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Original Article

A Randomized Controlled Trial of Tai Chi for Tension Headaches

Ryan B. Abbott[1], Ka-Kit Hui[1], Ron D. Hays[2], Ming-Dong Li[1] and Timothy Pan[1]

[1]Center for East West Medicine, Department of Medicine and [2]Division of General Internal Medicine and Health Services Research, David Geffen School of Medicine, University of California at Los Angeles, Los Angeles, CA 90095, USA and RAND Corporation, Santa Monica, CA 90407, USA

This study examined whether a traditional low-impact mind–body exercise, Tai Chi, affects health-related quality-of-life (HRQOL) and headache impact in an adult population suffering from tension-type headaches. Forty-seven participants were randomly assigned to either a 15 week intervention program of Tai Chi instruction or a wait-list control group. HRQOL (SF-36v2) and headache status (HIT-6™) were obtained at baseline and at 5, 10 and 15 weeks post-baseline during the intervention period. Statistically significant ($P < 0.05$) improvements in favor of the intervention were present for the HIT score and the SF-36 pain, energy/fatigue, social functioning, emotional well-being and mental health summary scores. A 15 week intervention of Tai Chi practice was effective in reducing headache impact and also effective in improving perceptions of some aspects of physical and mental health.

Keywords: complementary and alternative medicine – health-related quality-of-life – integrative medicine – Tai Chi – tension-type headache – traditional Chinese medicine

Introduction

A Clinical and Epidemiological Description of Tension-Type Headaches

According to the National Headache Foundation, more than 45 million Americans suffer from chronic headaches, with losses of $50 billion a year to absenteeism and medical expenses and an excess of $4 billion spent on over-the-counter medications (1). Tension-type headaches (TTH), which represent approximately 78% of all headaches (1), occur either in single episodes or chronically, and are often the result of temporary stress, anxiety, fatigue or anger. Symptoms include soreness and pain, a tightening band-like sensation around the head, pressure sensations, and contracted head and neck muscles. Symptoms are bilateral and are not aggravated by physical activity. Standard care for TTH includes relaxation routines, massage, biofeedback, pharmacological interventions (such as over-the-counter pain killers and muscle relaxants) and stress reduction (2).

The Usage of Complementary and Alternative Medicine in the US is Substantially Increasing

In the US, complementary and alternative medicine (CAM) use has increased substantially in recent years [CAM is a group of diverse medical and health care systems, therapies and products that are not presently considered to be a part of conventional medicine (examples include chiropractics, ayurveda, homeopathy, naturopathy, etc.) (3)]. In 2002, 62% of the US adults polled said that they had used some form of CAM within the past year (3). In 1997, it was estimated that the US public had spent between $36 billion and $47 billion on CAM therapies, with between $12.2 billion and $19.6 billion spent out-of-pocket for professional CAM services (more than the out-of-pocket fees for all hospitalizations in that year, and about half that paid for all out-of-pocket physician services) (3).

Traditional Chinese medicine (TCM) is a complete system of medicine representative of CAM practices. TCM dates before the common era in written form, and its techniques

For reprints and all correspondence: Ka-Kit Hui, UCLA, 2428 Santa Monica Boulevard, Suite 208, Santa Monica, CA 90404, USA. Tel: +1-310-828-9358; Fax: +1-310-829-9318; E-mail: khui@mednet.ucla.edu

include acupuncture, herbal medicine and practices such as Tai Chi.

Tai Chi is a Traditional Mind–Body Exercise and an Evidence-Based Treatment for a Variety of Conditions

Tai Chi is a form of traditional Chinese exercise that purports to improve health by changes in mental focus, breathing, coordination and relaxation. The goal of Tai Chi is to 'rebalance' the body's own healing capacity. Tai Chi has been practiced in China for hundreds of years and is now widely practiced throughout the world. It has been estimated that over 100 million people regularly practice Tai Chi in China alone (4).

