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THE EFFECTIVENESS OF SHORTWAVE DIATHERMY IN OSTEOARTHRITIC KNEE: A RANDOMIZED CONTROLLED TRIAL

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วิไล คุปต์นิรัติศัยกุล : การศึกษาประสิทธิภาพของความร้อนลึกในการรักษาผู้ป่วยข้อเข่าเสื่อม (THE EFFECTIVENESS OF SHORTWAVE DIATHERMY IN OSTEOARTHRITIC KNEE: A RANDOMIZED CONTROLLED TRIAL) อ. ที่ปรึกษา : ผศ.พญ. มนาธิป โอศิริ, อ.ที่ปรึกษาร่วม : ศ.นพ.วิษณุ ธรรมลิขิตกุล. 69 หน้า. ISBN 974-17-6163-5.

ความเป็นมา : มีการใช้ความร้อนลึกในการรักษาผู้ป่วยข้อเข่าเสื่อมมานาน แต่ไม่มีการศึกษาที่ดีพอจะยืนยันผลของความร้อนลึก ไม่ว่าจะเป็นเรื่องรูปแบบการศึกษา วิธีการ หรือการวัดผลอย่างเป็นรูปธรรมที่ชัดเจน วัตถุประสงค์การวิจัย : เพื่อศึกษาประสิทธิภาพของการใช้ความร้อนลึกในการลดอาการปวดของผู้ป่วยข้อเข่าเสื่อม รูปแบบวิจัย : Double blind randomized placebo controlled trial วิธีการ : ผู้ป่วยข้อเข่าเสื่อมจำนวน 132 ราย ที่มีอาการปวดเข่า จะได้รับการประเมินระดับความปวด และวัดอัตราเร็วในการเดิน ผู้ป่วย 66 รายได้รับการสุ่มเข้ากลุ่มควบคุมซึ่งได้รับการอบความร้อนลึกหลอก อีก 66 ราย เข้ากลุ่มรักษาซึ่งได้รับการอบความร้อนลึกจริง นานครั้งละ 15-20 นาที สัปดาห์ละ 3 ครั้ง ต่อเนื่อง 3 สัปดาห์ การวัดผล : ความแตกต่างของคะแนน WOMAC, อัตราเร็วในการเดิน, การประเมินผลการรักษาในภาพรวม, และระดับความพึงพอใจระหว่างสองกลุ่ม ผลการวิจัย : ไม่พบค่าความแตกต่างของคะแนน WOMAC ก่อนและหลังรักษา ไม่ว่าจะวิเคราะห์คะแนนรวม หรือวิเคราะห์แยกส่วน (คะแนนปวด ,คะแนนความตึงหรือคะแนนความสามารถในการทำกิจวัตรประจำวัน) นอกจากนี้การวิเคราะห์แบบกลุ่มย่อยแยกตามค่า WOMAC ก่อนการรักษาก็ได้ผลเช่นเดียวกัน ไม่พบความแตกต่างของอัตราเร็วในการเดิน,การประเมินผลการรักษาในภาพรวม และอุบัติการณ์ของผลข้างเคียงของความร้อนลึกระหว่างสองกลุ่ม แต่กลุ่มศึกษามีความพึงพอใจดีมากกว่ากลุ่มควบคุม (ค่าพี 0.015) นอกจากนี้ยังพบว่ากลุ่มศึกษามารับการอบความร้อนลึกอย่างสม่ำเสมอดีมีจำนวนมากกว่า และมีการใช้ยาต้านอักเสบมากกว่ากลุ่มควบคุมอย่างมีนัยสำคัญทางสถิติ (ค่าพี 0.002, 0.021 ตามลำดับ) ส่วนกลุ่มควบคุมมีจำนวนผู้บริหารกล้ามเนื้อเข่าสม่ำเสมอดีมากกว่า (ค่าพี <0.001) เมื่อนำปัจจัยที่แตกต่างกันในทั้งสองกลุ่มมาเข้าสมการถดถอย (Multiple Linear Regression) คือ กลุ่ม, ระยะเวลาที่เป็นโรค, ความร่วมมือในการมาอบความร้อนลึก, ความร่วมมือในการออกกำลังกล้ามเนื้อเข่า และจำนวนยาต้านอักเสบที่ใช้ พบว่ามีเพียงปัจจัยเดียวเท่านั้นที่มีผลต่อค่าคะแนนความแตกต่างของ WOMAC คือ ระยะเวลาที่เป็นโรค ภายหลังการปรับด้วยค่าระยะเวลาที่เป็นโรคแล้ว พบว่ากลุ่มศึกษามีผลต่างของคะแนน WOMAC ภายหลังการรักษามากกว่ากลุ่มควบคุม เมื่อเทียบกับคะแนนพื้นฐาน มีค่าเปลี่ยนแปลงประมาณร้อยละ 9 ซึ่งไม่มีความสำคัญทางคลินิก ส่วนผลข้างเคียงของการอบความร้อนลึกไม่รุนแรง และไม่แตกต่างกันทั้งสองกลุ่ม (ร้อยละ 6) สรุป : ไม่มีหลักฐานยืนยันถึงประสิทธิภาพของความร้อนลึกในการลดอาการปวดของผู้ป่วยข้อเข่าเสื่อมด้วยโปรแกรมการรักษาแบบนี้ อย่างไรก็ดีน่าจะได้มีการศึกษาเพิ่มเติมเกี่ยวกับประสิทธิภาพของความร้อนลึกด้วยโปรแกรมการรักษาแบบอื่น

สาขาวิชา การพัฒนาสุขภาพ ลายมือชื่อนิสิต.....

ปีการศึกษา 2547 ลายมือชื่ออาจารย์ที่ปรึกษา.....

ลายมือชื่ออาจารย์ที่ปรึกษาร่วม.....

#4575432430 : MAJOR HEALTH DEVELOPMENT

KEY WORD: KNEE OSTEOARTHRITIS / SHORTWAVE DIATHERMY / EFFECTIVENESS / WOMAC SCORE / RANDOMIZED CONTROLLED TRIAL

VILAI KUPTNIRATSAIKUL : THE EFFECTIVENESS OF SHORTWAVE DIATHERMY IN OSTEOARTHRITIC KNEE: A RANDOMIZED CONTROLLED TRIAL . THESIS ADVISOR : ASSIST. PROF. MANATHIP OSIRI, THESIS COADVISOR : PROF. VISANU THAMLIKITKUL, 69 pp. ISBN 974-17-6163-5

Background: Shortwave diathermy (SWD) has been prescribed for years without definitely scientific proof of its effect. Design and methodology of the previous studies were still questionable. Objective: To compare the effectiveness of SWD for pain relief in knee osteoarthritis. Study design: A double blind randomized placebo-controlled trial. Materials and Methods: One-hundred and thirty-two patients with knee pain were randomized to control group (n=66) receiving sham SWD, or treatment group (n=66) receiving SWD, 15-20 min/session, 3 sessions / week, for 3 consecutive weeks. Outcome measured: WOMAC score (total score, pain, stiffness, and function dimensions), gait speed, global assessment and patient's satisfaction. Results: There was no statistically significant difference between the treatment and control groups in all dimensions of WOMAC score, patient gait speed, global assessment and incidence of adverse events. Subgroup analysis based on baseline WOMAC score also demonstrated the same results. Only the patient's satisfaction score was significantly different (p=0.015); with higher percentage of very satisfied subjects in treatment group. The SWD compliance and amount of NSAID used were also higher in the treatment group. (p = 0.002, 0.021 respectively). But the percentage of subjects with good exercise compliance was higher in the control group. However, the two groups were non-comparable in the following parameters; duration of disease, SWD compliance, exercise compliance and amount of NSAID used. After statistical adjustment using multiple linear regressions analysis, a trivial improvement (approximately 9% difference) of WOMAC score in the treatment group over the control group was revealed. The adverse events of SWD were not serious and not different between 2 groups (approximately 6%). Conclusion: There was no evidence to confirm the effectiveness of SWD for OA knee patients using this treatment protocol. However, other SWD treatment protocol should be re-evaluated to confirm the effectiveness.

Field of study HEALTH DEVELOPMENT Student's signature .....

Academic year 2004 Advisor's signature .....

Co-advisor's signature .....

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TABLE OF CONTENTS

TABLE OF TABLES

Page

TABLE OF FIGURES

Page

CHAPTER 1
INTRODUCTION

RATIONALE AND BACKGROUND

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 World adults over the age of 65 years.[2] It causes pain and dysfunction in 20% of elderly persons.[3] It can affect any joint containing hyaline cartilage, troublesome symptoms occur most often in the weight-bearing joints of the lower extremities.[4] Osteoarthritis of the knee, the most commonly affected,[5] can be found in one third of the population between the ages of 63 and 94 years.[6] A prevalence of knee pain from a recent survey of musculoskeletal disorders in Greater Manchester, was between 21-35% in men and women aged 45 or over.[7] Another study from Thailand revealed the prevalence of knee OA in the community of Bangkok ranged from 34.5-45.6%.[8] Knee OA manifests with pain, deformity, inflammation, stiffness, muscle atrophy and progressive loss of independence.[9] It is a leading cause of functional disability in the elderly.[10]

The pathophysiologic deficits of knee OA are associated with joint instability,[11] reduced joint range of motion(ROM),[12] and disuse atrophy of quadriceps muscle[13] which finally produce clinical concern of pain, decreased activity and physical deconditioning which, in turn, attenuate the ability to carry out activities of daily living.[13, 14] Physical disability arising from pain and loss of functional capacity reduces quality of life and increases the risks of further morbidity and mortality.[15]

Most treatment interventions are aimed at reducing pain with analgesics and non-steroidal anti-inflammatory drugs (NSAIDs), surgical correction, and conservative physical interventions. NSAIDs are the commonest symptomatic treatment for OA but have major adverse effects [16] and might even worsen the osteoarthritic process.[17] There is also some evidence that NSAIDs may be overused.[18] Non-pharmacological conservative management includes superficial and deep heat, cold, exercise, weight loss, acupuncture, transcutaneous electrical nerve stimulation, low energy laser, vibration, topically applied creams, pulsed electromagnetic fields, and orthotic devices.[4] The cost and risks associated with surgical correction make it a later resort for most patients.

There are many strategies for the treatment of knee OA but no curative method has yet been found.[4] Treatment is therefore directed to symptom relief and prevention of further functional deterioration,[19, 20] and often includes a number of physical therapy modalities.[21] However, it is unclear whether any of these modalities is efficacious, over and above the placebo effect.[22]

In clinical practice, rehabilitation specialist usually prescribes therapeutic heat plus exercise for pain control and functional improvement in knee OA for a long time. Shortwave diathermy (SWD) is one of deep heat widely applied to alleviate the symptoms associated with OA joints disease.[23] Only few clinical trials studied about the effect of diathermy or deep heat, other than that data from those trials were insufficient to determine whether it worked or not.[24, 25] Results from literature review varied from extremely positive,[26] to extremely negative[27] due to different methodologies, number of sample size, outcome assessment of different protocols. Indeed, no definite conclusions could be reached.[22]

REVIEW OF LITERATURES

Osteoarthritis of the knee is a common rheumatologic disease characterized by pain, stiffness and decreased range of motion.[6, 28] It is a major cause of morbidity, physical limitation and increased health care utilization, including total joint arthroplasty, especially in the elderly. The disease processes are characterized by the progressive erosion of articular cartilage, leading to joint space narrowing, subchondral sclerosis, marginal osteophyte formation, subchondral cysts and synovial inflammation.[29] The processes include a failure of cartilage remodeling, inflammation, ligamentous damage, altered neurological and muscle function, muscle damage, and pathological changes in the surrounding tissues which can increase articular compression and promote further joint damage.[30]

Nowadays there is no cure for OA,[4, 31, 32] so treatment is primarily focused on managing the condition by minimizing morbidity. Current recommendations, including guidelines published by the American College of Rheumatology, focus on the relief of pain and stiffness and maintenance or improvement in functional status as important goals of therapy.[33] Regarding to the medical treatments for reducing disease symptoms, SWD is often recommended for the treatment of OA and is claimed to have beneficial effects. SWD, a form of electromagnetic therapy, produces an oscillating electromagnetic field in the frequency range of 27.12 MHz. It is thought to cause movement of ions, distortion of molecules and creation of eddy currents within the field.[34] The deep heating effect of continuous SWD may induce an anti-inflammatory response,[35] reduce joint stiffness,[36] stimulate connective tissue repair,[37] reduce muscle spasm and pain, restore the action potential of traumatized muscle and aid healing of muscle tissue[38] and of bone.[39]

The earliest evidence of a reasonably favorable outcome for the application of SWD was reported by Wright[40]. He compared the outcome of six weeks

of placebo tablet, fortnightly injection of normal saline, and SWD applied for 20 minutes three times per week to 38 subjects with knee OA. Four efficacy measures were pain, tenderness, analgesic intake levels, and walking time. Patient was considered improved if two of the four efficacy parameters showed improvement. The results showed that more knees improved after a course of SWD than after a course of placebo tablet. There was no significant difference between the improvements observed after SWD and those after placebo injections. However, the sample size was small, a power analysis was not forthcoming, and the type, frequency and intensity of SWD used were not recorded. In addition, SWD group also seemed to be more disabled than the other groups.

Valtonen and Alaranta[41] studied 160 patients, of whom 132 had radiologically diagnosed of knee OA. After being treated with a self-tuning SWD (intensity that did not exceed a comfortable sensation of warmth) for 15-20 minutes three times weekly for an average of 13-14 treatments, approximately one-fifth of these patients improved markedly, three-fifths were slightly improved, and only one-fifth showed no beneficial treatment effects. The main limitations were the concurrent application of exercise therapy and the lack of a control group.

