Responsiveness of the Thai version of the Patient Reported Outcomes Measurement Information System-29 (PROMIS-29) in patients with chronic low back pain

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A Thesis Submitted in Partial Fulfillment of the Requirements
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การตอบสนองของแบบประเมิน Patient Reported Outcomes Measurement Information System-29 (PROMIS-29) ฉบับภาษาไทย ในผู้ป่วยที่มีอาการปวดหลังส่วนล่างเรื้อรัง

น.ส.กรกนก ขูทก

วิทยานิพนธ์นี้เป็นส่วนหนึ่งของการศึกษาตามหลักสูตรปริญญาวิทยาศาสตรมหาบัณฑิต
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Field of Study	Physical Therapy
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กรกนก ขูทก : การตอบสนองของแบบประเมิน Patient Reported Outcomes Measurement Information System-29 (PROMIS-29) ฉบับภาษาไทย ในผู้ป่วยที่มีอาการปวดหลังส่วนล่างเรื้อรัง. (Responsiveness of the Thai version of the Patient Reported Outcomes Measurement Information System-29 (PROMIS-29) in patients with chronic low back pain) อ.ที่ปรึกษาหลัก : ผศ. ดร.รสลัย กัลยาณพจน์พร, อ.ที่ปรึกษาร่วม : ศ. ดร.ประวิตร เจนวรรธนะกุล

ที่มา: แบบประเมิน Patient-Reported Outcomes Measurement Information System-29 (PROMIS-29) เป็นแบบประเมินที่เกี่ยวข้องกับคุณภาพชีวิต 7 ด้าน ในปัจจุบันยังขาดหลักฐานงานวิจัยในเรื่องการตอบสนองของแบบประเมิน PROMIS-29 และค่าความแตกต่างที่เกิดขึ้นที่น้อยที่สุดที่สามารถแสดงนัยสำคัญทางคลินิกในผู้ป่วยที่มีอาการปวดหลังส่วนล่างเรื้อรัง *วัตถุประสงค์:* เพื่อศึกษาค่าการตอบสนองและค่าความแตกต่างที่น้อยที่สุดที่สามารถแสดงนัยสำคัญทางคลินิกของแบบประเมิน PROMIS-29 ในผู้ป่วยที่มีอาการปวดหลังส่วนล่างเรื้อรัง *ระเบียบวิธีวิจัย:* ผู้เข้าร่วมวิจัยที่มีอาการปวดหลังส่วนล่างเรื้อรังจำนวน 183 คน ตอบแบบประเมินที่จุดเริ่มต้น และที่ 4 และ 8 สัปดาห์ การคำนวณหาค่าการตอบสนองของแบบประเมิน PROMIS-29 โดยใช้การคำนวณค่าเฉลี่ยของคะแนนที่เปลี่ยนแปลง สถิติค่า effect sizes (ESs) ค่า standardized response means (SRMs) และค่าความสัมพันธ์กับตัวแปรภายนอก นอกจากนี้ค่าความแตกต่างที่น้อยที่สุดที่สามารถแสดงนัยสำคัญทางคลินิกถูกทดสอบโดยการหาจุดตัดพื้นที่ใต้กราฟ receiver operating characteristic อีกทั้งระบุค่าความคลาดเคลื่อนมาตรฐานของการวัดของแบบประเมิน PROMIS-29 *ผลการศึกษา:* ที่ 4 สัปดาห์ในกลุ่มผู้ที่มีอาการดีขึ้นอย่างมาก พบการตอบสนองที่ดีของแบบประเมิน PROMIS-29 ในด้านความรุนแรงของอาการปวด ความสามารถทางกายภาพและด้านความวิตกกังวล (ESs and SRMs $\geq$ 0.80) แต่อย่างไรก็ตาม ค่าความสัมพันธ์ระหว่างแบบประเมิน PROMIS-29 และตัวแปรภายนอกอยู่ในระดับน้อย ($r < 0.30$) ทั้งที่ 4 และ 8 สัปดาห์ ค่าความแตกต่างที่เกิดขึ้นที่น้อยที่สุดที่สามารถแสดงนัยสำคัญทางคลินิกของแบบประเมิน PROMIS-29 คือ ด้านความรุนแรงของอาการปวด 1.50 คะแนน ด้านความสามารถทางกายภาพ 3.60 คะแนน ด้านความวิตกกังวล 5.88 คะแนน ด้านภาวะซึมเศร้า 5.25 คะแนน ด้านความเหนื่อยล้า 7.75 คะแนน ด้านการรบกวนการนอนหลับ 3.90 คะแนน ด้านความสามารถในการมีบทบาทและเข้าร่วมกิจกรรมทางสังคม 4.58 คะแนน และด้านการรบกวนจากอาการปวด 4.85 คะแนน *สรุป:* แบบประเมิน PROMIS-29 มีการตอบสนองที่ดีมากในด้านของความรุนแรงของอาการปวด ความสามารถทางกายภาพและด้านความวิตกกังวลในกลุ่มผู้ป่วยที่มีอาการปวดหลังส่วนล่างเรื้อรัง

สาขาวิชา กายภาพบำบัด ลายมือชื่อนิสิต .....

ปีการศึกษา 2562 ลายมือชื่อ อ.ที่ปรึกษาหลัก .....

ลายมือชื่อ อ.ที่ปรึกษาร่วม .....

6076651837 : MAJOR PHYSICAL THERAPY
KEYWORD: chronic low back pain; longitudinal validity; minimal clinically important difference; patient-reported outcome measure; PROMIS; PROMIS-29; quality of life; questionnaire; responsiveness; self-report

Kornkanok Khutok : Responsiveness of the Thai version of the Patient Reported Outcomes Measurement Information System-29 (PROMIS-29) in patients with chronic low back pain. Advisor: Asst. Prof. ROTSALAI KANLAYANAPHOTPORN, Ph.D. Co-advisor: Prof. PRAWIT JANWANTANAKUL, Ph.D.

Background: The Patient-Reported Outcomes Measurement Information System-29 (PROMIS-29) questionnaire assesses 7 health related quality of life domains. However, research to evaluate the responsiveness and minimal clinically important differences (MCIDs) of the PROMIS-29 scores in patients with chronic low back pain (cLBP) is limited. Purpose: To evaluate responsiveness and estimate the MCIDs for PROMIS-29 scales in patients with cLBP. Method: One hundred and eighty-three participants with cLBP took part in the study. They completed the PROMIS-29 scales at baseline, 4 weeks, and 8 weeks of the study. Responsiveness of the PROMIS-29 scale scores was evaluated by examining the mean change scores, effect sizes (ESs), standardized response means (SRMs) based on the global perceived effect (GPE) over time, including correlations with GPE. MCIDs were estimated by computing optimal cut point on the receiver operating characteristic curve and standard error of measurement (SEM) statistics for each scale. Results: The mean change scores, ESs, and SRMs increased as a function of the GPE ratings. At 4-week follow-up, the ESs and SRMs showed large magnitudes (ESs and SRMs ≥ 0.80) for Pain Intensity, Physical Function, and Anxiety scales in very much improved group. The correlations between change scores and GPE ratings were mostly weak in magnitude at 4 and 8 weeks. The MCID estimates computed as Pain Intensity 1.50 points; Physical function 3.60 points; Anxiety 5.88 points; Depression 5.25 points; Fatigue 7.75 points; Sleep Interference 3.90 points; Ability to Participate in Social Roles and Activities 4.58 points; and Pain Interference 4.85 points. Conclusion: The PROMIS-29 scale scores assessing pain intensity, physical function, and anxiety evidenced the most responsivity in the study sample.

Field of Study:	Physical Therapy	Student's Signature .....
Academic Year:	2019	Advisor's Signature .....
		Co-advisor's Signature .....

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Kornkanok Khutok

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LIST OF ABBREVIATIONS

AUC	=	Area under the ROC curve
cLBP	=	Chronic low back pain
ES	=	Effect size
GPE	=	Global perceived effect
ICC	=	Intraclass correlation coefficient
LBP	=	Low back pain
MCID	=	Minimal clinically important difference
ODI	=	Oswestry disability index
PROMIS-29	=	Patient-reported outcomes measurement information system-29
PROM	=	Patient-reported outcome measure
r	=	Correlation coefficient
RMDQ	=	Roland Morris disability questionnaire
ROC	=	Receiver operating characteristic
SEM	=	Standard error of measurement
SF-36	=	Short-form health survey 36
SRM	=	Standardized response mean

CHAPTER I

INTRODUCTION

1.1 Background and Rationale

Chronic pain is a major global health issue with immense social and economic impacts (1, 2). Chronic pain is recognized as a major challenge as people age. Among the population, middle-aged and older adults are disproportionately affected making up approximately 80% of those who experience chronic pain. The increased prevalence of chronic pain is correlated with female sex (3, 4), increasing age (4, 5), marital status of divorced or separated, race/ethnicity (6, 7), lower socioeconomic status (4), lacking private health insurance (8), and less education level (5), and residence in public housing (4). Some other factors such as higher body mass index (9) and poor self-assessed health (8) have also found to be associated with chronic pain.

Low back pain (LBP) is a musculoskeletal condition that has the most impact on the health care system (10) and is the most common health problem that impact on quality of life (11-13). Approximately 50-80% of individuals at some point in their lives affected by LBP (14, 15). In Thailand, high prevalence of LBP was shown (16). The cost of LBP health care is high that ranging from $US 7,000 to $US 16,000 million per year (17, 18).

The use of patient-reported outcome measures (PROMs) as clinical tools in clinical effectiveness research is growing in order to obtain patient-reported outcomes for several health domains including physical function, pain intensity, and quality of life. PROMs allow patients to report on symptoms of particular conditions so that they can help professionals to better understand their patients' perceptions of health (19, 20). The validated PROMs are currently used in back pain such as the Oswestry Disability Index and the Roland and Morris Disability Scale (21). The Short-Form Health Survey 36 is used for assessing general health and quality of life (22). However, the lengthy process of completing multiple PROMs presents logistical challenges and concerns that respondents burden may lead to inaccurate or incomplete responses (23).

Recently, the Patient-Reported Outcomes Measurement Information System-29 (PROMIS-29) that effectively covers several health domains has been developed for use in chronic musculoskeletal pain condition (24). Currently, the Thai-version of the PROMIS-29 has been translated and tested for its reliability and construct validity by a group of researchers together with the developers. However, the measurement tool should also be tested for its responsiveness in order to provide clinical meaningful for health professions.

The aim of this study was to test the responsiveness (i.e. the ability of an instrument to detect changes in the construct to be measured over time) and the minimal clinically important difference (MCID, i.e. the smallest change in score of the construct to be measured that subjects perceive to be important) of the PROMIS-29.

1.2 Research Question

Does the Thai version of the PROMIS-29 have the responsiveness in patients with chronic low back pain (cLBP)?

1.3 Research Objectives

To assess the responsiveness over time of the Thai version of the PROMIS-29 in patients with cLBP.

1.4 Hypothesis of this Research

The Thai version of PROMIS-29 would have a moderate level of responsiveness in patients with cLBP.

1.5 Expected Benefits and Application of this Research

The information on the responsiveness of the Thai version of the PROMIS-29 might enhance the clinicians while choosing tool for assessing quality of life in patients with cLBP. Moreover, the MCID value will be useful for clinical decision-making about progression of the patients.

1.6 Conceptual Framework

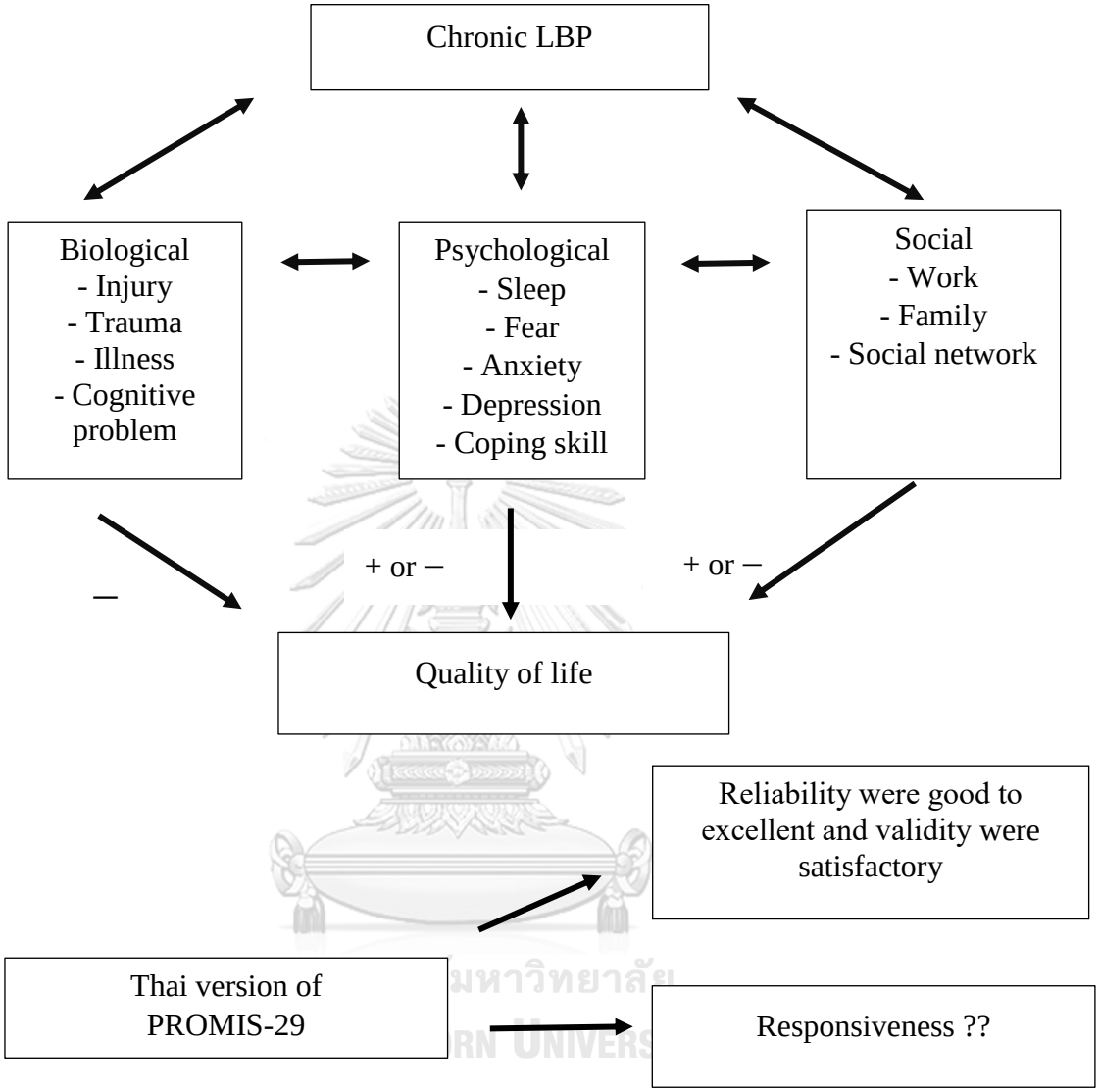

Figure 1.1 Conceptual framework of this study

CHAPTER II

LITERATURE REVIEW

This section will review the literature related to cLBP and its relevant outcome measures, patient-reported outcome measures, psychometric properties of the outcome measures, and measurement tools for measuring quality of life in cLBP.

