty percent of the participants expressed the intention to continue the Tai Chi training when possible.

Overall, the participants were very positive about the instructors; 98% considered their instructor to be good or very good (n= 87), 2% considered their instructor to be sufficient. The participants that withdrew during the intervention were only slightly less positive about their instructors (87% = good or very good and 13 % = sufficient).

Benefits reported by participants

We asked the participants that completed the intervention if they felt they had benefited from the TCC training regarding 12 different aspects (Table 3). The proportion of participants who felt they had benefited from the intervention ranged from 34% on the behavioural aspect 'avoidance of activities' to 78% on the psychosocial aspect 'I feel better'. Participants in the subgroup of those preferring TCC training scored statistical significantly better on self- reported benefits 'I feel better', 'I became more physically active' and 'My balance improved' compared to those not preferring TCC training (Pearson χ^2 = 10.031, 10.240, 6. 804; p = .007, .006 and .033 respectively).

Table 3 Benefits reported by participants and instructors

	Participants (N=86)*	Instructors (N=4; 11 groups)#
Because of participating in the TCC training	Number (%)	Number (%)
I feel better	66 (78)	7 (78)
I became more physically active	63 (74)	8 (89)
My balance improved	63 (74)	8 (80)
I behave more safely	59 (69)	4 (50)
My self-confidence has increased	58 (68)	7 (78)
My flexibility improved	57 (70)	8 (80)
I am less concerned to fall	55 (64)	4 (50)
My risk of falling is reduced	52 (62)	5 (56)
My walking pattern gained in stability	52 (66)	5 (63)
My muscle strength improved	44 (54)	7 (78)
I became more social active	39 (47)	7 (64)
I avoid fewer activities	29 (34)	2 (29)

* Due to missing values the number of responses varied from 79 to 86 per question

Due to missing values the number of responses varied from 7 to 11 groups. Instructors indicated per group whether the majority of the participants benefited from the Tai Chi training.

TCC = Tai Chi Chuan

Instructors' opinion of the intervention

We also asked the four instructors to give an overall opinion of the TCC training. Their mean score was slightly lower compared to the participants score: 7.9 (range 7-9, n=10 groups). The instructors qualified the overall dedication of the participants to the TCC training in the different groups as good (n=4) to very good (n=7). The instructors also had a favourable opinion of their own role, which was also qualified as good (n=3) to very good (n=1).

Benefits reported by instructors

The instructors reported on the same 12 aspects (concerning gained benefits) of the TCC training as the participants themselves (Table 3). One instructor did not answer most questions for the two groups she trained. In general the instructors were more

optimistic than participants about the gained benefits. They regarded the influence of the TCC training on physical aspects as 'increased physical activity', 'improved balance' and 'improved flexibility' as most positively in eight groups. Moreover they regarded the influence on 'muscle strength improvement' much higher but 'more safely behaviour' much lower compared to the participants. Like the participants, the instructors were less optimistic about the benefits in avoidance of activities.

Positive and less positive aspects and suggestions for improvement

We asked the instructors and participants to report positive and less positive aspects of the TCC training. All four instructors mentioned sessions ran well and they were explicitly positive regarding the motivation of the participants. They also mentioned the positive aspects of group training regarding group cohesion (n=3).

Among participants that completed the intervention most positively described aspects were benefits of TCC training (e.g. balance improvement, relaxation) (n=26), instructors role (n=29), 'everything' (n=15), exercise construction (n=12) and positive group interactions (n=7). Among participants that withdrew during the intervention the most frequently mentioned positive aspects were instructors role (n=11) and positive group interactions (n=10).

The less positive aspect mentioned most frequently by instructors was the absence of participants during the group sessions (n=3). Most participants that completed the intervention could not mention any less positive aspect (n=29) or had no opinion (n=15). Less positive aspects most frequently mentioned were training aspects (e.g. dose too high, too difficult to remember positions, movements are too easy or too slow) (n= 22) and aspects concerning location and time (e.g. accommodation too noisy, training too early in afternoon) (n=10). Half of the participants that withdrew could not mention any less positive aspects (n=10).

Most mentioned suggestions for improvements by instructors were more lessons and possibilities to tailor the training individually to the capabilities of the participants. Most participants that completed the intervention mentioned no improvements could be made or had no suggestions (n= 55). The most frequently suggested improvements were adjustments in dose (higher or lower dose) (n=11) and the use of supportive material (e.g. music, mirrors, video or description of the positions) during group and/or home practice (n=9). The participants that did not complete the intervention were not asked to mention improvements.

DISCUSSION

The aim of this study was to provide insight in process-related factors that may explain the lack of effect of a Tai Chi Chuan fall prevention training in Dutch older people in the Netherlands with a high fall risk.[11] Instructors reported no major protocol deviations. Twenty- five participants never started the training, mainly due to health problems, inconvenient timing and motivational problems. Of the 113 participants who did start, 89 (79%) completed the intervention. A minority of 65 out of 138 (47%) participants (who were considered to be adherent) attended at least 21 of 26 lessons (80%) of the lessons. According to self-report most participants (n=85) were adherent to their homework, but less than a third (n=25, 28%) practised at home twice a week for 10 minutes or longer per session, as recommended. All participants and instructors were positive about the programme and most participants reported benefits in various areas from the intervention. The most frequently mentioned suggestions for improvements concerned adjustments in dose and the possibilities to tailor the intervention individually to one's capabilities.

The main process related factors that may be responsible for lack of favourable effects of the intervention on falls and secondary outcomes are relatively high withdrawal and low adherence rates. In the positive fall prevention trial of Wolf et al. (1996) six Tai Chi participants (8%) withdrew during the intervention, but no data about adherence to the exercises were reported or a process evaluation was made. In our study 49 (36%) participants withdrew before or during the intervention. In total a minority of 47% of our participants were considered adherent. In two other positive fall prevention trials more participants were considered adherent. In one trial 59% followed 80% of the lessons[10] and in the other 80% (instead of our 72%) followed 64% of the lessons.[9] The higher number of withdrawal and lower adherence rate in our study may be explained by participant's characteristics. We included participants with high fall risk which was partly based on health related problems (e.g. reduced mobility, disturbed balance, medication use).[11] The three other positive trials selected overall more healthy participants.[8-10] As health problems were one of the main reasons for withdrawal, it seems plausible that our participants were more likely to withdraw because of pre-existing health problems.

Our results on self-reported benefits are in line with the earlier mentioned positive trial of Wolf et al. (1996) who reported most participants benefited from the Tai Chi intervention.[14] In our study allocation preference for TCC training positively influenced self-reported benefits by participants regarding well-being, physical activity level and balance improvement. However these benefits were not reflected in mean change scores on secondary outcomes.[11] This may indicate scales were not sensitive enough or

positive expectations and enthusiasm regarding TCC training influenced self-reported benefits.

A possible limitation of the study is the probability of socially desirable answers given by participants and instructors. To avoid this, questionnaires were filled out at home, a researcher blinded to the results made the telephone interviews and we assured confidentiality. A strong aspect of this study is that it is the first study to report on process-related intervention factors alongside a RCT evaluating the effects of Tai Chi on falls. Another strength of the study is that we were able to study the effect of allocation preference on self-reported outcome measures.

Recommendations

We recommend major adjustments to the programme in order to optimise theoretically the treatment effects. First, measures should be taken to increase the adherence to and reduce the withdrawal rate from the programme. The adherence might improve by individually tailoring the intervention to the capabilities of the participant. Second, dose could be adjusted individually. Yet, latter might not be feasible and will probably influence group cohesion negatively. Third, the use of supportive material for both lessons and homework might improve adherence by making it easier for participants to learn and remember the exercises. Finally, selection of a healthier population could decrease withdrawal (because one of the main reasons for withdrawal were health problems) but in that way the aim of the intervention (to prevent falls in older people with a high fall risk) will change and hence is no real solution for the high withdrawal.

Also we recommend screening possible participants of the intervention more objectively for balance deficits and only offering the intervention to participants if balance disturbance is indeed present. Although the results of this process evaluation showed self-reported balance improvements, these self-reported improvements were not reflected in mean scores of the validated Berg Balance Scale (which was used in this trial) and did not result in lower fall risk. Participants with more balance problems might theoretically benefit more.[11] The uptake of the intervention would benefit from additional measures. The Prevention of Falls Network Europe (ProFaNE) made some recommendations for promoting the engagement of older people in activities to prevent falls.[15] One could raise the awareness that active training of balance and strengths can prevent falls and explicit give the information that this fall prevention training programme does not involve unwanted activity restriction. Moreover, it could increase self-efficacy and is a proactive way of self-management of one's health. One could mention that most participants in an earlier study on the effects of Tai Chi reported benefits of the interventions. When health professionals as general practitioners, physiotherapists and nurses would carry out this information it will make

the message even stronger. Finally, we recommend assessing the effectiveness and feasibility of the adjusted programme before implementing it in regular care.

CONCLUSIONS

Based on the results of this process evaluation and the clinical outcomes of the trial we do not recommend implementation of this Tai Chi Chuan programme for Dutch community-living older people with a high fall risk, in regular care with the aim to prevent falls.

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4

The Effects of Tai Chi on Fall Prevention, Fear of Falling and Balance in Older People: A Meta-analysis

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ABSTRACT

Objective. Tai Chi (TC) is an exercise training that is becoming increasingly popular as a single intervention for fall prevention. This meta-analysis was performed to evaluate the efficacy of TC on fall rate, fear of falling and balance in older people.

Methods. Randomised controlled trials published between 1988 and January 2009 were included. In the Netherlands (2009) we used random effects models for the analyses, with data reported as incidence rate ratios (IRR) for falls and standardised mean differences (SMD) for fear of falling and balance.

Results. Nine trials (representing 2,203 participants) were included in the analyses. Compared with exercise controls, TC participants showed significant improvements in fall rates (2 trials included, IRR: 0.51, 95% CI 0.38-0.68) and static balance (2 trials included, SMD: 0.47, 95% CI 0.23-0.72). Compared with non-exercise controls, no improvement was found for TC participants in fall rates (5 trials, IRR: 0.79, 95% CI 0.60-1.03) or static balance (2 trials, SMD: 0.30, 95% CI -0.50-1.10), but a significant improvement was found for fear of falling (SMD:0.37, 95% CI= 0.03-0.70).

Conclusions. Currently there is insufficient evidence to conclude whether TC is effective in fall prevention, decreasing fear of falling and improving balance in people over age 50 years.

INTRODUCTION

Each year approximately 30% of community-living persons aged 65 years and older experiences a fall. Of these falls, 55-70% result in physical injury of which 20% require medical attention.[1-3] Estimated costs of falls (for the year 2000) range from almost one billion pounds in the UK to 19.2 billion dollars in the USA.[4, 5] Given the individual burden of falls and the societal costs, prevention of falls is desirable.

Until now, the merits of Tai Chi (TC) as a fall prevention intervention are promising but remain inconclusive.[1,6-18] The integrated physical and cognitive components in TC could represent the additional value of TC compared with other exercise programs which mainly focus on physical aspects only. Besides the improvement of balance, TC might increase 'self-awareness of balance' and thereby decrease the fear of falling.[19-23]

Based on the type of TC, exercise dose, intervention duration and the study population, the effects of TC might vary. If TC is to be used as a community-based fall prevention intervention, insight is needed into the effectiveness of TC with regard to different populations, optimal exercise dose and effect maintenance.

This meta-analysis assesses the effectiveness of TC as a single intervention on fall rate, fear of falling and balance in healthy older people, to provide insight into the effectiveness of TC regarding setting, intervention dose and duration of follow-up.

METHODS

Search strategy

A broad literature search on TC interventions was made covering Medline, Cinahl, Psychlit and the Cochrane Database for Systematic Reviews (CDSR) until January 31 2009. For all databases we used the highly sensitive search strategy for randomised clinical trials (RCTs) as suggested in the Cochrane Handbook. References in relevant reviews and identified RCTs were also screened.

Study selection

Studies were included when 1) the design was an RCT, 2) participants were aged 50 years or older, 3) the population comprised healthy participants, 4) one of the interventions was a form of TC, and 5) the article included one of the outcome measures of interest (falls, fear of falling, and/or balance). After selection based on title and abstract, the full-text articles were retrieved and two reviewers (AV and IL) independently performed study selection. Studies in English, French, German or Dutch were eligible. Study selection was based on consensus, otherwise a third reviewer (BK) solved any disagreements.

Risk of bias assessment

Two reviewers (MF and EvR) independently performed methodological assessment of the included trials using the Delphi criteria list (Table 1).[24] Differences in scores were resolved by consensus or in conjunction with a third party (IL). For one trial in the review, in which two of the current reviewers were both co-authors, two other reviewers performed the methodological assessment.[25]

All items have a 'yes'/'no'/'don't know' answer option. If bias was unlikely the criterion was rated positive ('yes'). In case information was lacking or insufficient the criterion was rated 'don't know', and if bias was likely to be negative ('no'). All 'yes' scores were summed to an overall risk of bias score, with higher scores indicating lower risk of bias. The cut-off point between high and low risk was set at 5 points, i.e. ≤ 4 points indicating a high risk of bias and ≥ 5 points indicating a low risk of bias.

Table 1 The Delphi list containing the methodological assessment criteria used for risk of bias assessment

	Delphi items
1	Was a method of randomisation performed?
2	Was the treatment allocation concealed?
3	Were the groups similar at baseline regarding the most important prognostic indicators?
4	Were the eligibility criteria specified?
5	Was the outcome assessor blinded?
6	Was the care provider blinded?
7	Was the patient blinded?
8	Were point estimates and measures of variability presented for the primary outcome measures?
9	Did the analysis include an intention-to-treat analysis?

Data extraction

Data on characteristics of the study population, the intervention and outcome measures, i.e. number of falls, estimates of fall rate ratio and mean values (± standard deviations; SD) of fear of falling and balance, were extracted using standardised forms. We refer to 'static balance' when balance was measured when the body has a constant (or static) basis of support and we refer to 'dynamic balance' when balance was measured during movement. One reviewer (IL) extracted the data; these data were subsequently checked by a second (reviewer AR). Wherever possible, authors of included articles were contacted to complete missing data.

Statistical Analysis

When we considered studies clinically homogeneous regarding intervention, the study population and outcome measures results were combined using random effect models. Where possible, longer follow-up times were used (e.g. 12 months rather than 6 months). The I^2 statistics were calculated, which describe the heterogeneity among

study results for each effect. Values of 30-60%, 50-90% and 75-100% represent moderate, substantial and considerable heterogeneity.[26]

TC versus non-exercise controls and versus exercise controls (e.g. low intensity, brisk walking) were compared separately.

For falls the estimates of incidence rate ratios (IRR) were calculated using data on the total number of falls, or the number of falls per person and exposure times. The Hedges' adjusted *g* effect sizes (ES) were calculated to evaluate the effects of TC on fear of falling and balance. An effect size of 0.2-0.5 was defined as small, 0.5-0.8 as medium and 0.8 and higher was defined as a large effect size.[27] The subgroups of interest were: setting (community dwelling, facility), intervention dose (< 40 sessions, ≥ 40 sessions) and duration of follow-up (post-treatment, follow-up). A greater relative effect of exercise on fall rates was seen in programs that included a higher dose (>50 hours); 40 sessions is roughly equivalent to 50-60 hours.[13]

The software package STATA (version 10.0) was used for the analyses (StataCorp, College Station, Texas, USA) together with Review Manager 5.0.

RESULTS

Search strategy

The search strategy resulted in 524 titles of potentially eligible studies. Based on title and abstract we selected 41 references of which full-text articles were obtained. One full-text article could not be retrieved.[28] Finally, 21 papers were included in this systematic review, representing 15 trials (Figure 1).[10, 11, 16, 21, 25, 29 - 44] The results of the Atlanta FICSIT trial were reported in three papers,[38-40] as were the results of another trial conducted by Wolf et al.[36,41,42] Li et al. conducted two different trials [10, 32] of which the results of one trial were reported in three papers.[10,11,21]

Risk of bias assessment

Disagreement mainly occurred because of reading errors and differences in interpretation. The agreement between the two authors was acceptable (kappa=0.69). After the consensus meeting no disagreements persisted.

The overall score ranged from 3 to 7 (median=6). Nine trials met our definition of low risk of bias (Table 2). In 7 trials the outcome assessor was blinded. None of the trials blinded the care provider or participant; in one trial these aspects remained unclear.

