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What Do We Really Know About the Safety of Tai Chi?: A Systematic Review of Adverse Event Reports in Randomized Trials

Peter M. Wayne, PhD, **Danielle L. Berkowitz, BS**, **Daniel E. Litrownik, BA**, **Julie E. Buring, ScD**, and **Gloria Y. Yeh, MD, MPH**

From the Osher Center for Integrative Medicine, Brigham and Women's Hospital, Harvard Medical School, Boston, MA (Wayne and Berkowitz); Harvard Medical School, Boston, MA (Wayne, Yeh and Buring); Division of General Medicine, Beth Israel Deaconess Medical Center, Boston, MA (Litrownik and Yeh), Division of Preventive Medicine, Brigham & Women's Hospital, Boston, MA (Wayne, Berkowitz and Buring)

Abstract

Objective—Systematically review frequency and quality of adverse event (AE) reports in randomized clinical trials (RCTs) of Tai Chi (TC).

Data Sources—Electronic searches of PubMed/MEDLINE and additional databases from inception through March 2013 of English-language RCTs. Search terms were tai chi, taiji, tai chi chuan. Data were independently extracted by two investigators.

Study Selection—We included all available randomized controlled trials (RCTs) that were published in English and used Tai Chi as an intervention. Inclusion and exclusion of studies were reported in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines.

Data Extraction—Eligible RCTs were categorized with respect to AE reporting: 1) No mention of protocols for monitoring AEs or reports of AEs; 2) Reports of AEs either with or without explicit protocols for monitoring AEs.

Corresponding Author and Reprint Requests: Peter M. Wayne, PhD, Osher Center for Integrative Medicine, Division for Preventive Medicine, Brigham and Women's Hospital, Harvard Medical School, 900 Commonwealth Avenue, 3rd Floor, Boston, MA 02215, USA, pwayne@partners.org, Phone: 617-732-6271.

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Data Synthesis—153 eligible RCTs were identified, most targeting older adults. Only 50 eligible trials (33%) included reporting of AEs, and of these, only 18 trials (12% overall) also reported an explicit AE monitoring protocol. Protocols varied with respect to rigor of systematic monitoring in both Tai Chi and comparison groups. Reported AEs were typically minor and expected, and primarily musculoskeletal related (e.g., knee and back pain); no intervention-related serious AEs were reported.

Conclusions—Tai Chi is unlikely to result in serious adverse events, but may be associated with minor musculoskeletal aches and pains. However, poor and inconsistent reporting of AEs greatly limits the conclusions that can be drawn regarding the safety of Tai Chi.

Keywords

Tai Chi; Safety; Adverse Event; Randomized Controlled Trial

Paralleling the rapidly expanding adult population in the U.S. is a growing appreciation for the benefits of exercise and physical activity in the prevention and rehabilitation of age-related disease. [1, 2]Abbreviations Poor adherence to exercise programs, especially in older adults,[3] has motivated research to identify novel, cost-effective, and sustainable exercises—including complementary and alternative therapies—to address this population need. Tai Chi is a low-impact, mind-body exercise originating in China that has become increasingly popular [4-6] and has become a recognized therapeutic tool by the Western medical community. One of the key features that has made Tai Chi a promising intervention, especially for older and rehabilitating adults, is its purported safety. However, to our knowledge, there has not been a formal review of the literature that has specifically and comprehensively evaluated the reporting of adverse events and the safety of Tai Chi.

Adverse event (AE) reporting within clinical trials is an important source for evaluating the safety of new therapies. An AE is broadly defined as any unfavorable or unintended event that occurs during the course of a study. Typically, identification and reporting of AEs is not restricted to events believed a priori to be directly related to the intervention; in some studies, relatedness is only appreciated after review of all events during a trial.[7] Monitoring of safety and AEs during clinical trials is required by Institutional Review Boards, and international research guidelines for all human research involving the delivery of treatment interventions have been developed. The CONSORT has suggested that AEs should be described in the results section of published articles.[8] However, even in pharmacological trials, where guidelines are well developed and definitions of AEs are relatively clear, reporting is inconsistent.[9-12] Complete and consistent reporting of AEs in trials of non-pharmacological interventions can be even more problematic, due to less developed guidelines.[13, 14]

The main purpose of this systematic review is to evaluate the frequency and type of AE occurrences in RCTs of Tai Chi for all populations. A secondary aim is to evaluate the consistency and quality of AE monitoring protocols used in the included trials. We conclude with recommendations for improving our understanding of the safety of Tai Chi, including guidelines for reporting AEs in future trials of Tai Chi and related mind-body exercises.

Methods

Literature Search

Electronic literature searches were conducted using PubMed/MEDLINE, EBSCOhost and the Cochrane Library from inception through March 2013. Search terms were tai chi, taiji, tai chi chuan; searches were limited to English-language RCTs. Hand searches were performed of retrieved articles for additional references.

Eligibility Criteria

We first included all available randomized controlled trials (RCTs) that were published in English and used Tai Chi as an intervention. No exclusions were made on the basis of population, type of Tai Chi intervention or intervention controls. Inclusion and exclusion of studies were reported in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines.

All identified RCTs were then categorized into two groups with respect to their reporting of adverse events. Group I studies did not report AEs in the results or discussion and did not include any formal protocols for monitoring and reporting and were thus excluded from further analysis. Group II studies did report AEs in the results or discussion, with or without a formal protocol for monitoring and reporting AEs.

Data Extraction and Synthesis

Data pertinent to AE reporting and AE monitoring protocols, as well as study design, location, duration, subject population, and Tai Chi and control interventions were independently extracted by two reviewers in a standardized manner. Discrepancies were resolved through discussion, and a third arbiter when needed. Synthesis of data on AEs is summarized for all Group II studies in narrative form, including explicit report and detail of an AE monitoring protocol, details of study design, and types and frequencies of AE's. Our analytic methods were based on descriptive statistics which were calculated within an Excel database. The methodological quality of reporting for the subset of studies that included an explicit AE reporting protocol was further assessed using criteria from the CONSORT extension checklist of ten recommendations when reporting harms in randomized controlled trials.[8] Key criteria are: defining adverse events (#3), clarifying how harms-related information was collected (#4), describing plans for presenting and analyzing information on harms (#5), and describing information on harms for all treatment arm s (#6).

