EFFECTIVENESS OF ULTRASOUND COMBINE TRANSCUTANEOUS ELECTRICAL NERVE STIMULATION (TENS) IN TREATMENT OF UPPER TRAPEZIUS MYOFASCIAL PAIN: A RANDOMIZED CONTROLLED TRIAL

Mrs. Bootsakorn Loharjun

A Thesis Submitted in Partial Fulfillment of the Requirements

for the Degree of Master of Science Program in Health Development

Faculty of Medicine

Chulalongkorn University

Academic Year 2012

ประสิทธิผลของการใช้เครื่องอัลตร้าซาวน์ผสมกระแสไฟฟ้าบำบัดเพื่อรักษากลุ่มอาการปวดมัยโอฟาสเชียลในกล้ามเนื้อแทรบปีเซียสส่วนบน: การวิจัยเชิงทดลองแบบสุ่มและมีกลุ่มควบคุม

นางบุษกร โลหารชุน

วิทยานิพนธ์นี้เป็นส่วนหนึ่งของการศึกษาตามหลักสูตรปริญญาวิทยาศาสตรมหาบัณฑิต

สาขาวิชาการพัฒนาสุขภาพ

คณะแพทยศาสตร์ จุฬาลงกรณ์มหาวิทยาลัย

ปีการศึกษา 2555

Thesis Title	EFFECTIVENESS OF ULTRASOUND COMBINE TRANSCUTANEOUS ELECTRICAL NERVE STIMULATION (TENS) IN TREATMENT OF UPPER TRAPEZIUS MYOFASCIAL PAIN: A RANDOMIZED CONTROLLED TRIAL
By	Mrs.Bootsakorn Loharjun
Field of study	Health Development
Thesis Advisor	Associate Professor Jariya Boonhong, M.D.

Accepted by the Faculty of Medicine Chulalongkorn University in Partial Fulfillment of the Requirements of the Master's Degree

……..Dean of the Faculty of Medicine

(Associate Professor Sophon Napathorn, M.D.)

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……..Chairperson

(Professor Thewarug Werawatganon, M.D.)

……. Thesis Advisor

(Associate Professor Jariya Boonhong, M.D.)

..... Examiner

(Saowalak Hunnangkul, Ph.D.)

..... External Examiner

(Daranee Suvaparn, M.D.)

บุษกร โลหารชุน: ประสิทธิผลของการใช้เครื่องอัลตร้าซาวน์ผสมกระแสไฟฟ้าบำบัด เพื่อรักษากลุ่มอาการปวดมัยโอฟาสเชียล ในกล้ามเนื้อแทรบปีเซียสส่วนบน: การวิจัยเชิงทดลองแบบสุ่มและมีกลุ่มควบคุม. (EFFECTIVE NESS OF ULTRASOUND COMBINE TRANSCUTANEOUS ELECTRICAL NERVE STIMULATION (TENS) IN TREATMENT OF UPPER TRAPEZIUS MYOFASCIAL PAIN: A RANDOMIZED CONTROLLED TRIAL) อ.ที่ปรึกษาวิทยานิพนธ์หลัก : รศ.พญ. จริยา บุญหงษ์, 43 หน้า:

กลุ่มอาการปวดมัยโอฟาสเชียลพบเป็นสาเหตุของการปวดกล้ามเนื้อที่พบบ่อย การรักษาสามารถทำได้หลากหลายวิธี ปัจจุบันมีการใช้เครื่องมือชนิดใหม่ที่สามารถให้การรักษาผู้ป่วยกลุ่มอาการดังกล่าวด้วยคลื่นเหนือเสียงหรือเครื่องอัลตร้าซาวน์และกระแสไฟฟ้าบำบัดในเวลาเดียวกัน (US-TENS) การศึกษานี้มีเป้าหมายเพื่อประเมินประสิทธิผลของการใช้เครื่องอัลตร้าซาวน์ผสมกระแสไฟฟ้าบำบัด เพื่อรักษากลุ่มอาการปวดมัยโอฟาสเชียล ในกล้ามเนื้อแทรบปีเซียสส่วนบนโดยใช้การวิจัยเชิงทดลองแบบสุ่มและมีกลุ่มควบคุม ดำเนินการที่ศูนย์สิรินธรเพื่อการฟื้นฟูสมรรถภาพทางการแพทย์แห่งชาติ ผู้เข้าร่วมวิจัย จำนวน 40 รายซึ่งมีอาการปวดบ่า จากกลุ่มอาการปวดกล้ามเนื้อแทรบปีเซียสส่วนบนตรงตามเกณฑ์คัดเข้า ได้รับการสุ่มเป็น 2 กลุ่ม กลุ่มศึกษาเป็นกลุ่มที่ได้รับการรักษาด้วยเครื่องอัลตร้าซาวน์ผสมกระแสไฟฟ้าบำบัด กลุ่มควบคุมใช้เครื่องอัลตร้าซาวน์ผสมภาวะกระแสหลอก (ปิดกระแสไฟฟ้า) ผู้เข้าร่วมวิจัยได้รับการรักษาด้วยเครื่องมือตามกลุ่ม จนครบ 10 ครั้ง การศึกษานี้ใช้การตรวจประเมินค่าแรงกด คะแนนความปวด การนับจำนวนเม็ดยาบรรเทาปวดที่ใช้และการรักษาร่วมอื่นๆในช่วงที่เข้าร่วมวิจัยเป็นค่าพิจารณาผลการวิจัย โดยประเมินค่าแรงกดและคะแนนความปวดก่อนเริ่มรักษาและหลังสิ้นสุดการรักษาและนำมาคำนวณหาค่าการเปลี่ยนแปลง

ผลการวิจัยพบว่ากลุ่มทดลองเหลือผู้เข้าร่วมวิจัย 19 ราย พบมีค่าแรงกดเพิ่มขึ้น ร้อยละ 9.6 คะแนนความปวดขณะพักลดลง ร้อยละ 57 คะแนนความปวดขณะทำกิจกรรมลดลง ร้อยละ 56.2 คล้ายคลึงกับผลของกลุ่มควบคุมที่ผู้เข้าร่วมวิจัยทั้ง 20 คน มีค่าแรงกดเพิ่มขึ้น ร้อยละ 17.9 คะแนนความปวดขณะพักลดลง ร้อยละ 64.2 คะแนนความปวดขณะทำกิจกรรมลดลง ร้อยละ 50.7 การศึกษานี้ไม่พบความแตกต่างของผลการรักษาด้วยเครื่องมือทั้งสองชนิด และยืนยันว่าทั้งเครื่องอัลตร้าซาวน์ผสมกระแสไฟฟ้าบำบัดและเครื่องอัลตร้าซาวน์มีประสิทธิผลในการรักษากลุ่มอาการปวดมัยโอฟาสเชียลในระยะเฉียบพลันและกึ่งเฉียบพลัน

สาขาวิชา การพัฒนาสุขภาพ ลายมือชื่อนิสิต .....

ปีการศึกษา 2555 ลายมือชื่ออ.ที่ปรึกษาวิทยานิพนธ์หลัก……..

##547 49130 30: MAJOR HEALTH DEVELOPMENT

KEYWORDS: MYOFASCIAL PAIN SYNDROME/ULTRASOUND/TENS/ COMBINED THERAPY/RANDOMIZED CONTROL TRIAL

BOOTSAKORN LOHARJUN: EFFECTIVENESS OF ULTRASOUND COMBINE TRANSCUTANEOUS ELECTRICAL NERVE STIMULATION (TENS) IN TREATMENT OF UPPER TRAPEZIUS MYOFASCIAL PAIN: A RANDOMIZED CONTROLLED TRIAL. ADVISOR: ASSOC. PROF.JARIYA BOONHONG, M.D., 43 pp.

Myofascial pain syndrome (MPS) is one of the most common causes of musculoskeletal pain. Among various therapeutic approaches, the simultaneously combined treatment using ultrasound and transcutaneous electrical nerve stimulation (or US-TENS) may provide a novel curative strategy for MPS victims. We assessed the simultaneously combined treatment using ultrasound and transcutaneous electrical nerve stimulation (or US-TENS) in comparison with solely therapeutic ultrasound (US) for treatment of MPS in upper trapezius muscle. This study was a randomized single-blind placebo control trial, conducting at Sirindhorn National Medical Rehabilitaion Centre (SNMRC).

