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Effects of External Qigong Therapy on Osteoarthritis of the Knee A Randomized Controlled Trial

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Abstract

Objectives—To assess the efficacy of external qigong therapy (EQT), a traditional Chinese medicine practice, in reducing pain and improving functionality of patients with knee osteoarthritis (OA).

Methods—112 adults with knee OA were randomized to EQT or sham treatment (control); 106 completed treatment and were analyzed. Two therapists performed EQT individually, 5–6 sessions in 3 weeks. The sham healer mimicked EQT for the same number and duration of sessions. Patients and examining physician were blinded. Primary outcomes were WOMAC pain and function; other outcomes included McGill Pain Questionnaire, time to walk 15 meters and range of motion squatting. Results of patients treated by the 2 healers were analyzed separately.

Results—Both treatment groups reported significant reduction in WOMAC scores after intervention. Patients treated by Healer 2 reported greater reduction in pain (mean improvement −25.7 ± 6.6 vs. −13.1 ± 3.0; $p < .01$) and more improvement in knee function (−28.1 ± 9.7 vs. −13.2 ± 3.4; $p < .01$) than those in the control group. These patients also reported a greater reduction in negative mood, but not in anxiety or depression. Patients treated by Healer 1 experienced improvement similar to the control group. The results of therapy persisted at 3 months follow-up for all groups. Mixed-effect models confirmed these findings with controlling for possible confounders.

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Conclusion—EQT might have a role in the treatment of OA, but EQT healers are not equivalent. The apparent efficacy of EQT appears to be healer-dependent. Further study, on a larger scale, with multiple EQT healers is necessary to determine the role (if any) for EQT in the treatment of OA and to identify differences in EQT techniques.

Keywords

Qigong; Chinese medicine; knee osteoarthritis; pain; functionality; WOMAC

INTRODUCTION

Arthritis is the leading cause of disability in the US [1,2], and osteoarthritis (OA) is the most common form of arthritis, affecting about 21 million Americans [3]. Current pharmacotherapy is limited by incomplete responses, cost, and toxicities (4, 5). Patients suffering from OA are increasingly utilizing complementary and alternative medicine (CAM) treatments, including acupuncture [6,7], herbal medicine [8], massage [9], and Tai chi [10,11]. Qigong therapy, a form of traditional Chinese medical practice, is also used in China for treating arthritis [12, 13], but few randomized controlled trials have been conducted to investigate its efficacy.

Qigong is a general term for a variety of traditional Chinese energy exercises and therapies. Traditional Chinese medicine (**TCM**) posits the existence of a subtle energy (*qi*), circulating throughout the body and in the surrounding environment. According to TCM, good health is the result of free-flowing, well-balanced *qi*, while sickness or pain is the result of a blockage of the qi flow or unbalanced *qi* in the body [14,15]. Although there has been lack of scientific evidence concerning the nature of qi, all TCM therapies, including herbs, acupuncture, massage, and qigong, are based on this concept or assumption. A recent review of randomized controlled trials provided encouraging evidence of external Qigong therapy (EQT) for pain relief [16].

Qigong therapy can be of “internal” or “external” forms. Internal qigong refers to the self practice of mind-body-breathing integration techniques such as Tai chi or meditation. EQT involves hand movements, similar to therapeutic touch, acupressure on specific points, focused attention (possible visualization), and other mind healing techniques to direct the therapist’s own *qi* into the patient. This is intended to break *qi* blockages or remove sick *qi* returning balance to the *qi* system, relieving pain or eliminating disease. There is considerable variability in the forms of EQT practice, varying by school and practitioner.

Some studies in China reported diminution of severe arthritis symptoms after qigong therapy [13,17]. Qigong practice and EQT may diminish symptoms of arthritis by relaxing diseased tissues and enhancing blood flow to the area [18,19]. Increased blood flow leads to more efficient delivery of oxygen, nutrients and pain-killing substances as well as drugs and more efficient removal of mediators of pain and metabolic waste products that contribute to pain [14,18].

Qigong has received increased attention and interest in the U.S. [20] and around the world. However, there is little scientific documentation regarding efficacy or mechanism of qigong therapy for musculoskeletal conditions. Only a few studies have used blinded, randomized and controlled designs; thus controversy continues, with the therapeutic effects of qigong being labeled as purely psychological [21]. Thus, there is a need for well designed clinical trials to investigate the efficacy of qigong therapy.

The purpose of this randomized, placebo controlled pilot study was to evaluate the efficacy of EQT, as measured by pain reduction and functional improvement, in patients with knee OA. We also examined the effect of EQT on negative moods, such as anxiety or depression.