2.1 Chronic Low Back Pain and Relevant Outcome Measures

LBP is shown to be the most common health problem that impacts on quality of life (11-13) and approximately 50-80% of individuals will be affected at some point in their lives (14, 15). The cost of personal health care spending for LBP is also high which brings about extensive lost wages and additional medical expenses with the total cost ranging from $US 7,000 to $US 16,000 million per year (17, 18).

LBP is a symptom not a disease. It is defined by the location of pain and discomfort that locates between the lower rib margins and the gluteal crease (25). People may have LBP with one or both legs and/or have associated neurological symptoms in lower limbs. The cause of LBP can be classified as specific pain when the cause is known and non-specific LBP if the pain has unknown abnormalities or mechanism of injury (26, 27). Regarding the duration of symptom, LBP can be classified into 3 categories. They are acute LBP as pain less than 6 weeks, subacute LBP as pain between 6 and 12 weeks, and chronic LBP as pain that lasts for 12 weeks or more (28). In general, most patients with LBP are treated successfully in primary care with approximately 90% of the patients with LBP were found to recover and return to work within 8 weeks (29). Approximately 10-15% develop chronic symptoms (30, 31).

In chronic condition, LBP not only show abnormal anatomy or biomechanics but also demonstrates impairment in biopsychosocial factors (Figure 2.1) such as cognitive (e.g., unpleasant beliefs, catastrophizing, maladaptive coping strategies, low self-efficacy), psychological (e.g., anxiety, depression, fear), and social factors (e.g., work and family problem, inactivity and sleep disturbance) (32-34). Disability is a state of decreased functioning associated with health conditions (35). Disability is a

core issue in LBP that affects physical performance and work productivity (36). In addition, there were recommendations that 6 outcome domains are highly relevant to patients with LBP which should be assessed in research and practice. They are physical functioning, pain intensity, health-related quality of life, work, psychological functioning, and pain interference (37) which are described below:

a. Physical function

Physical function is referred to the ability of an individual to perform their daily activities (38). In a systematic review, a moderate negative correlation relationship was found between high level of disability and low level of physical activity in patients with cLBP ($r = -0.33$, 95% confidence interval = −0.51 to −0.15) (39).

b. Pain intensity

Pain intensity is defined as how much a patient hurts that reflects the overall magnitude of experienced pain (40). Pain was reported in 89% of clinical trials that tested rehabilitation interventions for patients with LBP (41). The perceived pain intensity is considered high in individuals with cLBP (42). Higher pain level is statistically significantly related with poorer health-related quality of life in patients with cLBP (43).

c. Health-related quality of life (HRQoL)

HRQoL can be defined as physical, psychological, and social domains of health that are influenced by a person's experiences, beliefs, expectations, and perceptions as well as pain catastrophizing anxiety, depression, and fear avoidance (44, 45). The HRQOL of patients with LBP also depends on their functional status and psychological factors (46).

d. Work

Work is described in 2 domains. Work ability is referred to a worker ability to meet physical and/or psychological work demands while work productivity is referred to the economic impact of LBP on paid or unpaid job employment,

including absenteeism and presenteeism (44). cLBP affects the ability of a patient to work as it was reported that many patients returned to work before they were physically, mentally, or emotionally free of pain (47).

e. Psychological functioning

Psychological functioning is defined as levels of anxiety, depression, anger, or other types of psychological distress that are considered particularly important by clinicians and patients (44). Patients with LBP show significantly higher anxiety (9.5% versus 6.2%), depression (13.7% versus 8.5%), and somatization (14.9% versus 8.3%) than patients without LBP (48, 49). Depression is often found to be co-morbid with cLBP in which patients with greater pain severity show more depression (50, 51). These psychological abnormalities were reported to have a mediator role in the relationship between functional disability and quality of life in patients with cLBP (52).

f. Pain Interference

Pain interference is referred to the extent of pain that is related to aspects of a patient's life which includes the impact of pain on physical, cognitive, emotional, social, and recreational activities as well as sleep and enjoyment in life (44, 53). Pain interference is a recognized core outcome of pain research and clinical care (54).

In addition to the 6 outcome measures mentioned above, the other interesting outcome measures related to cLBP are as follows:

a. Fatigue

Fatigue is defined as a persistent tiredness that is not alleviated by rest (55). Fatigue is a symptom that can be particularly problematic for LBP patients. It affects physical and mental health perceptions. Therefore, it can complicate and disrupt recovery as well as delay optimal return to daily life and work. Previous study showed that a total of 70% of the 569 cLBP patients with high pain intensity reported fatigue. Furthermore, women report fatigue more than men (56).

b. Sleep disturbance

Sleep is essential for keeping the normal status of emotional, mental, and physical health (57). Sleep disturbance would lead to decreased work ability, increased sick leave, and a higher injury rate. High prevalence of sleep disturbance was reported in 50% to 90% of cLBP patients (58). When sleep disturbance persists over a long term, it could become severe and lead to serious health conditions such as depression, obesity, type-2 diabetes, hypertension, and coronary artery disease (59, 60).

c. Satisfaction with social role

Patients with LBP often report a negative self-perception in social interactions which affects their ability to work. Men who had LBP showed significant low decision and low social support at work (61). The adverse macrosocial effect reduces not only the quality of life but also the workforce productivity of individuals with cLBP (47).

d. Cognitive problems

A study demonstrated that patients with cLBP showed no alteration in attention and recognition memory but they had low speed of information processing and working memory (62). However, more research on the effect of the cognitive problems in cLBP patients is needed.

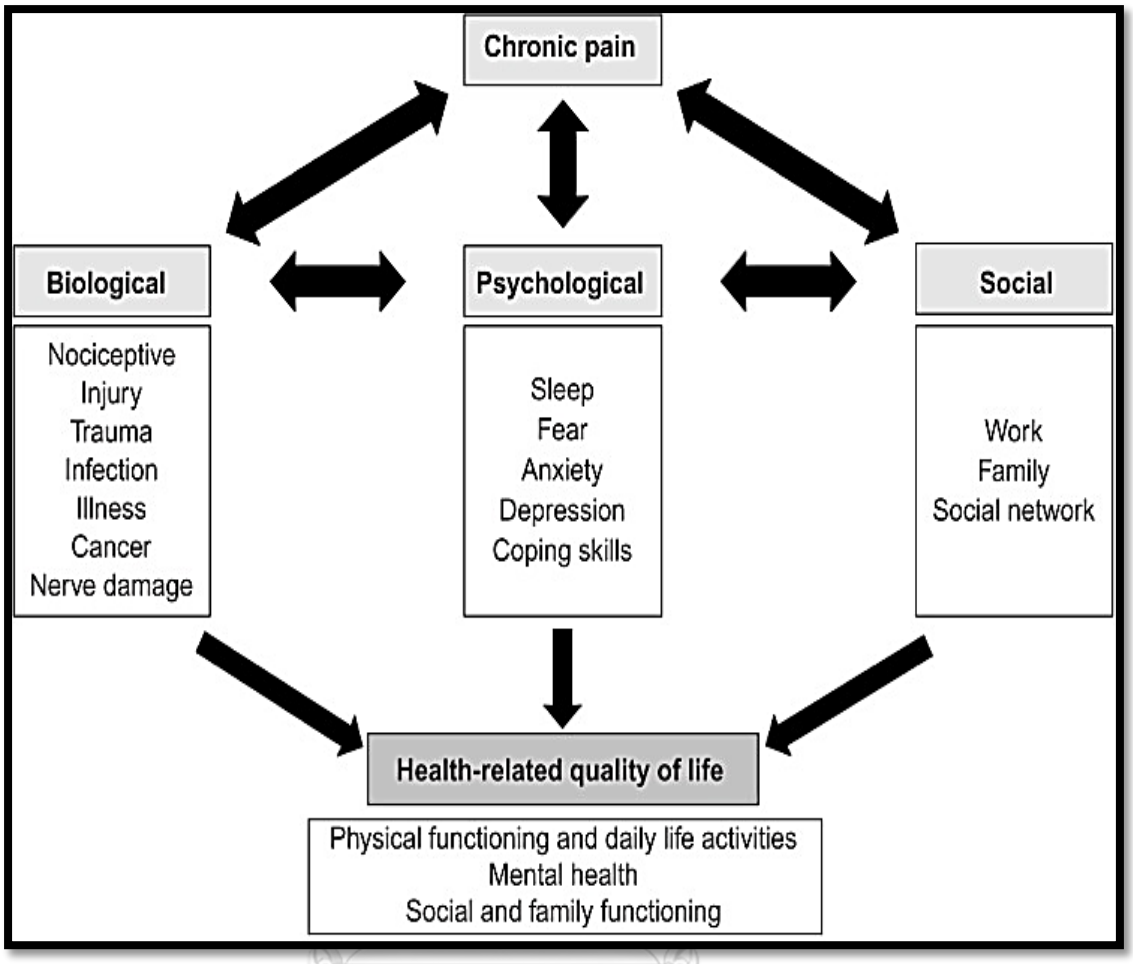

Figure 2.1 Biopsychosocial model of pain and consequences on the quality of life (63)

2.2 Patient-Reported Outcome Measures (PROMs)

In order to obtain the information that pertains to the patients' health, quality of life, or functional status associated with health care or treatment, the high-quality clinical care requires patients to provide information regarding the effects of disorders on several domains. The information should be directly reported by the patients without interpretation of the patients' response by a clinician or anyone else. To accomplish this, a tool commonly known as Patient-Reported Outcome Measures (PROM) is used (64).

The PROM is a questionnaire that can be either general in nature or disease-specific. The generic PROMs aim to assess patients' general health status by measuring multiple domains that are valuable in comparing health across a range of disease processes. In contrast, disease-specific PROMs are designed to identify specific symptoms and their impact on the function of those specific conditions (64, 65). The use of PROMs in clinical effectiveness research is growing. They are useful tools for improving quality of care and health outcomes. They allow patients to report on symptoms of particular conditions as well as physical, emotional, and social functioning. They can help providers to better understand their patients' perceptions of health, health-related quality of life, and other health-related constructs to professionals (19, 20). The use of PROMs in clinical care can improve patient-provider communication which leads to a greater understanding of complex personal circumstances and greater patient satisfaction (20, 66). However, PROMs should demonstrate adequate psychometric properties to be effective (67).

2.3 Psychometric Properties of Patient-Reported Outcome Measures

The psychometric properties of PROMs which include their reliability, validity, responsiveness, and minimal clinically important difference will be described as follows:

2.3.1 Reliability

The reliability of a questionnaire is estimated via its internal consistency and reproducibility (68).

a. Internal consistency

Internal consistency is a measure of the extent to which items in a questionnaire (sub)scale are correlated (homogeneous) (69). It is estimated by Cronbach's alpha (70). A low Cronbach's alpha indicates a lack of correlation between the items in a scale. A very high Cronbach's alpha indicates high correlations among the items in the scale (69). Cronbach's alpha values range from 0 to 1 of which a score between 0.7 and 0.9 is generally acceptable (71). Values greater than 0.90 suggest repetition between items in an outcome measure (72).

b. Reproducibility

Reproducibility is examined by test-retest reliability to show the consistency of the scores over time in a stable population (73). Pearson's product moment correlation coefficient (r) and the intraclass correlation coefficient (ICC) are commonly used as reliability parameters for continuous measures (68). For the ordinal measures, the weighted Cohen's Kappa coefficient should be used (73). The accepted minimum reliability threshold is 0.70 (74).

2.3.2 Validity

The validity of a questionnaire refers to the extent to which it measures what it is intended to measure (70). Three fundamental types of validity have been widely used for evaluating the validity of PROMs. They are content validity, construct validity, and criterion validity.

a. Content validity

Content validity, which plays a primary role in development of the new questionnaires, examines the extent to which the targeted construct or concepts of interest are comprehensively represented by the items in the questionnaire (75). Essential to establishing the content validity of an instrument is clear definition of the domain, description of the intended purpose, and minimization of potential error variance (underrepresentation, overrepresentation, and misrepresentation) (76). Content validity can be evaluated by 2 methods which are judgmental and statistical methods (77). Both methods make use of subject matter experts (SMEs) who are

content experts and/or measurement experts that are the members of target population (76). Judgmental method of assessing content validity involves providing an index that reflects the degree to which the content of the instrument passes the considerations of SMEs (77). Statistical method consists of several methods such as multidimensional scaling, cluster analysis, or factor analysis to avoid bias or error in item ranking associated with judgmental method (77).

b. Construct validity

Construct validity examines how the items of the questionnaire correlate with theoretical concepts which they are supposed to be related to as well as not be related to (78). Generally, construct validity is the practical method. Construct validity can be tested in many aspects, i.e. structural validity (that the items of a scale produce the putative factor structure underlying the scale), incremental validity (that the scale evidences significant predictive capacities over other similarly existing measures), and group differences (that different known groups display mean level differences in expected directions) (79). Furthermore, it can be assessed by establishing convergent validity (that the scale correlates with other psychological measures which are similar characteristics/concepts) and discriminant validity (that the scale does not correlate with other psychological measures which are dissimilar characteristics/concepts) (79, 80). To obtain good construct validity, one must show a strong relationship with convergent validity and no relationship for discriminant validity (81). The multitrait-multimethod matrix is another method for assessing construct validity (82).

c. Criterion validity

Criterion validity examines the extent to which scores on a questionnaire relate to a "gold standard" (69, 83). The acceptable correlation with the gold standard is at least 0.70 (69). Criterion validity is made up of 2 subcategories. There are predictive validity that refers to the extent to which a survey measure forecasts future performance and concurrent validity that is demonstrated when a new measure is compared favorably with one that already considered valid (80). The benefit of establishing the concurrent validity is when claiming a new measure to be better such as shorter, cheaper, and fairer (80).