The MPS patients who met the inclusion criteria of the study were randomized into two groups. Participants had received ten treatment sessions of US-TENS (intervention group) or US with sham TENS (control group) for two weeks. They were assessed for pressure pain threshold (PPT). Visual analogue scale at rest (VAS-R) and that during activity (VAS-A) on the first day and the day after ten treatment sessions were also evaluated by the blind assessor. Among 19 participants who received US-TENS showed increase of PPT by 9.6%, reduction of VAS-R and VAS-A by 57.0% and 56.2%, respectively. In control group, 20 participants had the elevation of PPT by 17.9%, decrease of VAS-R and VAS-A by 64.2% and 50.7%, respectively. However, the therapeutic tendencies between US-TENS and US were comparable by which there were no differences in average change of PPT and both VAS values ($P > 0.05$) between these two groups. Either US-TENS or therapeutic US was effective when being used as physiotherapy for acute and sub-acute MPS. However, there was no significant difference found between these two types of treatment.

Field of study Health Development Student's signature…….

Academic year 2012 Advisor's signature…….

ACKNOWLEDGEMENTS

The author expressed gratitude to everyone who had made this thesis successful.

The author would like to acknowledge the following individuals; Associate Professor Jariya Boonhong as the advisor, Professor Thewarug Werawatganon, Professor Pichet Sampatanukul and Professor John J. Kavanagh for their expert and useful guidance.

The author also would like to acknowledge all staff at SNMRC and Clinical Epidemiology Unit, Faculty of Medicine, Chulalongkorn University for helpful suggestions, supports and comments.

This thesis was funded by Clinical Epidemiology Unit, Faculty of Medicine, Chulalongkorn University. The authors have no conflict of interest to declare.

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LIST OF ABBREVIATION

MPS	Myofascial pain syndrome
MTrP	Myofascial trigger point
US	Ultrasound
TENS	Transcutaneous electrical nerve stimulation
US-TENS	Simultaneous combine of ultrasound and transcutaneous electrical nerve stimulation
PPT	Pressure pain threshold
VAS	Visual analogue scale
VAS-R	Visual analogue scale at rest
VAS-A	Visual analogue scale during activity
RCTs	Randomized controlled trials
CI	Confidence interval
SD	Standard deviation

CHAPTER I

INTRODUCTION

1.1 Rationale and backgrounds

Myofascial pain syndrome (MPS), one of the common regional pain syndromes [1, 2], can be a prominent cause of disability, reduced quality of life and time lost from work. It is characterized by painful condition of musculoskeletal system, which is developed by myofascial trigger point (MTrP). MTrP is defined as hyperirritable spot in a taut band of skeletal muscle, which is painful on compression and can produce typical referred pain, stiffness, motor dysfunction and other disabilities [3, 8-12]. The actual pathophysiologic mechanism of MPS is still unclear [10, 11, 12]. Therefore, the principle of MPS management has largely focused on alleviation of pain and tightness of affected muscle by inactivating active MTrPs. Many treatment approaches are available for trigger point pain including invasive and non-invasive treatments [4, 5, 7]. Various studies recommend the rehabilitation program for MPS patients particularly on correction of muscle shortening by targeted stretching, strengthening of affected muscles, and improvement of aggravating postural and biomechanical factors [7, 13]. Physical modalities can also be useful in decreasing pain, allowing the patient to participate in an active exercise program [6]. A variety of techniques with different procedures have been demonstrated to be effective in some patients such as MTrPs injection, dry needling, acupuncture, massage, acupressure and physical agents [4, 7]. Therapeutic ultrasound (US) is one of the most frequently used physical modalities in patients with musculoskeletal conditions [15, 19]. The physiologic effects of US primarily relate to the resolution of trigger point pain. In this context, US generally alters nerve conduction velocity, increases muscle temperature, promotes connective tissue extensibility, and enhances blood flow [15, 20]. Electrotherapy is also considered as another type of effective physical modality which may have a critical role in central sensitization mechanism and gate control theory of pain modulation [16].

Transcutaneous electrical nerve stimulation (TENS) is one type of the most regularly employed electrotherapy [13, 16-18]. The use of TENS in treatment of MPS is mainly based on the concept of non-painful transcutaneous stimulus which can lead to analgesia.

In addition, electrotherapy is believed to give strong analgesic effects including increased pain threshold and promotion of muscle relaxation by both central inhibition of sympathetic nerve system and peripheral stimulus habituation [17, 18]. Due to the fact that US and TENS have distinct effects on MPS, the notion in simultaneous combination of these two regimes has been developed in the present study.

Also, in recent clinical practice, many physicians prefer to prescribe two concurrent therapies in musculoskeletal disorders despite the insufficient scientific evidence to prove this assumption. While the cost of these two approaches is different, the combination treatment is likely to be more expensive than the conventional US.

The objective of this investigation is to clarify if the US-TENS would give different effective outcome when comparing to the solely employed US for the treatment of acute and sub-acute MPS in upper trapezius muscle using randomized clinical trial.

CHAPTER II

LITERATURE REVIEW

2.1 Review of Related Literatures

MPS is a frequent pain conditions encounter in clinical practices [1]. However, this condition is often under-diagnosis, and the management is also inadequate or delay, and providing negative consequences. Because of the knowledge of MPS such as definition, pathophysiology, diagnostic criteria, and nature of disease are still unclear. To date, the definitions initially offered by *Simons et al*. stay the dominant definition of MPS and of MTrPs [31]. *Simons et al.* described an MPS as a "complex of sensory, motor and autonomic symptoms that are caused by myofascial trigger points" [8, 9, 31]. For MTrPs were defined as "spots of exquisite tenderness and hyperirritability in muscles or their fascia, localized in taut, palpable bands, which mediate a local twitch response of muscle fibers under a specific type of palpation (called snapping) and, if sufficiently hyperirritable, give rise to pain, tenderness and autonomic phenomena as well as dysfunction in areas usually remote from their site, called targets" [31]. Pathophysiology of myofascial pain is not well understood. Current research supports sensitization of low-threshold, mechano-sensitive afferents associated with dysfunctional motor endplates in the area of the MTrPs projecting to sensitized dorsal horn neurons in the spinal cord [3, 10, 11].

MPS is still required codification of diagnostic criteria, which might be developed on the basis of international multi-center studies or expert consensus meetings [6]. Nowadays, many MPS studies principal use diagnostic criteria for MTrPs by following the findings of *Simon et al*. [8, 9, 10] and *Gerwin et al.* [32].

Management of MPS has mainly focused on two principle targets; first is treatment of MTrPs and the latter is removal of causative or perpetuating factors. For MTrPs therapy, there are various handlings currently embraced for the deactivation of MTrPs. In consideration of the

equivocal definition of MTrPs and the lack of uniformity in using diagnostic criteria, the results of different studies and reviews revealed a variety of modalities and techniques as being effective or ineffective [6, 7, 18, 19]. Any therapy for MPS/MTrPs cannot be considered as definitive treatment without identification and modification of factors that have aggravated MTrP formation. Thus, any unusual postural attitude and incorrect muscle activity should be adjusted.

In addition, treatment outcomes measure in MPS is mostly pointed on evaluation of pain sensitivity. A number of studies have been performed to evaluate sensory changes at by measuring pain thresholds to different stimuli applied. A decrease pressure pain threshold (PPT) at the MTrP has been documented by several studies [13, 23]. Other aspects should be monitored such as functional ability, quality of life, recurrent rate *etc*. Several reviews suggested further placebo-controlled trials are required to prove the usefulness of conventional and recently proposed interventions for MTrPs [6, 18, 19].

There is currently a lack of reliable scientific evidence to support the effectiveness of this simultaneous combination therapy. Several trials suggested the effectiveness of combined therapy with pulsed US and electrotherapy on pain and sleep in fibromyalgia [14, 33]. They reported significant improvement in pain sensitivity and subjective/ objective sleep inventories. Therefore, it is important to assess the therapeutic effect of this relatively new modality comparing with the conventional method

CHAPTER III

RESEARCH METHODOLOGY

3.1 Research Questions

Primary research question

Is there any difference in therapeutic outcome between two therapeutic approaches (US-TEN and US) by pressure pain threshold (PPT) measuring?

Secondary research question

1. Is there any difference in VAS evaluating between two treatment approaches (US-TEN and US)?

2. Is the number of total consumption of acetaminophen in both groups different from each other?

3. Is there any alternative treatment (co-intervention) occurring in both two groups during treatment period?

3.2 Research Objectives

Primary objective

We assessed the effectiveness of simultaneously combined treatment using ultrasound and transcutaneous electrical nerve stimulation (or US-TENS) in comparison with solely therapeutic ultrasound (US) for treatment of acute and sub-acute MPS in upper trapezius muscle.