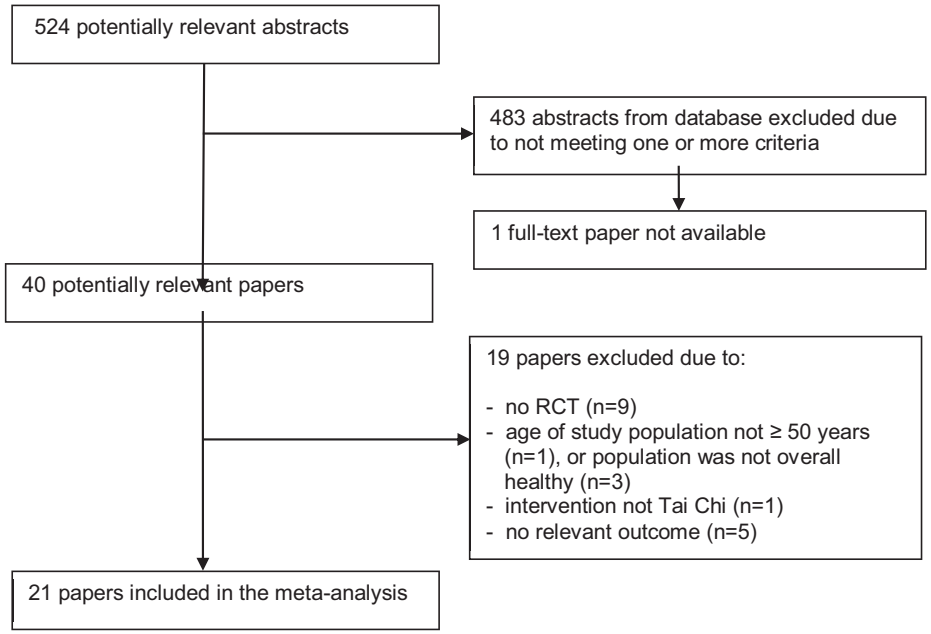

Figure 1 Overview of the search for relevant trials and papers

Table 2 Overview of risk of bias of the included studies scored with the Delphi list

Study	Randomisation	Treatment allocation concealed	Groups similar at baseline	Eligibility criteria specified	Outcome assessor blinded	Care provider blinded	Patient blinded	Point estimates and measures of variability presented for primary outcome	Intention to treat principle	Total score
1. Wolf 1996,1997,2003[38,39,40]	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**	No	No	**Yes**	*?*	**6**
2. Li 2004,2005,2005[11,21,32]	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**	No	No	**Yes**	**Yes**	**7**
3. Voukelatos 2007[16]	**Yes**	**Yes**	**Yes**	***Yes***	**Yes**	No	No	**Yes**	*?*	**6**
4. Woo 2007[43]	**Yes**	**Yes**	**Yes**	***Yes***	**Yes**	No	No	**Yes**	***Yes***	**7**
5. Logghe 2009[25]	**Yes**	**Yes**	**Yes**	**Yes**	*No*	No	No	**Yes**	**Yes**	**6**
6. Wolf 2003,2006[41,42]/ Sattin 2005[36]	**Yes**	?	**Yes**	**Yes**	***Yes***	*No*	*No*	**Yes**	***Yes***	**6**
7. Nowalk 2001[35]	**Yes**	?	**Yes**	*No*	*No*	No	*No*	No	**Yes**	3
8. Choi 2005[30]	***Yes***	*?*	*No*	**Yes**	No	No	No	**Yes**	*No*	3
9. Frey 2007[31]	**Yes**	?	**Yes**	***Yes***	?	No	No	**Yes**	*No*	4
10. Zhang 2006[44]	**Yes**	?	**Yes**	**Yes**	?	No	No	**Yes**	**Yes**	**5**
11. Audette 2006[29]	**Yes**	*?*	***Yes***	***Yes***	*?*	No	No	**Yes**	*?*	4
12. Wallsten 2006[37]	**Yes**	?	**Yes**	**Yes**	?	No	No	**Yes**	No	4
13. Nnodim 2006[34]	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**	No	No	No	***Yes***	**6**
14. Li 2004[10]	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**	No	No	**Yes**	**Yes**	**7**
15. Li 2008[33]	**Yes**	?	**Yes**	?	?	No	No	**Yes**	?	3

? = don't know ***In italics*** = after consensus

Study characteristics

The supplementary material presents the characteristics of the included trials. All papers were published between May 1996 and January 2009, and most trials were conducted in the USA (i.e. 10 of 21).

Study population

In total 2708 older people were included in the present review. Most of the participants were community living (71%, n=1927). The number of participants ranged from 8-353 per study group. The drop-out rates ranged from 2-55%.

Interventions

Three trials included two exercise groups and one (none-exercise) control group. Of the 12 two-arm trials, seven used a non-exercise control intervention and five used an exercise control group. In most trials the participants in the non-exercise control groups were advised to continue their current level of activity and not to practice TC. The dose of TC exercise programmes varied from 16 to 120 hours.

Outcome measures

Six trials explicitly reported on fall incidents[10,16,25,30,35,41] seven trials explicitly gathered data on balance[16,30,31,34,37,44] and four trials explicitly on fear of falling.[30,37,38,44] Most trials in community settings measured falls with fall calendars.[10,16,25,38] In facility setting, one trial used fall calendars,[41] one trial monitored weekly fall episodes and a third registered self-reported or witness-reported falls. Most trials assessed fear of falling with the Falls Efficacy Scale.[25,30,38,41,44] Eleven trials measured static balance with direct methods (e.g. force platform)[16,39,43] or indirect methods (e.g. single leg stance).[11,29,30,32-34,41,43,44] Six trials measured dynamic balance indirectly with quantifiable measures (e.g. Up and Go test)[11,16,31,34] or observational measures (e.g. Berg Balance Test).[25]

Effectiveness of TC versus non-exercise controls

Falls

Five studies were included in this meta-analysis.[16,25,38,41,43] The pooled estimate of the IRR was 0.79 (95% confidence interval (CI); 0.60-1.03) in favour of TC. There was a substantial level of heterogeneity (I^2 68.6%) (Figure 2). No changes in effects were found in the subgroup analyses according to setting, intervention dose and duration of follow up (Table 3).

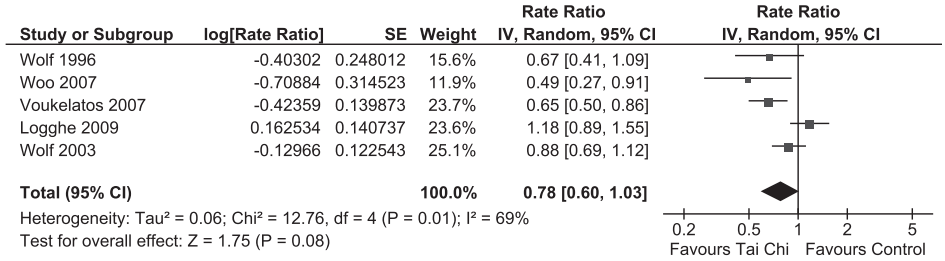

Figure 2 Forest plot Tai Chi versus non-exercise controls (IRR falls)

Fear of falling

This meta-analysis was performed with three studies.[25,41,44] A small but significant positive effect of TC was found for fear of falling (ES: 0.37 (95% CI; 0.03-0.70)). The effect became non-significant in all subgroups, except in the subgroup high intervention dose where the effect increased and remained significant (Table 3).

Table 3 Effect Tai Chi on falls, fear of falling and balance versus non-exercise controls. Overall results and results subgroup analyses

Outcome	**Analysis**	**Studies included**	**Effect: Pooled Incidence Rate Ratio (95% Confidence Interval)**
Falls	Overall result	Logghe[25], Voukelatos[16], Wolf(1996)[38],Wolf(2003)[41], Woo[43]	0.79 (0.60 - 1.03)
Subgroup analyses	Community setting	Logghe[25], Voukelatos[16], Wolf(1996)[38], Woo[43]	0.74 (0.50 - 1.09)
	High intervention dose > 40 sessions	Wolf(2003)[41], Woo[43]	0.71 (0.41 - 1.23)
	Low intervention dose < 40 sessions	Logghe[25], Voukelatos[16], Wolf(1996)[38]	0.81 (0.54 - 1.24)
	Post treatment	Logghe[25], Voukelatos[16]	0.81 (0.57 – 1.13)
Outcome	**Analysis**	**Studies included**	**Effect: Standardized differences in means (95% Confidence Interval)**
Fear of falling	Overall result	Logghe[25], Wolf(2003)[41],Zhang[44]	0.37 (0.03 – 0.70) †
Subgroup analyses	Community setting	Logghe[25], Zhang[44]	0.27 (-0.18 - 0.72)
	High intervention dose >40 sessions	Wolf(2003)[41], Zhang[44]	0.54 (0.29 -0.78) †
	Post treatment	Logghe[25], Zhang[44]	0.29 (-0.06 -0.65)
	Follow up (12 months)	Logghe[25], Wolf(2003)[44]	0.31 (-0.10 – 0.73)
Balance Direct measurement	Static Post treatment	Wolf(1997)[39], Voukelatos[16]	0.30 (-0.50 - 1.10)
Indirect measurement	Static Post treatment	Li(2008)[33], Zhang[44]	1.11 (-0.25 - 2.46)

† Significant result

Balance

Four studies could be included in our meta-analysis. Two studies provided post-treatment data with direct measurement methods[16,39] and two with indirect methods.[33,44] Non-significant effects of TC were found concerning static balance measured with both methods (Table 3).

The results of the trials on dynamic balance could not be pooled due to clinical heterogeneous outcome measures. Two studies found a statistically significant improvement[16,31] whereas another study found no effect in the TC group.[25] Therefore, the evidence for the effects of TC on dynamic balance is inconclusive.

Effectiveness of TC versus exercise controls

Falls

Our meta-analysis of two studies[10,43] showed a pooled estimate of the IRR of 0.51 (95% CI; 0.38-0.68) (Figure 3, Table 4).

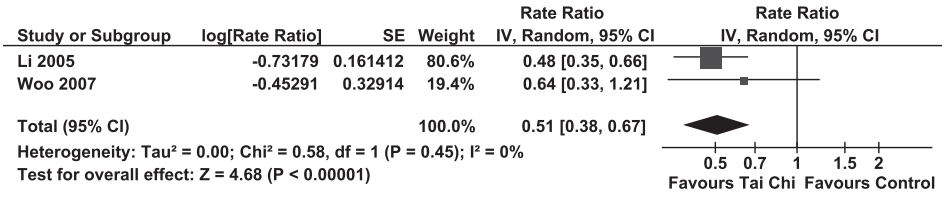

Figure 3 Forest plot Tai Chi versus exercise controls (IRR falls)

Fear of falling

One study measured fear of falling and the TC participants had significantly lower levels of fear of falling post-treatment; however this effect disappeared during follow-up.[10]

Table 4 Effect of Tai Chi on falls and balance versus exercise controls. Overall results

Outcome	Analysis	Studies included	Effect: Pooled Incidence Rate Ratio (95% Confidence Interval)
Falls	Overall result	Li(2005)[11], Woo(2007)[43]	0.51 (0.38-0.68) †
			Effect: Standardized differences in means (95% Confidence Interval)
Balance Indirect measurement	Static Post-treatment	Li (2004)[10], Li(2004)[32]	0.47 (0.23-0.72) †

† Significant result

Balance

Our meta-analysis of two studies[10,32] showed a small significant effect on static balance measured with Single Leg Stance (ES: 0.47, 95% CI; 0.23–0.72) (Table 4). The data of three studies that measured dynamic balance could not be pooled due to clinical heterogeneity of outcome and non-reported data. One study found a statistically significant improvement[11] and two studies found no effect.[31,34] The evidence for the effects of TC on dynamic balance is inconclusive.

DISCUSSION

Until now, no pooled estimates are available for the effects of TC alone on fall reduction. In the present study we found a non-significant overall fall reduction of 21% for TC compared to non-exercise controls. The amount of fall reduction is in line with earlier meta-analyses of exercise interventions on fall reduction, in which a significant 17% reduction in falls was found.[13,45] We also found a larger effect in a community setting and in exercise interventions using higher doses.[7,13]

Patient characteristics of community-dwelling elderly differed in aspects of activity level, fall risk and mean age, and the intervention characteristics varied in dose and TC styles. For example, the level of activity might be associated with the number of falls, and a higher level of physical activity might reduce the risk of recurrent falling.[46,47] All these aspects may have confounded the effects found in a community setting.

We expected to find no differences in effect between TC compared to exercise controls, because the difference between intervention and control groups is rather small. Nevertheless, we found a significant fall reduction of 49% in favour of TC. One explanation for this may be the nature of the intervention for the exercise controls. In one study this consisted of low- intensity exercise training without any strength or balance benefits, and in another study the intervention consisted of resistance training.[10,43] Given the more positive effects on fall reduction found in exercise interventions that challenge balance, it is plausible that the exercise control groups were comparable with placebo controls. Despite this, we cannot explain the large reduction in fall risk of TC versus exercise controls compared with TC versus non- exercise controls. The difference might suggest that exercise control interventions increased fall risk, which seems implausible. Another explanation might be a positive dose-effect relation. Studies evaluating TC versus exercises included only TC interventions with long term exercises, resulting in a higher dose compared to the dose in the studies on TC versus non-exercise controls. Finally, the unexpected result may have been occurred by chance, as only two studies were included in the comparison TC versus exercise-controls.

Although a fall reduction of 21% seems clinically relevant, it remains unclear whether a population-based implementation of a TC group intervention will be cost effective. Although TC is not an expensive fall prevention intervention, our results suggest that a higher dose of TC might be needed to be effective.

Our general findings regarding the positive effects of TC on fear of falling compared with non-exercise controls are in line with earlier reviews.[14,22] Also, positive effects become larger with higher intervention doses. However, the two studies that measured falls and fear and falling found positive effects on fear of falling but not on fall risk. The nature of the relationship between fear of falling and falls remains unclear. Due to limited number of studies we are unable to draw firm conclusions from our subgroup analysis.

No evidence was found for the effect of TC in improving balance compared with non-exercise controls under static conditions. These findings are in line with the Cochrane review of Howe et al. (2007) in which TC was part of an exercise program and no significant improvement in balance was observed. We found a small effect when TC was compared with exercise controls. This finding supports our earlier explanation for the unexpected results on fall reduction in the studies comparing TC with an exercise control group, which seems a good placebo control for balance. However, it seems unlikely that this small positive effect on static balance is responsible for the high fall reduction. In general, evidence for the effect of TC on balance remains unclear.

Strength and limitations

This is the first study in which data on the effects of TC on falls, fear of falling and balance were pooled and effect estimates provided. With additional subgroup analyses the present study also aimed to gain more insight into the effectiveness of TC with regard to different study populations, intervention characteristics and effect maintenance.

As in all systematic reviews, this study is potentially susceptible to bias. Publication bias was probably minimised by using a broad search strategy, but some language bias may exist. Reliability of the risk of bias assessment and data extraction was improved because two researchers performed procedures independently before consensus was obtained. Bias due to study design and quality was minimized by including only RCTs and giving an overview of the risk of bias assessment. In the present review, there was little possibility to study the influence of sources of heterogeneity due to the small number of studies. Furthermore, not all studies provided sufficient information about important study characteristics, which hampered subgroup analysis. We believe these analyses are needed, because the effectiveness of TC might change when using a different intervention dose and/or dose duration and/or another control group. Finally,

due to small number of included studies and the diversity in outcome measures used we could not investigate the relationships between falls, fear of falling and balance directly in meta-regressions.

CONCLUSIONS

Currently, there is insufficient evidence to conclude whether TC is effective in fall prevention, decreasing fear of falling and improving balance in people over age 50 years. However, the presence of a positive dose-effect relation in TC is highly likely. Further research should focus on the role of patient characteristics (e.g. living setting, activity level), intervention dose and effect maintenance on the measured outcomes.