2.3.3 Responsiveness

One important aspect of the PROMs is the ability of the questionnaire to detect clinically important changes over time even if these changes are small, which is referred to responsiveness (84, 85). A responsive instrument should be able to detect changes due to treatment effects or changes in the true value of the underlying construct (86, 87). Furthermore, the change must be statistically significant enough for research objectives and accurate enough to reflect increments of meaningful change for clinical application. The score of the questionnaire must not change when the patients' condition does not change and the score must change proportionally when the patients' condition change (88). The clinician should consider using the health status questionnaire with a high responsiveness in order to evaluate the clinical effect of a given intervention.

Two approaches are commonly used to assess the responsiveness (89, 90). The first method is the anchor-based method which compares the changes in scores to other clinically meaningful marker or external criterion. Importantly, the external criterion must be a valid measure of clinical change (89, 91). The second method is the distribution-based method which evaluates the change scores and their associated variability (i.e., standard deviation). The interpretation of the data is completely dependent on the variability of the data thereby limiting its ability to evaluate clinical relevance (89). However, experts do not agree on using a single preferred approach for responsiveness assessment but recommend using both anchor-based and distribution-based methods (92, 93). The assessments of the responsiveness will be explained as follows:

2.3.3.1 Anchor-based method

A common external criterion is the patient's ordinal rating of improvement or decline (90). The scales of the external criterion can range from "a great deal worse" to "a great deal better" with as few as 5 points and as many as 15 points, with zero indicating no change (90). Two evaluation methods of responsiveness via the anchor-based method will be described as follows:

a. Correlation analysis

This method calculates the correlation between the change scores (pre-/post-intervention scores) and the global rating scale (94). Due to the ordinal data associated with the global rating scale categories, Spearman rank correlation coefficient is used. Higher correlation coefficient indicates that the questionnaire responds to change in the patients' perspective. The correlation coefficient should be higher than 0.70 to be acceptable (95).

b. Receiver operating characteristic (ROC)

The ROC curve is a plot of the rate of negative cases that are incorrectly identified as positive by an assessment (false positives) along the X-axis against the rate of positive cases that are correctly identified by an assessment (true positives) along the Y-axis (96). The ROC curve is a very useful indicators of the relationship between a measure and an external indicator of change, such as the global perceived effect (97). By calculating the area under the ROC curve (AUC) , the responsiveness of the questionnaire in accurately classifying patients who improved and unimproved can be determined (84). The value of the AUC ranges from 0.50 (no ability to discriminating between the improved and unimproved patients) to 1.0 (perfect ability) (98). The AUC of greater than 0.70 is used as an indicator of acceptable high responsiveness (96).

2.3.3.2 Distribution-based method

There are various evaluation methods of responsiveness via the distribution-based approach, including the effect size, standardized response mean, and Guyatt's responsiveness index (99).

a. Effect size (ES)

The ES, which was first proposed by Cohen (100), provides direct information on the magnitude of change in the measure in regard to variation of the measures. It has been widely recommended for use as an indicator of responsiveness.

The formula for determining the ES of the measurement is as follows:

$$ES = \frac{\overline{X}_{follow-up} - \overline{X}_{baseline}}{SD_{baseline}}$$

When $\overline{X}_{follow-up}$ is the mean follow-up score and $\overline{X}_{baseline}$ is the mean baseline score. $SD_{baseline}$ is standard deviation of baseline measure of instrument. ES is affected by high level of variability of the baseline scores but it is not affected by the sample size (84, 90). The ES is interpreted as trivial for values < 0.20, small for values ≥ 0.20 to < 0.50, moderate for values ≥ 0.50 to < 0.80, and large for values ≥ 0.80 (100).

b. Standardized response mean (SRM)

The SRM is widely used today. It is the ratio of change score for an instrument divided by standard deviation of the change score (90). In the literature, the SRM is also referred to a responsiveness-treatment coefficient (101) or an efficiency index (102).

The formula for SRM is as follows:

$$SRM = \frac{\overline{X}_{follow-up} - \overline{X}_{baseline}}{SD_{change}}$$

When $\overline{X}_{follow-up}$ is the mean follow-up score and $\overline{X}_{baseline}$ is the mean baseline score. SD_{change} is standard deviation of change score of instrument (90). According to the commonly accepted criteria, it is interpreted the same as ES.

c. Guyatt's responsiveness index (GRI)

Guyatt et al., 1987 (103) developed an index that is another form of responsiveness which is viewed by some as the superior responsiveness statistics. The GRI uses the difference between baseline and posttest scores to represent a meaningful benefit in a group of patients. When the minimally clinically important change (described in next section) is known, it will be used instead of the difference between baseline and posttest scores.

The formula of GRI is as follows:

$$GRI = \frac{\text{MCID}}{\sqrt{2 * \text{MSE}_\text{x}}}$$

When MCID is minimally clinically important change on the measure and MSE_x is the mean squared error of X obtained from an analysis of variance model that examines repeated observations of the measure in clinically stable patients (e.g., multiple baseline measures prior to an intervention). Alternatively, if there are only 2 observations of the measure, MSE_x is the SD of the individual change scores in clinically stable patients (104). The disadvantage of this index is that data on stable patients may not always be available. Once again, the values of 0.20, 0.50 and 0.80 are used to represent small, moderate, and large effects (90).

2.3.3.3 Factors that impact on responsiveness

a. The population of patients under study

The level of responsiveness of a questionnaire can be affected by the population of patients under the study. The variation in scores for change is larger in a heterogeneous population compared to a homogeneous population. Women had a higher score on quality of life loss than men (105). Adults aged 55 years and older had greater score on mental health than younger adults (105). Participants from different ethnicity and race slightly differed in pain intensity and pain perception (105-107).

b. Floor and Ceiling Effects

Floor and ceiling effects are important factors that can interfere instrument responsiveness (108). When having more than 15% of all respondents rate the highest or lowest possible total score of a questionnaire, the floor and ceiling effects are considered to occur (69). The responsiveness of a questionnaire would be limited because the change is not measurable in these patients.

c. Recall window

Recall window or length of recall is another factor that may affect responsiveness. The longer recall window shows the less responsiveness to intervention effect. The current or past week recall shows better responsiveness (92).

2.3.4 Minimal Clinically Important Difference

The minimum rate of clinically significant change from the patients' or clinicians' perspective is also considered important (109). This value is referred to as the minimal clinically important difference (MCID) which is a method that aids the interpretability of numerical change scores from PROMs (110). It is defined as "the smallest difference in score in the domain of interest which patients perceive as beneficial and which would mandate, in the absence of troublesome side effects and excessive cost, as a change in the patient's management" (111). The MCID score is a single cut point estimate which can be represented as a change in the score (initial score minus the final score or a percentage-based change score from baseline) (112). The MCID is useful for clinical decision-making about progression of the patients (113). There is no specific method for establishing an MCID value (112). The methods to determine MCID can be divided into 2 categories which are anchor-based method and distribution-based method (114). Although different methods exist for estimating MCID, experts recommend that the anchor-based method should be given the most weight as it takes the patients' perspective into account (115).

The methods to determine MCID will be described as follows:

2.3.4.1 Anchor-based method

The anchor-based method compares the change in a patient-reported outcome with an external indicator which is either clinical-based (i.e., laboratory measures, physiological measures, and clinician ratings) or patient-based (i.e., global ratings of change or actual changes in PROMs). The MCID is specific to the target patient population. According to the amount of change, the target patient population are assigned into several groupings as unchanged, experiencing small, moderate, and large improvement or deterioration in clinical or health status (116). The change score

in each subgroup is used to estimate the MCID. To determine the MCID, a sample size of at least 50 patients is recommended (69). Four anchor-based approach for calculating the MCID have been described in the literature (117):

a. Within-patients score change

The MCID is defined as the mean change in scores of the patients who exhibit small change (117). The selection of groups of patients to be compared for the small change is arbitrary and vary between studies (118). They can be score difference between patients in the “much improved” and “unchanged” or between patients in the “slightly improved” and “unchanged”.

b. Between-patients score change

The MCID is defined as a score difference between two adjacent levels of change in patients’ perspectives (117). For a scale that has ‘‘much improved,’’ ‘‘improved,’’ ‘‘unchanged,’’ or ‘‘deterioration’’, the MCID may be calculated as the difference in the change score between ‘‘better’’ and ‘‘unchanged’’ patients. In this approach, the selection of the two adjacent levels is also arbitrary.

c. Sensitivity- and specificity-based approach

The MCID is a score that provides the best discrimination between the ‘‘improved’’ and ‘‘unchanged’’ patients. In diagnostic tests, sensitivity is based on proportion of true positives or patients with the condition who have a test positive result while specificity is based on proportion of true negatives or patients without the condition who have a test negative result (119). In concept of MCID, the sensitivity is based on proportion of patients who report an improvement on the external criterion while specificity is based on proportion of patients who do report an unchanged and/or deterioration on the external criterion. The statistics used for determining the MCID in this regard is the receiver operating characteristic (ROC) curve. The value that provides equal sensitivity and specificity is chosen as a MCID value (117).

d. Social comparison approach

This approach is not widely used. It requires patients to compare themselves with other patients. After discussion in pairs about their health situation, they rate themselves as the same or to varying degrees of better or worse than the patients whom they spoke with. The MCID is identified as the difference in scores of patients who rate themselves as ‘a little better’ or ‘a little worse’ as compared to the other patients (117).

2.2.4.2 Distribution-based method

Similar to the distribution-based method used for calculation of the responsiveness, the distribution-based method used for determining the MCID compares the change in PRO scores to some measure of variability or based on statistical characteristics of relevant sample. There are various methods including the standard error of measurement and the minimum detectable change. Furthermore, there are 2 methods for examining responsiveness that can be used to estimate MCID, which are the standard deviation and ES (115, 117).

a. Standard error of measurement (SEM)

SEM is the variation in the scores due to the unreliability or error of the scale or measurement. A change that is smaller than the SEM is likely to result from measurement errors than actual observed changes (117).Although there is no agreement yet that 1 SEM could be a general MCID value, 1 SEM may be used for individual true change score and possibly for mean group change score (117).

b. Minimal detectable change (MDC)

MDC is referred to the smallest detectable change that can be considered as the measurement error with a level of confidence (usually 95% confidence level) (120). To be valid for being the MDIC, the change score should be larger than the MDC (120).

c. Standard deviation (SD)

SD is a descriptive statistics that reflects variability or dispersion around the mean of sample scores (117). Norman et al. (121) found across a variety of studies that the value of 0.5 SD corresponded to the MCID. So, they suggested the threshold

of discrimination for changes appears to be approximately 0.5 SD. Furthermore, they noted that 0.5 SD is equal to 1 SEM.

d. Effect size (ES)

To calculate the change score equivalent to the MCID, one multiplies the SD of the baseline scores by 0.2 (small ES) (117). Score differences less than 0.2 SD are likely to be less than a MCID (122). However, others have argued that moderate ES of half a SD is a more reasonable for being a MCID threshold (121).

2.4 Measurement Tools for Measuring Quality of Life in cLBP Condition

Several validated PROMs are currently used in back pain population and are often collectively referred to as "legacy measures" (123). They include the Oswestry Disability Index, the Roland and Morris Disability Scale, the Short-Form Health Survey 36, and the Patient Reported Outcomes Measurement Information System-29.

2.4.1 Oswestry Disability Index (ODI)

The ODI measures the impact of LBP on the patients' pain that interferes with physical activities in 9 domains of daily life (personal care, lifting, walking, sitting, standing, sleeping, sex life, social life, and traveling) (Appendix A) (124, 125). The patients score their current functional status on each domain that consists of 6 responses ranging from 0 to 5, with 0 representing no difficulty in the activity and 5 representing maximal difficulty. The total ODI score is a sum score of all domains divided by the total possible score to obtain a final percentage of disability, with a higher percentage indicates greater disability (124, 125). It was shown to have good internal consistency with Cronbach's alpha ranging from 0.71 to 0.87 and high test-retest reliability (ICC ranges from 0.84 to 0.94) (126). Its construct validity which is indicated via a correlation coefficient between the ODI and the SF-36 was -0.64 (127). The ODI was translated into Thai version and was shown to have acceptable internal consistency with Cronbach's alpha of 0.81 in acute LBP patients (128). It was also proved to be sensitive in detecting clinical changes for cLBP (97, 129). The MCID of ODI is recommended to be at least 10 points in LBP (97, 130).

2.4.2 Roland Morris Disability Questionnaire (RMDQ)

The original RMDQ was developed in 1983 from the Sickness Impact Profile, for self-assessment of measuring disability in patients with back pain worldwide (131, 132). It consists of "yes/no" 24 items (Appendix B). The RMDQ score is calculated by adding up the number of "yes" items which ranges from 0 to 24 (132). The higher score shows higher level of pain-related disability. The test-retest reliability of the RMDQ is high (ICC ranges from 0.79 to 0.88) (133). The Thai version of the RMDQ was reported to be reliable for assessing functional disability of LBP in Thai patients. The overall Cronbach's alpha coefficient of the scale was 0.83 (134). The responsiveness of the RMDQ in cLBP was good which all pooled ES were well above 0.80 and all other statistics were high (135, 136). Its important change threshold or MCID is recommended to be approximately 5 points (137). It was found to be most sensitive for patients with mild to moderate disability due to cLBP (138).

2.4.3 Short-Form Health Survey 36 (SF-36)

The Short-Form Health Survey 36 (SF-36) (Appendix C) is the tool that frequently used for measuring the quality of life in cLBP (37). The SF-36 questionnaire has 8 domains of quality of life: 1) limitations in physical activities, 2) limitations in social activities, 3) limitations in usual role activities, 4) bodily pain, 5) general mental health , 6) limitations in usual role activities because of emotional problems, 7) vitality, and 8) general health perceptions (139). The items and dimensions in SF-36 were constructed using the Likert method of summated ratings. After data entry, items and scales are scored in 3 steps (140): 1) item recoding, 2) computing raw scale scores by summing across items in the same scale, and 3) transforming raw scale scores to a 0 - 100 scale. The scale 0 means worst possible health and 100 means best health state (141). The SF-36 survey was found to be reliable and valid (142, 143). In the general healthy people, the SF-36 Thai version showed adequate internal consistency with Cronbach's alpha 0.50 – 0.94 (144) and is considered to be a reliable tool for assessing functional disability of LBP in Thai patients (145). The item correlation coefficient for the 35 items within the 8 health aspects ranged from 0.43 to 0.80 (145). The SF-36 was found to be moderate responsiveness in cLBP patients (146, 147).

2.4.4 Patient-Reported Outcomes Measurement Information System-29 (PROMIS-29)

The Patient-Reported Outcomes Measurement Information System (PROMIS) questionnaire was developed by the U.S. National Institutes of Health (NIH) under the "Roadmap to Medical Research" initiative to assess self-reported outcomes in several domains that are associated with multiple clinical conditions. This effort began by identifying items from well-validated questionnaires, adapting them into large item banks, and modifying response options into standardized formats (24). The PROMIS conceptual model (Figure 2.2) is strongly founded in the World Health Organization definition of health. It was developed using modern measurement theory known as item response theory (148) that was calibrated and scored based on more-contemporary samples (149).