In a study by Lankhorst et al[26], 24 patients with knee OA were randomly divided into two comparable groups. The first group received a combination of SWD; 2-3 times a week for 15 minutes for six weeks, plus exercise, coordination training and walking training for 30 minutes during the last four weeks. The second group was treated with the same schedule, but received diathermy only. The maximal knee extensor torque and the walking speed improved significantly for both groups. It is possible that the marked improvements were due simply to a learning and for a Hawthorne effect. It is possible the application of SWD alone contribute to these very favorable results.

In contrast, Quirk et al [42] studied 38 patients with knee OA, randomly allocating them to three groups; interferential stimulation plus exercise, continuous SWD plus exercise, and exercise alone. Results showed all three groups had similar

decreases in pain intensity and an improved clinical condition suggesting no benefit of either the SWD or interferential treatments. Similar to the work of Clarke et al [43] who compared ice, continuous SWD and placebo SWD treatments for 48 knee OA, they found that all treatments had a similar effect on improving the subjects' pain at three months.

Some studies reported questionably results. Chamberlain et al [25] compared continuous SWD plus exercise with exercise alone in 42 patients with knee OA, and found both equally effective in relieving symptoms four weeks after treatment. However, the drop-out rate was higher for the exercise-group and the SWD group was also significantly weaker than the exercise-group at baseline. It is possible that permitting patients to use unlimited analgesic medication or using a sub optimal mode of application masked pain relief attributable to the SWD.

Another controlled trial performed by Jan and Lai.[44] They examined the effects of ultrasound (US) and SWD with or without exercise (at least 200 straight leg raise per day) in 61 women with knee OA. They were allocated to one of four groups: SWD for 20 minutes; US for 10 minutes; SWD plus exercise and US plus exercise. After an average of 41.2 (range 24-69) treatments, all patients improved their functional scores significantly, but the SWD treatment alone was not as effective as the exercise and SWD or the exercise and US. There was no difference between the effect of ultrasound and shortwave diathermy.

Marks et al [22] reviewed the literature on SWD and found that few studies suggested a favorable effect of SWD, but some showed questionable or non-favorable effect. They concluded that the prevailing clinical studies concerning the application of SWD for treating painful knee OA are essentially non-conclusive, given their poor methodological quality. The authors suggest that additional study is essential to determine whether SWD is indeed efficacious for knee OA.

In summary, the previous clinical trial had some problems due to poor methodology, inadequate sample size, or no non-treatment control group. Therefore, a randomized double-blinded, placebo-controlled trial on SWD therapy with adequate sample size will be performed to find out whether SWD is effective in pain reduction for knee OA.

CHAPTER 2
RESEARCH DESIGN

RESEARCH QUESTIONS

Primary research question

Was shortwave diathermy (SWD) beneficial and safe in decreasing pain and improving functions (assessed by total WOMAC score) in OA knee patients?

Secondary research questions

1. Was shortwave diathermy beneficial in improving the patients' score of global assessment of effect (patients' points of view)?
2. Was shortwave diathermy beneficial in increasing the satisfaction of the patients?
3. Was shortwave diathermy (SWD) beneficial in increasing the gait speed of patients?
4. What were the adverse effects of shortwave diathermy?

OBJECTIVES

Primary objective

To compare the effectiveness of SWD for the treatment of primary osteoarthritis (OA) of the knee in terms of total WOMAC score reduction.

Secondary objectives

1. To compare patients' global assessment of effect between two groups.
2. To compare the patients' satisfaction between two groups.
3. To compare the patients' gait speed between two groups.
4. To evaluate the adverse effects of both treatment regimens.

RESEARCH HYPOTHESIS

The difference in change at week 3 from baseline of total WOMAC score in the treatment group receiving the home based quadriceps exercise and joint protection program plus SWD was significantly different from the score in the control group receiving sham SWD.

Null hypothesis:

$$H_o: \mu_1 = \mu_2$$

Alternative hypothesis:

$$H_a: \mu_1 \neq \mu_2$$

where

μ_1= mean change at week 3 from baseline of total WOMAC score in the patients receiving sham SWD

μ_2= mean change at week 3 from baseline of total WOMAC score in the patients receiving SWD

CONCEPTUAL FRAMEWORK

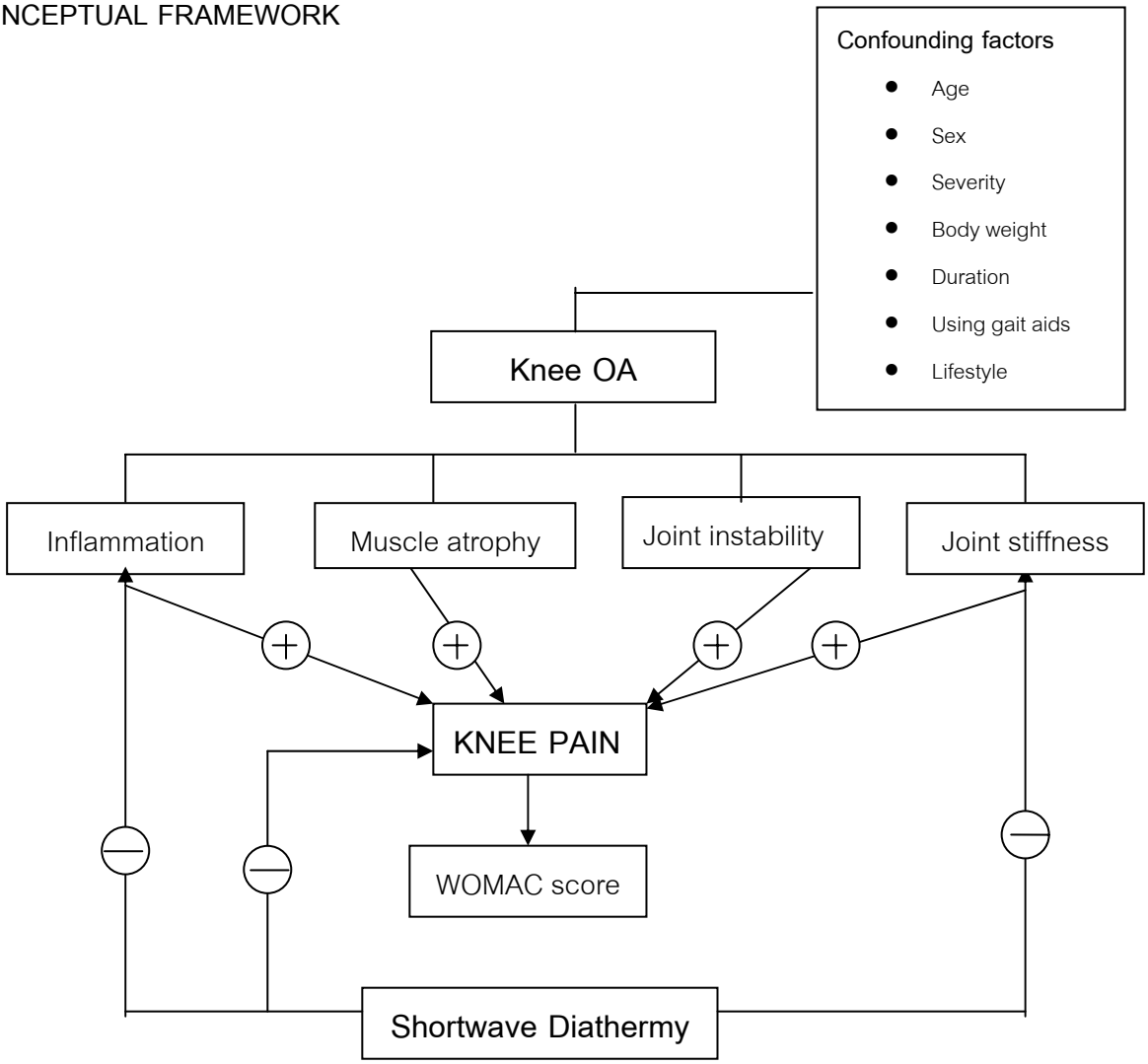


Figure 2.1 Conceptual framework demonstrates factors influencing pain elicited from disease of knee osteoarthritis

OPERATIONAL DEFINITIONS

Knee osteoarthritis

Diagnostic criteria are based on American College of Rheumatology classification: [33, 45] Knee pain and radiographic osteophytes and at least 1 of the following 3 items

1. Age > 50 years
2. Morning stiffness < 30 minutes in duration
3. Crepitus on motion

Compliance of exercise

Compliance of exercise means the completeness of exercise a patient can perform according to frequency and number of exercise and is categorized into 3 groups;

1. Good compliance means patient performs quadriceps exercise more than or equal to 50 repetitions per day and more than or equal to 5 days per week.
2. Fair compliance means patient performs quadriceps exercise more than or equal to 50 repetitions per day and less than 5 days per week or less than 50 repetitions per day and more than or equal to 5 days per week.
3. Poor compliance means patient performs quadriceps exercise less than 50 repetitions per day and less than 5 days per week.

Compliance of SWD treatment

Compliance of SWD treatment is categorized into 3 groups according to the frequency of SWD therapy sessions;

1. Good compliance means patient receives SWD for 7-9 sessions
2. Fair compliance means patient receives SWD for 4-6 sessions
3. Poor compliance means patient receives SWD for 1-3 sessions

Lifestyle

There are two types of lifestyle, i.e. active lifestyle and inactive lifestyle.

1. Active lifestyle means participants have something to do during the day, i.e. performing Tai-chi exercise, doing housework, or still working.
2. Inactive lifestyle means participants who have sedentary life, i.e. watching television the whole day, have nothing to do, or no exercise at all.

RESEARCH DESIGN

This study was designed as a prospective randomized and double blind (patient and assessor) controlled trial to answer the primary research question

CHAPTER 3
RESEARCH METHODOLOGY

POPULATION AND SAMPLE

Target population

The patients with primary knee osteoarthritis.

Study population

All of the patients who were diagnosed as knee osteoarthritis in out-patient clinic, Department of Rehabilitation Medicine and Department of Orthopaedic Surgery, Siriraj Hospital and met all the eligibility criteria would be recruited for this study.

Eligibility criteria

Inclusion criteria

- Patients with primary OA knee
- Age: 50 years old or more
- Agreed to participate in the study and sign consent form

Exclusion criteria

- Secondary causes of knee OA
- History of joint infection
- Severe joint instability
- History of intra-articular injection within 3 months
- History of previous shortwave diathermy (SWD)
- History of metallic implant around knee joint
- Suspected of malignancy around knee joint
- History of peripheral vascular disease
- Had significant cardiovascular disease
- Could not ambulate by walking

- On cardiac pacemaker
- Unable to understand how to score the symptoms

Sample size

The following table showed result from a pilot study of 17 patients. Among those patients, 5 patients lost to follow up whereas one patient gave unreliable response.

Table 3.1 Pilot study of 17 patients

Group	Change (Baseline-Week 3) in	n	Min	Max	Mean	SD
SWD	WOMAC total	6	-0.68	3.19	0.93	1.53
	WOMAC pain	6	-1.00	4.14	1.38	1.94
	WOMAC stiffness	6	-1.50	4.45	0.62	2.22
	WOMAC function	6	-0.74	2.38	0.79	0.99
Sham	WOMAC total	5	-1.24	1.28	0.08	1.04
SWD	WOMAC pain	5	-1.64	1.90	0.14	1.64
	WOMAC stiffness	5	-1.20	0.50	-0.30	0.69
	WOMAC function	5	-1.06	1.84	0.41	1.16

Sample size calculation in the case of comparison of two independent means was as follows:

$$\text{n/group} = \frac{2\,\sigma^2\,[Z_{\alpha/2} + Z\beta]^2}{[\mu_{SWD} - \mu_{sham}]^2}$$

where α = Probability of type I error = 0.05

β = Probability of type II error = 0.20 (power = 80%)

$Z_{\alpha/2}$ = 1.96 (two-sided)

Z_β = 0.84

μ_{SWD} = Mean change from baseline at week 3 of total WOMAC score in SWD group = 0.93

μ_{sham} = Mean change from baseline at week 3 of total WOMAC score in sham SWD group = 0.08

σ = Standard deviation of change from baseline of WOMAC score in each group = 1.53

Therefore, a total of 102 patients (51 per group) was required to have 80% power at 2-sided α of 0.05 to detect a difference in mean change from baseline of total WOMAC score of 0.85 (with SD of 1.53) between 2 treatment groups. To compensate for expected dropout of 30% (result from pilot study), the n / group became 66.

To prevent the high drop out rate, participants with severity score of 5-13 (moderate to very severe classification) would be recruited. For mild severity, they did not comply to the 3-week hospital based program and for extremely severe cases, they were more suitable for surgery due to severe pain and poor functions which incompatible with their lifestyle. In addition, the available phone numbers were recorded in order to remind subjects every week or when they do not attend program without notification to the therapist.

INTERVENTION

Allocation of treatments

Patients with knee OA who met the selective criteria were allocated to either treatment or control group by using random number table. Each code number was contained in a sealed opaque envelope, which was sequentially numbered. When a new patient was enrolled, an independent physical therapist would open the next in a series of envelopes, and prepared the trial treatment accordingly.