Reporting of Adverse Events

Adverse events were defined according to the National Institutes of Health (NIH) as follows:[15] “Unfavorable changes in health … that occur in trial participants during the clinical trial or within a specified period following the trial.” Using NIH guidelines, adverse events were further divided into two types, “Serious” and “Other (not including Serious).” Serious Adverse Events include adverse events that result in death, require either in-patient hospitalization or the prolongation of hospitalization, are life-threatening, result in a persistent or significant disability/incapacity or result in a congenital anomaly/birth defect. Other important medical events, based upon appropriate medical judgment, may also be

considered Serious Adverse Events if a trial participant's health is at risk and intervention is required to prevent an outcome mentioned. Other Adverse Events are those that are not Serious Adverse Events.

For the present systematic review, to qualify as a reported AE an incident had to be explicitly referred to as AE. However, to provide context for interpreting quality of reporting, we also systematically quantified all health events reported in publications, including explicit or implicit references to health related drop-outs in CONSORT flow diagrams, study results and discussion sections. For a study to qualify as having an AE reporting protocol, there had to be explicit mention of methods associated with monitoring, soliciting, and recording AE's (e.g., direct observation, during outcome visits, regular surveys or phone calls), either directly from participants or from staff or intervention instructors.

Results

Literature Search

Figure 1 summarizes the flow of our literature search and selection process. Our initial search resulted in 1,909 studies. Eight hundred and sixty-five publications were excluded because they were duplicate articles in different databases. Eight hundred and seventy-seven publications were further excluded for the following reasons: 342 irrelevant to the search (e.g., author last name “Tai”); 412 not randomized controlled trials; 64 did not report original data, 37 non-English language; 22 not full text articles (i.e., abstracts). Of the remaining 167 articles: 6 included only information on design methodology; 3 did not utilize Tai Chi as an intervention; and 5 reported identical duplicate data. This resulted in a total of 153 publications. Of these, 100 were excluded because they did not have a monitoring protocol or adverse event reports. Three additional studies included a monitoring protocol, but did not have adverse event reports. Fifty trials mentioned AE reporting and were included for quantitative synthesis.

Participant characteristics and study setting

The 50 trials identified by our search that included an AE report are summarized in Table 1. The average age of study participants was 65y (median= 69y, range 11-102y). Forty-two studies included men and women, 7 women only, and 1 men only. One trial was in adolescents. Twentysix studies recruited community dwelling individuals, 18 were based in hospital settings, 5 were based in independent or assisted senior living facilities, and 1 in a university setting. Twelve studies targeted individuals with balance impairments, musculoskeletal weakness, or reduced physical function; 20 with metabolic, cardiovascular, or immune disorders; 9 with chronic pain; and 4 with cognitive deficits or mood disorders. The remaining studies included healthy individuals that ranged from young to older adults (n= 5). One half of the studies were conducted in the United States (n = 25).

Intervention and control group characteristics

Tai Chi interventions varied greatly in content, dosage, duration and intensity. The majority of studies (n= 30) employed interventions described as ‘simplified’ research protocols,

and/or included a subset of movements typically learned in traditional Tai Chi choreographed sets; 13 employed complete traditional Tai Chi sets (e.g., Yang style 24-form); 1 integrated Tai Chi exercises within a multi-component intervention including other cognitive or physical exercises; 1 utilized community-based pragmatic interventions; and 5 studies did not provide Tai Chi intervention details.

Individual Tai Chi sessions varied in duration from 20 to 120 minutes. The frequency of sessions varied from 1 to 5 times per week, with overall training programs lasting 6 weeks to 1 year. Qualifications of instructors were mentioned in only 22 of 50 studies.

Twenty trials used active exercise control groups (e.g., resistance training, aerobics, flexibility, and balance training), 1 employed non-exercise activities (e.g., dietary supplements); 10 studies utilized group education and support programs; and 19 employed a non-intervention control including waitlist and usual care.

Patterns of Adverse Events Reporting

Of the 153 identified publications evaluating Tai Chi, 100 (65%) included no mention of either AE monitoring protocols or AEs, and an additional 3 studies only mentioned an AE protocol but no AE report. Of the 50 eligible studies that included an explicit AE report, only 18 trials included an explicit monitoring protocol, which provides a more reliable framework for interpreting the validity of AE reports. Information for all 50 trials is summarized in Table 1.

Reported AEs varied in scope and detail (Table 1). Fourteen studies[16-29] (28%) solely reported on intervention-related AEs; 15 studies[30-44] (30%) did not specify between groups; 20 studies[45-65] (40%) more comprehensively reported other AEs including non-intervention related hospitalizations and new medical diagnoses (e.g. cancer). One study[66] (2%) reported AEs only in the control group.

Among the 50 studies in Table 1, no serious AEs related to Tai Chi was reported, and 32 studies [18, 20, 21, 26-29, 31-34, 36-39, 41-44, 50-52, 55-57, 59-65] reported no occurrence of any AEs related to intervention. Fifteen [16, 17, 19, 23-25, 30, 45, 47-49, 53, 54, 58, 59] of the 50 studies specifically reported occurrences of minor musculoskeletal aches and pain, with complaints of lower extremity pain (knee and ankle) being most common. Six studies[16, 19, 24, 47, 49, 58] mentioned a report of back/spine related pain. In one[47] of these back pain reports, pain was severe leading to study withdrawal; subsequent analysis revealed a pre-existing condition of stenosis missed during screening. Falls were not consistently reported as AEs, in part because falls were considered as outcomes in many studies. Four[48, 52, 58, 66] studies reported falls.

AE monitoring protocols varied greatly among the studies in Table 1. Of the 18 studies that included an explicit AE monitoring protocol, slightly more than half included explicit tracking of AEs in both the Tai Chi intervention group and the control[16, 30, 31, 45-52, 67] (n = 10; 56%); 2 studies[17, 18] (11%) only reported monitoring protocols for Tai Chi and 6 studies[19, 32, 33, 53-55] (33%) did not explicitly state which groups were monitored. Details regarding how AEs were monitored also varied, with 7 studies[17, 19, 32, 33, 45, 48, 49, 67] (39%)

including multiple methods (e.g., study staff queries, instructor observation), 9 studies [16, 18, 31, 46, 47, 50-54] (50%) reported only one source of information, and 2 studies[30, 55] (11%) did not explicitly indicate how AE information was collected. Similarly, frequency of monitoring AEs also varied, with 5 studies[17-19, 32, 33] (28%) querying participants after each intervention session; 9 studies[30, 31, 45-52, 67] (50%) collecting AE reports at regular assessments (e.g., weekly or monthly); 1 (6%) study[53] relying on recall at the end of the intervention period; 3 studies[16, 54, 55] (17%) did not explicitly describe frequency of monitoring.