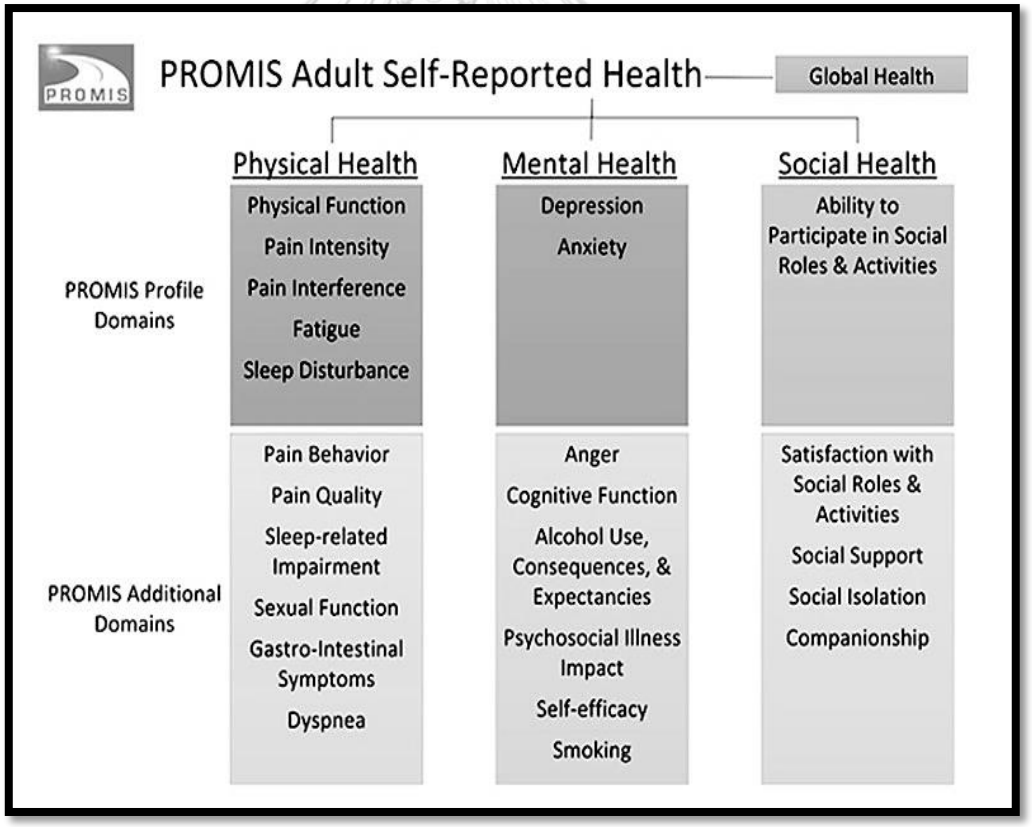

Figure 2.1 PROMIS conceptual framework (150)

The PROMIS-29 is a short form of PROMIS that assesses diverse dimensions including 7 health-related quality of life domains (Appendix D) (151). It can be thought of as a "modern" version of the SF-36 (152) in which it contains new content on sleep disturbance which is not directly measured in the SF-36. Seven domains of the PROMIS-29 are pain interference, physical function, fatigue, depression, anxiety, sleep disturbance, and satisfaction with social participation (24). The PROMIS-29 contains 29 items. Twenty-eight items (excluding pain intensity item) are Likert scales that range from 1 to 5. The higher scores mean better quality of life in terms of physical function and social role while the lower scores mean better outcomes for pain interference, fatigue, depression, anxiety, and sleep disturbance. The item of pain intensity is measured on a 0-10 numerical rating scale (24).

The PROMIS-29 has been translated in many languages such as Dutch (153), French (154), German (155), and Thai. The development of the Thai version of the PROMIS-29 was done using the Functional Assessment of Chronic Illness Therapy (FACIT) translation methodology. The FACIT translation methodology contains rigorous steps for translation that was shown to provide good overall accuracy among native language-speakers when being tested multilingual. This methodology was proposed to be less bias when using the same translation across cultural groups than in applying country-specific versions produced by different individuals who tend to introduce stylistic changes that are not necessarily country specific in nature. The native English speakers who developed the measure conducted a final quality review and the translations were finalized. In March 2018, the Thai version of the PROMIS-29 was completed.

The PROMIS-29 has been tested and validated in a variety of patient population. In addition to the deployment with a representative sample of the U.S. population (151), the PROMIS-29 has successfully measured quality of life in chiropractic patients (156), and people with rheumatoid arthritis, osteoarthritis, fibromyalgia, systemic lupus erythematosus (157), systemic sclerosis (158), spinal disorders (149), kidney transplant recipients (159), diabetes (19), chronic rhinosinusitis (160), and HIV (161). The PROMIS-29 has also been administered in a variety of settings (e.g., at the patient's home or in a medical clinic) and by a variety of methods (e.g., online or via paper and pencil) (162).

The reliability of the PROMIS-29 has been done in various population. For example, in older adults with chronic musculoskeletal pain who rated their pain as stable which found the test-retest reliability at 3 months around 0.70 as shown in Table 2.1 (24). The study in patients with idiopathic pulmonary fibrosis reported test-retest reliability of the PROMIS-29 to be acceptable to excellent for all scales (163). Furthermore, the patient with lower limb loss showed acceptable internal consistency ranged from 0.70 to 0.90 (164). In older adults with chronic musculoskeletal pain, the internal consistency was good to excellent with Cronbach's alpha between 0.81 and 0.95 for all scales (24). The subscales of the PROMIS-29 showed high internal consistency ranged from 0.87 to 0.97 in the patients with HIV (161). The Thai version of the PROMIS-29 showed good to excellent internal consistencies with Cronbach's alphas ranging from 0.84 to 0.94 for all scales (Table 2.2) (165). Test–retest reliability was moderate to good with ICCs (2,1) ranging from 0.57 to 0.74 (Table 2.3) (165).

Table 2.1 The test-retest reliability of PROMIS-29 in older adults with chronic musculoskeletal pain (24).

	ICC*(95% CI)	
PROMIS measure	Patient's pain "about the same" (n=91)	Pain intensity rating changed within +/- 1 point (n=98)
Pain Intensity	0.44 (0.29, 0.61)	---
Pain Interference	0.58 (0.44, 0.71)	0.67 (0.56, 0.77)
Physical Function	0.68 (0.56, 0.78)	0.70 (0.59, 0.79)
Fatigue	0.68 (0.56, 0.78)	0.76 (0.67, 0.84)
Sleep Disturbance	0.70 (0.58, 0.79)	0.74 (0.64, 0.82)
Depression	0.73 (0.62, 0.81)	0.74 (0.64, 0.82)
Anxiety	0.63 (0.50, 0.75)	0.69 (0.58, 0.78)
Satisfaction with social role	0.54 (0.39, 0.68)	0.57 (0.43, 0.70)
RTF Impact Score	0.73 (0.62, 0.82)	0.80 (0.71, 0.86)

Values are intraclass correlation coefficients (ICCs) for patients who rated their pain as "about the same" or whose pain intensity was within 1 point of baseline value at 3 months following baseline assessment.
*ICC = Intraclass Correlation Coefficient.

Table 2.2 The internal consistencies for the Thai version of PROMIS-29 scales (165).

T-PROMIS-29	Cronbach's alpha	Ceiling effect (%)	Floor effect (%)
Physical Function	0.87	**16**	0
Anxiety	0.90	0	13
Depression	0.92	0	**50**
Fatigue	0.88	0	7
Sleep Disturbance	0.84	0	6
Ability to Participate in Social Roles and Activities	0.89	**20**	0
Pain Interference	0.94	0	6

Bolded values are those exceeding 15%

Table 2.3 The test-retest reliability coefficients of the Thai version of PROMIS-29 scores (165).

T-PROMIS-29 scale	Baseline	1 week	$ICC_{(2,1)}$ (95% CI)	$SEM_{test\text{-}retest}$	$MDC_{95\%}$
Pain Intensity (1–10)	4.6 (2.1)	4.1 (2.1)	0.76 (0.66, 0.83)	1.05	2.90
Physical Function	44.1 (7.2)	44.2 (7.1)	0.61 (0.50, 0.70)	4.46	12.37
Anxiety	57.5 (8.8)	55.6 (8.7)	0.63 (0.51, 0.72)	5.38	14.91
Depression	48.6 (9.8)	48.9 (8.5)	0.71 (0.62, 0.78)	4.96	13.75
Fatigue	52.1 (7.2)	51.1 (7.7)	0.59 (0.48, 0.69)	4.77	13.22
Sleep Disturbance	48.1 (7.6)	47.8 (7.8)	0.74 (0.66, 0.80)	3.91	10.84
Ability to Participate in Social Roles and Activities	51.0 (8.0)	51.1 (7.4)	0.69 (0.59, 0.76)	4.29	11.89
Pain Interference	57.4 (6.3)	56.3 (6.5)	0.57 (0.46, 0.67)	4.20	11.63

ICC intraclass correlation coefficient, MDC minimal detectable change, SEM standard error of measurement

For validity, PROMIS-29 has high validity in French general population (154) and Australian systemic sclerosis patients (166). The PROMIS-29 Physical Functioning showed strong correlation with the SF-36 Physical component scores (r = 0.86) (167). It demonstrated discriminant validity when being tested in persons with and without work compensation, lower and greater catastrophizing score, and with and without fall in previous 3 months (Table 2.4). In addition, the Thai version of PROMIS-29 showed satisfactory of unidimensionality (Table 2.5), convergent validity, and divergent construct validity (Table 2.6) (165).

Table 2.4 Construct validity of baseline PROMIS measures and the derived impact score (24).

	Worker's compensation					Catastrophizing score (total)					Falls in previous 3 months				
PROMIS measure	Yes		No		P*	<14		≥14		P*	Yes		No		P*
N	29.0		169.0			109.0		78.0			57.0		139.0		
Pain intensity	6.9	(1.9)	5.8	(1.7)	**0.002**	5.5	(1.6)	6.6	(1.9)	**<.001**	6.3	(1.8)	5.8	(1.8)	0.106
Pain interference	65.0	(4.9)	59.8	(5.6)	**<.001**	58.6	(5.9)	63.4	(4.9)	**<.001**	62.7	(6.1)	59.7	(5.5)	**<.001**
Physical function	36.0	(4.4)	41.8	(6.7)	**<.001**	43.2	(7.4)	38.3	(6.2)	**<.001**	38.5	(5.9)	41.9	(6.8)	**0.001**
Fatigue	59.2	(8.7)	52.8	(8.5)	**<.001**	51.3	(8.3)	57.4	(9.3)	**<.001**	56.9	(8.7)	52.6	(8.6)	**0.002**
Sleep disturbance	56.2	(5.1)	51.8	(7.8)	**<.001**	50.9	(8.3)	54.5	(7.9)	**0.001**	53.0	(8.0)	52.2	(7.5)	0.473
Depression	57.0	(9.0)	48.6	(8.1)	**<.001**	46.5	(8.5)	54.2	(9.6)	**<.001**	53.8	(9.6)	48.3	(8.0)	**<.001**
Anxiety	57.5	(8.5)	51.3	(8.2)	**<.001**	49.2	(8.8)	56.2	(8.6)	**<.001**	55.9	(7.9)	50.9	(8.3)	**<.001**
Satisfaction with social role	39.1	(6.9)	46.1	(9.5)	**<.001**	47.1	(9.4)	42.5	(9.4)	**<.001**	42.4	(8.6)	46.2	(9.8)	**0.014**
Impact score	34.2	(6.1)	26.0	(7.4)	**<.001**	24.0	(6.8)	31.3	(6.7)	**<.001**	30.6	(7.3)	25.9	(7.6)	**<.001**

Tabled figures are all means (SD).
*T-test of means. Bolded P-values are significant (<0.05).

Table 2.5 The unidimensionality of Thai version of PROMIS-29 (165)

T-PROMIS-29 domain	CFI	RMSEA [90% CI]	SRMR
Physical Function	1.000	0.000 [0.000–0.119]	0.002
Anxiety	1.000	0.000 [0.000–0.079]	0.004
Depression	0.998	0.087 [0.000–0.214]	0.010
Fatigue	1.000	0.000 [0.000–0.055]	0.003
Sleep Disturbance	1.000	0.017 [0.000–0.173]	0.008
Ability to Participate in Social Roles and Activities	1.000	0.000 [0.000–0.167]	0.006
Pain Interference	0.999	0.045 [0.000–0.185]	0.006

CFI comparative fit index, RMSEA root mean square error of approximation, SRMR standard root mean square residual

Table 2.6 The construct validity of Thai version of PROMIS-29 (165)

T-PROMIS-29	SF-36 Physical Functioning	SF-36 Mental Health	SF-36 Social Role Functioning	SF-36 Bodily Pain	SF-36 Vitality	SF-36 General Health Perception
Physical Function	**0.54**	0.35				
Anxiety	−0.38	**−0.50**				
Depression	−0.42	**−0.64**				
Fatigue	−0.17				**−0.56**	
Sleep Disturbance	−0.23				**−0.45**	
Ability to Participate in Social Roles and Activities			**0.58**			0.40
Pain Interference	−0.48			**−0.67**		

Bolded values indicate correlation coefficients for convergent validity, unbolded values indicate correlation coefficients for discriminant validity

The responsiveness of the PROMIS-29 has been studied in patients with spinal disorders. In older adults with chronic musculoskeletal pain, a large responsiveness was reported as shown in Table 2.7 (24). The PROMIS-pain interference scale was responsive and comparable with legacy measures in cLBP (168). Furthermore, the PROMIS-physical function and PROMIS-pain interference scales demonstrated large responsiveness in a spine clinic population (149, 169). Four PROMIS domains which are anxiety, pain intensity, satisfaction with social roles and activities, and physical function were shown to have adequate responsiveness in adults with spinal deformity (170). The summary of responsiveness of PROMIS-domain in patients with spinal disorders in previous studies were showed in Table 2.8.

Table 2.7 Responsiveness of PROMIS measures and derived impact score in older adults with chronic musculoskeletal pain (24).

	Change in pain at 3 months compared to baseline						
	Much less (n =20)	A little less (n= 23)	About the same (n=91)	A little worse (n=47)	Much worse (n=16)	Spearman correlation coefficient	P
Mean score changes*							
Pain intensity (10-point scale)	-3.60	-1.48	- 0.37	0.45	1.25	0.500	<.0001
Pain interference	-6.84	-1.82	-0.76	0.74	3.78	0.367	<.0001
Physical function	3.85	0.09	-0.57	-1.34	-3.85	-0.295	<.0001

Table 2.7 Responsiveness of PROMIS measures and derived impact score in older adults with chronic musculoskeletal pain (24).