Secondary objectives

1. We also compared the patient's complaint in pain intensity by VAS evaluating between both groups.

2. We evaluated the total consumption of acetaminophen between these two groups.

3. We monitored the other alternative treatments or co-intervention (*e.g.* superficial heat, massage, topical analgesic drug, other modality) during treatment period in both two groups.

3.3 Hypothesis

Research hypothesis

The average change of PPT values in US-TENS group comparing with those of US group should be similar.

Statistical hypothesis

Null hypothesis Ho: $\mu t = \mu c$

Alternative hypothesis Ha: $\mu t \neq \mu c$

Where μt: mean change of PPT in US-TENS group or intervention group

μc: mean change of PPT in US or control group

3.4 Conceptual Framework

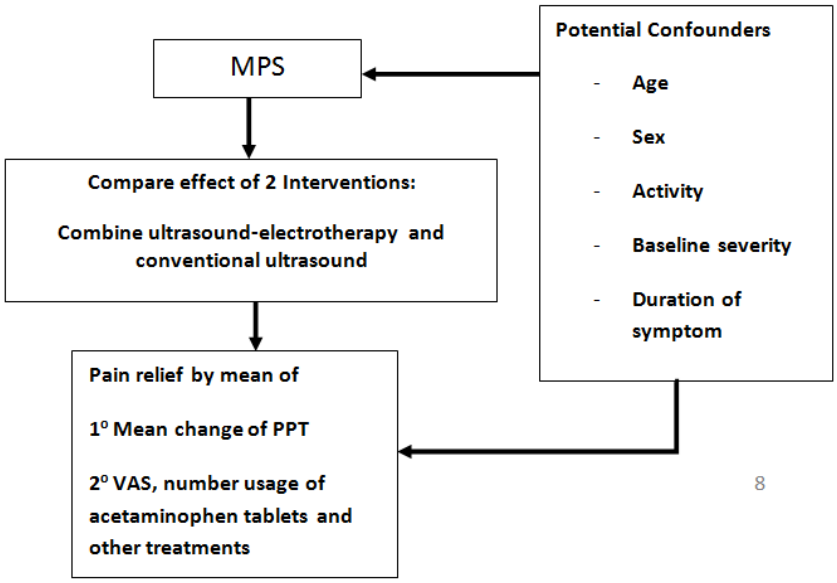

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Figure 1 Illustration of conceptual framework

3.5 Keywords

myofascial pain syndrome, ultrasound, TENS, combine therapy, randomized control trial

3.6 Operational Definitions

1. This current study used diagnostic criteria for MTrP by following the findings of *Simon et al*. [8, 9, 10] and *Gerwin et al.* [32].

Essential criteria for identifying an active or latent MTrP include the following:

- Palpable taut band if the muscle is accessible

- Exquisite spot tenderness (hypersensitive tender spot) of a nodule in a taut band

- Reproduction of the typical referred pain pattern of the MTrPs in response to compression

- Local twitch response provoked by the snapping palpation of the taut band

- Spontaneous present of typical referred pain pattern and/or patient recognition of the referred pain as familiar (active MTrP)

- Painful limit to full ROM stretch of the involved muscle

2. Simultaneous combine of ultrasound and transcutaneous electrical nerve stimulation (US-TENS) is the one type of physical agent which provides many options/parameters of electrotherapy and/or ultrasound therapy in one unit. Therapists can use these two components independently or in combination pattern.

3.7 Research Design

Randomized double (patient-assessor) blinded controlled trial

3.8 Research Methodology

3.8.1 Population and Sample

Population

Target population: Acute and Sub-acute MPS patients

Study population: MPS patients who met the diagnostic criteria of this study

Sampling process

Setting: Out-patient rehabilitation clinic at Sirindhorn National Medical Rehabilitation Centre (SNMRC)

All patients who complained of acute and sub-acute muscle pain around shoulder were evaluated.

Patient who met the full filled diagnostic criteria of MPS in upper trapezius muscle (s) and compatible with the study inclusion/exclusion criteria after taking history and physical examination was recruited.

3.8.2 Inclusion Criteria/Exclusion Criteria

Inclusion criteria

- Age ≥ 20 years old

- Has muscle pain around unilateral or bilateral shoulder region persisted ≥ 1 week but less than 6 months before recruitment time, first or recurrence episodes

- Baseline VAS ≥ 4 at upper trapezius muscle (choose the more severe pain if participant has bilateral sides)

- Full filled criteria for diagnosis of MPS in upper trapezius muscle

Exclusion criteria

- During the past 4 weeks had received injection or physical therapy at upper trapezius muscle or shoulder area

- Had experience of US combine TENS

- Had history of accidence or severe trauma to shoulder region

- Had serious musculoskeletal condition that need surgical intervention or oral anti-inflammatory drug such as acute shoulder subluxation, abnormal neurological examination, cervical radiculopathy.

- Insensate skin, skin infection or sensory impairment around shoulder area

- Had contraindication for U/S such as cardiac pacemaker, implantation, malignancy in relevant area, bleeding disorder, acute inflammatory musculoskeletal disease, pregnancy, lactation

- Unable to communication

- Unable to complete treatment session and follow protocol

3.8.3 Sample Size Estimation

Estimation of the sample size was based on the type of primary outcome measurement. Since this study compared mean change from baseline of PPT between groups

The following formula for comparing of the two independent means was used.

$$n / group = \frac{2\sigma^2 [Z_\alpha + Z_\beta]^2}{(\mu_c - \mu_t)^2}$$

Where α = type 1 error = 0.05 (2 sided), $Z_\alpha = 1.96$

β = type 2 error = 0.20, $Z_\beta = 0.84$ (power 80%)

μ_c = average change of PPT value of control group

μ_t = average change of PPT value of intervention group

σ = standard deviation of PPT value from control and intervention groups

From literature review; there were several investigation exploring therapeutic effect of combine therapy [13, 15]. The substantial difference of PPT values between two groups was at least 0.85, the standard deviation of PPT values was 0.9. We used two-sided analysis so α of 0.05, power of study is 80%. So the number of patients per group is equal

$$n = \frac{2\,(0.9)^2\,(1.96 + 0.84)^2}{(0.85)^2} = 18 \text{ / group}$$

Assumptions of 10% drop out rate; the sample size per group will be equal. Sample size in each group was 20. Finally, total sample size was 40.

3.8.4 Randomization and Allocation Concealment

This study applied computer-generated mixed-size block randomization and allocation concealment with opaque envelopes.

3.8.5 Blinding Method

We assigned placebo/sham TENS (placed skin electrode with turn-off electrical current unit) in control group for participant's masking or blinding and blinded assessor who measured primary outcome (PPT) at baseline and the day after complete treatment session.

3.8.6 Research Instruments

1. Simultaneous combination of ultrasound - electrotherapy machine – Sonopuls 492 (Enraf-Nonius, Lisburn, UK) containing US apparatus incorporated with electrotherapy unit was used in this study. It consists of treatment ultrasound head with a surface area of 5.8 cm^2, ERA (Effective Radiating Area) of 5.0 cm^2, BNR (Beam Non-uniform Ratio) as 5.0 and electrotherapy unit. The output is selected as either constant current or constant voltage.

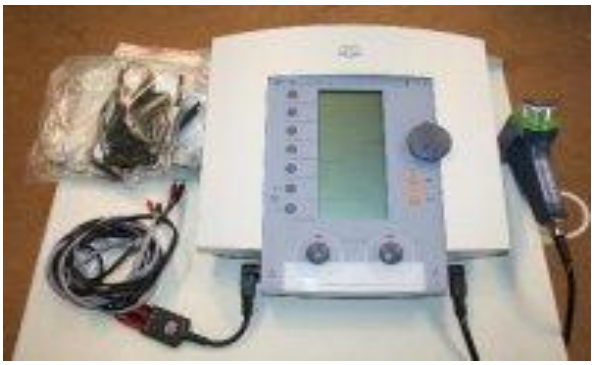

Figure 2.1 Illustration of combination ultrasound-electrotherapy machine

2. Pressure algometer or Dolorimeter for PPT measure – Baseline instrument push-pull dolorimeter SKU 12-0304 (Fabrication Enterprises, New York, USA). It consists of a gauge that is attached to a round tip with 1 cm in diameter. The gauge is calibrated in kg/ cm^2 and ranges from 1 to 10 kg/ cm^2 (Figure 2.2).

Figure 2.2 Illustration of pressure algometer or dolorimeter

All instruments in research were calibrated and validated annually.

