

**INVESTIGATION OF THE THERAPEUTIC
EFFECTS OF AN INNOVATIVE LUMBAR
SUPPORT COMPRISING HOT PACK
AND CORE MUSCLE ACTIVATION
FEEDBACK IN INDIVIDUALS
WITH LOW BACK PAIN**

DUANGRUEDEE DISSANGUAN

**DOCTOR OF PHILOSOPHY
IN BIOMEDICAL SCIENCES**

**GRADUATE SCHOOL
CHIANG MAI UNIVERSITY
JANUARY 2021**

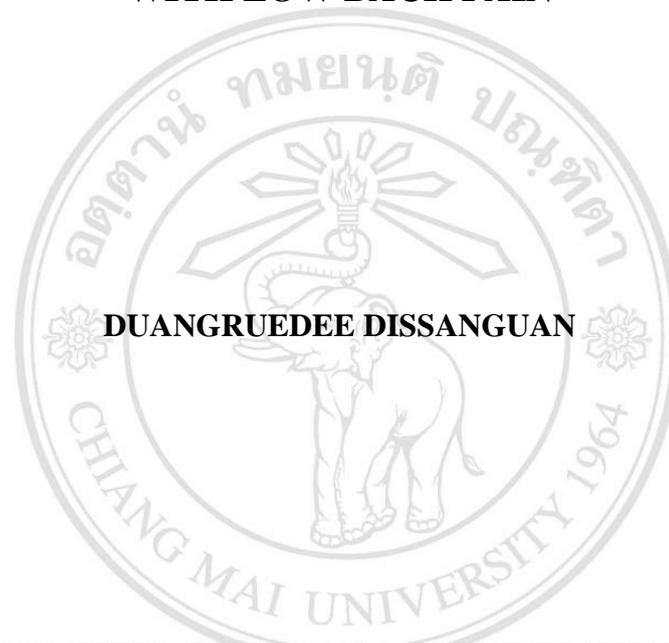
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**A THESIS SUBMITTED TO CHIANG MAI UNIVERSITY IN PARTIAL
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IN BIOMEDICAL SCIENCES**

**GRADUATE SCHOOL, CHIANG MAI UNIVERSITY
JANUARY 2021**

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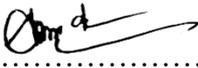
THIS THESIS HAS BEEN APPROVED TO BE A PARTIAL FULFILLMENT OF
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DOCTOR OF PHILOSOPHY
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Duangruedee Dissanguan

หัวข้อคุณลักษณะ	การศึกษาผลการรักษาของนวัตกรรมอุปกรณ์พยุงหลังที่มีการประคบร้อนและการให้ข้อมูลป้อนกลับของการทำงานกล้ามเนื้อแกนกลางในผู้ที่มีอาการปวดหลังส่วนล่าง	
ผู้เขียน	นางสาวดวงฤดี คิชสงวน	
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	ดร. ลีโอนาร์โด เฮนรี โจเซฟ	อาจารย์ที่ปรึกษาร่วม

บทคัดย่อ

อาการปวดหลังเป็นปัญหาสุขภาพที่พบอุบัติการณ์ได้สูงในประชาชนทุกประเทศ ซึ่งส่งผลกระทบต่อการทำงานและการดำรงชีวิตประจำวันค่อนข้างมาก อุปกรณ์พยุงหลังเป็นหนึ่งในอุปกรณ์ที่ได้รับการแนะนำเพื่อช่วยในการจัดการอาการปวดหลังส่วนล่าง อย่างไรก็ตามการใช้อุปกรณ์พยุงหลังยังมีการใช้งานที่จำกัด เนื่องจากความกังวลเกี่ยวกับภาวะแทรกซ้อนของกล้ามเนื้อลำตัวอ่อนแรงจากการใช้งานเป็นเวลานาน ดังนั้นจึงมีการออกแบบอุปกรณ์พยุงเอวใหม่โดยมีคุณสมบัติเพิ่มเติมในตัว เช่นการบำบัดด้วยความร้อนและอุปกรณ์ให้ข้อมูลป้อนกลับเพื่อออกกำลังกล้ามเนื้อแกนกลาง ทั้งนี้จำเป็นต้องมีการประเมินผลการรักษาของนวัตกรรมอุปกรณ์พยุงหลังที่มีการประคบร้อนและการให้ข้อมูลป้อนกลับของการทำงานกล้ามเนื้อแกนกลางลำตัวในการจัดการอาการปวดหลังส่วนล่างก่อนจะนำไปใช้จริงสำหรับประชากรที่มีอาการปวดหลัง

การศึกษาแรกมีวัตถุประสงค์เพื่อศึกษาประสิทธิผลในการลดปวดและเพิ่มคุณภาพชีวิตของการใช้อุปกรณ์พยุงหลัง โดยทำการรวบรวมบทความที่เกี่ยวข้องจากฐานข้อมูลโดยใช้คำสำคัญ “back pain, lumbar support belt, lumbar belt, back belt” ซึ่งระบุประสิทธิภาพของอุปกรณ์พยุงหลังในการลดอาการปวดและเพิ่มคุณภาพชีวิต พบการศึกษาทดลองแบบสุ่มและมีกลุ่มควบคุมที่คุณภาพดีจำนวน 5 บทความ ซึ่งการทบทวนอย่างเป็นระบบชี้ให้เห็นว่าการใช้อุปกรณ์พยุงหลังร่วมกับการดูแลรักษาตามปกติช่วยลดอาการปวดและคุณภาพชีวิตที่ดีขึ้นในผู้ที่มีอาการปวดหลังส่วนล่าง โดยการใส่เครื่องพยุงเอว 6 - 8 ชั่วโมงเป็นประจำทุกวันอย่างน้อยหนึ่งเดือนจะให้ผลในเชิงบวก การศึกษาที่สองมี

วัตถุประสงค์เพื่อพัฒนาและตรวจสอบความถูกต้องและความน่าเชื่อถือของอุปกรณ์ให้ข้อมูลป้อนกลับของการทำงานกล้ามเนื้อแกนกลางลำตัว โดยทำการศึกษาในอาสาสมัครสุขภาพดีจำนวน 20 คน อุปกรณ์ให้ข้อมูลป้อนกลับจะถูกติดที่ด้านในของอุปกรณ์พยุงหลัง อาสาสมัครทำ Abdominal drawing-in maneuver เพื่อกระตุ้นการทำงานของกล้ามเนื้อ Transversus abdominis โดยใช้ pressure biofeedback unit (PBU) ในการกำหนดเป้าหมายที่ 64, 66, 68 และ 70 mmHg ซึ่งค่าจากอุปกรณ์ให้ข้อมูลป้อนกลับจะถูกรวบรวมในเวลาเดียวกันกับการเก็บภาพอัลตราซาวด์ของกล้ามเนื้อ Transversus abdominis ทำการทดลองซ้ำอีกครั้งโดยเว้นช่วงระยะเวลา 24 ชั่วโมง การตรวจสอบความน่าเชื่อถือจะใช้ค่าสัมประสิทธิ์สหสัมพันธ์ภายในชั้น ค่าสัมประสิทธิ์การแปรผันและค่าความคลาดเคลื่อนมาตรฐานของการวัด ความถูกต้องของอุปกรณ์ได้จากการหาความสัมพันธ์ระหว่างค่าที่ได้จากอุปกรณ์ให้ข้อมูลป้อนกลับ และการทำงานของกล้ามเนื้อ Transversus abdominis ซึ่งวิเคราะห์โดยใช้สัมประสิทธิ์สหสัมพันธ์ของเพียร์สัน ผลการทดลองพบว่าความน่าเชื่อถือในการวัดซ้ำของอุปกรณ์ให้ข้อมูลป้อนกลับอยู่ในระดับดีเยี่ยม (ICC = 0.946, CV = 2.6%, SEMs = 0.54%) ค่าที่ได้จากอุปกรณ์ให้ข้อมูลป้อนกลับมีความสัมพันธ์ในระดับปานกลางอย่างมีนัยสำคัญกับการวัดการทำงานของกล้ามเนื้อโดยใช้อัลตราซาวด์ ($r = -0.514, p < 0.001$)

การศึกษาที่สามมีวัตถุประสงค์เพื่อศึกษาประสิทธิภาพของนวัตกรรมอุปกรณ์พยุงหลังที่มีการประคบร้อนและการให้ข้อมูลป้อนกลับของการทำงานกล้ามเนื้อแกนกลางลำตัวต่ออาการปวดหลังส่วนล่าง การทำงานของกล้ามเนื้อแกนกลางลำตัว ความสามารถในการทำกิจกรรม และคุณภาพชีวิต อาสาสมัครที่มีอาการปวดหลังส่วนล่างจำนวน 80 คน ถูกสุ่มแบ่งออกเป็น 4 กลุ่มๆละ 20 คน ดังนี้ 1) อุปกรณ์พยุงหลังทั่วไป 2) นวัตกรรมอุปกรณ์พยุงหลังร่วมกับการประคบร้อน 3) นวัตกรรมอุปกรณ์พยุงหลังร่วมกับการฝึกกล้ามเนื้อแกนกลางลำตัว 4) นวัตกรรมอุปกรณ์พยุงหลังร่วมกับการประคบร้อนและการฝึกกล้ามเนื้อแกนกลางลำตัว อาสาสมัครทุกคนจะได้ทดลองใช้อุปกรณ์เป็นเวลา 20 นาที และได้รับคำแนะนำในการใส่อุปกรณ์ด้วยตนเองทุกวันเป็นเวลา 8 สัปดาห์ ตัวแปรที่ศึกษาหลักได้แก่ ความรุนแรงของอาการปวดหลัง อัตราการไหลเวียนโลหิต ระดับขีดกันความเจ็บปวดจากแรงกด ระดับขีดกันความเจ็บปวดจากความร้อนและความเย็น และความหนาของกล้ามเนื้อ Transversus abdominis ตัวแปรที่ศึกษารองได้แก่ ความสามารถในการควบคุมความมั่นคงของเชิงกราน ขนาดของกล้ามเนื้อ Multifidus ความสามารถในการทำกิจกรรม และคุณภาพชีวิต ตัวแปรทั้งหมดถูกประเมินก่อนการรักษา หลังใช้อุปกรณ์ 20 นาที หลังได้รับการรักษา 4 สัปดาห์ หลังสิ้นสุดการรักษา และติดตามผล 3 เดือน ผลการศึกษาไม่มีอาสาสมัครหายไปในช่วงที่ติดตามผลการรักษา ตัวแปรที่ศึกษาหลักและรองในทุกกลุ่มดีขึ้นทุกช่วงของการติดตามผล ($p < 0.05$) ยกเว้นผลของขนาดกล้ามเนื้อ Transversus abdominis และ Multifidus และความสามารถในการควบคุมความมั่นคงของเชิงกรานที่

พบได้ในกลุ่มที่ 3 และ 4 เท่านั้น ผลการศึกษาในภาพรวมเมื่อเปรียบเทียบกับกลุ่มที่ 1 พบว่า อาสาสมัครกลุ่มที่ 2 และ 4 มีการลดลงของความรุนแรงของอาการปวด ระดับจิตใจความเจ็บปวดจากแรงกด ความร้อน และความเข็งมากกว่า อาสาสมัครกลุ่มที่ 3 และ 4 ($p < 0.05$) อีกทั้งมีขนาดของกล้ามเนื้อแกนกลางลำตัวและความสามารถในการควบคุมความมั่นคงของเชิงกรานมากกว่า ($p < 0.05$) ทั้งนี้ยังพบว่าอาสาสมัครในกลุ่มที่ 4 ความสามารถในการทำกิจกรรมและคุณภาพชีวิตที่ดีกว่า ($p < 0.05$) อีกด้วย

การศึกษานี้เสนอแนะว่าการใช้อุปกรณ์พยุงหลังมีประสิทธิผลที่ดีเมื่อใช้ร่วมกับการได้รับการดูแลรักษาตามปกติในการจัดการอาการปวดหลังส่วนล่างที่ไม่เฉพาะเจาะจง โดยใส่ 6-8 ชั่วโมงเป็นระยะเวลาอย่างน้อยหนึ่งเดือน นอกจากนี้นวัตกรรมอุปกรณ์พยุงหลังที่พัฒนาขึ้นยังมีความถูกต้องและน่าเชื่อถือสำหรับการใช้งานทางคลินิกเพื่อบ่งชี้การทำงานของกล้ามเนื้อ transversus abdominis การค้นพบโดยรวมชี้ให้เห็นว่านวัตกรรมอุปกรณ์พยุงหลังที่มีการประคบร้อนและการให้ข้อมูลป้อนกลับของการทำงานกล้ามเนื้อแกนกลางลำตัวนั้นมีประสิทธิภาพมากกว่าอุปกรณ์พยุงหลังแบบดั้งเดิม ซึ่งอาจพิจารณาใช้เป็นอุปกรณ์เสริมในการฟื้นฟูผู้ที่มมีอาการปวดหลังส่วนล่างเรื้อรังแบบไม่เฉพาะเจาะจง

Dissertation Title	Investigation of the Therapeutic Effects of an Innovative Lumbar Support Comprising Hot Pack and Core Muscle Activation Feedback in Individuals with Low Back Pain	
Author	Ms. Duangruedee Dissanguan	
Degree	Doctor of Philosophy (Biomedical Science)	
Advisory Committee	Assoc. Prof. Dr. Aatit Paungmali	Advisor
	Asst. Prof. Dr. Patraporn Sitalertpisan	Co-advisor
	Dr. Leonard Henry Joseph	Co-advisor

ABSTRACT

Low back pain is a health problem with a high incidence in people of all countries. It affects work performance and activity in daily living. Lumbar supports are suggested as one of the assistive devices in the management of low back pain. However, there was limited use due to the concerns about the complication of trunk muscle weakness from prolonged usage. Therefore, it was decided to redesign lumbar support with additional built-in features such as superficial heat therapy and biofeedback to exercise the core muscles. The therapeutic effects of innovative lumbar support including hot pack and core stability activation in the management of low back pain are warranty to prove before launching to the larger population.

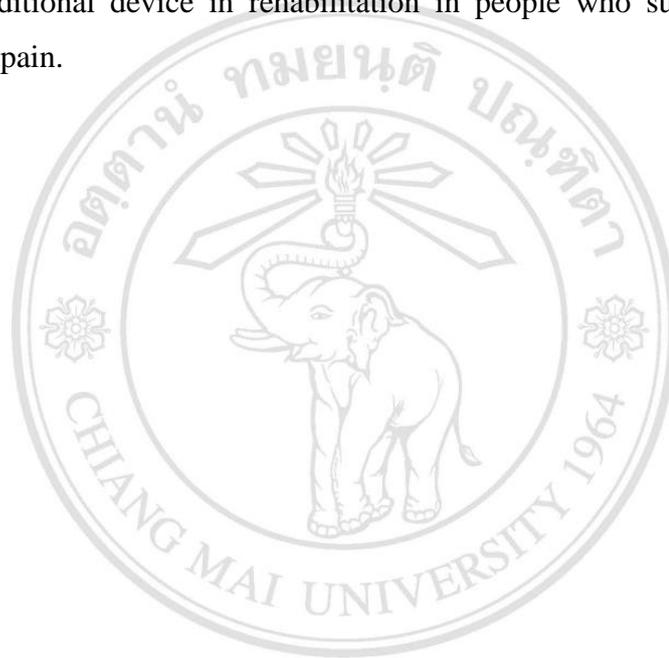
The first study aimed to explore the effectiveness of pain modulation and quality of life of the lumbar support belt in patients with low back pain. The relevant articles using keywords “back pain, lumbar support belt, lumbar belt, back belt” were collected from the databases to identify the effectiveness of lumbar support for pain reduction and quality of life. Five of them were good quality randomized controlled trials. A systematic review showed that using lumbar support with receiving usual care reduced pain and improved quality of life in individuals with low back pain. The prescription of lumbar support, which showed positive results, was wearing lumbar support 6 – 8 hours daily for at least one month.

The second study aimed to examine the validity and reliability of the feedback device for TrA muscle contraction. Twenty healthy participants were studied. The feedback sensor was applied at the front of the trunk attached to the lumbar support. Participants performed an abdominal drawing-in maneuver (ADIM) to activate TrA, and the values from the feedback sensor were collected at the same time. Ultrasound imaging of the TrA was also collected simultaneously. The feedback sensor collected values at the different clinical levels of the pressure biofeedback unit at 64, 66, 68, and 70 mmHg. The protocol was repeated with 24 hr. intervals. The intraclass correlation coefficient, coefficient of variation, and standard error of measurements were used to examine reliability. The validity of the values obtained from the relationship between the feedback sensor and TrA thickness was analyzed using Pearson's correlation coefficients. Results: Test-retest reliability of the feedback sensor was excellent (ICC = 0.946, CV = 2.6%, SEMs = 0.54%). The values of feedback sensor reported a significant moderate correlation with the gold standard ultrasound measurement ($r = -0.514$, $p < 0.001$).

The third study aimed to investigate the effectiveness of innovative lumbar support comprising hot pack and core muscle activation feedback on pain, muscle function, quality of life, and disability. Eighty participants with chronic non-specific low back pain were randomly allocated into 4 groups, 20 participants for each group: 1) traditional lumbar support, 2) innovative lumbar support with a hot pack, 3) innovative lumbar support with core muscle exercise, and 4) innovative lumbar support with a hot pack and core muscle exercise. All participants were instructed to use lumbar support daily for 8 weeks. The primary outcomes were pain intensity, pressure pain threshold, thermal pain threshold, tissue blood flow, and transversus abdominis muscle thickness. The secondary outcomes were lumbopelvic stability control, the cross-section area of lumbar multifidus muscle, quality of life, and disability. Blinded outcome measures were taken at baseline, 4-week intervals, after treatment, and at 3-month follow-up. The results showed that there was no loss to follow-up. All groups improved in primary and secondary outcome measures at all periods of assessment ($p < 0.05$) except the size of core muscles and lumbopelvic stability control, which were improved in only groups 3 and 4. Overall results when compared to group 1, participants in groups 2 and 4 had more significantly reduced in pain intensity, pressure pain threshold, and thermal pain threshold ($p < 0.05$), participants in groups 3 and 4 had greater core muscle size and core muscle

function ($p < 0.05$), and participants in group 4 had greater improved in quality life and disability ($p < 0.05$).

This study suggested that the lumbar support seems to be effective as additional intervention along with usual care in the management of non-specific low back pain and using 6 – 8 hours at least a month. The innovative device had potential reliability and validity for clinical usage to indicate transversus abdominis muscle activation. The overall finding highlights that innovative lumbar support comprising a hot pack and core muscle activation feedback is more effective than traditional lumbar support. It could be considered an additional device in rehabilitation in people who suffer chronic non-specific low back pain.



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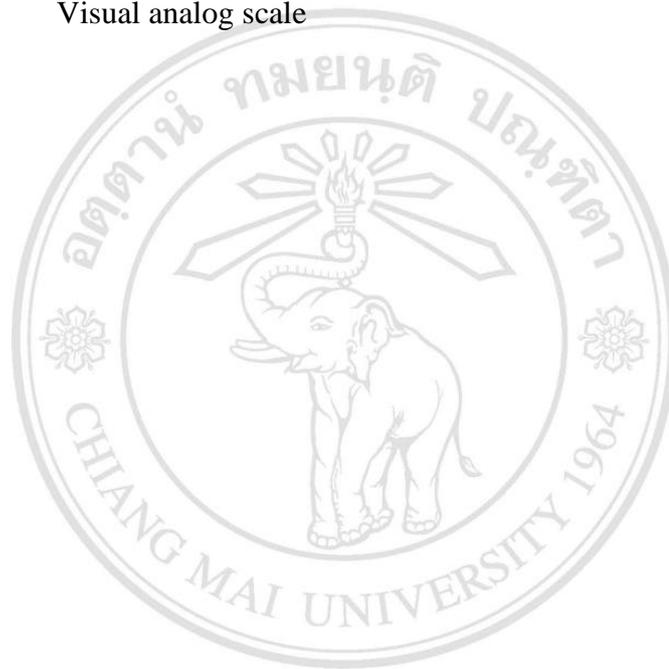
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LIST OF ABBREVIATIONS

ADIM	Abdominal drawing-in maneuver
ANOVA	Analysis of variance
ASLR	Active straight leg raising
BMI	Body mass index
BPU	Pressure Biofeedback Unit
CNLBP	Chronic non-specific low back pain
CNS	Central nervous system
CPT	Cold pain threshold
CSA	Cross sectional area
CSE	Core stability exercise
CV	Coefficient of variation
EMG	Electromyography
EO	External oblique
HPT	Heat pain threshold
IAP	Intra-abdominal pressure
ICC	Intraclass correlation coefficients
IO	Internal oblique
LBP	Low back pain
LM	Lumbar multifidus muscle
LPS	Lumbopelvic stability
LPST	Lumbopelvic stability test
LS	Lumbar support
MCID	Minimal clinically importance difference
MVC	Maximal voluntary contraction
ODI	Oswestry Disability Index
PEDro	Physiotherapy Evidence Database scale
PPT	Pressure pain threshold
RCT	Randomized controlled trial

RDQ	Roland-Morris Disability Scale
RTUS	Real-time ultrasound
SEMs	Standard error of measurements
SHT	Superficial heat therapy
TBF	Tissue blood flow
TLS	Traditional lumbar support
TPT	Thermal pain threshold
TrA	Transversus abdominis muscle
VAS	Visual analog scale



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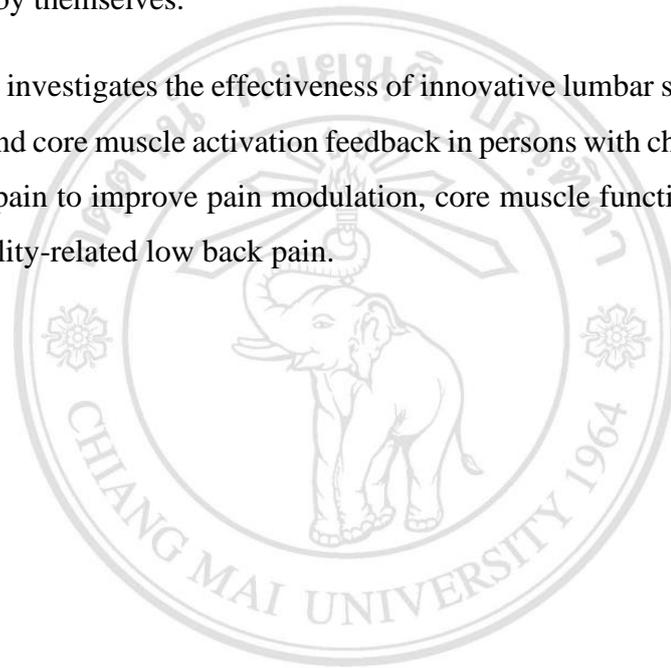
ข้อความแห่งการริเริ่ม

- 1) วิทยานิพนธ์นี้เป็นการคิดค้น พัฒนานวัตกรรมในการฟื้นฟูรักษาอาการปวดหลังส่วนล่าง ซึ่งเป็นการรวมกันของแนวทางการรักษาที่มีประสิทธิภาพทางกายภาพบำบัด ได้แก่ อุปกรณ์พยุงหลัง การรักษาด้วยความร้อนชื้น และการออกกำลังกายกล้ามเนื้อแกนกลางลำตัว เพื่อใช้เป็นอุปกรณ์เสริมที่ผู้ป่วยสามารถนำไปในการบำบัดรักษาอาการปวดหลังส่วนล่างได้ด้วยตนเอง
- 2) การศึกษานี้ได้ทำการตรวจประเมินประสิทธิภาพในการบำบัดรักษาของนวัตกรรมอุปกรณ์พยุงหลังที่มีการประคบร้อนและการให้ข้อมูลป้อนกลับของกล้ามเนื้อแกนกลางในผู้ที่มีอาการปวดหลังส่วนล่างเรื้อรัง เพื่อช่วยพัฒนาแนวทางปฏิบัติทางคลินิกในการลดอาการปวดหลังส่วนล่าง เพิ่มการทำงานของกล้ามเนื้อแกนกลางลำตัว เพิ่มคุณภาพชีวิต รวมไปถึงลดความบกพร่องในการทำกิจกรรมอันเนื่องมาจากอาการปวดหลัง

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STATEMENTS OF ORIGINALITY

- 1) This study creates and develops a new rehabilitation device that combines the effective treatment methods in physical therapy including lumbar support, superficial heat therapy, and core muscle training for considering use as an additional treatment device that patients can use to manage their low back pain symptom by themselves.
- 2) This study investigates the effectiveness of innovative lumbar support comprising hot pack and core muscle activation feedback in persons with chronic non-specific low back pain to improve pain modulation, core muscle function, quality of life, and disability-related low back pain.



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CHAPTER 1

Introduction

Low back pain (LBP) is one of the most common musculoskeletal disorders in the general population. LBP can be caused of disability that affects working performances (1, 2). About 60 - 70% of the population suffered from LBP at least once in their lifetime (3). The prevalence of chronic low back pain is about 23%, with 11-12% of the population being disabled by low back pain (1). There are various treatments for LBP, such as medication, acupuncture, massage, and physical therapy. In previous clinical studies, superficial heat therapy (SHT), core stability exercise (CSE), and lumbar support (LS) were commonly used for physical therapy management of chronic LBP due to good efficacy and fewer complications.

Furthermore, the systematic review (4) suggested that SHT was commonly used for LBP management, both by physical therapists and patients at home, because of its good efficacy and convenience. SHT also decreased pain intensity and improved quality of life (4, 5). CSE provides both short- and long-term benefits by improving spinal stability, resulting in pain relief and prevention of LBP episodes (6). Moreover, lumbar support is practical for LBP management as it improves the lumbar posture, provides support to the lumbar spine, and minimizes LBP incidence (7). Several studies and mechanisms of action in the literature support the benefits of these potential physical interventions (i.e., SHT, CSE, LS) for LBP management.