	Change in pain at 3 months compared to baseline						
	Much less (n =20)	A little less (n= 23)	About the same (n=91)	A little worse (n=47)	Much worse (n=16)	Spearman correlation coefficient	P
Fatigue	-2.47	1.45	0.20	-0.39	1.64	0.057	0.43
Sleep interference	-2.43	1.17	0.49	1.32	3.62	0.188	0.01
Depression	-2.44	3.67	-0.24	-0.54	1.74	0.004	0.95
Anxiety	-5.82	-0.19	-1.19	0.48	-1.32	0.137	0.06
Satisfaction with social role	3.09	-0.55	0.11	-1.37	-2.79	-0.159	0.03
Impact score (8–50 scale)	-10.16	-2.78	-0.64	1.53	6.06	0.497	<.0001
Effect sizes (change/baseline SD)							
Pain intensity (10-point scale)	-1.93	-0.79	-0.20	0.24	0.67	†	
Pain interference	-1.03	-0.28	-0.08	0.17	0.71		
Physical function	0.68	0.07	-0.04	-0.16	-0.57		
Fatigue	-0.37	0.20	0.05	-0.05	0.14		
Sleep interference	-0.32	0.10	0.04	0.17	0.41		
Depression	-0.24	0.30	-0.02	-0.06	0.30		
Anxiety	-0.57	0.03	-0.14	0.04	0.02		
Satisfaction with social role	0.34	0.01	0.01	-0.15	-0.39		
Impact score (8–50 scale)	-1.30	-0.36	-0.08	0.20	0.78		
Standardized response means (change/SD of change)							
Pain intensity (10-point scale)	-1.61	-0.66	-0.17	0.20	0.56	†	
Pain interference	-1.07	-0.29	-0.08	0.18	0.74		
Physical function	0.87	0.09	-0.05	-0.20	-0.72		
Fatigue	-0.50	0.28	0.07	-0.08	0.20		
Sleep interference	-0.39	0.12	0.04	0.21	0.50		
Depression	-0.29	0.37	-0.02	-0.08	0.37		
Anxiety	-0.66	0.03	-0.16	0.05	0.02		
Satisfaction with social role	0.39	0.01	0.01	-0.17	-0.44		
Impact score (8–50 scale)	-1.53	-0.42	-0.10	0.23	0.91		

*Means are T-scores with population mean of 50 unless otherwise specified. Correlations and P-values calculated on raw values.
† P-values are the same as for the mean score changes.

Table 2.8 Responsiveness of PROMIS-domain in patients with spinal disorders in previous studies

			Responsiveness		
Study	PROMIS	Population	ES	SRM	Correlations
Deyo et al.2016 (24)	PROMIS-29	Older adults with chronic musculoskeletal pain, aged ≥ 55 years	Absolute ESs ranged from 0.24 (Depression) to 1.93 (Pain Intensity)	Absolute SRMs ranged from 0.29 (Depression) to 1.61 (Pain Intensity)	-
Chen et al.2019 (168)	PROMIS-PI (4a)	Patients with moderate to severe cLBP	-	Retrospective Global Pain of Change Better group 0.60 Same group 0.23 Worse group -0.25 Prospective Global Pain of Change Better group 0.80 Same group 0. .36 Worse group -0.53	-
Hung et al. 2019 (149)	PROMIS PF v1.2	An orthopaedic spinal population, aged ≥ 18 years	3-month follow-up 0.98 >3-month follow-up 0.97 6-month follow-up 1.11 >6-month follow-up 0.98	1.31 1.07 0.97 1.03	For NDI ranged from −0.60 to −0.72 For ODI ranged from −0.66 to −0.80
	PROMIS PI v1.1		3-month follow-up 1.39 >3-month follow-up 1.19 6-month follow-up 1.29 >6-month follow-up 1.12	1.16 1.31 0.94 1.12	For NDI ranged from 0.71 to 0.81 For ODI ranged from 0.59 to 0.83
Schalet et al. 2016 (169)	PROMIS-PF 124 item	Patient with back pain	-	Better 0.64 About the same 0.49 Worse 0.29	-
Raad et al. 2019 (170)	4 PROMIS CAT: anxiety, pain intensity, satisfaction with social roles, and activities, and Physical function	Adult spinal deformity, aged ≥ 18 years	Anxiety 0.46 Pain intensity 0.80 Satisfaction with social roles and activities –0.55 Physical function –0.29	-	-

The MCID of the PROMIS-29 was tested in several population groups. In patients with joint disorders, the MCID value for physical function domain ranged from 2.45 to 21.55 (171). In patients with knee osteoarthritis, the MCID values of

physical function ranged from 1.90 to 2.20, anxiety ranged from 2.30 to 3.40, depression ranged from 3.00 to 3.10, and pain interference ranged from 2.35 to 2.40 (172). The change of 3 points in the PROMIS-29 pain, anxiety, depression, fatigue, and sleep disturbance scales represented a reasonable MCID (173). In patients with lumbar degenerative disease, the MCID values for pain was 7.05, physical function was 5.48, anxiety was 4.28, depression was 5.19, fatigue was 5.42, sleep disturbance was 7.44, and social satisfaction was 8.31 (174). In the patients with LBP, the MCID of pain interference scale considered meaningful ranged from 3.50 to 5.50 (175). The summary of MCIDs of PROMIS-domain in previous studies were showed in Table 2.9. However, the studies of the MCID of the PROMIS-29 in cLBP patients are limited.

Table 2.9 MCIDs of PROMIS-domain in previous studies

			PROMIS-domain							
Study	PROMIS	Population	Pain Intensity	Physical Function	Anxiety	Depression	Fatigue	Sleep Disturbance	Ability to Participate in Social Roles and Activities	Pain Interference
Deyo et al. 2016 (24)	PROMIS-29	Older adults with chronic musculoskeletal pain, aged ≥ 55 years	2.0	2.0	-	-	-	-	-	2.0
Kroenke et al. 2014 (176)	PROMIS-29	Patients with chronic pain	-	-	2.5	2.2	-	-	-	-
Chen et al. 2018 (122)	PROMIS-PI	Patients with chronic low back pain, hip or knee osteoarthritis pain, and a history of stroke	-	-	-	-	-	-	-	2 to 3
Kroenke et al. 2019 (177)	PROMIS Anxiety 4-item	Patients with chronic musculoskeletal pain comorbid with depression and/or anxiety, aged ≥ 18 years	-	-	4	-	-	-	-	-
Kroenke et al. 2020 (178)	PROMIS Depression (4a)	Patients with chronic low back pain, hip or knee osteoarthritis pain, and a history of stroke	-	-	-	3 to 4	-	-	-	-

Table 2.9 MCIDs of PROMIS-domain in previous studies

Study	PROMIS	Population	PROMIS-domain							
			Pain Intensity	Physical Function	Anxiety	Depression	Fatigue	Sleep Disturbance	Ability to Participate in Social Roles and Activities	Pain Interference
Swanholm et al. 2014 (179)	PROMIS Depression and Anxiety CATs	Patients with chronic/ persistent pain, aged ≥18 years	-	-	3.0 to 5.5	3.5 to 5.5	-	-	-	-
Amtmann et al. 2016 (175)	PROMIS-PI	People with LBP, aged ≥18 years	-	-	-	-	-	-	-	3.5 to 5.5
Purvis et al. 2017 (180)	PROMIS health domains	Patients undergoing anterior cervical spine surgery, aged ≥18 years	-	4.5	-5.7	-4.6	-5.8	-7.4	4.4	-5.2
Hung et al. 2018 (181)	PROMIS PF version 1.2, PROMIS PI version 1.1	Spine patients, aged ≥18 years	-	3 to 10	-	-	-	-	-	3 to 9
Steinhaus et al. 2019 (182)	PROMIS PF and PI CATs	Adult patients undergoing cervical spine surgery	-	4.5	-	-	-	-	-	4.9

Among several measurement tools have been used in cLBP, the PROMIS-29 was found to be superior to the others. It contains several domains within one tool which provides general view of the patients' health status.

2.5 Summary

From the literature, cLBP affects multiple outcome domains which highly relevant to physical functioning, pain intensity, health-related quality of life, work, psychological functioning, and pain interference. To measure these multiple outcome domains and patients' health status, PROMs are developed. To be effective, the PROMs should demonstrate adequate psychometric properties of which they should be reliable, valid, and responsive. In cLBP population, several validated PROMs are available including the ODI, the RMDQ, the SF-36, and the PROMIS-29. The PROMIS-29 hold potential to become a widely accepted and standardized tool for assessing patient-reported outcomes. At present, the reliability and validity of the Thai

version of the PROMIS-29 in individuals with cLBP have been established. However, the responsiveness and the MCID of the Thai version of the PROMIS-29 are lacking.

The responsiveness is the ability of the PROMs to detect clinically important changes over time even if these changes are small. Two methods, which are the anchor-based and distribution-based methods, are commonly used. The MCID which is the minimum rate of clinically significant change from the patients' perspective is also considered important. To be confident in the MCID, the magnitude of the MCID must be larger than the measurement error (183).

CHAPTER III

METHODOLOGY

This chapter describes research design, characteristics of participants, outcome measurements, and the processes of data collection.

3.1 Research Design

This study used a prospective cohort design with 4 weeks and 8 weeks follow-ups.

3.2 Characteristics Participants

Individuals with cLBP and patients who were evaluated for possible physical therapy treatment for cLBP at 4 government hospitals (Bhumibol Adulyadej Hospital, Klang Hospital, Lerdsin Hospital, Phramongkutklao Hospital, and Phra Nakhon Si Ayutthaya Hospital) were invited to participate.

3.2.1 Inclusion criteria

To be eligible, participants needed to be 18 years old or older and were presenting with cLBP. The pain had to locate in the area between the lower rib margins and above the gluteal crease (25). To identify cLBP, the participants were screened using 2 questions based on the Research Task Force, i.e. (1) “How long has back pain been an ongoing problem for you?” and (2) “How often has LBP been an ongoing problem for you over the past 6 months?” (21). A response of “greater than 3 months” to question 1 and a response of “at least half the days in the past 6 months” to question 2 would be defined as cLBP. Moreover, the participants had to have the pain severity of at least 3 out of 10 on the 11-point numerical pain rating scale (NRS) (184, 185). The NRS is a numbered version of the VAS in which the patient can select one number that best describes the pain severity (186). The 0 indicates no pain and 10 indicates worst imaginable pain (186, 187). All participants were able to understand and completed questionnaires in Thai.

3.2.2 Exclusion criteria

The exclusion criteria were the individuals who had unstable neurological symptoms, cauda equine syndrome, cancer, spinal cord injury, vertebral fractures, multiple sclerosis, tumor, and mental disorders. Pregnant women were also excluded.

3.3 Sample Size

Two hundred and two participants were recruited. The sample size was calculated by

$$\text{Total sample size} = N = \left[\frac{(Z\alpha + Z\beta)}{C}\right]^2 + 3 \qquad (188)$$

When $Z\alpha$ = the standard normal deviate for α

α (two-tailed) = threshold probability for rejecting the null hypothesis. Type I error rate.

Z_β = the standard normal deviate for β

β = probability of failing to reject the null hypothesis under the alternative hypothesis. Type II error rate.

C = $0.5 * \ln[(1+r)/(1-r)]$.

r = the expected correlation coefficient

$$\text{Total sample size} = N = \left[\frac{(2.697 + 1.282)}{0.310}\right]^2 + 3 = 168$$

Form equation above, this study identified $\alpha = 0.007$ and $\beta = 0.10$. In addition, the hypothesis was expected to moderate correlation. So the expected correlation coefficient was set as 0.3. When calculation was $Z\alpha = 2.697$, $Z\beta = 1.282$, and C=0.310. Therefore, the number of participants was 168. To accommodate for possible dropout which might occur during the longitudinal study, additional 20% of the estimated participants were needed. Finally, approximately 202 participants were needed for this study.

3.4 Materials

1) PROMIS-29 Thai version

The paper-based of Thai version of PROMIS-29 version 2.1 described in 2.4.4 was used in this study (Appendix E). In brief, it measures 7 health-related quality of life domains: physical function, anxiety, depression, fatigue, sleep disturbance, ability to participate in social roles and activities, and pain interference. Twenty-eight items (excluding the Pain Intensity item) ask respondents to rate the symptom or item using 1-5 Likert scales and a single item assessing pain intensity is measured using a 0-10 numerical rating scale with 0 = "No pain" and 10 = "Worst pain imaginable." Responses to the items for each domain were summed and then transformed into T-scores (mean 50 and SD 10; http://www.healthmeasures.net).

2) Global Perceived Effect (GPE) scale

The GPE scale was used as an external criterion for the anchor-based method in the responsiveness analysis. It was a measure that specifies whether the patients' current condition was improved or deteriorated compared to when the episode started (189). It was a 7-point scale that ranges from 1 = "Very much improved," 2 = "Much improved," 3 = "A little improved," 4 = "Not changed," 5 = "A little deterioration," 6 = "Much deterioration," and 7 = "Very much deterioration." The GPE scale was shown to be reliable when used in patients with musculoskeletal conditions (190). The Thai version of the GPE was used in this study (Appendix F) and was kept it in an envelope to avoid the bias of the participants' responses if they hesitate to answer the unconcealed questionnaire. All participants were asked to rate their condition to the previous 4 weeks: baseline for 4-week follow-up and at 4 weeks for 8-week follow-up.

3) Roland Morris Disability Questionnaire Thai version

The paper-based Thai version of RMDQ described in 2.4.2 was used in this study (Appendix G). The RMDQ is self-assessment of measuring disability in patients with back pain that consists of "yes/no" 24 items. The total score ranges from 0 to 24. The higher score is interpreted as higher level of pain-related disability.

3.5 Procedure

All participants received information about the project (Appendix H) and provided written informed consent (Appendix I) to participate in the study. Ethical approval was obtained from the Research Ethics Review Committee for Research Involving Human Research Participants, Health Sciences Group, Chulalongkorn University (COA No. 156/2018) (Appendix J) and Lerdsin Hospital Human Research Ethics Committee, Lerdsin Hospital (No. 112/2019) (Appendix K). Next, all participants were asked to completed 4 questionnaires at baseline which were screening questionnaire (Appendix L), demographic questionnaire (Appendix M), the Thai version of the PROMIS-29, and the Thai version of the RMDQ. At 4- and 8-week follow-ups, they were again administered the 7-point GPE scale, the Thai version of PROMIS-29, and the Thai version of RMDQ either in the clinic or returned the completed measures via mail. Figure 3.1 summarizes the procedure of the study.