3.8.7 Interventions

All participants were randomly allocated into two groups as follows;

Group 1 (n = 20): participants were received the US-TENS (intervention or US-TENS group). Sonopuls 492 (Enraf-Nonius, Lisburn,

UK) containing US apparatus incorporated with electrotherapy unit was used in this study. It consists of treatment ultrasound head with a surface area of 5.8 cm2, ERA (Effective Radiating Area) of 5.0 cm2, BNR (Beam Non-uniform Ratio) as 5.0 and electrotherapy unit. The output is selected as either constant current or constant voltage. US-TENS regime was conducted using US parameters (as continuous mode, 1 MHz in frequency and 1 w/cm2 for intensity and circular stroking of sound head over affected upper trapezius muscle throughout treatment period) in parallel with selective TENS settings (pulse frequency 100-150 pps, pulse duration 50- 80 μs and adjust amplitude as produce tingling for 10 minutes). The skin electrode was placed near the active trigger in area of trapezius muscle.

Group 2 (n = 20): participants were treated with solely US (control group or the therapeutic US combine sham TENS group) using Sonopuls 492 with similar US parameters to those in group 1. However, it functioned without any TENS settings. A skin electrode was placed in the same manner to that in the intervention group but with no electric output throughout the 10 minutes-treatment period.

All participants were received 10 consecutive treatments within 2 weeks. Additionally, all participants were obtained a home-based exercise program including proper stretching exercises of trapezius muscle and medications containing a package of topical analgesic drug and 20 tablets of acetaminophen. The coordinator individually monitored participants' symptoms and usage of analgesic drugs before proceed the next treatment session.

The intervention would be terminated as following conditions;

1. If the participants have progressive pain until they cannot be tolerated.

2. If the participants have full recovery from pain at affected upper trapezius muscle (by subjective reply or VAS as zero).

3. If the participants request to terminate the intervention in any reason before 10 session of treatment without sign of improvement or full recovery as describe in second condition.

In case of early termination, the participant was re-evaluated immediately and early proper management or further treatment should be done in condition of treatment failure.

We controlled contamination by education, design and following standardized of procedures and regular monitoring throughout the period of data collection.

This study attempted to control co-intervention by allowing symptomatic treatment such as acetaminophen, hot pack, stretching exercise or other analgesic medications during 2 weeks of treatment period. Participants should encourage informing the other alternative treatment or co-intervention during treatment period (*e.g.* method, dose, frequency of other treatment) and be recorded in case record form.

3.9 Data Collection

1. **Demographic data**; age (years), gender, occupation, duration of symptom (weeks)

All participants were interviewed by the researcher.

2. **Baseline characteristics**;

- Baseline VAS-R and VAS-A with identifying type of activity

All participants were encouraged estimating their pain intensity into VAS and clarification both VAS-R and VAS-A values by using VAS score card.

- Baseline PPT (kg/cm^2)

The procedure of PPT measure was conducted by well-trained assessor who identified active MTrP before placing the tip of algometer

on the selected MTrP. The pressure of compression was increased gradually at a speed of approximately 1 kg/s. Each participant was asked to reply ‘‘yes’’ as soon as he or she began to feel pain or any discomfort. The assessor stopped compression and recorded the actual pressure. The participant was asked to remember this level of pain and was applied the same criterion for the next measurement. Three repetitive assessments at an interval of 60 seconds were performed at the same site. The average value of 3 readings (kg/cm^2) was used for data analysis.

3. **Primary outcome variable;**

- Average changes of PPT values (from baseline to completion of treatment); the calculation equation was $PPT_{diff} = PPT_{time\ (i)} – PPT_{baseline}$

All participants were assessed PPT measure two times (baseline and completion of treatment) by the same assessor.

4. **Secondary outcome variables;**

- Average changes of VAS-R and VAS-A values from baseline to treatment completion were calculated.

- The total consumptions of acetaminophen tablet during treatment session were recorded.

- Participant’s information in scope of alternative treatment/ co-intervention during treatment period was also analyzed.

All secondary outcome measures were interviewed and recorded by the researcher on the appointment day after completion of treatment session.

3.10 Research Administration

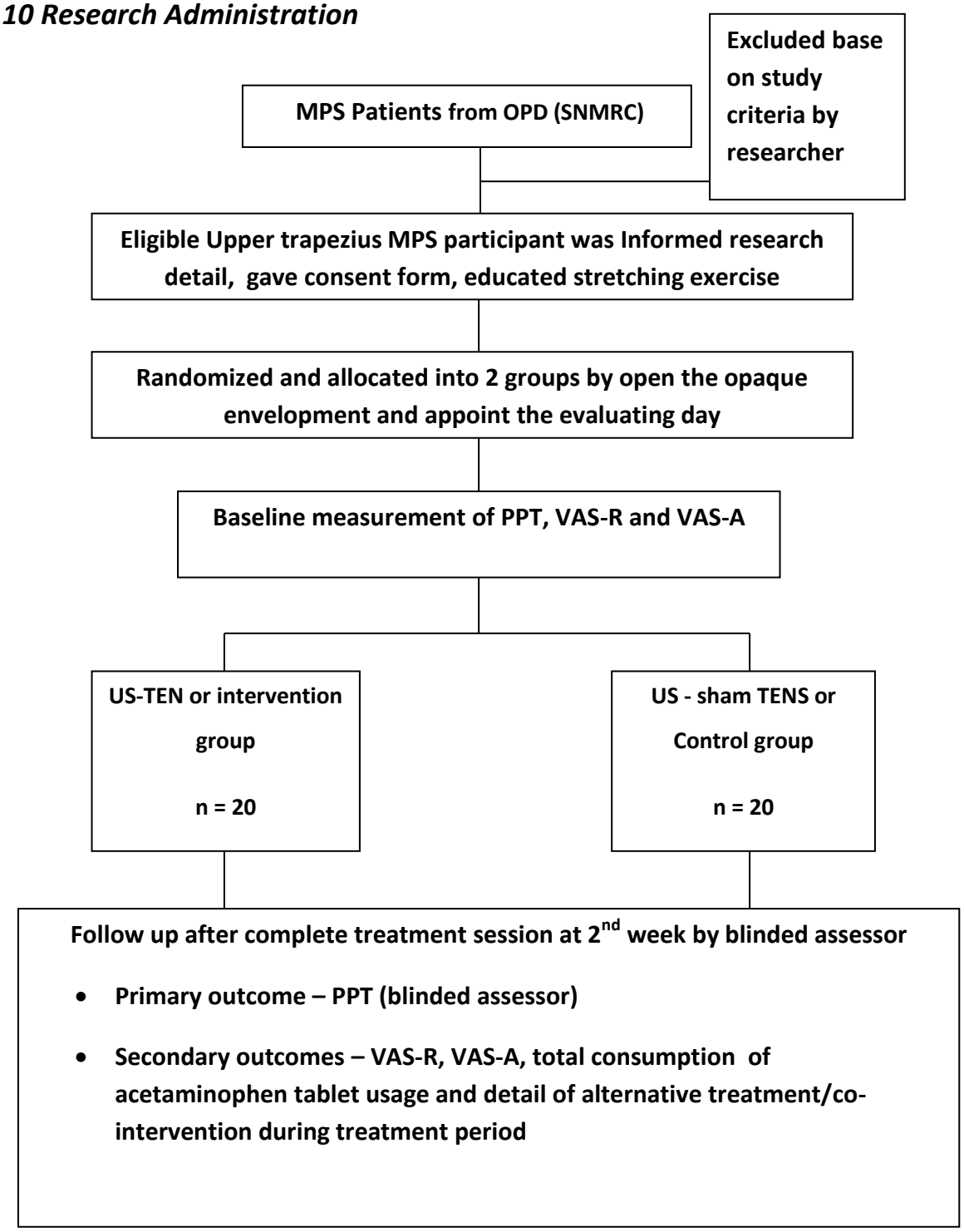

Figure 3 Illustration of research administration

3.11 Data Analysis

1. **Demographic data and baseline variables**

The demographic and baseline data were analyzed by descriptive statistics. Gender, occupation and duration of symptom were described in frequency of distribution. The continuous data (age, baseline VAS-R, VAS-A and PPT) were tested for normal distribution. The mean (±SD) or median (IQR) was used for describing data as appropriate.

Variable	Type of variable	Statistic
Age (years)	Continuous	Mean (±SD)
Gender (male/female)	Categorical	Frequency,% female
Occupation	Categorical	Frequency,%
Duration of symptom	Continuous	Mean (±SD)
(week)	Continuous	Mean (±SD)
Baseline PPT (kg/cm^2)	Continuous	Mean (±SD)
Baseline VAS-R	Continuous	Mean (±SD)
Baseline VAS-A		

The level of significance in all analyses was set at 5%. Analyses were performed using Social Package of Social Sciences (SPSS) for Windows statistical software (version 11.5, SPSS Inc., Chicago, USA).