SHT is commonly used in the management of LBP. The effects of SHT are associated with reducing muscle spasms, pain, anxiety, and disability (8). SHT increases blood flow, cellular metabolic rate, provides sedative effects and analgesia. A randomized controlled trial study (9) reported that SHT significantly benefited from the prevention and treatment of delayed onset muscle soreness condition for the low back region. SHT is more effective than oral acetaminophen or ibuprofen for short-term pain relief and improved physical functions, as evaluated by the Roland-Morris Disability Questionnaire

(RDQ) (4, 5). SHT is cost-effective when compared with oral analgesics in the management of LBP (10). However, previous studies' outcomes were often in the form of subjective information such as pain intensity by visual analog scale, the number of days with LBP, and disability questionnaire. There is limited evidence concerning clinical aspects, physiological changes, and various objective outcomes such as tissue blood flow, mechanical pain, and thermal pain to determine the pathological change and improvement of LBP condition.

Core muscles, such as deep abdominal and back muscle contribute to trunk stability (11). LBP patients have reduced core muscle strength and core stability (12). The onset of contraction of deep abdominal muscles in chronic LBP is delayed while doing limb movements (11). CSE is an effective management to minimize the disability in chronic LBP (13) and reduce the recurrence of LBP (14). CSE provides adequate dynamic control of the lumbar spine that eliminates repetitive injury to spinal segments' structures and related structures (14, 15). CSE improves the strength and endurance of deep muscles such as transversus abdominis (TrA) and lumbar multifidus muscle (LM) (16). A systematic review (6) suggested that the CSE combined with manual therapy are more effective than treatment by general practitioner alone in both short term and long term outcomes on disability and pain. Most studies considered the effects of core stability training and core muscle changes in terms of subjective assessments using questionnaires. There is a need for studies that evaluate muscle thickness and function of core muscles (using meaningful clinical measures such as real-time ultrasound imaging and lumbopelvic muscle function) to evaluate the effectiveness of LBP treatment methods.

Lumbar support is frequently used in LBP management to prevent the onset and recurrent back injuries (7, 17). LS affects the restriction of lumbar movement, decreases the load on the trunk, and increases intra-abdominal pressure (18). Also, LS is reported to reduce pain intensity and the number of days lost from work (17-19). A systematic review (7) showed that lumbar support improved functional ability more than superficial massage. However, some previous studies showed that using lumbar support for a longer period led to decreased abdominal and back muscle activity (20). Several studies (18, 21, 22) documented the effects of LS through reduced pain intensity, improved quality of life, and enhanced work performance. Therefore in this study, it is important to consider assessing the therapeutic effects of LS in the LBP population.

The effectiveness of using lumbar support for the prevention and management of low back pain was demonstrated in previous systematic reviews (7, 23). However, there were no systematic reviews that gathered how to use lumbar support for management of low back pain effectively (for example, in terms of types of LS, cases of application, a period of wearing LS per day, frequency of wearing LS, duration of total intervention, and possible adverse effects). Therefore, this thesis performed a systematic review to explore the clinical application of lumbar support for the management of low back pain effectively.

Innovations in health care service lift the professional practice to advanced levels. Innovative physical therapy care for LBP is always most welcomed for the benefit of patients and therapists. This brings about the idea of innovative development for the management of LBP. Although using a combination of lumbar support, superficial heat therapy, and core stability exercise seems to be the potential effective management of LBP, there are no biomedical innovations that combine these treatments' concepts. If available, the patients can obtain all three treatment methods simultaneously and be able to manage themselves while being at home or doing routine work. Combining treatment innovation was an additional tool for managing LBP and providing clinical benefits for LBP patients. Therefore, this thesis study developed innovative lumbar support that combined potential therapeutic methods (i.e., SHT and CSE) for low back pain people. Furthermore, this study also investigated the therapeutic effect of innovative lumbar support in individuals with low back pain.

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CHAPTER 2

Literature Review

This review of literature provides an overview of research findings related to low back pain. The first and second sections are the review of characteristics and biomechanical changes of low back pain. The third section focuses on the outcome measures related to low back pain. The last section is a review of the potential components for the development of innovation for the management of LBP

2.1. Characteristics of low back pain

2.1.1 Definition

Low back pain (LBP) (1, 24) is pain and discomfort between the 12th rib and inferior gluteal fold, with or without leg pain. Some cases are specific LBP, such as infection, trauma, structural deformity, tumor, fracture, spinal stenosis, and disc herniation. However, most of the cases are defined as non-specific LBP.

Non-specific LBP is general back pain and not focusing on the specific pathology. There is no indication of the structure which causes the pain. Although there is no structural change in non-specific LBP, it can cause poor health status, activity limitation, and disability.

2.1.2 The epidemiology of LBP

The lifetime prevalence of LBP in the general population was estimated at 60– 70%. One-year prevalence was about 15– 45%. The LBP prevalence increased and peaked between 35 to 55 years old (3). Approximately 20 - 44% of LBP patients can be found in the working population and usually have recurrent episodes within one year (24).

2.1.3 The classification of LBP

Low back pain can be divided into three episodes according to the duration of pain (24).

- Acute LBP is sudden onset and lasting less than six weeks. Patients with acute LBP often reported high levels of pain, distress, and muscle guarding. Most cases will recover within six weeks (25), and 10 – 15% of patients can become chronic LBP.
- Sub-acute LBP is lasting about 6 to 12 weeks. It is the continuation of the acute phase. Patients with sub-acute LBP should receive a rehabilitation program to prevent transition to chronic LBP.
- Chronic LBP is lasting for more than 12 weeks. It can be constant or intermittent pain for more than one time in 12 months. Pain has occurred gradually and steadily. The characteristics of pain may be unclear, such as the duration of pain. Most are caused by degeneration, lack of exercise, obesity, and psychosomatic pain disorders. Moreover, psychosocial factors may also be involved in chronic LBP (1).

2.1.4 Characteristics and symptoms of low back pain

In clinical guidelines, diagnosis of low back pain is described in the form of diagnostic triage. Patients are classified as having non-specific LBP, specific LBP, and sciatica/radicular syndrome (24). The red flag is used as an indicator of possible pathology, including nerve root problems. Red flags include age < 20 or > 55 years, non-mechanical pain, thoracic pain, history of carcinoma or HIV, feeling unwell, weight loss, widespread neurological symptoms, and structural spinal deformity. Indicators for nerve root problems are unilateral leg pain more than back pain, radiates to foot or toes, numbness and paresthesia, straight leg raising test induces more leg pain, and localized neurology. When red flags are not present, patients are considered to have non-specific low back pain (26). In general, most pain and related disability can resolve within a couple of weeks (25), and most patients with low back pain have stopped consulting the doctor within three months (27). However, patients with low back pain can be developed to

chronic low back pain if they have the risk factors for chronicity (e.g., obesity, high level of pain or disability, depressive mood, job dissatisfaction) (28).

2.1.5 Contributing factors related to low back pain

The factors that contribute to LBP are divided into two factors, internal factors and external factors.

2.1.5.1 Internal factors related to low back pain

1) Effects of age on low back pain

Aging is more likely to result in more low back pain episodes. It was the result of the degeneration of body structures and the decreased flexibility with age. The aging process causes the collagen to break down, increasing tension of muscles and ligaments (29).

2) Effects of gender on low back pain

Females have more chance to occur LBP than males because there are less muscle mass and strength. Besides, sex hormones play an essential role in degenerative musculoskeletal diseases. A study demonstrated the higher prevalence in adolescent girls than boys due to psychological factors, female hormone fluctuation, and menstruation. LBP prevalence also increased in post-menopausal women than men due to relative estrogen deficiency (29).

3) Effects of physical factors on low back pain

Weight and height were physical factors that affected the chance to occur low back pain. Taller people had more potential risk for low back pain due to external loading (30). The meta-analysis demonstrated that overweight and obese people had a higher prevalence of low back pain than healthy people (31). Obese people often had abdominal muscle weakness, and the center of mass also shifted forward, resulting in more back muscle working to achieve balance (32).

2.1.5.2 External factors related to low back pain

1) Effects of occupational factors on low back pain

Low back pain is associated with working postures such as static work posture, prolonged trunk bending or twisting, and repetitive trunk movement (3). These postures can increase the risk of LBP because of unrecovered fatigue of muscles. In addition, heavy physical work such as lifting can affect the higher risk of LBP in workers because the spine must support more weight for a long time. It resulted in the degeneration of the lumbar spine and the imbalance working of muscles and ligaments, which lead to low back pain (3).

2) Effects of smoking on low back pain

The meta-analysis (33) demonstrated that smokers had a higher prevalence of LBP than non-smokers. The nicotine in cigarettes disrupted the disc's metabolism process, resulting in faster degeneration of the disc. Moreover, prolonged smoking reduced oxygen in the blood, which affected the tissue healing process.

2.1.6 The management of low back pain

The goals of LBP management are pain reduction, improvement of activity, and disability (3). The treatment of LBP can be divided into conservative treatment and surgery (34). Conservative treatments intended to reduce pain and prevent a recurrence, such as resting, are recommended for acute low back pain patients. In addition, medications, physical therapy, and alternative medicine are also used for treating low back pain. Surgery is an effective treatment in reducing pain for patients who have indications of surgery. Patients with low back pain treated by surgery are usually caused by nerve root compression or cord compression. The criteria used to consider surgery include severe leg pain that persists for more than four weeks or leg muscle weakness. However, surgery has little benefit for patients without surgery indications, and there may be a risk of complications after surgery.

In physical therapy, there is various management of low back pain used in the clinical setting (e.g., manual therapy, exercise therapy, thermotherapy, orthotics, etc.). This thesis focused on chronic low back pain management. The systematic reviews (35,

36) demonstrated the positive effect of exercise therapy in reducing pain and functional improvement. Exercise is likely to decrease the risk of recurrent back pain due to returning to normal function (35). The evidence suggested that exercise therapy was more effective than back school or physician consultation alone for chronic low back pain due to restoring normal lumbosacral motion and strengthening trunk muscles (37). Another systematic review (13) reported that core stability exercise is superior to the other types of exercises (e.g., strengthening exercises, stretching exercises) in reducing pain and disability. Therefore, exercise therapy is likely to be an effective treatment for chronic low back pain due to the promotion of the related structures to function normally. In addition, superficial heat therapy is one of the traditional treatments that are commonly used. A randomized controlled trial study reported that superficial heat therapy was effective in pain relief and disability improvement (38). It was also found that superficial heat combined with exercise was more effective than only superficial heat or exercise (39).

Moreover, lumbar support is a common additional device prescribed for the treatment and prevention of low back pain. A systematic review (5) showed that wearing lumbar support improved disability in patients with low back pain more than superficial massage. Lumbar support was also reported in reducing pain intensity and the number of days lost from work (17, 19).

2.2 Biomechanical changes in patients with low back pain

2.2.1 Low back pain and trunk muscle activation

Alteration in the recruitment of trunk muscles has been reported in people with low back pain. A previous study (40) described this change in the context of the pain–spasm–pain model that pain results in increased muscle activity referred to spasm, which will cause pain. Treatment modalities based on this model involve relaxation and reduce guarding and spasm of involved muscles. For the pain adaptation model, pain results in reducing muscle activation when active muscles are agonists. Several studies (41, 42) showed that patients with CLBP had deficits in muscle strength and fatigue resistance. The highly fatigable back muscles may result in the development of LBP. In patients with CLBP, the ability of core muscle function was decreased. The study of TrA and LM muscle activity using electromyography (EMG) showed lower maximal

voluntary control during abdominal hollowing than healthy subjects (43). It related to the study using ultrasound imaging for evaluating core muscle function. The thickness of abdominal muscles and the size of LM muscle were smaller in patients with CLBP. They also had less muscle contraction (TrA and LM) during abdominal hollowing (44). Moreover, a previous study (12) reported that patients with CLBP had delayed onset muscle activation of TrA during lower limb movement. Therefore, it is important to consider the changes in deep trunk muscles in the choice of LBP management methods.

2.2.2 Low back pain and lumbopelvic instability

Lumbopelvic stability consists of three components: passive subsystem, active subsystem, and neural control subsystem. A previous study compared lumbopelvic stability between healthy subjects and patients with LBP. There was no correlation between the severity of the passive subsystem (e.g., facet joints, discs, ligaments) damage and the intensity of lumbar symptoms (45). It seems that active and neural control subsystems are more crucial for training and adaptation. The active subsystem can be divided into global (superficial paraspinal muscles) and local (core muscles) muscles. People with chronic low back pain (CLBP) were commonly demonstrated to decrease core muscle function, which is the key structure of the spinal stability components (43, 44). Therefore, patients with CLBP had reduced the stability of the spine. Moreover, patients with chronic pain condition also had an impairment of motor control. Impaired motor control can lead to poor control of joint movement, repeated microtrauma, and pain. The muscle system's efficacy depends on its controller, the central nervous system (CNS). The CNS continually interprets the status of stability and movement, plan mechanisms to overcome predictable challenges, and rapidly initiates activity in response to unexpected challenges (46). Several studies (12, 47) showed the impairment of the neural control subsystem according to the motor control, such as patients with CLBP that had a slower response for unexpected limb movement and delayed activity of TrA during rapid limb movement. Lumbopelvic instability can lead to the excessive movement of the unstable spine, could stretch or compress the pain-sensitive structure and lead to more injuries (48). There were lumbopelvic stability evaluations used in clinical such as the active straight leg raising test (ASLR) (49) and the modified lumbopelvic stability test (50). The results showed in the same direction that patients with CLBP had more

inadequate motor control. Therefore, lumbopelvic stability is important in considering methods for treatment and prevention of LBP.

2.3 The outcome measurements related to LBP

2.3.1 Pain-related outcomes

Pain reduction is one of the important goals for the management of low back pain. Thus, the parameters assessing pain severity are determined in the investigation of treatment effects.

2.3.1.1 Pain intensity

Pain intensity is a quantitative estimate of the severity of perceived pain. There are various tools to assess pain intensity in low back pain, such as a numerical rating scale (NRS) and visual analog scale (VAS). The numerical rating scale (NRS) is a discontinuous scale that is in numeric format. Pain intensity is rated on 11- point scale where 0 indicates no pain and 10 indicate worst pain (49). The visual analog scale is a continuous scale consisted of a horizontal line, 100 millimeters in length. It is anchored by “no pain” on the left hand and “pain as bad as possible” on the right hand. The systematic review of measures used to assess chronic musculoskeletal pain reported that the visual analog scale (VAS) was the most commonly used tool (51). Although the numerical scale may easy to use, it has an inherent lack of sensitivity due to the digital scales (51). The visual analog scale was reported more sensitivity to change in pain intensity (52). Thus, many recent studies (53-55) have been used a VAS as a parameter to assess pain intensity. A reported minimum clinically important difference (MCID) of VAS in the chronic low back pain population equaled to 18 - 19 mm. (56). However, pain intensity assessment, especially VAS, is the subjective examination that affects gender. A previous study reported that females had higher pain rates and experienced more severe pain than males (57). In addition, the rate of pain from chronic disease was higher in females than males (58). It might be suggested that female was more sensitive to pain perception than male. Factors that affect the differences in the pain assessment between genders are stimulus-specific factors (e.g., pressure, heat, electrical), sex-role expectation, psychological factors, and neural differences (58-60). Therefore, gender is an essential factor in pain assessment. A research model that considers the influence and gender difference of pain should be recognized in the research process.

2.3.1.2 Pressure pain threshold (PPT)

The sensory perception of mechanical pain can be evaluated by a pressure pain threshold, a parameter for assessing the level of pain induced by pressure. A pressure pain is based on A-delta fibers' activation, a thin myelinated sheath (61). Pressure Pain Threshold is the minimal amount of pressure that produces pain (62). In people with abnormal sensory perception, there is a hypersensitivity to stimulus. Pain can be exacerbated even when there is little mechanical pressure. This hypersensitivity is a typical characteristic of primary hyperalgesia.

Currently, a pressure algometer is commonly used for assessing pressure pain threshold (61). Jensen and colleagues (63) measured the PPT of the temporalis muscle in healthy subjects using a pressure algometer. There was a high correlation between the sides of temporalis muscles ($p < 0.001$) and between PPT values obtained with a 3-week interval ($p < 0.001$). They suggested that a pressure algometer was a reliable method to evaluate PPT, and it was easy and convenient to operate in the clinical setting. In most previous studies (64, 65), a probe with a 1 cm diameter was used because the probe's size was equivalent to the fingertip while providing pressure. The target area should be greater than 0.5 cm or 0.196 cm² so that the force can be transmitted to the deep tissue. The amount of pressure passed to the tissue is at a minimum level, safe and can induce pain quickly (66). The pressure pain threshold was demonstrated excellent reliability (ICC = 0.99), and it was suitable for assessing the sensitivity to response (67). However, the measurement was more reliable if it was performed by only one assessor (68).

In long-term musculoskeletal pain conditions, the evidence reported sensory perception alteration (62, 69-71). Pain perception change due to pressure stimuli was found in patients with LBP (62, 70, 71). Farasyn and colleagues (70) demonstrated that patients with subacute LBP had lower PPT than healthy controls ($P < 0.0001$). The lowest PPT in patients with subacute LBP was lowest at the L3 and L5 erector spinae levels. The studies by Imamura et al. (62) and Ozdolap et al. (71) also reported lower PPT in patients with chronic non-specific LBP than healthy subjects. There was a negative correlation between PPT and disability score. Ozdolap et al. (71) also found the lower PPT at an unaffected area in patients with CLBP, suggesting

widespread pain in CLBP. Pressure pain threshold is one of the potential parameters in investigating the effectiveness of treatment for LBP.

Factors affecting the pressure pain threshold that were gender and age (72-75). Males exhibited a higher-pressure pain threshold than females. In other words, females had more sensitive than males. The decrease in pressure pain threshold indicated the sensitivity to pain (76). Age also affected the pressure pain threshold. Jensen and colleagues (77) demonstrated that pressure pain thresholds varied by age. As the age increased, the pressure pain threshold increased as well. In addition, external factors were affecting the pressure pain threshold. The size of the probe should be appropriate to the target area. A 1 cm diameter probe was mostly used due to the size close to the fingertip while providing pressure, and the pressure distribution was better than using a small probe (64). The angle of the probe is also important. It must be perpendicular to the target area for good pressure distribution (not to slide against the tissue). It also reduced the probe shift during providing the pressure that often occurred while providing high pressure (78). Another important factor is the rate of delivering pressure. Increasing at a slower rate, such as 40 kPa/s will make the subjects better aware of the pressure than increase with faster speed. This strategy can reduce the overestimation generated by the subject's reaction time response mechanism. The pressure control is should also be constant (63).

2.3.1.3 Thermal pain threshold (TPT)

The level of response to sensory stimulation with thermal pain can be evaluated by the thermal pain threshold, which is based on the activation of A-delta fibers (thin myelinated sheath) and C fibers (unmyelinated sheath) (61). Thermal pain threshold has been used as an outcome measure of the therapeutic effect of treatment for musculoskeletal disorders. It is a reliable variable (ICC = 0.87) (79). Those with secondary hyperalgesia are more sensitive to stimuli and have higher pain intensity, especially mechanical pain but not thermal pain (80).

TPT is divided into two types, including heat pain threshold and cold pain threshold (81). The heat pain threshold is the minimum temperature that produces pain from heat, as the cold pain threshold is the minimum temperature that produces pain from cold. Previous studies (82) demonstrated the increased sensitivity to cold and heat pain in people with persistent pain more than healthy controls. The

significant differences showed in the cold more than heat pain. Hubcher and colleagues (83) reported that patients with chronic pain demonstrated a lower cold pain threshold in the primary area of pain than healthy controls. This report may suggest that the central nervous system's abnormal response can occur in patients with persistent pain, and the cold pain threshold may be more sensitive than the heat pain threshold.

Gender and age were important factors affecting the thermal pain threshold. Fillingim and colleagues (84) found a lower thermal pain threshold in females compared with males, both stimulation with the slow rate (0.5 Celsius per second) and with the fast rate (4.0 Celsius per second). Increasing temperature with a slow rate stimulated the C-fibers while increasing with a fast rate stimulated the A-delta fibers. Heat pain threshold produced a good response when stimulating with a slow rate. Edwards and colleagues (85) found a different response to thermal pain stimulation in older adults and younger. Thermal pain response related to age, severity, and impact of chronic pain. Older adults had higher pain perceived intensity when induced by high temperature (e.g., 49 and 51 degrees Celsius) than younger and middle age (86). This report could be explained that the elderly were more likely to experience a decrease in thermal pain threshold due to the reduction of ability to discriminate feeling about temperature, which may be caused by the defects of A-delta and C fibers (87). In addition, anxiety and depression were also the causes of pain severity increasing, especially in females who often experienced anxiety and depression more than males. The occurred pain could stimulate psychological problems (73). Harkins and colleagues (86) also found a relationship between the thermal response and the effect of psychological status in the middle age and elderly. Thermal pain threshold is the sensitive variable to temperature response, but many factors contribute to factors such as gender, age, and mental health that influence thermal pain perception. Thus, these factors should be controlled to reduce the variance of the measurement.

The receptors in tissue are primarily stimulated by mechanical and thermal stimuli and delivered the nociceptive impulse through neurotransmitters. If there are increases in receptor response to noxious stimuli, it is called peripheral sensitization. Then, peripheral nerves delivered the sensory input to the central nervous system in the dorsal horn of the spinal cord. The modification of sensory input signals in the central nervous system leads to central sensitization, increasing the magnitude and duration of

response to the noxious stimuli. This is the cause of primary hyperalgesia. If it is spread to the uninjured tissue surrounding the injury site, it is secondary hyperalgesia. Therefore, pressure pain threshold and thermal pain threshold are essential variables for evaluating mechanical and thermal stimuli' response. Chronic pain conditions often result in an abnormal response in the central nervous system. It can lead to alterations of the central processing mechanism, promoting neural plasticity at the spinal cord, thereby affecting somatosensory performance. In patients with CLBP, there were changes in somatosensory sensation, especially pressure pain threshold, thermal pain threshold and tissue hyperalgesia. Persistent nociceptive impulses in CLBP are related to cortical and subcortical reorganization. The potential alteration in the somatosensory system may be due to alteration in the cerebral cortex and neurochemical changes. The management of CLBP might be associated with these changes (88). Thus, the pressure pain threshold and thermal pain threshold measurements were used to evaluate the effectiveness of the treatment for the patient with chronic low back pain in this study.

2.3.1.4 Tissue blood flow

Tissue blood flow (TBF) is the factor to indicate the quality of healthy tissue and its potential for the healing process. Increasing TBF to pathological areas may help facilitate the tissue healing process by supplying more oxygen, nutrients, and hormones to the affected area and removing waste products from the tissue (89). Various physical therapy treatments such as massage, hot packs, and physical exercise are considered to induce vasodilation and increase tissue blood flow (89-91). Therefore, tissue blood flow was widely used as outcome measures to evaluate the physiological effect of treatment (89, 92). In addition, tissue blood flow measurement was reported as a good reliable (ICC = 0.89) and suitable method (79). Okada and colleagues (92) demonstrated increased blood flow in masseter muscles after hot packs were applied for 20 minutes. Furthermore, Paungmali and colleagues (89) reported that tissue blood flow immediately increased in the lumbosacral area after performing lumbopelvic core stability training.

Therefore, tissue blood flow is one of the most important variables for indicating and evaluating the therapeutic effect of treatment for tissue response

through a laser doppler flow meter sensitive to the circulatory response. It is also easy and convenient to use for clinical assessment.

2.3.2 Functional disability and quality of life

The restoration of normal function is considered a key outcome of physical therapy for low back pain management. This thesis also assessed the functional disability and quality of life of individuals with chronic low back pain after interventions.

2.3.2.1 Disability related to low back pain

Chronic low back pain has been reported to be limited to the individual functional ability. It can cause long-term disability and absence from work (93). Self-report questionnaires that aim to evaluate functional limitation due to low back pain have been developed in various forms. The two most commonly used disability scales for people with low back pain are the Roland-Morris Disability Scale (RDQ) and the Oswestry Disability Index (ODI). The RDQ was developed in 1983 for use in primary care. It consists of 24 items with yes or no response, representing the execution of daily physical activities and functions that may be affected by low back pain (e.g., housework, sleeping, mobility, dressing, etc.). The RDQ total score is calculated by the sum of the “yes” answers or the checked items. The total score ranges from 0 (no disability) to 24 (maximum disability) (94). The Oswestry Disability Index Questionnaire was developed by John O’Brien et al. in 1976 for assessing pain related to disability in people with low back pain. It consists of 10 questions with six response categories of the disturbance in activity daily living through low back pain. It covered 1 item on pain and nine items on daily living activities (personal care, lifting, walking, sitting, standing, sleeping, sex life, social life, and traveling). Each item is scored from 0 (first response option) to 5 (last response option), and the percentage is calculated for the total score. Interpretations of total scores are as follow: 0-20 indicates “minimal disability,” 21-40 indicates “moderate disability,” 41-60 indicates “severe disability,” 61-80 indicates “housebound,” and 81-100 indicates “bedbound” (94). Sanjaroensuttikul and colleagues (95) translated the ODI Thai version in 2007, and it was initially evaluated the validity in patients with acute low back pain. The ODI Thai version has a good consistency for disability assessment in acute low back pain (The content validity of each item ranged from 0.6-1.0, and the Cronbach's alpha of all items was 0.8107). The ODI Thai version by Nimanussornkul (96) was also

reliable for assessing functional disability in chronic low back pain with radiculopathy. (The Cronbach's alpha of all items was 0.891. The inter-item correlation coefficient for the ten items ranged from 0.177 to 0.699).

Although, both instruments were validated questionnaires to evaluate functional disability in the low back pain population. The ODI was more sensitive to detect changes due to the level of limitation in each activity.

2.3.2.2 Quality of life

Health-related quality of life becomes widely used in clinical researches. A previous study reported people with chronic low back pain decreased in quality of life in dimensions of physical, psychological, and work categories (93). It is also essential to measure the perception of health to assess the benefit of interventions.

The short form 36 health survey (SF-36) is the most widely used for measuring health status. The SF-36 is subdivided into physical component score and mental component score. It consists of eight health dimensions, including physical functioning, social functioning, role limitations due to physical problems, role limitation due to emotional problems, mental health, energy and vitality, pain, and general perception of health. It takes the patients about 5 – 10 minutes to complete. The SF-36 was studied in the population with chronic low back pain, and its reliability and validity were well-established (97). In addition, Jirattanaphochai and colleagues (98) translated SF-36 version 2.0 to the Thai version and evaluated the reliability in both acute and chronic low back pain patients. The study showed that the Thai version of SF-36 version 2.0 is reliable for assessing the quality of life in low back pain patients (The Chronbach's alpha coefficient of eight scales ranging was 0.72 - 0.94).