There were no restrictions on the type or amount of treatments that they received during the 8 weeks of the study. However, either the physiotherapy treatments or other treatments which participants had received were noted during the 8 weeks of the study (Appendix N) (191).

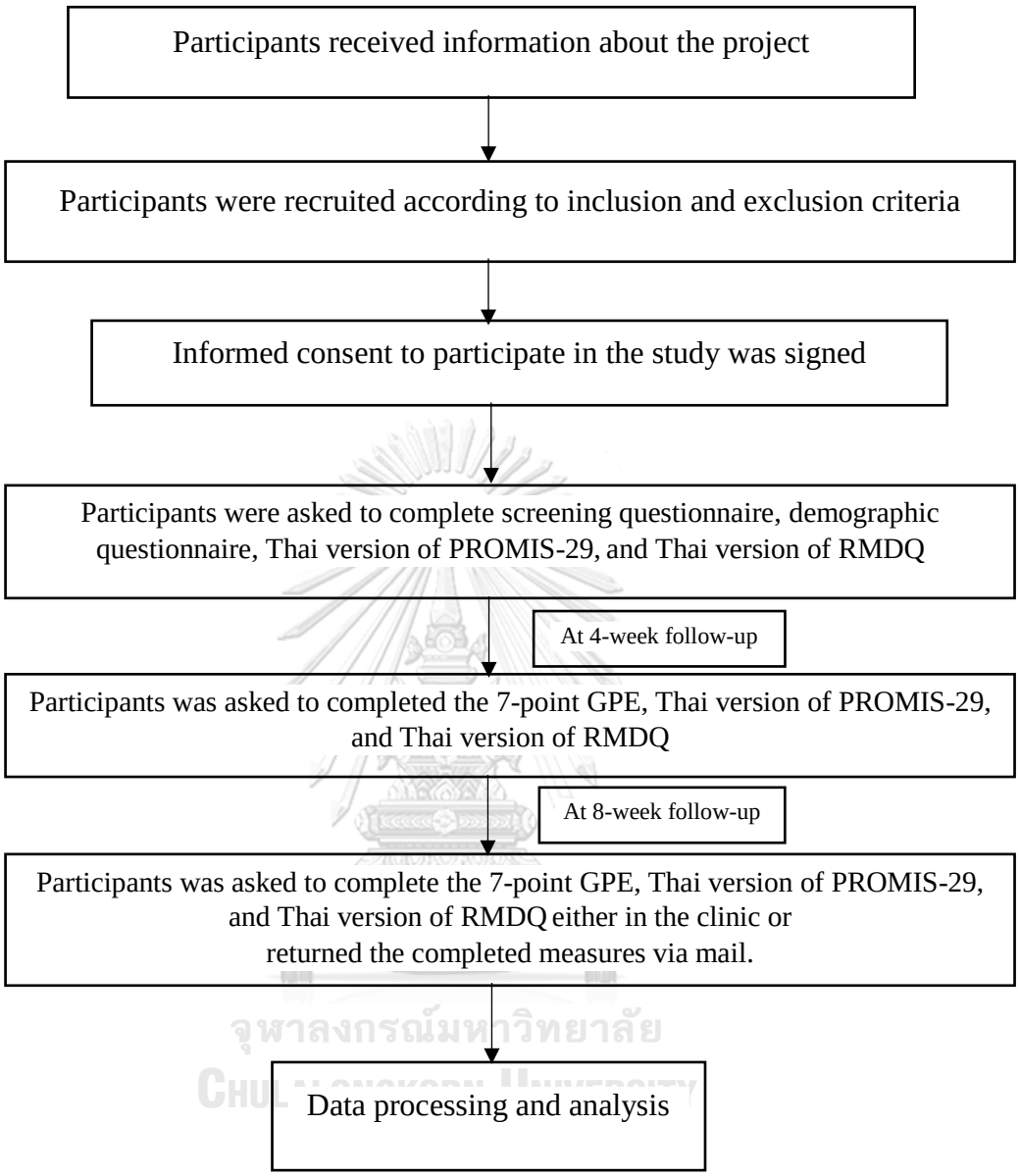

Figure 3.1 Flowchart outlining of participants in this study

3.6 Statistical Analysis

Baseline demographics of the participants were calculated using means and standard deviations for continuous variables while using counts and percentages for categorical variables. Data were analyzed separately for 4- and 8-week follow-ups. The statistical analysis for floor and ceiling effects and responsiveness are described as follows:

The floor and ceiling effects

The floor and ceiling effects for the PROMIS-29 scales were examined. The proportion of participants who rated the highest or lowest total score at baseline (or at 4 weeks) was calculated. When each proportion was more than 15% of all participants, it was referred to as the ceiling and floor effects, respectively.

The responsiveness

Both distribution-based and anchor-based methods were employed in this study. For the distribution-based method, 3 values (change scores, ESs, and SRMs) were calculated. Change scores for the PROMIS-29 scales were calculated by subtracting the initial score from the follow-up scores. A positive value indicated an improvement in Physical Function and Ability to Participate in Social Roles and Activities while a negative value indicated an improvement in the remaining domains. The ESs were calculated as the difference between baseline and follow-up scores divided by the SD of baseline scores. The SRMs were computed by the score change divided by the SD of those score changes. The magnitude of the ES and SRM of 0.20 or less is indicative of small, 0.50 is considered moderate, and a value of 0.80 or greater represents strong responsiveness (100). The change scores, ESs, and SRMs were examined as a function of GPE category.

For the anchor-based method, this study calculated the Spearman's rank order correlation coefficients between the change scores of the PROMIS-29 scales with the 7-point GPE. The coefficients $r < 0.30$ = low, $0.30 < r < 0.60$ = moderate, and $r > 0.60$ = high correlation (24, 192).

The MCID at baseline and 4-week follow-up

The MCID was determined by using the point closest to upper left corner of the ROC curve (104, 193). Each participant was classified as “improved” or “not improved” based on his or her GPE response (improved = responding with very much improved and much improved and not improved = all other GPE responses) (194). As a check on this estimate, SEM for each domain was also computed as the SD of baseline scores multiplied by square root of 1 - $ICC_{(2,1)}$ (90). Only the data from the participants who rated their condition in each domain as being “not changed” were used for computing the ICC value. If the SEM was larger than the optimal cut point value on the ROC curve, the SEM as a better representation of the MCID (195).

All statistical analyses were conducted using SPSS version 22.0 and $p < 0.05$ was considered statistical significance.

CHAPTER IV

RESULTS

Data collection for this study began in November 2018 and continued through October 2019. A total of 240 participants with cLBP were invited to join the study in which 20 participants were excluded (7 patients refused to participate and 13 patients were unable to read Thai or had vision problems). Therefore, 220 participants completed the questionnaires at baseline while 183 and 168 participants completed the questionnaires at 4-week and 8-week follow-ups, respectively. All participants were reminded by the researcher via telephone or text message at 4- and 8-week follow-ups. Thirty-seven participants were lost to follow-up (24 at 4 weeks and 7 at 8 weeks of the study) and 21 participants withdrew from the study (13 at 4 weeks and 8 at 8 weeks of the study) (Figure 4.1).

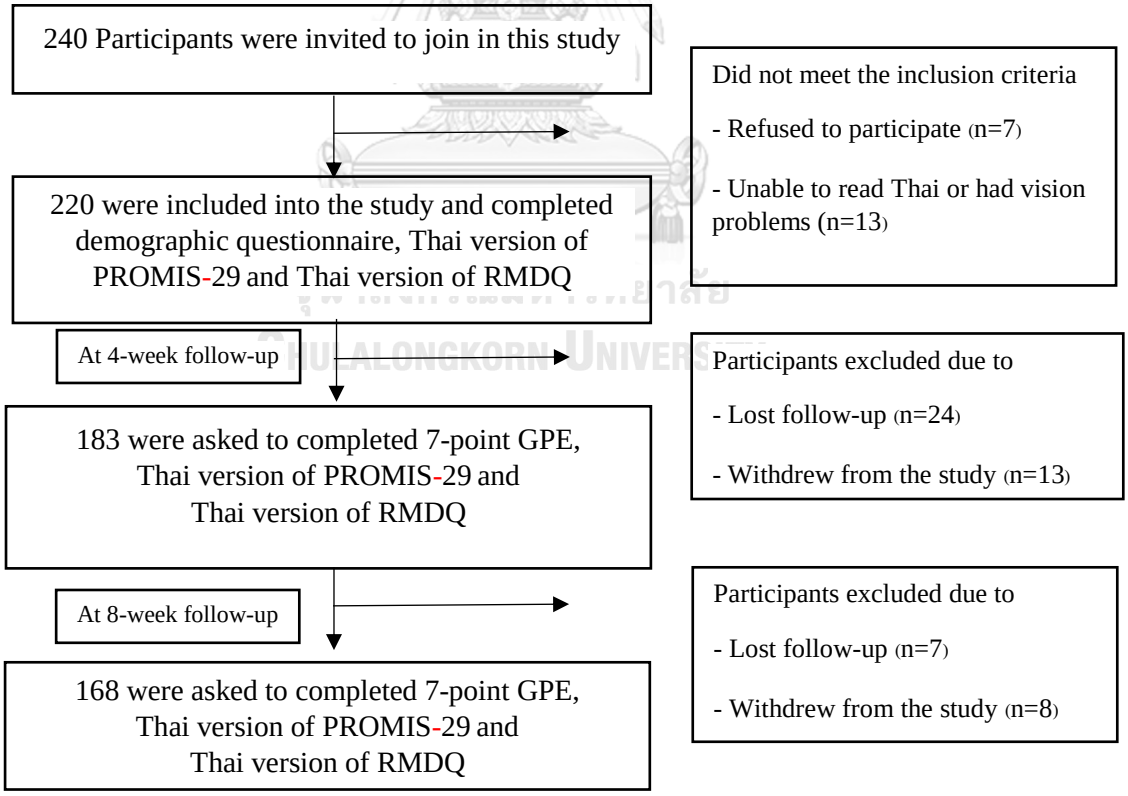

Figure 4.1 Flow diagram of the participations included in this study

4.1 Demographic Characteristics of Participants in this Study

The demographic characteristics of the participants at 4- and 8-week follow-ups are presented in Table 4.1. Because there were no restrictions in the type or amount of treatments that the participants received during the 8 weeks of the study, 90 participants did not receive any treatments. Most participants in this study received therapy treatments for cLBP which consist of physical therapy, self-exercise, massage, and acupuncture including drug therapy. As a result, the duration and repetitions of the treatment varied from person to person. Table 4.2 shows similar average scores on the PROMIS-29 and RMDQ at 3-time points.

Table 4.1 Demographic characteristics of the participants at 4 and 8-week follow-ups

Characteristics	**Participants who completed 4-week follow-up (n = 183)**		**Participants who completed 8-week follow-up (n = 168)**	
	n (%)	**Mean (SD)**	**n (%)**	**Mean (SD)**
Sex				
Women	122 (67)		113 (67)	
Men	61 (33)		55 (33)	
Employment status				
Working full time	138 (75)		129 (77)	
Unemployed	45 (25)		39 (23)	
Age (years)		47.7 (17.5)		46.8 (17.0)
Height (cm)		161.4 (7.8)		161.6 (8.0)
Weight (kg)		64.1 (12.2)		64.4 (12.4)
Body mass index (kg/m^2)		24.6 (4.2)		24.7 (4.3)
Duration of symptoms (months)		46.2 (61.1)		46.8 (62.7)

Table 4.2 Scores on patient-reported outcomes at each time

	Baseline (n=183)		**4-week follow-up (n=183)**		**8-week follow-up (n=168)**	
	Mean	**SD**	**Mean**	**SD**	**Mean**	**SD**
PROMIS-29						
Pain Intensity (0–10)	5.2	1.8	4.1	2.2	3.7	2.1
PROMIS-29 (T-scores)						
Physical Function	42.9	7.4	43.6	7.3	44.9	7.6
Anxiety	57.6	9.1	55.8	8.9	53.6	8.9
Depression	50.7	9.1	50.1	9.1	49.2	8.7
Fatigue	51.6	8.9	50.2	8.0	48.8	8.3
Sleep Disturbance	50.2	7.2	49.3	7.1	48.3	7.4
Ability to Participate in Social Roles and Activities	50.5	8.1	51.7	7.9	52.2	7.9
Pain Interference	58.0	6.2	56.2	6.5	54.5	7.1
RMDQ	8.3	5.5	6.9	5.0	6.0	5.4

n number of participants, SD standard deviation , PROMIS-29 Thai-PROMIS-29, RMDQ Thai version of the RMDQ

4.2 Between Baseline and 4-week Follow-up

4.2.1 Floor and ceiling effects

The percentages of scores at either the highest or lowest possible score for most domains of the PROMIS-29 were generally low (Table 4.3). A risk for a floor effect was evident for the Depression scale and a risk for a ceiling effect was found for the Physical Function and Ability to Participate in Social Roles and Activities.

Table 4.3 Percentages of scores responses that were the lowest and highest possible at the baseline and 4-weeks follow-up.

	n =183			
	Percent of responses at baseline		**Percent of responses at 4-week follow-up**	
	Lowest possible score	**Highest possible score**	**Lowest possible score**	**Highest possible score**
PROMIS-29				
Pain Intensity (0–10)	0	1	2	0
PROMIS-29 (T-scores)				
Physical Function	1	**16**	1	**16**
Anxiety	14	1	15	0
Depression	**40**	0	**43**	1
Fatigue	9	1	9	1
Sleep Disturbance	5	0	5	0
Ability to Participate in Social Roles and Activities	0	**17**	0	**18**
Pain Interference	6	1	10	0

Bolded values are those greater than 15%.

n number of participants, SD standard deviation, PROMIS-29 Thai-PROMIS-29

4.2.2 Responsiveness

Because of the small number of participants reporting that they had "Much deterioration" or "Very much deterioration" in their condition at 4-week follow-up, these responses were merged with the "A little deterioration" response into a single "Deterioration" group. As shown in Table 4.4, the mean change scores, ESs, and SRMs tend to increase from "Not changed" to "Very much improved." Large responsiveness were observed for the Pain Intensity, Physical Function, and Anxiety scales (absolute ES and SRM values ≥ .80) among those who reported that they were very much improved.