Trial treatments

All participants had to attend the class advising about joint protection program, how to use NSAID and how to perform quadriceps exercise by the author. The physical therapist knew which intervention was given to participants. The assessor (author) and the patients were blinded from the treatment. The treatment program provided to each patient was as the following:

Control group

- Sham SWD 20 min/session, 3 times/week for consecutive three weeks

Treatment group

- SWD 20 min/session, 3 times/week for consecutive three weeks

Instrument

SWD machine used in this study was ULTRAMED (Bosch) model 11s 601 ser no 3660340 with the 10-cm diameter condenser plates. This machine operated at a frequency of 27.12 MHz. Its power input was 300 watt, and generated mean power output of 3.2 watt.

SAFETY MEASURES

- The study protocol was terminated if serious adverse event occurred, or upon patient's request.
- Patients rang the bell if they felt too much warm around the knee joint during treatment.
- Cardiopulmonary resuscitation instruments and medications were available.

EXPERIMENTAL PROCEDURE

Patients fulfilling the criteria had a class explaining about their disease, how to do knee exercise and how to use knee properly. In addition, they received booklets containing advises on muscle exercise technique and joint protection program of knee activities, for example avoid squatting and kneeling.

Then they were randomly allocated into either the study group or the control group. Both groups had to attend the program at the hospital 3 times a week for 3 consecutive weeks. The study group received a SWD combined with home-based exercise program and joint protection program. The control group received sham SWD which was similar to the treatment group except that the power switch was not turned on.

The home-based exercise program consisted of quadriceps exercise at home on a daily basis with frequency of 50-100 repetitions on each leg. The exercise included: 1) Isometric contraction of quadriceps muscle in full extension held for five seconds (subject sit on floor with back supported and legs extended, with rolled up towel under one knee and contracted quadriceps by pushing into the floor against towel). 2) Isotonic resistive quadriceps contraction held in mid flexion for five seconds (subject sit on a chair in cross leg position, pushed upper leg down and lift lower leg up to partially extended position and held).

During the study, all subjects had no other treatment except acetaminophen and NSAID for pain relief. They were advised to record the frequency of exercise each day and also to bring the medicine back at the follow up period for counting. In addition, they were expected to report any abnormalities happening after each therapy session (potential adverse effects). The intervention would be terminated if one of the following 3 conditions occurred: 1) pain deterioration, 2) the patients or doctor decision to stop, 3) serious complications occurred such as severe joint effusion, intractable pain or acute joint inflammation.

DATA COLLECTION

After all subjects signed the informed consent form, they were interviewed about their baseline characteristics, and asked to complete the questionnaire including three dimensions of WOMAC score. If they were illiterate or had problem with eyesight, the research assistant read the questionnaire and made sure that they understand each question. The research assistant did not know which group they were. In addition, gait speed was calculated from time spent for 100-meter walk.

At the end of the third week, they completed the questionnaire, including complications occurred, their satisfaction and the overall improvement.

WOMAC score

The primary outcome variable was the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC).[46] It was a disease-specific questionnaire developed specifically for persons with OA of the hip and knee. Only 24 items on 3 dimensions were considered important for subjects with OA: pain (5 items), stiffness (2 items), and functional difficulty (17 items).

In this study, WOMAC was assessed by numerical rating scale anchored with terms describing the extremes of symptoms intensity. There were 2 descriptors, i.e. “no symptom” at the number 0, and “intolerable pain/can not do” at the number 10 (see Data collection form in APPENDIX III). Patients were instructed to indicate the intensity of their symptoms experience by marking a number. The total WOMAC score was derived by summing the WOMAC score from three dimensions: pain, stiffness and function. The WOMAC score ranged from 0-10, the higher the score was, the worse the pain and the function were. In this study, the WOMAC score was measured at baseline and after three weeks of treatment. The change from baseline of WOMAC score was compared between groups.

This questionnaire (original English version) was translated into Thai language by physiatrist who had been working in this field for more than 10 years. The translated version was validated by back translation into English by a professional English translator without giving any information regarding to this instrument. The reliability and validity of the Thai version WOMAC questionnaire was tested before using. Two items in WOMAC function dimension were discarded, i.e. bending to floor (item F5), lying in bed (item F12), due to low content validity (IC = 0.00), so modified Thai version of WOMAC score included only 22 items. (Appendix II)

Patients' global assessment of the treatment

At the end of the third week, the patient was asked to rate his/her global assessment of the SWD treatment which were a 6-categorical scale, i.e. complete recovery, much improved, moderately improved, slightly improved, no different, or getting worse.

Patients' satisfaction to the treatment

At the end of third week, the patient was asked to rate his/her satisfaction to the SWD treatment which were a 5-categorical scale, i.e. very satisfied, moderately satisfied, little satisfied, indifferent, or unsatisfied.

Safety monitoring

The patient was asked to report to the therapist regarding any symptoms occurring during SWD treatment. Adverse events of SWD, e.g. burn, scald, edema of skin, subcutaneous and muscle, joint effusion, joint inflammation, persistent pain more than 2 hours after treatment, and feeling more disability in the next morning, were evaluated at the three-week follow up.

MEASUREMENT

All of the measured variables including administrative variables, baseline variables, efficacy variables, and safety variables were tabulated in table 3.2.

Table 3.2 Summary of measured variables

Administrative variables		
■ Name		
■ Identification no.		
■ Telephone no.		
Baseline variables / Covariates		
■ Age (yr)	Continuous numerical	Mean ± SD
■ Sex	Dichotomous categorical	N (%)
■ Body mass index (Kg/m^2)	Continuous numerical	Mean ± SD
■ Education level	Ordinal categorical	N (%)
■ Duration of disease (yr)	Continuous numerical	Mean ± SD
■ Affected side	Nominal categorical	N (%)
■ Using gait aids	Dichotomous categorical	N (%)
■ Using knee support	Dichotomous categorical	N (%)
■ Activity level	Nominal categorical	N (%)
■ Severity score	Continuous numerical	Mean ± SD
Efficacy variables		
■ WOMAC total score	Continuous numerical	Mean ± SD
■ WOMAC pain score	Continuous numerical	Mean ± SD
■ WOMAC stiffness score	Continuous numerical	Mean ± SD
■ WOMAC function score	Continuous numerical	Mean ± SD
■ Gait speed (m/min)	Continuous numerical	Mean ± SD
■ Patient's global assessment	Ordinal categorical	N (%)
■ Patient's satisfaction	Ordinal categorical	N (%)
Safety variables		
■ Adverse events	Nominal categorical	N (%)

Note: WOMAC = The Western Ontario and McMaster Universities Osteoarthritis Index.

CHAPTER 4
DATA ANALYSIS

GENERAL CONSIDERATIONS

The statistical analysis was focused on the detection of significant differences between the treatment and the control groups with respect to the WOMAC score as measured by numerical rating scale.

Analyses of efficacy and adverse outcomes were based on Intention to Treat population.

All tests of hypotheses were conducted at the **two-sided**, and **0.05 level of significance**.

The statistical analysis was performed using SPSS for Windows, release11.0.1 (SPSS, Inc).

PLAN FOR STATISTICAL DATA ANALYSES

Baseline characteristics

The study groups were examined for comparability on their baseline characteristics. Statistical analysis was applied to compare the baseline characteristics between the study groups. Owing to randomization, it was expected that the baseline characteristics of both groups would be comparable. However, if there was clinically significant difference between groups in some baseline variables that were potential to affect the primary outcome, these variables were planned to be statistically adjusted using multiple linear regression analysis.

Efficacy analyses

Statistical analysis was performed to compare the outcomes between the two treatment groups. The statistical analysis was summarized in Table 4.1. Since the primary outcome (WOMAC score) was the continuous variable that was normally distributed, parametric test (Unpaired t-test) was used primarily for the hypothesis testing.

For the secondary outcomes, gait speed was not normally-distributed, non-parametric test (Mann-Whitney U-test) was applied. The patient's global assessment and satisfaction index were analyzed by Fisher's exact test.

Multiple linear regressions were used to adjust for confounders. Assumption of regression was tested by Regression diagnostics.

Safety analyses

The frequency of adverse events in both treatment and control groups were presented with descriptive statistics. Test of statistical hypothesis was not applied because the adverse events were expected to occur in very low frequency.

Table 4.1 Summary of statistical analysis

Outcome	Statistical test
Primary efficacy variable	
■ WOMAC total score	Unpaired t-test
■ WOMAC pain score	Unpaired t-test
■ WOMAC stiffness score	Unpaired t-test
■ WOMAC function score	Unpaired t-test
Secondary efficacy variables	
■ Patient's global assessment of effect	Fisher's exact test
■ Patient's satisfaction to treatment	Fisher's exact test
■ Gait speed	Mann-Whitney U-test
Safety variables	
■ Adverse events	No statistical test

CHAPTER 5
ETHICAL CONSIDERATION

GENERAL CONSIDERATION

This study was conducted in accordance with the ethical principles stated in the most recent version of the Declaration of Helsinki. This study was approved by the ethical committee of Faculty of Medicine, Siriraj Hospital and the ethical committee of Faculty of Medicine, Chulalongkorn University.

Prior to recruitment into this study, the patients were thoroughly informed about the following items:

1. Objectives of the study
2. The information about details of the interventions
3. Treatment outcomes and potential side effects
4. The patients' right to withdraw from the study without interference with their proper medical care.

A signed informed consent was obtained from the patient without enforcement. (For consent form, see APPENDIX V).

SPECIFIC CONSIDERATION

The complications of the treatment regimens such as burn, scald, joint effusion and inflammation were carefully detected. To avoid these potential complications,

1. Wooden bed was selected because SWD was high frequency electrical current
2. Towel covering SWD applicator should be dry
3. The patient was informed to ring the bell if he/she felt too much warm
4. Close observation one hour after treatment was performed

If adverse events did occur, cold packs as well as medications were prepared and available for burn, scald, joint effusion or inflammation. If they had persistent pain or more disability, intensive investigation was performed and/or second opinion from orthopedist was requested.

CHAPTER 6
RESULTS OF THE STUDY

FLOW OF STUDY PARTICIPANTS

Figure 6.1 demonstrated flow of study participants. One hundred and thirty-two eligible patients were randomized. Sixty-six patients were assigned to the control group (sham SWD) but 7 cases were lost to follow up (3 cases due to moving out, 3 cases due to unavailability and 1 case due to other medical problem). Sixty-six cases were assigned to the treatment group (SWD) but 3 cases were lost to follow up (1 case due to moving out, 1 case due to inaccessibility, and 1 case had knee operation). Characteristics of all 10 lost cases were similar to those of included cases. Therefore, data of 122 cases were finally included in the analysis.

BASELINE AND DEMOGRAPHIC DATA

Table 6.1 demonstrated baseline and demographic data of the patients. Data of the control and the treatment groups were examined for comparability on their baseline characteristics using statistical analysis. It was found that almost all baseline variables were comparable except for the duration of disease.

The comparable variables between the control and the treatment groups were summarized as mean ± SD as follows: age (62.9 ± 8.3 vs. 63.6 ± 7.3 yr), sex (female: 90.9% vs. 80.3%), body mass index (26.0 ± 4.1 vs. 25.7 ± 3.8 kg/m^2), education level (Illiterate: 4.5% vs. 12.1%), affected side (unilateral 54.6% vs. 42.4%), using gait aids (9.1% vs. 9.1%), using knee support (30.3% vs. 40.9%), lifestyle (active: 77.8% vs. 89.4%), baseline WOMAC total score (3.9 ± 1.5 vs. 3.6 ± 1.4), WOMAC pain score (3.7 ± 1.7 vs. 3.7 ± 1.6), WOMAC stiffness score (4.2 ± 2.2 vs. 3.7 ±1.9), WOMAC function score (3.6 ± 1.4 vs. 3.5 ± 1.4), and gait speed (65.1± 12.1 vs. 64.0 ± 13.4 m/min).

The baseline variable that was different between the control and the treatment groups was only the duration of disease (median: 2 vs. 5 yr).

EFFICACY OUTCOME

The histogram of change from baseline of WOMAC score after 3-week of SWD treatment (Figure 6.2) revealed normal distribution, which was confirmed by Kolmogorov-Smirnov test (WOMAC total: p = 0.902 and 0.704, WOMAC pain: p = 0.595 and 0.498, WOMAC stiffness: p = 0.756 and 0.249, WOMAC function: p = 0.843 and 0.999 for the treatment and the control group, respectively). Therefore, the comparison WOMAC scores between the control and the treatment groups were performed by parametric test (Unpaired t-test).

Effectiveness of the treatment was demonstrated in Table 6.2. The change from baseline in WOMAC total score in the control group was similar to that in the treatment group (1.05 ± 1.62 vs. 1.07 ± 1.43, p = 0.943). In addition, the change from baseline in WOMAC pain (1.32 ± 1.81 vs. 1.30 ± 1.67, p = 0.953), WOMAC stiffness (1.13 ± 2.36 vs. 1.09 ± 1.89, p = 0.909) and WOMAC function (0.64 ± 1.38 vs. 0.86 ± 1.39, p = 0.378) were also not statistically significantly different between the control and treatment groups respectively.

The secondary efficacy outcomes of SWD treatment were demonstrated in Table 6.3. Since the histogram of change from baseline in patients' gait speed was not normally distributed (Figure 6.3), the Mann Whitney U-test was applied. The difference in change from baseline of gait speed between two groups did not reach statistical significance (p=0.065). The global assessment of SWD effect was not different between two groups (p = 0.081), even though the number of patients who rated themselves as much improved was higher in treatment than in control group (25.4% vs. 8.6%). Only the patients' satisfaction index was statistically significantly different between two groups (p= 0.015).