PATIENTS AND METHODS

Design and Setting

This was a randomized, placebo-controlled trial, conducted at a single site and was approved by the Institutional Review Board of UMDNJ-Robert Wood Johnson Medical School. Patients were recruited from January 2005 to May 2006 from the rheumatology clinic at Robert Wood Johnson Medical School, as well as in response to flyers posted in local communities. Treatments were delivered at our facility in Piscataway, New Jersey, which has multiple exam rooms used mostly for clinical studies or treatment of psychiatric patients.

Participants

Eligible participants met the clinical criteria for OA of the knee based on the ACR clinical guidelines, i.e. knee pain (≥ 25 on a 100 pain VAS) plus at least three of the following: age > 50 years; stiffness < 30 minutes; crepitus; bony tenderness; bony enlargement; no palpable warmth [22]. The study physician (AP or AL) performed a physical examination before the study to confirm the diagnosis of OA(no review of X-rays). All subjects had been diagnosed with OA at least 6 months prior to evaluation, were cognitively able to complete the outcome assessments and agreed to maintain a stable analgesic dose for 14 weeks.

Exclusion criteria included: 1) Lack of ability to communicate in English; **2) Starting a** new NSAID or analgesic within last 2 weeks; 3) Diagnosed with fibromyalgia or other maladies that might interfere with his/her ability to judge improvement in OA pain, 4) Recipient of any investigational drug within 30 days; 5) Presence of any inflammatory disease; 6) OA pain at entry less than 25 on the 0–100 VAS; 7) Body Mass Index (BMI) greater than 40; 8) Speak or understand Chinese; and 9) Previous experience with EQT.

After giving informed consent, the patients were assigned a sequential ID number and were examined by the study physician to confirm the diagnosis of OA. Qualifying subjects were classified into one of 8 strata, determined by age (under or above 50), laterality (bilateral or unilateral) and the type of OA (localized or systemic). The research coordinator randomized each subject into one of two treatments within that stratum.

Randomization

The research coordinator randomly assigned qualified patients into treatment groups according to a pre-determined randomization scheme, which has a constant block size of two in a fixed order. The research coordinator was not concealed to the randomization order, but did not know the subject's stratum until after physical examination and immediately before treatment.

Power analysis was based on change in VAS pain after EQT treatments in an open trial without control [23], which reported an effect size d = 1.3 in pain reduction. Assuming up to 35% pain reduction in sham treatment, we used a conservative effect size d = 0.8 for sample size calculation, which found n=35 would give us 95% power to detect group differences (alpha = 0.05). Assuming a 30% dropout rate, we targeted n=100 for initial recruitment to have at least 70 effective cases for the final analysis. However, after realizing that two healers insisted on having their data analyzed separately as the condition for their participation, we increased the sample size slightly to keep up with designed statistical power.

The Intervention

Two qigong therapists (both trained in China but from different traditions) were invited to perform EQT in this study, based on their reputation and on selection criteria used in the field [24]. Although both healers started qigong training as teenagers, their career paths to EQT master were different. Healer 1 was 55 years old, started martial-art training at the age of 13, and started full-time qigong teaching and healing at age 40. As the lineage holder of a Taoist tradition, Healer 1 was well known for his anti-cancer training and achievement in China [25]. Healer 2 was born into a TCM family and was the fifth generation of a qigong family healing tradition. He started treating patients at the age of 13, but did not go to medical school. He was 49 at the time he participated in this study, after 12 years of full-time qigong healing in the U.S.

There is no standard procedure of EQT in the field. The specific healing movement or length of each treatment varies by patient and session, depending upon the healer's perception of the patient's qi status. Although the two healers used different techniques, the basic procedures of EQT for arthritis are similar -- to emit *qi* energy to the painful area to break the blockage and let *qi* and blood flow smoothly in the joint area. Table 1 summarizes the procedures used by the two healers, including both similarities and differences.

The control condition

As qigong healing involves bio-field energy and healing intention, both healers considered it difficult to do sham treatment without thinking of healing. Therefore, we used a sham healer to mimic EQT. A Chinese man without qigong experience was trained to mimic EQT movements for the same number of sessions. During placebo treatment the sham healer would speak only Chinese, as the real healers did, with the same interpreter present during both real and sham healing sessions.

All patients were physically blinded by a black eye-cover; and a dark curtain hung across the exam table to assure the patient could not see the healer. The physician performing physical exam before and after treatment was blinded to group identity. To minimize the possibility that the sham healer may have and use healing energy unintentionally, he was instructed to do a mental arithmetic exercise during healing. All patients were asked to guess the healer's identity after the first treatment to examine the quality of blinding procedure.