As examined in two recent review articles (5,6), studies have shown that Tai Chi can help to improve balance and prevent falls in the elderly (7,8), improve musculoskeletal conditions (9,10), lower hypertension (11), enhance cardiovascular and respiratory function (12), improve mental health (13,14), and enhance endocrine and immune functioning (15–17).

This study sought to examine whether Tai Chi would prove to be effective in the treatment of TTH. As early as 1990, relaxation therapy and biofeedback had been shown to be effective in the treatment of TTH (18), and Tai Chi may have an effect similar to both of these interventions. Also, it has been demonstrated that acupuncture is effective in the treatment of TTH (19,20), and it is believed in TCM theory that acupuncture and Tai Chi operate along the same principles (21).

Methods

Study Approval, Participant Criteria and Recruitment

The protocol and informed consent forms were reviewed and approved by the Institutional Review Board (IRB approval#: 03-12-063-01) at the University of California at Los Angeles (UCLA).

Inclusion criteria were as follows: adults between 20 and 65 years of age at time of trial with the ability to undertake 30 min of mild exercise a day, who were diagnosed with TTH [using International Headache Society (IHS) criteria (10)] by a physician at the UCLA Center for East West Medicine (CEWM). Exclusion criteria were as follows: having any headache condition other than, or in addition to, TTH (e.g. migraine, cluster headaches, etc.); having previous practice of Tai Chi or Qi Gong (Qi Gong refers to all traditional Asian health practices involving what is thought to be the circulation of energy in pathways throughout the body, whereas Tai Chi is a martial art developed from Qi Gong practices and is considered a form of Qi Gong); significant comorbid illness that would be expected to prevent completion of the study; any additional conditions (e.g. severe hearing loss, respiratory, cardiovascular or neurological problems) that might interfere with the required intervention and evaluations; any acute intercurrent illness that might interfere with the interpretation of the study (e.g. influenza); and self-reported inability to commit to the intervention schedule.

Participants were volunteers recruited from the Los Angeles area who responded to advertisements circulated by the UCLA Department of Medicine and posted in local newspapers seeking adults with tension headaches wishing to receive free treatment. Interested participants were asked to telephone and were screened to determine eligibility. Informed consent was obtained during the first visit to the CEWM, where participants were then independently screened for recruitment criteria.

Out of 122 Potential Participants 47 Met All Recruitment Criteria and Were Randomized into Either the Control or Intervention Group

A total of 122 phone calls were received from potential participants (see Fig. 1). Of these, 29 (24%) did not respond to follow-up contact, 4 (3%) were unwilling to provide eligibility information, 29 (24%) were deemed ineligible from phone interview and 9 (7%) potential participants were no longer interested in participation after hearing details of the study. After screening, 4 (3%) additional potential participants were deemed ineligible. It was determined that 47 (39%) participants met all recruitment criteria and were randomized into either the control group ($n = 23$) or intervention group ($n = 24$).

Thirty of the Forty-Seven Randomized Participants Completed the Study

After randomization, five participants declined to participate as a result of a time delay between recruitment and randomization, or due to conflicts with the intervention schedule. Hence, a total of 42 participants were randomized to the treatment ($n = 21$) or the control group ($n = 21$). During the course of intervention, an additional 8 participants dropped out of the treatment group and 4 participants dropped out of the control group, leaving 30 participants who completed the study (13 in the treatment group; 17 in the control group).

The Intervention Consisted of 15 Weeks of Bi-Weekly Instruction in the Yang Style Short Form of Tai Chi

Participants in the intervention group received bi-weekly sessions an hour in duration for 15 weeks. There were two cohorts for the intervention group to provide more flexibility to participants. Classes were taught at a local park distinct from the location of study assessment.

Subjects were taught the classical Yang style of Tai Chi short form. This 24 standardized movement form is the most widely practiced style of Tai Chi (4). An instructor with over 20 years of experience in Tai Chi instruction and practice administered sessions.

Handouts were provided summarizing the Tai Chi movements, and a video of the form was provided to assist participants.