When evaluated according to the CONSORT extension checklist for reporting harms in randomized controlled trials,10 studies (56%)listed addressed adverse events with definitions for each (recommendation #3), 13 (72%) clarified how harms-related information was collected (#4), 1 (6%) described plans for presenting and analyzing harms (#5), 7 (39%) described for each arm the participant withdrawals due to harms (#6), and 6 (33%) provided a balanced discussion of benefits and harms (#10) (see Table 2).

Discussion

Tai Chi is increasingly recognized by the Western medical community as an effective exercise for rehabilitation and prevention of multiple medical conditions, and Tai Chi programs are now offered through academic medical centers, assisted living facilities, and community senior centers across the United States.[68] Tai Chi's purported safety, along with evidence of its clinical effectiveness and cost-effectiveness, has likely contributed to growth in its health-related use, especially among older adults and those deconditioned by chronic illnesses.

Our systematic review has identified significant flaws in the reporting of adverse events in trials of Tai Chi, which greatly limits the conclusions that can be drawn to date regarding Tai Chi's safety. Based on 153 randomized trials of Tai Chi published between 1977 and 2013, we found highly inconsistent, and overall, very poor reporting of AE monitoring protocols and AEs. Sixty five percent of these trials (n = 100) included no mention whatsoever of either monitoring protocols or AEs, and an additional 23% (n = 35) did not include the adequate information required for evaluating the validity of AE reports (i.e., information on the monitoring protocols used to solicit information on AEs, or the AEs themselves). Of note, 39% of the 100 studies that included no explicit mention of an AE included reports of health-related drop-outs in either the study's CONSORT diagram or in the publication text, suggesting that AEs were under-reported. Only 18 of the 50 trials included in Table 1 (representing < 12% of all 153 trials) reported both an AE monitoring protocol and explicit AE reports, and the quality of reporting in these studies was variable with only a small proportion of studies adequately meeting important CONSORT recommendations for reporting harms in RCTs. Some studies[53] relied on monitoring procedures with a high risk of bias (e.g., recall of AEs at a single time point at the end of the study), or only monitored and reported AEs for the Tai Chi group making it impossible to assess if the frequency or types of events observed in a group learning Tai Chi differs from control interventions or natural history. By comparison, the less biased studies included monitoring protocols applied repeatedly throughout the study (e.g., weekly or monthly),

and/or solicited information from multiple sources (e.g., patient self-reports, instructor reports), and monitored and documented AEs in both the intervention and control groups. Additionally, reports of AEs in more reliable studies were more comprehensive, not limited to intervention-related events, and provided quantitative data (e.g. frequency of event types). Based on this small subset of more reliable studies, there were no reports of serious AEs, the majority of the reported AEs were unrelated to study interventions, and AEs that were deemed related to the Tai Chi intervention were minor and anticipated musculoskeletal aches and pains.

Reports of minor musculoskeletal pain related to Tai Chi training are consistent with AEs reported in other exercise studies,[69, 70] including studies of mind-body therapies like yoga,[71, 72] but lower than AEs reported in more combat-oriented martial arts. [73-75] Of note, lower extremity, and especially knee pain, was reported in 9 [17, 19, 23, 25, 30, 48, 54, 58, 59] of the 50 trials in Table 1. Biomechanic studies support that during Tai Chi training, practitioners experience higher shear force and frontal plane torques at the ankle, knee, and hip joints, as compared to natural walking.[76-79] A recent commentary on Tai Chi safety emphasized that Tai Chi practice requires the knee joint to regularly conform to a semi-flexed position, thus incurring high mechanical load and putting it at risk for injury.[80] The commentary cites two observational studies from China with reports of knee injury higher than those observed in our study. In one study, 32 of 219 (15%) novice Tai Chi practitioners experienced some form of knee complication after 3 to 6 months of training.[81] In another study of 200 longer-term Tai Chi practitioners, 23% had a history of knee joint injury, 8.5% had patella strain, 7% had meniscus injury, 3.0% had knee fat pad injury, 2.0% had medial collateral ligament injury, 1.5% had cruciate ligament injury, and 1% had lateral collateral injury. The commentary concluded that to minimize knee injuries, Tai Chi training requires careful attention to appropriate load, biomechanics, and overall effort.[80] However, these results are difficult to interpret as the prevalence of these injuries in age-matched individuals in the same population is not known. Nevertheless, these observations reflect more widespread concerns expressed in the lay literature about Tai Chi's safety for knees and other musculoskeletal conditions[80, 82, 83] especially in those with pre-existing conditions. Of note, no intervention-related cardiovascular adverse events were reported, including in the higher quality studies of heart failure and COPD patients, although these studies are relatively small. Finally, our review also found no reports of psychological AEs, which have been reported in related mind-body exercises including qigong and meditation.[84, 85]

There is a rich literature highlighting a long history of poor reporting of AEs in clinical trials of both pharmacological and non-pharmacological interventions.[86, 87] To address these concerns, the CONSORT Statement extension with recommendations on the reporting of harms was published in 2004. Nevertheless, a recent review of orthopedic physical therapy studies found AE reporting poorly complied with CONSORT guidelines, and like our study, observed that 58% of all studies did not show evidence of any AE monitoring whatsoever.[88, 89] Similarly, a Cochrane review on exercise for reducing osteoporosis-related fractures found that none of the 7 reviewed RCTs included AE reporting.[90]

In keeping with the broad guidelines of the CONSORT Statement Extension of the reporting of harms statement, we emphasize the following guidelines for the reporting of AEs in Tai

Chi studies. First, protocols for defining and monitoring AEs should be clearly defined in the methods section of all studies. Second, protocols should include assessments repeated throughout the course of the entire trial. Third, AEs should be assessed using multiple sources of information, including self-reports by patients, pro-active queries by study staff, physician report (if appropriate) and observations by teachers or intervention administrators, as relying on individual sources can be limited. Fourth, monitoring of AEs should take place in all groups (intervention and control) using equivalent protocols. Fifth, all unfavorable changes in medical conditions should be reported as potential AEs, not just those deemed to be intervention related. Finally, reports should be made quantitatively, with information on frequency of occurrence.