Outcome Assessments

Physical examination and self-administered questionnaire assessments were done at base-line, immediately after intervention and 3 months after intervention. Demographic data and medical history were collected. Patients were asked to not alter current medications and other therapies unless medically necessary. Use of analgesics and NSAIDs was monitored during the trial, allowing us to measure changes in drug dosage without the confounding issue of new drugs or therapies. Patients were instructed to keep a diary on their daily use of medications and other therapies.

The primary outcomes are pain and functionality scores in the Western Ontario and MacMaster University OA (WOMAC) Index [26], which consists of 24 questions (5 for pain, 2 stiffness, and 17 physical functions). A reduction of scores from baseline indicates an improvement. All items are rated on a 0–100 visual analog scale (VAS) (from no symptom or limitation and to maximum symptoms or limitation). Scores were standardized by calculating the mean of the corresponding unweighted item scores in each of the subscales [27]. The global score was computed by weighting each subscale differently by significance, a formula proposed by Bellamy [27].

Additional outcome measures included the McGill Pain Questionnaire (MPQ-SF) [28], time to walk a 15-meter straight path, and range of motion when squatting down to the lowest position without pain, using a standard goniometric assessments performed by the same physician. Assessment of mood disorder included the Spielberger State-Trait Anxiety Scale [29], the CES-Depression scale [30], and an adopted general mood index with four VAS to measure general feelings, mood, sickness and energy level.

Analytic Strategy

Summary statistics were computed for all variables. The *t*-test and chi-square tests were used to assess if randomization achieved its purpose of balancing the distribution of the baseline variables. For the main effects (difference between EQT and sham groups), we modeled the two measurements using linear random intercept regression models to account for the positive correlation. Other predictors include the baseline measurement of the respective outcome, gender, age, body mass index (BMI), belief in complementary and alternative medicine (CAM) therapies, and years of OA pain. Data were analyzed using SAS statistical software (SAS Program). Significance for the 2-tailed *t* test was set at $p < .05$. Since every subject who received treatment were included in the Mixed-effect analysis as randomized (including those lost in follow-up), this also serves as intent-to-treat analysis.

The results from two qigong healers were analyzed separately, since the healers required us to analyze the outcomes separately as the condition for their participation. Like psychotherapy, there are large variations in style and efficacy among healers and it is scientifically important to document those differences. The techniques used by two healers are indeed quite different. Healer 1 and Healer 2 are therefore treated as two experimental conditions in the analysis.

RESULTS

Of the 162 screened candidates, 112 qualified for the study (Figure 1). Forty one (25%) were ineligible for various reasons (Figure 1), mostly the presence of other complicating diseases. Of the 112 qualified, 60 were randomized to the EQT group and 52 to sham treatment. The difference in number of subjects seen by each healer was due to differences in available time and scheduling conflicts. In addition, the study was designed for 2, not 3, randomization arms.

Six patients dropped out during the treatment (2 in Healer 1, 1 in Healer 2 and 3 in sham group); 106 (94.6%) completed scheduled treatments. Fifteen patients did not have a 3 month follow-up (6 from Healer 1, 2 from Healer 2 and 7 from sham group).

Baseline data of the two groups were similar in all key demographic and outcome measures (Table 2). The majority of participants were female (71.7%), Caucasian (84%), college-educated (79.3%), with OA of both knees (75%). Two-thirds believed in Complementary and Alternative Medicine (CAM) therapies and had previous experience with some CAM therapies. Thirty percent did not take any medication at the time of study entry.

Primary Outcomes

Figure 2 presents the means of the WOMAC pain and functionality scores, at baseline, immediately after and 3 months after treatment for the 3 treatment groups (Sham, Healer 1 and Healer 2) respectively. The difference between the Sham and Healer 1 groups is small but much larger between sham and Healer 2 groups.

The two points of measures for primary outcomes (pain, functionality and total WO-MAC) were modeled in mixed-effect model. The predictors included Healer 1 versus placebo, Healer 2 versus placebo, baseline measurements, gender, age, BMI, belief in CAM therapies, and duration of OA pain. These predictors were selected to enter the final model using backward

elimination. The regression coefficients of intercept, baseline effect, and main effects are given in Table 3. For all 3 outcomes, the respective baseline value was found to be positively associated with their values at, after treatment and at 3 month follow-up. There was no statistically significant difference between Sham group and Healer 1 group, but there was a significant difference between sham group and Healer 2 group for pain ($p < .01$), functionality ($p < .01$) and for total WOMAC scores ($p < .01$). Most potential confounders were not statistically significant, except for belief in CAM therapy, which was a significant covariate predicting treatment outcomes immediately after treatment ($p < .05$), but not significant for the outcome in three months follow-up. This covariate did not wipe out the significance of the main effects.