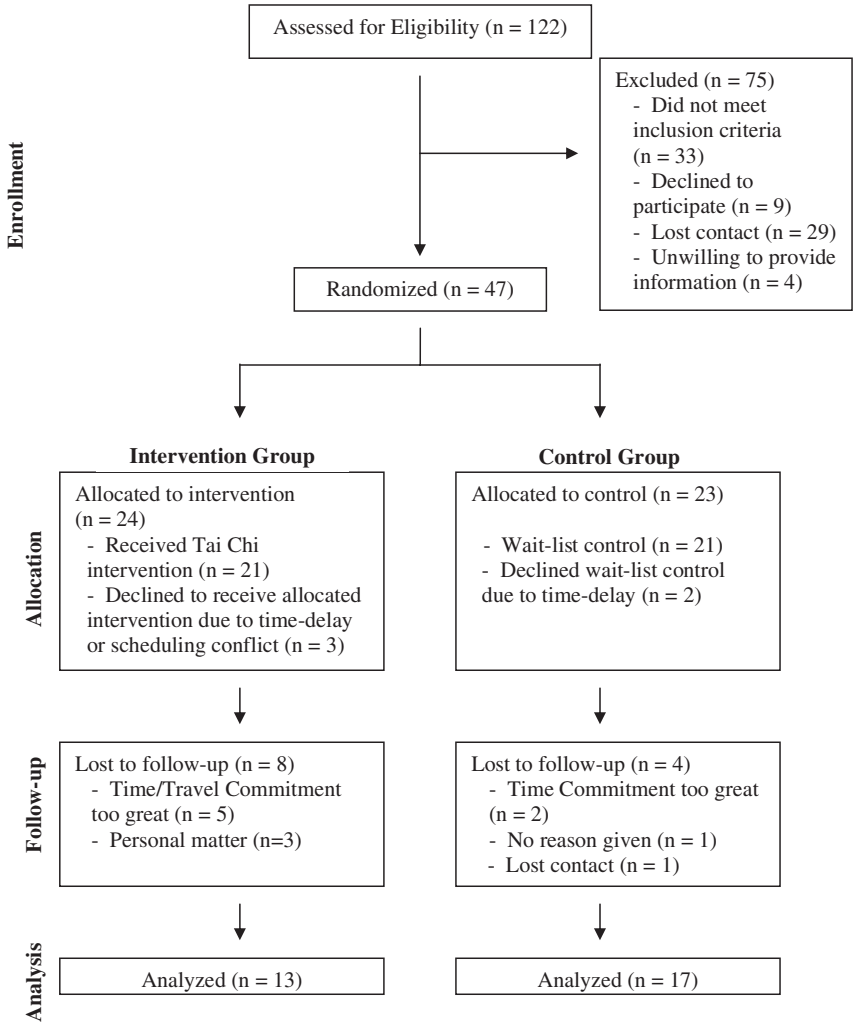

Figure 1. Study design and flow of subjects.

Improvement was Assessed with the Health-Related Quality-of-Life Measure SF-36v2 and the Headache Impact Measure HIT-6™

Health-related quality-of-life (HRQOL) was assessed with the SF-36v2, a generic measure that has been extensively used in both clinical and research settings (22). The SF-36v2 measures eight domains of health as follows: general health perceptions (5 items); physical functioning (10 items); role limitations due to physical problems (4 items, role-physical); bodily pain (2 items); energy/fatigue (4 items); social functioning (2 items); role limitations due to emotional problems (3 items, role-emotional); and emotional well-being (5 items).

The HIT-6™ is a 6-item fixed-length, short-form version of the DYNHA® Headache Impact Test designed to capture the effect of headache and its treatment on an individual's functional status and well-being. The items in HIT-6™ cover the content areas found in widely used measures of headache impact, including pain, ability to carry out usual activities, social functioning, energy/fatigue, cognitive functioning and psychological distress. HIT-6™ is useful both for screening and for monitoring change in disease impact (23).