Moreover, SF-36 was developed into an abbreviated version, called SF-12. The SF-12 contains a subset of 12 items taken from the 8-health dimension of SF-36. It was developed to lessen administration time. However, it was not widely used in researches as SF-36 (99).

2.3.3 Muscle function measurement related to LBP

2.3.3.1 Real-time ultrasound imaging (RTUS)

Ultrasound imaging is a radiological tool for pathological investigation. It is widely used in health professions due to its safety, cost-effectiveness, and readily accessible internal organ and musculoskeletal structure examination methods. Tissues that can be imaged by ultrasound imaging include muscles, tendons, joints, ligaments, and bursa (43).

The gold standard measurements of muscle activity are electromyography (EMG) and real-time ultrasound imaging (RTUS) (43, 100). EMG is an invasive method that inserted a fine-wire electrode into the muscles, limiting adoption (43). Real-time ultrasound imaging is a non-invasive method of recording muscle activity in deep layers. It has been used to measure muscle size and thickness during static and dynamic contractions. Some muscles are restricted by the deeper layers of muscles such as TrA and LM, which are located close to the spine. Hodges and colleagues (101) compared ultrasonography for measuring muscle architectures with EMG activity. Subjects performed isometric contractions from 0 to 100% maximal voluntary contraction (MVC). There was a strong relationship between EMG activity of TrA and IO and changes in muscle thickness. Real-time ultrasound imaging was the reliable method for measuring lateral abdominal muscle thickness (TrA, IO, and EO) ($ICC > 0.93$), and it was also a high correlation with EMG activity of LM ($r = 0.79$, $p < .001$) (100).

The association between low back pain and deep local core muscle function had been reported. Several studies (44, 47) used RTUS to evaluate the muscle function of TrA and LM in terms of muscle thickness, cross-sectional area, and contraction ratio. Ferreira and colleagues (47) assessed the change in TrA muscle recruitment in individuals with low back pain. They found that the LBP group had a smaller increase in TrA thickness during isometric leg tasks than controls. Similarly to the TrA result, there were significantly lesser CSA and a percentage of LM contraction thickness (44). It might represent the alteration of motor control in individuals with LBP. Moreover, previous study 108 demonstrated that RTUS showed improved TrA recruitment about 7.8% after motor control exercise training for eight weeks.

This thesis developed innovative lumbar support including core stability activation. Thus, real-time ultrasound imaging on the size of core muscles is an important parameter to indicate the activity of deep core muscles, which is a non-invasive technique and considered equivalent to using electromyography.

2.3.3.2 Active straight leg raising test

Active straight leg raising (ASLR) is a clinical test for measuring effective load transfer between the trunk and lower limbs. When the lumbopelvic region functions optimally, the leg should rise easily from the table, and the pelvic should not move. It requires proper activation of both local and global muscles, which stabilize the thorax, low back, and pelvic (102). ASLR was used to assess the neuromuscular control strategies of the lumbopelvic region in the LBP population (103, 104). Patients performed alternately lifting each leg from the table about 20 cm. and rated their perceived difficulty in performing the movement using a six-point scale (102). Liebenson and colleagues (104) demonstrated that ASLR has usefulness for evaluating lumbar spine stability and abdominal bracing ability. Abdominal bracing during ASLR reduced the center of pressure movement on the pressure mat in lumbar rotation. They suggested that ASLR was strongly associated with lumbar spine stability. In addition, Mens and colleagues (102) demonstrated that ASLR correlated with Quebec back pain disability ($r = 0.7$) and correlated with self-reported pain intensity ($r = 0.53$). It may be suggested that ASLR could be a parameter for the severity of the disease.

Previous studies (105, 106) demonstrated that compression around the pelvis by manual compression or using lumbosacral support improved the ASLR test score. It might be described that compression augmented the stability in the passive subsystem, which affected the need for a neuromuscular system to contribute stability (106). In other words, compression around the pelvis could improve force closure or the active components of pelvic stability (105).

This information could suggest that ASLR can be used as an outcome variable to detect the change and evaluate the therapeutic effects of improvement in lumbopelvic stability.

2.3.3.3 Lumbopelvic stability test

Lumbopelvic stability test (LPST) is mainly used to assess the active subsystem because it can be evaluated easily and reflect the passive subsystem and control subsystem's interaction. Lumbopelvic stability test can be considered in several ways, including assessing the function of deep muscles using electromyography (107), evaluating the endurance of trunk muscles, and evaluating the ability to control the spine, pelvis, and lower body while increase difficulty in movement of legs.

The lumbopelvic stability test (50) is used to evaluate lumbopelvic stability in this study. It assessed the ability to maintain the spine while increasing the load on lower limbs. It can be detected by the change of pressure biofeedback unit (PBU) under the lumbar spine. There were seven levels of lumbopelvic stability control, from easy to difficult. The difficulty of LPST was increased by the movement of legs in each level (Table 2.1).

The lumbopelvic stability test was a good reliable method for evaluating lumbopelvic stability (k coefficient: intra-tester = 0.61, inter-testers = 0.62). It was also represented good agreement in subjects with chronic non-specific low back pain (kappa = 83.1%) (79). A study by Hagins and colleagues (50) demonstrated that after four weeks of training of lumbopelvic stabilization exercise in asymptomatic subjects, there was a significant increase of lumbopelvic stability level ($p = 0.01$).

Therefore, the lumbopelvic stability test is a reliable and suitable variable to indicate the effectiveness of treatment for lumbopelvic control.

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Table 2.1 Levels of lumbopelvic stability test

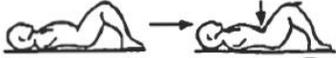
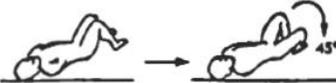
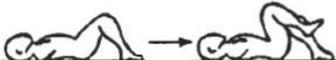
Levels of lumbopelvic stability test (50)	
	<p>Level 1 – abdominal hollowing</p> <p>The subject is positioned supine with the hip and knee in 70° and 90° of flexion and feet flat on the floor. While the subject exhales, the subject brings their belly button to the spine. Try to maintain the contraction and normal breathing.</p>
	<p>Level 2 – unilateral abduction</p> <p>The subject is positioned supine with the hip and knee in 70° and 90° of flexion and feet flat on the floor. The subject creates abdominal hollowing by contracting lower abdominal muscles. While maintaining the contraction and normal breathing, abduct the right leg to approximately 45 degrees to the floor. Keep breathing and return the leg to the starting position.</p>
	<p>Level 3 – unilateral knee raise</p> <p>The subject is positioned supine with the hip and knee in 70° and 90° of flexion and feet flat on the floor. The subject creates abdominal hollowing by contracting lower abdominal muscles. While maintaining the contraction and normal breathing, raise the right leg to the chest until hip flexion approximately 90 degrees. Don't move the head, neck, or shoulders, and don't press down the left foot. Keep breathing and return to the starting position.</p>

Table 2.1 Levels of lumbopelvic stability test (continued)

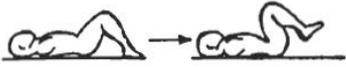
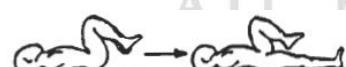
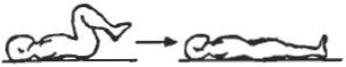
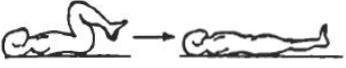
Levels of lumbopelvic stability test (50)	
	<p>Level 4 – bilateral knee raise</p> <p>The subject is positioned supine with the hip and knee in 70° and 90° of flexion and feet flat on the floor. The subject creates abdominal hollowing by contracting lower abdominal muscles. While maintaining the contraction and normal breathing, raise the right leg to the chest until hip flexion approximately 90 degrees. Hold the right knee in this position and then raise the left leg to the same position. Return the right leg to the starting position and then the left.</p>
	<p>Level 5 – unilateral heel slide</p> <p>The subject is positioned supine with the hip and knee in 70° and 90° of flexion and feet flat on the floor. The subject creates abdominal hollowing by contracting lower abdominal muscles. While maintaining the contraction and normal breathing, raise the right leg to the chest until hip flexion approximately 90 degrees. Hold the right knee in this position and then raise the left leg to the same position. From this position, lower and straighten the right leg and slide the heel along the floor until the leg is straight. Then slide the heel back to the starting position with both hips flexed.</p>

Table 2.1 Levels of lumbopelvic stability test (continued)

Levels of lumbopelvic stability test (50)	
	<p>Level 6 – bilateral heel slide</p> <p>The subject is positioned supine with the hip and knee in 70° and 90° of flexion and feet flat on the floor. The subject creates abdominal hollowing by contracting lower abdominal muscles. While maintaining the contraction and normal breathing, raise the right leg to the chest until hip flexion approximately 90 degrees. Hold the right knee in this position and then raise the left leg to the same position. From this position, lower and straighten both legs and slide the heels along the floor until the legs are straight. Then slide the heels back to the starting position with both hips flexed.</p>
	<p>Level 7 – bilateral heel hover</p> <p>The subject is positioned supine with the hip and knee in 70° and 90° of flexion and feet flat on the floor. The subject creates abdominal hollowing by contracting lower abdominal muscles. While maintaining the contraction and normal breathing, raise the right leg to the chest until hip flexion approximately 90 degrees. Hold the right knee in this position and then raise the left leg to the same position. From this position, lower both feet toward the floor, and both heels are approximately 3 inches from the ground. Keep breathing, and do not let the feet touch the base. Then return the knees to the chest.</p>

2.4 The potential components for the development of innovation for the management of LBP

This thesis plans to develop an innovative physical therapy device for patients with chronic low back pain. Previous literature (4, 13, 21) suggested that lumbar support, superficial heat therapy, and core stability exercise benefit in treating low back pain. Combining these three components into one innovative device may be useful and convenient for people with chronic LBP as a part of their management choices.

2.4.1 Lumbar support

Lumbar support is a type of lumbosacral supportive device. In the past, spinal support was made of leather and metal. It is used for correcting the position in the unstable area, such as fractures and deformities. Besides, lumbar support has been used for the treatment of scoliosis. Nowadays, lumbar support is mainly made of various materials such as cotton and soft, flexible fabric, plastic, and Velcro strap, which may have rigid reinforcement (108). These materials provide more options for modification into different shapes and suit for specific treatment purposes.

The effects of lumbar support had been reported as following (109):

- Lumbar support increases intra-abdominal pressure (IAP). Intra-abdominal pressure contributes to mechanical spine stability through co-activation of trunk flexor and extensor muscles. As the abdominal contract intra-abdominal pressure increases and converts the abdomen into a rigid cylinder, it dramatically increases the spinal stability.
- Lumbar support affects spinal rigidity increasing by limiting the end range of movement. It helps to protect the spine from extreme movement. The excessive trunk motions seemed to be the cause of back injury(19). Thus, the prevention of excessive back movement may lead to a reduced risk of low back pain. The study of van Poppel and colleagues (17) reported that both elastic and rigid lumbar support affected reducing trunk movement in flexion, extension, and lateral bending with an overall effect size of 0.7.
- Lumbar support helps to decrease the load on the trunk. Nachemson and colleagues (110) demonstrated that wearing lumbar support

significantly reduced load on the trunk in various situations, and lumbar spine compression was also reduced in tasks with trunk flexion.

- Lumbar support helps to prevent injury or re-injury of the lower back. The systematic review of intervention to prevent back pain in nurses (23) found a positive effect with less back injury of wearing lumbar support during patient transfers.

Several studies reported the effectiveness of lumbar support in patients with LBP to decrease pain intensity, functional disability, and the number of days with low back pain (17-19). Calmels and colleagues (21) studied the effect of wearing lumbar support in 197 patients with subacute low back pain for three months. They found higher functional capacity scores and lower pain intensity and medication consumption in the lumbar support group than the control group. Chiou and colleagues (22) also demonstrated improved quality of life in patients with low back pain after wearing lumbar support for three months. Also, Saito and colleagues (18) reported that wearing lumbar support for three months could decrease the number of days with low back pain over time when following up every month. Moreover, lumbar supports seem to be cost-effective as an additional treatment to usual care. Patients who use lumbar support reported significantly lower direct health care costs than the control group (111).

Although lumbar support's positive effects had been reported in several studies, there are some adverse effects unless appropriately used. Adverse effects reported were skin irritation, discomfort during sitting, and excessive sweating (109). Muscle wasting can also potentially occur after long-term use (7). Wearing lumbar support during waking hours for eight weeks showed decreased lateral abdominal muscle thickness and size of lumbar multifidus muscles, which are the essential components in the lumbopelvic stability system (112). Therefore, innovative lumbar support developed in this thesis added the core stability activation in innovative lumbar support to facilitate the core muscles.

2.4.2 Superficial heat therapy

Superficial heat therapy is a common therapeutic application in physical therapy for LBP management. It is also commonly used by patients at home. Superficial

heat therapy seems to be an effective treatment for pain relief, muscle relaxation, and improvement in functional disability in people with LBP (4, 113).

Physiological effects of superficial heat therapy (114)

1) Heat increases cellular metabolic rate. When the temperature rises 10 degrees Celsius, the cellular metabolism increases 2-3 times. It causes more oxygen and nutrients to deliver for tissue repairing.

2) Heat increases blood flow and vasodilation. The increased temperature affects vasodilation through axon reflex, spinal reflex, histamine secretion, prostaglandin, and bradykinin.

3) Heat decreases pain and muscle spasms. As a result of the vasodilation and increase blood flow, the waste product is expelled through the blood. Pain and muscle spasms are reduced. In addition, pain can also be reduced through the gate control theory. The heat causes the secretion of endorphin, which affects pain reduction.

4. Heat increases connective tissue extensibility. Viscous and elastic properties of connective tissue are changed after received heat. The elongation of connective tissue is the most effective, while muscle temperature increases to therapeutic temperature (40 – 45 degrees Celsius). The increase of connective tissue extensibility also results in a decrease in joint stiffness.

The effectiveness of superficial heat therapy in people with LBP was demonstrated in several studies. Lewis and his colleagues (8) showed that superficial heat therapy could reduce muscle spasms in CLBP patients. Pain intensity, anxiety, and functional disability also improved after applied a hot pack. Like the study of Mayer and colleagues (9), superficial heat therapy had benefits in preventing and treating delayed onset muscle soreness of the lower back muscles. It affected reducing pain intensity and disability after vigorous exercises. Also, Mayer et al. demonstrated that the combination of superficial heat therapy and exercise had greater effectiveness in pain relief and functional improvement than superficial heat therapy alone or exercise alone (39). Moreover, superficial heat therapy had more significant pain relief and lower cost than

paracetamol and ibuprofen (10). In Thailand, superficial heat was reported as the most common treatment prescribed for LBP patients by physical therapists (115).

However, to access superficial heat therapy (i.e., hot pack hydrocollator), the patients usually need to go to the hospital or clinical service center. It may inconvenience, loss of traveling and waiting time, and more expensive health care. Thus, this thesis considers combining superficial heat therapy as a part of an innovative device. It may be convenient for patients with chronic low back pain to manage themselves at home and workplace.

2.4.3 Core stability exercise

The core muscles can be described as a muscular box with the abdominal muscles in the front, paraspinal muscles in the back, the diaphragm as the roof, and the pelvic floor as the bottom. The core muscle co-contraction causes greater stability of the spine. The core muscles provide the proximal stability for distal mobility, allowing proper contraction and efficient movement of the arms and legs (116).

The spine stability system consists of a passive subsystem, an active subsystem, and a neural control subsystem. The passive subsystem includes the osseous and articular structures and the spinal ligaments, contributing to spinal movement and stability control. The active subsystem refers to the force-generating capacity of the muscles, which provides the stability of the spinal segments. The neural control subsystem must coordinate muscle activity in advance of predictable challenges to stability and coordinate responses to afferent feedback from unpredictable challenges. These three subsystems work together, and these subsystems can be compensated if some components are lacking (48).

Core stability exercise is the restoration of the ability of the neuromuscular system to control and protect the spine from injury or re-injury. The core stability exercise concept is a co-contraction of the key local muscles such as the transversus abdominis and the lumbar multifidus by drawing in the abdominal wall. The co-contraction exercise activates the transversus abdominis is a low level and continuous contraction less than 30-40% of maximum voluntary contraction (MVC), with no rapid and phasic contraction (117). It affects increasing intra-abdominal pressure (IAP) and stiffens the spine (117).

Strategies of core stability exercise can be divided into two main steps:
(118)

1) Muscle capacity of the trunk muscles is restored by activating the proper muscles such as the transversus abdominis, lumbar multifidus, and global nearby. This strategy is associated with the activation of the active subsystem to provide stability of the spine.

2) Motor learning strategy is the restoration of coordination and control of trunk muscles to improve lumbar spine and pelvis control. Stability and control of the spine depend on the muscles and central nervous system (CNS), which is the coordination between the active subsystem and the neural control subsystem. When an internal or external force challenges stability, the CNS will plan and implement muscle activity strategies to control the spine.

Patients with chronic low back pain are associated with reducing core muscle strength and function (12, 119). Several studies (119, 120) suggested core stability exercise as an effective treatment in minimizing pain and disability in patients with chronic low back pain. The electromyography of the rectus abdominis, internal oblique, and transversus abdominis of the 10-week specific exercise in non-specific low back pain patients showed a better recovery of core muscle function than the usual care (119). This study suggests that specific stabilizing exercises can help restore impaired muscle function. The 8-week stabilization exercise program in non-specific chronic low back pain patients improved the Oswestry Disability Questionnaire Scores improved about 35%. It suggested that stabilization exercise could help pain management in patients with chronic low back pain (120). In addition, recent evidence (6, 121) from the systemic review and clinical guideline support that core stabilizing exercise is one of the effective treatments for chronic low back pain. In addition, core stability exercise provides adequate dynamic control of lumbar spine forces that eliminated repetitive injury to spinal segments' structures and related structures (14, 15). Core stability exercise also improved the strength and endurance of deep muscles such as transversus abdominis (TrA) and lumbar multifidus muscle (LM), which increase lumbopelvic stability (16). Moreover, s

systematic review suggested that the CSE combined with manual therapy is more effective in short- and long-term disability and pain (6).

From the information above, core stability exercise is an effective treatment for low back pain management. It resulted in pain reduction, functional improvement, and restoration of core muscle function, which may prevent the adverse effect of long-period lumbar support use. Therefore, this thesis developed the biofeedback exercise unit for core stability activation during wearing lumbar support as part of innovation.

2.5 Summary statement

Based on Thailand's economic development policy or government economic development model "Thailand 4.0," which aims to go into "Value-Based Economic," the main idea is to shift the commodity production to innovation. It focuses on technology-driven creativity, innovation, and services. This thesis developed an innovation related to health care in patients with chronic low back pain who often have a high cost in health care services to meet the government's economic policy. Innovative lumbar support in this thesis is a combination of three physical therapy treatments: lumbar support, superficial heat therapy, and core stability activation, which is expected to reduce pain, increase lumbopelvic stability, and improve function and injury prevention. The development of this innovation was done jointly with the domestic operators, affecting the reduction of imports from abroad. The hot pack component of innovative lumbar support was made from locally available wheat to create value for the local products and contribute income to the agricultural sector.

Moreover, the investigation of the therapeutic effect of innovative lumbar support in patients with chronic low back pain would help apply it as an additional treatment option for the chronic low back pain population.

2.6 Purposes of the study

This thesis comprises three studies, including the systematic review of lumbar support application for management of low back pain, design and development of innovative lumbar support comprising hot pack and core stability activation, and the

therapeutic effect of innovative lumbar support comprising hot pack and core stability activation. Therefore, the main purposes of this thesis are:

- To explore the effective application of the lumbar support for the management of LBP
- To develop the prototype of innovative lumbar support including hot pack and core stability activation
- To evaluate the therapeutic effects of innovative lumbar support on pain, core muscle function, and quality of life and disability in individuals with non-specific low back pain



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CHAPTER 3

Materials and methods

3.1 Systematic review of using lumbar support for management of low back pain – Main Study I

3.1.1 Introduction

Lumbar supports are commonly used to manage low back pain and are also used in the workplace to prevent low-back pain injuries (122). Lumbar supports affect lumbar spinal movement restriction, increase spinal stabilization, decrease the mechanical load on the trunk, and increase the intra-abdominal pressure (110). Lumbar supports are provided as a treatment for people suffering from LBP with the aim to decrease impairment and disability.

Previous systematic reviews (7, 123) reported limited evidence that lumbar supports are more effective than no treatment and need more high-quality research on lumbar support effectiveness. However, there are more studies on the efficacy of lumbar support in the past ten years. The present study reviewed the up-to-date studies on the efficacy of lumbar support. Moreover, there was no information about the clinical application (dosage) of lumbar support usage in efficiently managing low back pain. Therefore, this review is interested in collecting the suitable clinical applications of lumbar support for LBP. The research question for this systematic review is “How to use lumbar support for management of low back pain effectively?”.

3.1.2 Objective

To explore the effectiveness and clinical applications of lumbar support in patients with low back pain.

3.1.3 Study design

This study utilized a systematic review of a randomized trial and quasi-experimental trials.

3.1.4 Methods

The study was exempt from consideration of ethical clearance from the Institutional Ethics Committee.

The related articles were searched through the electronic databases, including Pubmed, ScienceDirect, and Scopus, from January 1995 to December 2017. The keywords were “lumbar supports, lumbar belts, back supports, back belts” and “back pain, lumbar pain, backache.” The search was carried out of the individual keywords and with a combination of Boolean Logics (AND). In addition, articles that were published in English only were considered for inclusion in the study.

3.1.4.1 Criteria for considering studies

Both randomized controlled trials and quasi-experimental trials were included in the review process.

3.1.4.2 Participants and interventions

The population of all studies was subjects with non-specific low back pain. The studies which included subjects with specific low back pain such as infection, cancer, scoliosis, or fracture were excluded. Any types of lumbar supports for the treatment of low back pain were also included. The special type of lumbar supports for severe scoliosis and after lumbar surgery was excluded.

3.1.4.3 Outcome measures

The studies that used the related outcome measures for determining the progression of low back pain symptoms were included such as pain intensity (Visual Analog Scale, Numerical Rating Scale), overall improvement (Numerical Rating Scale), quality of life (SF-36, SF-12), and back pain-specific functional status (Oswestry disability questionnaire, Roland-Morris disability score, Quebec disability score), etc.

3.1.4.4 Methodological quality checking

Two independent assessors assessed the methodology quality. A consensus method with the agreement of a third independent assessor was used to resolve disagreements concerning the methodological quality assessment. The studies' methodological quality was assessed using the Physiotherapy Evidence Database (PEDro) scale, the criteria lists for quality assessment of randomized controlled trials. There are 10- checklist items to consider the quality of the study. The scale assesses randomization, allocation concealment, comparability at baseline, blinding of subjects, blinding of therapists, blinding of assessors, measurement of at least one key outcome obtained from more than 85% of the subjects initially allocated to groups, intention to treat analysis, between-group comparison tested statistically for at least one key outcome measure, and point measures and measures of variability provided for at least one key outcome measure. Each criterion was scored as either positive or negative according to the definitions of the requirements. Validity items were scored as positive when the available information regarding that item did not reveal any bias and negative when no information was provided regarding that item or the available information. The PEDro scores were considered to be excellent (9 - 10), good (6 - 8), fair (4 - 5), and poor (<4) (124).

3.1.4.4 Data extract and analysis

The data was extracted on the characteristics of the study population (pathology, stage of LBP), characteristics of studied intervention (i.e., types of lumbar support, the number of hours per day that the subjects were prescribed to wear the lumbar support, duration of the intervention period), adverse effects due to the interventions, and the final results for each outcome measures on the effectiveness of lumbar supports.

The levels of evidence were analyzed using an updated method guideline for systematic reviews proposed by van Tulder and colleagues (125). The assessment method accounts for consistent findings among multiple high-quality studies as strong; consistent multiple low quality or one high-quality studies as moderate; one low-quality study as limited; and inconsistent findings among studies as conflicting.

Drawing conclusion was based on the high-quality articles to report the effectiveness and suggestion for clinical application. Moreover, the details of related studies were clarified in the tubular form.

3.1.5 Results

3.1.5.1 Study selection

The electronic database search resulted in 297 articles; 88 articles were identified in Pubmed, 28 articles in Sciencedirect, and 181 articles in Scopus. After the exclusion of duplicated articles, 162 articles have screened the title and abstract. After screening the title and abstract, 11 potentially relevant articles were assessed for the eligibility criteria. Finally, eight articles were included in the review (Figure 3.1).