Table 6.4 revealed the proportion of the patients with good SWD compliance which was higher in the treatment group (92.1%) than in the control group (67.2%) and the difference was statistically significant (p = 0.002). In contrast to the exercise compliance (Table 6.5), patients in the control group had higher percentage of good compliance than those in treatment group (60.3% vs. 25.4%) which was also statistically significant (p < 0.001). In addition, amounts of NSAID used were statistically higher in the treatment group. (p = 0.021, Table 6.6).

Since duration of disease at baseline, SWD compliance, exercise compliance, and amount of NSAID used were not comparable between two groups, multiple linear regression was applied to adjust for these factors. Four regression models were fitted for change from baseline (score week 0 – week 3) of WOMAC score i.e., total score, pain score, stiffness score and function score. Independent variables included in each model were treatment group (0 = control, 1 = treated), duration of disease (0=≥5yrs, 1=< 5yrs), SWD compliance (0=poor, 1=good), exercise compliance (0=poor, 1=good), and amount of NSAID used. Results of the regression analysis (Table 6.7) demonstrated that treatment group, SWD compliance, exercise compliance and amount of NSAID used had no effect on change from baseline in WOMAC total score after adjusting for the other variables (p=0.330, 0.750, 0.801 and 0.706 respectively). Duration of disease was the only factor affecting change from baseline in WOMAC total score (p=0.035). Subjects with duration of disease less than 5 years had more change of WOMAC total score (difference = 0.712) compared to those with duration of disease at least 5 years. The difference in change from baseline in WOMAC score between the 2 groups after adjusted for duration of disease at baseline, compliance of SWD treatment and exercise, and amount of NSAID used was shown in Table 6.8.

Results from regression analysis of change from baseline in WOMAC pain, stiffness and function scores showed similar results as WOMAC total score. That is, there was no effect of treatment group, SWD compliance, exercise compliance and amount of NSAID used on these three WOMAC scores. Duration of disease still had

impact on WOMAC pain and stiffness score (p=0.029 and 0.014 respectively), but not on WOMAC function score (p=0.788).

Table 6.9 demonstrated subgroup analysis based on baseline WOMAC total score. In the subgroup with low baseline WOMAC score (<5), the improvement in WOMAC score of the treatment group was somewhat better than that of the control group. On the other hand those with high baseline score (≥ 5), the control group had better improvement than the treatment group. However, these difference neither reached clinical nor statistical significant.

Subgroup analysis of secondary outcomes was demonstrated in table 6.10. In the subgroup with low baseline WOMAC score, there was statistically significant improvement of gait speed and global assessment level in the treatment group, whereas those with high baseline WOMAC score, the improvement of gait speed was better in the control group. Other secondary outcomes were not statistically different between the treatment groups even after subgroup analysis.

SAFETY OUTCOME

The adverse events of SWD were demonstrated in Table 6.11. The incidence of adverse events in the control (6.8%) and in the treatment groups (6.3%) was similar. The events included mild pain, mild swelling and feeling of vasodilatation. There was one subject in the treatment group that had increased pain and needed knee operation.

The adverse events occurring during exercise were also recorded (Table 6.12). The incidence was not statistically significantly different (33.9% vs. 39.7% in the control and treatment respectively: p = 0.635). The events were increased crepitus sound, mild tightness of muscle, fatigue, and mild pain. All these events were not serious.

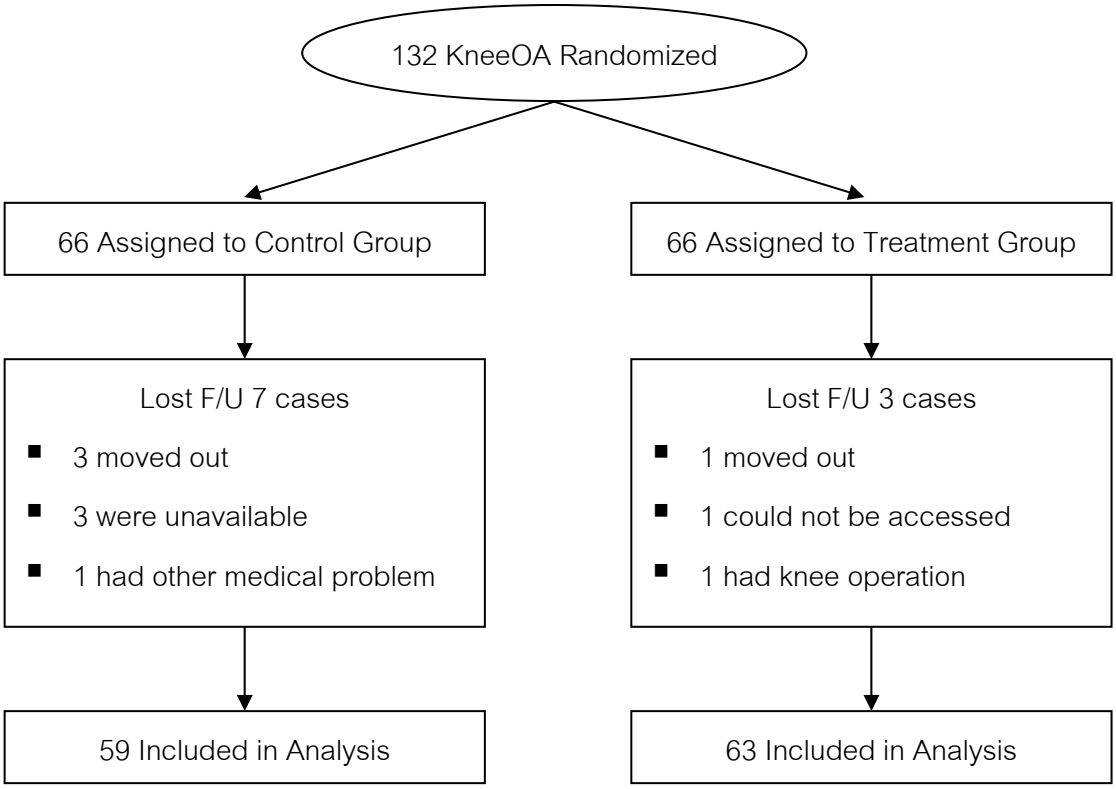


Figure 6.1 Flow of study participants

Table 6.1 Baseline characteristics in the control and the treatment groups

Characteristics	Control (n = 59)	Treatment (n = 63)	P-value@
Age (yr)	62.9 ± 8.3	63.6 ± 7.3	0.648
Sex (female)	60 (90.9%)	53 (80.3%)	0.083
Body mass index (kg/m^2)	26.0 ± 4.1	25.7 ± 3.8	0.643
Educational level (yr)			
Illiterate	3 (4.5%)	8 (12.1%)	0.344
Primary school	36 (54.5%)	31 (47.0%)	
Secondary school	10 (15.2%)	13 (19.7%)	
University	17 (25.8%)	14 (21.2%)	
Duration of disease (yr)	2(1,10)	5(1,11.3)	<0.001*
Affected side			
Unilateral	36 (54.6%)	28 (42.4%)	0.164
Bilateral	30 (45.4%)	38 (57.6%)	
Using gait aids	6 (9.1%)	6 (9.1%)	1.000
Using knee support	20(30.3%)	27 (40.9%)	0.203
Lifestyle			
Active	52 (78.8%)	59 (89.4%)	0.096
Inactive	14 (21.2%)	7 (10.6%)	
Severity score	9.1 ± 3.0	9.0 ± 2.9	0.872
WOMAC total score	3.9 ± 1.5	3.6 ± 1.4	0.301
WOMAC pain score	3.7 ± 1.7	3.7 ± 1.6	0.915
WOMAC stiffness score	4.2 ± 2.2	3.7 ± 1.9	0.137
WOMAC function score	3.6 ± 1.4	3.5 ± 1.4	0.533
Gait speed (m/min)	65.1 ± 12.1	64.0 ± 13.4	0.611

Note: Data were mean ± SD, median (90%Central value) or n (%) otherwise specified

@ Unpaired t-test or Mann-Whitney U-test for quantitative data,

Chi-square test for qualitative data

* Statistically significant

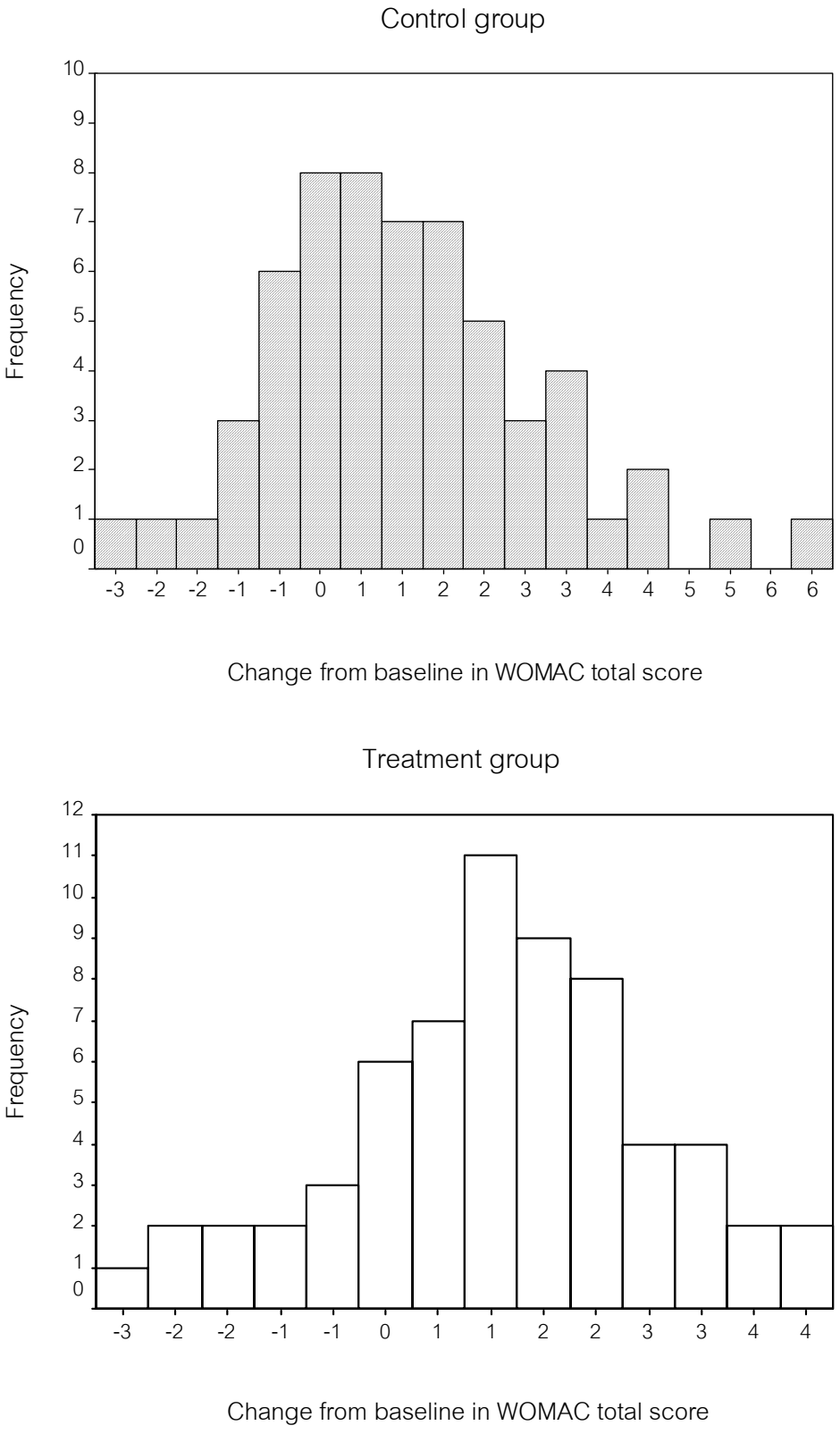
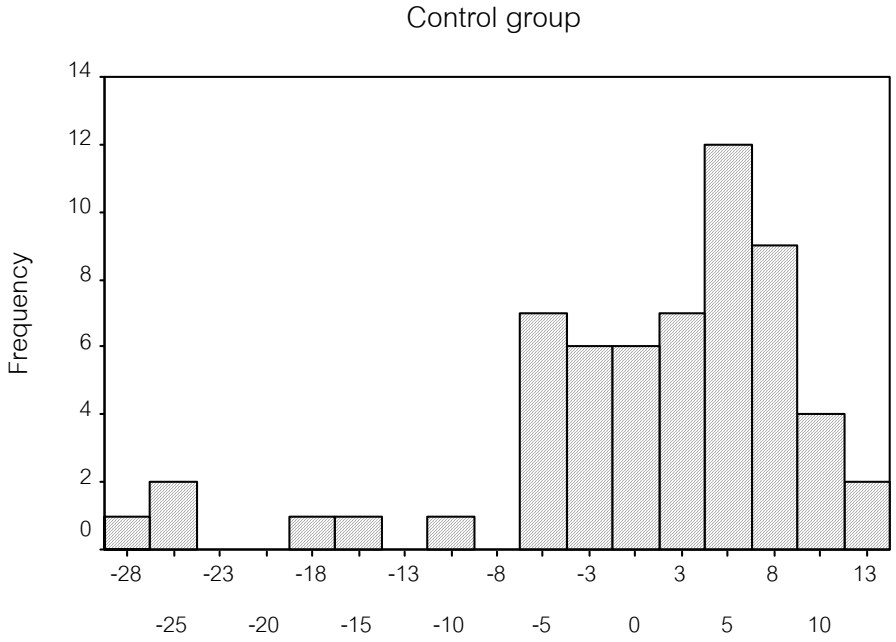


