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No additional benefit of shortwave diathermy over exercise program for knee osteoarthritis in peri-/post-menopausal women: an equivalence trial[1]

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Summary

Objective: To evaluate the benefit of shortwave diathermy (SWD) supplemented to an exercise program for knee osteoarthritis (OA) in peri-/post-menopausal women.

Methods: A double-blind randomized placebo-controlled equivalence trial was conducted in a university hospital. Participants including 113 women aged 50–85 years with primary knee OA were instructed to do regular quadriceps exercise, and randomized to control ($n=60$) and treatment ($n=53$) groups receiving sham SWD and therapeutic SWD, respectively. The treatment being evaluated was continuous SWD, 20 min/session, 3 sessions/week for 3 weeks. The outcomes including Thai Western Ontario and McMaster Universities OA (WOMAC) index, 100-m walking speed, stair ascent-and-descent time, global assessment, patient's satisfaction, and adverse events were assessed at baseline and end of treatment.

Results: At the end of treatment, both groups had trivial but statistical improvement in all outcomes. Intention-to-treat analysis showed no statistically significant difference between the two groups in all outcomes. Per protocol analysis demonstrated the equivalence in Thai WOMAC total score, as the 95% confidence interval of difference (−0.62, 0.92) was within confidence limits of ±1 cm.

Conclusion: The addition of SWD to an exercise program for knee OA in peri-/post-menopausal women is not superior to the exercise program alone.

Key words: Equivalence trial, Knee, Osteoarthritis, Shortwave diathermy, Thai, WOMAC.

Introduction

Osteoarthritis (OA) is the most common degenerative joint disorder, resulting in significant morbidity and health care expense[1]. It affects more than 60% of Western adults over the age of 65 years[2]. It causes pain and dysfunction in 20% of elderly persons[3]. The knee is the most commonly affected joint found in one third of the population between the ages of 63 and 94 years[4]. The community prevalence of knee OA in Thailand is 34.5–45.6%[5].

There are many treatment modalities for knee OA but a curative method has not yet been discovered. Goals of treatment as stated in various current recommendations, including guidelines by the American College of Rheumatology[6] and European League Against Rheumatism (EULAR)[7] focus on the relief of symptoms and the maintenance or the improvement in functional status. Regarding the symptomatic relief, shortwave diathermy (SWD) is often prescribed and is claimed to be effective. SWD is a form of electromagnetic therapy which produces an oscillating electromagnetic field, which causes movement of ions, distortion of molecules, and creation of eddy currents, and as a result heat is produced in deep tissue[8]. Its claimed mechanism of action includes inducing an anti-inflammatory response[9], reducing joint stiffness[10], stimulating connective tissue repair[11], and reducing muscle spasm and pain. However, the efficacy of SWD on knee OA is still inconclusive. Outcomes of clinical trials vary from positive[12–16] to null[17–22] effects. The difference in such outcomes is largely due to methodological deficiencies. Therefore, a double-blind randomized, placebo-controlled trial with adequate power is necessary to evaluate the effectiveness of SWD for the treatment of knee OA. In the present study we evaluate the benefit of SWD supplemented to an exercise program on the reduction of pain and the increment of function in peri-/post-menopausal women with knee OA.

Methods

A randomized and double-blind placebo-controlled equivalence trial was carried out in the out-patient clinic, Department of Rehabilitation Medicine, Faculty of Medicine, Siriraj Hospital, Mahidol University from January to June 2004. The study was conducted in accordance with the ethical principles stated in the most recent version of the Declaration of Helsinki. The study protocol was approved by the Ethic Committee of the Faculty of Medicine, Siriraj Hospital.

The eligible patients were peri-/post-menopausal women aged 50–85 years. All patients had primary knee OA based on the diagnostic criteria of the American College of Rheumatology[23,24] and without the following conditions: inability to walk, severe joint instability, history of previous SWD treatment, intra-articular injection within 3 months, metallic implant around knee joint, suspicious of malignancy around knee joint, significant cardiovascular disease, and inability to understand how to score the symptoms.

[1]This trial is registered at www.ClinicalTrials.gov, trial number NCT 00199914.