While the above recommendations will greatly improve our estimates of potential shorter-term AEs in clinical settings, they will not inform longer-term potential adverse effects in more typical community-based settings where Tai Chi is typically practiced. Thus, the study of AEs in Tai Chi should also include systematic cross-sectional and longitudinal surveys and audits of short- and long-term practitioners in community-based settings as has been done in other emerging integrative medical therapies.[91, 92]

Study Limitations

There are a number of limitations to this study. First, our study only included trials published in the English language. Future studies might include other languages for a better global estimate of AE reporting. Asian language journals, for example, may be more likely to publish Tai Chi research. Second, because of the small number of studies as well as the heterogeneity of both interventions and controls, our study only employed descriptive statistics and narrative summaries of AE reports. As the literature evolves, future studies with more formal meta-analyses for assessing relative harms of Tai Chi when compared to other control interventions may be helpful. Finally, our study only included AEs reported in randomized trials. As noted above, data from audits and cross-sectional studies, especially of longer-term practitioners, as well as uncontrolled longitudinal studies may better inform long-term effects in the community.

Conclusions

Estimates of potential harm related to any novel therapy is a critical component of the evidence required by the medical community for informing policy and referrals. Similarly, patient concerns regarding exercise safety and injury may limit broader compliance with recommendations for exercise and more active lifestyles.[6] Poor and inconsistent reporting of AEs greatly limits the conclusions that can be drawn regarding the safety of Tai Chi. Based on a small number of less biased studies, Tai Chi is unlikely to result in serious adverse events, but may be associated with minor musculoskeletal aches and pains. Until AE reporting in Tai Chi trials is improved, we cannot draw more definitive conclusions regarding its safety. Already existing CONSORT guidelines for comprehensive monitoring and reporting of AEs in future trials of Tai Chi should be enforced. Additionally, these guidelines should be supplemented by systematic audits of short- and long-term practitioners in community based setting.

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List of Abbreviations

AE Adverse Event

TC Tai Chi

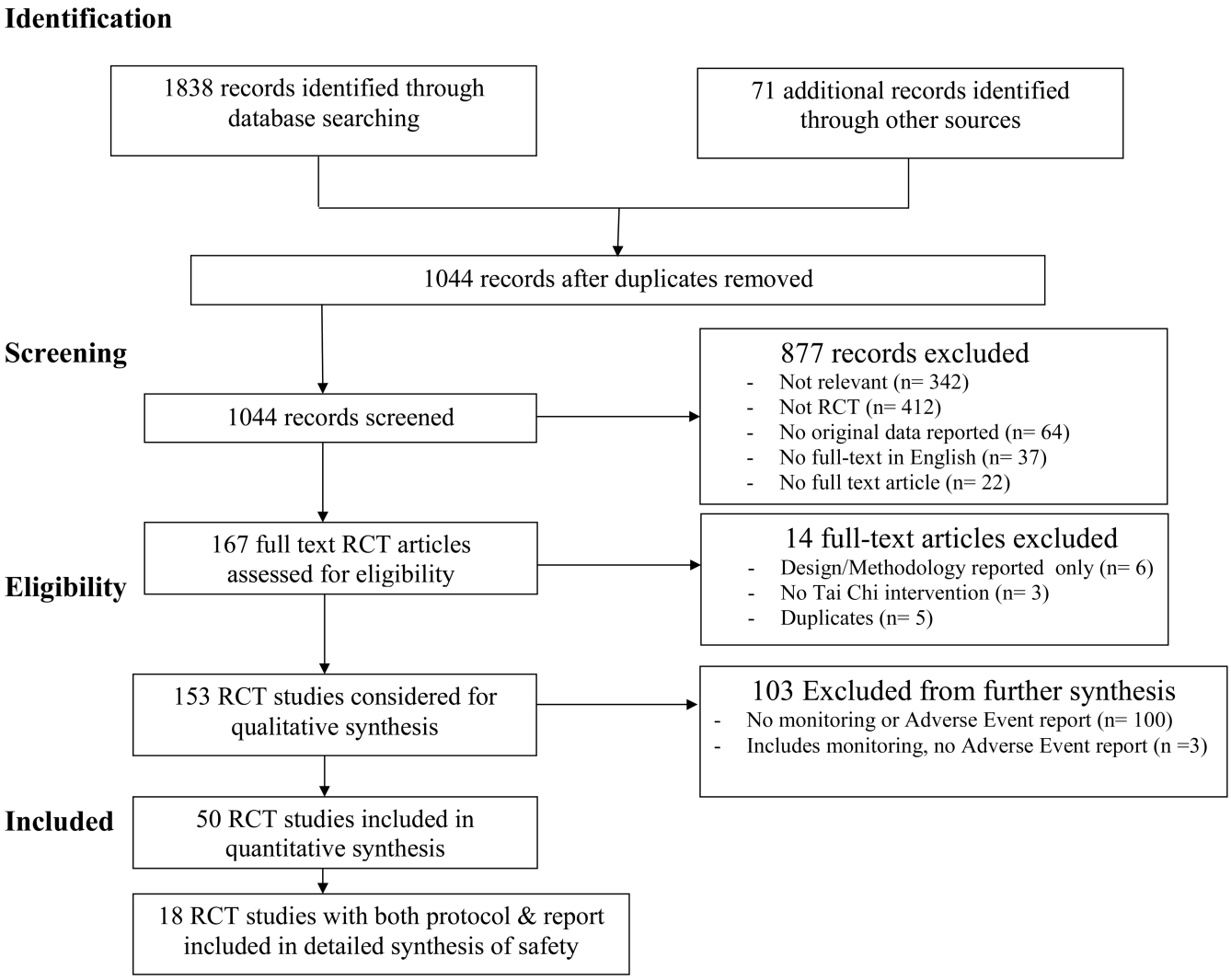

Figure 1. PRISMA

Table 1

Randomized controlled trials of Tai Chi (TC) that include reporting of adverse events (Aes) (n= 50)

Population **Author last name (Year)**	**Interventions** **type; dose; sample size (n)**	**AE Protocol included (Y/N)?** **If Y,** • **All groups observed (Y/N)?** • **AE information source (s)?** • **Frequency of monitoring?**	**AEs reported by author**	**AEs reported for all groups (Y/N)?**
Healthy adults				
Irwin et al (2008)[56]	• TC: 40 min, 3x/wk for 16 wks followed by practice for 9 more wks (n= 59) • Health education; 40 min, 3x/wk for 16 wks followed by a 9 wk assessment (n= 53)	• N	• "No AEs associated with either intervention."	• Y
Li et al (2004)[32]	• TC: 8-form Yang style; 60 min, 3x/wk for 24 wks (n= 62) • Low-impact exercise; 60 min, 3x/wk for 24 wks (n= 56)	• Y – Not specified – Study staff, instructors – Each class	• "No exercise-related injuries…"	• Not specified
Liu et al (2012)[20]	• TC: 24-form, Yang style; 45 mins, 2x/wk for 16 wks (n= 20) • Proprioception exercise: Static and dynamic balance exercises; 45s, 2x/wk for 16 wks (n= 20) • No structured exercise (n= 20)	• N	• "No discomfort while testing; no discomfort while practicing Tai Chi."	• N (TC only)
Nedeljkovic et al (2012)[21]	• TC: Taiji, 18 sequence of 37 Chen Man-Ch'ing Yang style; 60 min, 2x/wk for 12 wks (n= 35) • Wait-list (n= 35)	• N	• "No AEs of the Taiji training were observed."	• N (TC only)