Assessment Methods

Assessment was performed before the first treatment session (post-randomization), at Weeks 5, 10 and 15 during the 15 week intervention period. Each participant received a mailing on the first day (Monday) of each assessment week containing all self-report measures with instructions, and was asked to return the assessments in an enclosed self-addressed stamped envelope by the end of the week. Participants were called on the second day (Tuesday) of each assessment week to verify that the mailing had been received. Participants were called on the fourth day (Thursday) and fifth day (Friday) of the week as a reminder. All outcome measures were held in a secure location at the CEWM in sealed envelopes until the completion of the intervention period.

Statistical Analysis

An administrative assistant (in no other way connected with the study) was the only person given access to the data, and was responsible for entering all raw data into Microsoft excel for analysis. We evaluated the extent to which randomization

Table 1. Demographic characteristics of participants

	Treatment group ($N = 13$)	Control group ($N = 17$)	Total population ($N = 30$)
Male	23%	29%	27%
Female	77%	71%	73%
Age	47 years	42 years	44 years (SD 13) (range 23–64 years)

Table 2. Differences in changes in HRQOL and headache impact between treatment and control groups

Scale	Beta coefficient for control (standard error)	*t*-statistic	Probability
Physical functioning	2.55 (1.70)	1.50	0.15
Role limitations: physical	5.82 (2.99)	1.94	0.064
Pain	6.36 (2.94)	2.16	0.040
General health	0.91 (2.50)	0.37	0.7175
Energy/fatigue	8.17 (2.62)	3.12	0.0045
Social functioning	6.36 (3.03)	2.10	0.046
Role limitations: emotional	2.90 (3.03)	0.96	0.35
Emotional well-being	7.69 (3.10)	2.48	0.020
Physical health summary	3.57 (1.87)	1.91	0.068
Mental health summary	6.94 (2.70)	2.57	0.016
HIT Score	6.94 (1.32)	5.25	<0.0001

was successful by comparing the age and gender of the treatment and control groups (Table 1). We computed *t*-tests to assess the statistical significance of the difference in changes in SF-36 scores and the HIT score between the treatment and control groups (Table 2). The 15 week follow-up data was used if available. If not available, the 10 week data was used. If still not available, the 5 week data was used. This approach allowed us to maximize the sample size for the analysis. There was too few observations at the individual follow-up intervals to justify a trend analysis.

Results

There were no Differences in Gender or Age Between Groups

There were no significant differences in gender or age between the treatment and control groups (Table 1). The proportion of people randomized to the intervention and control groups that had data and were included in the analysis did not differ significantly (54 versus 74%, $\chi^2 = 1.98$, df = 1, $P = 0.159$).

The Intervention Improved HRQOL and Reduced Headache Impact

There were five significant differences in which the control group scored higher at baseline than the intervention group (see Fig. 2): physical functioning ($t = 2.98$, $P = 0.0083$, df = 17), role limitations due to physical health ($t = 4.21$, $P = 0.002$, df = 28), vitality ($t = 2.57$, $P = 0.0157$, df = 28), social functioning ($t = 2.59$, $P = 0.0151$, df = 28) and the PCS ($t = 3.24$, $P = 0.0031$, df = 28). Because of baseline differences, we regressed follow-up scores on an indicator of group assignment, controlling for age, gender and baseline score on the outcome measure. This analysis revealed six statistically significant effects of the intervention on the outcome variables (differences in adjusted change in parentheses) as follows: pain (6), energy/fatigue (8), social functioning (6), emotional well-being (8), the mental health summary score (7) and the HIT score (7) [the HIT score has been inverted for ease of interpretation (a lower score indicates reduced headache impact)]. Each of these differences favored the treatment group.

Discussion

The results of the study reveal significant positive effects of Tai Chi on generic health outcomes for people with TTH. The magnitude of the effects was noteworthy ranging from 0.64 to 0.82 of a standard deviation for the significant differences observed.

Rationale for Study Design

This study was designed based on IHS guidelines for pharmaceutical trials (2) and the designs of other Tai Chi research studies. A notable departure from IHS guidelines was the lack of double-blind design and placebo control. Unfortunately, the nature of the intervention precludes blinding participants to their group assignment. A recent review article of Tai Chi studies (5) notes that of the 47 studies judged to be of sufficient academic rigor (9 RCTs, 23 NRSs and 15 observational studies), none were double-blind.