Acknowledgments

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A

Supplementary data

APPENDIX A

For the included studies: Number and general characteristics of participants, information on the interventions, follow-up times, outcome measures, number of drop-outs, loss to follow-up, adherence and results regarding falls, fear of falling and balance

First author, year and country of publication	**Characteristics of participants. N randomized**	**Intervention[a] Follow-up[b]**	**Outcome (measure)[c]**	**Drop-outs[d] Loss to follow-up[e] Adherence**	**Results [f, g] Falls: IRR, Log rate ratio (SE) Unadjusted estimate of fall rate ratio (95% CI) Fear of falling and Balance: Standardised mean difference (95% CI)**
Wolf1996[38] + Wolf (reprint) 2003[40] USA	Community living, Healthy Mean age 76 yr. N=200	**TC:** 10 forms derived from 108 forms Yang style, twice weekly for 45 min + twice 15 min home training; n=72. **EC: Balance training** on balance platform, weekly for 45 min; n=64. **C: Education** Discussion control group, weekly for 60 min; n=64. **Follow-up:** Post-treatment =15 weeks/4 months Follow-up=20 months	***Falls*** (fall calendars), biomedical variables functional variables psychosocial well-being ***Fear of falling*** (Modified FES)	**Drop-outs:** n=13 (6.5%): 6 in TC, 4 in EC, 3 in C. **Loss to follow-up: Falls** (8months) n=7 (13%) **Fear of falling** n=35 (18%):12 in TC, 13 in EC, 10 in C. **Adherence:** NR	**Falls** (defined using Atlanta sub definition): 0.67, -0.40 (0.25)[f] **HR multiple falls** 0.67 (0.41-1.09)[g] **Fear of falling** No mean FES scores reported
Wolf1997[39]	Subgroup: Less active (compared with Wolf '96) Mean age 77 yr. N=72	TC: n=24; EC: n=24; C: n=24.	**Balance**: postural control (Chattecx Balance system)	**Loss to follow-up:** n=18 (25%): 5 in TC, 8 in EC, 5 in C.	**Static Balance/Post-treatment** Direct measurement 0.77 (0.11-1.44)[f]

First author, year and country of publication	Characteristics of participants. N randomized	Intervention[a] Follow-up[b]	Outcome (measure)[c]	Drop-outs[d] Loss to follow-up[e] Adherence	Results [f, g] Falls: IRR, Log rate ratio (SE) Unadjusted estimate of fall rate ratio (95% CI) Fear of falling and Balance: Standardised mean difference (95% CI)
Li 2004[32] Li 2005[21] Li 2005[11] USA	Community living, Healthy, inactive. Mean age 78 yr. N=256	**TC:** 24 forms Yang-style, 3 times a week, 60 min; n=125. **EC: Stretching Control**; low intensity exercise program (without strength and balance training benefits), 3 times a week, 60 min; n=131. **Follow-up:** Post treatment= 26 weeks /6 months Follow-up= 12 months	***Falls*** (fall calendar), ***Fear of falling*** (SAFFE, Falls self-efficacy (modified ABC scale)), **Balance**; functional (BBS, DGI, FR, SLS, Up & Go) physical performance e.g. 50 feet speed walk.	**Drop–outs:** n=81 (32%): 34 in TC, 47 in EC. **Loss to follow-up:** Long term: n=68 (27%): 30 in TC, 38 in EC. **Adherence:** median both groups:78%. range TC 39-99% range EC 45-100%	**Falls** 0.48, -0.74 (0.28)[f] **HR falls** 0.48 (0.28-0.83)[g] **Fear of falling / Post-treatment** TC significantly better than EC [g] **Follow-up** No significant difference between groups [g] **Static Balance/Post-treatment** Indirect measurement 0.57 (0.32- 0.82)[f] **Dynamic Balance/ Post-treatment and follow-up** TC significantly better than EC[g]

Voukelatos 2007[16] Australia	Community living, Healthy, Mean age 69 yr. N=702	**TC:** 83% Sun style, 3% Yang style, 14% mixture of styles, once weekly for 1 hour; n=353. **C: Instruction not to practice TC**; n=349. **Follow-up:** Post treatment**=** 16 weeks Follow-up= 24 weeks	***Falls*** (daily fall calendar) **Balance** (6 balance tests: Sway on floor, Sway on mat, Leaning balance, Lateral stability, Coordinated stability, Choice stepping reaction time)	**Drop-outs:** n=18 (3%): 6 in TC, 12 in C. **Loss to follow-up:** **Falls** Follow-up: n= 18 (3%) 6 in TC, 12 in C. **Balance** Post treatment: n=157 (22%) 76 in TC, 81 in C. **Adherence:** Average TC: 71% (59% attended 81% of the lessons)	**Falls**: 0.65, -0.42 (0.14)[f] **HR falls** 0.67 (0.49-0.93)[g] **Static Balance/Post-treatment** Direct measurement: -0.05 (-0.22-0.12)[f]
Woo 2007[43] China	Community living Mean age 69 yr. N=180	**TC:** Yang style 24 forms, 3 times a week 45 min, n=60. **EC: Resistance training group** resistance training with a theraband of medium strength, 3 times a week, n=60. **C: no prescribed exercise**, n=60. **Follow-up:** Post-treatment**=** 12 months	***Falls*** (fall incidents retrospectively gathered)[h] **Balance** (SMART Balance Master and SLS), bone mineral density, physical fitness	**Drop-outs:** n=4 (2%): 2 in TC, 1 in EC, 2 in C. **Loss to follow-up:** **Falls** NR **Balance** Post treatment: n=4, see drop-outs **Adherence:** Average TC: 81%, EC: 76%	**Falls** 0.49, -0.71 (0.31)[f] No estimates of fall rate ratio reported **Static Balance** No significant difference between groups[g]

First author, year and country of publication	Characteristics of participants. N randomized	Intervention[a] Follow-up[b]	Outcome (measure)[c]	Drop-outs[d] Loss to follow-up[e] Adherence	Results [f, g] Falls: IRR, Log rate ratio (SE) Unadjusted estimate of fall rate ratio (95% CI) Fear of falling and Balance: Standardised mean difference (95% CI)
Logghe 2009[25] Netherlands	Community living, High fall risk Mean age: 77 yr. N=269	**TC:** Yang style 10 forms, 2 times a week 60 min; n=138. **C: Usual care** n=131 **Follow-up:** Post-treatment= 13 weeks Follow-up= 12 months	***Falls*** (fall calendar) ***Fear of Falling*** (FES) **Balance** (BBS) General Perceived health, biological variables	**Drop-outs:** n=26 (9.7%): 12 in TC, 14 in C. **Loss to follow-up:** **Falls** Follow-up: n=56 (21%) 24 in TC, 32 in C. **Fear of Falling/ Balance** Follow-up: n=67 (25%) 29 in TC, 38 in C. **Adherence:** 47% attended 80% of the lessons	**Falls** 1.18, 0.16 (0.14)[f] **HR multiple falls** 1.17 (0.84-1.63)[g] **Fear of falling/ Post-treatment** 0.59 (0.00-1.17)[f] **Follow-up** 0.10 (-0.13-0.34)[f] **Dynamic Balance/ Post-treatment and follow-up** No significant difference between groups[g]
Wolf 2003[41] USA	Living facilities seniors "transitioning to frailty" Mean age: 81 yr. N=311	**TC:** 6 out of 24 simplified forms, twice a week from 60 to 90 min; n=158. **C: Wellness education program** divers instruction sessions on health-related subjects, one hour weekly; n=153. **Follow-up:** Post-treatment= 48 weeks/12 months	***Falls*** (weekly returned fall calendar) functional variables psycho-social variable e.g. depression.	**Drop-outs:** n=94 (30%): 50 in TC, 44 in C. **Loss to follow-up:** idem drop-out **Adherence:** Mean in % ± SD (range) TC: 76 ± 19 (6-100) C: 81 ± 17(10-100)	**Falls** 0.88, -0.13 (0.12)[f] **Adj. (for center) HR multiple falls 48 weeks** 0.75 (0.52-1.08)[g]

Sattin 2005[36]			***Fear of falling*** (modified FES and ABC)		**Fear of falling** TC significantly better than C[g]
Wolf 2006[42]			**Balance** (SLS, time to complete 360° turn, time required to pick up an object from the floor, FR) functional variables behavioural variables biomedical variables		**Static and Dynamic Balance** No significant difference between groups[g]
Nowalk 2001[35] USA	Senior housing communities Mean age 85 yr. N=112	**TC: Living and Learning (LL)/ TC** LL are behavioural and psychotherapeutic methods to modulate fear of falling, once a week, TC no forms mentioned[a], 3 times a week; n=38. **EC: Fit NB Free** individualized, progressive, strength training and conditioning program, 3 times a week; n=37. **C: team management and education residents** 3 educational programs to enhance quality-of- life programming for all residents; n=35. **Follow-up:** Post-treatment = 13-24 months	***Falls*** (reported by faller or witness, written down in incident report), functional ability cognitive status depression	**Drop-outs:** n=32 (29%): **Loss to follow-up:** See drop-outs **Adherence:** Mean in % ± SD (range) TC: 24 ± 31 (19-37) EC: 56 ± 29 (45- 64)	**Falls** No estimates of fall rate ratio reported No significant difference between groups[g]

First author, year and country of publication	Characteristics of participants. N randomized	Intervention[a] Follow-up[b]	Outcome (measure)[c]	Drop-outs[d] Loss to follow-up[e] Adherence	Results [f, g] Falls: IRR, Log rate ratio (SE) Unadjusted estimate of fall rate ratio (95% CI) Fear of falling and Balance: Standardised mean difference (95% CI)
Choi 2005[30] Korea	Residential care facilities, higher fall risk Mean age 78 yr. N=68	**TC:** 12 forms Sun style, 3 times a week, 35 min; n=34. **C: routine activities**; no participations in any regular exercise classes; n=34. **Follow-up:** Post-treatment **=** 12 weeks	**Falls** (weekly monitored fall episode) ***Fear of falling*** (FES) **Balance** (SLS: eyes open/ eyes closed) physical fitness	**Drop-outs**: n=9 (13%): 5 in TC, 4 in C. **Loss to follow-up:** See drop-outs **Adherence:** Average TC: 80%	**Falls** No estimates of fall rate ratio reported **Relative risk ratio 12 weeks** 0.62 (0.32-1.19)[g] **Fear of falling** No significant difference between groups[g] **Static Balance** TC significantly better than C[g]
Frey 2007[31] USA	Community living, Sedentary Mean age 69 yr. N=84	**TC:** Yang style 10 forms, 3 times a week 60 min; n=31. **EC: Low impact exercise** cardiovascular and strength training, 3 times a week 60 min; n=30. **C: non-exercise**[a], n=23. **Follow-up:** Post-treatment**=** 12 weeks	***Falls*** **Balance** (dynamic) **and agility**; (8 foot up-and-go test), physical fitness, biomedical variables, psychological variables	**Drop-outs:** n=12 (14%): 8 in TC, 2 in EC, 2 in C. **Loss to follow-up:** see drop-outs **Adherence:** Average class attendance (range) 72.2%-100%. TC: 91.4% attended at least 80% of the classes	**Falls** No data or results reported **Dynamic Balance (and agility)** TC better than C[g] (significance not reported) No significant difference between TC and EC[g]

Zhang 2006[44] China	Community living, Less robust (lower ability to maintain balance) Mean age 70 yr. N=49	**TC:** Simplified TCC with 24 forms, 7 times a week for 1 hour; n= 25. **C: Instruction to continue current level of physical activity;** n=24. **Follow-up:** Post-treatment**=** 8 weeks	***Fear of falling*** (FES-10) **Balance** (OLS) Physical fitness e.g. flexibility and walking speed.	**Drop-outs:** n= 2 (4%): 1 in TC, 1 in C. **Loss to follow-up:** see drop-outs **Adherence:** Average: 92% of the participants (n=22) practiced 4 or more hours a week (average 32 hours practised)	**Fear of falling/Post-treatment** 0.59 (0.00-1.17)[f] **Static Balance** Indirect measurement 1.81 (1.12-2.49)[f]
Audette 2006[44] USA	Community living, Healthy, sedentary status, Mean age 72 yr. N=19	**TC:**10 modified forms Yang style, 3 times a week, 55-65 min; n=11. **EC: Brisk walking group** progressively increasing walking duration conform protocol, 3 times a week, 10-30 min; n=8. **Follow-up:** Post-treatment**=** 12 weeks	**Balance** (SLS), biomedical variables psychological variables, quality of life.	**Drop-outs:** n=7 (27%): 0 in TC, 7 in EC. **Loss to follow-up:** see drop-outs **Adherence:** Average TC: 95%, EC: 95%	**Static Balance** No significant difference between groups[g]
Wallsten 2006[37] USA	Living independently in continuing care retirement communities Mean age 81 yr. N=77	**TC: Tai Chi early group:** 10 forms Yang style, twice a week, 60 min; n=41. **C: Tai chi late group/Control group**[a]; n=36. **Follow-up:** Post-treatment**=** 20 weeks	**Balance** (calculated overall performance score on balance, strength and gait).	**Drop-outs:** n=42 (55%): 19 in TC, 23 in C (drop-outs during first 20 weeks: 16 in TC, 8 in C) **Loss to follow-up:** see drop-outs **Adherence:** Average TC**:** NR	**Balance** **Overall performance (including balance, strength and gait)** Remainders showed statistically significant higher scores than drop-outs in overall performance[g]

First author, year and country of publication	Characteristics of participants. N randomized	Intervention[a] Follow-up[b]	Outcome (measure)[c]	Drop-outs[d] Loss to follow-up[e] Adherence	Results [f, g] Falls: IRR, Log rate ratio (SE) Unadjusted estimate of fall rate ratio (95% CI) Fear of falling and Balance: Standardised mean difference (95% CI)
Nnodim 2006[34] USA	Seniors' centres and congregate housing facilities Mild balance impairment Mean age 78 yr. N=213	**TC:** 12 forms Yang style, 3 times a week, 60 min; n=107. **EC: Combined Balance and Stepping Training** exercise program focused on improving dynamic balance and stepping, 3 times a week, 60 min; n=106. **Follow-up:** Post-treatment= 10 weeks	**Balance** (static balance: US, TS dynamic balance; stepping measures and TUG), functional variables (stepping)	**Drop-outs:** n= 51 (24%): 26 in TC, 25 in EC. **Loss to follow-up:** see drop-outs **Average attendance** TC: 83%, EC: 86% Mean number± SD (range) TC: n=25.0 ± 2 (20-30) EC: n=25.7 ± 2 (20-30)	**Static Balance** No statistically significant difference in odds ratios favouring EC over TC in US[g] Statistically significant difference in odds ratios favouring EC over TC in TS[g] **Dynamic Balance** Statistically significant difference in odds ratios favouring EC over TC [g]
Li 2004[10] USA	Community living, Healthy, inactive Mean age 75, 4 yr. N=118	**TC:** Yang style 8 forms easy Tai Chi, three times a week 60 min; n=62. **EC: Low impact exercise** seated exercise accompanied with controlled breathing, stretching and relaxation, three times a week 60 min; n=56. **Follow-up:** Post-treatment= 24 weeks	Self-related sleep quality and day-time sleepiness Quality of life, Physical performance including **Balance** (SLS)	**Drop-outs**: n=7 (6%): 1 in TC, 6 in C. **Loss to follow-up:** see drop-outs **Adherence:** Median compliance**:** 60 sessions (out of 74 sessions) (range 33-71) TC: 93% followed ≥70% C: 81% followed ≥70%	**Static Balance** Indirect measurement 0.31 (-0.05-0.67)[f]

Li 2008[33] USA	Community living, Healthy Mean age 65 yr. N=118	**TC:** 24 form Tai Chi, four times a week 60 min; n=25. **C: discussion group** Sedentary control group, instruction not to change exercise level once a week 60 min discussion group; n=25. **Follow-up:** Post-treatment= 16 weeks	**Balance** (SLS, TS) Kinaesthesia knee and ankle joints	**Drop outs:** n=10 (20%): 3 in TC, 7 in C. **Loss to follow-up:** see drop-outs **Adherence:** Mean participation rate TC: 92% (range 80-100%)	**Static Balance** 0.42 (-0.21-1.06)[f]

[a] More information on the various forms of Tai Chi used can be found in the original articles. When no intervention details were available this is indicated with ([a]).
[b] Follow-up: measurement in weeks or months after randomisation divided into post-treatment and follow-up
[c] *In italics* = self-reported outcomes of falls, fear of falling or balance
[d] Drop-outs: participants who withdrew from the intervention during the intervention period
[e] Loss to follow-up: participants who withdrew from the intervention after the intervention period had finished
[f] Results as calculated in the meta-analysis of the present authors
[g] Results as presented in the original article
[h] Additional information obtained from author(s) of the published article
Significant differences when $p < .05$.

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5

The Prediction of Falls related to Minor Injuries in Older Community-Living People with High Fall Risk: An Explorative Study

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ABSTRACT

Background. Fall risk increases with age. The majority of falls only result in minor injuries but little is known about these falls. Insight in risk factors preceding and during the fall (e.g. description of the place of the fall) may be useful to optimise fall prevention programs. We evaluated which circumstances are related to falls and built a predictive model for falls related to minor soft tissue injuries in community-living people.

Methods. Participants of a fall prevention trial registered falls on a daily basis for one year, including circumstances and consequences of the falls. Possible predictors for falls related to minor soft tissue were identified and multivariate logistic regression techniques were used to build predictive models.

Results. During the study 117 out of 213 participants fell once or more; 205 falls were reported of which 108 were injurious. For eight reported falls it was unknown whether they were related to injuries or not or in which circumstances they took place. Most injurious falls resulted in minor soft tissue injuries (94%); six falls resulted in a fracture. The discriminative ability of the risk prediction model for falls related to minor soft tissue injuries was moderate (Area under the Curve = 0.67)(95% Confidence interval = 0.59-0.75).

Conclusion. A simple risk prediction model (including age, female sex, previous falls and fear of falling) can moderately well predict the probability in which falls will be related to minor soft tissue injuries.

INTRODUCTION

Fall risk increases with age. The most serious fall related injuries are hip fractures, which are estimated to occur in two percent of all fallers aged 65 and older.[1] The majority of falls only result in minor soft tissue injuries, but these falls may threaten seriously the independence of the faller due to a restriction in activities.[2,3] Although fall prevention programs can be effective in reducing the number of both falls and injurious falls in community-living older people, few randomised controlled trials (RCTs) registered minor fall related injuries.[4] If effects on injurious falls are reported they are mostly reported as effect on severe injury or as a combination of both minor and severe injuries.