Population **Author last name (Year)**	**Interventions** **type; dose; sample size (n)**	**AE Protocol included (Y/N)?** **If Y,** • **All groups observed (Y/N)?** • **AE information source (s)?** • **Frequency of monitoring?**	**AEs reported by author**	**AEs reported for all groups (Y/N)?**
Wolfson et al (1996)[19]	• Balance Training (B): 45 min, 3x/wk for 3 months (n= 28) • Strength Training (S): 45 min, 3x/wk for 3 months (n= 28) • Balance + Strength Training (B+S): 90 min, 3x/wk for 3 months (n= 27) • Education; usual activities (n= 27) • All groups then received TC: 60 min, 1x/wk for additional 26 wks	• Y – Not specified – Instructors, study staff – Each exercise class	• "Musculoskeletal complaints developed in 10 of 55 subjects in the S and B+S groups."	• N (AEs not reported during TC training)
Impaired balance, musckuloskeletal health, reduced physical function				
Day et al (2012)[22]	• TC: Modified 46-form Sun style; 60 min, 2x/wk for 24 wks (n= 250) • Stretching and flexibility: 60 min, 2x/wk for 24 wks (n= 253)	• N	• "There were 6 AEs, 5 of which were among intervention participants." 4 associated with testing protocol. "1 participant became unwell at a TC class because of a medical condition."	• N (TC only)
Dechamps et al (2009)[57]	• TC: Modified Yang style for elderly; 30 min, 4x/wk for 24 wks (n= 26) • Cognition-action: 30 min progressing to 40 min, 2x/wk for 24 wks (n= 26)	• N	• "4 participants were hospitalized for health-related causes independent of training (n = 4 in TC)…"	• Y
Dechamps et al (2010)[42]	• TC: Adapted variations of Yang style for elderly; 30 min, 4x/wk for 6 months (n= 51) • Cognition-action: 30-45 min, 2x/wk for 6 months	• N	• "None of the observed deaths (n=18) was directly or indirectly attributable to an AE due to the intervention."	• Not specified

Population Author last name (Year)	Interventions type; dose; sample size (n)	AE Protocol included (Y/N)? If Y, • All groups observed (Y/N)? • AE information source (s)? • Frequency of monitoring?	AEs reported by author	AEs reported for all groups (Y/N)?
	(n= 49) Control: Usual care (n= 60) (n= 49) Control: Usual care (n= 60)			
Li et al (2004)[33]	• TC: 24-form Yang style; 60 min, 3x/wk for 6 months (n= 125) • Exercise stretching; 60 min, 3x/wk for 6 months (n= 131)	• Y – Not specified – Study staff, instructors – Each class	• "No exercise-related injuries occurred…"	• Not specified
Li et al (2005)[43]	• TC: 24-form, Yang style; 60 min, 3x/wk for 6 months (n= 125) • Stretching, including controlled breathing and relaxation; 60 min, 3x/wk for 6 months (n= 131)	• N	• "No intervention-related injuries or falls reported…"	• Not speicified
Li et al (2012)[58]	• TC: Modified 8 form routine; 60 min, 2x/wk for 24 wks (n= 65) • Resistance Training: strengthening muscles, 8-10 exercises with a weighted vest and ankle weights; 60 min, 2x/wk for 24 wks (n= 65) • Stretching; 60 min, 2x/wk for 24 wks (n= 69)	• N	• "No serious AEs were observed during tai chi training.." • TC: In class (2 falls, 1 muscle soreness or pain); Out of class (19 falls, 4 low back pain, 1 ankle sprain) • Resistance: In class (4 falls, 4 muscle soreness or pain, 3 dizziness or faintness, 3 symptoms of hypotension); Out of class (31 falls, 3 symptoms of chest pain or discomfort, 1 symptoms of hypotension, 4 low back pain, 2 ankle sprains) • Stretching: In class (5 falls, 1 muscle soreness or pain, 2 dizziness or faintness, 1 symptoms of hypotension); Out of class (26 falls, 2 symptoms of chest pain or discomfort, 2 symptoms of hypotension, 5 low back pain, 1 ankle sprain)	• Y

Population **Author last name (Year)**	**Interventions** **type; dose; sample size (n)**	**AE Protocol included (Y/N)?** **If Y,** • **All groups observed (Y/N)?** • **AE information source (s)?** • **Frequency of monitoring?**	**AEs reported by author**	**AEs reported for all groups (Y/N)?**
Ming-Chien et al (2010)[23]	• TC: 24-form, Yang style; 60 min, 3x/wk for 24 wks (n= 30) • No exercise intervention (n= 31)	• N	• "Sporadic complaints of minor muscle soreness and foot and knee pain…during the first few days of the intervention."	• N (TC only)
Sattin et al (2005)[59]	• TC: Modified Yang style; 60 min and progressing to 90 min, 2x/wk over the course of 48 wks (n= 158) • Wellness Education (WE); 60 min, 1x/wk for 48 wks (n= 153)	• N	• "No AEs occurred during the TC or WE intervention. One participant sustained an ankle abrasion during the medical evaluation."	• Y
Shen et al (2010)[45, 67]	• Placebo + TC: 500 mg medicinal starch daily and 24-form Yang style; 60 min, 3x/wk for 24 wks (n= 42) • Green Tea Polyphenol (GTP) + TC: 500 mg GTP daily and 24-form Yang style; 60 min, 3x/wk for 24 wks (n= 38) • GTP: 500 mg GTP daily for 24 wks (n= 47) • Placebo: 500 mg medicinal starch daily for 24 wks (n= 44)	• Y – Y – Participants, study staff, instructors, blood markers – At baseline and every 4 wks throughout the study period	• "Four participants reported AEs during the study. One subject in the Placebo arm experienced nausea and diarrhea… One subject in the GTP arm had elevated AST and ALT levels…One subject in the Placebo + TC arm reported having retinal bleeding on a non-exercise day and another subject in the Placebo + TC arm reported having a broken wrist on a non-exercise day… These four reports, as judged by the safety monitoring team, were unlikely related to the study protocol. No AEs due to TC was observed or reported in this study…sporadic complaints about muscle soreness during the first two weeks."	• Y