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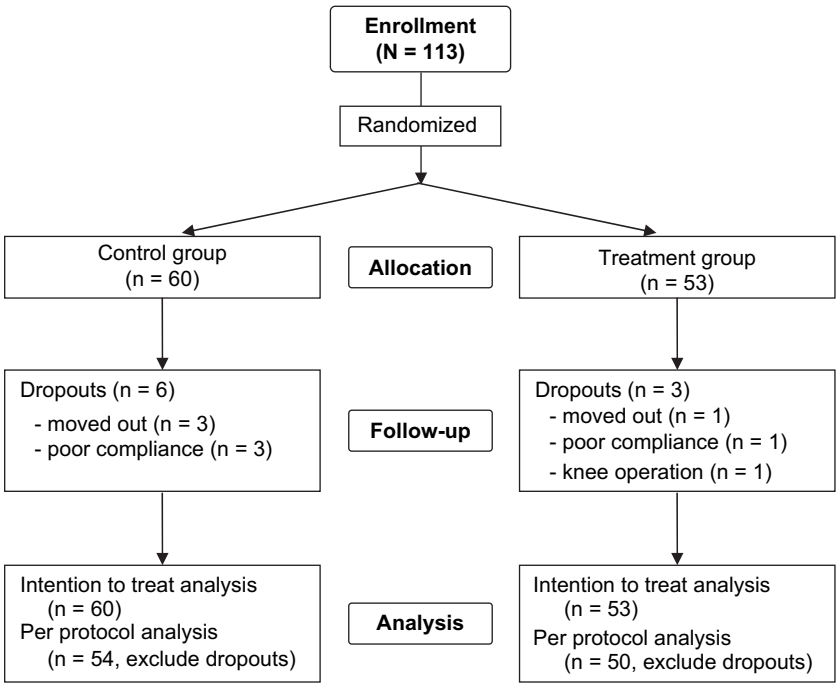

Fig. 1. Flow of study participants: treatment = SWD + quadriceps exercise, control = sham SWD + quadriceps exercise.

TREATMENT ALLOCATION

After a written informed consent was obtained, the patient was allocated to either a control or treatment group using a random number table. Each treatment code was concealed in an opaque envelope, which was serially opened by an independent physical therapist who performed the SWD treatment accordingly. Only this physical therapist knew which treatment was being provided to the patient. The physician who assessed the treatment outcomes and the patient were unaware for the patient's group of treatment.

The patient lied on a treatment bed which had an opaque screen between the bed and a SWD machine. The screen was used to blind the patient from any procedure being performed on the SWD machine by the physical therapist. The treatment group received continuous SWD using an ULTRAMED (Bosch) model 11s601 serial number 3660340 with a 10-cm diameter condenser plate operating at a frequency of 27.12 MHz, an input of 300 W, and a mean output of 3.2 W. In each treatment session, the condenser plate was wrapped around the affected knee(s) and the power was on for 20 min. A course of treatment included nine SWD sessions, which were completed in three consecutive weeks. The control group received a sham SWD treatment, which had exactly the same treatment procedure as the treatment group, except that the power switch was off. At the end of the study period, each patient was asked to guess the treatment group that she was in. This question was to assess the adequacy of our blinding technique.

Table I
Baseline characteristics of the ITT population (N = 113)

Characteristics	Control ($n = 60$)	Treatment ($n = 53$)
Age (years)	62.48 ± 8.47	63.32 ± 7.61
Body mass index (kg/m^2)	26.17 ± 4.15	25.64 ± 4.03
Duration of symptoms (years)	2.78 ± 2.23	5.47 ± 3.60
WOMAC total score	3.88 ± 1.54	3.73 ± 1.47
Pain subscale	3.73 ± 1.71	3.87 ± 1.72
Stiffness subscale	4.19 ± 2.22	3.78 ± 1.98
Function subscale	3.66 ± 1.41	3.57 ± 1.45
100-m walking speed (m/min)	64.71 ± 11.02	62.82 ± 12.24
Stair ascent-and-descent time (s)	25.45 ± 8.93	28.81 ± 14.92
Education ≤ 12 years	37 (61.67%)	33 (62.26%)
Active lifestyle	50 (83.33%)	46 (86.79%)
Bilateral affected site	26 (43.33%)	31 (58.49%)
Gait-aid use	4 (6.67%)	5 (9.43%)
Knee-support use	18 (30.00%)	21 (39.62%)

Data are mean ± SD or *n* (%).