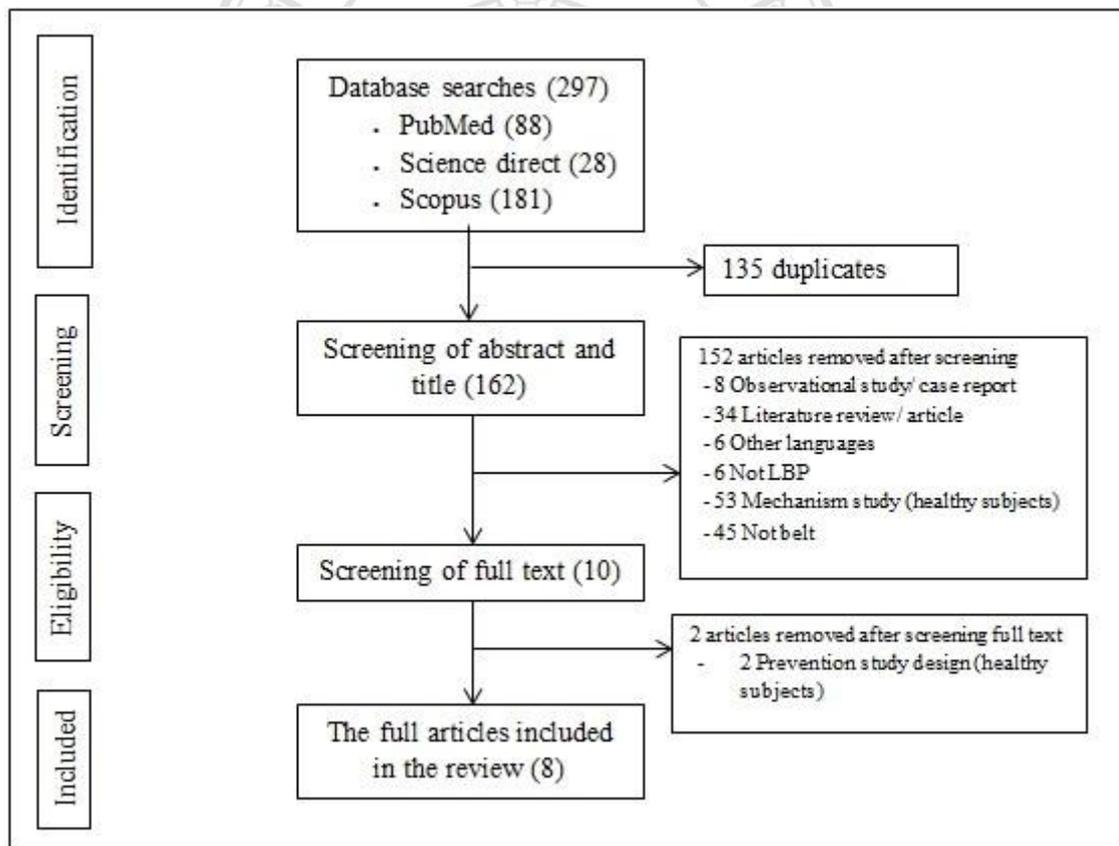


Figure 3.1 The flow chart of the articles reviewed

3.1.5.2 Methodological quality

The methodological quality of the selected studies was assessed using the Physiotherapy Evidence Databases (PEDro) scale. The two reviewers initially agreed on 77/88 (87.5%) items on the PEDro scales. All differences in PEDro scales were resolved after the discussion and consensus among the reviewers. The results of the quality scores were shown in Table 3.1. The quality scores ranged from 3/10 to 8/10. Five studies (21, 111, 126-128) demonstrated good quality, two studies (18, 129) were fair-quality studies, and one study (130) was a poor quality study.

Table 3.1 Methodological quality of studies on the effectiveness of lumbar supports

PEDro items	van Poppel et al., 1998	Oleske et al., 2007	Roelofs et al., 2007	Calmels et al., 2007	Roelofs et al., 2010	Sato et al., 2012	Morrisette et al., 2014	Saito et al., 2014
1	Y	Y	Y	Y	Y	Y	Y	Y
2	Y	Y	Y	Y	Y	Y	Y	Y
3	N	Y	N	N	Y	N	Y	N
4	Y	Y	Y	Y	Y	N	Y	Y
5	N	N	N	N	N	N	N	N
6	N	N	N	N	Y	N	N	N
7	N	Y	Y	N	N	N	N	N
8	Y	Y	N	Y	N	N	Y	N
9	N	Y	Y	Y	Y	N	Y	N
10	Y	Y	Y	Y	Y	Y	Y	Y
11	Y	Y	Y	Y	Y	Y	Y	Y
Total	5/10	8/10	6/10	6/10	7/10	3/10	7/10	4/10

Note: Item 1 related to the external validity (as the Pedro criteria did not include the total score)

3.1.5.3 Study characteristics

Study characteristics were summarized in Table 3.2. Of the eight studies, six (21, 111, 126-129) were randomized controlled studies, and two (18, 130) were quasi-experimental studies.

3.1.5.4 Effects of lumbar support

3.1.5.4.1 Lumbar support versus control comparisons

One good quality RCT (21) compared the effect of lumbar support with no intervention. The result showed a significant improvement in LBP and disability in a lumbar support group. There is limited evidence that lumbar supports are more effective than no intervention. Four studies (111, 126, 128, 130) compared the effect of lumbar support with the usual care. Three of them were good quality RCT (111, 126, 128), and the other one was a poor quality quasi-experimental study (130). Roelofs et al. (111, 128) demonstrated lumbar support groups had a greater improvement in the severity of LBP disability than the usual care group. Lumbar support also significantly reduced the number of days with LBP over 12 months and directly related healthcare costs. There was no difference in sick leave and quality of life. Morrisette et al. (126) found that receiving usual care with inelastic lumbar support significantly improved disability and patient-specific activity compared with only usual care. There was no difference between elastic lumbar support and inelastic lumbar support or usual care. Sato et al. (130) also found that lumbar support can reduce LBP's severity more than pharmacological consumption. There was strong evidence that lumbar supports plus usual care was superior to only usual care. One good quality RCT (127) and one fair-quality RCT (129) compared the effect of lumbar support with education. Oleske et al. (127) found that both lumbar support and education could decrease pain and disability and increase physical health after 12 months of intervention. Also, van Poppel et al. (129) reported the subgroup analysis of LBP subjects at baseline. Lumbar support can reduce the number of days with LBP per month compared with no lumbar support. However, both studies demonstrated no significant difference between the group in all outcomes. There is moderate evidence that lumbar supports plus education are not more effective than education.

3.1.5.4.2 Comparison of the different types of lumbar supports

One RCT (126) and one quasi-experimental study (18) compared the effects of the different types of lumbar support. Morrisette et al. (126) compared the effects of elastic and inelastic lumbar support. They found that using inelastic lumbar support for two weeks significantly improved functional ability while there was no improvement in an elastic lumbar support group. Saito et al. (18) studied the new type of lumbar support (wear-type support) and traditional lumbar support. The results showed both types of lumbar support significantly decreased pain severity and the number of days with LBP, but there was no significant difference between groups. There is limited evidence that which types of lumbar support are more effective than the others?

3.1.5.4.3 Clinical application of lumbar support

1) Population

Two studies (18, 21) were performed in subacute LBP. Calmels et al. (21) found wearing lumbar support significantly improved functional status, pain level, and pharmacologic consumption. As a result of Saito and colleagues (18), this reported decreased pain intensity and the number of days with LBP after wearing lumbar support. There is limited evidence that lumbar supports are useful for subacute low back pain. One study (130) was chronic low back pain. This also showed wearing lumbar support can decrease the severity of LBP. There is limited evidence that lumbar supports are effective for chronic low back pain. Four studies (111, 126-128) were a mixed LBP duration; all of them demonstrated the positive effects of wearing the lumbar support. There is strong evidence that lumbar supports are useful for the population with various durations of LBP. In the other study (129), there was no information given about LBP duration.

Table 3.2 Characteristics of the studies

Study	Participants	Interventions	Outcomes	Results	Note
van Poppel et al. 1998	Workers whose jobs included manual material handling. Exclusion criteria: subjects who had a permanent partial work disability 172 subjects with previous LBP, 49 subjects with LBP at baseline. N = 312 Female, Male = N/A Age = 35.1 ± 7.8 yrs.	1. Lumbar support + education 2. Lumbar support *use LS during working hr. 3. Education: lifting instruction 4. Control *6 months	LBP incidence, sick leave due to back pain	No difference in LBP incidence and sick leave between groups after 6 months.	In subgroup, subjects with LBP at baseline, LS reduced no. of day with LBP/month (median; 1.2 vs 6.5 days/month, p = .03) Compliance with wearing the lumbar support at least half of the time was 43%. No adverse event
Oleske et al. 2007	Workers who had a nontraumatic work-related low back disorder (within 8 weeks). Exclusion criteria: subjects who had other work-related conditions N = 433 Female = 20.1%, Male = 79.9% Age = 46.1 ± 7.6 yrs.	1. Lumbar support + education *use LS during working hr. 2. Education *12 months	Pain intensity, disability level, physical health, mental health, recurrence, lost working time, medical care utilization	Significant decreases in pain, disability and neurogenic symptoms, and increase in physical health in both grp. Over 12 mo. LS + education had a lower likelihood of WR-LBD recurrence No difference between grp. in all outcomes.	Working hours = 47.6 ± 13.7 hrs/wk (6-7 hrs/day) Compliance to use LS: 78% using after 1-month, 51% using LS as instructed at the 12-month study visit No adverse event

Table 3.2 Characteristics of the studies (continued)

Study	Participants	Interventions	Outcomes	Results	Note
Roelofs et al. 2007	<p>Home care workers who had LBP symptoms at the time of inquiry had experienced ≥ 2 episodes (≥ 2 consecutive days) of LBP in 12 mo.</p> <p>Exclusion criteria: specific LBP (RA, fracture), pregnancy, receiving medical treatment for high BP</p> <p>N = 360 Female = 98%, Male = 2% Age = 41.7 ± 9.7 yrs.</p>	<p>1. Lumbar support + usual care *use LS during working hr.</p> <p>2. Usual care</p> <p>*12 months</p>	<p>No. of day with LBP, sick leave, severity of LBP, function</p>	<p>Significant differences in no. of day with LBP, pain intensity, and function between grp.</p>	<p>Working hours = 25.3 ± 7.9 hrs/wk (5 hrs/day) Compliance: 78% wore LS for at least one-third of total no. of day with LBP, subj. wore LS 5.5 day/mo.(90% of no of day with LBP) No adverse event</p>
Calmels et al. 2009	<p>Patients with subacute LBP 20 – 60 yr of age.</p> <p>Exclusion criteria: used LS during the last 6 mo., neurological sign, suffered from LBP 6 mo. Preceding inclusion, spinal surgery, pregnancy, unstable chronic cardiac/ respiratory complaint, LBP with inflammatory/ tumor/ infection.</p> <p>N = 197 Female = 45.2%, male = 54.8% Age = 43 ± 10.7 yrs.</p>	<p>1. Lumbar support *use LS during the whole day</p> <p>2. Control</p> <p>*3 months</p>	<p>Function (EIFEL), pain intensity, overall cost of associated medical treatment</p>	<p>LS grp had higher decrease in EIFEL (d0, d30 and d90), lower VAS at d30 and d90, decrease medication intake at d90</p>	<p>Duration of wearing belt D30: 5 d/wk, 8 hr/day D60: 4 d/wk, 6 hr/day D90: 3 d/wk, 5 hr/day No adverse event</p>

Table 3.2 Characteristics of the studies (continued)

Study	Participants	Interventions	Outcomes	Results	Note
Roelofs et al. 2010	<p>Home care workers who had LBP symptoms at the time of inquiry had experienced ≥ 2 episodes (≥ 2 consecutive days) of LBP in 12 mo.</p> <p>Exclusion criteria: specific LBP (RA, fracture), pregnancy, receiving medical tx for high BP</p> <p>N = 360 Female = 98%, Male = 2 % Age = 41.7 ± 9.7 yrs.</p>	<p>1. Lumbar support + usual care *use LS during working hr.</p> <p>2. Usual care</p> <p>*12 months</p>	<p>No. of day with LBP, sick leave, quality of life, direct and indirect costs</p>	<p>LS grp. reported fewer days with LBP.</p> <p>No difference in sick leave and quality of life.</p> <p>Direct costs were lower in LS grp.</p>	<p>Working hour = 5 hr/day</p> <p>No adverse event</p>
Sato et al. 2012	<p>Patients with CLBP (> 3 mo.)</p> <p>Exclusion criteria: infection, osteoporosis, metastasis of malignant tumor, LE symptoms, neurological deficit</p> <p>N = 50 Female = 50%, Male = 50% Age = 30 – 78 yrs.</p>	<p>1. Corset wearing grp. *use LS all day except bath and bedtime</p> <p>2. Control grp. – received NSAIDs</p> <p>*6 months</p>	<p>Severity of LBP Muscle endurance Muscle fatigue</p>	<p>Corset improved LBP and increased muscle endurance for a short period.</p> <p>No difference in muscle fatigue.</p>	<p>No report of compliance and duration of wearing LS per day</p> <p>No adverse event</p>

Table 3.2 Characteristics of the studies (continued)

Study	Participants	Interventions	Outcomes	Results	Note
Morrisette et al. 2014	<p>Patients with acute, subacute, and chronic LBP aged > 18 yr</p> <p>Exclusion criteria: spinal surgery, neurological disease, systematic inflammatory disease, pregnancy, fracture, tumor, infection, LE pain</p> <p>N = 98 Female = 61%, Male = 39% Age = 48.4 ± 15.3 yrs.</p>	<ol style="list-style-type: none"> 1. Standard care – medication and physical therapy 2. Standard care + elastic lumbar support 3. Standard care + inelastic lumbar support <p>*2 week</p>	<p>Disability, patient-specific activity, pain, fear-avoidance questionnaire</p>	<p>Standard care + Inelastic LS showed greater improvement of ODI and specific activity than standard care only.</p> <p>No difference between 1)&2) and 2)&3).</p>	<p>Chronic LBP 64%</p> <p>Mean wearing time for eLSO = 4.8 hr/day, 78% wear daily</p> <p>For iLSO = 5 hr/day, 62% wear daily</p> <p>No adverse event</p>
Saito et al. 2014	<p>Nurses with LBP (NRS ≥ 3) at least once a week for the past 3 months</p> <p>Exclusion criteria: LE pain, spinal surgery, psychiatric disorders, mental disorders</p> <p>N = 144 Female = 93.75%, Mail = 6.25% Age = 39.5 ± 11 yrs.</p>	<ol style="list-style-type: none"> 1. Wear-type lumbar support 2. Traditional lumbar support <p>*use LS all time except bath and bed at 1st mo. after that wore when LBP occurred</p> <p>*3 months</p>	<p>Quality of life, disability, severity of LBP, no. of day with LBP</p>	<p>Significantly decrease of pain severity, no. of day with LBP in both grp. overtime, no difference between grp. overtime</p>	<p>Duration of wearing LS</p> <p>1st mo: SW 9hr/day LS 6 hr/day</p> <p>2nd mo: SW 7 hr/day LS 5 hr/day</p> <p>3rd mo: SW 6 hr/day LS 4 hr/day</p> <p>No adverse event</p>

2) Prescriptions of wearing a lumbar support

Out of all selected studies, the apparent protocol of wearing lumbar support was not given. Four studies (111, 127-129) prescribed participants to wear lumbar support during working hours. One study by van Poppel et al. (129) reported that subjects with LBP at baseline had reduced the number of days with LBP per month, while Oleske et al. (127) and Roelofs et al. (111, 128) demonstrated that using lumbar support during working hours can reduce pain intensity, direct costs of health care and increase functional ability. Three studies (18, 21, 130) prescribed participants to wear lumbar support for the whole day except bath and bedtime. Low back pain symptoms were improved in all studies. One study (126) did not give any information about wearing lumbar support. However, three studies (18, 21, 126) demonstrated the average hours of wearing lumbar support from the participant's records, which was about 6 – 8 hours daily. Calmels et al. (21) revealed that participants wore lumbar support 8, 6, and 5 hours per day at the 1st, 2nd, and 3rd month, respectively. This study found the improvement of LBP and disability since the 1st month of follow-up. Morrisette et al. (126) showed the average time of wearing lumbar support, which was 4.8 and 5 hours daily for elastic lumbar support and inelastic lumbar support, respectively. Saito et al. (18) demonstrated that the average time of wearing lumbar support was 6, 5, 4 hours per day at the 1st, 2nd, and 3rd month, respectively. This study also found an improvement of LBP since the 1st month.

3) Duration of the intervention period

Three trials (111, 127, 128) studied the effects of using lumbar support in workers for 12 months. All of them found lumbar support reduced pain intensity, disability, and costs of health care. Also, the rate of LBP recurrence was lower in workers who wore lumbar support (127). Two trials (129, 130) studied the effects of using lumbar support for six months. van Poppel and colleagues (129) reported that LBP subjects at baseline who received lumbar support had fewer days with LBP per month. Sato and colleagues (130) also found an improvement of LBP after wearing lumbar support for six months. Two trials (18, 21) studied the effect of using lumbar support for three months. Both studies demonstrated the improvement of pain intensity and functional status since the 1st month of follow-up and continually improved at each

time point. Morrisette and colleagues (126) studied the effects of using lumbar support for two weeks. There was significantly improved disability in the inelastic lumbar support group but no change in the elastic lumbar support group.

4) Adverse effects

There was no adverse event reported in all of the identified studies.

3.1.6 Discussion

3.1.6.1 Selection bias

Although there is a well-defined search strategy to identify the studies on lumbar support's effectiveness, some studies may be missed. The missing studies may be in other databases, unpublished sources (e.g., theses) inaccessible.

3.1.6.2 Methodologic quality

The methodologic quality was assessed by the two reviewers who were not blinded to authors and journals. Potential bias from the non-blinded assessment was expected to be low because the major reviewers were professionals in the field of low back pain and familiar with the literature. The other one is a layperson in the field of low back pain.

The internal validity criteria were used to assess the methodologic quality of the eligible studies. It referred to the characteristics of the study, which may be related to bias. The methodologic quality of the included studies seemed to be high. Five of 8 studies that scored in the range 6/10 – 8/10 were good quality studies. Only 3 studies scored lower than 6/10, which was considered poor to fair quality. All 8 studies demonstrated the proper method of randomization. Among 6 randomized controlled trial studies, only 3 studies described a method of concealment. Blinding of subjects in the efficacy studies of lumbar support is very difficult. Blinding of assessors, which is an essential criterion, was reported in only 2 studies. However, most of the outcome measures in the eligible studies were subjective outcomes. Blinding of assessors may not be necessary.

3.1.6.3 Effectiveness of lumbar support

Overall of this review, the evidence for the effectiveness of using lumbar support in the management of low back pain was conflicting, which is mostly in agreement with the previous review (7, 123). However, the comparisons of lumbar support with the other treatments showed strong evidence that lumbar supports plus usual care are more effective than only usual care in managing low back pain. This result was different from a previous review by van Duijvenbode and colleagues (123), which reported conflicting evidence that lumbar support is a useful additional treatment. This difference may be due to recent studies considering the effectiveness of lumbar support as an additional treatment. There is moderate evidence that lumbar supports plus education are not more effective than education, and limited evidence that lumbar supports are more effective than no intervention. This conflict results may be a potential effect of overestimation because of the bias from subjective outcomes.

Further studies may be needed to evaluate the objective outcomes to confirm the effects of lumbar support. Considering the different types of lumbar support, there is limited evidence. There are a small number of studies that compared the different types of lumbar support.

3.1.6.4 Clinical application of lumbar support

The results of this review showed that there is strong evidence, which lumbar supports are effective for studies with a mixed duration of low back pain. It may be convenient for the recruitment of a large number of participants. A small number of studies in subacute (18, 21) and chronic low back pain are available (130). There is limited evidence for the effectiveness of using lumbar support in subacute low back pain. For chronic low back pain, there is limited evidence, which is only a poor-quality study. There is no study regarding acute low back pain. Therefore, it may not be concluded that lumbar support is appropriate for a specific stage of low back pain.

Three good-quality studies (111, 127, 128) reported wearing lumbar support during working hours. Working hours reported in these studies was an average of 5 – 7 hours per day. It may be assumed that wearing lumbar support 5 – 7 hours daily affected pain and function improvement. In addition, it also reduced the rate of LBP recurrence. However, the compliance and duration of wearing lumbar support

should be recorded by the participants. Of all identified studies, three studies (18, 21, 126) demonstrated the duration of using lumbar support per day from participant's records. In 1st month, participants wore lumbar support on average 5-8 hours daily. After that, the duration of wearing lumbar support was decreased. When considering the results, the 1st-month follow-up showed the most significant improvement of pain and disability and then less change. This reduction of the duration of wearing lumbar support after the 1-month intervention may be associated with improving symptoms.

Most of the identified trials (111, 127-130) studied the effects of wearing lumbar support for a long time (6, 12 months) without the intersection assessment. It cannot be known the suitable duration of wearing lumbar support for management of low back pain. The previous study (112) demonstrated that core muscle function was reduced after wearing lumbar support for 8 weeks. Therefore, it may not be proper to wear lumbar support continuing for an extended period. However, one good and one fair-quality study demonstrated that pain and function could be improved at a 1-month follow-up.

3.1.7 Conclusion

This study's results may not point out that lumbar supports are superior in managing low back pain than the other treatments because there was inconclusive evidence. However, this review suggested that lumbar support seems to be effective as an additional intervention and usual care to manage low back pain.

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3.2 Design and development of innovative lumbar support comprising hot pack and core stability activation – Main Study II

3.2.1 Introduction

From the literature review, using lumbar support, superficial heat therapy, and core stability exercise seem to be the potential effective management of LBP. Core stability exercise is one of the recommended treatments for chronic low back pain regarding a meta-analysis by Wang and colleagues which showed that core stability exercise is more effective than general exercise in reducing pain and improving physical function (13). Superficial heat therapy is typical traditional management for low back pain in the physical therapy clinic. The systematic review by French and colleagues (4) demonstrated the positive effect of superficial heat therapy on reducing pain and disability in the low back pain population. In addition, lumbar support is usually recommended for patients with low back pain due to decreased pain during physical activity and prevents further injury. There is a number of evidence that reported the potential positive effects of using lumbar support. Calmels and colleagues (21) demonstrated that using lumbar support for 90 days affected the improvement of pain and functional status and the reduction of medication consumption. Furthermore, lumbar supports seem to be a cost-effectiveness additional management to usual care (7).

Usually, the conventional treatments for low back pain must be done at the hospital or clinic area, and each treatment session takes a long time. It may result in both time and money spent on health services and travel. In a competitive society, finding a way to reduce cost and time is probably good. If patients have an effective additional management device in self-care, it could be a benefit. This is the source of the combination of these treatments and leads to the design and development of innovative lumbar support, including hot pack and core stability activation. Patients can take all three physical therapy treatments (i.e., LS, SHT, CSE) at the same time and be able to manage themselves while being at home or doing routine work. In addition, we often find that patients who wear lumbar support often used it for long periods and sometimes neglected self-care. Long periods of wearing lumbar support have been reported in the adverse effect of muscle weakness. This innovation is designed to be an assistance to activate the core muscles while wearing lumbar support. Innovative lumbar support consisted of a hot

pack and the visual biofeedback sensor to activate the core muscle. Moreover, there was a removable shoulder sling component to support the upper trunk and help in correcting posture.

3.2.2 Objectives

- To design and produce the prototype of innovative lumbar support, which include hot pack and core stability activation in itself
- To determine the validity and reliability of innovative lumbar support for TrA muscle contraction by using real-time ultrasound imaging as a comparative tool

3.2.3 Hypotheses

Force production of core muscles is strongly correlated to the gold standard (real-time ultrasound).

3.2.4 Study design

Descriptive and correlation study designs were utilized in this study.

3.2.5 Methods

3.2.5.1 Development of the feedback sensor unit

The innovative lumbar support was designed to combine three physical therapy treatments, including lumbar support, superficial heat therapy, and core muscle exercise. There was an inside pocket for a moist herbal hot pack unit (Figure 3.2). The feedback sensor unit was developed using a pressure sensor (Figure 3.3), which had a working principle similar to the pressure biofeedback unit (PBU). The sensor was attached to the inner side of the lumbar support. The decrease in the value of pressure on the feedback sensor is interpreted as increased activation of TrA. Also, there was a removable shoulder sling to support the upper trunk and help in correcting posture.

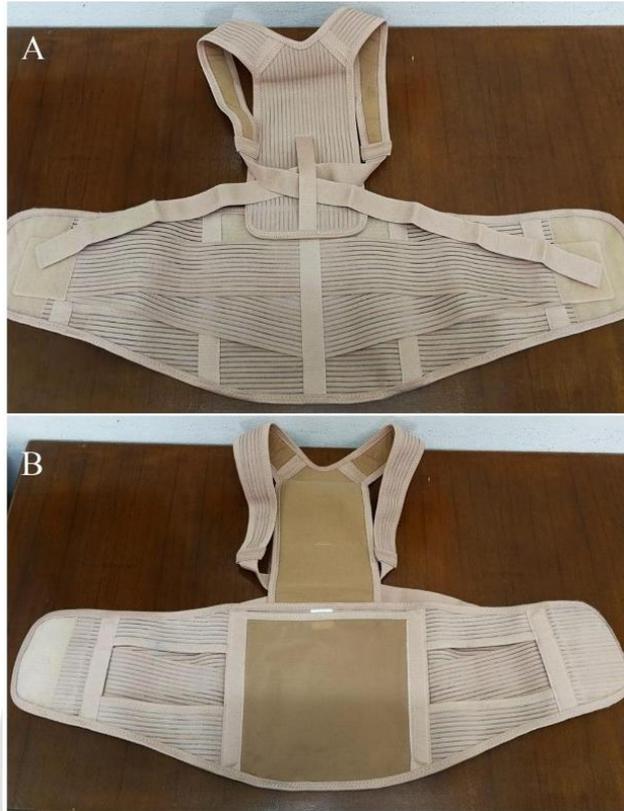


Figure 3.2 The prototype of lumbar support: A) the back of lumbar support, B) the front of lumbar support.



Figure 3.3 The prototype of feedback sensor

3.2.5.2 Setting and participants

In a pilot study, the sample size of twenty healthy subjects aged between 20 – 55 years, both males and females were studied. Participants with a history of low back pain in the past three months, history of lumbar surgery, history of neuromuscular or joint disease, or neurological conditions affecting the trunk or pregnancy were excluded.

The study was approved by the ethical committee of the Faculty of Associated Medical Sciences, Chiang Mai University (No. 342/2017). The participants provided written informed consent before the study began.

3.2.5.3 Procedure

Participants were screened according to the eligibility criteria. All eligible participants were instructed about performing an abdominal drawing-in maneuver (ADIM) using the pressure biofeedback unit (PBU) as feedback. Participants were positioned supine with knee flexion 70 degrees and feet flat on the floor. For familiarization of TrA activation, the pressure biofeedback unit was placed under the lumbar spine (L2 – S1). The pressure transducer was pumped to 40 mmHg. The participants were instructed to bring the belly button to the spine while exhale and maintain the pressure within 40 ± 4 mmHg.