Often, little is known about the circumstances under which falls take place. Insight in intrinsic and extrinsic risk factors preceding and during the fall (e.g. the level of activity during the fall and a description of the time and place of the fall) may be useful to optimise fall prevention programs.

The effectiveness of fall prevention programs might improve by referring only older persons at high risk of falling to these programs. Previous falls is an important predictor for future falls and many older persons at high risk have been fallen before. It is plausible that previous falls related to minor injuries will increase falls risk more than previous non-injurious falls, as a person might restrict more activities after injuries. Risk prediction models can be used to select older persons at high risk. In community-living older people numerous studies have been conducted on risk factors for falls and fracture related falls, but only few have investigated minor injuries.[5-8] Similarly, the risk prediction models that have been developed do not predict minor fall related injuries.[9-14]

This study evaluates which circumstances are related to the falls and investigates whether it is possible to predict fall related minor soft tissue injuries in community-living older people with high fall risk.

METHODS

Population

The study population consisted of 269 community-living older Dutch people with high fall risk who participated in an RCT on the effects of Tai Chi on falls.[15] High fall risk was defined either 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 or the use of benzodiazepines or diuretics. Participating general practitioners invited patients aged 70 years and older by mail, and if the patients were eligible and willing to participate they were enrolled in the study.

Data collection

At baseline, all participants completed self-administered questionnaires that covered general sociodemographic characteristics, falls history, the self-reported risk factors for falling, fear of falling and physical activities. Participants filled out a fall calendar on a daily basis for one year. Whenever a fall occurred, circumstances and consequences were self-reported using a standardised form. An independent research assistant received the calendars and forms every month by mail and contacted the participants when outcome was missing or incomplete. During this short telephone survey the research assistant noted the answers given by the participants.

According to the identified risk factors for falls and injurious falls in the literature relevant potential predictors for injurious falls were identified: age, sex, falls in the year preceding the study, balance, physical activities, fear of falling and characteristics of the fall (location, time and fall type). Balance was assessed with the Berg Balance Scale[16], fear of falling with the Falls Efficacy Scale[17] and physical activity with the Physical Activity Scale for the Elderly.[18]

Definition of falls, circumstances and injuries

A fall was defined as "unintentionally coming to rest on the ground, floor or other lower level". [19] Circumstances of falls were categorised by type, time of falls and location (outside or inside). The types of falls were classified according to the International Classification of Diseases, 10th revision (ICD-10). Falls from a bicycle were classified as additional fall type, because in the Netherlands cycling is a common means of transport and falls might occur during cycling. Bruises, contusions and wounds were defined as minor soft tissue injuries and major injuries included fractures and dislocations.

Statistical analysis

Analyses were performed with SPSS (15.0). Falls resulting in major injuries were excluded from the analyses because we only want to predict minor soft tissue injuries. First, univariate logistic regression analyses were performed with injurious falls as the dependent variable and each of the potential predictors as the independent variable. Second, we checked if predictors were highly correlated with each other. Third, the potential predictors were included in a multivariate logistic regression model.

Prior to our analysis, nine predictors were identified for inclusion. Physical activities were excluded, because the calculation and interpretation of the final score of the questionnaire is time consuming making it less feasible to use in clinical practice. The allocation to intervention or control group was included as independent predictor, because the data were gathered in a RCT.[20] Results are reported using odds ratios (OR) and 95% confidence intervals (CIs).

Because some of the predictors are unknown at the time that the clinicians will use the model or are assessed in the standard assessment procedure (i.c. balance) we decided to build a second model wherein we excluded these variables. Finally, the Area Under the receiver-operator Curve (AUC) and the 95% confidence interval (CI) were computed to evaluate the discriminative ability of the models. A value of 0.5 indicates no predictive discrimination and a value of 1.0 indicates perfect separation of falls with and without minor soft tissue injuries.[21] The Hosmer- Lemeshow test was used to evaluate how well the model fits the data.

RESULTS

Frequency of falls and injurious falls

Over a period of one year 213 (79%) participants monthly returned their fall calendars and standardised forms and these were used for the analyses. The intervention group filled out on average 332 fall calendar days (89%) and the control group 322 days (86%). Over a period of 12 months 117 participants (44%) fell once or more resulting in 205 falls [mean incidence rate = 851/1000 persons years (PY)]. In the intervention group, 58 of 138 (42%) participants fell, and in the control group 59 of 131 (45%) fell. All missings (n=56) were considered as non-fallers. Of the 117 fallers, 94 (80%) were women and 86 (74%) had experienced a fall previous to our study. Of the 152 non-fallers, 97 (64 %) were women and 81 (53%) had experienced a fall previous to our study. The baseline characteristics of the study population are presented in table 1. The number of falls per participant ranged from 0 to 6.

Table 1 Baseline characteristics fallers and non-fallers in older community-living people with high fall risk

	Fallers (n=117)	Non-Fallers (n=152)*
Age, mean (SD)	77.3 (4.6)	77.0 (4.7)
Female sex, n (%)	94 (80.3)	97 (63.8)
Previous falls, n (%)	86 (73.5)	81 (53.3)
Balance: BBS (0-54), mean (SD)	51.3 (4.7)	51.6 (4.5)
Physical activity: PASE (0-244)[a], mean (SD)	72.2 (45.0)	75.4 (43.5)
Functional status: GARS (18-72), mean (SD)	24.9 (7.4)	25.0 (7.2)
Fear of falling: FES (0-30)	6.2 (5.0)	5.6 (5.0)
Tai Chi group, n (%)	58 (49.6)	80 (52.6)
Living alone, n (%)	60 (51.3)	73 (48.0)
Walking device (yes), n (%)	35 (29.9)	58 (35.7)
Co morbidity (yes), n (%)	47 (40.2)	62 (40.8)
(chronic obstructive pulmonary disease, cardio logical problems, diabetes mellitus, cancer)		

* All missings (n=56) were considered as non-fallers.

[a] range in this population: a higher score means more physical activity.

n = number of participants in group; SD = standard deviation; BBS = Berg Balance Scale; PASE = Physical Activity Scale for the Elderly; GARS = Groningen Activity Restriction Scale; FES = Falls Efficacy Scale

Of the 205 falls, 108 falls (53%) were injurious and of 8 falls (4%) the standardised forms were missing. The mean incidence rate for injurious falls is 448/1000 PY. More women than men experienced injuries after a fall (83% vs.17%). Nearly all injurious falls (94%) related to minor soft tissue injuries and six falls resulted in a fracture. No dislocations were reported. The falls related fractures occurred equally in men and women (each n=3). The baseline characteristics of the injurious and non-injurious falls are presented in table 2.

Table 2 Characteristics non-injurious and injurious falls in older community-living people with high fall risk (n=197)*

	Non-injurious falls (n=89)	Injurious falls (n=108)[a]
Participant baseline characteristics		
Age, mean (SD)	77.4 (4.7)	77.0 (4.7)
Female sex, n (%)	58 (65.2)	90 (83.3)
Previous falls, n (%)	64 (71.9)	85 (78.7)
Balance: BBS (0-54)[b], mean (SD)	50.7 (5.6)	51.9 (3.8)
Physical activity: PASE (0-244)[c], mean (SD)	74.6 (47.8)	72.7 (43.8)
Functional status: GARS[d](18-72), mean (SD)	25.3 (8.2)	24.0 (6.5)
Fear of falling: FES[d](0-30)	6.1 (5.2)	6.4 (5.0)
Tai Chi group, n (%)	53 (59.6)	58 (53.7)
Circumstances falls		
Outside house**,** n (%)	31 (35.6)	66 (61.6)
Type of fall		
Trips, slips, stumbling**,** n (%)	27 (30.3)	48 (44.4)
Other fall on same level due to collision with, or pushing by, another person**,** n (%)	2 (2.2)	5 (4.6)
Fall on and from stairs and steps, n (%)	9 (10.1)	9 (8.3)
Other fall on same level (e.g. bumping against object, on and off the toilet)**,** n (%)	25 (28.1)	11 (10.2)
Unspecified fall**,** n (%)	17 (19.1)	19 (17.6)
Fall involving cycles[e]**,** n (%)	9 (10.1)	16 (14.8)

* Of 8 (out of 205) falls it is unknown whether they were injurious as the standardised forms were missing

[a] includes soft tissue injuries and major injuries
[b] higher score means better balance
[c] range in this population: a higher score means more physical activity.
[d] higher score means worse functional status / more fear of falling
[e] item not mentioned in ICD

n = number of participants in group; SD = standard deviation; BBS = Berg Balance Scale; PASE = Physical Activity Scale for the Elderly; GARS = Groningen Activity Restriction Scale; FES = Falls Efficacy Scale

Predictors for minor soft tissue injuries

The univariate analyses showed that the probability of fall related minor soft tissue injury was higher in women (OR 3.10; 95% CI 1.54-6.24), in falls that occurred outside (OR 2.80; 95% CI 1.55-5.06) and falls caused by slipping, tripping and stumbling compared with all other types of falls (OR 1.96; 95% CI 1.08-3.56). In falls on level due to other causes compared with all other falls the probability of getting injured was less (OR 0.37; 95% CI 0.18-0.75). All other candidate variables did not affect the occurrence of injurious falls (data not published). Because the different fall types correlated well with each other (0.60-0.70) we decided to use only the fall types due to trips, slip and stumbling (yes/no) and other falls on level (yes/no) in our multivariate model. Table 3 presents the full model for the prediction of minor soft tissue injuries related to falls.

Table 3 Risk models for the prediction of falls resulting in minor soft tissue injuries vs non-injurious falls obtained by logistic regression (n=191)*

Predictors	B	(SE)	OR	95% CI
Full Model (n=189)*				
Age	-0.03	0.04	0.97	0.90 - 1.04
Female sex[a]	0.82	0.40	2.27	1.04 - 4.92
Previous falls, yes	0.31	0.38	1.37	0.66 - 2.85
Balance, BBS	0.02	0.04	1.02	0.94 - 1.11
Fear of falling, FES[a]	0.08	0.04	1.08	1.00 - 1.16
Place, outside[a]	0.90	0.33	2.47	1.29 - 4.72
Type of fall: trips, slip, stumbling[b]	0.33	0.37	1.39	0.68 - 2.81
Type of fall: other fall on level (e.g. bumping against object)[b]	-0.61	0.45	0.54	0.23 - 1.31
Participant of the intervention group, yes	-0.04	0.35	0.96	0.48 - 1.89
Constant	-1.85	4.24	0.16	
AUC	0.71	0.04		0.63 - 0.78
Model 2 (clinical practice)				
Age	-0.05	0.03	0.96	0.90 - 1.02
Female sex[a]	1.17	0.37	3.21	1.56 - 6.63
Previous falls, yes	0.46	0.35	1.58	0.80 - 3.12
Fear of falling, FES	0.04	0.03	1.04	0.98 - 1.11
Constant	1.02	2.74	2.76	
AUC	0.67	0.04		0.59 - 0.75

* Of the 205 falls, 8 standardised forms were missing and 6 falls were excluded as they resulted in major injuries

** Only complete cases were included in the analysis

[a] independent predictor [b] versus all other types of fall

N = Number of participants; B = regression coefficient; (SE) = standard error; OR = odds ratio; 95% CI = 95% confidence interval; AUC = Area Under the receiver-operator Curve

Of the 205 falls, 8 standardised forms were missing and 6 falls were excluded as they resulted in major injuries. Only complete cases were included in the analyses. The full model fits the data well [The Hosmer- Lemeshow test was not significant (p=0.52)]. The AUC was 0.71 (95% CI 0.63-0.78), indicating that 71% of the fall related minor soft tissue and non-injurious falls can be classified correctly by this model. In the second model including only age, sex, falls in the year preceding the study and fear of falling the discriminative ability was 0.67 (95% CI 0.59 - 0.75) (table 3).

DISCUSSION

This study shows that more than half of the falls in older people with a high fall risk were injurious and nearly all injurious falls related to minor soft tissue injuries. More injurious falls occurred outside the house compared to inside the house and the most common fall type were falls on level due to slipping, tripping and stumbling. An average of 67% of the fall related minor soft tissue injuries and non-injurious falls can be classified correctly by a model which includes age, sex, falls history and fear of falling.

The percentage of fallers (44%) is comparable to the percentage found in an Australian cohort, wherein only older people in high fall risk were included (48%) and incidence rates were higher than in those found in other cohorts wherein non-selected older people were included.[22,23,24] However, the proportion of falls resulting in injury in our study was lower than the one found in the Australian cohort (53% vs. 63%).[22] Differences in proportions of falls resulting in injuries might be explained by the use of different definitions of falls, injurious falls and high fall risk.

A main objective of this study was to investigate if fall related minor soft tissue injuries can be predicted in community-living older people with high fall risk. The screening process that identifies at-risk populations may profit from discrimination between falls related to minor soft tissue injuries and non-injurious falls and preventive interventions might be targeted better. The consistently reported best predictors for falls are a history of falls and abnormalities in gait or balance (self-reported or clinically detected). [9-12] We found three independently predictors for fall related minor soft tissue injury; female sex, fear of falling and an outdoor fall. In line with earlier research we found female sex to be an independent predictor.[7,25,26] Although we do know that falls are related to both fear of falling and location, these variables were not yet identified as independent risk factors for falls related to minor injuries. The presence of these predictors in the multivariate model suggests that - in community-living older people with high fall risk- the ones who will benefit most from a preventive intervention are women who are more afraid of falling. Furthermore, a preventive intervention could be optimised by given more attention to the prevention of outdoor falls.

In contrast with the prediction of falls, history of falls and balance are not independently predictors for falls related to minor soft tissue injuries. These findings are in line with those of Vellas et al. (1998) and confirm that it is possible to discriminate between falls and injurious falls in a screening process.[7]

Because the location of the fall cannot be used in a screening process we have built a second model including only predictors known at the time the screening process will take place. This model has modest predictive ability to discriminate between fall related minor soft tissue injuries and non-injurious falls (AUC = 0.67; 95% CI 0.59-0.75). Yet, the model is not ready for use in clinical practice because it is not externally validated and no impact studies have been performed yet.[27,28] Finally, the optimal cut-off point must be investigated. If the model is to be used as a screening instrument to refine the referral to a comprehensive risk assessment, a high specificity is preferred because this assessment is time consuming and costly. If the model is to be used to optimise the referral to a targeted preventive intervention, the sensitivity could be higher.

Strengths and limitations

Our participants filled out the fall calendars on a daily basis and were contacted by telephone when calendars were not returned by the end of the month, so the validity of the results is probably not influenced by recall bias. However, our study has some limitations. First, the participants in this study were also participants in an RCT and therefore this is not a population-based sample. Although the findings on mean incidence rates are in line with other studies, generalisations to other older people should be made with caution. Moreover the risk prediction model was not external validated and therefore it should be evaluated in other samples before it can be used for clinical practice. Second, registration of injurious falls was self-reported and because most injuries were minor soft tissue injuries they were not reported to medical services but only registered on the form. It is possible that the results could have been subject to reporting bias. Finally, most participants did not mention what they were doing when they fell, so either we have no data on these circumstances or we had to derive this information ourselves. We decided not to use this information, because we could not exclude bias. In further research it would be useful to explicitly ask the participants to describe what they were doing when they fell as this information will be helpful to optimise preventive interventions.

CONCLUSIONS

This study shows that more than half of the falls in older people with a high fall risk were injurious and nearly all injurious falls were related to minor soft tissue injuries.

A model which includes age, sex, falls history and fear of falling can moderately well predict fall related minor soft tissue injuries. After validation and the investigation of clinical useful cut-off points, this model could be used in a screening process. Due to the explorative character of our analyses we recommend further research into the relationship between falls, injurious falls and outdoor activities.

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6

External Validation of a Simple Risk Prediction Model for Recurrent Falling in Older People in Primary Care.

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ABSTRACT

Objective. We aimed to assess the validity of a risk prediction model to predict recurrent falling in community-dwelling persons aged 65 years and over in primary care.

Method. The risk prediction model was validated in 269 older Dutch people (70+) with a high fall risk who consulted their general practitioner (GP) near Rotterdam. Falls were prospectively registered over a one-year period until January 2006. Associations with combinations of included predictors were calculated and the Area Under the receiver-operator Curve (AUC) and the diagnostic values were computed.

Results. The discriminative ability of the risk prediction model for recurrent falling was moderate [AUC = 0.64 (95% Confidence Interval (CI) 0.37- 0.88)]. The risk prediction model predicted the risk of becoming a non-recurrent faller better than the risk of becoming a recurrent faller (specificity = 86%, negative predictive value (NPV) = 84%, sensitivity = 27% and positive predictive value (PPV) = 30%). The ability of the risk prediction model for fallers was lower [AUC = 0.61 (95% CI 0.55 - 0.68)].