All patients were instructed to perform regular quadriceps exercise and practice joint protection behavior. One cycle of quadriceps exercise comprised two steps: (1) isometric contraction held in full extension of knee for 5 s, and (2) isotonic resistive contraction held in mid flexion of knee for 5 s. The patients were instructed to record exercise diaries which would be used to assess the exercise compliance. The exercise compliance was categorized into three groups as follows: (1) good, exercise ≥50 repetitions/day and ≥5 days/week; (2) fair, exercise ≥50 repetitions/day and <5 days/week, or <50 repetitions/day and ≥5 days/week; and (3) poor, exercise <50 repetitions/day and <5 days/week.

The patients were allowed to take acetaminophen or a non-steroidal anti-inflammatory drug (NSAID: Diclofenac sodium 25 mg) for pain relief as needed. The medications were provided at each visit and the leftover pills were returned for drug accountability at the subsequent visit. The patients who took any analgesic medications during the 3-week treatment period were classified as analgesic users. Concomitant medications, exercise frequency, and potential adverse events were recorded.

The treatment would be terminated if: (1) the patient reported pain deterioration, (2) the patients or doctor decided to stop, or (3) there were serious complications such as severe joint effusion or acute joint inflammation. After the end of the 3-week treatment period, the patients were advised to continue the quadriceps exercise.

OUTCOME MEASURES

The baseline characteristics being collected included age, body mass index, duration of symptoms, education levels, lifestyle, number of affected sites, and the use of gait-aid and knee-support.

The primary outcome was evaluated using a modified Thai version of the Western Ontario and McMaster Universities OA (WOMAC) index. The WOMAC index is a three dimensional, disease-specific, self-administered health status instrument. The original version has 24 items in three dimensions (five pain, two stiffness, and 17 function) valid for evaluating symptoms and functions of the patients with hip or knee OA[25]; whereas the modified Thai version has 22 items in three dimensions (five pain, two stiffness, and 15 function) valid only for knee OA[26]. The response is on 10-cm horizontal visual analog scales (VAS) with two descriptors, i.e., "no symptom" or "no problem" at the left end, and "intolerable pain" or

Table II
Outcomes of treatment at the end of week 3 in per protocol population (N = 104)

Outcomes	Control ($n = 54$)	Treatment ($n = 50$)	Mean difference [95% CI]* or RR (95% CI)	P†
Changes from baseline (delta)				
Total WOMAC score	−1.09 [−1.55, −0.63]	−1.04 [−1.45, −0.62]	0.15 [−0.62, 0.92]	
Pain subscale	−1.37 [−1.88, −0.85]	−1.30 [−1.77, −0.83]	0.26 [−0.59, 1.12]	
Stiffness subscale	−1.14 [−1.81, −0.47]	−1.04 [−1.61, −0.47]	−0.06 [−1.16, 1.04]	
Function subscale	−0.68 [−1.06, −0.29]	−0.81 [−1.19, −0.42]	−0.11 [−0.57, 0.80]	
Walking speed (m/min)	0.97 [−1.43, 3.36]	4.37 [2.51, 6.22]	2.35 [−1.49, 6.18]	
Stair ascent-and-descent time (s)	−2.54 [−4.27, −0.80]	−4.45 [−6.52, −2.38]	−0.05 [−3.26, 3.17]	
Global assessment (score 1−6)				0.142
Improved (4−6)	26 (48.15%)	31 (62.00%)		
Indifferent (2−3)	26 (48.15%)	15 (30.00%)		
Deteriorated (1)	2 (3.70%)	4 (8.00%)		
Satisfaction index (score 1−5)				0.208
Satisfied (4−5)	47 (87.00%)	45 (90.00%)		
Indifferent (2−3)	7 (13.00%)	3 (6.00%)		
Unsatisfied (1)	0 (0.00%)	2 (4.00%)		
Analgesic users‡	32 (53.3%)	44 (83.0%)	1.80 (1.30, 2.47)	0.001
Exercise compliance (good)	31 (57.40%)	11 (22.00%)	0.50 (0.35, 0.72)	0.000

Data are mean [95% CI] or RR (95% CI) or n (%).

*Adjusted for duration of symptoms, analgesic use, and exercise compliance.

†Unpaired t test for continuous data or Chi-square test for categorical data.

‡Patients who took any analgesic medications during the 3-week treatment period.

"unable to do" at the right end. The score of each item therefore ranges from 0 to 10. The higher score means the worse symptoms or functions. The score of each dimension is the average of scores from all items in the same dimension. The total WOMAC score is the average of scores from all dimensions.