2. Primary and secondary outcome variables

The average changes of PPT, VAS-R and VAS-A values were assessed for normal distribution using one sample Kolmogorov-Smirnov test.

The independent t-test was used to analyze the average changes of PPT, VAS-R and VAS-A values between two groups (difference, *P*-value and 95% CI).

The participant's information of alternative treatment/co-intervention during treatment period was described.

3.12 Ethical Consideration

1. This study was approved by the ethical committee of Sirindhorn National Medical Rehabilitation Centre (SNMRC) before the study would be done.

2. The participants were informed point of the study, risk and benefit and informed consent is needed. However, they could withdraw from the study at anytime.

3. There was a lot of personal data. All data was kept in a personal computer belongs to the investigator. The entrance to the data will need a password.

4. Results of the study were presented in general, not as individual data.

3.13 Limitation

1. The main purpose of this study was comparing therapeutic effect between two interventions by pain relief in short-term period. We did not concern about other aspects such as functional outcome**,** quality of life, recurrent rate and psychosocial aspect.

2. It was impossible for blinding the physiotherapist regarding the type of intervention. However, the research therapists should follow the standard of procedure and research protocol.

3.14 Expected benefit of the study

The results of this current study should be useful for the physicians in decision making in MPS management.

CHAPTER IV

RESULTS

4.1 Participants characteristics and treatment

Sixty-five MPS participants were initially enrolled in this study. There were 23 participants who did not meet the inclusion criteria and 2 participants declined to participate program. Total 40 participants were randomly allocated into 2 groups, each consisted 20 participants. There was only one participant dropped out from the intervention group due to common cold after 2nd treatment session. Finally, data from 19 participants in intervention group and 20 participants in control group were analyzed, as shown as a flowchart in Figure 4. The demographic and baseline characteristics data of both groups were presented in Table 1. There was no significant difference between 2 groups at baseline with respect to age, sex, duration of pain, affected side, PPT, VAS-R and VAS-A values.

Table 1 Baseline characteristics

Characteristics	**Participants randomized to intervention**		**Participants completing intervention***	
	US combine TENS (n = 20)	US combine sham TENS (n = 20)	US combine TENS (n = 19)	US combine sham TENS (n = 20)
Age, yrs	39.65 ± 13.93	39.50 ± 12.74	38.95 ± 13.95	39.50 ± 12.74
Gender,% female	18 (90)	17 (85)	17 (89.5)	17 (85)
Duration, week	4 ± 2.59	5.35 ± 4.99	4.05 ± 2.50	5.35 ± 4.99
Side, right	17 (85)	13 (65)	16 (84.2)	13 (65)
Baseline PPT, kg/cm^2	2.59 ± 0.72	2.68 ± 0.96	2.58 ± 0.73	2.68 ± 0.96
Baseline VAS-R	3.68 ± 1.29	3.63 ± 2.21	3.60 ± 1.28	3.63 ± 2.21
Baseline VAS-A	6.14 ± 1.08	6.35 ± 1.16	6.19 ± 1.08	6.35 ± 1.16

Data are presented in mean ± SD or number (%); US = therapeutic ultrasound, TENS = transcutaneous electrical nerve stimulation, PPT = pressure pain threshold, VAS = visual analogue scale, * One participant dropped out from intervention group.

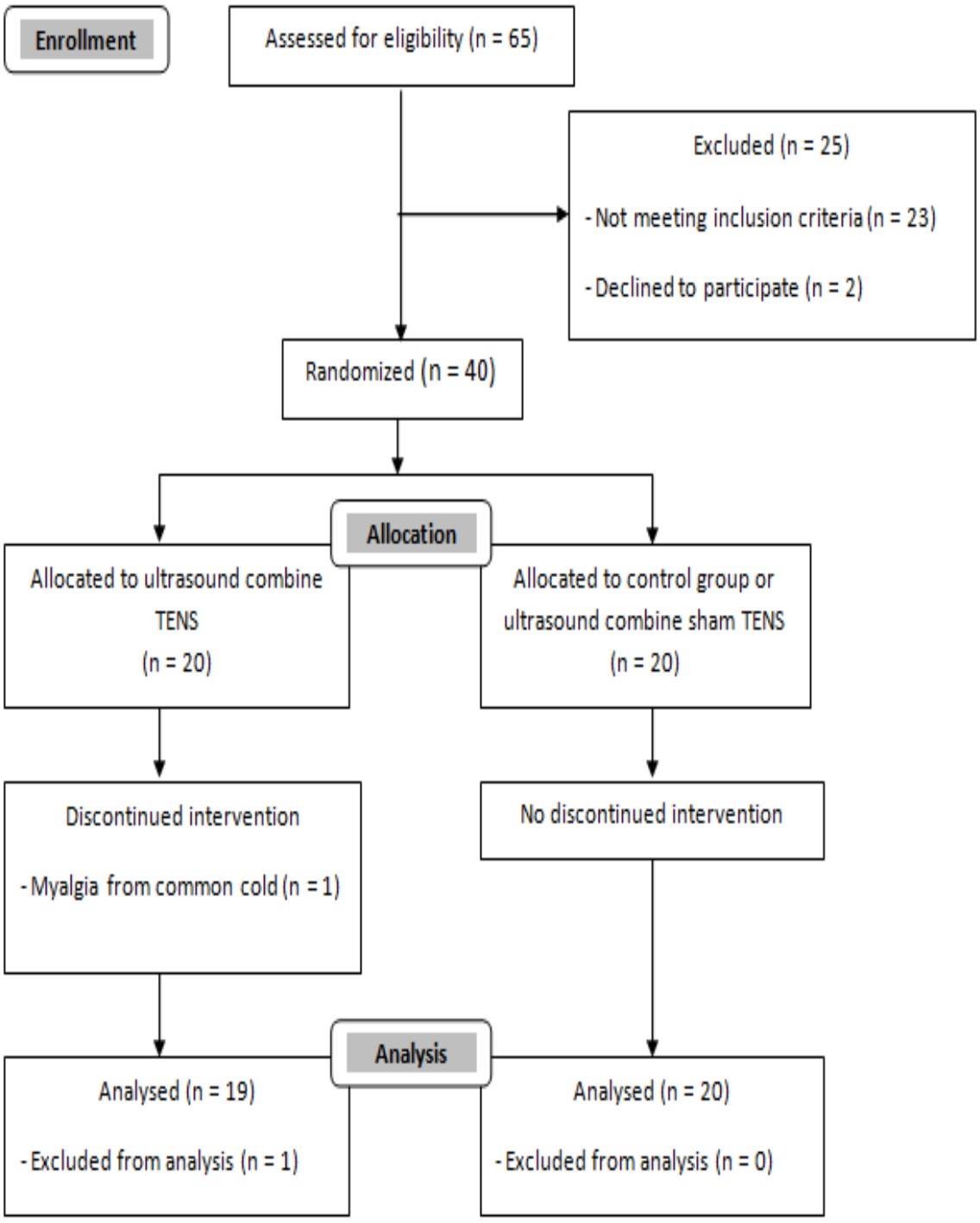

Figure 4 Illustration of flow diagram of subject progress through the phase of randomized trial

4.2 Outcome of treatment

Primary outcome analysis: PPT

Average baseline PPT value in the intervention group was 2.58 (± 0.73). After the completion of 10 treatment sessions, it increased by 9.6%. We found a similar trend for a control group by which average change of PPT also raised by 17.9%. Average changes for both groups appeared in normal distribution according to analysis using one-sample Kolmogorov-Smirnov test. Thus, independent t-test was used to compare the difference in change of PPT. The average changes (± SD) of PPT were 0.26 (±0.51) and 0.48 (±0.78) kg/cm^2 in the intervention and control group, respectively. However, there was no statistically significant difference in mean change of PPT values between these two groups (0.23; 95%CI: -0.20 – 0.65, P = 0.29), as shown in Table 2.

Secondary outcome measure: VAS-R, VAS-A, total consumption of acetaminophen and alternative treatment during treatment session

Average baseline VAS-R and VAS-A values in the intervention group were 3.60 (± 1.28) and 6.19 (±1.08), respectively. The control group had baseline VAS-R and VAS-A as 3.63 (± 2.21) and 6.35 (± 1.16), respectively. After the achievement of 10 treatments, these values decreased by 57.0% and 56.2 %, respectively. We also detected a comparable tendency for the VAS-R and VAS-A values in the control group. There were 64.2 % and 50.7 % reduction of VAS-R and VAS-A values, respectively (Table 2).