Other Outcomes

Table 4 presents the results of other outcomes and emotional variables after treatment. There are significant differences between Healer 2 and placebo group in reduced pain measured by MPQ ($p < .05$) and slightly reduced time for walking 15 meters ($p = .08$) after treatment. Differences in pain reduction are smaller between Healer 1 and the placebo group ($p = 0.09$), and are not statistically significant for reduced time in walking 15 meters ($p = 0.35$). Improvement in range of motion when squatting did not reach statistical significance.

For psychological outcomes, no significant differences were found in depression or anxiety scales. There was a marginal reduction in negative mood among those treated by Healer 2 in comparison to the sham control ($p = 0.07$), but not among those treated by Healer 1.

To examine the quality of the blind, participants were asked to guess which group they were in after the first treatment. The proportions that thought they received real EQT treatment was 47% for group treated by Healer 1, 91% for group treated by Healer 2, and 45% for placebo group (rest answered “not sure”) – more subjects treated by Healer 2 guessed they were being treated by a real healer than other two groups ($p = 0.04$).

Among those who used pain-killers at baseline (63%), the proportion of participants who reduced their medication use after intervention was 38% in Healer 1 group, 20% in Healer 2 group and 25% in sham group correspondingly. The proportion reducing medication use 3-month later was 35% in Healer 1 group, 50% in Healer 2 group, and 27% in sham group. None of differences are statistically significant.

Safety Data

Subjects were asked to report any adverse events related to treatment during the trial. One subject in the EQT group reported continuous pain after treatment and went to previously scheduled surgery. One receiving EQT reported increased pain in an unrelated area. Two subjects in control reported increased pain after intervention, and asked for medical advice for additional modalities. Three participants in real EQT reported increased pain after the first 2 sessions, but recovered to baseline or better level when coming back for the next treatment.

DISCUSSION

To the best of our knowledge, this is the first randomized controlled trial assessing the efficacy of EQT for OA. This study is inconclusive, but highlights the methodological challenges in conducting trials of EQT, in that the two healers produced significantly different outcomes. EQT may be a safe and effective modality for knee OA, but all qigong healers are not the same; rigorous clinical studies are needed to identify the true healing capability of a qigong healer.

The placebo effect generated by a sham healer mimicking EQT movement worked well in this study. Assessment of quality of the blinding found no difference on guessing the treatment

conditions between the two groups (except group by Healer 1). The control group with sham healer achieved quality blinding and the placebo (expectation) effect of 26% reduction in pain and 29% reduction in functionality after treatment. This magnitude of the placebo effect is similar to that achieved for sham acupuncture in a large study of knee OA [6]. However, use of a sham procedure in such a trial may also underestimate the true treatment effect [32].

The results of this study show that both EQT and placebo groups reported significant reduction in pain and functionality scores from baseline ($p < .05$) after intervention. Patients treated by Healer 2 reported greater reduction in pain and functional difficulty than those in control ($p < .01$). This improvement persisted 3 months later. However, those treated by Healer 1 reported no significant difference from those in the sham-treatment group. These were true with controlling for age, gender, BMI, and belief in CAM therapy. The results from secondary outcomes, such as MPQ and walking 15 meters, are also consistent with these findings.

A previous study of EQT reported significant reduction in anxiety [33]. Our study found no significant change in anxiety or depression index in any treatment group.

We were cautious in selecting capable healers for this study since we knew that not all qigong masters produce measurable outcomes in a controlled study. We have worked with both healers in previous studies [23,34–36], including some laboratory studies. Healer 1 demonstrated the capability to generate measurable outcomes in laboratory studies to inhibit tumor growth [34,35]. In the previous uncontrolled pilot study, the average pain reduction in 6 patients treated by Healer 1 was about 70% after 3 treatments.[23] However, in this study patients treated by Healer 1 reported improvement no better than those sham-treated patients. It is possible that Healer 1 may work more effectively in oncologic than with rheumatologic cases.

Some obvious limitations to this study include: 1) a small sample size with homogeneous participants limits the study's power for subgroup analysis and the generalizability of results; 2) treatment is short (3 weeks)- OA is a chronic disease and this duration/dosage might have been inadequate; 3) only two healers were tested in this study, and they are not the average or representative healers in the field to represent EQT in general; and 4) although we asked the participants not to switch medication during the study period and to keep a diary on their use of medications and other therapies, only one third of them returned that diary so we could not reliably estimate if change in medication dosages had affected our results (point assessments gave use and type of medications only, no dosage information).