The secondary outcomes were as follows: (1) walking speed (the speed of walking a 100-m distance, m/min); (2) stair ascent-and-descent time (time to ascend and descend 12 steps of 18-cm step, s); (3) global assessment (6-point Likert scales) categorized into deteriorated (score 1), indifferent (score 2−3), and improved (score 4−6); and (4) patient's satisfaction index to the treatment (5-point Likert scales) categorized into unsatisfied (score 1), indifferent (score 2−3), and satisfied (score 4−5). The latter two outcomes were self-administered, except for the illiterate or poor eyesight patient whose outcomes were assessed by an interviewer who was a well-trained research assistant unaware of the patient's treatment group.

The outcomes were assessed at baseline (week 0), immediately after the last SWD session (week 3), and at 3-week follow-up (week 6), except for the global assessment and the satisfaction index that were assessed only at week 3.

SAMPLE SIZE

The sample size was calculated using a formula to detect the difference of two independent means. When alpha = 0.05, power = 80%, minimal clinically important improvement (MCII) of VAS knee OA = 1 cm[27] and standard deviation (SD) of difference deriving from our pilot study = 1.5, the sample size was calculated at 36 per group to test the superiority of the additional SWD over exercise alone. The sample size was also calculated to test the equivalence since it was possible that the additional SWD might not be beneficial. When the power = 90% and other conditions were the same as the above, the sample size was 48 per group. With 10% compensation, the sample size of at least 53 per group would have adequate power to detect both the superiority and the equivalence.

STATISTICAL ANALYSIS

The data were analyzed using SPSS for Windows, version 11.0.1. Data were presented as mean ± SD, n (%), or line graph with error bar (SD). Comparative analysis was focused at the end of treatment (week 3). Within group change from baseline value of a continuous variable was presented in mean change (delta) and 95% confidence interval (CI), and tested using a paired t test; whereas between groups difference in the delta was tested using an unpaired t test. The between group equivalence of the variable was demonstrated using an adjusted mean difference of delta and 95% CI; the value of which was adjusted for confounding factors using multiple linear regression. The between groups comparison in global improvement and satisfaction index were presented using relative risk (RR) and 95% CI, and tested using Chi-square or Fisher's exact test. Statistical analyses to test the superiority were based on the intention-to-treat (ITT) population, and those chosen to demonstrate the equivalence were based on the per protocol population. The "worst-case-scenario" was applied to the dropouts in the ITT analyses. All tests were two-sided, and had a significant level at a P-value < 0.05. The equivalence of the primary outcome (Thai WOMAC index) was considered when the two-sided 95% CI for the between group difference in the Thai WOMAC total score was within confidence limits of ±1 cm.

Results

Figure 1 shows flow of the study participants. From January to June 2004, 113 eligible patients were randomized into control group (sham SWD, $n = 60$) and treatment group (SWD, $n = 53$). There were nine dropouts, six cases in the control group (three moving out and three poor compliance) and three cases in the treatment group (one moving out, one knee operation, and one poor compliance). Characteristics of all dropouts were similar to those of the completed cases and their data were included in the ITT population.

Table I shows baseline and demographic data of the ITT population. Data of the control and the treatment groups were comparable except that the control group had a shorter duration of symptoms (mean ± SD of control vs treatment, 2.55 ± 1.85 vs 5.68 ± 3.59 years).

Since the ITT analysis with the worst-case-scenario revealed no statistical difference between the two groups (data not shown); the per protocol analysis was performed to demonstrate the equivalence. Table II, Figs. 2 and 3 show outcomes of the per protocol population. The within group comparison demonstrated a statistically significant change from baseline in all continuous outcome variables of both groups.

The between group comparison of the change from baseline (delta) at week 3 was adjusted for confounding factors, which were independent variables that were not comparable between the two groups. Multiple linear regression