We used independent t-test to compare the difference in VAS-R, VAS-A values and total consumption of acetaminophen. The mean (±SD) changes of the VAS-R value were 2.02 (±1.20) and 2.50 (±2.29) for the intervention and control group, respectively. There was no substantial difference in average change of VAS-R values between these two groups (0.47; 95%CI: -0.72 – 1.66, P = 0.42). The mean (±SD) changes of the VAS-A value were 3.45 (±1.79) and 3.26 (±2.28) in the intervention and control group, respectively. Similar to the observation of VAS-R values,

we found no considerable VAS-A value difference (-0.20; 95%CI: -1.52 – 1.13, P = 0.76). There was also no remarkable difference in total consumption of acetaminophen between these two groups (-0.36; 95%CI:-2.45 – 1.74, P = 0.73), as revealed in Table 2. We found that our principle results (average change of PPT, VAS-R and VAS-A) included negative and positive values. Participants in both groups did not receive any alternative treatment or co-intervention during treatment period.

Table 2 Comparison of all measures between two groups

Outcomes	**Mean (±SD)**		***P* value**	**Different (95%CI**
	US combine TENS (n = 19)	US combine sham TENS (n = 20)		
Baseline				
PPT, kg/cm^2	2.58 (0.73)	2.68 (0.96)	0.72	0.10(-0.45 – 0.64)
VAS-R	3.60 (1.28)	3.63 (2.21)	0.92	-0.06(-1.22 –1.11)
VAS-A	6.19 (1.08)	6.35 (1.16)	0.57	0.21(-0.51 – 0.92)
Complete treatment				
PPT, kg/cm^2	2.83 (1.02)	3.16 (1.24)	0.37	0.33(-0.40 – 1.07)
VAS-R	1.58 (1.29)	1.23 (1.28)	0.40	-0.35(-1.18 – 0.48)
VAS-A	2.74 (1.91)	3.09 (1.97)	0.57	0.35(-0.91 – 1.62)
Number of acetaminophen usage	2.21 (2.86)	1.85 (3.54)	0.73	-0.36(-2.45 – 1.74)
Average change				
PPT, kg/cm^2	0.26 (0.51)	0.48 (0.78)	0.29	0.23(-0.20 – 0.65)
VAS-R	2.02 (1.20)	2.50 (2.29)	0.42	0.47(-0.72 – 1.66)
VAS-A	3.45 (1.79)	3.26 (2.28)	0.76	-0.20(-1.52 – 1.13)

Data are presented in mean (±SD); US = therapeutic ultrasound, TENS = transcutaneous electrical nerve stimulation, CI = confidence interval, PPT = pressure pain threshold, VAS-R = visual analogue scale at rest, VAS-A = visual analogue scale during activity

CHAPTER V

DISCUSSION

To our knowledge, this is the first study which assessed the effectiveness of the simultaneous combined treatment using US and TENS (US-TENS). The US and TENS techniques are the commonly accepted as non-invasive approaches for acute and sub-acute MPS victims. Therapeutic effects of US-TENS were compared with those of the conventional US in this study in order to provide the scientific evidence if the combined therapy would give different results.

We are mainly interested in the effect of pain relief, which could facilitate the better living of victims. Thus, the pain sensitivity was quantified using the PPT and VAS measures, which represented both objective and subjective indices for pain measurements, respectively. PPT measure has been proven in validity, reliability and reproducibility in pain evaluation [22 - 25]. There are previous reports showing the reduction of PPT in patients with pain related conditions such as active MPS and fibromyalgia comparatively with normal values [13, 23]. Evaluation of VAS is believed to be a simple and reliable method for pain estimating [29, 30], by which we can convert an uncountable value to a numbering data in the present study.

In this current study, we found that our principle findings, especially 95%CI indicated the insufficient power to illustrate the different between these two treatments. These might be because of inadequate sample size. There is a possibility that if we increase the number of samples, we might found the different between these two approaches in either superior or inferior directions.

However, we found that our participants had a mean increase of 15% in PPT and the average reduction in VAS-R and VAS-A values were 60 % and 53%, respectively. The within-group analysis, PPT values were increased by 9.6% and 17.9% in intervention and control group, respectively. Results of VAS-R and VAS-A analysis revealed the reduction

of 57% and 56 %, respectively in the intervention group and of 64% and 51%, respectively in a control group. These also represented the analgesic effect of therapeutic ultrasound and US-TENS in MPS.

In context of ultrasound effects, our results were consistent with other studies showing therapeutic effects of US in MPS patients [15, 20]. There was a study which encouraged the usefulness of ultrasound in decreasing active trigger point pain sensitivity by 44% after complete a session of US treatment [15]. Another investigation also reported short term segmental anti-nociceptive effect by using low dose US [20]. In addition, many studies suggested the advantage of US in management of MPS as combination therapy with other modalities such as exercise, trigger point compression [14, 27]. There have also been several studies which documented TENS could provide the therapeutic effect in MPS [16, 17, 26, 28]. Nonetheless, the knowledge of simultaneous combination therapy of TENS is largely unclear. The results of this study illustrated that the short-term therapeutic effect of the US-TENS approach had no substantial difference to that of US treatment. Another interesting point in our study is that the curative effect of US was slightly better than that of US-TENS. It is possible that the anti-nociceptive effect of TENS may develop very rapidly after treatment [13, 20, 26]. We, however, measured both PPT and VAS values at the completion of 10-treatment session which required at least 24 hours. Period of TENS effect monitoring should therefore be considered for further investigation as a critical factor as same as the TENS placement. Other reports indicated that applying TENS at the actual acupoint could lead to 39% reduction in pain sensitivity comparing with stimulation of the non-acupoint [16, 28].

For clinical implication, we support the usefulness of US as a treatment of choice in acute and sub-acute MPS patients. Either US-TENS or therapeutic US was valuable when being used as management for acute and sub-acute MPS. The additional information of US-TENS on other relevant disability aspects such as limitation of motion and incapability in daily performance as well as the cost-effectiveness of this treatment is worthy of further investigation.

CHAPTER VI

CONCLUSION

From this study, we conclude that either US-TENS or therapeutic US was effective when being used as physiotherapy for acute and sub-acute MPS. We detected the increase of PPT and reduction in VAS (VAS-R and VAS-A) values in US and US-TENS. It is suggested that only US or US-TENS treatments can improve pain sensitivity. We found from this study that results from US-TENS showed no significant difference to the conventional US treatment.

However, our results also suggested further investigations which maintain larger populations, different and adequate measurements such as immediate, short-term and long term effects, patient satisfaction, cost effectiveness and recurrent rate should be performed to illustrate the different therapeutic effects between these two treatments.

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APPENDICES

APPENDIX A

Case Record Form

Case Record Form

RCT ultrasound combine TENS in treatment of sub-acute MPS

Participant ID (HN) _ _ / _ _ _ _ **code _ _ _ _**

Age _ _ years **(MUST ≥ 20 years-old)**

Gender **O** 1.Male **O** 2.Female

Occupation (Describe) _____

Complain of shoulder(s)/around shoulder(s) pain OR other area with shoulder(s)

O 1. Yes **O 2.** No → **Exclude**

Duration of pain symptom (From 1month to less than 6 months)

O 1. Yes **O 2.** No → **Exclude**

Estimate duration of pain symptom _ _ (weeks)

Screening physical examination for identify TrP in upper trapezius muscle. Are there any myofascial trigger points or tender taut band in this participant? ***(Performed by researcher)***

O 1. Yes **O 2.** No → **Exclude**

Screening for full-field diagnosis of TrP in upper trapezius muscle ***(By researcher)*** **– Meet these items as follow → put √ in O**

Affected side **O 1.**Right **O 2.**Left **O3.**Bilateral

O Palpable taut band in upper trapezius muscle

O Exquisite spot tenderness (hypersensitive tender spot) of a nodule in a taut band

O Reproduction of the typical referred pain pattern of the lateral aspect of ipsilateral arm and lower neck/shoulder

O Spontaneous present of typical referred pain pattern and/or patient recognition of the referred pain as familiar (active TrP)

O Local twitch response provoked by the snapping palpation of the taut band

O Painful limit to full ROM stretch of the upper trapezius muscle

Screening (Follow by Exclusion criteria) – Perform by research assistant or researcher