Then, participants received innovative lumbar support, which includes a core muscle activation feedback unit. Innovative lumbar support was designed to have space at the anterolateral area of the lumbar support for applying ultrasound probe to monitor the thickness of TrA, and there was the pressure sensor near the center of the monitoring space that measuring TrA muscle thickness. One pressure biofeedback unit was put between the lumbopelvic region (upper border at L2 level) and the lumbar supports; another pressure biofeedback unit was placed centrally between the umbilicus and the lumbar support. The lumbar support was worn firmly, and the pressure biofeedback unit at the front was pumped to 70 mmHg, and the PBU at the back was pumped to 40 mmHg. Core stability activation was performed in a functional standing position by doing an abdominal drawing-in maneuver (ADIM) on various levels, which triggers the visual/auditory feedback sensor in innovative lumbar support until the pressure of PBU at the umbilicus is reduced to 68, 66, 64 mmHg, respectively. The

pressure of PBU at the back remained 40 mmHg as maintain the spinal neutral position. When participants perform ADIM to the target pressure, the amount of force production from the visual feedback sensor was displayed simultaneously. During performing ADIM at each level, the feedback sensor's values and TrA muscle images were collected simultaneously. The decrease in the sensor values indicated amounts of TrA muscle activation. Participants were allowed to rest for 1 minute between trials. At each level of pressure, the image was collected three times. The average value was calculated. Participants were also scheduled to study the reliability of monitoring with 24 hours intervals between two sessions.

3.2.5.4 Outcome measures

Real-time ultrasound imaging was used to investigate the amount of TrA muscle contraction while performing various levels of ADIM against the force production from the feedback sensor attached to the lumbar support. The ultrasound scanner (Toshiba, Famiio 8, SSA-530A) in B-mode with a 5-MHz curvilinear transducer was used to assess the TrA muscle thickness. Participants were positioned standing in an upright position. The ultrasonic gel was applied between the transducer and the skin. The transducer was placed in the transverse plane at a point 2.5 cm anteromedial to the midpoint between the lower rib and iliac crest on the mid-axillary line (43). The image was captured at the end of the exhalation. After that, muscle thickness was measured during TrA activation at each pressure level of PBU. The thickness of TrA was randomly measured on both sides. The images of TrA and measurements were obtained using NIH (Bedthesda, MD) Image J software (V 1.8). The mean thickness of the three measures on each side was calculated.

3.2.5.5 Statistical analysis

The test-retest reliability of force production was determined using intraclass correlation coefficients (ICCs). The coefficient of variation (CV) and standard error of measurements (SEMs) was also included in determining the variability of measurements. The measurements were determined to acceptable reliability if the ICC value was greater than 0.85, CV was less than 15%, and SEMs was less than 5% (131). The validity of the values obtained from the relationship between the FS and TrA

thickness was analyzed using Pearson's correlation coefficients. The statistical analysis was performed using the SPSS statistical package.

3.2.6 Results

Table 3.3 showed the intraclass correlation coefficients (ICC), coefficient of variation (CV), and standard error of measurements (SEMs) for all measures. The feedback sensor and the measurement of TrA thickness were considered to be acceptable reliability (i.e., ICC > 0.9, CV < 10%, SEMs < 5%).

Table 3.3 The test-retest reliability results of the feedback sensor device and the real-time ultrasound imaging of TrA thickness.

Measurements	ICC	%CV	SEMs
Feedback sensor	0.946	2.6	2.47 (0.54%)
TrA thickness	0.931	8.05	0.104 (2.09%)

ICC: Intraclass correlation coefficients; CV: Coefficient of variation; SEMs: Standard error of measurements

The validity of the feedback sensor for the activation of TrA muscle was presented in Table 3.4. There was a significant correlation (moderate to strong positive) between PBU and feedback sensor ($r = 0.657$, $p < 0.001$). The value of the feedback sensor at each level of PBU was shown in figure 3.4. There was strong negative correlation between PBU and TrA thickness ($r = -0.793$, $p < 0.001$). The thickness of TrA at each level of PBU was shown in figure 3.5. There was a significant correlation (moderate to strong negative) between feedback sensor and TrA thickness ($r = -0.514$, $p < 0.001$). The correlation between the feedback sensor and TrA thickness also showed in figure 3.6.

Table 3.4. Correlation between the feedback sensor device and the thickness of transversus abdominis muscle

Measurements	Pearson's correlation coefficient (r)	P values
PBU vs Feedback sensor device	0.657	< 0.001
PBU vs TrA thickness	-0.793	< 0.001
Feedback sensor device vs TrA thickness	-0.514	< 0.001

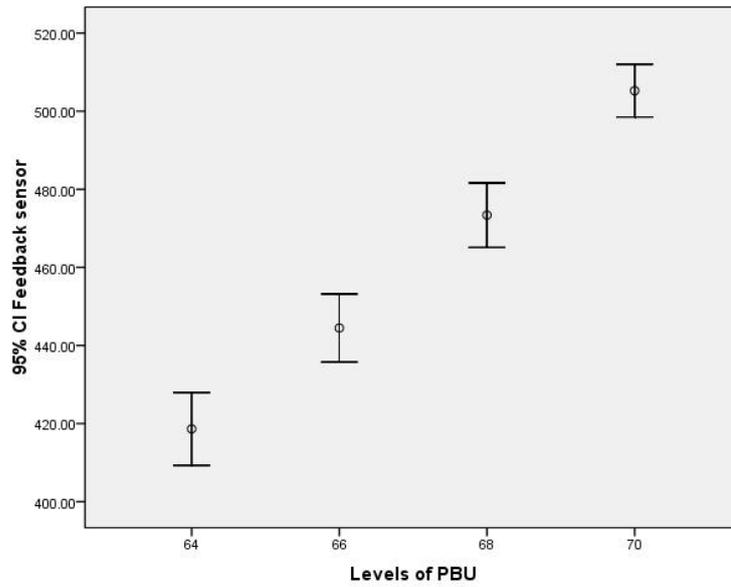


Figure 3.4 Relationship between levels of pressure biofeedback unit (PBU) and feedback sensor device

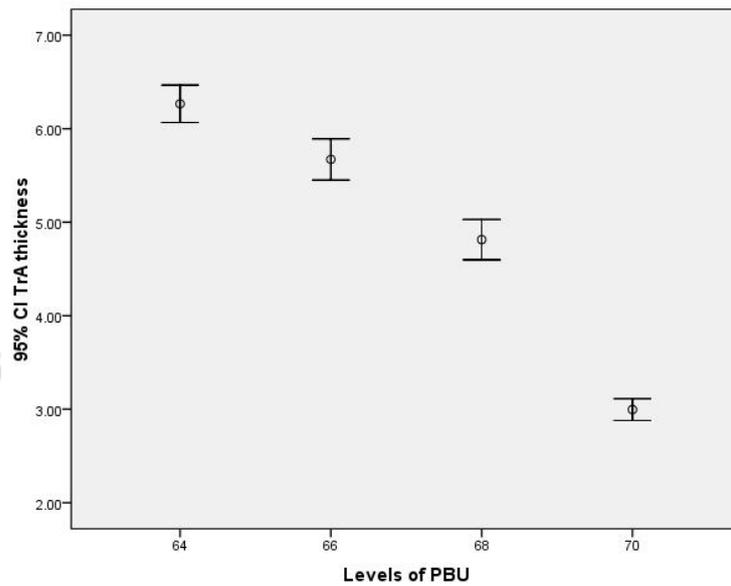


Figure 3.5 Relationship between levels of pressure biofeedback unit (PBU) and the thickness of transversus abdominis muscle

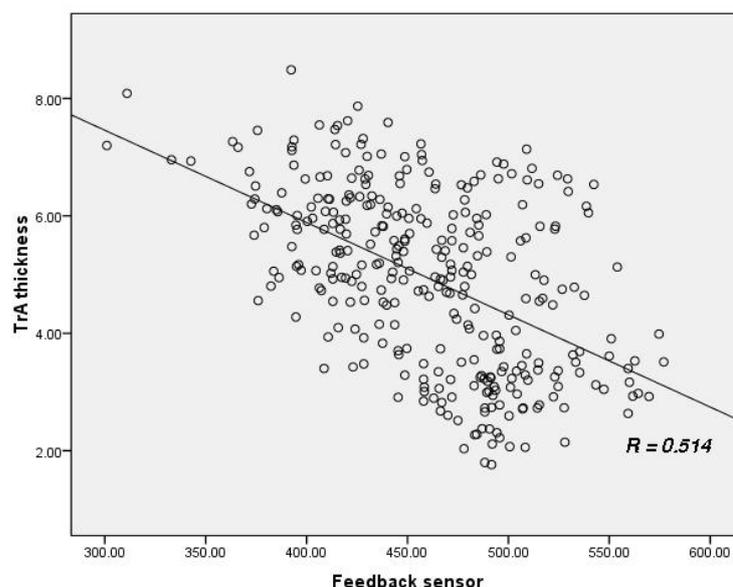


Figure 3.6 Relationship between the feedback sensor device and the thickness of transversus abdominis muscle

3.2.7 Discussion

The purposes of this study were to evaluate the reliability and validity of the feedback device for activation of TrA muscle compared with the RTUS and report the test-retest reliability of the device. We found excellent reliability of the feedback sensor and TrA thickness measurement using RTUS in a standing position (ICC = 0.946 and 0.931, respectively). It suggested that the feedback sensor and the measurement method of TrA thickness in this study were reliable methods. Previous studies (43, 132) also found very high reliability in the ultrasound measurement of TrA muscle (ICC > 0.9) in the supine position. In the upright position, there was also a high intraclass correlation for TrA thickness consistency with the result of standing position in this current study (ICC > 0.9) (133).

A significant (moderate to strong) relationship was found between the feedback sensor and the thickness of TrA. It could be considered utilizing the feedback sensor of this study to give the TrA activation information during performing ADIM in an upright functional position. The negative relationship between the feedback sensor and the TrA thickness was as expected. The feedback sensor was put between the lumbar support and abdominal muscles. When performing ADIM, the pressure values from the feedback sensor and the PBU, which are located between the lumbar support and the

abdominal muscles, were decreased. At the same time, TrA was activated by doing ADIM, which was presented in increased muscle thickness. This was supported by the study of McMeekan et al. (43), which showed an excellent correlation between the activity and thickness of TrA. Also, Lee and colleagues (134) reported that ADIM training with feedback method (i.e., ultrasound imaging and PBU) for 15 minutes resulted in significantly thicker TrA muscle than manual contact. They suggested that using the feedback method may be more effective than manual contact only in improving the TrA muscle function. Therefore, this current study's feedback device may be useful as an indicator of TrA activation for LBP patients, especially for self-training at home or the workplace, because it is easy to use and affordable.

3.2.8 Conclusion

This study demonstrated that the feedback device developed in this study is considered a reliable and valid tool for providing TrA activation information during ADIM. It could be clinically useful for simultaneous feedback on TrA muscle activation and encouraging patients with LBP to precisely perform core stability activation.

3.3 The therapeutic effects of innovative lumbar support comprising hot pack and core stability activation – Main Study III

3.3.1 Introduction

Innovative lumbar support tested in this study for the treatment of low back pain is a new device that is designed and developed combining the features of the traditional lumbar support (TLS) with the new features of core muscle activation feedback along with superficial heat therapy. Lumbar support (LS) is commonly recommended to patients with low back pain due to its effects on decreasing pain during physical activity and preventing further injury (7, 17). Lumbar support (LS) increases lumbopelvic stability, intra-abdominal pressure, and reduces the impact of load on the trunk (18). Using lumbar support is effective for LBP management as it improves the lumbar posture, provides support to the lumbar spine, and minimizes LBP incidence (7). Previous studies (18, 21, 22) documented that the LS reduced pain intensity, improved quality of life, and enhanced work performance. However, there were some challenges in applying the traditional lumbar support to clinical practice to manage CNLBP. The current scientific evidence questions the effectiveness of TLS and raises concerns about the use of lumbar support (123). It has been reported that prolonged use of TLS caused trunk muscle weakness and reduced core muscle function (112, 135, 136). Core stability exercise is one of the recommended treatments for low back pain as it reduces pain and improves physical function better than general exercises (13). Core stability exercise (CSE) provides both short- and long-term benefits by improving spinal stability, which results in pain relief and prevents LBP episodes (6). The CSE also enhances the strength and endurance of deep trunk muscles such as transversus abdominis (TrA) and lumbar multifidus muscle (LM) (16). In addition, superficial heat therapy is a commonly recommended treatment for LBP, both by physical therapists and by patients at home because of its therapeutic efficacy and convenience of application. Superficial heat therapy reduces muscle spasms, pain, anxiety and improves disability (4, 8). Therefore with the inclusion of these additional features of core muscles feedback and superficial heat therapy, the effects of the innovative lumbar support against the traditional lumbar support were needed to investigate among patients with non-specific low back pain before launching to the larger population. The immediate effects on innovative lumbar support

were investigated to understand its potential mechanism of action. Moreover, the long-term effects were investigated to prove its clinical therapeutic effects.

3.3.2 Objectives

- To investigate the immediate effects and long-term benefits of using innovative lumbar support comprising hot pack and core stability activation on pain modulation, muscle function, quality of life, and disability in subjects with non-specific low back pain
- To compare the therapeutic effect of innovative lumbar support comprising hot pack and core stability activation with traditional lumbar support on pain, muscle function, quality of life, and disability variables in subjects with non-specific low back pain

3.3.3 Hypotheses

- The outcomes of pain, muscle function, quality of life, and disability would be improved after using innovative lumbar support comprising hot pack and core stability activation
- An innovative lumbar support comprising hot pack and core stability activation would be superior to traditional lumbar support in improving outcomes of pain intensity, pressure pain threshold, thermal pain threshold, muscle function, lumbopelvic stability, health-related quality of life, and disability.

3.3.4 Study design

The trial utilizes a single-blinded randomized controlled design, which conforms to the CONSORT recommendations (137).

3.3.5 Methods

3.3.5.1 Sample size calculation

The sample size calculation was based on the following assumption: (a) a power analysis of 0.8, (b) a significant alpha level of 0.05, (c) estimated effect size of 0.54, (d) ANOVA repeated measures within-between interaction models. A minimal sample size of 64 participants was required. In addition, to account for dropouts (20 %), a sample size of 80 subjects was required in the study.

3.3.5.2 Setting and participants

Eighty participants with non – specific low back pain, aged between 20 – 55 years, both male and female, were recruited into the study from advertising in local hospitals, universities, and communities. A research assistant screened participants via telephone interview. They were eligible for the study if they met the study criteria. The inclusion and exclusion criteria were as following.

3.3.5.2.1 Inclusion criteria

- Presence of mild to moderate low back pain (visual analog scale of 3/10 – 7/10) in the area between 12th rib to gluteal fold for more than 3 months
- Body mass index (BMI) more than 18.5 kg/m² but less than 30 kg/m²
- Communicating in Thai fluently
- Willing to participate

3.3.5.2.2 Exclusion criteria

- Referred pain or numbness in lower limbs
- An impaired sensation at the body and lower limbs
- History of past surgery of spine or lower extremities
- History of injury from an accident in the previous 3 months
- Structural deformities of the spine
- Pregnancy
- Specific spinal disorders or nerve root compression
- Inflammation or infection at spine and back
- Severe medical conditions such as cardiovascular disease, renal failure, hypertension, diabetes
- Received manual therapy in the previous 3 months

3.3.5.2.3 Withdrawal criteria

- Getting accident or injury during the study period

The study was approved by the ethical committee of the Faculty of Associated Medical Sciences, Chiang Mai University (No. 342/2017). Participants

provided informed consent before the study began. The study protocol had been registered in a clinical trial registry database on clinicaltrials.in.th with a trial registration number (TCTR20190905002)

3.3.5.3 Randomization and allocation concealment

Participants were randomly allocated to one of four intervention groups (1:1:1:1 ratio): 1) traditional lumbar support, 2) innovative lumbar support including hot pack, 3) innovative lumbar support including core stability activation, or 4) innovative lumbar support including hot pack and core stability activation to evaluate the effects of the innovative lumbar support combining hot pack and/or core muscle training compared with controls. Randomization was stratified by severity of back pain (i.e., pain intensity). Random sequence was generated by an internet randomized scheme generator (<https://www.sealedenvelope.com/simple-randomiser/v1/lists>) in blocks of eight. Randomization and allocation were undertaken by an independent staff who is a part of the research team.

3.3.5.5 Interventions

1) Traditional lumbar support (TLS)

Participants received traditional lumbar support, which fit each participant's body size. They were instructed to wear lumbar support around the lumbopelvic region (the upper edge of lumbar support is just below the 12th ribs) firmly. At the first visit, participants wore traditional lumbar support firmly and completed 4 rounds of standing for 4 minutes and rest by sitting for 1 minute (for a total time of 20 minutes). The standing and sitting positions are represented the functional activities and common gestures of working in daily life. After that, participants were instructed to wear lumbar support during the daytime at least 7 hours per day.

2) Innovative lumbar support including hot pack (LS + HP)

Participants received innovative lumbar support, which fit each participant's body size. They were instructed to wear lumbar support around the lumbopelvic region (the upper edge of lumbar support is just below the 12th ribs). At the first visit, participants wore innovative lumbar support with a hot pack and position as described in group 1). After that, participants were instructed to wear lumbar support

during the daytime at least 7 hours per day. In addition, participants also received superficial heat from a hot pack component of innovative lumbar support for 20 minutes twice a day (in the morning and evening). Their compliance was also recorded in a log-book.

Note: The hot pack used in this study was a wheat herbal hot pack (Pretty patent no. 6909; Department of Intellectual Property, Ministry of Commerce, Thailand). The main ingredients include: *Zea Mays Linn.*, *Zingiber Cassumunar Roxb*, *Citrus Hystrix*, *Cymbopogon Citratus*, *Curcuma Longa L.* Hot pack component can be prepared by heating in a microwave for 3 minutes and put into the inner sleeve at the back of the innovative lumbar support.

3) Innovative lumbar support including core stability activation (LS + CSE)

Participants received innovative lumbar support, which fit each participant's body size. They were instructed to wear lumbar support around the lumbopelvic region (the upper edge of lumbar support is just below the 12th ribs). At the first visit, participants were asked to wear innovative lumbar support firmly. They performed core stability activation by doing an abdominal drawing-in maneuver (ADIM), which triggers the target of a visual feedback sensor on innovative lumbar support. Participants were prescribed to do ADIM in a standing position and hold for 10 seconds per contraction, 20 times per set for 4 sets. Overall, this took approximately 20 minutes. After that, participants were instructed to wear lumbar support during the daytime at least 7 hours per day and activate core stability muscles as per previous protocol twice a day (in the morning and evening). Their compliance was recorded in a log-book.

4) Innovative lumbar support including hot pack and core stability activation (LS + HP + CSE)

Participants received innovative lumbar support, which fit each participant's body size. They were instructed to wear lumbar support around the lumbopelvic region (the upper edge of lumbar support is just below the 12th ribs). At the first visit, participants wore lumbar support, receive a hot pack, and activate core stability muscles as the protocol in groups 2) and 3). The experimental condition took overall about

20 minutes. After that, participants were instructed to wear lumbar support during the daytime at least 7 hours per day. Participants were asked to activate core stability and receive superficial heat as previous protocol twice a day. Their compliance was also recorded in a log-book.

3.3.5.6 Outcome measures

Outcome measures were divided into 3 paradigms, including pain-related outcomes, muscle function, and quality of life and disability. Pain-related outcomes consist of visual analog scale (VAS), pressure pain threshold (PPT), thermal pain threshold (TPT), and tissue blood flow. Outcomes related to muscle function consist of lumbopelvic stability test (LPST), real-time ultrasound imaging of TrA muscle thickness and cross-sectional area of LM muscle, and modified active straight leg raising test (ASLR). Outcomes related to the quality of life and disability consists of the short form 36 health survey (SF-36) and the Oswestry disability questionnaire (ODI). The primary outcomes are pain intensity and pressure pain threshold. Secondary outcome measures are tissue blood flow, thermal pain threshold, lumbopelvic stability test, modified active straight leg raising test, ultrasound imaging of TrA muscle thickness and CSA of LM muscle, quality of life, and disability.

3.3.5.6.1 Pain-related outcomes

1) Pain intensity

A visual analog scale (VAS) was used to assess pain intensity. It is a continuous scale consisted of a horizontal line, 100 millimeters in length. It is anchored by “no pain” on the left hand and “pain as bad as possible” on the right hand. Participants were asked to mark the line corresponding to their average pain intensity in the past week.

Note: Pain intensity at baseline of the immediate effect study was rated for pain intensity on the day of the 1st visit to reflect for the current stage of their pain intensity before receiving the treatment conditions.

2) Pressure pain threshold (PPT)

Pressure pain threshold (PPT) was assessed using a pressure algometer (Somedic Production, Algometer type II, Sweden). The algometer

consists of a 1-cm² circular stimulation probe connected to a pressure transducer. The device was calibrated in the laboratory with a 100- kPa weight before administration with participants. The pressure was applied perpendicularly to the skin at a constant speed of 40 kPa/s. The participants were instructed to press the button when they feel the sensation changing from pressure to pain. The pressure pain threshold was randomly measured over the standard fixed point (facet joints) of L4 – L5 on both sides. The pressure pain threshold was assessed 3 times with 30-sec resting between trials, and the mean of the 3 trials was used for analysis (79).

3) Thermal pain threshold (TPT)

Thermal pain threshold (TPT) was assessed by using a Thermal Sensory Analyzer (Medoc Ltd., Neuro Sensory Analyzer Model TSA-II, Israel) for cold pain threshold (CPT) and heat pain threshold (HPT). A 5-cm² thermode was applied directly to the skin over the L4-5 interspinous space. The initial temperature was set at 32° C with the rate change of 1 degree Celsius/ second for heat pain and 2 degrees Celsius/ second for cold pain. The cut-off temperature was set at 0° C for cold pain threshold and 4° C for heat pain threshold for preventing tissue damage. The participants were instructed to press the button when they feel the sensation change from heat or cold to pain. The thermal pain threshold was assessed 3 times, and the mean of the 3 trials was used for analysis (82).

4) Tissue blood flow

The tissue blood flow was monitored using a laser Doppler blood flow meter (Moor instruments DRT4, UK) in units of flux/min. The participants lie in a prone position with arms by the side. The electrode was applied over the individual's standard fixed point on the tenderest point over the L4-5 area and recorded every minute for 5 minutes (79). The mean value was used for analysis.

3.3.5.6.2 Muscle function

1) Lumbopelvic stability test (LPST)

Lumbopelvic stability was assessed by using the lumbopelvic stability test according to the methods described by Hagins and colleagues (50), which consists of 7 levels of lumbopelvic stability control. The participants laid in

a supine position with knee flexion 70 degrees. The pressure biofeedback unit was used to monitor the stability of the lumbopelvic position by placing it under the lumbar spine (L2 – S1). The pressure transducer was pumped to 40 mmHg. The participants were asked to maintain trunk stability at each level. Participants were considered to pass each level if they can maintain the pressure within 40 ± 4 mmHg.

2) Real-time Ultrasound Imaging

Real-time ultrasound imaging was used to assess muscle function of core muscles (TrA and LM). For transversus abdominis muscle, the ultrasound scanner in B-mode with 5 MHz with curvilinear transducer was used to assess the muscle thickness. Participants were positioned in crooked lying with a pillow under their head and knees (30 degrees of hip flexion). The ultrasonic gel was applied between the transducer and the skin. The transducer was placed in a transverse plane at a point 2.5 cm. anteromedial to the midpoint between the lower rib and iliac crest on the midaxillary line (47). The images were collected at the end of the exhalation. The thickness of TrA was randomly measured on both sides. The mean thickness of the three measurements was calculated.

For lumbar multifidus muscle, the cross-sectional area (CSA) was measured using a 5 MHz curvilinear transducer in B-mode. Participants were positioned prone lying with a pillow under the abdomen. Investigator palpated the spinous process of L5 and marked on the skin. The ultrasonic gel was applied, and the transducer was placed longitudinally along the lumbar spine's midline to confirm the location of the L5 spinous process. The transducer was rotated transversely and placed in the middle of the L5 spinous process (138). The image was taken at the end of the exhalation. The CSA measurement was made by tracing the inner border of the LM muscle. CSA of LM was also randomly measured on both sides. The average CSA of three measurements was recorded.

3) Modified active straight leg raising test (ASLR)

A modified active straight leg raising test was used to evaluate the outcome of spinal stability while wearing lumbar support. The standardized procedure of the modified active straight leg raising test followed through the protocol of Mens and colleagues (102). Participants lied in a supine position with a

straight leg. They were asked to raise their legs with knee straight alternately. Participants raised their legs until the heels are 20 cm. above the table and hold them for approximately 10 seconds. The bar was placed at the mark of 20 cm. above the ankle joint to prevent participants from raising their legs over 20 cm. A standardized instruction such as “try to raise your legs, 20 cm. above the bench without bending the knees, one after the other” was used during the tests. The participants performed three repetitions of the test (performance of the test on both the left and the right side constitutes one repetition). The whole procedure was done with and without lumbar support at the first visit. The outcome of ASLR test was scored by each participant on 6-point Likert scale; 0 = not difficult at all, 1 = minimally difficult, 2 = somewhat difficult, 3 = fairly difficult, 4 = very difficult, 5 = unable to do.

3.3.5.6.3 Quality of life and disability

1) Quality of life

Quality of life was assessed using the short form 36 health survey questionnaires (SF-36 Thai version) (98). The SF-36 consists of 36 items of 8 health dimensions: physical functioning, social functioning, role limitations due to physical problems, role limitation due to emotional problems, mental health, energy and vitality, pain, and general perception of health. The scores were coded, summed, and transformed to a scale from 0 to 100. The higher scores show better health status.

2) Disability induced by low back pain

Disability was assessed using the Oswestry Disability Index (ODI), the specific questionnaire for low back pain. The participants rated their physical disability in activity daily living that are deficit by back pain such as self-care, walking, lifting, and sleeping, and so on. The ODI consists of 10 questions with 6 response categories of level of activity disturbance due to low back pain. Each item can be scored 0 to 5, the higher value representing the greater disability. The total score was expressed as a percentage. The Oswestry Disability Questionnaire (1.0) Thai version (95) was used in this study.