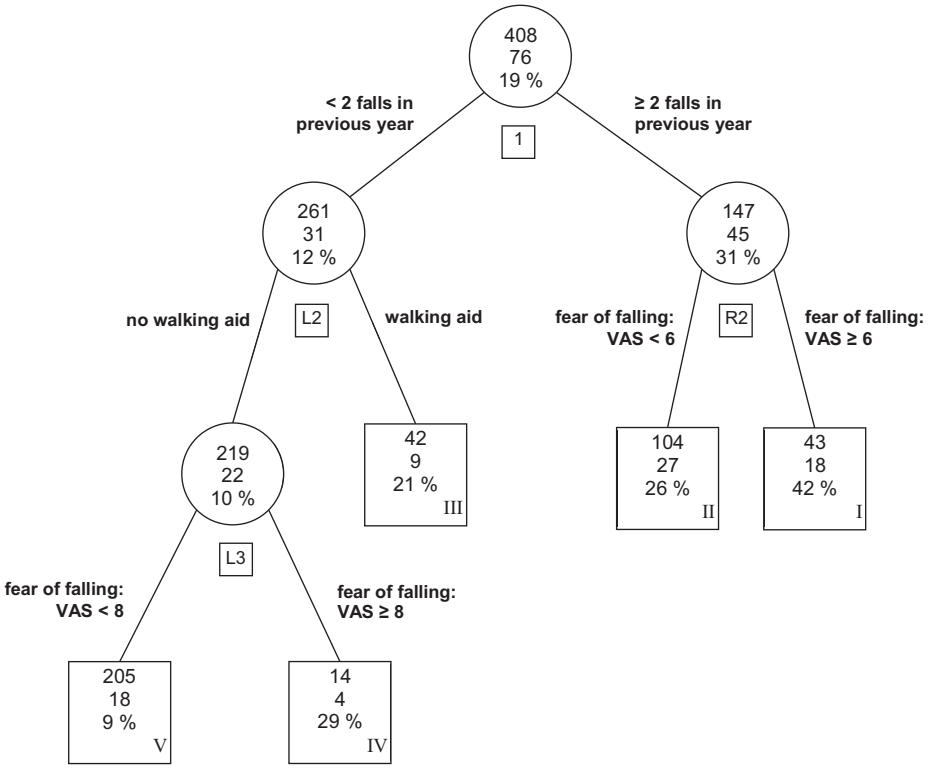
Conclusion. In primary care, the predictive validity of the risk prediction model for recurrent falling is acceptable. This simple tool might help GPs to identify older people who do not need a comprehensive fall risk assessment.

INTRODUCTION

In the past years, research has shown that the most effective fall prevention programs in community-living older people are targeted on specific risk factors e.g. balance impairments and medication usage.[1-3] Because of the multifactorial nature of falls, comprehensive assessment including anamnesis (e.g. fall history and medication review), physical examination (e.g. balance and blood pressure) functional assessment (e.g. use of walking aids) and environmental assessment (e.g. home visits) is needed to identify fall risk factors and tailor the fall preventive strategy for a specific person. [4-6] However, complete fall risk assessment of all older people is time consuming, expensive and not feasible given the increasing aging population. The (cost) effectiveness of both fall risk assessment and fall preventive strategies may be higher in older people with the highest fall risk. Risk prediction models can optimise the selection of those elderly persons.

So far, the majority of the risk prediction models are aimed at predicting the risk of falling and some predict the risk of recurrent falling.[7-14] Recurrent fallers may be more in need of preventive measures as recurrent falls usually are caused by physical, cognitive and behavioural factors within the person. Single falls are more often coincidental and more difficult to prevent.[15] Alternatively, if prediction of a single and/or first fall is possible, risk factors can be identified in an early stage and with effective strategies single fallers may be prevented to become recurrent fallers. In daily clinical practice, a simple and quick tool is needed to select those older people who may benefit from comprehensive assessment. At the same time in older people with a low risk a comprehensive assessment can be withhold.

In the Netherlands, a simple risk prediction model has been developed to predict recurrent fallers in community-dwelling older persons aged 65 years and over who consulted the general practitioner (GP) or emergency department (ED) after a fall (see Figure 1).[9] Using Tree Structured Survival Analysis, three predictors that were easy and quick to measure were selected (i.e. fall history, use of walking aid and fear of falling). The predictive ability of the risk prediction model is moderate but promising; 69 and 71 % of the participants in the derivation sample and the validation sample, respectively, were correctly classified as either a recurrent faller (persons who fell twice within 6 months) or non-recurrent faller. However, the validity of the risk prediction model in primary care setting remains unclear as the majority of the selected participants consulted the ED after their fall (90%).[9] Validation is needed, because differences in health care setting, population characteristics and measurement methods influence the accuracy of a model.[16] This study aimed to assess the predictive validity of this risk prediction model in a primary care setting for both falling and recurrent falling.



Squares indicate the end notes, and circles indicate the intermediate nodes. The numbers in the squares and circles indicate the number of participants, the number of recurrent fallers and the proportion of recurrent fallers, respectively.
VAS: Visual Analogue Scale.

Figure 1 The risk model as developed in community-dwelling older persons aged 65 years and over who consulted the general practitioner (GP) or emergency department (ED) after a fall (Peeters et al., 2010).[9]

METHODS

Study Population (validation sample)

The study population for the validation in primary care consisted of 269 community-living older Dutch people with a high fall risk who participated in a randomised controlled trial (RCT) on the effects of Tai Chi (TC) on falls and other outcomes. This TC trial was conducted between March 2004 and April 2006. The institutional medical ethics review committee approved the study and the results of the trial are described in details elsewhere.[17] In short, participating general practitioners invited patients aged 70 years and older by mail. When the patients were eligible and willing to participate they were enrolled in the study. Inclusion criteria were being 70 years

or older, living at home and having a high fall risk. High fall risk was defined either 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. Of the 5,931 patient files screened from the database of 23 participating GP's, 483 patients were willing to participate. Finally, 138 patients were randomised to the TC group and 131 to the control group. For the current study, data was used from all participants randomised as the intervention was ineffective regarding fall prevention; the adjusted hazard ratio comparing fall rates between the groups during 12 months follow-up was 1.16 (95% confidence interval (CI) 0.84 -1.60).[17]

Definitions and measurements of falls and predictors

A fall was defined as "unintentionally coming to rest on the ground, floor or other lower level".[17,18] The risk of becoming a recurrent faller was defined as the risk of becoming a person who fell twice or more in a six-month period.[10] The risk of becoming a non-recurrent faller is complementary to the risk of becoming a recurrent faller and includes the risk of becoming a non-faller, a once-fallers and a more than once-faller during the study period. The risk of becoming a faller was defined as the risk of becoming a person who fell once or more in the study period.

Falls were measured with fall calendars filled out by the participants on a daily basis for 12 months. An independent research assistant received the fall calendars every month and contacted the participants by telephone when forms were missing or incomplete. During this short telephone survey the research assistant inquired whether and when the participant had fallen in the past month or past three months.[17] The predictors included in the risk prediction model were measured at baseline. Participants completed (self-administered) questionnaires that covered general sociodemographic characteristics, fall history and risk factors for falling (e.g. use of walking aids). Fear of falling was assessed with the Falls Efficacy Scale (FES) that consists of 10 subquestions, scored on 4-point scales.[19]

Statistical analysis

In the derivation sample, fear of falling was measured with the FES and with a single question "How afraid are you that you may fall?" scored on a 10-point scale. Because the discriminative ability of both measurements was similar in the derivation sample, preference was given to the single question in the risk prediction model. Therefore prior to the validation, the optimal cut-off values for fear of falling (as measured with the FES) were determined in the validation sample. For each cut-off value, Kaplan-Meier survival curves of the two resulting groups were created and log rank statistics were calculated. A higher log rank statistic indicated a better discrimination between

the (recurrent) fallers and non-(recurrent) fallers. The cut-off values with the highest log rank statistics were used to validate the risk prediction model in the validation sample. Survival time was defined as time from baseline to the time of recurrent fall (i.e. time of the second fall within a six-month period) and time to first fall.

The validity of the risk prediction model was evaluated by examining the discriminative and the predictive ability of the risk prediction model, both for risk of recurrent falling and the risk of falling. The Area Under the receiver-operator Curve (AUC) and the 95% CI were computed to evaluate the discriminative ability of the risk prediction models. A value of 0.5 indicates that discriminative ability is equal to chance and a value of 1.0 indicates perfect distinction of (recurrent) fallers and non-(recurrent) fallers. We defined an AUC of 0.59 and lower as poor, 0.60 to 0.69 as moderate and 0.70 and higher as good validity. As most simple models do not exceed an AUC of 0.70, we define an AUC of 0.70 and higher as acceptable.[14, 20]

The sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) were computed to evaluate the predictive ability of the risk prediction models. For the calculation of these diagnostic values, high risk was defined as ≥ 30% risk of recurrent falling and as ≥ 55% risk of falling. Using these definitions, being at high risk means that the usual annual risk of recurrent falling (15%) and falling (30%) in community living older persons is (nearly) doubled.[21-23] Because a past fall is one of the strongest predictors of a further fall, the validity of the risk prediction model was tested separately in the subgroup of participants with a high fall risk based on one or more self-reported fall incidents in the year preceding the study. Analyses were performed with SPSS (SPSS Inc., 17.0).

RESULTS

The baseline characteristics of the participants of the validation sample are described in Table 1. At baseline, the proportion of female participants was just over 70 % and the mean age was 77.1 (standard deviation (SD) = 4.6) years. After one year of follow-up, 49 participants (18.2%) became recurrent fallers and 117 participants (43.5%) fell once or more. The mean time to the recurrent fall was about 180 days and mean time to first fall was about 152 days.

In the validation sample, 92 (34.2%) participants reported two or more falls in the previous year and the same number of participants reported the use of walking aids; 238 participants (88.5%) reported fear of falling (FES >1).

Discriminative and predictive validity for recurrent fallers

The risk prediction model for recurrent fallers in the total group is presented in Figure 2.

Table 1 Baseline Characteristics validation sample

Variable	Validation sample (n= 269)
Age in years, mean (± SD) (range)	77.1 (4.6) (69-93)
Female sex, n (%)	191 (71.0)
Previous falls, n (%)	167 (62.1)
Number of falls, median (IQR 25% -75%)	1 [0-2]
Medication use (yes), n (%)	263 (97.8)
Diuretics (yes), n (%)	94 (34.9)
Benzodiazepines (yes), n (%)	86 (32.0)
Living alone (yes), n (%)	133 (49.4)
High school education or higher, n (%)	186 (69.1)
Visual problems	
Difficulty reading, n (%)	41(15.4)
Use of walking aids, n (%)	92 (34.2)
Alcohol use (yes), n (%)	158 (58.7)
Glasses weekly, mean (± SD)	6.6 (7.0)
Co-morbidity	
COPD, n (%)	32 (12.1)
Cardio logical problems, n (%)	24 (9.1)
Diabetes, n (%)	55 (20.8)
Arthritis, n (%)	104 (39.4)
Cancer, n (%)	15 (5.7)
None, n (%)	38 (14.1)
Balance: BBS (0-56), mean (± SD)	51.5 (4.6)
Fear of falling:	
FES (0-30), median (IQR 25 -75%)	4 [2-9]
Physical activity: PASE (0-356)[a], mean (± SD)	74.0 (44.1)
Functional status: GARS (18-72)	
n (%) in IQR [0-25%] : GARS <31.5[b]	218 (81.0%)
Mental health (0-100), mean (± SD)[c]	
SF-36, Mental component	70.5 (18.2)

Baseline characteristics of the validation sample (Rotterdam, 2010)

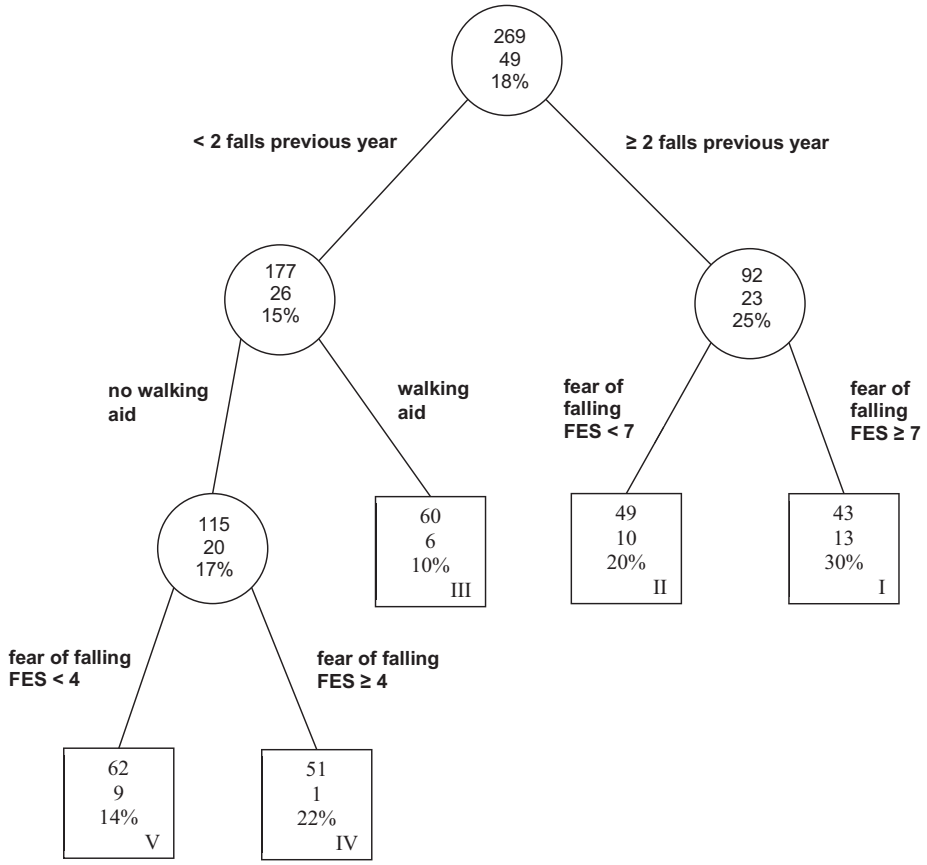
IQR = inter quartile range [25%, 75%]; COPD = Chronic Obstructive Pulmonary Disease; BBS = Berg Balance Scale; FES = Falls Efficacy Scale; PASE = Physical Activity Scale for the Elderly; GARS = Groningen Activity Restriction Scale; SF-36 = Short Form 36.

[a] range in this population: a higher score means more physical activity.

[b] Lower scores indicate better functional status.

[c] Higher scores indicate better mental health.

After one year of follow-up, 18% became recurrent fallers. Among people with no history of recurrent falling, i.c. fell less than twice in the previous year, who did not use a walking aid and had no fear of falling, the a priori chance of becoming a recurrent faller decreased from 18% to 14%. In older people who fell twice or more in the previous year and were afraid of falling the a priori chance of becoming a recurrent faller increased from 18% to 30%.



Squares indicate the end notes, and circles indicate the intermediate nodes. The numbers in the squares and circles indicate the number of participants, the number of recurrent fallers and the proportion of recurrent fallers, respectively.
FES: Falls Efficacy Scale for the Elderly.

Figure 2 Risk model for the prediction of recurrent fallers used in primary care in a community-living older population who consulted the GP and were in high fall risk.

In the subgroup of older persons who had fallen in the previous year, 22% became recurrent fallers. The a priori chance decreased from 22% to 14% if no risk factors were present and increased from 22% to 30% if the person fell twice or more in the previous year and was afraid of falling. In the total group, the AUC was moderate [0.64 (95% CI 0.37- 0.88)], meaning 64% of the recurrent and non-recurrent fallers can be classified correctly by the model. In the subgroup of older persons who had fallen in the previous year, the AUC was acceptable [0.70 (95% CI 0.44-0.96)]. The sensitivity and the PPV of the risk prediction models were low in both the total group and the subgroup (≤35%); the specificity and NPV were much higher (≥77%) (Table 2).

Discriminative and predictive validity for fallers

Both the discriminative and predictive validity of the risk prediction models for fallers were lower than these for recurrent fallers. In the total population the AUC was moderate [0.61 (95% CI 0.55-0.68)] and in the subgroup of older persons who had fallen in the previous year the AUC was poor [0.58 (95% CI 0.49-0.66)]. The sensitivity and the PPV were higher in both the total group and the subgroup (≥44 % and 57% respectively) compared to those for recurrent fallers (≤ 35%). The specificity and NPV were lower (≤ 74% and ≤ 63% respectively) compared to ≥77% for recurrent fallers (Table 2).