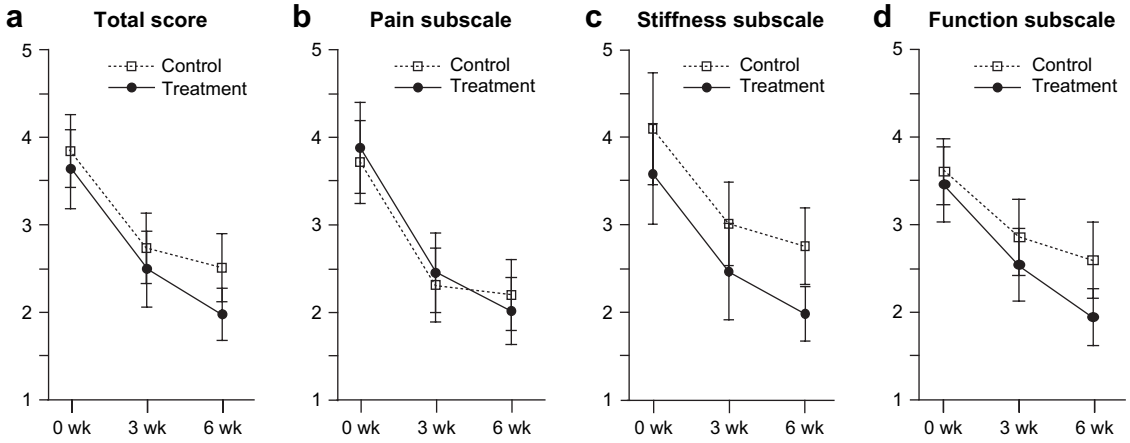

Fig. 2. Outcomes in the per protocol population: (a) WOMAC total score, (b) WOMAC pain subscale, (c) WOMAC stiffness subscale, (d) WOMAC function subscale; WOMAC, modified Thai version; week 0–3 = treatment period (quadriceps exercise + SWD in the treatment group or sham SWD in the control group), week 3–6 = follow-up period (quadriceps exercise alone in both groups).

models included the following variables: treatment group (0 = control and 1 = treated), duration of symptoms (0 = ≥5 years and 1 = <5 years), exercise compliance (0 = poor and 1 = good), and analgesic use (0 = no and 1 = yes). The adjusted mean difference of the deltas [95% CI] of the Thai WOMAC total score (0.13 [−0.68, 0.95] cm) was within the equivalence limits of ±1 cm. The adjusted mean differences of deltas [95% CI] of other outcomes including pain (0.26 [−0.59, 1.12] cm), stiffness (−0.06 [−1.16, 1.04] cm), function (−0.11 [−0.57, 0.80] cm), walking speed (2.35 [−1.49, 6.18] m/min), and stair ascent-and-descent time (−0.05 [−3.26, 3.17] s) were not statistically significant. There were no differences in the satisfaction index and global assessment scores between the two groups.

Table III shows the adverse events of SWD and exercise. The incidence of SWD side effects was similar in both control and treatment groups (7.4% and 8.0%, respectively). The events included mild pain, mild swelling and feeling of vasodilatation. One patient in the treatment group had deteriorating pain necessitating a knee operation. The incidence of exercise side effects was also similar between the two groups (33.9% and 37.0%, respectively). The events included increasing crepitus sound, mild tightness of muscle, fatigue, and mild pain.

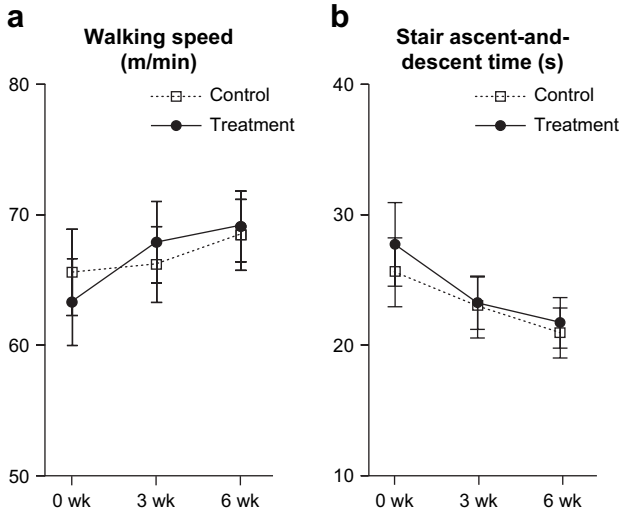

Fig. 3. Outcomes in the per protocol population: (a) walking speed, (b) stair ascent-and-descent time; week 0–3 = treatment period (quadriceps exercise + SWD in the treatment group or sham SWD in the control group), week 3–6 = follow-up period (quadriceps exercise alone in both groups).