3.3.5.7 Procedure

Participants were screened according to the eligibility criteria. The eligible participants provided written informed consent and complete the general questionnaire. Participants were asked to complete the general screening form, VAS, SF-36, and Oswestry disability questionnaires. Then, participants were measured tissue blood flow, CPT, HPT, PPT, ultrasound imaging, ASLR, and LPST, respectively. The measurements were performed by an assessor who is blinded to the participant's treatments.

Then, participants were stratified by the severity levels of LBP and randomly allocated into the traditional lumbar support (TLS), innovative lumbar support with hot pack (LS + HP), innovative lumbar support with core stability activation (LS + CSE), or innovative lumbar support with hot pack and core stability activation (LS + HP + CSE) group. Participants in each group were instructed about the application of each condition for 8 weeks. The LBP features (intensity, frequency, and duration), compliance with the study protocol, and any possible adverse effect of using lumbar support and medication intake were recorded in a logbook by each participant.

Intra-rater reliability was established prior to the enrollment of participants and data collection, with an acceptable value of agreement greater than 80% (i.e., LPST, ASLR), and also intraclass correlation coefficients (ICCs) ranged from 0.87 – 0.99 for all measures (i.e., PPT, CPT, HPT, TBF, thickness of TrA, CSA of LM). All of the outcome measures were assessed by blinded assessors immediately after receiving intervention for 20 minutes, 4- weeks, and 8- weeks of intervention, and follow up at 3 months after the end of the intervention (except SF-36 and ODI were assessed at the end of 20 minutes of intervention). Participants were asked to complete the general, VAS, SF-36, and Oswestry disability questionnaires and measured tissue blood flow, CPT, HPT, PPT, ultrasound imaging, ASLR, and LPST, respectively.

3.3.5.8 Statistical analysis

Descriptive statistics were used to present demographic data. The collected data were analyzed for normal distribution using the Shapiro Wilk test. If the data is normal distribution, a mix-model two-way repeated-measures analysis of variance (ANOVA) was used to consider the interaction effects and main effects of the experimental conditions and time. The least significant difference (LSD) test was used

for post-hoc analysis. A level of significance was set at $p < 0.05$. Data were analyzed using a statistical software package (SPSS).

Estimates of effect size were calculated using partial eta squared (η^2_p). An effect size of 0.01 is regarded as small, 0.06 as medium, and 0.14 as large (139).

3.3.6 Results

A total of 80 patients with chronic non-specific low back pain (CNSLBP) were recruited for the study, and none were lost to follow-up. The flow diagram of participant recruitment was presented in Figure 3.7. The pre-intervention characteristics of the participant are provided in Table 3.5. There were no significant differences between the study groups in baseline characteristics ($p > 0.05$).

Participants in all groups completed 8 weeks of intervention. From the logbook, the participants in the TLS group used lumbar support for an average of 48.1 ± 3.5 days, in the ILS + HP group for an average of 49.4 ± 2.3 days, in the ILS + CSE group for an average of 49.9 ± 2.8 days, in the ILS+HP+CSE group for an average of 49.4 ± 3.1 days. In the TLS group, the number of daily hours on using lumbar support was 7.2 ± 2.4 hours at week 4 and 5.9 ± 2.2 hours at week 8. In the ILS+HP group, the number of daily hours using lumbar support was 7.4 ± 1.7 hours at week 4 and 6.2 ± 1.3 hours at week 8. In ILS+ CSE, the number of daily hours using lumbar support was 6.8 ± 1.6 hours at week 4 and 5.7 ± 1.8 hours at week 8. Finally in the ILS+HP+CSE group, the number of daily hours using lumbar support was 7.4 ± 1.9 hours at week 4 and 6.1 ± 2.3 hours at week 8. Two participants (10%) in the TLS group and one participant (5%) in the ILS+ CSE group took paracetamol to relieve low back pain. No significant adverse events with treatment were reported in any group.

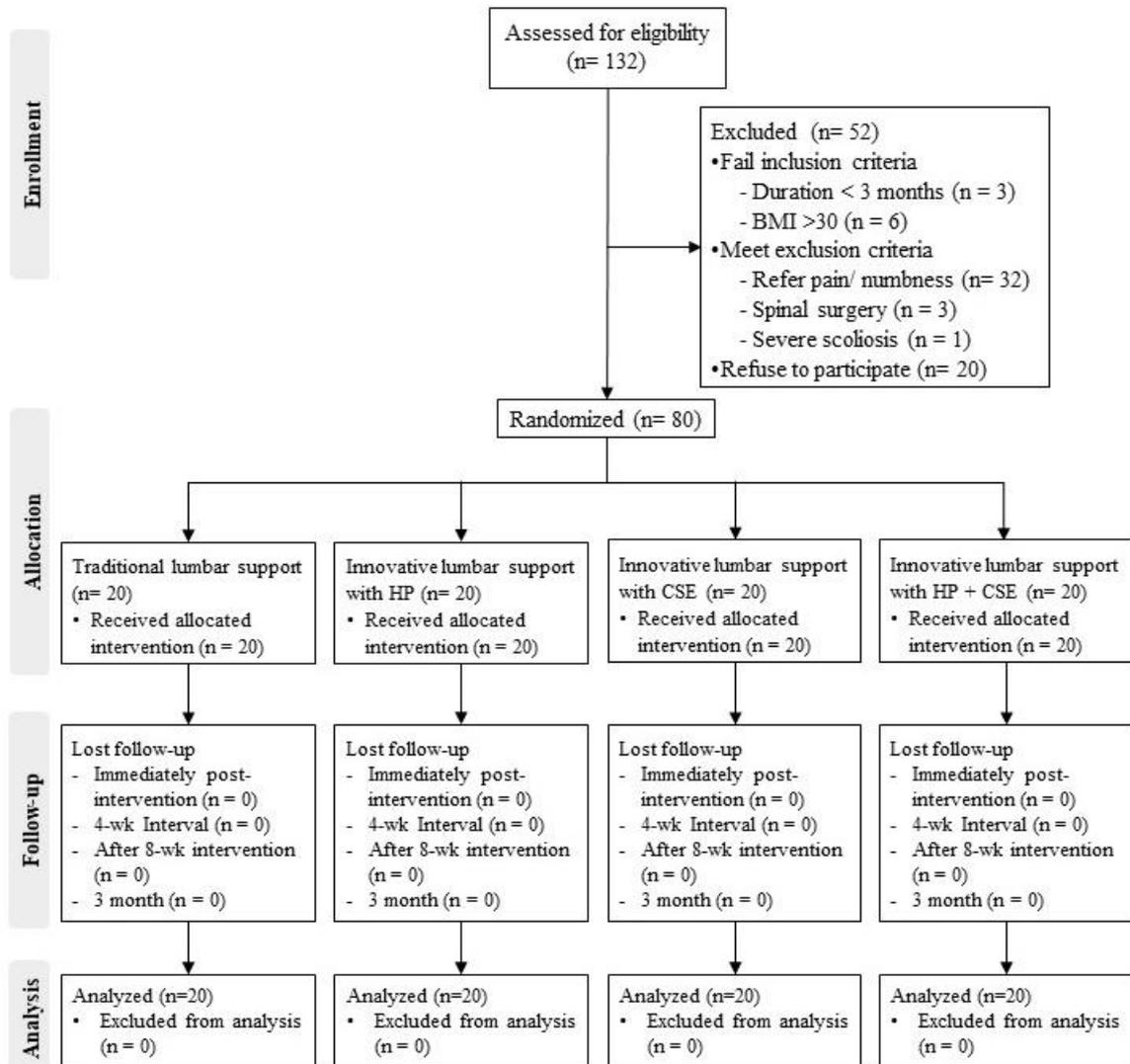


Figure 3.7 Flow diagram of the trial

Table 3.5 Demographic data are shown as mean \pm standard deviation (SD).

Variables/ Group	TLS (n = 20)	ILS+HP (n = 20)	ILS+CSE (n = 20)	ILS+HP+CSE (n = 20)	p- value
Gender (M/F)	8/12	10/10	6/14	9/11	0.614
Age (years)	40.5 \pm 9.99	41.45 \pm 9.93	40.45 \pm 7.8	43.05 \pm 8.82	0.789
BMI (kg/m ²)	23.46 \pm 3.96	23.96 \pm 2.86	22.55 \pm 3.33	24.24 \pm 2.75	0.384
Onset of LBP (months)	24.75 \pm 22.87	28.05 \pm 28.69	42.1 \pm 42.9	40.0 \pm 38.42	0.29
Pain intensity (mm.)	49.55 \pm 9.64	53.1 \pm 9.89	53.9 \pm 13.23	49.75 \pm 12.94	0.521
ODI score (%)	22.43 \pm 12.04	18.94 \pm 10.73	19.01 \pm 11.42	19.18 \pm 10.4	0.711

3.3.6.1 Immediate effect

There was no significant difference in the baseline of any variables among the study groups ($p > 0.05$). Table 3.6 presented the two-way repeated measure ANOVA results on the interaction effect between groups and time in all variables ($p < 0.05$). The participants in TLS group showed the significant interaction in pain intensity ($p < 0.01$), and PPT ($p < 0.01$) compared to baseline. The participants in ILS+HP group showed the significant interaction in pain intensity ($p < 0.001$), TBF ($p < 0.001$), PPT ($p < 0.001$), CPT ($p < 0.001$), and HPT ($p < 0.001$), however no interaction was found in TrA thickness ($p > 0.05$), and lumbopelvic stability ($p > 0.05$). The results presented that the participants in ILS+ CSE group showed the significant interaction in pain intensity ($p < 0.001$), TBF ($p < 0.05$), PPT ($p < 0.001$), CPT ($p < 0.05$), TrA thickness ($p < 0.001$), CSA of LM ($p < 0.001$), and lumbopelvic stability ($p < 0.001$). The participants in ILS+HP+CSE group showed the significant interaction in all variables (all $p < 0.001$). Post-hoc analysis showed that the ILS+HP+CSE was superior to TLS in all outcomes ($p < 0.05$). Also, The ILS+HP+CSE was superior to ILS+HP in some variable such as HPT ($p < 0.05$), TrA thickness ($p < 0.05$), CSA of LM ($p < 0.05$), and lumbopelvic stability ($p < 0.05$), as well as superior to ILS+CSE in all outcomes ($p < 0.05$) except TrA thickness and CSA of LM ($p > 0.05$). For ASLR, there was no significant interaction effect between groups ($p > 0.05$) but a significant main effect was observed between conditions (with and without LS) on the difficulty of leg lifting ($p < 0.001$).

Table 3.6 Data of all variables for the immediate effects and mean difference values are shown as mean (SD)

Outcomes		Groups				Interaction effect	
		TLS (n=20)	ILS+HP (n=20)	ILS+CSE (n=20)	ILS+HP+CSE (n=20)	p-value	η_p^2
VAS (mm)	Pre	30.65 (22.74)	36.25 (18.37)	34 (22.49)	33 (18.49)	0.001	0.2
	Post	20.9 *** (18.36)	17.4 *** (13.39)	23.35 *** (16.57)	15.65 *** (12.93)		
	Mean Diff (95% CI)	-9.75 ^{b,d} (-13.37, -6.13)	-18.85 ^{a,c} (-22.56, -12.14)	-11 ^{b,d} (-14.98, -7.02)	-17.4 ^{a,c} (-21.07, -13.73)		
	Percentage Change (%)	-43.47 (32.76)	-57.36 (22.24)	-36.56 (20.84)	-61.72 (26.34)		
TBF (flux/ min)	Pre	10.13 (3.54)	9.94 (2.88)	10.07 (2.3)	10.41 (3.33)	< 0.001	0.71
	Post	12.17 (3.92)	41.05 *** (15.95)	14.00 * (9.54)	43.44 *** (13.83)		
	Mean Diff (95% CI)	2.03 ^{b,d} (0.52, 0.72)	31.12 ^{a,c} (23.66, 38.58)	3.93 ^{b,d} (-0.79, 8.64)	33.04 ^{a,c} (26.11, 39.96)		
	Percentage Change (%)	24.24 (34.7)	341.99 (208.3)	47.07 (118.34)	368.08 (234.71)		
PPT (kPa)	Pre	416.09 (136.92)	452.75 (183.74)	445.62 (179.35)	457.35 (195.92)	<0.001	0.48
	Post	441.78 ** (132.44)	562.73 *** (207.32)	500.97 *** (185.33)	569.79 *** (199.41)		
	Mean Diff (95% CI)	25.69 ^{b,c,d} (8.25, 43.13)	109.98 ^{a,c} (92.54, 127.42)	55.35 ^{a,b,d} (37.91, 72.79)	112.44 ^{a,c} (95, 129.88)		
	Percentage Change (%)	9.51 (18.17)	26.73 (11.78)	14.13 (15.41)	28.92 (13.57)		
CPT (°C)	Pre	2.4 (3.03)	3.15 (2.6)	1.97 (2.46)	2.97 (3.1)	< 0.001	0.24
	Post	2.12 (2.78)	1.0 *** (1.42)	1.19 * (2.06)	0.7 *** (1.4)		
	Mean Diff (95% CI)	-0.28 ^{b,d} (-0.43, 0.98)	-2.16 ^{a,c} (-2.87, -1.45)	-0.78 ^{b,d} (-1.49, -0.08)	-2.27 ^{a,c} (-2.98, -1.56)		
	Percentage Change (%)	-13.57 (30.09)	-66.08 (36.03)	-36.19 (41.8)	-62.19 (38.35)		
HPT (°C)	Pre	43.49 (3.46)	43.91 (2.8)	45.16 (2.83)	44.35 (3.43)	<0.001	0.59
	Post	43.72 (3.36)	47.76 *** (2.03)	45.02 (3.02)	47.06 *** (2.51)		
	Mean Diff (95% CI)	0.23 ^{b,d} (-0.4, 0.87)	3.85 ^{a,c,d} (3.21, 4.48)	-0.14 ^{b,d} (-0.78, 0.49)	2.71 ^{a,b,c} (2.08, 3.35)		
	Percentage Change (%)	0.57 (2.21)	8.96 (4.34)	-0.34 (2.87)	6.34 (3.72)		
TrA thickness (mm)	Pre	2.6 (0.71)	2.59 (0.48)	2.43 (0.44)	2.54 (0.47)	<0.001	0.76
	Post	2.62 (0.75)	2.6 (0.44)	3.05 *** (0.55)	3.23 *** (0.58)		
	Mean Diff (95% CI)	0.02 ^{c,d} (-0.6, 0.11)	0.003 ^{c,d} (-0.08, 0.09)	0.63 ^{a,b} (0.54, 0.71)	0.69 ^{a,b} (0.61, 0.77)		
	Percentage Change (%)	0.81 (5.76)	0.64 (7.01)	25.58 (7.26)	27.58 (9.97)		

Table 3.6 Data of all variables for the immediate effects and mean difference values are shown as mean (SD) (continued)

Outcomes		Groups				Interaction effect				
		TLS (n=20)	ILS+HP (n=20)	ILS+CSE (n=20)	ILS+HP+CSE (n=20)	p-value	η_p^2			
CSA of LM (mm ²)	Pre	451.75 (53.09)	456.08 (45.36)	447.79 (48.68)	445.04 (56.72)	<0.001	0.607			
	Post	452.77 (53.79)	453.09 (49.12)	472.23*** (45.02)	471.08*** (57.55)					
	Mean Diff	1.02 ^{c,d}	-2.99 ^{c,d}	24.43 ^{a,b}	26.04 ^{a,b}					
	(95% CI)	(-3.16, 5.2)	(-6.08, 0.09)	(18.89, 29.99)	(19.23, 32.84)					
	Percentage Change (%)	0.23 (2.0)	-0.73 (1.46)	5.63 (2.97)	5.96 (3.61)					
	LPS (level)	Pre	1.95 (0.39)	2.15 (0.37)	2.05 (0.39)			1.75 (0.44)	<0.001	0.4
	Post	1.95 (0.39)	2.15 (0.37)	2.45*** (0.51)	2.4*** (0.5)					
Mean Diff	0 ^{c,d}	0 ^{c,d}	0.4 ^{a,b,d}	0.65 ^{a,b,c}						
(95% CI)	(0, 0)	(0, 0)	(0.16, 0.64)	(0.42, 0.88)						
Percentage Change (%)	0	0	22.5 (30.24)	45.0 (39.4)						
ASLR (0-5)	Without LS	1.23 (0.8)	1.48 (0.92)	1.28 (0.97)	1.1 (0.98)	0.414	0.037			
With LS	0.53 (0.66)	0.55 (0.6)	0.58 (0.75)	0.43 (0.54)						
Mean Diff	-0.7	-0.93	-0.68	-0.75						
(95% CI)	(-0.97, -0.43)	(-1.2, -0.67)	(-0.89, -0.51)	(-0.95, -0.4)						
Percentage Change (%)	-60.42 (42.82)	-65.17 (32.61)	-60.18 (36.95)	-50.75 (39.88)						

No significant differences in the baseline data among 4 conditions ($p > 0.05$)

Significant differences between pre-post (* $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$)

^a Significant difference between control ($p < 0.05$)

^b Significant differences between LS+HP ($p < 0.05$)

^c Significant differences between LS+CSE ($p < 0.05$)

^d Significant differences between LS+HP+CSE ($p < 0.05$)

η_p^2 = Partial eta-squared

3.3.6.2 Long term effects

There was no significant difference in the baseline of any variables among the study groups ($p > 0.05$). Table 3.7 presented the two-way repeated measures ANOVA results on the interaction effect between groups and time in pain intensity ($p < 0.05$), PPT ($p < 0.001$), CPT ($p < 0.001$), lumbopelvic stability ($p < 0.001$), ASLR ($p < 0.001$), and quality of life ($p < 0.05$).

3.3.6.2.1 Pain-related variables

All groups showed a significant reduction in pain intensity at all times compared to baseline ($p < 0.001$). For 3-month follow-up assessment, the ILS+HP+CSE group presented significant greater reduced pain intensity when compared to the TLS ($p = 0.034$) and ILS+HP ($p = 0.04$) groups. There was no significant difference in change of TBF both within and between-group comparisons ($p > 0.05$). All groups showed a significant increase in PPT at all time point when compared to baseline ($p < 0.01$) except the TLS group at 3-month follow-up ($p = 0.054$). The ILS+HP+CSE group also presented a significantly greater pressure pain threshold after the 8-week intervention ($p = 0.049$) and 3-month follow-up assessment ($p = 0.021$) compared to the TLS group. For the thermal pain threshold, the result of CPT and HPT were similar. All groups showed a significant reduction in CPT and HPT in all groups at any point of time ($p < 0.001$), except the TLS group ($p > 0.05$). Post-hoc analysis showed that the ILS+HP, ILS+CSE, and ILS+HP+CSE group demonstrated a higher cold pain threshold after the 8-week intervention and 3-month follow-up assessment when compared to the TLS group ($p < 0.05$).

3.3.6.2.2 Core muscle function

For the real-time ultrasound imaging, changes in the thickness of TrA and the cross-sectional area of LM muscle were found in the ILS+CSE and ILS+HP+CSE group. The thickness of TrA was significantly thicker at all points of time in the ILS+CSE and ILS+HP+CSE group compared to baseline ($p < 0.001$). The thickness of TrA in the ILS+CSE and ILS+HP+CSE group also more significant than the TLS and ILS+HP group ($p < 0.05$). Also, the CSA of LM was significantly greater at all periods in the ILS+CSE and ILS+HP+CSE group than baseline ($p < 0.001$ and $p < 0.01$, respectively). There was no significant difference between groups at all periods ($p > 0.05$).

For clinical assessment, the improvement of lumbopelvic stability control was found in the ILS+CSE and ILS+HP+CSE groups. The ILS+CSE and ILS+HP+CSE group demonstrated the improvement of lumbopelvic stability level at any time point when compared to baseline ($p < 0.001$). The lumbopelvic stability level in ILS+CSE and ILS+HP+CSE group was also significantly greater than the TLS and

ILS+HP group ($p < 0.05$). Similarly, The ILS+CSE and ILS+HP+CSE group presented a significant improvement of ASLR score at all time point when compared to baseline ($p < 0.05$), and the improvement was more significant than the TLS and ILS+HP groups ($p < 0.05$).

3.3.6.2.3 Quality of life and Disability

All groups showed a significant improvement in the quality of life (SF-36) scores at all time point when compared to baseline ($p < 0.01$). After 8-week intervention, the ILS+HP+CSE group presented the significant greater SF-36 score when compared to the TLS ($p = 0.027$) and ILS+CSE ($p = 0.041$) groups. At 3-month follow-up assessment, the ILS+HP and ILS+HP+CSE groups showed the significant greater SF-36 score than the TLS group ($p = 0.026$ and $p = 0.013$, respectively).

The Oswestry Disability Index (ODI) score was significantly improved in all groups at all time point when compared to baseline ($p < 0.01$). At a 4-week interval assessment, the ODI score in the ILS+HP group was significantly lower than the TLS group ($p = 0.031$). After 8-week intervention, the ILS+HP+CSE group demonstrated the significant lower ODI score than the TLS and ILS+CSE groups ($p = 0.035$, $p = 0.043$, respectively). At a 3-month follow-up assessment, the ILS+HP+CSE group also presented a significantly lower ODI score than the TLS group ($p = 0.025$).

3.3.6.2.4 Additional analysis compared the 4-week interval assessment and the end of intervention assessment

Comparisons between the 4-week interval assessment and after the completion of 8-week intervention, the results showed that the ILS+HP+CSE group had the significant improvement in pain intensity ($p < 0.01$), PPT ($p < 0.01$), CPT ($p < 0.01$), HPT ($p < 0.05$), core muscle function ($p < 0.001$), ODI scores ($p < 0.01$), and disability ($p < 0.01$) after the 8-week intervention when compared with the 4-week interval assessment. Similarly, the ILS+CSE group showed a significant improvement in all variables as the ILS+HP+CSE group, except HPT, quality of life, and ODI scores. The ILS+HP group showed lower pain intensity ($p < 0.01$) and higher PPT ($p < 0.01$) after 8-week intervention when compared with the 4-week interval assessment. The TLS group

demonstrated the greater improvement in pain intensity ($p < 0.01$), PPT ($p < 0.05$), quality of life ($p < 0.01$) and ODI scores ($p < 0.01$) at the end of intervention when compared with the 4-week interval assessment.



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Table 3.7 Data of all variables of the long-term effects are shown as mean (SD)

Outcomes		Groups				Interaction effect	
		TLS (n=20)	ILS+HP (n=20)	ILS+ CSE (n=20)	ILS+HP+CSE (n=20)	p-value	η_p^2
VAS (mm)	Baseline	49.55 (9.64)	53.1 (9.89)	53.9 (13.23)	49.75 (12.94)	0.03	0.08
	Week 4	23.15*** (16.52)	26.05*** (9.7)	22.95*** (13.2)	22.6*** (12.8)		
	Week 8	14.95*** (11.34)	16.5*** (12.48)	15.0*** (11.67)	13.4*** (13.56)		
	3-month follow-up	15.5***,d (15.05)	15.2***,d (15.15)	9.25*** (9.14)	6.95***, a,b (9.26)		
TBF (flux/min)	Baseline	10.13 (3.54)	9.94 (2.88)	10.07 (2.3)	10.41 (3.33)	0.112	0.08
	Week 4	10.62 (3.16)	10.22 (2.61)	10.27 (2.02)	10.89 (2.86)		
	Week 8	10.12 (3.12)	10.23 (2.9)	10.52 (2.03)	11.22 (3.0)		
	3-month follow-up	10.5 (3.26)	10.34 (2.43)	10.58 (2.01)	10.75 (2.64)		
PPT (kPa)	Baseline	416.09 (136.92)	452.75 (183.74)	445.62 (179.35)	457.35 (195.92)	<0.001	0.14
	Week 4	446.38** (137.98)	548.48*** (180.68)	499.14*** (183.82)	524.62*** (184.06)		
	Week 8	465.53***,d (139.18)	571.16*** (180.57)	523.45*** (186.8)	575.24***,a (181.5)		
	3-month follow-up	446.47 ^d (136.19)	542.18*** (174.05)	512.91*** (181.9)	568.66***,a (160.24)		
CPT (°C)	Baseline	2.4 (3.03)	3.15 (2.6)	1.97 (2.46)	2.97 (3.1)	< 0.001	0.16
	Week 4	2.08 (2.47)	1.39*** (1.6)	1.16** (1.96)	1.62*** (1.84)		
	Week 8	2.18 ^{b,c,d} (2.42)	1.0***,a (1.18)	0.72***,a (1.51)	0.9***,a (1.47)		
	3-month follow-up	2.16 ^{b,c,d} (2.33)	1.09***,a (1.38)	0.92***,a (1.24)	0.82***,a (1.34)		
HPT (°C)	Baseline	43.49 (3.46)	43.91 (2.8)	45.16 (2.83)	44.35 (3.43)	0.149	0.06
	Week 4	44.79 (3.38)	45.85** (2.49)	46.13 (2.84)	46.28** (2.85)		
	Week 8	44.32 ^{a,b,c} (3.08)	46.68***,a (3.06)	46.41*,a (2.82)	47.18***,a (2.47)		
	3-month follow-up	44.23 ^{a,b,c} (3.53)	46.31***,a (3.2)	46.84*,a (3.14)	46.6**,a (2.92)		
TrA thickness (mm)	Baseline	2.6 (0.71)	2.59 (0.48)	2.43 (0.44)	2.54 (0.47)	< 0.001	0.76
	Week 4	2.55 ^d (0.7)	2.55 ^d (0.45)	2.98*** (0.48)	3.1***,a,b (0.49)		
	Week 8	2.53 ^{c,d} (0.7)	2.53 ^{c,d} (0.44)	3.3***,a,b (0.51)	3.46***,a,b (0.49)		
	3-month follow-up	2.5 ^{c,d} (0.74)	2.48 ^{c,d} (0.44)	3.28***,a,b (0.53)	3.44***,a,b (0.55)		

Table 3.7 Data of all variables of the long-term effects are shown as mean (SD)
(continued)

Outcomes		Groups				Interaction effect	
		TLS (n=20)	ILS+HP (n=20)	ILS+ CSE (n=20)	ILS+HP+CSE (n=20)	p-value	η_p^2
CSA of LM (mm ²)	Baseline	451.75 (53.09)	456.08 (45.36)	447.79 (48.68)	445.04 (56.72)	< 0.001	0.68
	Week 4	450.60 (53.63)	452.62 (49.35)	478.46*** (46.56)	477.69*** (58.04)		
	Week 8	447.7 ^{c,d} (54.71)	451.67 ^{c,d} (49.91)	498.77***, a,b (51.34)	497.62***, a,b (60.07)		
	3-month follow-up	446.82 ^{c,d} (53.23)	448.78 ^{c,d} (50.03)	492.91***, a,b (50.56)	491.54***, a,b (65.6)		
	LPS (1-7)	Baseline	1.95 (0.39)	2.15 (0.37)	2.05 (0.39)		
Week 4	2.0 ^{c,d} (0.46)	2.15 ^{c,d} (0.37)	2.75***,a,b (0.55)	2.8***,a,b (0.52)			
Week 8	1.9 ^{c,d} (0.31)	2.05 ^{c,d} (0.22)	3.35***,a,b (0.49)	3.35***,a,b (0.49)			
3-month follow-up	1.89 ^{c,d} (0.31)	2.05 ^{c,d} (0.22)	2.84***,a,b (0.59)	2.79***,a,b (0.52)			
ASLR (0-5)	Baseline	1.23 (0.8)	1.48 (0.92)	1.28 (0.97)	1.1 (0.98)	<0.001	0.18
Week 4	1.33 ^d (0.88)	1.28 ^d (0.77)	1.0 ^{*d} (0.79)	0.5***,a (0.51)			
Week 8	1.4 ^{c,d} (0.77)	1.25 ^{c,d} (0.62)	0.38***,a,b (0.53)	0.28***,a,b (0.38)			
3-month follow-up	1.35 ^{c,d} (0.78)	1.3 ^{c,d} (0.59)	0.48***,a,b (0.5)	0.43***,a,b (0.44)			
Disability (ODI, 0-100)	Baseline	22.43 (12.04)	18.94 (10.73)	19.01 (11.42)	19.18 (10.4)		
Week 4	13.84***,b (9.12)	8.29***,a (4.94)	11.97** (9.18)	11.44*** (7.99)			
Week 8	9.68***,d (9.26)	7.19*** (4.77)	10.67***,d (7.37)	5.97***,a,c (5.28)			
3-month follow-up	10.93***,d (12.05)	6.87*** (8.08)	7.17*** (7.73)	4.73***,a (5.0)			
Quality of life (SF- 36, 0-100)	Baseline	66.23 (15.57)	62.12 (11.52)	63.07 (11.14)	65.53 (8.93)	0.031	0.09
Week 4	71.22** (12.99)	74.59*** (11.42)	73.36*** (8.88)	76.44*** (10.7)			
Week 8	75.56***,d (13.96)	79.97*** (9.83)	76.13***,d (7.48)	82.75***,a,c (7.76)			
3-month follow-up	73.75***,b,d (13.64)	80.91***,a (8.75)	76.11*** (8.11)	81.81***,a (8.42)			

No significant differences in the baseline data among 4 conditions ($p > 0.05$)
Significant differences between pre-post (* $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$)
^a Significant differences between control ($p < 0.05$)
^b Significant differences between LS+HP ($p < 0.05$)
^c Significant differences between LS+CSE ($p < 0.05$)
^d Significant differences between LS+HP+CSE ($p < 0.05$)
 η_p^2 = Partial eta-squared

3.3.7 Discussion

This randomized controlled trial provides evidence of the effectiveness of the innovative lumbar support comprising hot pack and core muscle activation feedback in individuals with chronic non-specific low back pain. Overall, the results demonstrated that the 8-week use of the innovative lumbar support comprising hot pack and core muscle activation feedback (ILS+HP+CSE) was superior to the traditional lumbar support in improving pain symptoms, lumbopelvic stability, quality of life, and disability-related low back pain. The benefits of the innovative lumbar support comprising hot pack and core muscle activation feedback (ILS+HP+CSE) were observed at 4-week interval assessment, after 8-week interventional assessment, and maintained at 3 months.