Due to the specific focus of this study, we did not take full advantage of qigong therapy, since we did not include a self-practice component as part of the treatment. Qigong is considered mostly as a self-care tool in health, and active self-practice is one of the key concepts of qigong therapy [15]. EQT is an important beginning step, as a helping tool to assist the patient to restore *qi* balance, or gain strength and confidence in qigong. Therefore, future studies should include patient self-practice (internal qigong) as part of the treatment procedure. It is important to verify the efficacy of EQT since EQT is said to be able to restore the balance of *qi* in patients who cannot do so themselves. EQT is particularly important because not everyone is willing or able to commit to qigong practice daily. It may need scientific proof of the efficacy of EQT before patients will believe in qigong enough to commit to qigong practice [37].

Little is known about the mechanism behind qigong therapy. TCM believes that open meridians (smooth *qi* flow) support health, while *qi* blockage is the source of many pains and diseases. It is assumed that qigong healer could use EQT to break the *qi* blockage to get rid of the pain [14]. Wang [38] reported that qigong therapy – both self-practice and EQT -- increased the pain threshold for patients with various diseases. Zhang [39] reported the analgesic effect of EQT in a placebo-controlled study, and found that EQT increased the human skin pain threshold as measured by the method of potassium-mediated pain. These findings may partially

explain the therapeutic effect of EQT observed in this study. Future research should include in-depth studies of mechanisms of EQT, including psycho-physiological measures for both patients and healers during treatment, and X-ray or MRI examination for pathological changes after the treatment.

In short, the results of this study are inconclusive on efficacy of EQT. It would appear that for one of these healers, EQT might be an effective complementary treatment for OA with beneficial outcomes persisting for 3 months. However, treatment effects vary with utilization of different healers. Further study on a larger scale with multiple healers from the same qigong tradition is needed to confirm the preliminary findings, and to determine optimal treatment protocol, cost-effectiveness, and generalization to other patient groups. Given the limitation and potential adverse effects of pharmacological intervention for OA, qigong therapy might prove to be a valuable option as an adjunct to conventional modalities.

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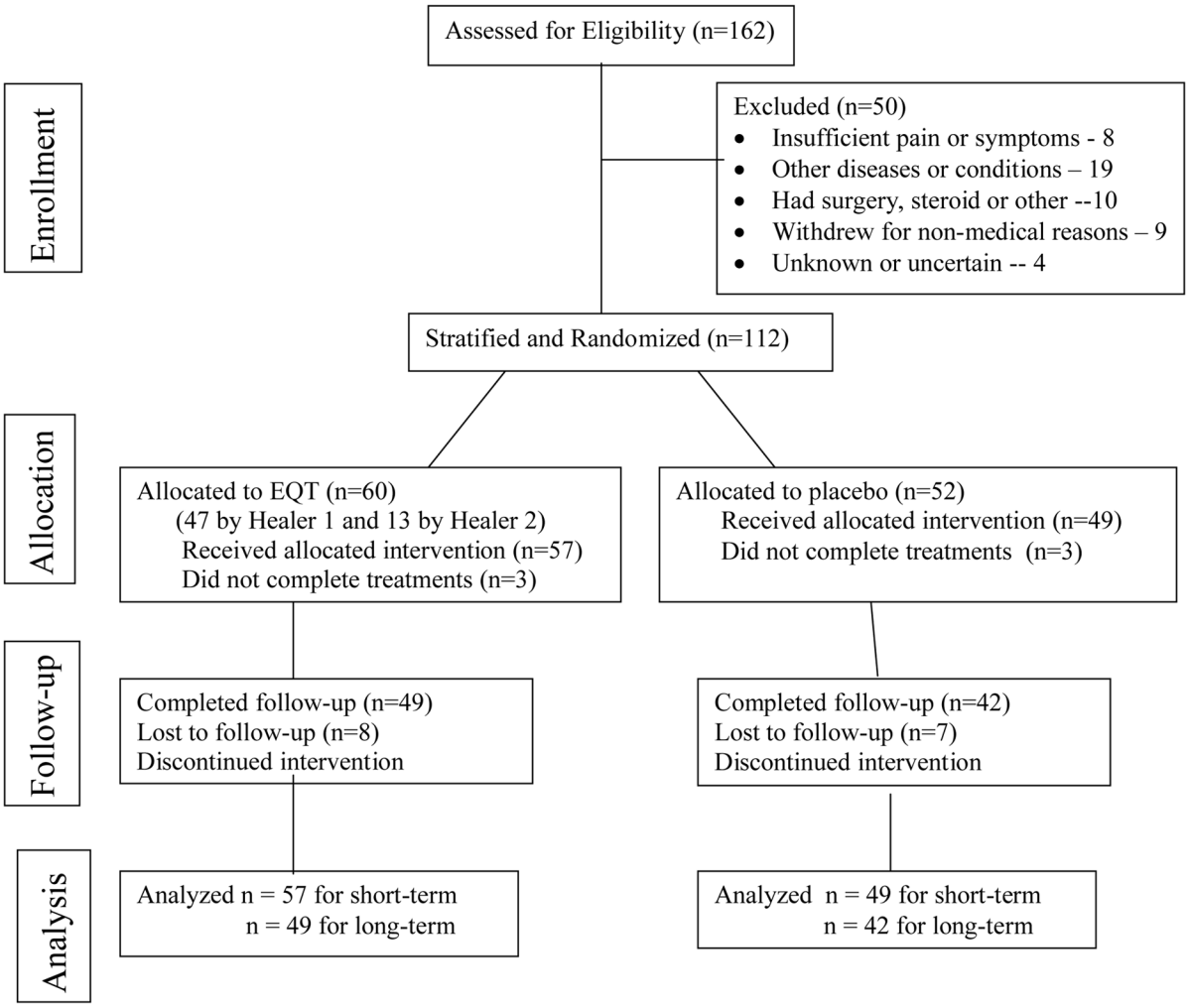

