23 (2015) 570–576

Contents lists available at ScienceDirect

Complementary Therapies in Medicine

journal homepage: www.elsevierhealth.com/journals/ctim

A supplemental report to a randomized cluster trial of a 20-week Sun-style Tai Chi for osteoarthritic knee pain in elders with cognitive impairment

Pao-Feng Tsai [a,*], Jason Y. Chang [b], Cornelia Beck [c], Yong-Fang Kuo [d], Francis J. Keefe [e], Karl Rosengren [f]

[a] College of Nursing, University of Arkansas for Medical Sciences, 4301 West Markham St. Slot 529, Little Rock, AR 72205, USA
[b] Department of Neurobiology and Developmental Sciences, College of Medicine, University of Arkansas for Medical Sciences, 4301 West Markham St. Slot 510, Little Rock, AR 72205, USA
[c] Department of Geriatrics, College of Medicine, University of Arkansas for Medical Sciences, 4301 West Markham St. Slot 808, Little Rock, AR 72205, USA
[d] Department of Preventive Medicine and Community Health, University of Texas Medical Branch, 301 University Blvd, Galveston, TX 77555, USA
[e] Department of Psychiatry and Behavioral Science, Duke University Medical Center DUMC 3159, Durham, NC 27710, USA
[f] Department of Psychology, University of Wisconsin-Madison, 1202 West Johnson St. Madison, WI 53706, USA

ARTICLE INFO

Article history:
Received 2 September 2014
Received in revised form 6 May 2015
Accepted 2 June 2015
Available online 9 June 2015

Keywords:
Tai chi
Knee osteoarthritis
Pain report
Pain behavior
Cognitive impairment

ABSTRACT

Objective: This was a secondary data analysis of a cluster-randomized clinical trial that tested the efficacy of a 20-week Sun-style Tai Chi (TC) program in reducing pain in community-dwelling elders with cognitive impairment and knee osteoarthritis (OA). The study also examined whether elders' level of cognitive function was related to the outcomes of the TC program.
Method: Elders ($N = 55$) were recruited from 8 study sites. Each site was randomly assigned to participate in either a 20-week TC or an education program. Verbal report of pain was measured by a Verbal Descriptor Scale (VDS) at weeks 1, 5, 9, 13, 17 and 21 (designated as times 1–6). Pain behaviors and analgesic intake were also recorded at times 1–6.
Results: At post-test, scores on the VDS and observed pain behaviors were significantly better in the TC group than in the control group ($p = 0.008$–0.048). The beneficial effects of TC were not associated with cognitive ability.
Conclusion: These results suggest that TC can be used as an adjunct to pharmacological intervention to relieve OA pain in elders with cognitive impairment.
Trial registration: Clinical Trial.gov NCT01528566.

1. Introduction

Osteoarthritis (OA) is a painful musculoskeletal disorder. The prevalence of OA in elders with cognitive impairment is comparable to that in elders without cognitive impairment. Among people with cognitive impairment, 38.2–52% are reported to have OA, compared with 31.8–60% of people without cognitive impairment.[1,2] The knee is particularly affected because it is a major weight-bearing joint and is ranked 2nd in years lost to disability among all diseases and injuries.[3] Pharmacological interventions for OA knee pain have shown limited efficacy,[4] and in elders they can produce side effects such as impaired concentration, agitation, increased risk of hypertension and hip fracture, and decreased renal function.[5–9] Alternative non-pharmacological interventions should therefore be considered to treat knee OA pain in this frail population.

Non-pharmacological interventions for elders with knee OA pain include land-based exercise, water-based exercise, strength training, self-management and education.[10] Among these, land-based exercise and strength training have the largest effect sizes in treating pain associated with knee OA (land-based exercise: 0.34–0.63 vs. strength training: 0.38) and improving function (land-based exercise: 0.25 vs. strength training: 0.41).[10–12] Because of the pain, elders with knee OA tend to avoid activity, including land-based exercise such as walking and running.[13] However, they may

* Corresponding author. Fax: +1 501 296 1765.
E-mail addresses: tsaipaofeng@uams.edu (P.-F. Tsai), jychang@uams.edu (J.Y. Chang), Corneliabeck@uams.edu (C. Beck), yokuo@utmb.edu (Y.-F. Kuo), francis.keefe@duke.edu (F.J. Keefe), krosengren@wise.edu (K. Rosengren).

http://dx.doi.org/10.1016/j.ctim.2015.06.001
0965-2299/

be willing to participate in mild exercise that does not worsen pain. Tai Chi (TC), a low-impact aerobic exercise, has shown promise in reducing OA knee pain in elders with an effect size of 0.72 (95% CI: 0.97, 0.47).[14–19] It is also recommended by the United States Arthritis Foundation for treating OA.[20] However, studies examining the efficacy of TC have largely excluded elders with clinical cognitive impairment,[15–19] even though cognitive impairment is common among elders.

If TC can reduce OA knee pain in elders with cognitive impairment, perhaps these elders can perform activities of daily living longer, thus delaying their institutionalization. In addition to reducing OA knee pain, benefits of TC have been shown to improve or maintain cognition in elders with very mild to moderate CI.[21–23] However, without directly testing the efficacy of TC in the cognitively impaired, we cannot prescribe the right dose or appropriate strategies for teaching TC to this vulnerable population. Therefore, a randomized controlled trial was designed to test the efficacy of a TC program in reducing OA knee pain among elders with subtle-to-moderate cognitive impairment.