The traditional lumbar support presents some significant challenges in its application to clinical practice to manage CNLBP. The current scientific evidence questions the effectiveness of TLS and raises concerns about the use of lumbar support (123). It has been reported that prolonged use of TLS caused trunk muscle weakness and reduced core muscle function (112, 135, 136). Although many different lumbar support brands are available, all are designed to provide passive support to the lumbar region. Therefore, it was decided to redesign the lumbar support device with additional features built into it, such as superficial heat therapy and biofeedback to exercise the core muscles. Therefore, two additional study groups, ILS+HP and ILS+CSE, were added as an additional comparison group in this trial to study and evaluate the effects of superficial heat therapy and biofeedback mechanism in the lumbar support. Finally, the ILS+HP+CSE group was added and studied as the experimental intervention group to evaluate the combined effects of adding superficial heat therapy and biofeedback mechanism in the lumbar support. Before the current trial, the design and function of the innovative lumbar support were tested and proven to be reliable and accurate (140). Therefore, this thesis study examined the design properties of innovative lumbar support comprising hot pack and core muscle activation feedback and advocated the inclusion of new features in the device, such as superficial heat therapy and biofeedback to engage the core muscles activation provided desirable benefit to CNLBP patients.

This study's results were divided into 2 parts, including the immediate effect and long-term effect of the innovative lumbar support comprising hot pack and core muscle activation feedback. The immediate effect was needed to help define the potential pain

responses (both in subjective and objective outcomes) and changes in core muscles after the use of innovative lumbar support. It provided evidence of physiological changes and pathological changes for the improvement of LBP condition. The long-term effect was also needed to prove the clinical effects of innovative lumbar support.

3.3.7.1 Immediate effects

The study results supported the hypothesis that the innovative lumbar support with a hot pack and core muscle activation feedback compared to TLS had superior therapeutic effects in all primary and secondary outcomes among CNLBP patients.

The findings suggested that wearing the innovative lumbar support comprising hot pack and core muscle activation feedback (ILS+HP+CSE) for 20 minutes induced immediate physiological changes, noticeable by an increase in TBF in the lumbar region. Increasing TBF is suggested to promote the healing processes by delivering more oxygen and nutrients to the injured area and eliminating waste products and irritant substances (114). Therefore, the magnitude of changes in TBF reported in studies might have positive effects on CNLBP patients. The increase in TBF was found to be higher in the ILS+HP+CSE group, and the effect was clinically significant with a larger effect size (partial eta-squared (η_p^2) - 0.7) in comparison with the other three groups. Generally, a quantitative sensory test (QST) is used to assess hypersensitivity and hyperalgesia associated with long-term pain conditions such as CNLBP (141). Therefore, QST (PPT, HPT, and CPT) is used as a standard outcome measure together with the pain intensity to assess the effects on pain modulation (51, 141). Besides the increase in TBF, this study found that the ILS+HP+CSE group had immediate effects on pain modulation. The results showed that the percentage increase in PPT was higher in the ILS+HP+CSE group (28.92%) than the TLS group (9.51%). Since PPT was suggested to predict CNLBP (142), the clinically meaningful change in PPT among participants in the ILS+HP+CSE group could be considered a useful finding in this study. In addition to increased mechanical pain tolerance, CPT and HPT showed significant positive changes in the ILS+HP+CSE group, with CPT decreased by approximately 62.2% and HPT increased by 6%. In addition, pain intensity was a clinically meaningful decrease (61.7%) in the ILS+HP+CSE group compared to the other three groups. Superficial heat therapy results

in decreased pain, reduced muscle stiffness, and increased flexibility in LBP patients (113). The innovative lumbar support is designed to provide superficial heat therapy to the back muscles, which could explain the overall superior effect of pain modulation found in the ILS+HP+CSE group compared to the TLS group.

Deep trunk muscles, such as TrA and LM, provide stability to the lumbopelvic region. TrA and LM were reported to be impaired in people with LBP (6). Therefore, TrA muscle thickness, CSA of LM, and LPS were evaluated to measure core muscle activity changes. Compared to the TLS group, participants in the ILS+HP+CSE group showed a higher increase in TrA thickness and LPS level, with 27.5% and 45% percent changes, respectively. The innovative lumbar support had a feature of biofeedback mechanism to support and assist participants in exercising the deeper trunk muscles. Prior to the current study, the reliability and accuracy of biofeedback mechanisms in lumbar support for core muscle activation were established (140). The observed changes in LSP level and TrA thickness might be related to the fact that participants in the ILS+HP+CSE group used biofeedback devices and exercised their core muscles while they put on the innovative lumbar support. It is also possible that an increase in TrA muscle activity and LPS might be related to the pain-modulating effects reported in study participants.

Moreover, lumbar support had been utilized as the effect of an external stabilizer for the lumbopelvic region. Previous studies have suggested that the amount of positive ASLR test results might be higher for patients who had pain in the lumbopelvic region (143), and it was proven that patients with LBP were more likely to perceive difficulty when performing ASLR test due to pain in the lower back area (144). ASLR was used to prove the immediate effect of lumbar support in improving lumbopelvic stability. The results showed that participants in all groups felt much easier to lift their leg during the ASLR test by approximately 60% when lumbar support was applied. This result might help to verify the stabilizing role of lumbar support in the lumbopelvic region. A lower score in the ASLR test during used lumbar support showed less effort to lift the leg. This indicated that the load transfer strategy from the trunk to the pelvis was more optimized.

3.3.7.2 Long term effects

The study results supported the hypothesis that the innovative lumbar support with a hot pack and core muscle activation feedback compared to TLS had superior therapeutic effects in pain, core muscle function, quality of life, and disability-related low back pain among CNLBP patients.

Overall, the results demonstrated that using traditional lumbar support and innovative lumbar support significantly improved low back pain, mechanical pain tolerance, health-related quality of life, and disability-related low back pain after 4-week, 8-week intervention, and 3-month follow-up. All groups had similar significant effects in relieving low back pain after using lumbar support for 4, 8 weeks, and 3-month follow-up. The improvement in pain intensity was met the minimal clinically important difference (MCID) at all periods (145). However, ILS+HP+CSE was superior to the TLS in maintaining pain reduction at a 3-month follow-up. This finding was consistent with the previous studies on the effectiveness of LS in pain relief, which demonstrated that wearing LS with usual care could release pain since the 4th week of intervention and gradually decreased (18, 126). Besides the pain intensity, which is a subjective pain outcome, objective pain outcomes including PPT, CPT, and HPT were also evaluated the effects on pain modulation. In chronic pain conditions, the continuous firing of nociceptive impulses resulted in the hypersensitivity of neurons of the dorsal horns, leads to temporal summation of the symptoms (146). In CLBP, the dorsal neurons may be sensitized by nociceptive impulses originating from the lumbopelvic region due to poor motor control and instability. It is possible that the constant source of pain due to peripheral sensitization led to a decrease in pain tolerance and increase pain intensity (62). The results of this study showed that all groups had increased PPT after using lumbar support for 4, 8 weeks, and 3-month follow-up, except the maintained effect of TLS was not found at 3-month follow-up. The increase in PPT might result from the stabilizing effect of LS on a lumbopelvic region, which could reduce nociceptive impulses. It corresponded to the decrease in pain intensity.

In addition, ILS+HP+CSE demonstrated the superior effect to the TLS after 8 weeks and 3-month follow-up. It could be the additional effect of the superficial heat and core muscle exercise (147). For the thermal pain threshold, significant changes in CPT and HPT were detected in only innovative lumbar support (ILS+HP, ILS +CSE,

ILS+HP+CSE) groups at all periods. These changes suggested the additional effect of superficial heat and core muscle exercise in pain modulation. It was consistent with a previous study that reported a significant improvement in HPT after performing core stability training (147). However, there is no evidence regarding the effect of lumbar support on the QST. There are no data from previous literature available to compare the effects of lumbar support on PPT, CPT, and HPT.

For core muscle function, the results demonstrated that the ILS+ CSE and ILS+HP+CSE groups were significant effects in improving TrA thickness, CSA of LM, and lumbopelvic stability control (LPS, ASLR) after 4-, 8-week, and 3-month follow-up. This result was consistent with the purpose of developing the innovative lumbar support that desired to improve lumbopelvic stability in CLBP patients. Previous studies demonstrated that patients with chronic low back pain are associated with reducing core muscle strength and function (12, 119). In addition, there were concerns about prolonged use of lumbar support on trunk muscle weakness and decreased core muscle function (112, 135, 136). Therefore, the innovative lumbar support in this study was designed to have the biofeedback mechanism for improving core muscle function and prevent the adverse effect. In this study, core muscle exercise was performed by doing ADIM under the biofeedback mechanism. The basis behind this treatment concept is that the stability of the lumbar spine is controlled by deep muscles such as the multifidus and transversus abdominis, which are anatomically connected to the lumbar spine (148). The result showed that the thickness of TrA muscle in the ILS+ CSE group and ILS+HP+CSE group was significantly increased by 17 – 24% at 4 weeks and by 31 – 37% at 8 weeks of intervention. The TrA thickness changes were also clinically meaningful, as it was greater than the SEMs in the main study II. An increase in TrA thickness was also maintained at a 3-month follow-up. It was consistent with the previous study, which reported an increase of 7.8% in TrA recruitment after 8-week motor control training (149). However, this difference might result from the different exercise prescriptions (i.e., exercise method, frequency) and different methods of outcome measure. Besides the TrA thickness, this study found the increase in CSA of LM muscle in the ILS +CSE and ILS+HP+CSE group at 4 and 8 weeks with approximately by 6 – 10% and also maintained at 3-month follow-up. Accordingly, this study demonstrated the improvement in the clinical test of lumbopelvic stability control (i.e., LPST, ASLR). Participants who

received core muscle exercise showed a higher level of lumbopelvic stability. This suggested that participants had a greater ability to maintain spinal stability during the load on lower limbs (50). As well as the ASLR test, participants felt much easier to lift their legs. The ASLR test is considered a tool to evaluate the effective load transfer from trunk to legs (102). Various studies pointed out that the difficulty of performing the ASLR test indicates an interrupted load transfer function across the lumbopelvic region (143, 150). The ASLR score improvement might indicate optimal lumbopelvic stability during load transfer due to optimal neuromuscular control.

Moreover, the improvement in patient's quality of life and disability-related low back pain was observed in all intervention groups after 4-, 8-week intervention and maintained at 3-month follow-up. Lumbar support, superficial heat therapy, and core muscle exercise are extensively demonstrated in improving quality of life and disability-related low back pain in patients with LBP (18, 22, 39, 120, 127). The results of this study confirm the findings of these previous studies. All groups reported that the disability-related score was significantly improved at all periods of assessment compared to baseline. The improvement in the ILS+HP+CSE group was superior to the TLS group after the 8-week intervention (68.9% vs 56.8%) and 3-month follow-up (75.3% vs 51.3%). In addition, the changed ODI score was higher than the MCID (20 points) after 8 weeks (145). It suggested that the improvement of disability score was clinically meaningful. This might be associated with a decrease in pain intensity, increased pain tolerance, and improved lumbopelvic stability in the patients. Also, the quality of life in all intervention groups was significantly improved after 4-, 8-week intervention, and 3-month follow-up compared to baseline. The improvement in the quality of life in the ILS+HP+CSE group was superior to the TLS group after the 8-week intervention (26.3% vs 14.1%) and 3-month follow-up (24.8% vs 11.3%).

In addition to the effects of lumbar support and core muscle exercise, the ILS+HP+CSE provided superficial heat therapy by herbal hot pack component. The ingredients of herbs might have aromatic properties, providing a relaxation effect and emotionally pain relief. Aromatherapy is widely used to enhance physical and psychological well-being due to olfactory stimulation. A previous study revealed that aromatherapy could immediately reduce pain, as well as physiological changes in brain activity (151). The meta-analysis suggested that aromatherapy had a

combination effect with conventional treatments in successful pain relief (152). Therefore, patients might also benefit from the effect of aromatherapy in addition to the effect of superficial heat.

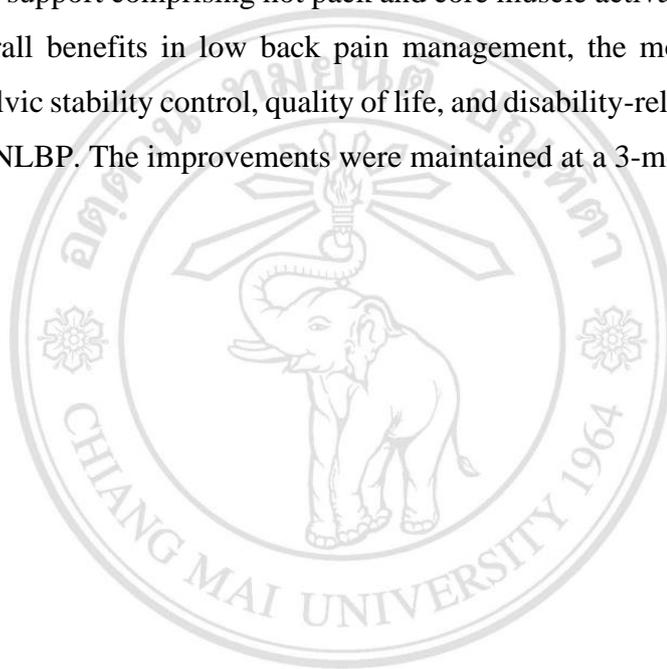
The results of this study confirm the effectiveness of the innovative lumbar support comprising hot pack and core muscle activation in relieving low back pain symptom, improving health-related quality of life, reducing disability-related low back pain, and improving core muscle function in patients with chronic non-specific low back pain. Overall results revealed the usefulness of ILS+HP+CSE in dramatically improving all outcome measures since the 4th week of intervention. The improvement gradually continued until the 8th week and was maintained at a 3-month follow-up. The trend of improved symptoms might be related to the duration of wearing lumbar support, which averaged approximately 7 hours per day for the first 4 weeks and remained about 6-7 hours per day for the last 4 weeks. Decrease duration of wearing lumbar support could be due to an improvement in LBP symptoms for the patients.

However, there are some limitations to this study. Participants in this study were chronic non-specific low back pain patients with mild to moderate pain severity and minimal to moderate disability. This result was limited to generalize to the other stage and type of LBP as well as severe LBP symptom. Blinding of the physiotherapist and participants were not possible. In the immediate effect part, the ILS+HP+CSE provided superficial heat therapy to the back region for about 20 minutes, which might have caused changes in the skin and muscles' tissue temperature. As the post-study measurements were conducted immediately after the heat therapy application, the skin temperature change could be a potential confounder to the thermal pain threshold measurements. However, having the TLS group as a control group and observing the changes in the thermal threshold among the TLS group helped to interpret the thermal threshold findings in the study. Several factors such as sleep quality and patterns, psychosocial factors, pain medications, underlying medical history, caffeine intake, gender, age, and body composition may influence sensory perception and outcomes of sensory testing. While a few factors such as BMI, pain medication, underlying medical conditions were monitored and controlled in the trial, other factors were not controlled, which could be potential confounders. Furthermore, the innovative lumbar support effects on the biomechanical changes were not investigated in this study. Future investigations

would benefit to explain the possible mechanisms of the effects of innovative lumbar support.

3.3.8 Conclusion

The innovative lumbar support comprising hot pack and core muscle activation feedback showed potential beneficial effects on pain modulation and core muscle function among patients with CNLBP compared to traditional lumbar support. Furthermore, a clinical trial evaluating the long-term clinical effects of the innovative lumbar support comprising hot pack and core muscle activation feedback also provided the overall benefits in low back pain management, the morphology of core muscles, lumbopelvic stability control, quality of life, and disability-related low back pain for people with CNLBP. The improvements were maintained at a 3-month follow-up.



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CHAPTER 4

Discussion

This thesis aimed to develop innovative lumbar support comprising hot pack and core muscle activation feedback and provide evidence towards its effectiveness in managing patients with chronic non-specific low back pain. The first study in this thesis demonstrated that lumbar support seemed to be beneficial when used in conjunction with the conventional treatment for managing low back pain. The benefits were observed when wearing lumbar support 6 - 8 hours daily at least a month. The first study also provided a guideline for the prescription of using lumbar support in the study of the effectiveness of the developed innovative lumbar support in this thesis. The second study showed that the developed sensor device in the innovative lumbar support for providing feedback on core muscle activation was reliable and accurate enough to be used in clinical practice. The second study also helps to confirm that the developed device can be used to provide feedback for core muscle exercise. The third study demonstrated potential physiological effects of innovative lumbar support comprising hot pack and core muscle activation feedback on pain modulation and core muscle function that were observed after a session of 20-minute use. The observed physiological changes were also superior to traditional lumbar support in improving low back pain, mechanical and thermal pain tolerance, core muscle morphology and function, quality of life, and disability-related low back pain. The third study results suggested the effectiveness of innovative lumbar support in managing low back pain in persons with chronic non-specific low back pain. The findings of this thesis highlight the potential benefits of innovative lumbar support comprising hot pack and core muscle activation feedback, which was developed. Despite the fact that lumbar support has been widely prescribed to persons who suffer low back pain and is also used to prevent lower back injuries in the workplace (7, 122). Various studies had reported the mechanism of action of lumbar support, such as the restriction of lumbar spinal movement, increased

stabilization of the spine, decreased the mechanical load on the trunk, increased intra-abdominal pressure, as well as maintain correct posture (17, 110, 153). In addition, several clinical studies revealed that lumbar support was significantly effective in relieving low back pain, improving quality of life and functional capacity, decreasing the frequency of low back pain symptoms as well as reducing direct costs of healthcare (21, 22, 111, 126-128). Also, patients with low back pain reported more confidence to perform physical activities because they felt safer and more stable when wearing lumbar support (135, 154). Although, Cochrane systematic review mentioned that lumbar support alone might not be more effective than no intervention in preventing or treating CLBP (123). Possibly, the lumbar support might be more effective when incorporating exercises and usual care of CLBP management as presented in the first study. Besides, prolonged use of lumbar support is reported to cause trunk muscle weakness and decreased trunk muscle activity (112, 135). According to these challenges, there was an idea to redesign lumbar support, which might be more effective than traditional lumbar support.

Innovative lumbar support in this thesis was developed with built-in additional features such as superficial heat therapy and biofeedback to exercise the core muscles, which has been reported as the effective intervention for LBP management (8, 10, 39, 119, 120). Innovative lumbar support was redesigned with shoulder straps to improve upper trunk posture, superficial moist heat component to back muscles for pain relief and improving blood circulation, and the feedback sensor device for activating core muscles. The feedback sensor's reliability and validity were investigated in the second study, which presented excellent test-retest reliability and moderate correlation with gold standard ultrasound measurement. This helped support that the feedback sensor could be used in clinical practice. However, before the innovative lumbar support can be widely used, it needs to be investigated its effectiveness in managing back pain compared with the traditional one. The findings in the third study provide evidence to support its potential application. The third study demonstrated that the 20-minute use of the innovative lumbar support comprising hot pack and core muscle exercise could induce physiological changes as detected by an increase of tissue blood flow in the lower back region. In contrast, this change was not seen in traditional lumbar support. This result suggested that wearing innovative lumbar support with a hot pack and/or core muscle exercise could improve the circulatory at the affected area. Superficial heat therapy has been known to

improve blood circulation, which helps to deliver oxygen and nutrient for the healing process as well as eliminate the waste product from the pathological area (114). Also, heat can induce endorphin secretion, which affects pain reduction. Moreover, exercise can also improve blood circulation, as observed in participants who received core muscle exercise. This result is consistent with the previous study, which demonstrated that a single lumbopelvic stability training session could increase tissue blood flow at the lumbar region by approximately 54% (89). Exercise training has been reported to increase the capillary network, decrease lactic acid production in the muscle and blood to promote skeletal muscle oxygenation (155). These might be caused by greater pain relief in innovative lumbar support. The third study results showed the immediate effect of core muscle exercise with feedback sensors in improving core muscle function and ability to control lumbopelvic stability. This result suggested that participants were able to recruit muscle tone, as observed in increased muscle size. An increase in core muscle size has also been reported in the previous study after lumbopelvic stability training (149).

Furthermore, the third study also demonstrated the effectiveness of using innovative lumbar support at home or workplace for 8 weeks. The results indicated that all groups had a similar effect in pain relief during the intervention period, but participants in the innovative lumbar support with a hot pack and core muscle exercise reported a lower pain intensity than the traditional lumbar support at 3-month follow-up. This suggested that the additional features might provide a superior and longer-lasting effect in pain modulation. This notion was supported by an increase in mechanical and thermal pain tolerance, which could be observed in the innovative lumbar support with hot pack and/or core muscle exercise. Hypersensitivity, especially to mechanical stimuli observed in chronic pain conditions, suggested pathophysiological alterations in the central nervous system (79). In chronic low back pain, the dorsal neuron might be sensitized by nociceptive impulses from the lumbopelvic region due to poor motor control and instability. Probably, the source of constant pain from the lumbopelvic region due to peripheral sensitization drives to central sensitization. This phenomenon may lead to decrease pain tolerance and increase pain perception. In addition, impaired motor control of the lumbopelvic region may lead to hypermobility, recurrent microtrauma, and subsequent nociceptive impulses. Innovative lumbar support could provide lumbopelvic stability and served motor control improvement, and then it was possible to control

peripheral nociceptive drive (48). This was supported by decreased pain intensity and decreased mechanical and thermal pain tolerance in the innovative lumbar support groups. As expected, the improvement in core muscle function and lumbopelvic stability control was observed in participants who performed core muscle exercise. However, the decrease in core muscle function after applying lumbar support for 8 weeks was not seen in this study. It was inconsistent with the previous study (112), which reported 8-week using lumbar support could induce impairment in core muscle function. It might possibly be due to the differences in characteristics of the participants, prescription, and type of lumbar support. Finally, the participants in all groups reported an improvement in health-related quality of life and disability-related low back pain at all periods of assessment. A more significant improvement was observed in participants who received innovative lumbar support compared to traditional lumbar support.

Overall, the findings in this thesis suggested that lumbar support is an effective tool as a supplement to conservative treatment. LS may be suggested as an additional management tool for patients with low back pain. The findings also demonstrated that the innovative lumbar support comprising hot pack and core muscle activation feedback effectively reduced pain perception, pain tolerance, core muscle function, quality of life, and disability in persons with chronic non-specific low back pain. It may be considered as an additional therapeutic device for patients who have limitations to travel to the medical care unit for managing their low back pain symptoms by themselves at home or workplace (e.g., home-office based).