Table 2 Diagnostic values risk prediction models

	Derivation sample [a] (n=408)	Validation sample (n= 269)	Validation sample: subgroup "high fall risk based on a previous fall" (n= 167)
Prediction recurrent faller [b]			
Sensitivity, % (95% CI)	24 (14-33) [c]	27 (14-39)	35 (20-51)
Specificity, % (95% CI)	92 (90-95) [c]	86 (82-91)	77 (70-84)
Positive Predictive value, % (95% CI)	42 (27-57) [c]	30 (17-44)	30 (17-44)
Negative Predictive value, % (95% CI)	84 (80-88) [c]	84 (79-89)	81 (74-88)
AUC (95% CI)	0.69 (0.63-0.76)	0.64 (0.37-0.88)	0.70 (0.44-0.96)
Prediction faller [d]			
Sensitivity, % (95% CI)	49 (44-54)	44 (35-53)	72 (63-82)
Specificity, % (95% CI)	74 (65-78)	74 (67-81)	42 (31-53)
Positive Predictive value, % (95% CI)	59 (54-64)	57 (46-67)	57 (48-66)
Negative Predictive value, % (95% CI)	66 (57-71)	63 (56-70)	59 (46-71)
AUC (95% CI)	0.65 (0.60-0.71)	0.61 (0.55-0.68)	0.58 (0.49-0.66)

CI = Confidence interval; AUC = Area Under the receiver-operator Curve.

[a] In the derivation sample, the diagnostic values for the prediction of recurrent fallers were presented in Peeters et al.[9] The diagnostic values for the prediction of fallers were calculated for this article.

[b] Cut-off point prediction recurrent faller in validation sample: High risk: ≥ 30% risk of recurrent falling.

[c] Cut-off point prediction recurrent faller in derivation sample: High risk: > 30% risk of recurrent falling.

[d] Cut-off point prediction faller in both samples: High risk: ≥ 55% risk of falling.

DISCUSSION

We validated an existing risk prediction model for recurrent falling in a population of community-dwelling older persons who consulted their GP. In this primary care setting, the discriminative ability and predictive validity of the risk prediction model for recurrent falling was only moderate. However, in the subgroup of older persons who had fallen in the previous year, the discriminative ability was somewhat, but

not significantly, higher. The risk prediction model predicts the risk of becoming a non-recurrent faller better than the risk of becoming a recurrent faller. The validity of the risk prediction model for falls is moderate to poor.

The characteristics of the participants in the derivation and validation sample were largely similar but there were also some differences, likely to be due to differences in recruitment strategies and inclusion criteria. The characteristics of the participants of both samples are presented in Table 3.

Although both samples recruited participants with a history of falls, the validation sample also included participants with other self-reported risk factors. In both samples, similar measurements methods were used for outcome and predictors. The differences between the samples and settings became evident in the distributions of the included predictors and partly explain the lower discriminative ability of the tree in the validation sample.

Although the performance of the risk prediction model is less good in primary care than in the ED setting it may still be clinically useful. Because the (cost) effectiveness of both fall risk assessment and fall preventive strategies may be higher in older people with the highest fall risk, GPs might use the risk prediction model to select those persons. With this first selection, it will be possible to refer a smaller group of older persons to a comprehensive assessment. In both samples, high specificity and NPVs were obtained. The high NPV (84%) of the risk prediction model in the validation sample means that GPs will classify 84% of the persons at low risk of recurrent falling correctly. Only few (16%) older people who should be referred to comprehensive assessment will be incorrectly classified as low risk. In the older people who will be incorrectly classified as persons at high risk the comprehensive assessment will identify few risk factors and consequently costs for fall preventive strategies will be low.

The risk prediction model was not able to predict falling. The poor performance in predicting falling might be explained by the inclusion of persons with single (coincidental) falls. Due to the multifactorial nature of falls it is very hard to identify strong predictors for these coincidental falls. Although identification of risk factors in an early stage is still desirable to enhance primary prevention, this simple risk prediction model does not facilitate the prediction of a single and/or first fall.

Strength and limitations

A limitation of the study is the small sample size (n=269). Especially, the size of the subgroup of persons with high fall risk based on a previous fall (n= 167) was relatively small and results in wide confidence intervals meaning the results were less precise. To be able to calculate the diagnostic values, we used definitions of high risk wherein the usual annual risk for recurrent falling and falling was (nearly) doubled. The use of other definitions will directly change the diagnostic values.

Table 3 Baseline characteristics of both the validation and derivation sample

Variable	Validation sample (n= 269)	Derivation sample (n=408)
Age in years, mean (± SD) (range)	77.1 (4.6) (69-93)	77.9 (7.1) (65-96)
Female sex, n (%)	191 (71.0)	299 (73.3)
Previous falls, n (%)	167 (62.1)	408 (100)
Number of falls, median (IQR 25% -75%)	1 [0-2]	2 [1-2]
Medication use (yes), n (%)	263 (97.8)	392 (96.6)
Diuretics (yes), n (%)	94 (34.9)	102 (25.0)
Benzodiazepines (yes), n (%)	86 (32.0)	83 (20.3)
Living alone (yes), n (%)	133 (49.4)	245 (60.0)
High school education or higher, n (%)	186 (69.1)	205 (50.2)
Visual problems		
Difficulty reading, n (%)	41(15.4)	42 (10.3)
Use of walking aids, n (%)	92 (34.2)	84 (20.6)
Alcohol use (yes), n (%)	158 (58.7)	278 (68.1)
Glasses weekly, mean (± SD)	6.6 (7.0)	7.8 (6.7)
Co-morbidity		
COPD, n (%)	32 (12.1)	11 (2.7)
Cardio logical problems, n (%)	24 (9.1)	127 (31.1)
Diabetes, n (%)	55 (20.8)	38 (9.3)
Arthritis, n (%)	104 (39.4)	165 (40.4)
Cancer, n (%)	15 (5.7)	81 (19.9)
None, n (%)	38 (14.1)	103 (25.2)
Balance: BBS (0-56), mean (± SD)	51.5 (4.6)	-
Tandem stand n (%)		
Unable	-	134 (32.8)
Able 1-9 seconds	-	75 (18.4)
Able >=10 seconds	-	193 (47.3)
Fear of falling:		
FES (0-30), median (IQR 25 -75%)	4 [2-9]	1 [0-2]
VAS (0-10), mean (± SD)	-	3.5 (2.6)
Physical activity: PASE (0-356)[a], mean (± SD)	74.0 (44.1)	-
Functional status: GARS (18-72)		
n (%) in IQR [0-25%] : GARS <31.5[b]	218 (81.0%)	-
Functional status Barthel Index (0-20)		
n (%) in IQR [75%-100%], Barthel Index >15 [c]	-	377 (92.4%)
Functional status Lawton IADL (0-8)		
n (%) in IQR [75%-100%], Lawton IADL >6 [c]	-	269 (65.9%)
Mental health, mean (± SD)[d]		
SF-12, Mental component	-	52.0 (9.5)
SF-36, Mental component	70.5 (18.2)	-

IQR = inter quartile range [25%, 75%]; COPD = Chronic Obstructive Pulmonary Disease; BBS = Berg Balance Scale; FES = Falls Efficacy Scale; VAS= Visual Analogue Scale; PASE = Physical Activity Scale for the Elderly; GARS = Groningen Activity Restriction Scale; IADL= Instrumental Activities of Daily Living; SF-12 = Short Form 12; SF-36 = Short Form 36.

[a] range in this population: a higher score means more physical activity. [b] lower scores indicate better functional status. [c] higher scores indicate better functional status. [d] Higher scores indicate better mental health.

To our knowledge, few simple risk prediction models exceed an AUC of 0.70 and we pre-specified acceptable discriminative ability of the model as an AUC of 0.70 or higher. However, the determination of what is acceptable is arbitrary and also depends on the availability of alternative models. So far, we found no other publications concerning the external validation of available simple risk prediction models in primary care. The risk prediction model was developed and validated in RCTs, meaning large numbers of older persons refused consent and selection bias may have occurred. Finally, due to the small number of predictors (3) it is possible that important predictors were omitted and under fitting occurred. To confirm current results, repetition of the validation process in a larger population-based sample of older persons reporting themselves at the GP after a fall is needed.

CONCLUSION

In conclusion, taking into account the small sample size, the multi-causal nature of fall risk and the fact that few simple risk prediction models exceed an AUC of 0.70, we find the predictive validity of the risk prediction model appropriate for use in community-dwelling persons with a fall history in a primary care setting. The model is acceptable to predict the risk of recurrent falling but insufficient to predict the risk of a fall. This simple tool helps GPs to easily and quickly estimate which individuals do not need a comprehensive fall risk assessment.

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7

General Discussion

Despite increased focus on fall prevention, falls and fall-related injuries are still common among people aged 65 years and older. The main objective of this thesis was to evaluate the effectiveness of Tai Chi in the prevention of falling in community-living older persons. In addition, various options related to the prediction of fall risk in primary care were explored.

In this chapter, we first describe the main findings of this thesis. This is followed by a discussion about our findings in relation to other studies, and various theoretical and methodological aspects are addressed. Finally, recommendations are made for fall prevention in primary care, suggestions are made for future research, and some general conclusions are drawn.

EFFECTIVENESS OF TAI CHI

Due to the wide variability among older persons and health care settings, an effective strategy in one research setting may not be effective in another. One of the reasons to perform the randomised clinical trial (RCT) presented in this thesis, was that an earlier RCT (USA; published 1996) reported a reduction in fall rate of 47.5% in community-living older persons who practised Tai Chi for 1 hour twice a week for 15 weeks, compared to an educational control group without Tai Chi.[1] To evaluate the robustness and generalisation of this finding we evaluated the effects of a comparable Tai Chi intervention in a trial among Dutch community-living people aged 70 years and older with high fall risk (Chapter 2).[2] After 12 months follow-up no beneficial effects of Tai Chi could be demonstrated on the number of falls or the fall rates. In addition, no beneficial effects were found on the secondary outcomes, i.e. balance, fear of falling, physical activities and functional status.

More recently, there has been increasing evidence for the beneficial effects of exercise interventions, such as Tai Chi, in fall prevention in community-living older people. In 2003, this evidence was summarized in a comprehensive Cochrane review.[3] Of the 47 RCTs that reported the effects of fall prevention interventions, 23 evaluated exercise interventions but only one evaluated the effect of Tai Chi.[1,3] Five years later, the Cochrane review was updated and from the 111 RCTs, 43 evaluated exercise interventions of which five evaluated Tai Chi.[1,4-8] The RCT presented in this thesis was not included in that Cochrane review.

The evidence for a positive effect of exercise intervention on fall prevention is consistent over recent years and seems robust. Three separate meta-analyses concluded that exercise interventions are able to effectively reduce fall risk by 14-35% and reduce fall rate by 17-37%.[8-10] In these meta-analyses Tai Chi is regarded as one of the effective specific forms of exercise, although the evidence on Tai Chi alone is

less robust. Results of reviews specifically investigating Tai Chi are conflicting: two reviews concluded that Tai Chi effectively reduces falls, and two reviews concluded that there is only scattered evidence to support positive effects of Tai Chi.[11-14] Despite moderate and sometimes conflicting evidence, clinical guidelines seem to favour Tai Chi interventions.[15,16] However, the results of the RCT and meta-analysis presented in this thesis cannot support these recommendations.

Currently, most of the available evidence for lowering fall risk using exercise interventions is related to exercise that challenges balance.[8-10] Multi-component exercise interventions, and interventions that include gait or functional training, are also effective in reducing fall risk.[8] The integrated physical and cognitive components in Tai Chi might constitute an additional value of Tai Chi compared to other exercise programs which mainly focus on physical aspects. In general, balance improvement and reduction of fear of falling are considered to underlie the supposed beneficial mechanisms of Tai Chi.[1,4-6,10,12-14,17-28]

However, in the meta-analysis presented in this thesis we found only moderate evidence for the effects of Tai Chi on balance and fear of falling.[29] Moreover, effects on fall reduction and balance were only found when Tai Chi was compared to exercise controls, and not when compared to non-exercise controls. Possible explanations for these unexpected findings are discussed in Chapter 4. Thus far, it remains unclear which components of Tai Chi might be responsible for any positive results. Although exercise is effective in fall prevention, we found insufficient evidence for the specific effectiveness of Tai Chi.

High-risk population

Clinical guidelines recommend referring only older persons at high risk of falling to comprehensive fall risk assessment and if needed to subsequent interventions.[15,16,30] Until now, evidence on effects of exercise was mostly collected from unselected populations and the evidence from high-risk populations is conflicting. Two meta-analyses found no differences in effects between high-risk and unselected populations[8,9] while one meta-analysis found smaller effects in high-risk populations. Overall, the effects were positive in high-risk populations.[10] Thus, the evidence for the effects of Tai Chi in a high-risk population remains unclear.

In the RCT presented in this thesis, only high-risk participants were enrolled. High risk was based on self-reports of previous falls, balance problems, mobility problems, dizziness or medication use. The most reported and strongest risk factors for falling are previous falls and balance problems, indicating that high-risk populations include older persons who have previously fallen and have balance problems.[15] One recent meta-analysis found that gait problems, use of walking aids, vertigo, Parkinson disease and use of anti-epileptic drugs are most strongly associated with falls.[31] Indeed, the

majority of our population reported a previous fall, and predefined subgroup analysis showed fall rates were higher in this group compared to the group without a previous fall. As discussed in Chapter 2, the lack of effects of our Tai Chi intervention may be because, at baseline very few older persons had a high fall risk based on balance problems or high levels of fear of falling, indicating that the Tai Chi intervention may not have been well targeted. Moreover, only two risk factors, i.e. balance problems and mobility problems were modifiable by exercises.

In earlier meta-analyses, effects of exercises were evaluated in subgroups of high-risk populations, but high risk was defined in different ways (e.g. living situation and incidence rates falls control group) and different methods were used. Meta-regression techniques describe observational relationships across studies and might therefore be influenced by confounders that vary between the trials.[32] Subgroup analyses may overcome confounding problems, but are often hampered by small study numbers making it impossible to draw firm conclusions.

In the meta-analysis presented in this thesis, the characteristics of the high-risk subgroups varied considerable between the RCTs.[29] This hampered analysis, and no subgroup analysis on high-risk populations could be performed.

Intervention dosage

The RCT presented here evaluated a low-dose Tai Chi intervention (< 50 hours), for which adherence was relatively low. It is possible that the dosage was too low to achieve positive effects. However, in previous studies both low and high-dose Tai Chi proved to be effective.[1,4,5,7] One meta-analysis on exercise showed greater relative effects in higher dose programs, but in Tai Chi the presence of a positive dose-effect relation has not yet been evaluated.[10,29]

In our meta-analysis the aim was to obtain more insight into the dose-effect relationship; however, the small number of included studies and the differences in reported adherence hampered the subgroup analyses. Therefore, the minimal dose of Tai Chi needed to achieve positive results on fall prevention remains unclear.

Adherence

Besides the frequency and duration of the group sessions, dose is strongly influenced by adherence rates and home-based practice. Furthermore, we often found that data on adherence were missing or reported in different ways. The process evaluation running parallel to our RCT showed adherence rates to be (very) low because 25 participants (18%) did not start with the intervention and 24 participants (17%) withdrew because of health problems during the intervention (Chapter 4). Also, many participants did not perform their home exercises, mainly because they had forgotten the Tai Chi positions. Other low-intensity exercise programs, like the Nijmegen Falls

Prevention Program (a five-week program), indicate that it is easier to incorporate these programs in daily life because exercises are practised in simulated potentially hazardous situations of daily life, which will be more familiar.[33] This theory is in line with a study by Clemson and colleagues (2010), who found that an individualised home-based program which incorporates balance and strengths training principles into daily living activities (LiFE) proved to be more effective in reducing fall risk compared to another exercise program consisting of balance and strengths exercise but non-functional tasks.[34] However, RCTs comparing Tai Chi with these programs are needed to evaluate this hypothesis.

Outcomes

Falls

The outcome of fall prevention interventions may vary considerably depending on the definitions and measurement tools used. Falls have been defined in different ways and the use of an operational definition is needed for adequate interpretation of the results of different studies.[8,35,36] The variation in the way falls are identified and analysed is even broader. The most effective way to identify falls is by self-report, i.e. filling out fall calendars on a daily basis, which is often considered the gold standard of measuring falls.[37,38]

In 2005, a common set of outcome definitions and measures for future trials and meta-analyses was developed by the Prevention of Falls Network Europe (ProFaNE) to standardise the definitions and measurements used in fall prevention research, and to facilitate the collaboration necessary for large-scale clinical research.[39] At the time we started the RCT described here, these recommendations were not yet available; however, in our study, the definitions and measurements methods used for falls are in line with the ProFaNE recommendations.

For future trials, ProFaNE emphasises the need to summarise fall data (at least) as the number of falls, number of fallers (c.q. non-fallers, frequent fallers), fall rate per person-years of follow-up, and time to first fall.