Population Author last name (Year)	Interventions type; dose; sample size (n)	AE Protocol included (Y/N)? If Y, • All groups observed (Y/N)? • AE information source (s)? • Frequency of monitoring?	AEs reported by author	AEs reported for all groups (Y/N)?
Taylor et al (2012)[53]	• TC: 10-form Sun style; 60 min, 1x/wk for 20 wks (n= 233) • TC: 10-form Sun style; 60 min, 2x/wk for 20 wks (n= 220) • Low-level exercise; 60 min, 1x/wk for 20 wks (n= 231)	• Y – Not specified – Participants – At end of intervention	• "No serious AEs resulting from participation in any of the exercise programs. When asked whether participation in the program caused any problems, 11 (Low Level Exercise), 19 (TC 1) and 15 (TC 2) reported problems. The most commonly reported problem was an increase in aches and pains (4 Low Level Exercise, 4 TC 1 and 3 TC 2)."	• Y
Wayne et al (2012)[49]	• TC: Pragmatic (community TC classes); 60 min, 2x/wk for 1 month, then 1x/wk for 8 months; >=30 min home practice or additional classes 2x/wk for 1st month and 3x/wk for remaining 8 months (n= 43) • Waitlist; (n= 43)	• Y – Y – Study staff, instructors, participants – Monthly	• "No serious AEs. A total of nine minor AEs were reported. Seven in the TC group and two in the control group. Reports in both groups were largely musculoskeletal related (e.g. shoulder or back pain); none in the TC were attributed directly to TC training."	• Y
Wolf et al (2003)[55]	• TC: 6 out of 24 moves; 60 min progressing to 90 min, 2x/wk for 48 wks (n= 145) • Wellness education; 60 min, 1x/wk for 48 wks (n= 141)	• Y – Not specified – Not specified – Not specified	• "…no AEs occurred during the TC or Wellness Education intervention."	• Y
Adults with chronic pain				
Abbott et al (2006)[41]	• TC: 24-form Yang style; 60 min, 2x/wk for 15 wks (n= 24) • Waitlist; (n= 23)	• N	• "No participant reported an adverse effect from the intervention."	• Not specified
Brismee et al (2007)[17]	• TC: 24-form Yang style; 40 min, 3/wk for 6 wks,	• Y – N (TC only)	• "Sporadic complaints of minor muscle soreness and foot and knee pain were	• N (TC only)

Population Author last name (Year)	Interventions type; dose; sample size (n)	AE Protocol included (Y/N)? If Y, • All groups observed (Y/N)? • AE information source (s)? • Frequency of monitoring?	AEs reported by author	AEs reported for all groups (Y/N)?
	then 6 wks of home-based TC training (n=22) then 6 wks of home-based TC training (n=22) • Health lectures; 40 min, 3/wk for 6 wks, then 12 wks of no activity (n=19)	– Participants, instructors – Each class	made mainly during the first few days of the intervention."	
Fransen et al (2007)[24]	• TC: Modified 24-form Sun style; 60 min, 2x/wk for 12 wks (n= 56) • Hydrotherapy: 60 min, 2x/wk for 12 wks (n= 55) • Waitlist; (n= 41)	• N	• "11 participants reported a serious AE requiring hospitalization. None…could be related to the interventions. One participant withdrew from hydrotherapy and one withdrew from TC due to exacerbation of low back pain."	• N (TC + Hydrotherapy)
Hall et al (2011)[16]	• TC: TC for Health Program; 40 min, 2x/wk for 8 wks, then 1x/wk for 2 wks (n= 80) • Waitlist, usual health care (n= 80)	• Y – Y – Participants – Not specified	• "Three people discontinued treatment after 3 weeks due to medical complications not associated with the intervention…Three participants reported a small initial increase in back pain symptoms that were alleviated by the third or fourth week of treatment, and 1 participant reported an increase in upper back pain that was alleviated once they corrected upper extremity posture."	• N (TC only)
Jones et al (2012)[44]	• TC: Simplified 8-form Yang style; 90 min, 2x/wk for 12 wks (n= 51) • Education; 90 min, 2x/wk for 12 wks (n= 50)	• N	• "No AEs were observed."	• Not specified
Ni et al (2010)[30]	• TC: 24-form Yang style; 30 min, 2x/wk for 8wks, 3x/wk for 8 wks, 4x/wk for 8 wks (n= 18) • Wellness education and stretching; 45 min, 1x/wk for 24 wks (n= 17)	• Y – Y – Not specified – Weekly	• "No AEs were reported, though in 5 patients, sporadic complaints of minor muscle soreness and foot and knee pain were made mainly during the first few days of the intervention."	• Not specified

Population Author last name (Year)	Interventions type; dose; sample size (n)	AE Protocol included (Y/N)? If Y, • All groups observed (Y/N)? • AE information source (s)? • Frequency of monitoring?	AEs reported by author	AEs reported for all groups (Y/N)?
Song et al (2003)[25]	• TC: 12 move Sun style (TC for Arthritis by Dr. Paul Lam); 3x/wk for 2 wks with a instructor or by themselves, then supervised 1x/wk, home practice 20 min/day, 3x/wk for 10 wks recorded in a exercise log (n= 38) • Waitlist (n= 34)	• N	• "…slight soreness of the knee and leg muscles was reported during the first week of exercise…"	• N (TC only)
Wang et al (2009)[54]	• TC: 10-form Yang style; 60 min, 2x/wk for 12 wks, 20 min of home practice daily (n= 20) • Wellness education and stretching; 60 min, 2x/wk for 12 wks, 20 min of home stretching daily (n= 20)	• Y – Not specified – Study staff – Not specified; medication use at each study visit	• "One participant in the TC group reported an increase in knee pain at the 2-week assessment. This was resolved following modification of the participant's TC techniques. One participant in each assignment group reported newly diagnosed cancer (1 breast cancer, 1 colon cancer) during the 12-week intervention period."	• Y
Wang et al (2010)[31]	• TC: 10 form Yang-style; 60 min, 2x/wk for 12 wks, home practice ≥ 20 min daily (n=33) • Wellness Education and stretching; 60 min, 2x/wk for 12 wks, home practice 20 min daily (n= 33)	• Y – Y – Study staff – Each study visit	• "No AEs were reported."	• Not specified
Metabolic, cardiovascular, and immune disorders				
Barrow et al (2007)[60]	• TC: Wu Chian Chuan (Orchid Hand 21) style; 55 min, 2x/wk for 16 wks (n= 32) • Standard medical supervision and drug treatment (n= 33)	• N	• "No AEs occurred in the TC sessions… one patient in the intervention and one in the control withdrew due to worsening heart failure symptoms. Two patients in the control withdrew because of worsening co-morbidities. One patient died in the intervention and two died in the control."	• Y