The control group was placed on a wait list for Tai Chi instruction instead of receiving a placebo intervention. This wait list control design was also used in a recent study of Tai Chi for varicella-zoster virus specific immunity and health function by Irwin *et al*. (15,16).

There are different styles of Tai Chi, and the studies that have examined Tai Chi to date have not examined a standardized style. However, it should be noted that all forms of Tai Chi studied share a low-impact nature, and involve the practice of changes in mental focus, breathing, coordination and relaxation. The differences between various forms of Tai Chi may be negligible in terms of their efficacy. Even so, instruction was given in the most popular form of Tai Chi, the Yang style short form.

The most significant difficulty encountered during the study was a relatively high dropout rate. No participant reported an adverse effect from the intervention. Of the eight dropouts in the intervention group, five (62%) participants who dropped out stated that the time commitment and travel required by them was too much to attend and three (38%) participants dropped out of the study due to personal reasons. Of the five dropouts in the control group, three (60%) participants stated that the time commitment for the evaluations was too much,

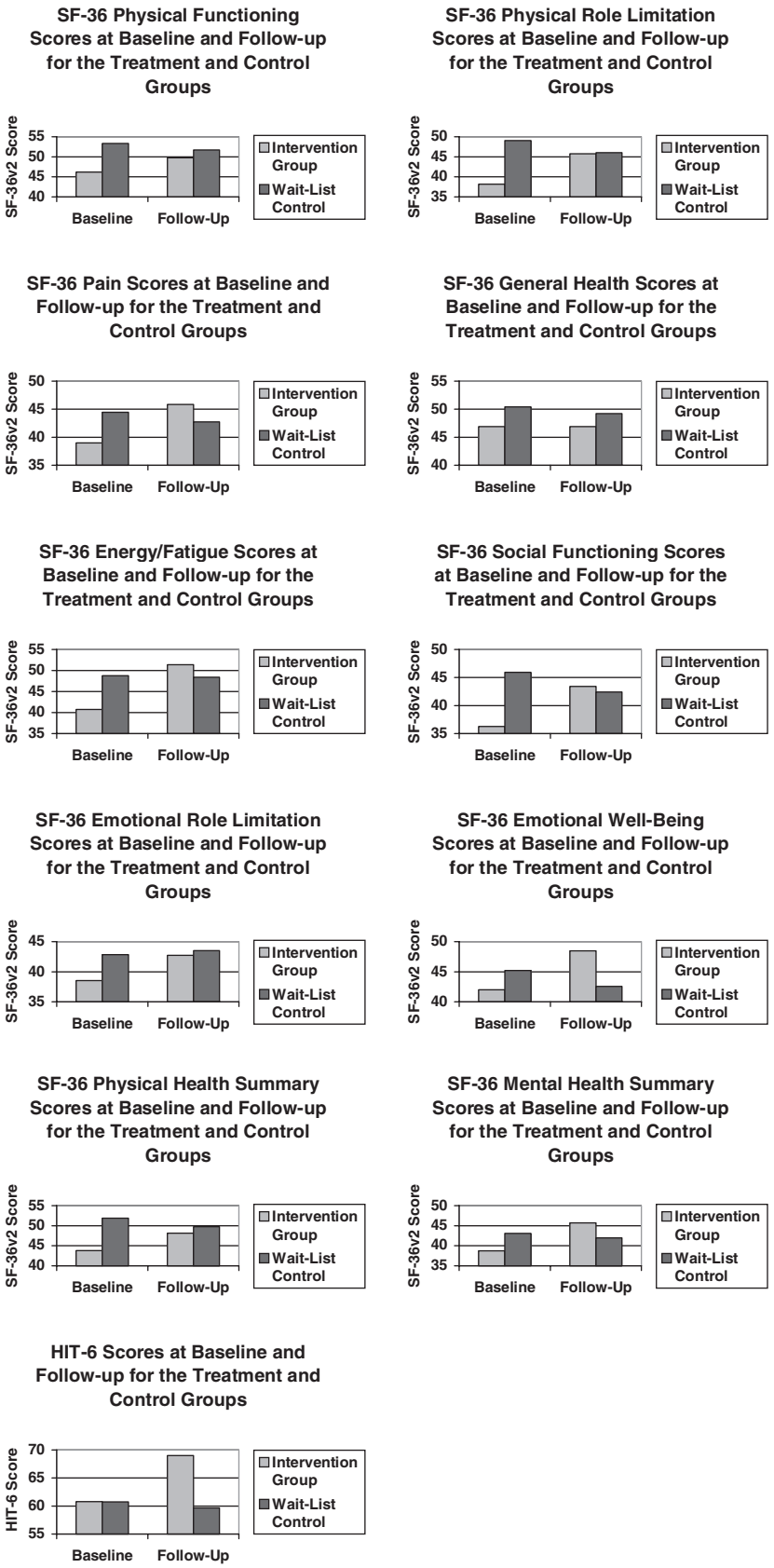

Figure 2. SF-36 and HIT scores at baseline and follow-up for the treatment and control groups.

one (20%) participant declined to give a reason for dropout, and one (20%) participant could not be contacted. In future trials, additional participant compensation may reduce the dropout rate.

This study has provided evidence of the efficacy of Tai Chi in treating TTH and improving HRQOL. Given these results, a larger study is warranted with increased sample size. In future research, the population may be expanded to include other types of headache conditions.

Benefits of Tai Chi Compared with Pharmaceutical Intervention

As an intervention for headache, Tai Chi offers several benefits over conventional treatment. Virtually all pharmaceutical-based interventions include some risk to the patient of side-effects or complications, particularly over a long-term course of use. Of the most widely utilized drugs for TTH, acetaminophen (the active ingredient in Tylenol and other pain medications) can cause liver toxicity, and NSAIDS (such as ibuprofen and aspirin) can cause gastrointestinal symptoms and bleeding. To the extent that treatment can be refocused to exercise-based therapies, this will provide significant benefit to the patient.