Discussion

The present double-blind, randomized, placebo-controlled equivalence trial demonstrated that the use of SWD for the symptomatic treatment of knee OA provided no additional benefit over the baseline treatment using quadriceps exercise alone. SWD has been prescribed for various medical conditions since the early twentieth century[28] without definite proof of its effect. Previous clinical studies of SWD effect on OA showed either positive or null effect. The differences in the outcomes are largely due to the difference in materials and methods of the studies. The studies that demonstrated positive effect have some methodological deficiency, e.g., lacking or using inappropriate control groups[12,13], or using non-validated outcome measures[14–16]. The studies that demonstrated null effect[17–19,21] may have inadequate power to detect the difference, have placebo effect in the control

Table III
Adverse events of treatments in per protocol population (N = 104)

Adverse events	Control (*n* = 54)	Treatment (*n* = 50)
Shortwave diathermy	4 (7.4%)	4 (8.0%)
Mild pain	2	3
Mild swelling	1	0
Feeling of vasodilatation	2	0
Deterioration of pain, needed operation	0	1
Quadriceps exercise	18 (33.3%)	20 (37.0%)
Increased crepitus sound	6	8
Mild tightness of muscle	13	16
Fatigue	3	0
Mild pain	4	2

Some cases may have multiple adverse events.

group, use an active control group but without adequate power to demonstrate the equivalence, or use non-validated outcome measures.

In 2006, McCarthy *et al.* published a systematic review on pulsed electromagnetic field (PEMF) or SWD therapy for pain relief in knee OA[29]. The authors found five good quality randomized controlled trials (RCTs) reported in 1996–2005[20,22,30–32]. These five studies used different types of PEMF and different protocols of treatment. All of them showed null effect of the SWD. The authors performed meta-analysis and concluded that the PEMF has little value in the management of knee OA. Among these five studies, the one by Laufer *et al.* had the treatment protocol similar to ours but it had limitations including non-randomized allocation and small sample size per group[31]; therefore, the no difference does not have enough power to show equivalence. Our present double-blind randomized, placebo-controlled trial had enough power to show the equivalence of the Thai WOMAC total score, considering that a MCII of WOMAC total score for knee OA is 1 cm[27]. In 2005, Tubach *et al.* reported that the MCII varied with the baseline WOMAC score. According to their study, the patients with intermediate baseline score (similar to our participants' score) need MCII of −27.4 (95% CI −29.7 to −24.6) and −11.8 (95% CI −13.0 to −10.4) mm for WOMAC pain and function scores, respectively[33]. With this large MCII, the sample size needed to demonstrate either the superiority or the equivalence is smaller than the one used in our study. Therefore, our study had enough power to declare the equivalence. Moreover, all of the studies in the review by McCarthy *et al.*[29] might also show equivalent outcomes.

The equivalent outcome cannot completely reject the possible beneficial effect of SWD as was shown in *in vitro* and in animal studies, or in clinical trials using surrogate outcomes[11,32,34,35]. It is possible that an RCT using an inactive control may be able to demonstrate this effect. However, we cannot use the inactive control in our study because effective standard treatments have been available by the time we began the study. The recommended treatments for all OA patients include lifestyle modification (i.e., weight reduction and exercise) and analgesic medications (paracetamol and/or NSAIDs)[6,7], both of which were prescribed to all participants in our study. These basic treatments caused improvement with time in symptoms and functions in our participants. The addition of SWD did not add any benefit over the basic treatments.

The strength of the present study is a well-conducted process. We were meticulous about the blinding technique which was very important for the study using subjective outcomes. However, the technique could not efficiently blind the participants in the treatment group. Although none of the participants had previously undergone SWD therapy, 80% of the treatment group correctly told that they got the treatment whereas 52% of the control group wrongly told that they got the treatment (data not shown). In spite of such bias, the treatment group did not have better outcomes than the control group did.

The present study has limitations in generalizability. Although our study population was peri-/post-menopausal women who formed the majority of the knee OA patients, all of them were Thai whose lifestyle might be different from that of other ethnic groups. The relatively short duration of treatment might not be sufficient to show the benefit of SWD treatment. Only one SWD machine with a unique output power was used in order to homogenize the provided treatment. All of these conditions would make the results inapplicable to different situations such as populations with different baseline characteristics, different treatment protocol, or the treatment using a different type of SWD with a different output power. However, the review by McCarthy *et al.* demonstrated that different studies using various types and regimens of SWD had the similar outcomes, i.e., null effect[29]. It is possible that further study of SWD would not give a different result.

In conclusion, according to our criteria of equivalence (±1 cm for Thai WOMAC total score), the addition of SWD to the exercise program for knee OA in peri-/post-menopausal women is not superior to the exercise program alone.

Conflict of interest

Both of the authors are full time staff members of the Faculty of Medicine, Siriraj Hospital, Mahidol University, which is a government non-profit university hospital. The authors declare no conflict of interest.

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