Currently, fall data are analysed in many different ways. In RCTs, using the number of (multiple) fallers or the number of falls results in fall risk or fall rates, respectively. The effects in fall risk are summarised as relative risk (RR) or hazard ratio (HR). Both measures compare the number of fallers in the intervention group with the control group, but in the hazard ratio the time to the first (or second) fall is taken into account. By summarising effects in fall risk, the power of the study will decrease. The effects in fall rate are summarised as incidence rate ratio or hazard ratio. Both ratios compare the number of falls per person in the intervention group with the control group, taking the individual follow-up time into account. Different statistical models

are used which require that other assumptions be checked (e.g. the hazard ratio is assumed to be constant over time). In the RCT described in this thesis, hazard ratios were calculated with survival analysis models which allow adjustments to be made for confounding variables, follow-up time of individual participants, and recurrence of falls (multiple falls per person) in a non-normal distribution.[2,40]

Fall-related outcomes

When evaluating a fall prevention intervention, domains other than falls (e.g. psychological consequences, health-related quality of life) also need to be considered.[39] When evaluating Tai Chi, especially the effects on potentially inter-related outcomes like balance, fear of falling and activity levels, need to be considered.

Insight into which components of Tai Chi might be responsible for positive results on lowering fall risk and fall rate might help to better target the application of Tai Chi. For example, the level of activity and the presence of unsafe behaviours related to fear of falling might influence the effects of Tai Chi. If Tai Chi is able to increase the level of activity, risk of recurrent falling might be reduced.[41] If Tai Chi reduces the fear of falling, this might lead to an overestimation of one's capacities, which might initiate unsafe behaviours and risk of falling may increase. The process evaluation showed that most of the Tai Chi participants in our trial felt that they behaved more safely and were less concerned about falling. Also, they felt they did not change with regard to avoidance of activities, indicating that they did not overestimate their capabilities.[42]

HIGH-RISK ASSESSMENT

Not every fall is preventable but, given the individual burden and the societal costs, the prevention of falls is desirable. To improve cost-effectiveness in both clinical practice and research settings the identification of older persons with high-fall risk who might benefit from targeted prevention interventions is recommended. In the recently updated (2010) clinical guidelines of the American and British Geriatric Society and the American Academy of Orthopaedic Surgeons Panel on Falls Prevention (AGS/BGS), health care providers are recommended to screen all older persons aged 65 years and over once a year for fall risk. Using a two-step strategy, older persons with high fall risk are to be identified in a screening or 'case-finding' process, followed by a comprehensive assessment wherein individual modifiable risk factors are identified. The comprehensive assessment includes history taking, physical examination, functional assessment and environmental assessment.[15]

The case-finding process is primarily aimed at secondary prevention and is based on the detection of two important independent risk factors for falling: falls history and

balance deficits. If a person seeks care after a fall, or fell twice or more in the prior year (recurrent faller) or reports difficulties with walking or balance, direct referral to comprehensive fall risk is recommended. If a person sustained a single fall in the prior year, a performance test of balance is recommended, followed by referral to comprehensive assessment if balance deficits are found.

However, if a person presents with an acute fall or a single fall in the prior year, a clinician has to estimate whether this fall was 'just an occasional fall' or 'the first fall of recurrent falling'. Recurrent fallers may be more in need of preventive measures as recurrent falls are usually caused by physical, cognitive and behavioural factors 'within' the person. Occasional falls are more often coincidental and may be caused by environmental factors.[43] Due to the multi-factorial origin of falling, the variability in community-living older persons and interactions between risk factors, the use of individual prognostic models wherein absolute risks are assessed might be helpful in the case-finding process.

Risk prediction models in primary care

Risk prediction models consist of different combinations of risk factors. A simple risk prediction model, consisting of three easily measurable predictors (i.e. falls history, use of walking aids and fear of falling) was developed by Peeters and colleagues (2010) using data from participants of a fall prevention trial.[44]In the developmental sample most participants (90%) sought care in Emergency Departments after their fall. We performed an external validation of this simple risk prediction model in the dataset of our Tai Chi trial to predict recurrent falling in community-living persons aged 70 years and older. Participants of our Tai Chi trial were selected based on high fall risk reported in the files of their general practitioner (Chapter 6).[45] The discriminative ability of the risk prediction model was moderate, but specificity was high. This meant that the model predicted the risk of becoming a non-recurrent faller better than it did the risk of becoming a recurrent faller.

Since the release of the national multidisciplinary guideline 'Prevention of fall incidents in older persons' in 2004[16], several risk prediction models for identifying community-living older people with high fall risk in primary care have been developed.[44,46-51] However, only three of these models have been externally validated.[45,51,52] All three risk prediction models used recurrent falling as outcome, but this was defined in different ways. Both the simple model presented in this thesis and the LASA fall risk profile defined recurrent falling as $\geq$ 2 falls within six months, whereas the third tool defined recurrent falling as $\geq$ 2 falls within one year. Therefore, comparison of predictive values of the three models is difficult.

In line with the LASA fall risk profile, our risk prediction model had a moderate predictive value and predicted the risk of becoming a non-recurrent faller better than

it did the risk of becoming a recurrent faller. Comparable results were found in the subgroup of participants who fell in the year prior to the study (Chapter 6). Both risk prediction models are easy to administer, but some attributes (e.g. grip strengths dynamometer) are necessary and more time is needed to administer the LASA fall risk profile.

For the case-finding process in older community-living persons, the risk prediction model presented in this thesis seems valid, and the easiest and quickest tool to select persons at low risk of falling. Nevertheless, use of the risk prediction model for identification of modifiable risk factors to target fall prevention interventions is not yet evaluated.

Diagnostic values

The case-finding process should, preferably, identify all older persons with high fall risk for recurrent falling; in this case the sensitivity of the case-finding process instrument should then be high. However, if sensitivity is too high then too many persons with low fall risk will be referred to comprehensive assessment, and the added value of the screening process will then become questionable. Therefore, case-finding process instruments should have a higher specificity than sensitivity. Currently, risk prediction models that were validated in primary care have higher specificity than sensitivity and therefore seem suitable for the selection of high-risk persons in the general population.

The accuracy of the screening questions recommended in the AGS/BGS guidelines for case finding in the general populations is not adequately evaluated, and little is known about the diagnostic values.[15] The case finding in persons who sustained a single fall in the prior year is not optimal, as the predictive ability of the recommended balance performance screening tests for future falls is moderate.[47] Moreover, risk factors other than balance (e.g. fear of falling) might be responsible for the fall risk of a single faller.[53] In line with the simple risk prediction model presented in this thesis, the recommended balance performance tests have higher specificity than sensitivity. Two out of four recommend tests have lower discriminative ability than the simple model presented in this thesis (AUC 0.56-0.61;confidence intervals not reported). A wide range of sensitivity values (0.23 to 0.80) were reported and for two tests no diagnostic values were reported.[15,47] In contrast to the simple model presented in this thesis, all balance performance tests predict fallers instead of recurrent fallers, which might explain the lower diagnostic values.

Content

Given the strict time constraints in a primary care consultation, only a simple model will be feasible. Preferably, a comprehensive assessment should be made of the medi-

cal condition of the older person by a specialist, as complex trade-offs must be made. More specialised risk prediction models may be used. The 'easy to use in clinical practice' models include easy to assess factors like falls history, female sex, living alone, use of a walking aid, medication use, fear of falling, and functional tests for balance, strength and reaction time. However, risk prediction models vary across professions and setting. For example, physiotherapists are likely to use models consisting of (balance) performance tests,[51] while general practitioners are more likely to use models consisting of medication review, chronic diseases and psychosocial factors necessary to decide the most appropriate care or referral for their patients.[49].

Whether older people sustained previous falls is a factor included in nearly all risk prediction models; it appeared to be the strongest predictor for future falls. However, it is a non-modifiable risk factor and, until now, little is known about why it is such a strong risk factor. Better understanding of the mechanisms behind the predictive role of previous falls might be the key to better selection and treatment of high-risk groups.

Outcomes

Risk prediction models may predict different outcomes. In general, risk prediction models predict either the risk of becoming a faller or the risk of becoming a recurrent faller. Falls are sometimes classified by the injury that is reported, but classifications of injurious falls vary and minor injuries are underreported.[47] One study showed that just over half of the screening instruments for predicting fall risk among independently living older people used 'falls' as outcome; the other instruments used 'recurrent falls' or 'injurious falls'. This lack of standardisation hampers the evaluation of screening instruments for fall prediction.[36]

Minor injuries

Nowadays, different primary care workers (e.g. general practitioners, physiotherapists, occupational therapists and nurses) feel responsible for the case finding of people at risk. However, 55 to 70% of all falls results in physical injury of which only 20% requires medical attention.[8,54,55] Consequently, most injurious falls will be related to minor injuries and no medical care for these falls will be sought. Little is known about falls related to minor injuries and the impact these falls might have on a faller.[56-58]

To obtain more insight into falls related to minor injuries, we carried out an exploratory study in which circumstances related to these falls were registered (Chapter 5). Proportions of falls resulting in injuries are in line with other studies, and differences between studies can probably be explained by the use of different definitions of falls, injurious falls and high fall risk.[59-61]

Circumstances studied were categorised by fall type, time and location (outside or inside). The most common fall types in our study were falls due to slipping, tripping and stumbling, which is in line with previous findings in older women.[62] However, the categories studied are non-modifiable to interventions and more detailed information on the activity at the time of the fall may help to optimise prevention interventions.

The explorative risk prediction models suggested that falls resulting in minor injuries can be moderately well discriminated from non-injurious falls. These findings are in line with data from Vellas and colleagues (1998), indicating that it is possible to discriminate between falls and falls related to minor injuries in a screening process.[63]

RECOMMENDATIONS

Recommendations for primary care

First, we recommend that primary care physicians pay more attention to primary prevention, because a previous fall is a strong predictor for future falls. We advise the use of community strategies to promote the potential benefits of exercise, rather than focusing on falls. General practitioners could play a key role in this, as a routine screen (once a year) of all older persons aged 65 years and over for fall risk might be an effective starting point to evaluate activity levels and to promote exercises.[64,65]

Second, the national Dutch guidelines for the prevention of falls in community-living older people should be updated to include new evidence on the exercises clinicians might decide upon when considering which exercises will probably work best for their patients.

Third, the need to use validated risk prediction models in the case finding should be emphasised. This is because, currently, both the national Dutch guideline and the AGS/BGS guidelines recommend using instruments that are not validated, and are primarily based on the presence or absence of the two important independent risk factors for falling.

Finally, as primary care plays a key role in the primary and secondary prevention of falls, more attention should be paid to fall prevention in the basic and specialised curricula of primary care workers. Fall prevention should be included in on-going education programs, because new evidence is rapidly accumulating. For example, if an older person has a high fall risk based on previous falls, a clinician might prescribe exercises when it seems plausible that lack of exercise is a causal factor and this is related to activity restriction and/or loss of confidence.[8-10] However, one might also refer the older person to a successful cognitive behavioural program when fear of falling is present.[66]

Recommendations for future research

Several issues need further investigation.

First, the case finding of older persons with high fall risk needs further validation. Second, we suggest to evaluate the effect of the simple risk prediction model (presented in this thesis) on the selection of older persons at high risk if used for persons who present themselves with an acute fall or a single fall in the previous year.

Third, we need to establish why a previous fall is such a strong predictor for a future fall. Differentiation in fall status (i.e. single fallers or recurrent fallers) might be helpful when risk factors for recurrent falling are evaluated. Furthermore, longitudinal ageing studies which collect information on the consequences of falling after an injurious fall and during follow-up might be helpful. More detailed assessment of behaviours in daily activities like activity level, balance performance and the (dis)use of assistive devices in relation to concepts like fear of falling and self-efficacy before and after a (injurious) fall might help to elucidate this topic.

Fourth, more research is needed to establish whether it is useful to differentiate between falls with or without minor injuries in the case finding process.

Fifth, to facilitate comparison between risk models predicting recurrent falling, the time period between two falls should be standardised (e.g. 6 months or 1 year) or outcome on both time periods should be reported.

Sixth, the development of effective exercise interventions in older persons with high fall risk needs further attention.

Seventh, if exercise interventions on effectiveness are evaluated, for future studies we strongly recommend compliance with the common set of outcome definitions and measures as presented by ProFaNE, to facilitate comparison between trials. Furthermore, consensus should be reached regarding outcome measures involving balance, fear of falling and physical activities, as well as the definition of a high-risk population. In line with others, we recommend to use negative binomial regression models for evaluation of the effects of fall prevention programs.

Eight, dosage, exercise uptake and adherence are important aspects when evaluating the effect of exercise interventions; the influence of these aspects also needs further investigation.

Finally, more data are needed about the effects of Tai Chi on balance and fear of falling in direct relation to falling, when Tai Chi is used as a fall preventive exercise intervention in community-living older people.

GENERAL CONCLUSIONS

Currently there is insufficient evidence to conclude whether or not Tai Chi is effective in fall prevention, in decreasing the fear of falling, and improving balance in older community-living people. A simple risk prediction model consisting of three easily measured predictors (i.e. fall history, use of walking aid and fear of falling) was validated in community-living people in the Netherlands who consulted their general practitioner. Given the high specificity (86%) of this model we suggest to evaluate the effects of the model on the selection of older persons at high risk who are suitable for subsequent referral for comprehensive assessment in primary care.

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Summary

Worldwide, one of the major health concerns in older people is falling. In developed countries, each year approximately 30% of community-living persons aged 65 years and older experiences a fall. Falls in older people may have several adverse consequences. Physical injuries are registered in 55 to 70% of the fall incidents. Of the fall-related injuries, fractures (which occur in 5% of the falls) account for the majority of the costs, morbidity and mortality. The majority of fall related physical injuries results in minor injuries (like bruises) in which no medical attention is needed; the adverse consequences of these falls are less well registered. Common fall related adverse consequences include functional decline and loss of independence. In addition, a fall may lead to adverse psychosocial and behavioural consequences like fear of falling and restriction in activities. Given the individual burden of falls and the societal costs, prevention of falls is desirable.

Fall prevention preferably aims at identifying people with high fall risk (i.c. case-finding) and tailors the fall preventive strategy for a specific person. Only few strong risk factors for falls are identified. History of falls is the most mentioned independent risk factor for falling and currently the case-finding process recommended in clinical guidelines primarily consists in the identification of previous falls. Due to the multifactorial origin of falling, the variability in community-living older persons and interactions between risk factors, the use of individual risk prediction models wherein absolute risks are assessed might be helpful in the case-finding process.

Reviews, meta-analyses and guidelines report exercise training including balance training are likely to be beneficial to prevent falls. One of the most promising exercise interventions is Tai Chi. Tai Chi originally is a martial art but nowadays taught and practised as an integral part of the Traditional Chinese Medicine and more often practised as a healing art. A low dose Tai Chi programme reduced highly effectively the fall rate of American community-living older persons by 47.5% compared to an educational control group. To evaluate the robustness and generalisation of this finding we evaluated the effects of a comparable Tai Chi intervention in a randomised clinical trial (RCT) among Dutch community-living people aged 70 years and older with high fall risk.

Chapter 1 is a general introduction to the research subject. It reports on the incidence and consequences of falls and the risk factor and predictors for falls in community-living older persons. In addition it considers some aspects in fall risk assessment and fall preventive strategies and Tai Chi as a fall prevention intervention.

The main objective of this thesis is to explore the effectiveness of Tai Chi in the prevention of falling in community-living older persons in The Netherlands and to explore various options concerning the prediction of falls in primary care.

Chapter 2 presents the results of the RCT evaluating the effectiveness of a Tai Chi intervention compared to usual care, in Dutch community-living people aged 70 years and older with high fall risk. High fall risk was defined as one or more self-reported fall incidents in the year previous to 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. A total of 269 participants were enrolled and randomly allocated to the Tai Chi intervention (n=138) or usual care group (n=131). At baseline, both groups received a brochure explaining how to prevent falls in and around the house. The intervention group received 1 hour of Tai Chi training twice a week for 13 weeks. After 12 months follow-up there were no significant differences between the groups concerning falls rates, balance, fear of falling, physical activities and functional status. When participants who attended 80% of the lessons or more were compared to the usual care group, comparable results as in the intention to treat analysis were found. In the predefined subgroup of participants who had high fall risk based on a previous fall (n=167) the fall rates were higher but difference was also statistically non-significant. We concluded that Tai Chi may not be effective in older community-living persons with high fall risk.

The objective in **Chapter 3** was to gain insight in the process related factors that may have influenced the effectiveness of our Tai Chi intervention. This process evaluation showed no major protocol deviations were made. Of all participants allocated to the intervention group a small minority reached our definition of being sufficient adherent (visiting at least 80% of the lessons). The adherence to the intervention was not optimal and the most common reasons for non-adherence were health problems of the participants or spouse. All participants and instructors were positive about the intervention and reported intervention benefits like "feeling better" and increased physical activity and balance. The main-process related factors that may have influenced the lack of beneficial effects on falls, balance, fear of falling and other outcome are the relatively high withdrawal and low adherence rates.