Check √ in O for each item after participant reply "No", if participant *reply "Yes" in any item* should be *excluded*

O During the past 4 weeks had received injection or physical therapy at upper trapezius muscle or shoulder area

O Had experience of ultrasound combines TENS

O Had history of accidence or severe trauma to shoulder region

O Had serious musculoskeletal condition (need surgical intervention) eg. acute shoulder subluxation, abnormal neurological examination

O Insensate skin or sensory impairment around shoulder area

O Skin infection at shoulder area (in affected side)

O Had contraindication for U/S such as cardiac pacemaker, implantation, malignancy in relevant area, bleeding disorder, acute inflammatory musculoskeletal disease, pregnancy, lactation

O Unable to communication (Confuse, severe demention)

O Unable to complete treatment session and follow protocol

Physical examination (By Blinded Assessor)

<u>Part I</u> Assessment for localization active TrP in upper trapezius muscle

Side of affected **O 1.** Right **O 2.** Left **O 3.** Bilateral
Chosen side **O 1.** Right **O 2.** Left
Latent TrP **O 1.** Yes **O 2.** No **Number _ _ point**
Active TrP **O 1.** Yes **O 2.** No **Number _ _ point**
Identify location/characteristic of chosen active TrP

Osize/depth/consistency_____

O distance from acromion _ _ cm. from spine of scapular _ _ cm.

Draw picture in the square below (Use bony landmark – bilateral scapular)

Note: If this participant has other active trigger point in this region eg. Infraspinatus, rhomboid, levator, supraspinatus, deltoid please identify_____
_____
_____

<u>Part II</u> Baseline measurement – At enrollment day

1. PPT (Use Pressure Algometer - *Blinded assessor*) – After training participant at contra-lateral side

PPT 1st time _ _. _ _ Kg/cm^2
PPT 2nd time _ _. _ _ Kg/cm^2
PPT 3rd time _ _. _ _ Kg/cm^2 Average PPT _ _. _ _ Kg/cm^2

2. VAS (Use VAS card and instruction *by research assistant*)

VAS at rest _ _ VAS during activity _ _

Identify activity(Most pain)_____

<u>Part III</u> Follow-up before every each treatment session – *By Research assistant*

<u>First week</u>

First week	Session 1	Session 2	Session 3	Session 4	Session 5
Pain I/S/D*					
Continue Px Y/N					
Use paracet Y/N + No.					
Other treatment Y/N(detail)**					
Next visit					
Remark					

*** I = Increased, S = Stable or same, D = Decreased**

<u>Second week</u>

First week	Session 6	Session 7	Session 8	Session 9	Session10
Pain I/S/D*					
Continue Px Y/N					
Use paracet Y/N + No.					
Other treatment Y/N(detail)**					
Next visit					
Remark					

*** I = Increased, S = Stable or same, D = Decreased**

<u>Part IV</u> **Detail of participant's information in scope of alternative treatment/ co-intervention during treatment period

1st week **O** Do you have other treatment during this week?	**O 1.Yes** **-What is (are) the extra treatment(s)?** O Superficial heat/hot pack O Cold pack/ ice/ O Topical analgesia/balm/spray O Massage O Sauna/stream O Exercise except stretching as prescribe O Acupuncture O Portable electrotherapy O Oral drug 1. NSAID 2. Muscle relaxant 3. Tranquilizer/Antidepressant 4. Analgesic drug except paracetamol 5. Others_____ Dose of drug _____tablet/day O Other _____ **-Why? Relate to pain** O 1. Yes O 2.No _____ **-How often?** O _ _ time/day O _ _ time/week	**O 2.No**

2nd week **O** Do you have other treatment during this week?	**O 1.Yes** **-What is (are) the extra treatment(s)?** O Superficial heat/hot pack O Cold pack/ ice/ O Topical analgesia/balm/spray O Massage O Sauna/stream O Exercise except stretching as prescribe O Acupuncture O Portable electrotherapy O Oral drug 1. NSAID 2. Muscle relaxant 3. Tranquilizer/Antidepressant 4 Analgesic drug except paracetamol 5. Others_____ Dose of drug _____tablet/day O Other _____ **-Why? Relate to pain** O 1. Yes O 2.No _____ **-How often?** O _ _ time/day O _ _ time/week	**O 2.No**

<u>Part V</u> Post-treatment evaluationDate _ _/_ _/ 2012 total _ _/10 times

1. PPT (Use Pressure Algometer - *Blinded assessor*) – After training participant at contra-lateral side

PPT 1st time _ _. _ _ Kg/cm^2

PPT 2ndtime _ _. _ _ Kg/cm^2

PPT 3rd time _ _. _ _ Kg/cm^2 Average PPT _ _. _ _ Kg/cm^2

2. VAS (Use VAS card and instruction *by research assistant*)

VAS at rest _ _ VAS during activity _ _

Identify activity (Most pain) *(Same as baseline)*

3. Number of paracetamol (500 mg) tablet usage _ _ / 50 tablets

4. Participant's information in scope of alternative treatment/co-intervention during treatment period

1st week Co-intervention O 1. Yes → Detail** O 2. No

2nd week Co-intervention O 1. Yes → Detail**O 2. No

****Do not** miss to complete detail in part V in case of co-intervention**

Part VI In case of the assigned intervention would be terminated before complete 10 sessions or 2 week of treatment *(Interview and complete by research assistance)* please √ in O

O Participants have progressive pain intensity until they cannot be tolerated

O Participant's request to terminate their assigned intervention

Reason (if can identify) _____

_____

_____

O Participants have full recovery from pain at affected upper trapezius muscle (by subjective reply or VAS as zero)

Part VII Note for adverse effect/ or serious adverse effect (if occur)

Problem:

Severity:

Causality:

Outcome:

Place:

Time:

Management: (Who and How)

APPENDIX B
Information sheet

คำแนะนำสำหรับผู้เข้าร่วมโครงการวิจัย

ชื่อโครงการวิจัย ประสิทธิผลของการใช้เครื่องอัลตร้าซาวน์ผสมกระแสไฟฟ้าบำบัด เพื่อรักษากลุ่มอาการปวดมัยโอฟาสเซียล ในกล้ามเนื้อแทรบปีเซียสส่วนบน: การวิจัยเชิงทดลองแบบสุ่มและมีกลุ่มควบคุม

ผู้วิจัย แพทย์หญิงบุษกร โลหารชุน

สถานที่วิจัย ศูนย์สิรินธรเพื่อการฟื้นฟูสมรรถภาพทางการแพทย์แห่งชาติ

ผู้สนับสนุนการวิจัย

ท่านได้รับการขอความร่วมมือในการเป็นอาสาสมัคร รับการรักษากลุ่มอาการปวดมัยโอฟาสเซียล ในกล้ามเนื้อแทรบปีเซียสส่วนบน ด้วยเครื่องมือกายภาพบำบัด

ทำไมต้องศึกษาเรื่องนี้ เนื่องจากกลุ่มอาการปวดมัยโอฟาสเซียล ในกล้ามเนื้อแทรบปีเซียสส่วนบนพบได้บ่อยและส่งผลกระทบต่อผู้ป่วยในหลายๆด้าน อีกทั้งยังมีความยากในการรักษา ซึ่งการรักษาด้วยเครื่องมือทางกายภาพบำบัดเป็นวิธีที่ปลอดภัยและมีประสิทธิภาพ แต่เครื่องมือมีความหลากหลายมาก จึงจำเป็นที่จะต้องมีการศึกษาวิจัยเพื่อเปรียบเทียบผลการรักษาที่ให้ประสิทธิภาพสูงสุด

วัตถุประสงค์ เพื่อศึกษาเปรียบเทียบผลการรักษาในแง่การลดอาการปวด ประเมินโดยแพทย์เวชศาสตร์ฟื้นฟู

จะปฏิบัติต่อท่านอย่างไร ก่อนการรักษาท่านจะได้รับการบันทึกข้อมูลในแบบบันทึกข้อมูลที่ประกอบด้วยข้อมูลทั่วไป ประกอบด้วยอายุ เพศ อาชีพ ระยะเวลาเริ่มปวด คะแนนความปวด และได้รับการตรวจร่างกาย เพื่อประเมินตำแหน่ง และความรุนแรงของอาการปวดบริเวณบ่าและไหล่ ท่านจะได้รับการแนะนำท่าทางการยืดกล้ามเนื้อบ่า ยาบรรเทาปวดชนิดรับประทาน (พาราเซตามอล 500 ม.ก.)และชนิดทาผิวหนัง พร้อมทั้งรับทราบกำหนดนัดรับการรักษาทางกายภาพบำบัด จำนวน 10 ครั้งหลังการรักษาจะมีการนัดตรวจติดตามผลการรักษา โดยการซักถามแบบสอบถามและการตรวจร่างกาย