Table 4.4 Mean change scores, effect sizes, and standardized response means of the PROMIS-29 scale in patients with cLBP at 4-week follow-up (n=183)

	Very much improved, n		**Much improved, n**		**A little improved, n**		**Not changed, n**		**Deterioration, n**	
Mean change scores										
Pain Intensity (0-10)	-2.57	14	-1.09	43	-1.20	70	-0.67	48	0.88	8
Physical Function	5.44	20	1.35	42	0.08	54	-0.24	55	-3.01	12
Anxiety	-7.46	23	-2.93	46	-3.35	47	1.81	51	3.00	16
Depression	-1.84	32	-1.28	37	-1.54	34	0.31	68	2.78	12
Fatigue	-6.36	16	-1.46	39	-1.89	45	0.35	53	-0.67	30
Sleep Disturbance	-1.60	22	-2.36	37	-0.89	39	-0.18	71	-0.44	14
Ability to Participate in Social Roles and Activities	2.18	22	1.28	42	0.48	39	1.39	67	0.67	13
Pain Interference	-5.17	22	-2.20	45	-1.57	49	-0.84	47	-0.25	20
Effect sizes (Cohen's *d*)										
Pain Intensity (0-10)	-1.31	14	-0.61	43	-0.65	70	-0.38	48	0.67	8
Physical Function	0.81	20	0.19	42	0.02	54	-0.03	55	-0.58	12
Anxiety	-0.90	23	-0.38	46	-0.40	47	0.18	51	0.32	16
Depression	-0.28	32	-0.15	37	-0.19	34	0.03	68	0.29	12
Fatigue	-0.56	16	-0.16	39	-0.24	45	0.04	53	-0.08	30
Sleep Disturbance	-0.18	22	-0.32	37	-0.16	39	-0.03	71	-0.06	14
Ability to Participate in Social Roles and Activities	0.30	22	0.17	42	0.06	39	0.17	67	0.14	13
Pain Interference	-0.80	22	-0.43	45	-0.26	49	-0.12	47	-0.04	20
Standardized response means										
Pain Intensity (0-10)	-1.65	14	-0.56	43	-0.69	70	-0.35	48	0.42	8
Physical Function	0.91	20	0.17	42	0.02	54	-0.03	55	-0.92	12
Anxiety	-1.13	23	-0.49	46	-0.37	47	0.17	51	0.51	16
Depression	-0.24	32	-0.15	37	-0.17	34	0.04	68	0.35	12
Fatigue	-0.80	16	-0.17	39	-0.22	45	0.04	53	-0.08	30
Sleep Disturbance	-0.17	22	-0.40	37	-0.18	39	-0.03	71	-0.11	14
Ability to Participate in Social Roles and Activities	0.39	22	0.17	42	0.06	39	0.17	67	0.12	13
Pain Interference	-0.77	22	-0.36	45	-0.22	49	-0.11	47	-0.04	20

All of the correlations between change scores in each of the PROMIS-29 domains and the associated GPE rating at 4 week were in the expected direction although they were mostly weak in magnitude ($r < 0.30$) (see in Table 4.5).

Table 4.5 Spearman rank order correlation coefficients between the PROMIS-29 change scores and global perceived effect in patients with cLBP at 4-week follow-up (n=183)

PROMIS-29 domains	*r*	*p*-value
Pain Intensity (0-10)	0.25	< .001
Physical Function	-0.26	< .001
Anxiety	0.34	< .001
Depression	0.16	.031
Fatigue	0.13	.072
Sleep Disturbance	0.16	.029
Ability to Participate in Social Roles and Activities	-0.02	.801
Pain Interference	0.19	.011

4.2.3 Minimal clinically important difference

The MCID estimates and SEMs for the PROMIS-29 domains are presented in Table 4.6. As can be seen, the MCIDs of the anxiety scale (3.95) and ability to participate in social roles and activities scale (2.05) were less than theirs corresponding SEMs (5.88 and 4.58, respectively). Therefore, the SEMs of the anxiety scale and ability to participate in social roles and activities scale were chosen to be the estimates for the MCIDs to ensure that the final MCIDs exceeded the measurement error of the scales. The MCIDs for clinical decision-making were improvement in physical function score 3.60 points and satisfaction in social roles score 4.58 points. While the improvement scores were reduction of 1.50 points for pain intensity, 5.88 for anxiety, 5.25 for depression, 7.75 for fatigue, 3.90 for sleep disturbance, and 4.85 for pain interference.

Table 4.6 Minimal clinically important differences (MCIDs) and standard error of measurements (SEMs) for each domain (n = 183)

PROMIS-29	OCP (MCID)	SEM
Pain intensity	**1.50**	1.03
Physical Function	**3.60**	3.49
Anxiety	3.95	**5.88**
Depression	**5.25**	4.28
Fatigue	**7.75**	6.56
Sleep Interference	**3.90**	3.16
Ability to Participate in Social Roles and Activities	2.05	**4.58**
Pain interference	**4.85**	4.22

Note: The estimated MCID chosen is in bold face text.
OCP optimal cut-off point, PROMIS-29 Thai-PROMIS-29.

4.3 Between 4- and 8-week Follow-ups

4.3.1 Floor and ceiling effects

Similar to the results at baseline and 4-week follow-up, the risk for the ceiling effect was found for PROMIS-29 domains at 4- and 8-week follow-ups (Table 4.7). However, the domains that showed floor effect at 8-week follow-up differed from the baseline and 4-week follow-up. At 8-week follow-up, floor effect was found in 3 domains which are Anxiety, Depression, and Pain Interference domains.

Table 4.7 Percentages of scores responses that were the lowest and highest possible at 4- and 8-weeks follow-up.

	n = 168			
	Percent of responses at 4-week		Percent of responses at 8-week	
	Lowest possible score	**Highest possible score**	**Lowest possible score**	**Highest possible score**
PROMIS-29 Pain Intensity (0–10)	2	1	2	0
PROMIS-29 (T-scores)				
Physical Function	1	**18**	0	**24**
Anxiety	15	0	**22**	0
Depression	**42**	1	**46**	0
Fatigue	10	1	14	0
Sleep Disturbance	5	0	10	0

Table 4.7 Percentages of scores responses that were the lowest and highest possible at 4- and 8-weeks follow-up.

	n = 168			
	Percent of responses at 4-week		Percent of responses at 8-week	
	Lowest possible score	Highest possible score	Lowest possible score	Highest possible score
Ability to Participate in Social Roles and Activities	0	**18**	1	**22**
Pain Interference	11	0	**18**	0

Bolded values are those greater than 15%.
n number of participants, SD standard deviation, PROMIS-29 Thai-PROMIS-29

4.3.2 Responsiveness

Table 4.8 shows the results of responsiveness between 4- and 8-week follow-ups. Based on the distribution-based method, smaller magnitude of responsiveness was shown between 4- and 8-week follow-ups than between baseline and 4-week follow-up. Moderate responsiveness (absolute ES and SRM values ≥ .50) was found for the Pain Intensity and Pain Interference domains.

Table 4.8 Mean change scores, effect sizes, and standardized response means of the PROMIS-29 scale in persons with cLBP at 8-week follow-up comparison to the previous 4-week follow-up (n=168)

	Very much improved, n		Much improved, n		A little improved, n		Not changed, n		Deterioration, n	
Mean change scores										
Pain Intensity (0-10)	-1.41	29	-0.19	47	-0.55	47	0.08	37	0.50	8
Physical Function	2.94	27	1.92	50	0.75	38	0.20	43	-1.84	10
Anxiety	-2.17	34	-1.88	41	-2.11	47	-2.99	38	-1.44	8
Depression	-0.96	43	-3.33	31	-1.82	33	0.13	57	-0.01	8
Fatigue	-1.19	29	-2.89	39	-1.42	43	-1.02	42	2.92	15
Sleep Disturbance	-2.18	36	-1.32	40	-1.11	33	-0.03	43	0.09	16
Ability to Participate in Social Roles and Activities	0.42	37	1.95	37	0.23	30	-0.23	56	-3.60	8
Pain Interference	-3.96	36	-1.61	39	-1.02	43	-1.07	40	2.92	10
Effect sizes (Cohen's *d*)										
Pain Intensity (0-10)	-0.62	29	-0.11	47	-0.24	47	0.04	37	0.32	8
Physical Function	0.37	27	0.27	50	0.14	38	0.03	43	-0.27	10
Anxiety	-0.26	34	-0.23	41	-0.26	47	-0.32	38	-0.30	8
Depression	-0.14	43	-0.37	31	-0.25	33	0.02	57	0.00	8
Fatigue	-0.13	29	-0.33	39	-0.20	43	-0.12	42	0.42	15
Sleep Disturbance	-0.24	36	-0.22	40	-0.24	33	0.00	43	0.02	16

Table 4.8 Mean change scores, effect sizes, and standardized response means of the PROMIS-29 scale in persons with cLBP at 8-week follow-up comparison to the previous 4-week follow-up (n=168)

	Very much improved, n		**Much improved, n**		**A little improved, n**		**Not changed, n**		**Deterioration, n**	
Ability to Participate in Social Roles and Activities	0.06	37	0.24	37	0.03	30	-0.03	56	-0.42	8
Pain Interference	-0.54	36	-0.23	39	-0.24	43	-0.17	40	0.29	10
Standardized response means										
Pain Intensity (0-10)	-0.67	29	-0.10	47	-0.28	47	0.06	37	0.54	8
Physical Function	0.38	27	0.36	50	0.15	38	0.04	43	-0.38	10
Anxiety	-0.26	34	-0.31	41	-0.42	47	-0.33	38	-0.19	8
Depression	-0.13	43	-0.39	31	-0.40	33	0.02	57	0.00	8
Fatigue	-0.13	29	-0.44	39	-0.23	43	-0.10	42	0.28	15
Sleep Disturbance	-0.28	36	-0.28	40	-0.32	33	-0.01	43	0.01	16
Ability to Participate in Social Roles and Activities	0.08	37	0.27	37	0.06	30	-0.04	56	-0.66	8
Pain Interference	-0.52	36	-0.22	39	-0.23	43	-0.24	40	0.37	10

All of the correlations between change scores in each of the PROMIS-29 domains and its associated GPE rating at 8-week follow-up comparison to the previous 4 weeks were similar to those found at 4-week follow-up. Overall, they were weak in magnitude ($r < 0.30$) (see in Table 4.9).

Table 4.9 Spearman rank order correlation coefficients between the promis-29 change scores and global perceived effect in patients with cLBP at 8-week follow-up (n=168)

PROMIS-29 domains	***r***	***p*-value**
Pain Intensity (0-10)	0.25	.001
Physical Function	-0.19	.022
Anxiety	0.01	.875
Depression	0.09	.239
Fatigue	0.16	.043
Sleep Disturbance	0.15	.049
Ability to Participate in Social Roles and Activities	-0.13	.107
Pain Interference	0.18	.019

CHAPTER V

DISCUSSION

This prospective study assessed the responsiveness and estimated the MCIDs of the Thai version of the PROMIS-29 domains in individuals with cLBP. The level of responsiveness and the values of the MCIDs of the PROMIS-29 scales varied across domains in the sample.

Between baseline and 4-week follow-up

Floor and ceiling effect

The floor and ceiling effects of the Thai version of the PROMIS-29 were found. At baseline and 4-week follow-up, a risk for the floor effect was reported on depression scale (40% and 43%) and the risk for the ceiling effect on physical function (16%) and ability to participate in social roles and activities domains (17% and 18%). These results were similar to the previous study of the Thai version of the PROMIS-29 in persons with cLBP (165). They found a floor effect on depression scale (50%) and ceiling effect on physical function (16%) and satisfaction with social role domains (20%) (165). These results were also similar to those of the original English version of the PROMIS-29 in older adults with chronic musculoskeletal pain which reported a risk for floor effect on depression domain (42%) at baseline and 3 months (24).

Responsiveness

This is the first study to our knowledge that examined the responsiveness of all 7 PROMIS-29 domains in a homogeneous group of persons with cLBP. The domain scores evidencing the most responsivity were those measuring pain intensity, physical function, and anxiety. The responsivity of the PROMIS-29 Pain Intensity and Physical Function scores is perhaps not surprising, because both pain and physical function are the primary targets of the treatments the study participants were receiving. Also, this finding is consistent with the findings from previous studies in patients with spinal disorders (with absolute ES values ranged from 0.98 to 1.39) (149)

and in older adults with chronic musculoskeletal pain (absolute ES values ranged from 0.57 to 1.93) (24), who were receiving a variety of treatments including multiple orthopedic procedures for treatment of spinal fractures.

The reasons for the high level of responsivity of the PROMIS-29 Anxiety score are perhaps less obvious because standard physical therapy treatments do not primarily target anxiety. It is possible that this finding is related to the fact that anxiety is a common comorbidity of chronic pain (196, 197) as well as to theories that argue that the resolution of pain-related anxiety is a common mechanism underlying many pain treatments including physical therapy (198). Consistent with this idea, the second highest PROMIS-29 score in the current sample at baseline – which is scored as a T-statistic with a mean of 50 and SD of 10 in the normative population – was Anxiety. Thus, unlike the Depression score, which evidenced a marked floor effect, substantial improvement in the PROMIS-29 Anxiety score in our sample was possible. In any case, the findings suggest that Anxiety is a viable outcome domain that appears to be sensitive to standard physical therapy treatments for cLBP.

The other PROMIS-29 scales evidenced less responsivity to changes over time in the current sample. A similar lack of responsivity in these scales, as evidenced by a weak association between change and a GPE anchor has been reported by other researchers (24). The lack of responsiveness for these measures in the current context could be related to a number of factors, including floor and ceiling effects (24, 165, 194), the possibility that the 7-point GPE does not adequately capture true change in the domains, the fact that the physical therapy treatments do not target many of these domains directly, or some other unknown factors related to the population studied. Future researchers could address these issues by: (1) ensuring that the study sample has adequate variability in the domain being assessed at baseline (i.e., avoid floor and ceiling effects); (2) consider alternative anchors for determining responsivity; and (3) evaluate responsivity of the measures in the context of treatments that are known to have large effects on each outcome.

MCID estimates

Although different methods exist for estimating MCIDs, including both anchor-based and anchor-free approaches, experts recommend that anchor-based methods should be given the most weight as they takes the patients' perspective into account (195). At the same time, experts also recommend that MCIDs derived from a variety of methods should be considered when determining the best single MCID value (195).

The MCIDs identified in this sample were similar to and also within the ranges of MCIDs found for PROMIS measures in other samples (24, 177, 179, 181). The estimated value for the scale scores (i.e., all of the scales except for Pain Intensity, which is scored on a 0-10 scale) was near the .50 SD value for T-statistics (i.e., near 5.00). The primary exception to this is the excepted possibility that the most appropriate MCIDs for the Anxiety, Depression, and Fatigue may need to be somewhat larger (e.g., 6.00, 6.00 and 8.00 points, respectively). The MCID for Pain Intensity of 1.50 points was close to the proposed MCID of 2.0 points recommended for this scale in clinical practice for low back pain (199).