Population Author last name (Year)	Interventions type; dose; sample size (n)	AE Protocol included (Y/N)? If Y, • All groups observed (Y/N)? • AE information source (s)? • Frequency of monitoring?	AEs reported by author	AEs reported for all groups (Y/N)?
Caminiti et al (2011)[61]	• TC: 10-move Yang style + endurance training (ET) on different days; 30 min, 3x/wk for 12 wks (n= 30) • Endurance training; 30 min, 3x/wk for 12 wks (n= 30)	• N	• "No patients had AEs during the exercise protocol. Worsening HF occurred in 1 patient of the ET group and was managed only by increasing the dose of furosemide."	• Y
Chan et al (2010)[34]	• TC Qigong (TCQ): 13 move of Breathing Regulating TCQ; 60 min; 2/wk for 3 months (n= 70) • Exercise: Breathing and walking; self practice for 1 h everyday + community gatherings weekly for 3 months (n= 69) • Maintain routine activities + community gatherings weekly for 3 months (n= 67)	• N	• "…during the intervention, no exercise related problems occurred."	• Not specified
Chen et al (2010)[35]	• TC: Simplified Chen style; 60 min, 3x/wk for 12 wks, given a DVD for home practice (n= 62) • Aerobic exercises (aerobic dance) 60 min, 3x/wk for 12 wks plus home based exercises (n=55)	• N	• "…very few adverse reactions or injuries were reported."	• Not specified
Dechamps et al (2008)[36]	• TC + diet: Modified Yang style; 120 min, 1x/wk for 10 wks (n= 11) • Conventional structured exercise program + diet:	• N	• "No AEs occurred during this study."	• Not specified

Population Author last name (Year)	Interventions type; dose; sample size (n)	AE Protocol included (Y/N)? If Y, • All groups observed (Y/N)? • AE information source (s)? • Frequency of monitoring?	AEs reported by author	AEs reported for all groups (Y/N)?
	120 min, 1x/wk for 10 wks (n= 10) 120 min, 1x/wk for 10 wks (n= 10)			
Hart et al (2004)[62]	• TC: 60 min, 2x/wk for 12 wks (n= 9) • Physiotherapy exercises focused on improvement of balance; 60 min, 2x/wk for 12 wks (n= 9)	• N	• "No side effects were seen in either group."	• Y
Jung et al (2012)[26]	• TC: 20 move, developed by Dr. Paul Lam; 60 min, 3x/wk for 12 wks + home practice logs (n= 28) • Waitlist (n= 28)	• N	• "No adverse effects associated with the practice of TC were reported."	• N (TC only)
Leung et al (2012)[27]	• TC: 21-form, Sun style ("TC for Arthritis"); 60 min, 2x/wk for 12 wks, home practice 30 min/ day, 5x/wk (n= 22) • Usual care; no exercise training (n= 20)	• N	• "…no AEs reported."	• N (TC only)
Sato et al (2010)[37]	• TC + conventional cardiac rehabilitation: 8 move, Yang style; 60 min, 1x/wk, home practice 3x/wk for 1 yr (n= 10) • Conventional cardiac rehabilitation and routine care for 1 yr (n= 10)	• N	• "During the study…no clinical events were recorded."	• Not specified
Taylor-Piliae et al (2012)[28]	• TC: 24-form, Yang style; 60 min, 3x/wk for 12 wks (n= 16) • Given information for participating in community-based	• N	• "There were no falls or other AEs during TC classes."	• N (TC only)

Population Author last name (Year)	Interventions type; dose; sample size (n)	AE Protocol included (Y/N)? If Y, • All groups observed (Y/N)? • AE information source (s)? • Frequency of monitoring?	AEs reported by author	AEs reported for all groups (Y/N)?
	physical activity for older adults (n= 12) physical activity for older adults (n= 12)			
Tsai et al (2003)[29]	• TC: 108-form Yang style; 50 min, 3x/wk for 12 wks (n= 37) • Sedentary; maintain usual lifestyle behaviors (n= 39)	• N	• "None of the subjects experienced angina, major ventricular arrhythmias, or significant myocardial ischemia during the TC exercise."	• N (TC only)
Tsang et al (2007)[46, 47]	• TC: 'hybrid' form,' 12 move Sun and Yang style; 60 min, 2x/wk for 16 wks (n= 18) • Sham exercise; 60, 2x/wk for 16 wks (n= 20)	• Y – Y – Study staff – Weekly	• "There were no exercise-related AEs, and no group differences in acute health problems. During the…study, diabetic medication was commenced by one TC, and ceased in one control participant." • "One subject (with pre-existing spinal stenosis) in TC found the exercise intolerable secondary to pain and fatigue, and did not attend after session 1…Over the 16 weeks 0 (0-2) falls per person were reported in TC, and 0 (0-2) in the controls (p= 0.2)."	• Y
Tsang et al (2010)[48]	• TC: 24-form, Yang style; 60 min, 3x/wk for 6 months (n= 8) • Kung Fu: 60 min, 3x/wk for 6 months (n= 12)	• Y – Y – Participants, study staff – Weekly	• "Most AEs not related to study participation (99%). There were no significant differences between groups in AEs, whether they were related to study participation (KF: 0 (0–2) versus TC: 0 (0–0); P = .30)), or not (KF: 13.9 ± 9.6 versus TC: 7.1 ± 4.2; P = .08)… AEs occurred in 2 KF participants only, where both participants fell during the jogging/star-jump-type exercise warm-up. 1 participants also reported knee pain…"	• Y
Wang et al (2008)[63]	• TC: Yang style; 60 min, 2x/wk for 12 wks, instructed to practice at least 20 min, 1x/day at home (n= 10)	• N	• "There were no AEs associated with TC or education and stretching training during the 12-week study period."	• Y