Figure 6.2 Histogram of change from baseline in WOMAC total score in each group



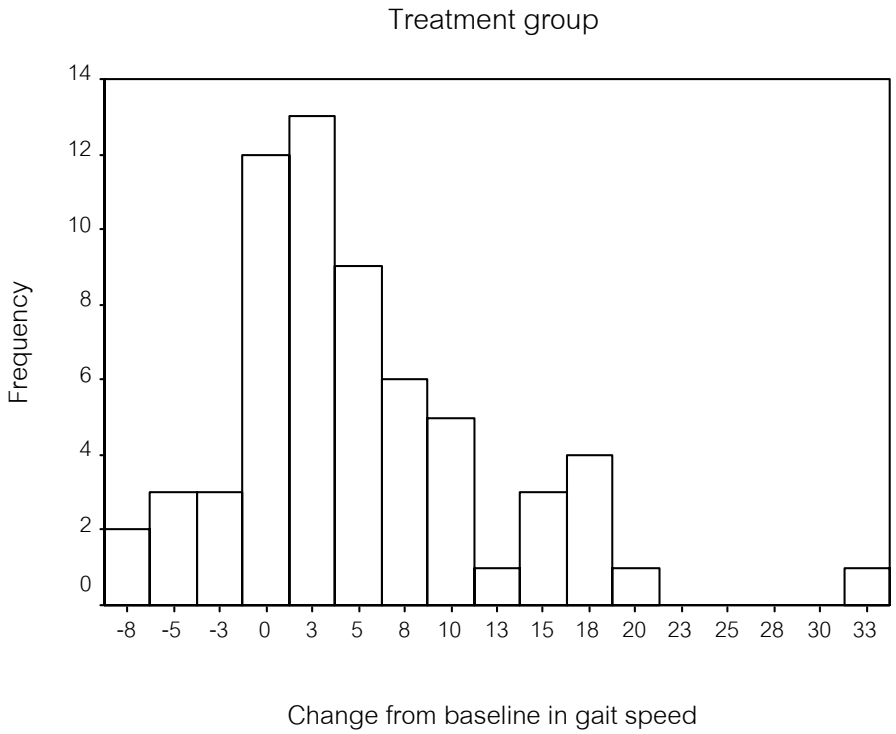


Figure 6.3 Histogram of change from baseline in gait speed in each group

Table 6.2 Primary efficacy outcomes of SWD treatment: Change from baseline in WOMAC score

WOMAC	Control (n=59)	Treatment (n=63)	Difference (Treatment-Control)	95% CI of difference	p-value[@]
	Mean ± SD	Mean ± SD			
Total score	1.05 ± 1.62	1.07 ± 1.43	0.02	-0.53, 0.57	0.943
Pain score	1.32 ± 1.81	1.30 ± 1.67	-0.02	-0.64, 0.61	0.953
Stiffness score	1.13 ± 2.36	1.09 ± 1.89	-0.04	-0.81, 0.72	0.909
Function score	0.64 ± 1.38	0.86 ± 1.39	0.22	-0.27, 0.72	0.378

Note: @ Unpaired t – test

Table 6.3 Secondary efficacy outcomes of SWD treatment: gait speed, patient's global assessment, and patient's satisfaction

Efficacy variables	Control (n = 59)	Treatment (n = 63)	P-value[@]
Change from baseline in gait speed(m/min)	1.9 (-25.9,12.2)	3.5 (-7.4,24.3)	0.065
Patient's global assessment			
■ Much improved	5 (8.6%)	16 (25.4%)	0.081
■ Moderately improved	24 (41.4%)	25 (39.7%)	
■ Little improved	22 (37.9%)	14 (22.2%)	
■ No difference	5 (8.6%)	4 (6.3%)	
■ Getting worse	2 (3.4%)	4 (6.3%)	
Patient's satisfaction			
■ Very satisfied	20 (34.5%)	39 (61.9%)	0.015*
■ Moderately satisfied	30 (51.7%)	18 (28.6%)	
■ Little satisfied	6 (10.3%)	3 (4.8%)	
■ Indifferent	1 (1.7%)	1 (1.6%)	
■ Unsatisfied	1 (1.7%)	2 (3.2%)	

Note: Data were median (90% central value) or n (%)

@ Fisher's exact test for qualitative data and Mann-Whitney U test for quantitative data

* Statistically significant

Table 6.4 SWD compliance between groups

SWD compliance	Control (n = 59)	Treatment (n = 63)	P-value[@]
Good	39 (67.2%)	58 (92.1%)	0.002*
Fair	7 (12.1%)	3 (4.8%)	
Poor	12 (20.7%)	2 (3.2%)	

Note: Data was n (%)

@ Fisher exact test

* Statistically significant

Table 6.5 Exercise compliance between groups

Exercise compliance	Control (n = 59)	Treatment (n = 63)	P-value[@]
Good	35 (60.3%)	16 (25.4%)	<0.001*
Fair	19 (32.8%)	42 (66.7%)	
Poor	4 (6.9%)	5 (7.9%)	

Note: Data was n (%)

@ Fisher exact test

* Statistically significant

Table 6.6 Amount of NSAID used of participants between two groups

NSAID	Control (n = 59)	Treatment (n = 63)	P-value[@]
Number of NSAID used	6 (0, 63)	30 (0, 63)	0.021*

Note: Data was median (90% central value)

@ Mann-Whitney U test

* Statistically significant

Table 6.7 Multiple linear regressions analysis of factors affecting change from baseline in WOMAC score

Factors[#]	WOMAC total		WOMAC pain		WOMAC stiffness		WOMAC function	
	b[@]	p	b[@]	p	b[@]	p	b[@]	p
Constant	0.488	0.302	0.478	0.371	0.189	0.773	0.702	0.110
Group	0.340	0.330	0.332	0.398	0.410	0.396	0.347	0.281
Duration	0.712	0.035*	0.836	0.029*	1.159	0.014*	0.083	0.788
SWD compliance	-0.116	0.750	-0.152	0.710	0.175	0.728	-0.248	0.459
Exercise compliance	-0.076	0.801	-0.020	0.954	-0.213	0.609	0.056	0.841
Amount of NSAID used	0.002	0.706	0.009	0.161	-0.004	0.628	0.000	0.971

Note: # Group: 0= control, 1= treatment

Duration (years): 0= $\geq$ 5, 1= < 5

SWD compliance: 0= fair to poor, 1= good

Exercise compliance: 0= fair to poor, 1= good

Amount of NSAID used (tablets)

@ Regression coefficient

* Statistically significant

Table 6.8 Adjusted differences in change from baseline in WOMAC score between treatment and control groups

WOMAC	Difference in WOMAC score (Treatment-Control)	
	Crude difference	Adjusted difference[@]
Total score	0.02	0.34
Pain score	-0.02	0.33
Stiffness score	-0.04	0.41
Function score	0.22	0.35

Note: @ Adjusted for the duration of disease, SWD compliance, exercise compliance and amount of NASID used

Table 6.9 Subgroup analysis of primary outcome based on baseline WOMAC score

Variables	Baseline WOMAC < 5		Baseline WOMAC ≥ 5	
	Control (n = 51)	Treatment (n = 55)	Control (n = 15)	Treatment (n = 11)
Baseline WOMAC score	3.29 ± 1.14	3.18 ± 1.03	5.83 ± 0.60	5.76 ± 0.75
Change from baseline	0.69 ± 1.30	1.06 ± 1.28	2.34 ± 1.99	1.14 ± 2.17
Crude difference of change from baseline	0.37		-1.20	
Adjusted difference[@] of change from baseline	0.50		0.72	
Percent difference of change from baseline	15.72 %		12.50%	

Note: @ Adjusted for the duration of disease, SWD compliance, exercise compliance and amount of NASID used

Table 6.10 Subgroup analysis of secondary outcomes based on baseline WOMAC score

Efficacy variables	Baseline WOMAC < 5			Baseline WOMAC ≥ 5		
	Control (n = 46)	Treatment (n = 53)	P-value@	Control (n = 13)	Treatment (n = 10)	P-value@
Change from baseline in gait speed(m/min)	1.15 (-21.69, 9.31)	3.50 (-7.4, 24.3)	0.003*	5.67 (-27.47, 11.94)	0.84 (-7.96, 9.85)	0.042*
Patient's global assessment						
■ Much improved	4 (8.7%)	15 (28.3%)	0.009*	1 (7.7%)	1 (10.0%)	0.050
■ Moderately improved	18 (39.1%)	24 (45.3%)		7 (53.8%)	1 (10.0%)	
■ Little improved	19 (41.3%)	11 (20.8%)		3 (23.1%)	3 (30.0%)	
■ No difference	3 (6.5%)	1 (1.9%)		2 (15.4%)	3 (30.0%)	
■ Getting worse	2 (4.3%)	2 (3.8%)		0	2 (20.0%)	
Patient's satisfaction						
■ Very satisfied	18 (39.1%)	32 (60.4%)	0.089	0	0	0.646
■ Moderately satisfied	20 (43.5%)	16 (30.2%)		3 (23.1%)	7 (70.0%)	
■ Little satisfied	6 (13.0%)	3 (5.7%)		10 (76.9%)	2 (20.0%)	
■ Indifferent	1 (2.2%)	1 (1.9%)		0	0	
■ Unsatisfied	1 (2.2%)	1 (1.9%)		0	1 (10.0%)	

Note: Data were median (90% central value) or n (%)

@ Fisher's exact test for qualitative data and Mann-Whitney U test for quantitative data

Table 6.11 Adverse events of SWD

Variables	Control (n = 59)	Treatment (n = 63)
Adverse events	4 (6.8%)	4 (6.3%)
■ Integument system (Burn, scald)	0	0
■ Musculoskeletal system (Joint effusion, inflammation, edema of skin, subcutaneous and muscle tissue)	0	0
■ Others		
Persistent pain > 2 hr	0	0
More disability	0	0
Mild pain	2	3
Mild swelling	1	0
Feeling of vasodilatation	2	0
Deterioration of pain, needed operation	0	1

Note: Data was n (%)

Some patients experienced more than one event

Table 6.12 Adverse events occurring during exercise

Variables	Control (n = 59)	Treatment (n = 63)	P-value[@]
Adverse events	20 (33.9%)	25 (39.7%)	0.635
Increased crepitus sound	6	10	
Mild tightness of muscle	13	16	
Fatigue	3	0	
Mild pain	4	2	

Note: Data was n (%)

Some patients experienced more than one event

@ Fisher's exact test.

CHAPTER 7
DISCUSSION, CONCLUSION AND RECOMMENDATION

DISCUSSION

Baseline characteristics

The main objective of the present study was to assess treatment effect of SWD on the intensity of pain measured by WOMAC score. The most reliable indicator of the existence and intensity of pain is patient self-reporting. As a result, assessment of pain experience is always subjective and the data obtained can be influenced by psychological (pain experience, pain expectation, cognitive function), social and medical factors.[47]

In this double blind randomized placebo controlled trial, the baseline factors that were controlled at the beginning were characteristics of the patients (i.e. eligibility criteria). According to randomization, other factors were expected to be comparable between two groups. The baseline variables that were comparable included age, sex, body mass index, education level, affected side, using gait aids, using knee support, lifestyle, severity score, WOMAC total, WOMAC pain, WOMAC stiffness, WOMAC function score and gait speed. Unfortunately, there was discrepancy in duration variable at baseline. Compared with the control group, the treatment group seemed to have longer period of duration (5 vs. 2 yrs, $p < 0.001$).

The difference in baseline characteristic may affect the outcomes. Duration could have negatively effect on WOMAC score. Therefore, multiple linear regression analysis was applied to statistically adjust the incomparable factor.

Effectiveness

In the present study, the effectiveness was estimated from primary outcome, i.e. WOMAC total score, and secondary outcomes, i.e. patient's gait speed, global assessment index, and patient satisfaction index.

For the primary outcome, the difference of WOMAC total score was not statistically significant between two groups with the 95% CI of difference of -0.53, and 0.57. In the present study, baseline WOMAC total score was 3.6 (treatment group). If the SWD treatment could reduce pain, the WOMAC total score in the treatment group would become 3.03 (equal to 3.6 minus 0.57), which was approximately the same level of severity as of the baseline level. Therefore this treatment effect was considered to have no clinical significance in the patient with low baseline WOMAC score.

Not only the difference of WOMAC total score but also of WOMAC pain, WOMAC stiffness and WOMAC function dimensions revealed no statistical significance. The author also analyzed the difference of pain score on level walking which was one item of WOMAC pain dimension. The result was similar to those WOMAC scores. Since the 95% CI was narrow, the results of this study should have enough power to consider as a true negative trial.

There were 5 factors possibly affecting the outcome and were not comparable between groups, i.e. treatment groups, duration of disease, SWD compliance, exercise compliance, and amount of NSAID used. Multiple linear regression analysis was applied to adjust these factors. The result of the analysis confirmed that duration of disease was the only factor affecting the change of WOMAC total score (p=0.035). The adjusted difference of change in WOMAC score was not much different from the crude score, i.e. 0.34 vs 0.02. The approximately 9% improvement of WOMAC score in the treatment group compared to that in the control was so trivial that had no clinical significance.

Because of low WOMAC score at the beginning (3.9 and 3.6 in control and treatment groups respectively), it might be difficult to demonstrate any treatment

effect. Patient with high baseline WOMAC score might respond to the SWD better than those with low score. However, after subgroup analysis based on baseline WOMAC score, there was no difference in improvement of WOMAC total score between the patients with low and high baseline score (15.7% and 12.5% respectively).