Furthermore, not all patients respond favorably to pain medications. Patients may find only partial relief for their symptoms, or may be completely unable to tolerate pharmaceutical intervention. To the extent that Tai Chi represents a viable alternative to medication, it provides a major addition to the arsenal of potential treatments.

Tai Chi may also help to control the cost of treatment because it requires only an initial period during which the patient receives training. This cost is low compared to newer (on-patent) pharmaceutical treatments (if required) which may include repeated physician visits to ensure proper progress, and also low compared with the long-term cost of over-the-counter medications (and their potential complications).

Finally, Tai Chi does more than alleviate pain or provide symptomatic relief; it benefits HRQOL. This may be because Tai Chi addresses an underlying cause of the pain associated with TTH, namely stress. The pain associated with TTH may be caused by, or exacerbated by, muscle contractions caused by stress. [The exact cause of TTH is not clear. Muscle tension or spasms of the head or scalp, neck, face or jaw have been thought to play a role. TTH pain may also be the result of the same biochemical changes in the brain and impaired blood flow in the scalp and neck that lead to migraine headaches (24,25).] Analgesics will only target the symptoms of stress. When medication stops, the pain may return because the underlying problem has not been adequately managed. With its emphasis on relaxation, breathing, focus and coordination, Tai Chi seems to directly affect stress and tension that contribute to the pain associated with TTH (16). In addition to affecting this pain, Tai Chi may affect other symptoms that arise from stress such as tachycardia, fatigue, anxiety, insomnia, etc., thus affecting HRQOL.

Conclusions

As a TCM/CAM therapy, Tai Chi offers a holistic approach to patient care that differs from the approach of conventional treatment. Tai Chi offers a range of benefits, and can be integrated with other modalities of TCM, CAM and conventional medicine. To integrate CAM and conventional medicine into a new model that is safer, accessible, affordable and effective will require additional research. Future well-designed clinical studies are needed.

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