Figure 1. Participants Flowchart (Qigong Therapy for OA of the Knees)

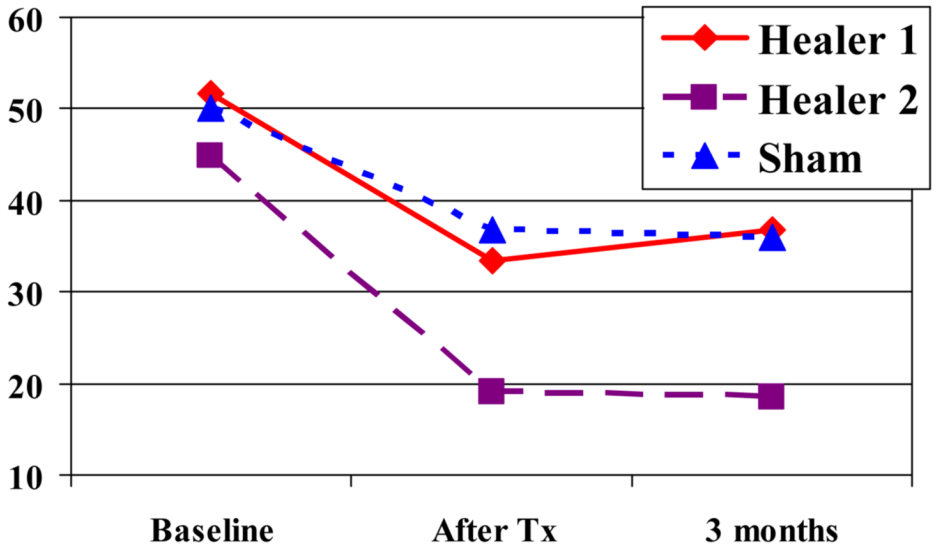

Fig 2b. WOMAC Functionality Scores Overtime

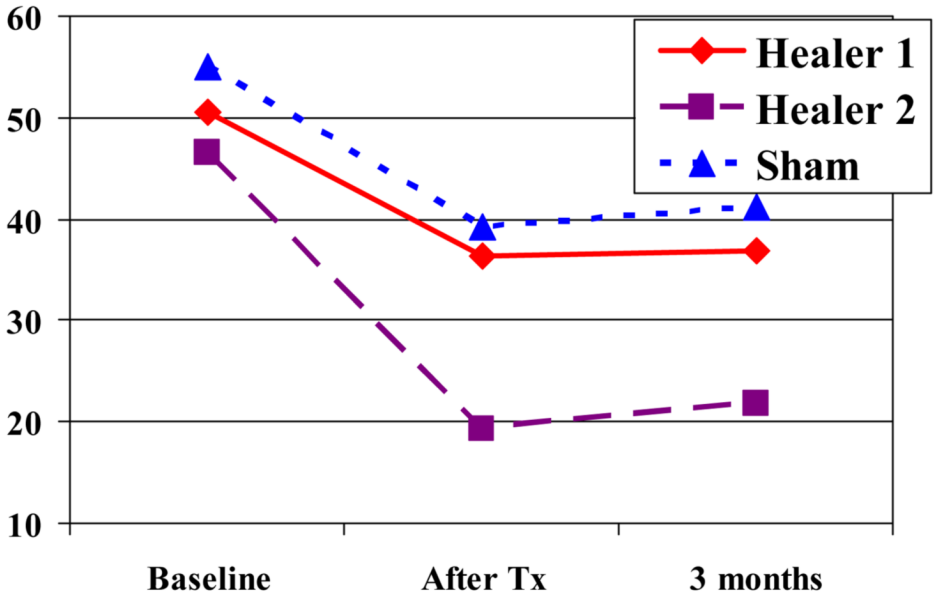

Figure 2. Mean Scores of Primary Outcomes Overtime by Group
(N=106 after treatment; N=91 at 3 months follow-up)