Compared to the previous articles that reported favorable outcome for the application of SWD, study of Wright [40] had small sample size, did not record the type, frequency and intensity of SWD used, and SWD group also seemed to be more disabled than the other groups. The study of Valtonen and Alaranta [41] had no control group. Another study of Lankhorst et al [26] chose maximal knee extensor torque and walking speed as the outcomes and had Hawthorne effect. This present study conducted with adequate sample size and the proper methodology of double-blinded placebo controlled trial, which revealed negative result of SWD on knee OA.

Regarding the secondary outcomes, analysis of gait speed and global assessment did not show statistical significance although the results seemed to favor the treatment, i.e. the improvement of these outcomes in the treatment group were better than those in the control group. Only the patients' satisfaction index was statistically significant different between the two groups. More subjects in the treatment group than in the control group rated themselves as very satisfied (61.9% compared to 34.5%). In subgroup analysis of the patient with low baseline WOMAC score, SWD favored the treatment group as there were improvements in gait speed and global assessment. However, there were opposite results in those with high baseline WOMAC score. Therefore SWD should be recommended in the patients with baseline WOMAC score of less than 5.

Compliance

Concerning the SWD compliance, the treatment group had better compliance than the control group. It might be due to sense of comfortable from heat generated by SWD that made the patients comply with the treatment program. Although the compliance was better in the treatment group, there was no improvement of WOMAC score.

Co-intervention

There were 2 co-interventions in this study i.e. exercise and NSAID. Unfortunately these co-interventions were not comparable between the 2 groups. Regarding exercise, the control exercised more often than the treatment group did, whereas the treatment group took more NSAID than the control group did. It was possible that the control group were more health conscious, so they performed exercise more regularly and took less NSAID.

Safety

SWD has been shown to be safe for chronic arthritis. [48] [23] In this study, adverse events occurred in approximately 6% of the patients. The common events found in the present study were mild pain, mild swelling including feeling of vasodilatation. The typical adverse events of SWD were burn, effusion or edema of skin, subcutaneous and muscle tissue. [49] Therefore, these events during the trial would be considered as adverse events that were not related to the SWD.

The incidence of adverse events occurring during exercise was approximately 34-40%. Those events were mild tightness of muscle, increased crepitus sound and mild pain, which could be found after stretching of muscle and tendon. All these events were not serious and resolved within a few days.

Limitation

This study had some limitation in generalizability, e.g. the results might not be applied to the patients with higher baseline WOMAC score, and it might not be applied to other setting using different type of SWD machine generating different power.

CONCLUSION AND RECOMMENDATION

There was neither clinical nor statistical improvement in WOMAC score after 3-week SWD treatment for knee osteoarthritis patients. There were statistically improvement in gait speed and global assessment in the subgroup of patient with low baseline WOMAC score. Therefore SWD should be recommended in the patient with low baseline WOMAC score.

The result of this study is applicable only with this treatment protocol. However, there are varieties of SWD protocol for knee osteoarthritis patients which should be evaluated for their effectiveness. Further studies should be planned to stratified study population according to duration and severity of disease since they are 2 factors that might affect the outcome of treatment.

REFERENCES

1. Goorman SD, Watanab TK, Miller EH, et al. Function outcome in knee osteoarthritis after treatment with hylan G-F 20: A prospective study. Arch Phys Med Rehabil 2000; 81: 479-83.
2. Lawrence JS, Bremner JM, Bier F. Osteo-arthritis-Prevalence in the population and relationship between symptoms and x-ray changes. Ann Rheum Dis 1986; 25: 1-24.
3. Lawrence RC, Hochberg MC, Kelsey JL, et al. Estimates of the prevalence of selected arthritic and musculoskeletal diseases in the United States. J Rheumatol 1989; 16: 427-41.
4. Puett DW, Griffin MR. Published trials of nonmedicinal and noninvasive therapies for hip and knee osteoarthritis. Ann Intern Med 1994; 121(2):133-40.
5. Davis MA. Epidemiology of osteoarthritis. Clin Geriatr Med 1988; 4: 241-55.
6. Felson DT, Naimark A, Anderson J, et al. The prevalence of knee osteoarthritis in the elderly:The Flamingham osteoarthritis study. Arthritis Rheum 1987; 30: 914-8.
7. Peat G, McCarney R, Croft P. Knee pain and osteoarthritis in older adults. a review of community burden and current use of primary health care. Ann Rheum Dis 2001;60:91-7.
8. Kuptniratsaikul V, Tosayanonda O, Nilganuwong S, et al. The epidemiology of osteoarthritis of the knee in elderly patients living an urban area of Bangkok. J Med Assoc Thai 2002; 85: 154-61.
9. Threlkeld AJ, Currier DP. Osteo-arthritis: Effect on synovial joint tissues. Phys Ther 1988; 68: 364-70.
10. Hochberg MC. Osteo-arthritis: Pathophysiology, clinical features, management. Hosp Pract 1984; 19: 41-53.
11. Dekker J, Tola P, Aufdemkampe G, et al. Negative affect, pain and disability in osteoarthritis patients; the mediating role of muscle weakness. Behav Res Ther 1993; 31: 203-6.
12. Messier SP, Loeser RF, Hoover JL, et al. Osteoarthritis of the knee: effects on gait, strength, and flexibility. Arch Phys Med Rehabil 1992; 73: 29-36.

13. Ettinger WH, Afable RF. Physical disability from knee osteoarthritis: the role of exercise as an intervention. Med Sci Sports Exerc 1994; 26: 1435-40.

14. Semble EL, Loeser RF, Wise CM. Therapeutic exercise for rheumatoid arthritis and osteoarthritis. Semin Arthritis Rheum 1990; 20: 32-40.

15. Rejeski WJ, Shumaker S. Knee osteoarthritis and health-related quality of life. Med Sci Sports Exerc 1994; 26: 1441-5.

16. Zeidler H. Epidemiology and NSAID induced gastropathy. J Rheumatol 1991; 28 (suppl):2-5.

17. Newman NM, Ling RS. Acetabular bone destruction related to non-steroidal anti-inflammatory drugs. Lancet 1985; 2: 11-4.

18. McAlindon T, Dieppe P. The medical management of osteoarthritis of the knee: an inflammatory issue? Br J Rheumatol 1990; 29: 471-3.

19. Dekker J, Boot B, Woude Luc HV, et al. Pain and disability in osteo-arthritis: A review of biobehavioral mechanisms. J Behav Med 1992; 15: 189-214.

20. Munice HI. Summary: Applications of the multi-disciplinary management of osteo-arthritis. Clin Ther 1986; 9: 67-8.

21. Marks R, Cantin D. Symptomatic osteo-arthritis of the knee. Physiotherapy 1997; 83: 306-12.

22. Marks R, Ghassemi M, Duarte R, et al. A review of the literature on shortwave diathermy as applied to osteo-arthritis of the knee. Physiotherapy 1999; 85: 304-16.

23. Vanharanta H. Effect of shortwave diathermy on mobility and radiological stage of the knee in the development of experimental osteo-arthritis. Am J Phys Ther 1982; 61: 59-65.

24. Falconer J, Hayes KW, Chang RW. Effect of ultrasound on mobility in osteoarthritis of the knee. A randonmized clinical trial. Arthritis Care Res 1992; 5: 29-35.

25. Chamberlain MA, Care G, Harfield B. Physiotherapy in osteoarthrosis of the knees. Int Rehab Med 1982; 4: 101-106.

26. Lankhorst GJ, van de Stadt RJ, van de Korst JK, et al. Relationship of isometric knee extension torque and functional variables in osteo-arthrosis of the knee. Scand J Rehabil Med 1982; 14: 7-10.

27. Klaber Moffett JA, Richardson PH, Frost H, et al. A placebo-controlled double-blind trial to evaluate the effectiveness of pulsed shortwave therapy for osteo-arthritic hip and knee pain. Pain 1996; 67: 121-7.

28. Davis MA, Ettinger WH, Neuhaus JM, et al. Knee osteoarthritis and physical functioning: evidence from the NHANES I epidemiologic follow up study. J Rheumatol 1991; 18: 591-8.

29. Doherty M, Jones AC. Osteo-arthritis. Med Interna 1994; 52: 129-35.

30. Marks R. Muscles as a pathogenic factor in osteo-arthritis. Physiother Canada 1993; 45: 251-60.

31. Creamer P, Hochberg MC. Osteoarthritis. Lancet 1997; 350: 503-8.

32.Guidelines of American College of Rheumatology Soceity. Recommendations for the medical management of osteoarthritis of the hip and knee: 2000 update. Arthritis Rheum 2000; 43: 1905-15.

33. Hochberg MC, Altman RD, Brandt KD, et al. Guidelines for the medical management of osteoarthritis. Part II. Osteoarthritis of the knee. American College of Rheumatology. Arthritis Rheum 1995; 38: 1541-6.

34. Goats GC. Continuous shortwave (radio-frequency) diathermy. Br J Sports Med 1989; 23: 213-6.

35. Kitchen S, Partridge C. Review of shortwave diathermy continuous and pulsed patterns. Physiotherapy 1992; 78: 243-52.

36. Wright V. Stiffness: A review of its measurement and physiological importance. Physiotherapy 1973; 59: 107-11.

37. Aaron RK, Ciomber DMK. Therapeutic effects of electromagnetic fields in the stimulation of connective tissue repair. J Cell Biochem 1993; 52: 42-6.

38. Bansal PS, Sobti VK, Roy KS. Histomorphochemical effects of shortwave diathermy on healing of experimental injury in dogs. Indian J Exp Biol 1990; 28: 766-70.

39. Aaron RK, Lennox D, Bunce GE, et al. The conservative treatment of osteonecrosis of the femoral head: A comparison of core decompression and pulsing electromagnetic fields. Clin Orthop 1989; 249. 209-17.

40. Wright V. Treatment of osteo-arthritis of the knees. Ann Rheum Dis 1964; 23: 389-91.

41. Voltonen EJ, Alaranta H. Comparative clinical study of the effect of shortwave and longwave diathermy on osteo-arthritis of the knee and hip. Scand J Rehabil Med 1971; 3: 109-12.

42. Quirk AS, Newman RJ, Newman KJ. An evaluation of interferential therapy, shortwave diathermy and exercise in the treatment of osteo-arthrosis of the knee. Physiotherapy 1985; 71: 55-7.

43. Clark GR, Willis LA, Stenner L, et al. Evaluation of physiotherapy in the treatment of osteo-arthrosis of the knee. Rheumatol Rehabil 1974; 13: 190-7.

44. Jan MH, Lai JS. The effect of physiotherapy on osteoarthritic knees of females. J Formos Med Assoc 1991;90: 1008-13.

45. Altman RD, Asch E, Bloch D, et al. Development of criteria for the classification and reporting of osteoarthritis: classification of osteoarthritis of the knee. Arthritis Rheum 1986; 29: 1039-1049.

46. Bellamy N, Buchanan WW, Goldsmith CH, et al. Validation study of WOMAC: A health status instrument for measuring clinically important patient relevant outcomes to antirheumatic drug therapy with osteoarthritis of the hip and knee. J Rheumatol 1988; 15:1833-1840.

47. Jensen MP, Karoly P. Self-report scales and procedures for assessing pain in adults. 2nd ed. New York: The Guilford Press; 2001.

48. Shields N, Gormley J, O'Hare N. Short-wave diathermy: current clinical and safety practices. Physiother Res Intern 2002; 7:191-202.

49. Lehmann JF. Therapeutic heat. 4th ed. Baltimore: Williams&Wilkins; 1984.

APPENDICES

APPENDIX I

SELECTION OF SUBJECTS

Inclusion criteria

Subjects must fulfill all of the following criteria for entrance into the study.

Criteria	yes	no
1. Primary OA knee	☐	☐
2. Age> 50 yr	☐	☐
3. Agree to participate in the study and sign consent form	☐	☐

Note: A "NO" for any inclusion criteria is sufficient to exclude the subject.

Exclusion criteria

Subjects fulfilling any of the following criteria will be excluded from the study.

Criteria	yes	no
1. Secondary causes of knee OA	☐	☐
2. History of joint infection	☐	☐
3. Severe joint instability	☐	☐
4. Previous history of Shortwave diathermy	☐	☐
5. History of intra-articular injection within 3 months	☐	☐
6. History of metallic implant around knee joint	☐	☐
7. Suspected of malignancy around knee joint	☐	☐
8. History of peripheral vascular disease	☐	☐
9. Had significant cardiovascular disease	☐	☐
10. Could not ambulate by walking	☐	☐
11. On cardiac pacemaker	☐	☐
12. Unable to understand how to score the symptoms	☐	☐

Note: A "YES" for any exclusion criteria is sufficient to exclude the subject.

APPENDIX II

THE WESTERN ONTARIO AND MCMASTER UNIVERSITIES OSTEOARTHRITIS INDEX (WOMAC)

WOMAC is a multidimensional, self-administered health status instrument for patients with OA of the hip and knee. The pain (5 items), stiffness (2 items), and functional function (17 items) subscales fulfill conventional criteria for face, content and construct validity, reliability, responsiveness and relative efficiency.[46] The response is on 100 mm horizontal visual analogue scales (VAS). Aggregate scores for each dimension will be determined by summing the component item scores for each dimension. The WOMAC final battery will be determined by summing the aggregate scores for the pain, stiffness and physical function dimensions. The WOMAC is a disease-specific questionnaire developed specifically for evaluative research in OA clinical trials.