Chapter 4 presents the results of the meta-analysis on the effects of Tai Chi on fall prevention, fear of falling and balance in older people. A total of 15 RCTs were included and the results of nine RCTs could be used to calculate overall estimates of effects. Pooled results of trials comparing Tai Chi versus exercise controls indicated a large significant improvement in fall rate (49%) and small improvements in static balance and fear of falling. However, the pooled results of trials comparing Tai Chi versus non-exercise controls indicated smaller and statistically non-significant improvements in fall rates (21%) and static balance. For fear of falling improvements stayed small

and statistically significant. The nature ship of the relations between falls and balance, and falls and fear of falling remains unclear. Due to the limited number of studies no firm conclusions could be made in our subgroup analyses regarding setting (community versus facility), intervention dose (< 50 hours and ≥ 50 hours) and duration of follow-up (post-treatment versus follow-up). Effects became larger when dose was higher and therefore the presence of a positive dose-effect relation is highly likely.

We found insufficient evidence to conclude whether Tai Chi is effective in fall prevention, decreasing fear of falling and improving balance.

Chapter 5 reports on an explorative study wherein a predictive model was built for falls related to minor soft tissue injuries using data from our Tai Chi trial. In a prediction model including nine variables we were able to discriminate correctly in 71% of the cases between falls related to minor soft tissue injuries and non-injurious falls. In a model including age, female sex, previous falls (yes) and fear of falling we were able to discriminate correctly in 67% of the cases. Results indicate it is possible to discriminate between falls related to minor injuries and non-injurious falls.

In **Chapter 6** we performed an external validation study in the dataset of our Tai Chi trial of a simple risk prediction model consisting of three easily measurable predictors (i.c. falls history, use of walking aids and fear of falling) to predict recurrent falling in community-living persons aged 65 years and older who seek care after a fall. The simple risk prediction model was developed by Peeters et al. (2010) using the data from participants of a fall prevention trial. The discriminative ability of the risk prediction model was moderate (AUC= 0.64; 95% CI 0.37-0.88), but specificity was high (86%; 95% CI 82-91). This meant that the model predicted the risk of becoming a non-recurrent faller better than the risk of becoming a recurrent faller. For the case-finding process in older community living persons aged 65 years and over, the risk prediction model presented in this thesis seems valid and the most easiest and quickest tool to select persons at low fall risk. Nevertheless, usage of the risk prediction model for identification of modifiable risk factors to target fall prevention interventions is not evaluated.

Chapter 7 summarizes and discusses the main findings of the studies presented in this thesis. Considerations in using exercises as Tai Chi as fall prevention intervention and considerations regarding fall risk assessment are made. Finally, recommendation for primary care and future research are given. On the whole, we found insufficient evidence to conclude whether Tai Chi is effective in fall prevention, decreasing fear of falling and balance improvement in older community-living people. Nevertheless, falls still have an important impact on the individual and the society and therefore we recommend primary care physicians to routinely screen (once a year) all older persons aged 65 and over for fall risk. We suggest evaluating the effect of the simple risk prediction model presented in this thesis on the selection of older persons at high risk and subsequent referral for comprehensive assessment in primary care.

Samenvatting

Vallen is wereldwijd één van de grootste gezondheidsproblemen bij ouderen. In westerse landen valt ongeveer 30 % van de zelfstandig wonende ouderen van 65 jaar en ouder één of meer keer per jaar. Valincidenten bij ouderen kunnen leiden tot verschillende negatieve gevolgen. Ongeveer 55 tot70 % van de valincidenten heeft lichamelijk letsel tot gevolg, bij 5 tot 6 % gaat het om ernstig letsel zoals een heupfractuur. Van alle val gerelateerde letsels nemen fracturen het grootste deel van de medische kosten en de verhoogde kans op morbiditeit en mortaliteit voor hun rekening. De meeste val gerelateerde letsels zijn echter niet zo ernstig (bv. blauwe plekken); medische hulp is vaak niet nodig en mede hierdoor is minder bekend over eventuele negatieve gevolgen. Andere veelgenoemde negatieve gevolgen van vallen zijn het ontstaan van functionele beperkingen en verlies van zelfstandigheid. Tenslotte heeft vallen vaak ook negatieve psychosociale en gedragsmatige gevolgen, zoals angst om te vallen en het vermijden van bepaalde activiteiten. Gezien de negatieve impact die een valincident kan hebben op de ouderen en de samenleving is het belangrijk om preventieve maatregelen te nemen om vallen te verminderen.

Preventie maatregelen richten zich meestal éérst op het opsporen van ouderen met een hoog valrisico (case-finding). Vervolgens wordt in deze hoog risico groep uitgebreid gezocht naar beïnvloedbare risicofactoren en indien noodzakelijk wordt uiteindelijk gericht een passende preventieve interventie ingezet. Een val in het verleden wordt als een belangrijke voorspeller voor toekomstige vallen gezien en is tot op heden één van de weinige sterke risicofactoren voor vallen die zijn geïdentificeerd. In de huidige valrichtlijnen speelt de valgeschiedenis dan ook een belangrijke rol bij de identificatie van ouderen met een hoog valrisico. Een prognostische model waarmee het absolute valrisico van een individu kan worden ingeschat zou gezien de multifactoriële oorzaak van vallen, de diversiteit onder zelfstandig wonende ouderen en de interacties tussen verschillende valrisicofactoren de "case-finding" positief kunnen ondersteunen.

Reviews, meta-analyses en richtlijnen concluderen dat oefentherapie -met name die gericht zijn op balansverbetering- zeer waarschijnlijk kan bijdragen aan het verminderen van het valrisico. Een veelbelovende vorm van oefentherapie is Tai Chi, een Chinese bewegingsleer. Tai Chi is van oorspronkelijk verspreid als een vechtkunst, maar wordt tegenwoordig veel gebruikt binnen de traditionele Chinese geneeskunst met als doel de gezondheid te bevorderen. In Amerika, was een laag gedoseerde

Tai Chi interventie in staat het valrisico van de Tai Chi beoefenaars met 47,5 % te verminderen in vergelijking tot de deelnemers van een controlegroep die een educatief programma volgden. Om de geldigheid van deze resultaten te evalueren in een Nederlandse situatie hebben we een vergelijkbare Tai Chi interventie aangeboden aan zelfstandig wonende Nederlandse ouderen van 75 jaar en ouder met een verhoogd valrisico en geëvalueerd door middel van een gerandomiseerd en gecontroleerd experimenteel onderzoek (RCT).

Hoofdstuk 1 geeft een overzicht van de incidentie en de gevolgen van valincidenten bij zelfstandig wonende ouderen, evenals de risico factoren en predictoren van vallen, preventie en Tai Chi als preventieve maatregel. Het belangrijkste doel van dit proefschrift is het vaststellen van de effectiviteit van Tai Chi, gericht op het voorkomen van valincidenten bij zelfstandig wonende ouderen in Nederland. Daarnaast worden verschillende mogelijkheden onderzocht om valrisico te voorspellen in de eerste lijn Gezondheidszorg.

Hoofdstuk 2 presenteert de resultaten van de RCT naar de effectiviteit van Tai Chi op het valrisico van zelfstandig wonende ouderen (70 jaar en ouder) in Nederland met een verhoogd valrisico. Verhoogd valrisico was gedefinieerd als "voorafgaand aan de studie gevallen of bij de huisarts bekend met minstens twee van de volgende risicofactoren: balansproblemen, mobiliteitsproblemen (gebruik rollator), duizeligheid en het gebruik van benzodiazepines of diuretica". De geselecteerde deelnemers werden willekeurig aan de interventiegroep (n=138) of aan de controlegroep (n=131) toegewezen. Alle deelnemers ontvingen op baseline een informatiebrochure over de mogelijkheden het valrisico in en om het huis te verminderen. De ouderen uit de controlegroep kregen de gebruikelijke zorg (bv het bijstellen van medicatie indien nodig). De ouderen uit de interventiegroep kregen daarnaast gedurende 13 weken, twee keer in de week, één uur Tai Chi Chuan groepstraining. Na twaalf maanden waren er geen significante verschillen te zien tussen de twee groepen ten aanzien van het aantal valincidenten, balans, valangst, fysieke activiteit en zelfredzaamheid. De resultaten van de ouderen die 80% of meer van de lessen gevolgd hadden waren vergelijkbaar met die van de totale groep , die volgens het "intention-to treat" principe waren geanalyseerd. In de subgroep van ouderen die in het jaar voorafgaand aan de studie gevallen waren er meer valincidenten binnen de Tai Chi groep dan de controle groep, maar het valrisico was niet significant verschillend tussen de groepen. We concludeerden dat we niet kunnen aantonen dat Tai Chi effectief is om het valrisico te verminderen bij zelfstandig wonende ouderen met een verhoogd valrisico.

Hoofdstuk 3 beschrijft de procesevaluatie die naast de effectevaluatie werd uitgevoerd om meer inzicht te krijgen in proces gerelateerde factoren die mogelijk van invloed zijn op de effectiviteit van de Tai Chi interventie. Uit de analyse bleek dat er

geen grote veranderingen in het protocol waren uitgevoerd. Een kleine minderheid van de deelnemers beantwoorde aan de door ons vooraf opgestelde definitie van therapietrouw (80% of meer van de lessen volgen). De therapie trouw was niet optimaal en de meest voorkomende redenen hiervoor waren gezondheidsklachten van de deelnemer of de partner. Alle deelnemers en Tai Chi docenten waren tevreden over de Tai Chi interventie en rapporteerden positieve effecten zoals zich beter voelen, en een toename in fysieke activiteit en balans. De belangrijkste proces gerelateerde factoren die verantwoordelijk lijken voor het uitblijven van effect zijn de relatieve hoge uitval en lage therapietrouw.

Hoofdstuk 4 presenteert de resultaten van de meta-analyse naar de effecten van Tai Chi op vallen, valangst en balans. In de meta-analyse werden 15 RCTs geïncludeerd, waarbij de resultaten van negen RCTs gepoold konden worden om overall effectschattingen te berekenen. Het poolen van de resultaten van de RCTs waarbij Tai Chi vergeleken werd met actieve controle groepen resulteerde in grote significante effecten op het valrisico (49% reductie) en kleine significante veranderingen op "statische balans" en valangst. Daarentegen resulteerde het poolen van de resultaten van de RCTs waarbij Tai Chi vergeleken werd met niet-actieve controlegroepen in kleinere en niet-significante effecten op het valrisico (21% reductie) en "statische balans". In deze vergelijking bleven de effecten van Tai Chi op valangst klein en significant. De aard van de relaties tussen Tai Chi, balans, valangst en vallen blijft hierdoor onduidelijk. Door de kleine aantallen geïncludeerde RCTs per subgroep konden we geen duidelijke conclusies trekken over de effectiviteit bij ouderen in verschillende woonsituaties (zelfstandig en verzorgingshuis), de effectiviteit bij lage of hogere dosering (< 50 uur en ≥50 uur) en de effectiviteit op korte en lange termijn. In het algemeen werden de effecten groter bij hogere doseringen, waardoor de aanwezigheid van een positieve dosis-effect relatie zeer waarschijnlijk lijkt. We vonden onvoldoende bewijs om conclusies te kunnen trekken over de effectiviteit van Tai Chi op vallen, valangst en balans.

Hoofdstuk 5 doet verslag van een explorerende prospectieve studie, waarin wordt onderzocht welke predictoren nieuwe valincidenten voorspellen die gepaard gaan met licht letsel. In een risicomodel bestaande uit negen predictoren liet zien dat 71% van de vallen gepaard gaande met licht letsel en vallen zonder letsel correct onderscheiden worden. In een risicomodel bestaande uit de variabelen leeftijd, geslacht, valgeschiedenis en valangst werden 67% van de vallen correct onderscheiden. De resultaten laten zien dat het mogelijk is om te voorspellen of een oudere bij een val "licht letsel" of "geen letsel" zal oplopen.

Hoofdstuk 6 rapporteert over een validatie studie van een eenvoudig valrisicoprofiel die de kans op herhaald vallen voorspeld met drie vragen over valgeschiedenis, loophulpmiddel en valangst, die is uitgevoerd met data van onze Tai Chi RCT. Het eenvoudige profiel is ontwikkeld door Peeters e.a. (2010), waarbij data uit een effec-

tiviteits onderzoek naar valpreventie werden gebruikt. Het discriminerende vermogen van het eenvoudige profiel was matig (AUC = 0.64; 95% CI 0.37-0.88), maar de specificiteit was hoog (86%; 95% CI 82-91). Dit betekent dat het profiel beter in staat was om de groep ouderen te identificeren waarbij de kans op herhaald vallen klein is dan de groep ouderen waarbij de kans op herhaald vallen groot is. De onderzoeksgroep bestond uit een gemengde groep van ouderen die óf nog nooit gevallen was, óf één keer gevallen was of vaker gevallen was en onder behandeling van de huisarts stond. Binnen de screening van ouderen op valrisico lijkt dit profiel op een valide, makkelijke en snelle manier ouderen met een laag valrisico te kunnen opsporen. Of het model ook geschikt is voor het opsporen van beïnvloedbare risicofactoren en de beslissing of een oudere valpreventieve maatregelen nodig heeft is niet onderzocht. Eerste lijns gezondheid professionals zouden het profiel met name kunnen gebruiken om snel in te schatten welke ouderen geen uitgebreide valrisico inventarisatie nodig hebben.

Hoofdstuk 7 bespreekt de belangrijkste bevindingen van dit proefschrift en geeft een beschouwing van de huidige stand van zaken met betrekking tot het gebruik van oefentherapie zoals Tai Chi als preventieve maatregel en verschillende mogelijkheden om valrisico te voorspellen. Tenslotte worden er aanbevelingen gegeven voor valpreventieve maatregelen in de eerste lijn gezondheidszorg en toekomstig onderzoek. Samengevat hebben we onvoldoende bewijs gevonden dat Tai Chi een effectieve interventie is voor het verminderen van het risico op vallen, het verbeteren van de balans en het verminderen van valangst bij zelfstandig wonende ouderen. Niettemin blijft vallen één van de grootste gezondheidsproblemen bij ouderen en daarom is onze aanbeveling dat eerste lijns gezondheidsprofessionals op regelmatige basis (één keer per jaar) blijven zoeken naar ouderen van 65 jaar en ouder met een verhoogd risico op vallen. Daarnaast zou het effect van het gebruik van het eenvoudige valrisico profiel binnen de "case-finding" zoals toegepast in de eerste lijn gezondheidszorg geëvalueerd kunnen worden.

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Inge

Curriculum Vitae

Inge Logghe is op 24 juli 1970 geboren te Valkenisse. Na het behalen van haar VWO diploma aan het St. Willibrord College te Goes startte zij in hetzelfde jaar de opleiding tot fysiotherapeut aan de Hogeschool West-Brabant. In 1992 rondde zij deze opleiding af en startte zij met de opleiding "Kort Bewegingswetenschappen" (KBW) aan de universiteit van Maastricht waar zij in 1994 afstudeerde. Tussen 1992 en 2000 werkte zij als fysiotherapeut in diverse settings. In 1996 werd ze aangesteld als hogeschooldocent bij de opleiding fysiotherapie aan de Hogeschool West-Brabant. In april 2007 startte zij als gastonderzoeker op de afdeling Huisartsgeneeskunde van het Erasmus MC, waar zij werkte aan de in dit proefschrift beschreven studies. Momenteel is zij werkzaam als hogeschooldocent bij de Academie voor Gezondheidzorg Onderwijs van de Avans Hogeschool, waar zij betrokken is bij diverse onderwijsprogramma's rondom ouderen en wetenschap.

PhD training

General academic skills	
Biomedical English Writing and Communication, 2009	1,4 ECTs
Research skills	
Interne Cursus STATA (vakgroep Huisartsen Geneeskunde), 2009	16 hours
Presentations	
Annual Conference of the Royal Dutch Society for Physical Therapy (KNGF) 2007, Amsterdam (oral presentation)	20 hours
Annual Conference of the Dutch College of General Practitioners (NHG) 2008, Rotterdam (oral presentation)	20 hours
International Conferences	
Annual Scientific Meeting of the Gerontological Society of America (GSA)	
2008, Washington (oral presentation)	20 hours
2009, Atlanta (abstract accepted, oral presentation)	
2010, New Orleans (oral presentation)	20 hours
XIXth World Congress of Gerontology and Geriatrics IAGG, 2009, Paris (2 poster presentations)	32 hours
Seminars and Workshops	
Kenniskring Gerontologie:	
"Slotconferentie RAAK", 2008 (workshop)	10 hours
"Broodje Gezond", 2010 (workshop)	10 hours
Kennisnetwerk Valpreventie:	
Hoofddorp, 2008 (oral presentation)	20 hours

TEACHING ACTIVITIES

Lecturing

Guest lecturer (Human Care Technology, Avans University of Applied Sciences), 2008, 2009 and 2010	12 hours

Other

Supervising medical student, 2009	80 hours
Supervising bachelor of health student, 2009	30 hours