Population Author last name (Year)	Interventions type; dose; sample size (n)	AE Protocol included (Y/N)? If Y, • All groups observed (Y/N)? • AE information source (s)? • Frequency of monitoring?	AEs reported by author	AEs reported for all groups (Y/N)?
	• Stretching and wellness education; 60 min, 2x/wk for 12 wks, instructed to practice at least 20 min, 1x/day at home (n= 10)			
Wang et al (2010)[38]	• TC: Yang style; 50 min, 1x/wk for 12 wks (n= 17) • Rehabilitation: 80 min (non-resistance 20 min + resistance 60 min), 1x/wk for 12 wks (n= 17)	• N	• "…no mental and/or physical AEs were reported…"	• Not specified
Yeh et al (2004)[50]	• TC: 5 moves, short form Yang style; 60 min, 2x/wk for 12 wks, videotape home practice ≥ 3x/wk (n= 15) • Waitlist, usual care; 12 wks (n= 15)	• Y – Y – Study staff – At follow up visits	• "No AEs occurred during the TC sessions. One patient in the intervention group and 4 in the control group were hospitalized during the study period for exacerbation of symptoms of heart failure…"	• Y
Yeh et al (2010)[51]	• TC: short form Yang style + Usual Care; 60 min, 2x/wk for 12 wks, encouraged (not required) 35 min instructional videotape home practice ≥ 3x/wk (n= 5) • Control: Waitlist, usual care (n= 5)	• Y – Y – Study staff – At follow up visits	• "No AEs occurred during the class sessions. No patients in either group were hospitalized during the study period for COPD exacerbation, and there were no deaths."	• Y
Yeh et al (2011)[52]	• TC: short form Yang style; 60 min, 2x/wk for 12 wks, 35 min instructional videotape home practice > 3x/wk (n= 50) • Heart health education program; 60 min, 2x/wk for 12 wks (n= 50)	• Y – Y – Study staff – At follow up visits	• "…no AEs related to the protocol. However, we documented several events during the study period, including 3 deaths (in the education), 6 hospitalizations (HF exacerbation/ angina/shortness of breath: 2 in the TC and 4 in the education), 2 arrhythmias in TC, 2 episodes of syncope in education, and 3 falls (2 in TC and 1 in education)."	• Y

Population Author last name (Year)	Interventions type; dose; sample size (n)	AE Protocol included (Y/N)? If Y, • All groups observed (Y/N)? • AE information source (s)? • Frequency of monitoring?	AEs reported by author	AEs reported for all groups (Y/N)?
Yeh et al (2012)[39]	• TC: 5-move, Yang style; 60 min, 2x/wk for 12 wks, encouraged to practice at home 3x/wk, provided with a 35 min instructional videotape (n= 8) • Aerobic Exercise; 60 min, 2x/wk for 12 wks, encouraged to practice at home 3x/wk, provided with a 35 min instructional videotape (n= 8)	• N	• "No AEs or hospitalizations occurred during class sessions or the study period."	• Not specified
Zhang et al (2008)[64]	• Tai Ji Quan: 24 style, short form; 60 min, 5x/wk for 14 wks (n= 10) • Free activity program; 60 min, 5x/wk for 14 wks (n= 10)	• N	• "In the study, there were no serious AEs or development of diabetic complications…as a result of the exercise intervention…one participant in the control had a cerebrovascular accident during the experimental period and was withdrawn from the study."	• Y
Adults with cognitive deficites or mood disorders				
Lam et al (2011)[66]	• TC: simplified 24-form; induction phase- with instructor 1x/wk for 8-12 wks, maintenance phase- no instructor ≥ 3x/wk for ≥ 30 min each time using a video up to 1 yr (n= 171) • Control: Muscle stretching exercise; induction phase- with an instructor 1x/wk for 8-12 wks, maintenance phase- no instructor ≥ 3x/wk for at ≥ 30 min each time using a video up to 1 yr (n= 218)	• N	• "1 subject in the control group had a fall with minor injury. No other AEs reported."	• N (Control only)

Population **Author last name (Year)**	**Interventions** **type; dose; sample size (n)**	**AE Protocol included (Y/N)?** **If Y,** • **All groups observed (Y/N)?** • **AE information source (s)?** • **Frequency of monitoring?**	**AEs reported by author**	**AEs reported for all groups (Y/N)?**
Lavretsky et al (2011)[40]	• Tai Chi Chih: 2 h, 1x/wk for 10 wks + 10-20 mg/day of escitalopram for 16 wks (n= 36) • Health education; 2 h, 1x/wk for 10 wks + 10-20 mg/day of escitalopram for 16 wks (n= 37)	• N	• "We did not observe any serious AEs. Common mild-to-moderate side-effects attributable to the medication included nausea, diarrhea, excessive sedation, daytime sleepiness, and rash."	• Not specified
Tsai et al (2012)[65]	• TC: 12-form Sun style (TC for Arthritis); 20 min gradually progressing to 40 min/, 3x/wk for 20 wks (n= 28) • Health education; 20-40 min, 3x/wk for 20 wks (n= 27)	• N	• "No AEs were found in either group."	• Y
Yeung et al (2012)[18]	• TC: 1st section of 108 moves Yang; 60 min, 2x/wk for 12 wks and 3x/wk home practice (n= 26) • Waitlist (n= 13)	• Y – N (TC only) – Instructors – Each class	• "No AEs due to the TC intervention were reported…"	• N (TC only)

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Table 2

CONSORT extension checklist of ten recommendations when reporting harms in randomized controlled trials (n = 18)

Author (Year)	1	2	3	4	5	6	7*	8**	9	10
Brismee et al (2007)[17]				X		X	X			
Hall et al (2011)[16]							X			
Li et al (2004)[33]							X			
Li et al (2004)[32]						X	X	X		
Ni et al (2010)[30]			X	X		X	X			
Shen et al (2010)[45, 67]	X	X	X	X			X	X		X
Taylor et al (2012)[53]				X			X	X		
Tsang et al (2007)[46, 47]	X		X	X		X	X			
Tsang et al (2010)[48]			X	X		X	X	X		
Wang et al (2009)[54]	X					X	X			
Wang et al (2010)[31]	X		X	X			X			X
Wayne et al (2012)[49]				X			X	X		
Wolf et al (2003)[55]			X			X	X			
Wolfson et al (1996)[19]			X	X			X			
Yeh et al (2004)[50]			X	X			X			X
Yeh et al (2010)[51]			X	X			X	X		X
Yeh et al (2011)[52]			X	X			X	X		X
Yeung et al (2012)[18]	X	X		X			X			X

*We considered study to have addressed recommendation 7 if the denominator for harms could be easily inferred from the CONSORT flow diagram or other text describing 'what follow up-time counts towards overall exposure'

**We considered study to have addressed recommendation 8 if adverse events were further categorized per arm by type, grade, OR seriousness (where we included relatedness to the intervention as a type). If there were no events in the control arm, this needed to be stated.