Original English version of WOMAC

Pain

1. Walking
2. Stair climbing
3. Nocturnal
4. Rest
5. Weight bearing

Stiffness

1. Morning stiffness
2. Stiffness occurring later in the day

Physical Function

1. Descending stairs
2. Ascending stairs
3. Rising from sitting
4. Standing
5. Bending to floor
6. Walking on flat
7. Getting in / out car
8. Going shopping

9. Putting on socks*
10. Rising from bed
11. Taking off socks*
12. Lying in bed
13. Getting in/ out bath*
14. Sitting
15. Getting on / off toilet
16. Heavy domestic duties
17. Light domestic duties

* Item 9 and 11 were modified to be putting on pants and taking off pants because lots of Thai people do not use socks in daily living especially elderly people. Putting on and taking off pants can represent knee function as well as putting on and taking off socks for people in Western country.

*Item 13 was modified to be taking a bath by oneself because Thai usually take a shower or a bath in a bathroom, not in a bathtub.

Development of Thai WOMAC

The original English version of the WOMAC was translated into Thai language by physiatrist who has been working in this field for more than 10 years. The translated version will be validated by back translation into English by a professional English translator (Trakoonsin W.) without giving any information regarding to this instrument. The back translation was shown below.

Joint pain

P1. Pain when walking
P2. Pain when stepping up- and downstairs
P3. Pain during the night
P4. Pain when resting
P5. Pain when putting body weight on knees

Stiff joint

S1. Stiff joint in the morning when waking up
S2. Stiff joint during the day

Joint working capacity

F1. Walking downstairs

F2. Walking upstairs

F3. Standing up from sitting posture

F4. Standing

F5. Bending down : hand touching floor

F6. Walking on flat ground

F7. Getting in and out of the car

F8. Going shopping

F9. Putting on pants

F10. Rising from bed

F11. Taking off pants

F12. Lying down on bed

F13. Taking a bath by oneself

F14. Sitting

F15. Using toilet

F16. Doing heavy house-chores

F17. Doing light house-chores

Assessment of validity

1. Face validity

   One physiatrist, one orthopedist, one geriatrician and one physical therapist from Siriraj Hospital will be asked to be content experts. All of these health care professionals work in their field for more than 10 years.

2. Content validity

   All experts will be asked to consider each item of Thai version of WOMAC and determine its validity; +1 for relatively valid item, -1 for relatively invalid item, 0 for not sure.

3. Criterion validity

   Because there is no real gold standard for this set of questionnaire, the Thai version of WOMAC can not be assessed for criterion validity.

4. Construct validity

   This is a translated version from the original WOMAC which has been already assessed in construct validity by operational defined and hypothetical construct.

All experts agreed that all items in Thai version of WOMAC had face validity. Regarding content validity, the score of each expert's opinion were presented in table below. The intra-class correlation coefficient of each item varied from 0.25-1.00.

Item	Expert 1	Expert 2	Expert 3	Expert 4	IC=$\frac{\Sigma R}{n}$
P1	1	0	1	1	0.75
P2	1	1	1	1	1.00
P3	1	1	0	0	0.50
P4	1	1	0	1	0.75
P5	1	1	1	1	1.00
S1	1	1	1	1	1.00
S2	1	1	1	1	1.00
F1	1	1	1	1	1.00
F2	1	1	1	1	1.00
F3	1	1	1	1	1.00
F4	1	1	1	1	1.00
F5	0	1	0	-1	0.00
F6	1	1	1	1	1.00
F7	1	1	1	1	1.00
F8	1	1	1	0	0.75
F9	1	0	1	1	0.75
F10	1	1	1	1	1.00
F11	0	0	1	0	0.25
F12	0	1	0	-1	0.00
F13	1	-1	1	0	0.25
F14	1	1	1	0	0.75
F15	1	-1	1	0	0.25
F16	0	1	1	0	0.50
F17	0	1	1	0	0.50

Assessment of reliability

After some modifications were carried out according to the expert's opinion and results of pilot test, the Thai version of WOMAC was tested for internal consistency in 35 eligible subjects. The average age of this group is 65.1 years old (SD=8.8). All of them had diagnosis of knee OA. The range of WOMAC score is 7.0-84.6 points with mean and SD of 39.1, 18.5 respectively.

The Internal consistency is assessed by calculating the Cronbach's coefficient alpha for the entire scale and for each sub-scale using SPSS version 11.0. The mean of inter-item correlation of 5 items in pain subscale is 0.44 (SD=0.04), whereas that for stiffness subscale is 0.75 (SD=0.00), and for physical function subscale is 0.49 (SD=0.04) respectively.

items	Corrected item-total correlation
P1	0.5180
P2	0.5500
P3	0.6332
P4	0.5930
P5	0.3396
S1	0.5333
S2	0.6919
F1	0.4911
F2	0.4199
F3	0.6266
F4	0.6694
F5	0.3744
F6	0.7525
F7	0.7105
F8	0.7285
F9	0.7862
F10	0.7319
F11	0.8405
F12	0.8181
F13	0.8435
F14	0.6596
F15	0.5611
F16	0.6073
F17	0.7237

The alpha coefficient for pain sub-scale is 0.7781, for stiffness sub-scale is 0.8542 and for function sub-scale is 0.9352 respectively. The Cronbach's alpha of all 24 items is 0.9424.

APPENDIX III

DATA COLLECTION FORM

แบบประเมินความรุนแรงของโรคข้อเข่าเสื่อม

1. ท่านมีอาการปวดเข่า ในขณะที่กำลังนอนตอนกลางคืนบ้างหรือไม่

- ☐ มีอาการน้อยมาก หรือเรียกได้ว่าไม่มี
- ☐ มีอาการเฉพาะเวลาขยับตัว หรือเมื่ออยู่ในท่าบางท่าเท่านั้น
- ☐ อยู่เฉย ๆ ก็มีอาการปวดเข่า แม้ไม่ได้ขยับตัว

2. ท่านมีอาการข้อฝืดตอนเช้า ซึ่งดีขึ้นเมื่อได้ลุกเดินสักครู่หนึ่ง

- ☐ มีอาการฝืดประมาณ 1 นาที หรือน้อยกว่า
- ☐ มีอาการเกิน 1 นาที แต่ไม่เกิน 15 นาที
- ☐ มีอาการนานกว่า 15 นาที

3. เมื่อต้องยืนนานประมาณ 30 นาที

- ☐ ไม่ปวดเข่าหรือมีอาการปวดเข่าน้อยมาก
- ☐ มีอาการปวดเข่า

4. ในขณะที่กำลังเดิน ท่านมีอาการปวดเข่าหรือไม่

- ☐ ไม่มีอาการปวดเข่า
- ☐ มีอาการปวดเข่า ถ้าต้องเดินไปสักระยะหนึ่ง
- ☐ มีอาการปวดเข่า หลังจากเริ่มเดินได้เดี๋ยวเดียว แต่ถ้าเดินต่อไป อาการปวดไม่มากขึ้น
- ☐ มีอาการปวดเข่า หลังจากเริ่มเดินได้เดี๋ยวเดียว ต่อจากนั้น ยิ่งเดินก็ยิ่งปวด

5. ในขณะที่ลุกขึ้นจากเก้าอี้

- ☐ ไม่มีอาการปวดเข่าหรือมีอาการปวดน้อยมาก
- ☐ มีอาการปวดเข่า

หัวข้อที่สอง ถามเกี่ยวกับระยะทางที่ท่านเดินได้ไกลที่สุด (แม้จะมีอาการปวดก็ตาม)

- ☐ ไม่จำกัด
- ☐ จำกัด แต่เดินได้ไกลเกิน 1 กิโลเมตร
- ☐ เดินได้ประมาณ 1 กิโลเมตร (ใช้เวลาประมาณ 15 นาที)
- ☐ เดินได้เกินครึ่งกิโลเมตร แต่ไม่ถึง 1 กิโลเมตร (ใช้เวลา 8-15 นาที)
- ☐ เดินได้ไม่ถึงครึ่งกิโลเมตร แต่เกิน 300 เมตร หรือเกิน 3 เสาไฟฟ้า
- ☐ เดินได้ประมาณ 100-300 เมตร หรือประมาณ 1-3 เสาไฟฟ้า
- ☐ เดินได้ระยะทางน้อยกว่า 100 เมตร หรือน้อยกว่า 1 เสาไฟฟ้า

ท่านต้องใช้อุปกรณ์เครื่องช่วยเดินใดๆหรือไม่

- ☐ เดินต้องใช้ไม้เท้า 1 ข้าง
- ☐ เดินต้องใช้ไม้เท้า 2 ข้าง หรือไม้ค้ำยัน

หัวข้อที่สาม ถามเกี่ยวกับ ความสามารถของการใช้เข่าในกิจวัตรประจำวัน

1. ท่านสามารถเดินขึ้นบันได 1 ชั้น (10-14 ขั้น)ได้หรือไม่
   - ☐ ไม่มีความลำบากใดๆ
   - ☐ มีความลำบากเล็กน้อย
   - ☐ มีความลำบากปานกลาง
   - ☐ มีความลำบากมาก
   - ☐ ไม่สามารถทำได้
2. ท่านสามารถเดินลงบันได 1 ชั้น (10-14 ขั้น)ได้หรือไม่
   - ☐ ไม่มีความลำบากใดๆ
   - ☐ มีความลำบากเล็กน้อย
   - ☐ มีความลำบากปานกลาง
   - ☐ มีความลำบากมาก
   - ☐ ไม่สามารถทำได้
3. ท่านสามารถนั่งยอง ๆ ได้หรือไม่
   - ☐ ไม่มีความลำบากใดๆ
   - ☐ มีความลำบากเล็กน้อย
   - ☐ มีความลำบากปานกลาง
   - ☐ มีความลำบากมาก
   - ☐ ไม่สามารถทำได้
4. ท่านสามารถเดินบนพื้นขรุขระ ได้หรือไม่
   - ☐ ไม่มีความลำบากใดๆ
   - ☐ มีความลำบากเล็กน้อย
   - ☐ มีความลำบากปานกลาง
   - ☐ มีความลำบากมาก
   - ☐ ไม่สามารถทำได้

แบบสอบถามข้อมูลผู้ป่วยข้อเข่าเสื่อมในโครงการประสิทธิภาพของการอบไฟฟ้า

ส่วนที่หนึ่ง : ข้อมูลทั่วไป

1. ชื่อ.....HN……Tel…….....No…….....
2. อายุ .....ปี
3. เพศ ☐ ชาย ☐ หญิง
4. น้ำหนักตัว ..... กิโลกรัม
5. ความสูง ..... เซนติเมตร
6. ระดับการศึกษา ☐ ประถม
   ☐ มัธยมศึกษา
   ☐ อุดมศึกษาหรือสูงกว่า
   ☐ อื่นๆ โปรดระบุ .....
7. ระยะเวลาที่ปวดเข่า .....เดือน / ปี
8. ปวดเข่า ☐ ข้างขวา ☐ ข้างซ้าย ☐ สองข้าง
9. ท่านต้องใช้อุปกรณ์ช่วยเดินหรือไม่
   ☐ ไม่ ☐ ใช้ไม้เท้า ☐ ใช้คอกช่วยเดิน ☐ อื่นๆ โปรดระบุ .....
10. ท่านต้องใช้สนับเข่าร่วมด้วยหรือไม่
    ☐ ไม่ ☐ ใช้นานๆ ครั้ง ☐ ใช้ค่อนข้างบ่อย ☐ ใช้ทุกครั้งที่เดิน
11. ปัจจุบันการใช้ชีวิตประจำวันของท่านส่วนใหญ่คือ
    ☐นั่ง ๆ นอน ๆ ☐ ทำงานนั่งโต๊ะ ☐ ยืนและเดินทั้งวัน
    ☐ทำไร่ ทำสวน ☐ ทำงานบ้าน ☐ อื่นๆ ระบุ……

แบบติดตามผลในโครงการประสิทธิภาพของการอบไฟฟ้าในผู้ป่วยข้อเข่าเสื่อม

ชื่อ.....หมายเลข.....ครั้งที่.....วันที่.....