Table 1

Outline of Intervention Procedures by Two Healers and the Differences

Description of procedure	Healer 1	Healer 2	Note
(a) Lightly touch the joint area with fingers to pinpoint the pain and discomfort point(s) – patient may feel some pain in this procedure.	Yes	Yes	Techniques are similar
(b) Use finger lightly point and shake the pain point for15–20 seconds to relax muscles around the joint to allow blockage area to be exposed to external qi	Yes	No	
(c) Apply strong acupressure to the affected joint to help the qi and blood flow in the area (for 1–2 minutes) and reduce pain afterward – patient feels pain most of time.	No	Yes	
(d) Use one palm or both palms to massage over the pain area for 30 to 40 seconds to generate qi flow in the area;	Yes	Yes	Techniques are different
(d) Place a palm 5–8 cm away from the knee, use“Lao Gong” point (at the center of palm) to send qi energy to the joint for 30 to 60 seconds;	Yes	Yes	Techniques are similar
(e) Place both palms on top of the pain area, breathe deeply, then discharge strong qi to the joint with a sudden shout (“Hei!”). The sham healer was not instructed about any intention, but simulating the physical movements and the shout only.	Yes	No	
(f) Holding patient’s feet with both hands to induce the sick qi out of Yong Chuan acupoint for 15–20 seconds	No	Yes	
(g) Ask the patient to think of the bottom of feet (Yong Chuan acupoint), and then use palms to induce the sick qi out of body from Yong-chuan.	Yes	Yes	Techniques are different
Average time of each treatment (Note: No limitation set on treatment time, healer took whatever he needed for the best healing outcome in each session	4–7 minutes	5–10 minutes	

Table 2

Participant Demographics and Baseline Characteristics by Treatment Group

Characteristics	*Real Qigong (N=57)*		*Sham Qigong*	*P* value
	Healer 1	Healer 2		
	N = 45	N = 12	N = 49	
Age, Mean yrs (*sd*)	63.9 (9.7)	58.8 (7.0)	62.9 (9.2)	.23
Sex, *n* (%)				.85
Men	14 (31.1)	3 (25.0)	13 (26.5)	
Women	31 (68.9)	9 (75.0)	36 (73.5)	
Race, *n* (%)				.80
White	39 (86.7)	10 (83.3)	40 (81.6)	
Non-white	6 (13.3)	2 (16.7)	9 (18.4)	
Education, *n* (%)				.30
No college	9 (20.0)	1 (8.3)	12 (24.5)	
Some college	29 (64.4)	6 (50.0)	27 (55.1)	
Graduate degree	7 (15.6)	5 (41.7)	10 (20.4)	
Target knees, n (%)				.83
Single knee	10 (22.2)	4 (33.3)	14 (28.6)	
Both knees	35 (77.8)	8 (66.7)	35 (71.4)	
Duration of knee pain, n (%)				.31
< 5 years	14 (33.3)	3 (27.3)	12 (26.7)	
5–9 years	15 (35.7)	1 (912)	15 (33.3)	
10+ years	13 (31.0)	7 (63.6)	18 (40.0)	
Chronic pain other than OA at knee, n (%)				.68
Yes	22 (52.4)	7 (63.6)	24 (49.0)	
No	20 (47.6)	4 (36.4)	25 (51.0)	
Belief in CAM therapies, n (%)				.55
None or a little	18 (40.0)	3 (25.0)	15 (30.6)	
Yes, quite a bit	11 (24.4)	3 (25.0)	18 (36.7)	
Yes, absolutely	16 (35.6)	6 (50.0)	16 (32.7)	
Previous Cam experience, n (%)				.71
Yes	28 (62.2)	9 (75.0)	32 (65.3)	
No	17 (37.8)	3 (25.0)	17 (34.7)	
Body Mass Index, M (sd)	29.6 (4.6)	33.3 (4.4)	31.0 (5.8)	.08
Duration of OA pain (years)	8.15 (8.6)	13.5 (9.8)	7.8 (5.4)	.07
Concurrent medications, n (%)				.98
None	14 (31.1)	5 (41.7)	13 (26.5)	
Simple analgesics	7 (15.6)	2 (16.7)	6 (12.2)	
NSAIDs	16 (35.6)	4 (33.3)	19 (38.8)	
COX-2 selective inhibitor	5 (11.1)	1 (8.3)	6 (12.2)	
Opioids	1 (2.2)	0(0.0)	3 (6.1)	
Multiple Rx medications	2 (4.4)	0 (0.0)	2 (4.1)	
WOMAC Scores, M (sd)				
Pain	51.6 (21.4)	45.0 (18.6)	49.9 (20.2)	.61
Functionality	50.5 (21.5)	46.5 (20.7)	55.3 (19.1)	.30
Global (total)	52.2 (20.7)	47.3 (18.0)	54.3 (18.2)	.52
McGill Pain Q score, M (sd)	11.5 (8.3)	9.8 (9.1)	11.0 (9.0)	.84
Time to walk 50 ft, M (sd)	15.2″ (3.5)	14.4″ (2.0)	15.0″ (3.6)	.77
Range of motion squatting, Degree, M (sd)	96.2° (25.1)	91.8° (18.9)	99.5° (21.4)	.54

Note: P values from Chi-square test for categorical variables, and F test in ANOVA for continuous variables.