Nevertheless, this thesis has some limitations, as previously mentioned in the discussion sections of study I, II, and III. Such limitations may hinder the generalizability of the studies. Therefore, the study findings should be interpreted with caution. Particularly in clinical practice, clinicians have to consider how the findings can be applied to individual patients. The suggestions given by this thesis must be tailored to the individual context.

CHAPTER 5

Conclusion

This thesis focused on the development of a new therapeutic device for low back pain management. Lumbar support is one of the common devices that has been prescribed to patients with low back pain. Although, the effectiveness and clinical application of lumbar support are questioned in current scientific evidence.

Therefore, the first part of this study investigated the effectiveness of using lumbar support in the management of low back pain. The study indicates that lumbar support seemed to be effective in low back pain management when incorporated with the usual care. The effectiveness of lumbar support was observed when wearing lumbar support for 6 – 8 hours at least one month. This finding was further used as the prescription in the study of the effectiveness of innovative lumbar support.

The second part of this study investigated the reliability and validity of the feedback sensor device in detecting core muscle activation. The study indicates that the innovative device had acceptable reliability and accuracy for indicating transversus abdominis muscle activation. This finding suggested the potential benefit in clinical use.

The third part of this study investigated the effectiveness of innovative lumbar support comprising hot pack and core muscle activation feedback on pain modulation, core muscle function, quality of life, and disability. The study indicates that innovative lumbar support is more effective than traditional lumbar support in improving pain, core muscle function, quality of life, and disability in persons with chronic non-specific low back pain. It could be considered as an additional therapeutic device for patients to manage their low back pain symptoms by themselves.

In summary, this thesis provides a new therapeutic device for low back pain management. Innovative lumbar support developed in this study has effectiveness in

pain modulation, core muscle function improvement, quality of life, and disability in patients with chronic non-specific low back pain.



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APPENDIX A

General questionnaire (Study III)

แบบสอบถามทั่วไป

ID number:

1. ข้อมูลทั่วไป

อายุปี เพศ ชาย หญิง
น้ำหนัก.....กิโลกรัม ส่วนสูง.....เซนติเมตร
อาชีพ

2. ข้อมูลด้านสุขภาพ

1. ท่านมีโรคประจำตัวหรือไม่
 ไม่มี
 มี โรค.....
2. ในระยะเวลา 1 สัปดาห์ที่ผ่านมา ท่านรับประทานยาหรือไม่
 ไม่ได้รับประทาน
 รับประทาน จำนวน.....ชนิด
โรค.....

3. ท่านเคยได้รับการผ่าตัดบริเวณกระดูกสันหลังหรือบริเวณขาทั้ง 2 ข้างหรือไม่

เคย ไม่เคย

4. ท่านเคยได้รับบาดเจ็บหรืออุบัติเหตุบริเวณกระดูกสันหลังและขาทั้ง 2 ข้าง ในช่วง 3 เดือนก่อนมาทดสอบหรือไม่

เคย ไม่เคย

5. ท่านกำลังอยู่ระหว่างตั้งครรภ์หรือไม่

ใช่ ไม่ใช่

3. คำถามเกี่ยวกับอาการปวดหลัง

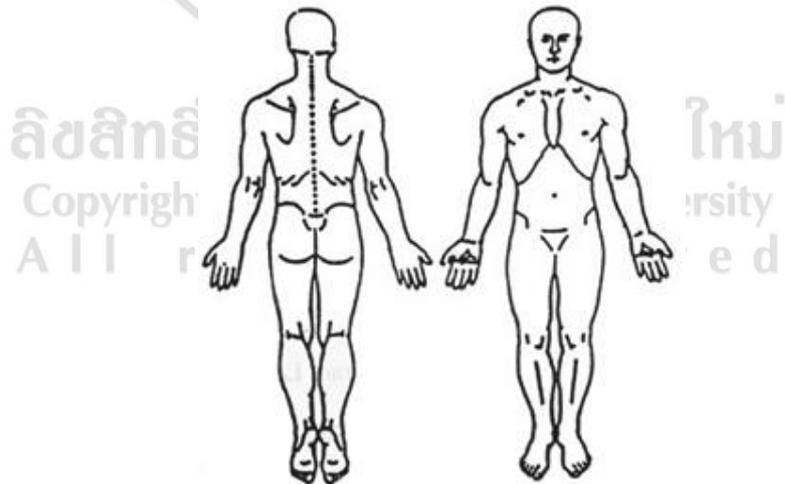
1. ในระยะเวลา 1 เดือนที่ผ่านมา ท่านมีอาการปวดหลังหรือไม่

ปวด ไม่ปวด

2. ท่านมีอาการปวดหรือชาบริเวณขาทั้ง 2 ข้างหรือไม่

ใช่ ไม่ใช่

3. กรุณาระบุบริเวณที่ท่านมีอาการปวดลงในภาพด้านล่าง



4. อาการปวดของท่านมีลักษณะ

มีอาการเป็นๆ หายๆ มีอาการปวดติดต่อกัน

5. ท่านเริ่มมีอาการปวดหลังตั้งแต่เมื่อใด
(ระยะเวลาที่ปวด.....วัน/เดือน/ปี)
6. ในระยะเวลา 7 วันที่ผ่านมา ท่านมีอาการปวดหลังเฉลี่ยอยู่ในระดับใด
(โปรดทำเครื่องหมายลงบนเส้นตรง)

ไม่มีอาการปวดเลย ปวดมากที่สุด

|-----|

7. ในระยะเวลา 24 ชั่วโมงที่ผ่านมา ท่านมีอาการปวดหลังเฉลี่ยอยู่ในระดับใด
(โปรดทำเครื่องหมายลงบนเส้นตรง)

ไม่มีอาการปวดเลย ปวดมากที่สุด

|-----|



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APPENDIX B

Thai version of short form 36 (SF-36)

แบบสอบถาม SF – 36 V2 สำหรับประเมินสุขภาพในผู้ป่วยปวดหลัง

คำแนะนำการตอบแบบสอบถาม

กรุณาตอบแบบสอบถามให้ครบทุกข้อ คำถามบางข้ออาจมีความคล้ายคลึงกันแต่มีความแตกต่างกัน โปรดใช้เวลาประมาณ 10 นาทีอ่านและตอบคำถามแต่ละข้อให้ถูกต้องตามความเป็นจริงโดยขีดเครื่องหมายถูก (☑) ในช่องที่ท่านเห็นว่าตรงกับลักษณะของท่านมากที่สุด

1. ในภาพรวม ท่านคิดว่าสุขภาพของท่าน

ดีเยี่ยม ดีมาก ดี ปานกลาง เลว

2. เมื่อเปรียบเทียบกับ 1 ปีก่อน ท่านคิดว่าสุขภาพของท่านปัจจุบันเป็นอย่างไร?

ปัจจุบันดีกว่า ปัจจุบันดีกว่า เท่า ๆ กับ ปัจจุบันเลวกว่า ปัจจุบันเลวกว่า

ปีที่แล้วมาก เล็กน้อย ปีที่แล้ว ปีที่แล้วเล็กน้อย ปีที่แล้วมาก

ลิขสิทธิ์มหาวิทยาลัยเชียงใหม่
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3. ท่านคิดว่าสุขภาพของท่านในปัจจุบันมีผลให้ท่านทำกิจกรรมต่าง ๆ ต่อไปนี้ลดลงหรือไม่เพียงใด?

กิจกรรม	ลดลงมาก	ลดลงเล็กน้อย	ไม่ลดลงเลย
3.1 กิจกรรมที่ออกแรงมาก เช่นวิ่ง ขกของหนัก เล่นกีฬาที่ต้องใช้แรงมาก			
3.2 กิจกรรมที่ออกแรงปานกลาง เช่นเลื่อน โต๊ะกวาดถูบ้าน เล่นกีฬาเบา			
3.3 ยกถือของเวลาไปซื้อของในห้างสรรพสินค้า			
3.4 ขึ้นบันไดหลายชั้น (จากชั้น 1 ไปชั้น 3 หรือมากกว่า)			
3.5 ขึ้นบันได 1 ชั้น (จากชั้น 1 ไปชั้น 2)			
3.6 ก้มลงเก็บของ กุกเข่า งอตัว			
3.7 เดินเป็นระยะทางมากกว่า 1 กิโลเมตร			
3.8 เดินเป็นระยะทางหลายร้อยเมตร			
3.9 เดินประมาณ 100 เมตร			
3.10 อาบน้ำหรือแต่งตัว			

4. ในช่วง 4 สัปดาห์ที่ผ่านมา ท่านมีปัญหาการทำงานหรือทำกิจวัตรประจำวันซึ่งเป็นผลเนื่องมาจากสุขภาพร่างกายของท่านหรือไม่?

ปัญหาการทำงานหรือกิจวัตรประจำวัน	ตลอดเวลา	ส่วนใหญ่	บางเวลา	ส่วนน้อย	ไม่ใช่
4.1 ต้องลดเวลาในการทำงานหรือทำกิจวัตร					
4.2 ทำงานหรือทำกิจวัตรได้น้อยกว่าที่ต้องการ					
4.3 ทำงานหรือทำกิจวัตรบางอย่างไม่ได้					
4.4 ทำงานหรือทำกิจวัตรได้ลำบากกว่าเดิม					

5. ในช่วง 4 สัปดาห์ที่ผ่านมา ท่านประสบปัญหาในการทำงานหรือทำกิจกรรมประจำวันซึ่งเป็นผลสืบเนื่องมาจากปัญหาทางอารมณ์หรือจิตใจ (เช่น รู้สึกซึมเศร้าหรือวิตกกังวล) หรือไม่?

ปัญหาการทำงานหรือกิจกรรมประจำวัน	ตลอดเวลา	ส่วนใหญ่	บางเวลา	ส่วนน้อย	ไม่ใช่
5.1 ต้องลดเวลาในการทำงานหรือทำกิจกรรม					
5.2 ทำได้น้อยกว่าที่ต้องการ					
5.3 ไม่สามารถทำได้อย่างระมัดระวังเหมือนปกติ					

6. ในช่วง 4 สัปดาห์ที่ผ่านมา ปัญหาสุขภาพหรืออารมณ์ความรู้สึกของท่านมีผลรบกวนต่อการมีกิจกรรมทางสังคมของท่านกับครอบครัว เพื่อน เพื่อนบ้าน หรือกลุ่มมากน้อยเพียงใด?

ไม่รบกวนเลย รบกวนเล็กน้อย รบกวนปานกลาง รบกวนค่อนข้างมาก รบกวนมาก

7. ท่านมีอาการปวดมากน้อยเพียงใด ในช่วง 4 สัปดาห์ที่ผ่านมา?

ไม่ปวดเลย ปวดน้อยมาก ปวดน้อย ปวดปานกลาง ปวดรุนแรง ปวดรุนแรงมาก

8. ในช่วง 4 สัปดาห์ที่ผ่านมา อาการปวดรบกวนการทำงาน (ทั้งที่ทำงานและที่บ้าน) มากน้อยเพียงใด?

ไม่รบกวนเลย รบกวนเล็กน้อย รบกวนปานกลาง รบกวนค่อนข้างมาก รบกวนมาก

9. คำถามต่อไปนี้เกี่ยวข้องกับอารมณ์ความรู้สึกที่เกิดขึ้นกับท่านในช่วง 4 สัปดาห์ที่ผ่านมา กรุณาให้คำตอบที่ตรงกับความรู้สึกของท่านมากที่สุดในแต่ละคำถามเกิดขึ้นบ่อยเพียงใดในช่วง 4 สัปดาห์ที่ผ่านมา?

ความรู้สึก	ตลอดเวลา	ส่วนใหญ่	บางเวลา	ส่วนน้อย	ไม่ใช่
9.1 รู้สึกกระปรี้กระเปร่ามาก					
9.2 รู้สึกหงุดหงิดกังวลมาก					
9.3 ซึมเศร้าไม่ร่าเริง					
9.4 รู้สึกสงบ					
9.5 รู้สึกเต็มไปด้วยพลัง					
9.6 รู้สึกหมดกำลังใจ ซึมเศร้า					
9.7 รู้สึกอ่อนเพลีย ไม่มีกำลัง					
9.8 รู้สึกมีความสุขดี					
9.9 รู้สึกเบื่อหน่าย					

10. ในช่วง 4 สัปดาห์ที่ผ่านมา ปัญหาสุขภาพหรืออารมณ์ความรู้สึกของท่านมีผลรบกวนต่อเวลาการมีกิจกรรมทางสังคมของท่าน (เช่น ไปเยี่ยมญาติหรือเพื่อน) มากน้อยเพียงใด?

ตลอดเวลา
 ส่วนใหญ่
 บางเวลา
 ส่วนน้อย
 ไม่มีเลย

11. ข้อความต่อไปนี้ตรงกับสุขภาพของท่านหรือไม่?

	ถูกต้องที่สุด	ส่วนใหญ่ถูกต้อง	ไม่ทราบ	ส่วนใหญ่ไม่ถูกต้อง	ไม่ถูกต้อง
11.1 ไม่สบายหรือเจ็บป่วยง่ายกว่าคนทั่วไป					
11.2 มีสุขภาพดีเท่ากับคนอื่นๆ					
11.3 คิดว่าสุขภาพจะเลวลง					
11.4 มีสุขภาพดีเยี่ยม					

APPENDIX C

Thai version of Oswestry Disability Index (ODI)

แบบสอบถามแบบสอบถามออสเวสตรี (รุ่นที่ 1.0) ฉบับภาษาไทยในผู้ป่วยปวดหลัง

คำชี้แจง แบบสอบถามนี้จัดทำขึ้นเพื่อแพทย์ได้รับทราบข้อมูลเกี่ยวกับอาการปวดหลังของท่านที่มีผลในการดำเนินชีวิตประจำวัน กรุณาตอบแบบสอบถามทุกข้อโดยทำเครื่องหมายถูก (✓) ลงใน 0 เพียงช่องเดียวที่สามารถอธิบายอาการได้ใกล้เคียงกับอาการของท่านมากที่สุด

1. ความรุนแรงของอาการปวด

- 0 อาการปวดของฉันพอทนได้โดยไม่ต้องใช้ยา
- 0 อาการปวดของฉันแสบมาก แต่ฉันก็จัดการได้โดยไม่ต้องใช้ยา
- 0 ยาแก้ปวดช่วยลดอาการปวดได้ทั้งหมด
- 0 ยาแก้ปวดช่วยลดอาการปวดได้บางส่วน (ประมาณครึ่งหนึ่ง)
- 0 ยาแก้ปวดช่วยลดอาการปวดได้เล็กน้อย
- 0 ยาแก้ปวดไม่ช่วยลดอาการปวดและฉันไม่ได้ใช้ยาแก้ปวดนั้น

2. การดูแลตัวเองในชีวิตประจำวัน (อาบน้ำ, แต่งตัว เป็นต้น)

- 0 ฉันสามารถอาบน้ำ, แต่งตัว ได้เหมือนปกติโดยไม่ทำให้มีอาการปวดมากขึ้น
- 0 ฉันสามารถอาบน้ำ, แต่งตัว ได้เหมือนปกติแต่ทำให้มีอาการปวดเกิดขึ้น
- 0 ฉันสามารถอาบน้ำ, แต่งตัว ได้แต่ต้องเป็นไปอย่างช้า ๆ และระมัดระวัง เพราะ ทำให้มีอาการปวด
- 0 ฉันสามารถอาบน้ำ, แต่งตัว ได้แต่ต้องมีผู้ช่วยเหลือบ้างบางส่วน
- 0 ฉันสามารถอาบน้ำ, แต่งตัว ได้แต่ต้องมีผู้ช่วยเหลือเกือบทั้งหมด
- 0 ฉันไม่สามารถอาบน้ำ, แต่งตัว ได้เอง และต้องอยู่แต่บนเตียง

3. การยกของ

- 0 ฉันสามารถยกของหนักได้โดยไม่มีอาการปวดมากขึ้น
- 0 ฉันสามารถยกของหนักได้แต่ทำให้เกิดอาการปวดมากขึ้น
- 0 ฉันไม่สามารถยกของหนักจากพื้นได้ แต่ถ้าของหนักอยู่สูงระดับโต๊ะ ฉันจะสามารถยกของหนักนั้นได้
- 0 ฉันไม่สามารถยกของหนักจากพื้นได้ แต่ถ้าของหนักอยู่สูงระดับโต๊ะ ฉันจะสามารถยกของได้แต่น้ำหนักของต้องไม่มากนัก
- 0 ฉันสามารถยกได้แต่ของน้ำหนักเบา ๆ
- 0 ฉันไม่สามารถยกของได้เลย

4. การเดิน

- 0 ฉันสามารถเดินได้ระยะทางเหมือนปกติโดยไม่มีอาการปวด
- 0 อาการปวดทำให้ฉันสามารถเดินได้ระยะทางไม่เกิน 1.6 กิโลเมตร (ประมาณ 5 ป้ายรถเมล์)
- 0 อาการปวดทำให้ฉันสามารถเดินได้ระยะทางไม่เกิน 800 เมตร (ประมาณ 2 ป้ายรถเมล์)
- 0 อาการปวดทำให้ฉันสามารถเดินได้ระยะทางไม่เกิน 400 เมตร (ประมาณ 1 ป้ายรถเมล์)
- 0 ฉันสามารถเดินได้แต่ต้องใช้เครื่องช่วยเดิน เช่น ไม้เท้า, ไม้ค้ำพุง
- 0 ฉันต้องอยู่แต่บนเตียง แต่ต้องคลานเวลาจะไปห้องน้ำ

5. การนั่ง

- 0 ฉันสามารถนั่งได้นานเหมือนปกติโดยไม่มีอาการปวด
- 0 ฉันสามารถนั่งได้นานเหมือนปกติโดยไม่มีอาการปวดเฉพาะเก้าอี้ที่ฉันนั่งเป็นประจำและสบายเท่านั้น
- 0 อาการปวดทำให้ฉันสามารถนั่งได้ไม่เกิน 1 ชั่วโมง
- 0 อาการปวดทำให้ฉันสามารถนั่งได้ไม่เกิน 30 นาที
- 0 อาการปวดทำให้ฉันสามารถนั่งได้ไม่เกิน 10 นาที
- 0 อาการปวดทำให้ฉันไม่สามารถนั่งได้เลย

6. การยืน

- ฉันสามารถยืนได้นานเหมือนปกติ โดยไม่มีอาการปวดมากขึ้น
- ฉันสามารถยืนได้นานเหมือนปกติแต่จะทำให้ฉันปวดมากขึ้น
- อาการปวดทำให้ฉันสามารถยืนได้ไม่เกิน 1 ชั่วโมง
- อาการปวดทำให้ฉันสามารถยืนได้ไม่เกิน 30 นาที
- อาการปวดทำให้ฉันสามารถยืนได้ไม่เกิน 10 นาที
- อาการปวดทำให้ฉันไม่สามารถยืนได้เลย

7. การนอน

- ฉันสามารถหลับได้เหมือนปกติ โดยไม่มีอาการปวด
- ฉันสามารถหลับได้เหมือนปกติแต่ต้องใช้ยา
- ถึงแม้จะใช้ยาแล้วก็ตามฉันสามารถหลับได้น้อยกว่า 6 ชั่วโมง
- ถึงแม้จะใช้ยาแล้วก็ตามฉันสามารถหลับได้น้อยกว่า 4 ชั่วโมง
- ถึงแม้จะใช้ยาแล้วก็ตามฉันสามารถหลับได้น้อยกว่า 2 ชั่วโมง
- อาการปวดทำให้ฉันไม่สามารถหลับได้เลย

8. การมีเพศสัมพันธ์

- ฉันสามารถมีเพศสัมพันธ์ได้เหมือนปกติโดยไม่มีอาการปวดมากขึ้น
- ฉันสามารถมีเพศสัมพันธ์ได้เหมือนปกติแต่จะทำให้ฉันปวดมากขึ้น
- ฉันสามารถมีเพศสัมพันธ์ได้เกือบเหมือนปกติ แต่มีอาการปวดมาก
- ฉันมีเพศสัมพันธ์ได้น้อยมากเพราะอาการปวด
- ฉันปวดมากจนแทบจะไม่สามารถมีเพศสัมพันธ์ได้
- ฉันปวดมากจนไม่สามารถมีเพศสัมพันธ์ได้เลย

9. การเข้าสังคม เช่น การไปตลาด ดูหนัง ไปห้างสรรพสินค้า

- ฉันสามารถเข้าสังคมได้เหมือนปกติโดยไม่มีอาการปวดมากขึ้น
- ฉันสามารถเข้าสังคมได้เหมือนปกติโดยมีอาการปวดมากขึ้น
- อาการปวดไม่ได้มีผลต่อการเข้าสังคมของฉันมากนักยกเว้นมีกิจกรรมที่ต้องเคลื่อนไหวมาก เช่น การ เดินรำ เล่นกีฬา
- อาการปวดทำให้ฉันไม่สามารถเข้าสังคมนอกบ้านได้บ่อย ๆ
- อาการปวดทำให้ฉันไม่สามารถเข้าสังคมนอกบ้านได้แต่สามารถเข้าสังคมที่จัดในบ้านได้
- อาการปวดทำให้ฉันไม่สามารถเข้าสังคมได้เลย

10. การเดินทาง

- 0 ฉันสามารถเดินทางไปที่ต่าง ๆ ได้โดยไม่มีอาการปวดมากขึ้น
- 0 ฉันสามารถเดินทางไปที่ต่าง ๆ ได้แต่มีอาการปวดมากขึ้น
- 0 อาการปวดของฉันแย่มาก แต่ฉันก็สามารถจัดการได้ และเดินทางได้มากกว่า 1 ชั่วโมง
- 0 อาการปวดทำให้ฉันสามารถเดินทางไปที่ต่าง ๆ ได้น้อยกว่า 1 ชั่วโมง
- 0 อาการปวดทำให้ฉันสามารถเดินทางไปใกล้ ๆ ได้ที่ใช้เวลาน้อยกว่า 30 นาที
- 0 ฉันไม่สามารถเดินทางไปที่ต่าง ๆ ได้ ยกเว้นไปพบแพทย์ หรือ ไปโรงพยาบาล



ลิขสิทธิ์มหาวิทยาลัยเชียงใหม่
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APPENDIX D

Certificate of the ethical clearance (Study II and III)



Certificate of Approval

No. 342/2017

Name of Ethics Committee : Ethics Committee, Faculty of Associated Medical Sciences, Chiang Mai University	
Address of Ethics Committee : 110 Intavaroros Rd., Amphoe Muang, Chiang Mai, Thailand 50200	
Principal Investigator : Ms. Duangrudee Disaguan Department of Medical Physical Therapy, Faculty of Associated Medical Sciences, Chiang Mai University	
Protocol title : Investigation of the Therapeutic Effects of an Innovative Lumbar Support Comprising Hot Pack and Core Muscle Activation Feedback in Individuals with Low Back Pain STUDY CODE: AMSEC-60EX-028	
Documents filed	Document reference
Research protocol	- Version 1.0 dated 23 August, 2017
Subject information sheet	- Version 2.0 dated 14 September, 2017
Informed consent document	- Version 1.0 dated 23 August, 2017
Questionnaires	- Version 2.0 dated 14 September, 2017
Advertisement	- Version 2.0 dated 14 September, 2017
Principle Investigator Curriculum vitae	- Version dated 23 August, 2017

Opinion of the Ethics Committee/Institutional Review Board : Expedited
The Ethics Committee has reviewed the protocol and documents above and give the favorable opinion

Date of Approval : September 18, 2017 **Expiration Date :** September 17, 2018

Progress report is required to be submitted to the Ethics Committee for continuing review

at 3 month interval

at 6 month interval

annually (in this case please submit at least 60 days prior to expiration date)

This Ethics Committee is organized and operates according to GCPs and relevant international ethical guidelines, the applicable laws and regulations.

Signed : *Nimit Morakote*

(Associate Professor Nimit Morakote, Ph.D)

Chairperson, Faculty of Associated Medical Sciences

Signed : *W. Sirirungsri*

(Assistant Professor Wasna Sirirungsri, Ph.D)

Dean, Faculty of Associated Medical Sciences

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Scholarship	2016-2021 Research and Researchers for Industries (RRI) Thailand Research Fund, Thailand
Publications	Dissanguan D, Sittilertpisan P, Kiatwattanacharoen S, Joseph LH, Puangmali P, Paungmali A. Reliability and Validity of the Feedback Sensor for Activation the Transversus Abdominis Muscle. <i>Open Biomedical Engineering Journal</i> . 2019; 13:67-72. Dissanguan D, Sittilertpisan P, Joseph LH, Paungmali A. Effectiveness of Lumbar Support in Management of Low Back Pain: A Systematic Review. <i>Online J Health Allied Scs</i> . 2018; 17(4):3
Conference	Poster presentation, Effects of an innovative lumbar support compared with a traditional lumbar support in patients with chronic low back pain: A preliminary study. <i>AMS-CMU Annual Conference 2019</i> . Duangtawan Hotel Chiang Mai, Chaing Mai, Thailand. 2019 November 6 – 8 Poster presentation, Validity Study of the Pressure Biofeedback Unit for detection of Transversus Abdominis Activation During Upright

Standing Position. Chiang Mai University – Kagawa University Joint Symposium 2018. Chiang Mai University, Chiang Mai, Thailand. 2018 August 27 – 29

Poster presentation, Design, production and evaluation for effectiveness of an innovative herbal hot pack-therapeutic exercise lumbar support in treatment of chronic back pain. RRI Congress IV: Unshelving research works with innovation tactics. Queen Sirikit National Convention Center, Bangkok, Thailand. 2018 July 23

Award

Outstanding research in the group of Industrial medicine, herbs, and medical sciences. RRI Congress IV: Unshelving research works with innovation tactics. Queen Sirikit National Convention Center, Bangkok, Thailand. 2018 July 23

Experiences

2014-2015 Physiotherapist at Petcharavej Hospital, Bangkok, Thailand

2016-2021 Physiotherapist at Physiotherapy clinic, AMS Clinical Service Center, Chiang Mai University, Chiang Mai, Thailand



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