The trial investigated TC's effects on pain (primary outcome) and other secondary health outcomes (discussed elsewhere).[24] The analysis found that cognitively impaired elders with knee OA who attended a 24-week TC program reported less pain than an education attention control group.[24] The elders verbally reported answers to the Western Ontario and MacMaster (WOMAC) pain scale, a 5-item OA-specific pain measurement, to a research assistant. However, it is not entirely clear whether the WOMAC pain scale is reliable with the cognitively impaired, because only one study has examined its reliability with this population.[25]

Therefore, to substantiate our findings, this secondary analysis used additional results obtained with the Verbal Descriptor Scale (VDS) for pain. This tool has been recommended as a way to evaluate verbal self-report of pain intensity in elders with dementia.[26,27] It is a 1-item verbal report tool with a list of words from "no pain" to "the most intense pain imaginable," to indicate the intensity of the pain experienced.[28] Information about the psychometric properties of this tool is detailed in the methods section below.

Elders' pain can also be manifested by both observable pain behaviors and analgesic intake.[29] Without examining changes in these pain manifestations, we cannot confidently claim that TC reduces pain in elders. Furthermore, TC forms consist of a series of upper- and lower-extremity movements performed in a particular choreographic manner. If those with impaired cognition have less learning capability, then TC may be less useful in reducing OA pain among these elders. Therefore, Aim 1 of this secondary data analysis examined the effects of TC on VDS pain reports, observed pain behaviors and analgesic intake. Aim 2 explored the relationship of cognitive level to the observed effects.

2. Materials and methods

2.1. Design

The study was a secondary analysis of data from a previous cluster-randomized clinical trial. In that study, we tested the efficacy of TC in reducing OA knee pain and improving other health outcomes in community-dwelling elders with varying levels of cognitive impairment. The methods of that clinical trial have been reported elsewhere.[24]

[The CONSORT flow diagram was published online at http://www.sciencedirect.com/ as supplementary data.]

The current study used the complete sample from the previous clinical trial and focused on multiple pain outcomes, including the VDS, pain behaviors and analgesic intake. Additionally, the relationships between these outcomes and cognition were analyzed.

2.2. Participants

Recruitment was conducted in 8 study sites (6 retirement apartments and 2 senior centers) between January 2008 and February 2010. A total of 123 elders in the 8 study sites were recruited and screened for eligibility; 55 in the 8 study sites were eligible and each site was randomly assigned to a TC group ($N = 28$) or an education control group ($N = 27$). Participants were aged ≥60 years; had moderate, mild or subtle cognitive impairment, defined as a Mini Mental State Exam (MMSE) score of 18–28; had a diagnosis of knee OA based on medical history reviewed with elders or family members/staff and confirmed by a health care provider; had self-report of knee OA pain ≥2 on the VDS or a pain score ≥3 on the WOMAC pain subscale; were able to speak English; had physician's/nurse practitioner's permission to participate; had not participated in a regular exercise program in the past month; could walk without assistance from staff or a walking device for 50 meters; and could stand and maintain balance for 1 minute without support.

We included only elders with MMSE scores of 18–28 to focus on those with less than optimum cognitive function. The MMSE score range used is consistent with several recent studies which categorized elders with MMSE scores equal to or less than 28 as having low cognitive function or symptomatic cognitive impairment.[30,31]

Elders were excluded if they had uncorrectable moderate or severe hearing or vision deficits; Parkinson's disease; cancer pain; chronic pain conditions, such as rheumatoid arthritis, fibromyalgia, or severe low back pain; diabetic neuropathy; arthroscopic surgery or total knee or hip replacement surgery in the past 6 months; fractures in the past 6 months; major psychiatric disorder or a positive screen for depressive symptoms (Geriatric Depression Scale-15 score ≥5) without taking medications; history of falls in the past 3 months; or vertigo in the past month. Approval by the University's Institutional Review Board was granted, and informed consent was obtained from all participants.

2.3. Randomization and blinding

Research assistants (RAs) recruited participants at each site and screened potential participants for eligibility. Assessor 1 conducted a pre-test for the outcome measures. The statistician, who was blinded to the characteristics of the sites and the elders, then randomly allocated each site to either the TC or the control arm.

The two lead investigators on the study (Tsai and Chang) were involved closely in the fieldwork and thus were not blinded to participants' group assignments. The RA who screened elders for eligibility, enrolled the elders, and collected data on site also could not be blinded to group assignment. The same instructors led both the TC and the control groups so they were not blinded. Assessor 1, who collected outcome data, could not be completely blinded because cognitively impaired participants revealed their group assignment during conversations with the assessor. The rest of the research team, including the three co-investigators and Assessor 2, who reviewed and coded pain behavior, were blinded to group assignment.

2.4. Power analysis

A sample of 40 per group (80 total) was required to provide 80% power to detect an effect size of 0.8 using a two-sided t-test with alpha = 0.05. We were able to recruit 55 participants over 3 years for the study. However, as noted in Table 2, the intracluster correlation (ICC) for the observed pain behaviors and analgesic intake was ≤0.0001, and the ICCs for the measure of VDS were 0.181. Based on these data, we estimated the effect size from the design effect of our randomized cluster design.[32] We had sufficient power to detect large effect sizes for observed behavior and the VDS measure (0.89