Table 3

Mixed effects regression analysis of the primary outcomes (Estimate of regression coefficients and 95% confidence interval)

	WOMAC Pain	Functionality	WOMAC Total
Intercept	11.8 (2.23, 21.2)	14.2 (3.94, 24.5)	11.54 (1.17, 21.9)
Baseline value of the respective outcome	0.49 (0.33, 0.66)	0.47 (0.31, 0.64)	0.51 (0.33, 0.68)
Healer 1 vs. placebo	−2.01 (−8.99, 5.13)	−0.96 (−8.02, 6.11)	−0.46 (−7.35, 6.42)
Healer 2 vs. placebo	−16.3 (−27.0, −4.84)	−16.12 (−27.2, −5.06)	−15.04(−25.8, −4.22)

Note: All models are estimated with individual participant as a random effect, control for age, gender, BMI and belief in CAM as covariates. (N = 91)

Table 4

Means and Standard Deviations of Other Outcomes at Three Points of Measure by Group

Outcome Measures	Point of measurement	Means (SD)			Coefficient (95% CI) in Mixed Model*	
		Healer 1 (N = 45)	Healer 2 (N=12)	Placebo (N=49)	Healer 1 vs. Pla cebo	Healer 2 vs. Placebo
Secondary Outcomes						
McGill Pain Questionnaire (Short Form)	Baseline	11.5 (8.2)	9.8 (9.1)	11.0 (9.0)	β = −0.25 (−0.54, 0.047 (p = .09)	β = −0.48 (−0.93, −0.016) (p = .04)
	After Tx	4.7 (5.9)	3.7 (4.1)	5.6 (6.0)		
	3-M follow-up	6.8 (7.0)	5.4 (10.2)	7.9 (9.3)		
Time (second) to walk 50 feet	Baseline	15.2 (3.6)	14.4 (2.0)	15.0 (3.4)	β = −0.02 (−0.070, 0.025) (p = .35)	β = −0.07 (−0.14, 0.0075) (p = .08)
	After Tx	13.3 (2.8)	12.9 (1.8)	13.5 (2.2)		
	3-M follow-up	13.3 (2.7)	11.8 (1.4)	13.6 (2.4)		
Range of motion squatting	Baseline	96.2 (25.1)	91.8 (18.9)	99.5 (21.4)	β = −0.80 (−7.18, 5.58) (p = .80)	β = 4.42 (−5.64, 14.49) (p = .38)
	After Tx	82.9 (24.0)	89.0 (17.7)	85.7 (23.1)		
	3-M follow-up	88.5 (27.2)	78.1 (20.1)	88.7 (23.5)		
Psychological Outcomes						
Negative mood in VAS	Baseline	32.3 (13.7)	34.9 (22.2)	30.0 (16.7)	β = 1.05 (−2.35, 4.46) (p = .54)	β = -4.91 (−10.26, 0.43) (p = .07)
	After Tx	26.7 (17.3)	23.8 (22.1)	30.3 (16.7)		
	3-M follow-up	31.4 (18.8)	22.8 (19.5)	32.2 (17.6)		
Spielberger Anxiety-state	Baseline	45.4 (8.1)	45.2 (5.4)	42.6 (8.8)	β = 0.21 (−0.91, 1.33) (p = .71)	β = 0.18 (−1.58, 1.95) (p = .84)
	After Tx	46.3 (4.4)	47.1 (3.2)	44.8 (8.1)		
	3-M follow-up	47.1 (4.9)	47.2 (4.9)	46.7 (5.0)		
CES Depression	Baseline	35.6 (4.3)	39.4 (6.6)	32.8 (9.0)	β = .001 (−0.0272, 0.0302) (p = .92)	β = .010 (0.036, 0.055) (p = .68)
	After Tx	34.2 (3.1)	36.7 (5.6)	34.4 (4.7)		
	3-M follow-up	36.4 (6.1)	38.8 (6.7)	36.0 (5.1)		

* Mix-effect regression models are done with baseline measure as one of predictors, individual participant as a random effect, and with control for gender, age, BMI and belief in CAM as covariates.