ประโยชน์ จะทำให้ทราบถึงผลการรักษาเมื่อเปรียบเทียบผลการรักษาด้วยเครื่องมือกายภาพบำบัด ต่างชนิดกัน

ท่านจำเป็นต้องเข้าร่วมโครงการนี้หรือไม่ ไม่จำเป็น ขึ้นอยู่กับตัวท่านเอง และแม้ว่าท่านไม่สะดวกที่จะเข้าร่วมโครงการวิจัย ก็จะไม่มีผลกระทบต่อการรักษาท่านแต่อย่างใด

ค่าตอบแทน

โครงการวิจัยจะให้ค่าตอบแทนในการให้ความร่วมมือ 200 บาทซึ่งจะให้เมื่อครบกำหนดในสัปดาห์ที่สองเมื่อท่านมาตรวจติดตามอาการ

การรักษาความลับของท่าน ผู้วิจัยจะเก็บข้อมูลเฉพาะเกี่ยวกับตัวท่านไว้เป็นความลับและจะเปิดเผยต่อหน่วยงานหรือสาธารณชนเฉพาะเป็นภาพรวมสรุปผลการวิจัยด้วยเหตุผลทางวิชาการ โดยไม่มีการระบุชื่อของท่าน

เจ้าหน้าที่หรือแพทย์ผู้ที่ท่านสามารถติดต่อได้ แพทย์หญิงบุษกร โลหารชุน ศูนย์สิรินธรเพื่อการฟื้นฟูสมรรถภาพทางการแพทย์แห่งชาติ โทรศัพท์ 0-25914242 ต่อ 6705, 08-1707-1976

APPENDIX B
Consent Form

หนังสือให้ความยินยอมเข้าร่วมในโครงการวิจัย

ทำที่ ศูนย์สิรินธรเพื่อการฟื้นฟูสมรรถภาพทางการแพทย์แห่งชาติ

วันที่.....

ข้าพเจ้า..... อายุ .....ปี

อยู่บ้านเลขที่ .....ถนน.....หมู่ที่ .....แขวง/ตำบล.....

เขต/อำเภอ.....จังหวัด.....

ขอทำหนังสือนี้ให้ไว้ต่อหัวหน้าโครงการวิจัยเพื่อเป็นหลักฐานแสดงว่า

ข้อ 1 ข้าพเจ้าได้รับทราบโครงการวิจัยของ **แพทย์หญิงบุษกร โลหารชุน** เรื่องประสิทธิผลของการใช้เครื่องอัลตร้าซาวน์ผสมกระแสไฟฟ้าบำบัด เพื่อรักษากลุ่มอาการปวดมัยโอฟาสเชียล ในกล้ามเนื้อแทรบปีเซียสส่วนบน: การวิจัยเชิงทดลองแบบสุ่มและมีกลุ่มควบคุม

ข้อ 2 ข้าพเจ้าเข้าร่วมโครงการวิจัยนี้ด้วยความสมัครใจ โดยมิได้มีการบังคับ ขู่เข็ญ หลอกลวงแต่ประการใด และพร้อมจะให้ความร่วมมือในการวิจัย

ข้อ 3 ข้าพเจ้าได้รับการอธิบายจากผู้วิจัยเกี่ยวกับวัตถุประสงค์ของการวิจัยวิธีการวิจัย ประสิทธิภาพความปลอดภัยอาการหรืออันตรายที่อาจเกิดขึ้นรวมทั้งประโยชน์ที่จะได้รับจากการวิจัยโดยละเอียดแล้วจากเอกสารการวิจัยที่แนบท้ายหนังสือให้ความยินยอมนี้

ข้อ 4 ข้าพเจ้าได้รับการรับรองจากผู้วิจัยว่าจะเก็บข้อมูลส่วนตัวของข้าพเจ้าเป็น ความลับ จะเปิดเผยเฉพาะผลสรุปการวิจัยเท่านั้น

ข้อ 5 ข้าพเจ้าได้รับทราบจากผู้วิจัยแล้วว่าหากมีอันตรายใดๆต่อข้าพเจ้า ในระหว่างการวิจัยหรือภายหลังการวิจัยอันพิสูจน์ได้จากผู้เชี่ยวชาญของสถาบันที่ควบคุมวิชาชีพนั้นๆ ได้ว่าเกิดขึ้นจากการวิจัยดังกล่าวข้าพเจ้าจะได้รับการดูแลและค่าใช้จ่ายในการรักษาพยาบาลจากผู้วิจัยและ/หรือผู้สนับสนุนการวิจัยตลอดจนมีสิทธิได้รับค่าทดแทนความพิการที่อาจเกิดขึ้นจากการวิจัยตามกฎหมายและในกรณีที่ข้าพเจ้าได้รับอันตรายจากการวิจัยถึงแก่ความตาย ทายาทของข้าพเจ้ามีสิทธิได้รับค่าชดเชยและค่าทดแทนดังกล่าวจากผู้วิจัยและ/หรือผู้สนับสนุนการวิจัยแทนข้าพเจ้า

ข้อ 6 ข้าพเจ้าได้รับทราบแล้วว่า ข้าพเจ้ามีสิทธิจะบอกเลิกการร่วมโครงการวิจัยนี้เมื่อใดก็ได้ และการบอกเลิกการร่วมโครงการวิจัยจะไม่มีผลกระทบต่อการได้รับบรรดาค่าใช้จ่าย ค่าชดเชยและค่าทดแทนตามข้อ 5 ทุกประการ

ข้อ7 หัวหน้าผู้วิจัยได้อธิบายเกี่ยวกับรายละเอียดต่างๆของโครงการตลอดจนประโยชน์ของการวิจัยรวมทั้งความเสี่ยงและอันตรายต่างๆที่อาจจะเกิดขึ้นในการเข้าโครงการนี้ให้ข้าพเจ้าได้ทราบ และตกลงรับผิดชอบตามคำรับรองในข้อ 5 ทุกประการ

ข้าพเจ้าได้อ่านและเข้าใจข้อความตามหนังสือนี้โดยตลอดแล้วเห็นว่าถูกต้องตามเจตนาของข้าพเจ้าจึงได้ลงลายมือชื่อไว้เป็นสำคัญ พร้อมกับหัวหน้าผู้วิจัยและต่อหน้าพยาน

ลงชื่อ……ผู้ยินยอม
(……...)

ลงชื่อ……หัวหน้าผู้วิจัย
(……...)

ลงชื่อ……พยาน
(……...)

ลงชื่อ……พยาน
(……...) หมายเหตุ

1) กรณีผู้ยินยอมตนให้ทำวิจัยไม่สามารถอ่านหนังสือได้ให้ผู้วิจัยอ่านข้อความในหนังสือให้ความยินยอมนี้ให้แก่ผู้ยินยอมให้ทำวิจัยฟังจนเข้าใจดีแล้วและให้ผู้ยินยอมตนให้ทำวิจัยลงนามหรือพิมพ์ลายนิ้วหัวแม่มือรับทราบในการให้ความยินยอมดังกล่าวด้วย
2) ในกรณีผู้ให้ความยินยอมมีอายุไม่ครบ 20 ปีบริบูรณ์จะต้องมีผู้ปกครองตามกฎหมายเป็นผู้ให้ความยิน ยอมด้วย

VITAE

Name Bootsakorn Loharjun MD

Date and place of birth February 24th, 1977, Phitsanulok, Thailand

Educational credentials

1994 – 2000	M.D., Faculty of Medicine, Siriraj Hospital, Mahidol University
2003 – 2006	Diploma of the Thai Board of Physical Medicine and Rehabilitation
Since 2012	Attending in the Master degree program of Health Development, Faculty of Medicine, Chulalongkorn University

Work experiences

2000 – 2003	Medical Physician (practitioner and professional levels) at Buddhacninnaraj Hospital, Phitsanulok
2006 – 2010	Rehabilitation doctor (senior professional level) at Buddhacninnaraj Hospital, Phitsanulok
Since 2010	Rehabilitation doctor (senior professional level) and head of research unit, Sirindhorn National Medical Rehabilitation Centre, Nonthaburi

Current work position and office

Rehabilitation doctor (senior professional level) and head of research unit, Sirindhorn National Medical Rehabilitation Centre,

88/26, Tiwanon Rd, Muang, Nonthaburi 11000, Thailand, Tel. +662-591-4242