ส่วนที่ 2 : **การประเมินอาการของโรคข้อเข่าเสื่อม**

โปรดกรุณากาเครื่องหมาย x บนเส้นให้ตรงกับอาการของท่านมากที่สุด
ระดับความปวด (0 – 10)โดย 0 หมายถึงไม่ปวดเลย และ 10 หมายถึงปวดมากจนทนไม่ได้

1. ปวดขณะเดิน

0 1 2 3 4 5 6 7 8 9 10

ไม่ปวดเลย ปวดมากจนทนไม่ได้

2. ปวดขณะขึ้นลงบันได

0 1 2 3 4 5 6 7 8 9 10

ไม่ปวดเลย ปวดมากจนทนไม่ได้

3. ปวดข้อตอนกลางคืน

0 1 2 3 4 5 6 7 8 9 10

ไม่ปวดเลย ปวดมากจนทนไม่ได้

4. ปวดข้อขณะพัก

0 1 2 3 4 5 6 7 8 9 10

ไม่ปวดเลย ปวดมากจนทนไม่ได้

5. ปวดข้อขณะยืนลงน้ำหนัก

0 1 2 3 4 5 6 7 8 9 10

ไม่ปวดเลย ปวดมากจนทนไม่ได้

ระดับอาการข้อฝืด,ข้อยึด (0–10) โดย 0 หมายถึงไม่มีอาการฝืดเลย และ 10 หมายถึง มีอาการฝืดมากที่สุด

1. ข้อฝืดช่วงเช้า (ขณะตื่นนอน)

0 1 2 3 4 5 6 7 8 9 10

ไม่ฝืดเลย ฝืดมากที่สุด

2. ข้อฝืดในช่วงระหว่างวัน

0 1 2 3 4 5 6 7 8 9 10

ไม่ฝืดเลย ฝืดมากที่สุด

ระดับความสามารถในการใช้งานข้อ (0 – 10)

โดย 0 หมายถึงไม่มีอาการฝืดเลย และ 10 หมายถึง ไม่สามารถทำกิจกรรมนั้นๆได้

1. การลงบันได

0 1 2 3 4 5 6 7 8 9 10

ทำได้ดีมาก ไม่สามารถทำได้

2. การขึ้นบันได

0 1 2 3 4 5 6 7 8 9 10

ทำได้ดีมาก ไม่สามารถทำได้

3. การลุกยืนจากท่านั่ง

0 1 2 3 4 5 6 7 8 9 10

ทำได้ดีมาก ไม่สามารถทำได้

4. การยืน

0 1 2 3 4 5 6 7 8 9 10

ทำได้ดีมาก ไม่สามารถทำได้

5. การเดินบนพื้นราบ

0 1 2 3 4 5 6 7 8 9 10

ทำได้ดีมาก ไม่สามารถทำได้

6. การขึ้นลงรถยนต์

0 1 2 3 4 5 6 7 8 9 10

ทำได้ดีมาก ไม่สามารถทำได้

7. การไปซื้อของ

0 1 2 3 4 5 6 7 8 9 10

ทำได้ดีมาก ไม่สามารถทำได้

8. การใส่กางเกง

0 1 2 3 4 5 6 7 8 9 10

ทำได้ดีมาก ไม่สามารถทำได้

9. การลุกจากเตียง

0 1 2 3 4 5 6 7 8 9 10

ทำได้ดีมาก ไม่สามารถทำได้

10. การถอดกางเกง

0 1 2 3 4 5 6 7 8 9 10

ทำได้ดีมาก ไม่สามารถทำได้

11. การอาบน้ำเอง

0 1 2 3 4 5 6 7 8 9 10

ทำได้ดีมาก ไม่สามารถทำได้

12. การนั่ง

0 1 2 3 4 5 6 7 8 9 10

ทำได้ดีมาก ไม่สามารถทำได้

13. การนั่งส้วม

0 1 2 3 4 5 6 7 8 9 10

ทำได้ดีมาก ไม่สามารถทำได้

14. การทำงานบ้านหนักๆ

0 1 2 3 4 5 6 7 8 9 10

ทำได้ดีมาก ไม่สามารถทำได้

15. การทำงานบ้านเบาๆ

0 1 2 3 4 5 6 7 8 9 10

ทำได้ดีมาก ไม่สามารถทำได้

ส่วนที่ 3 : **เวลาที่ใช้ในการเดิน**

เวลาที่ใช้ในการเดินแนวราบ 100 เมตร .....วินาที

เวลาที่ใช้ในการเดินขึ้นและลงบันได 1 ชั้น .....วินาที

ส่วนที่ 4 : **สอบถามอาการ**

1. ท่านมีอาการผิดปกติหลังจากได้รับการประคบไฟฟ้าดังต่อไปนี้หรือไม่

☐ รู้สึกบวมๆ ☐ แผลไหม้/ผิวหนังพอง

☐ ข้อบวม ☐ ข้ออักเสบ

☐ ปวดข้อนานกว่า 2 ชม. ☐ เดินไม่ได้ในวันรุ่งขึ้น ☐ อื่น.....

2. ท่านมีอาการผิดปกติหลังจากการบริหารข้อเข่าหรือไม่

☐ ข้อบวม ☐ ข้ออักเสบ

☐ ปวดข้อนานกว่า 2 ชม. ☐ เดินไม่ได้ในวันรุ่งขึ้น ☐ อื่นๆ.....

3. ท่านสามารถบริหารข้อเข่าได้มากน้อยเพียงใด

☐ ทำได้น้อยกว่า 50 ครั้ง / วัน ☐ ทำได้มากกว่าหรือเท่ากับ 50 ครั้ง / วัน

☐ ทำได้น้อยกว่า 5 วัน / สัปดาห์ ☐ ทำได้มากกว่าหรือเท่ากับ 5 วัน / สัปดาห์

4. โดยสรุปท่านคิดว่าอาการที่ข้อเข่าของท่านเป็นอย่างไร

☐ หายสนิทแล้ว ☐ ดีขึ้นมาก ☐ ดีพอประมาณ

☐ ดีขึ้นเล็กน้อย ☐ อาการคงที่ ☐ อาการแย่ลง

5. ท่านพอใจกับวิธีการรักษานี้หรือไม่

☐ พอใจมาก ☐ พอใจปานกลาง ☐ พอใจเล็กน้อย

☐ เฉยๆ ☐ ไม่พอใจ

6. จำนวนยาที่ใช้ไป.....เม็ด (Diclofenac/CoxII), จำนวนครั้งที่อบไฟฟ้า.....ครั้ง

APPENDIX IV

CASE RECORD FORM

Title: The Effectiveness of Shortwave Diathermy in Osteoarthritic Knee:

A Randomized Controlled Trial

Principal investigator: Vilai Kuptniratsaikul

Record ID ☐☐☐

Protocol……

Date……../……/……...

HN……

Telephone number…….

Baseline data

1. Age.....years
2. Sex ☐ Male ☐ Female
3. Weight.....kg
4. Height……cm
5. BMI…….kg/m^2
6. Education level……..
7. Duration of disease…….years
8. Affected side ☐ Right ☐ Left ☐ Bilateral
9. Using gait aids ☐ yes ☐ no
10. Using knee support ☐ yes ☐ no
11. Activity level……

Outcome data

Outcome	Baseline	After three weeks	Change from baseline
12. WOMAC pain			
13. WOMAC stiffness			
14. WOMAC function			
15. Total WOMAC			
16. Gait speed			

17. Number of NSAIDs use……per 3 weeks

18. Number of Acetaminophen use……per 3 weeks

19. Patients received SWD from other hospital ☐ yes ☐ no

20. Frequency of SWD treatment……

21. Compliance of SWD treatment ☐ good ☐ fair ☐ poor

22. Frequency of Quadriceps exercise……per day, …… days/week

23. Compliance of Quadriceps exercise ☐ good ☐ fair ☐ poor

Compliance of SWD treatment	Compliance of Quadriceps exercise
1 = good : SWD 7-9 treatments	1 = good : exercise ≥ 50/day, ≥ 5 days/week
2 = fair : SWD 4-6 treatments	2 = fair : exercise ≥ 50/day, < 5 days/week or exercise < 50/day, ≥ 5 days/week
3 = poor : SWD 1-3 treatments	3 = poor : exercise < 50/day, < 5 days/week

24. Patients' global assessment score……

25. Patients' satisfaction score……..

Global assessment score	Satisfaction score
1. complete recovery	1. very satisfied
2. much improve	2. moderately satisfied
3. moderately improve	3. little satisfied
4. slightly improve	4. indifferent
5. no different	5. unsatisfied
6. getting worse	

26. Adverse effects:	Yes	No
a. Swelling	☐	☐
b. Burn	☐	☐
c. Scald	☐	☐
d. Joint effusion	☐	☐
e. Joint inflammation	☐	☐
f. Persistent pain > 2 hr after treatment	☐	☐
g. More disability in the next morning	☐	☐
h. Others……..	☐	☐

APPENDIX V

หนังสือแสดงเจตนายินยอม

วันที่ …… เดือน……..พ.ศ……

ข้าพเจ้า …… อายุ …….. ปี อาศัยอยู่บ้านเลขที่ ……..
ถนน……ตำบล……อำเภอ…….
จังหวัด…….....โทรศัพท์……..…… โทรสาร…….
ขอแสดงเจตนายินยอมเข้าร่วมโครงการวิจัย " เรื่องประสิทธิภาพของความร้อนลึกในการรักษาผู้ป่วยข้อเข่าเสื่อม" โดยข้าพเจ้าได้รับทราบเกี่ยวกับรายละเอียดของโครงการ ดังต่อไปนี้

วัตถุประสงค์ของการวิจัย เพื่อศึกษาผลของการใช้ความร้อนลึกในการลดอาการปวด และเพิ่มความสามารถในการใช้งานข้อเข่าในผู้ป่วยข้อเข่าเสื่อม

ประโยชน์ที่คาดว่าจะได้รับจากการวิจัย ผู้เข้าร่วมโครงการจะทราบถึง

1. วิธีการดูแลข้อเข่าของตนเองอย่างถูกต้อง
2. วิธีบริหารข้อเข่าอย่างถูกต้อง
3. อาการปวดลดลง
4. เพิ่มการใช้งานข้อเข่า เช่น การเดิน, ขึ้นลงบันได และการเคลื่อนย้ายตนเอง
5. ผู้เข้าร่วมโครงการจะได้รับค่าเดินทางครั้งละ 200 บาท ต่อการติดตาม 1 ครั้ง

ความเสี่ยงหรือผลข้างเคียงที่อาจจะเกิดขึ้น ได้แก่ แผลไหม้ ผิวหนังพอง ข้อบวม แดง หรืออักเสบ

แนวทางป้องกัน/แก้ไข ความเสี่ยงหรือการแก้ไขผลข้างเคียงที่อาจจะเกิดขึ้น

ผู้วิจัยได้จัดเตรียมแผ่นเย็นประคบ พร้อมยาทาในกรณีเกิดแผลไหม้ ผิวหนังพอง รวมทั้งยาแก้ปวด–แก้อักเสบเพื่อลดอาการปวดและข้ออักเสบ

รายละเอียดและขั้นตอนที่ผู้ร่วมโครงการวิจัยจะได้รับการปฏิบัติ

1. ซักประวัติข้อมูลพื้นฐานเบื้องต้น
2. สัมภาษณ์ระดับอาการปวดและความรุนแรงโรค
3. อธิบายวิธีการดูแลข้อเข่าของตนเองและวิธีบริหารข้อเข่าอย่างถูกต้อง
4. จับเวลาที่ใช้ในการเดิน 100 เมตร
5. จับเวลาที่ใช้ในการขึ้นลงบันได 1 ชั้น (10-12 ขั้น)

6. อบข้อเข่าด้วยความร้อนลึก (อบไฟฟ้า) เป็นเวลานานประมาณ 20-30 นาที ต่อครั้ง สัปดาห์ละ 3 ครั้ง ติดต่อกันนาน 3 สัปดาห์
7. บันทึกจำนวนครั้งที่บริหารเข่า, จำนวนยาแก้ปวดและยาแก้อักเสบที่ใช้ในแต่ละวัน
8. มาพบแพทย์เพื่อประเมินอาการในสัปดาห์ที่ 3

การติดต่อกับผู้ป่วยในกรณีที่มีปัญหา (ตลอด 24 ชั่วโมง) สามารถติดต่อแพทย์หญิงวิไล คุปต์นิรัติศัยกุล ที่หมายเลข 02-419-7508 (ที่ทำงาน) หรือ 02-612-1349 (บ้าน)

หากข้าพเจ้าได้รับผลข้างเคียงหรือฤทธิ์ไม่พึงประสงค์หรือภยันตรายจากการวิจัย ข้าพเจ้าจะได้รับการรักษาตามมาตรฐานของโรงพยาบาลศิริราชโดยไม่คิดมูลค่าใดๆ และจะได้รับค่าชดเชยรายละ 1000 บาทเป็นการตอบแทน

หากผู้วิจัยมีข้อมูลเพิ่มเติมทั้งด้านประโยชน์และโทษที่เกี่ยวข้องกับการวิจัยนี้ ผู้วิจัยจะแจ้งให้ข้าพเจ้าทราบอย่างรวดเร็วโดยไม่ปิดบัง

ข้าพเจ้ามีสิทธิ์ที่จะของดการเข้าร่วมโครงการวิจัยโดยไม่ต้องแจ้งให้ทราบล่วงหน้า โดยการงดการเข้าร่วมการวิจัยนี้จะไม่มีผลกระทบต่อการได้รับบริการหรือการรักษาที่ข้าพเจ้าจะได้รับแต่ประการใด

ข้าพเจ้าได้รับทราบข้อมูลของโครงการข้างต้น ตลอดจนข้อดี ข้อเสีย ที่จะได้รับจากการเข้าร่วมโครงการในครั้งนี้และข้าพเจ้ายินยอมที่จะเข้าร่วมในโครงการดังกล่าว โดยขอให้ผู้วิจัยงดการเปิดเผยชื่อ ประวัติ ตลอดจนข้อมูลที่เกี่ยวข้องกับข้าพเจ้า แก่ผู้อื่นได้รับทราบ

ลงชื่อ ..... ผู้ให้ความยินยอม/ผู้แทนโดยชอบธรรม

( ) (ระบุความเกี่ยวข้อง)

วันที่.....

ลงชื่อ ..... ผู้วิจัย

(แพทย์หญิงวิไล คุปต์นิรัติศัยกุล)

ลงชื่อ ..... พยาน

( )

VITAE

Mrs. Vilai Kuptniratsaikul was born on the 12th of August, 1959 in Bangkok, Thailand. In 1985, she graduated with M.D. degree from the faculty of Medicine Siriraj Hospital, Mahidol University, Thailand. In 1991, she received Thai Board in Rehabilitation Medicine from Medical Council of Thailand. After studying abroad for 1 year in USA, she obtained a certificate of fellowship in Geriatric Rehabilitation from Case Western Reserve University, Ohio in 1993. Her present position is Associate Professor in the Department of Physical Medicine and Rehabilitation, Faculty of Medicine, Siriraj Hospital, Mahidol University, Thailand.