Nevertheless, the MCID in each study may be difference that depends on the statistical analysis and characteristics of the sample, such as baseline status, severity of disease, and direction of change, also study design and intervention (200). The comparison of MCID should be interpreted with caution also. Additional research in other populations is needed to confirm the appropriateness of these preliminary recommendations.

Between 4- and 8-week follow-ups

Floor and ceiling effects

At 8-week follow-up, the floor and ceiling effects were shown in the same domains as those found at baseline and at 4-week follow-up. However, 2 additional domains that measured anxiety and pain interference also demonstrated risk of floor effect. However, the floor effect of pain interference domain may depend on the patient population (201, 202). In addition, the variability of floor effect of pain interference scale may be partially due to differences in pain associated with varying

diagnoses, multifactorial in nature, differences in demographics, study design, and management (201).

Responsiveness

Pain intensity and pain interference scores were presented the responsivity of the measures in very much improved group. These domains possible play an important role in evaluating patient activity. In addition, they had no floor effect at 4-week so there was room for change. Noteworthy, the magnitudes of responsiveness were differed at time-period difference (203). A few changes at 8-week follow-up may reflect chronic nature of progression for cLBP.

Limitations of the study

This study has some limitations that should be considered when interpreting the results. First, this study was conducted in a sample of patients with cLBP who were seeking and receiving treatments. Thus, the findings may or may not generalize to individuals with LBP in the community or to individuals with other pain conditions. Second, this study did not include additional self-report measures (other than the GPE) or objective measures for assessing change across the domains assessed by the PROMIS-29 scales. Legacy self-report scales of the domains to be evaluated assessed at both time points and/or objective measures of function may provide more useful anchors for determining responsivity and for estimating MCIDs. Third, the majority of the study sample were recruited from the government hospitals that may have different characteristics from those in clinics or private hospitals. Finally, the majority of the participants in this study were regarded as having low disability on the RMDQ scale. Different responsiveness statistics would be found in participants with moderate or severe disability in which a number of quality of life domains could be affected. Further studies in additional samples of individuals with LBP receiving treatments with established effects on the domains assessed by the PROMIS-29 are needed to more definitively establish the most appropriate MCID for the PROMIS-29 scales.

CHAPTER VI

CONCLUSION

The Thai version of the PROMIS-29 scale scores assessing pain intensity, physical function, and anxiety evidenced the most responsivity in individuals with cLBP. The MCID for each domain was identified for clinical decision-making about clinically meaningful change of the patients.

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APPENDICES

APPENDIX A

Oswestry Disability Index (ODI)

Instructions: This questionnaire has been designed to give us information as to how your back or leg pain is affecting your ability to manage in everyday life. Please answer by checking ONE box in each section for the statement which best applies to you. We realize you may consider that two or more statements in any one section apply but please just shade out the spot that indicates the statement which most clearly describes

1. PAIN INTENSITY

□ I can tolerate the pain I have without having to use pain killers

□ The pain is bad but I manage without taking pain killers

□ Pain killers give complete relief from pain

□ Pain killers give moderate relief from pain

□ Pain killers give very little relief from pain

□ Pain killers have no effect on the pain and I do not use them

2. PERSONAL CARE (e.g. Washing, Dressing)

□ I can look after myself normally without causing extra pain

6. STANDING

□ I can stand as long as I want without extra pain

□ I can stand as long as I want but it gives me extra pain

□ Pain prevents me from standing for more than one hour

□ Pain prevents me from standing for more than 30 minutes

□ Pain prevents me from standing for more than 10 minutes

□ Pain prevents me from standing at all

7. SLEEPING

□ Pain does not prevent me from sleeping well

□ I can sleep well only by using

□ I can look after myself normally but it causes extra pain

□ It is painful to look after myself and I am slow and careful

□ I need some help but manage most of my personal care

□ I need help every day in most aspects of self-care

□ I don't get dressed, I was with difficulty and stay in bed

3. LIFTING

□ I can lift heavy weights without extra pain

□ I can lift heavy weights but it gives extra pain

□ Pain prevents me from lifting heavy weights off the floor, but I can manage if they are conveniently positioned, i.e. on a table

□ Pain prevents me from lifting heavy weights, but I can manage light to medium weights if they are conveniently positioned

□ I can lift very light weights

□ I cannot lift or carry anything at all

4. WALKING

□ Pain does not prevent me walking any distance

□ Pain prevents me walking more than

medication

□ Even when I take medication, I have less than 6 hrs sleep

□ Even when I take medication, I have less than 4 hrs sleep

□ Even when I take medication, I have less than 2 hrs sleep

□ Pain prevents me from sleeping at all

8. SOCIAL LIFE

□ My social life is normal and gives me no extra pain

□ My social life is normal but increases the degree of pain

□ Pain has no significant effect on my social life apart from limiting my more energetic interests, i.e. dancing, etc.

□ Pain has restricted my social life and I do not go out as often

□ Pain has restricted my social life to my home

□ I have no social life because of pain

9. TRAVELLING

□ I can travel anywhere without extra pain

□ I can travel anywhere but it gives me

one mile

□ Pain prevents me walking more than ½ mile

□ Pain prevents me walking more than ¼ mile

□ I can only walk using a stick or crutches

□ I am in bed most of the time and have to crawl to the toilet

5. SITTING

□ I can sit in any chair as long as I like

□ I can only sit in my favorite chair as long as I like

□ Pain prevents me from sitting more than one hour

□ Pain prevents me from sitting more than ½ hour

□ Pain prevents me from sitting more than 10 minutes

□ Pain prevents me from sitting at all

extra pain

□ Pain is bad, but I manage journeys over 2 hours

□ Pain restricts me to journeys of less than 1 hour

□ Pain restricts me to short necessary journeys under 30 minutes

□ Pain prevents me from traveling except to the doctor or hospital

10.EMPLOYMENT/ HOMEMAKING

□ My normal homemaking/ job activities do not cause pain.

□ My normal homemaking/ job activities increase my pain, but I can still perform all that is required of me.

□ I can perform most of my homemaking/ job duties, but pain prevents me from performing more physically stressful activities (e.g. lifting, vacuuming)

□ Pain prevents me from doing anything but light duties.

□ Pain prevents me from doing even light duties.

□ Pain prevents me from performing any job or homemaking chores.

APPENDIX B

Roland Morris Disability Questionnaire (RMDQ)

Instructions: As you read the list, think of yourself today. When you read a sentence that describes you today, put a tick against it. If the sentence does not describe you, then leave the space blank and go on to the next one. Remember, only tick the sentence if you are sure it describes you today

1. I stay at home most of the time because of my back.
2. I change position frequently to try and get my back comfortable.
3. I walk more slowly than usual because of my back.
4. Because of my back I am not doing any of the jobs that I usually do around the house.
5. Because of my back, I use a handrail to get upstairs.
6. Because of my back, I lie down to rest more often.
7. Because of my back, I have to hold on to something to get out of an easy chair.
8. Because of my back, I try to get other people to do things for me.
9. I get dressed more slowly then usual because of my back.
10. I only stand for short periods of time because of my back.
11. Because of my back, I try not to bend or kneel down.
12. I find it difficult to get out of a chair because of my back.
13. My back is painful almost all the time.
14. I find it difficult to turn over in bed because of my back.
15. My appetite is not very good because of my back pain.
16. I have trouble putting on my socks (or stockings) because of the pain in my back.
17. I only walk short distances because of my back.
18. I sleep less well because of my back.
19. Because of my back pain, I get dressed with help from someone else.
20. I sit down for most of the day because of my back.
21. I avoid heavy jobs around the house because of my back.
22. Because of my back pain, I am more irritable and bad tempered with people than usual.
23. Because of my back, I go upstairs more slowly than usual.
24. I stay in bed most of the time because of my back.

APPENDIX C

Short-Form Health Survey 36 (SF-36)

Instructions: Choose one option for each questionnaire item.

1. In general, would you say your health is:

O 1 - Excellent

O 2 - Very good

O 3 - Good

O 4 - Fair

O 5 – Poor

2. **Compared to one year ago**, how would you rate your health in general **now**?

O 1 - Much better now than one year ago

O 2 - Somewhat better now than one year ago

O 3 - About the same

O 4 - Somewhat worse now than one year ago

O 5 - Much worse now than one year ago

The following items are about activities you might do during a typical day. Does **your health now limit you** in these activities? If so, how much?

	Yes, limited a lot	Yes, limited a little	No, not limited at all
3. **Vigorous activities,** such as running, lifting heavy objects, participating in strenuous sport	O 1	O 2	O 3
4. **Moderate activities**, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	O 1	O 2	O 3
5. Lifting or carrying groceries	O 1	O 2	O 3

6. Climbing **several** flights of stairs	O 1	O 2	O 3
7. Climbing **one** flight of stairs	O 1	O 2	O 3
8. Bending, kneeling, or stooping	O 1	O 2	O 3
9. Walking **more than a mile**	O 1	O 2	O 3
10. Walking **several blocks**	O 1	O 2	O 3
11. Walking **one block**	O 1	O 2	O 3
12. Bathing or dressing yourself	O 1	O 2	O 3

During the **past 4 weeks**, have you had any of the following problems with your work or other regular daily activities **as a result of your physical health?**

	Yes	No
13. Cut down the **amount of time** you spent on work or other activities	O 1	O 2
14. **Accomplished less** than you would like	O 1	O 2
15. Were limited in the **kind** of work or other activities	O 1	O 2
16. Had **difficulty** performing the work or other activities (for example, it took extra effort)	O 1	O 2

During the **past 4 weeks**, have you had any of the following problems with your work or other regular daily activities **as a result of any emotional problems** (such as feeling depressed or anxious)?

	Yes	No
17. Cut down the **amount of time** you spent on work or other activities	O 1	O 2
18. **Accomplished less** than you would like	O 1	O 2
19. Didn't do work or other activities as **carefully** as usual	O 1	O 2

20. During the **past 4 weeks**, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?

O 1 - Not at all
O 2 - Slightly
O 3 - Moderately
O 4 - Quite a bit
O 5 – Extremely

21. How much **bodily** pain have you had during the **past 4 weeks**?
O 1 - None
O 2 - Very mild
O 3 - Mild
O 4 - Moderate
O 5 - Severe
O 6 - Very severe

22. During the **past 4 weeks**, how much did **pain** interfere with your normal work (Including both work outside the home and housework)?

O 1 - Not at all

O 2 - A little bit

O 3 - Moderately

O 4 - Quite a bit

O 5 – Extremely

These questions are about how you feel and how things have been with you **during the**

past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling.

How much of the time during the **past 4 weeks...**

	All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
23. Did you feel full of pep?	O 1	O 2	O 3	O 4	O 5	O 6
24. Have you been a very nervous person?	O 1	O 2	O 3	O 4	O 5	O 6
25. Have you felt so down in the dumps that nothing could cheer you up?	O 1	O 2	O 3	O 4	O 5	O 6
26. Have you felt calm and peaceful?	O 1	O 2	O 3	O 4	O 5	O 6
27. Did you have a lot of energy?	O 1	O 2	O 3	O 4	O 5	O 6
28. Have you felt downhearted and blue?	O 1	O 2	O 3	O 4	O 5	O 6
29. Did you feel worn out?	O 1	O 2	O 3	O 4	O 5	O 6
30. Have you been a happy person?	O 1	O 2	O 3	O 4	O 5	O 6
31. Did you feel tired?	O 1	O 2	O 3	O 4	O 5	O 6

32. During the **past 4 weeks**, how much of the time has **your physical health or emotional problems** interfered with your social activities (like visiting with friends, relatives, etc.)?

O 1 - All of the time

O 2 - Most of the time

O 3 - Some of the time

O 4 - A little of the time

O 5 - None of the time

How TRUE or FALSE is **each** of the following statements for you.

	Definitely true	Mostly true	Don't know	Mostly false	Definitely false
33. I seem to get sick a little easier than other people	O 1	O 2	O 3	O 4	O 5
34. I am as healthy as anybody I know	O 1	O 2	O 3	O 4	O 5
35. I expect my health to get worse	O 1	O 2	O 3	O 4	O 5
36. My health is excellent	O 1	O 2	O 3	O 4	O 5

APPENDIX D

Patient-Reported Outcomes Measurement Information System-29 (PROMIS-29) Profile v 2.0

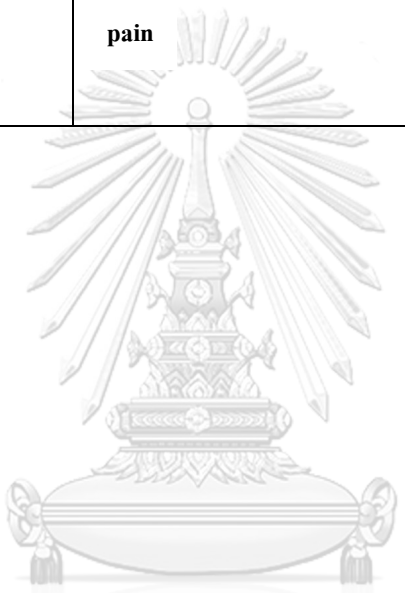
Instructions: Please respond to each question or statement by marking one box per row.

Physical Function	**Without any difficulty**	**With a little difficulty**	**With some difficulty**	**With much difficulty**	**Unable to do**
1. Are you able to do chores such as vacuuming or yard work?.....	☐	☐	☐	☐	☐
2. Are you able to go up and down stairs at a normal pace?.....	☐	☐	☐	☐	☐
3. Are you able to go for a walk of at least 15 minutes?.....	☐	☐	☐	☐	☐
4. Are you able to run errands and shop?.....	☐	☐	☐	☐	☐
Anxiety **In the past 7 days**	**Never**	**Rarely**	**Some times**	**Often**	**Always**
5. I felt fearful.....	☐	☐	☐	☐	☐
6. I found it hard to focus on anything other than my anxiety	☐	☐	☐	☐	☐
7. My worries overwhelmed me.....	☐	☐	☐	☐	☐
8. I felt uneasy.....	☐	☐	☐	☐	☐

Depression **In the past 7 days**	**Never**	**Rarely**	**Some times**	**Often**	**Always**
9. I felt worthless.....	☐	☐	☐	☐	☐
10. I felt helpless.....	☐	☐	☐	☐	☐
11. 9 I felt depressed.....	☐	☐	☐	☐	☐
12. I felt hopeless.....	☐	☐	☐	☐	☐
Fatigue **During the past 7 days**	**Not at all**	**A little bit**	**Some what**	**Quite a bit**	**Very much**
13. I feel fatigued.....	☐	☐	☐	☐	☐
14. I have trouble starting things because I am tired.....	☐	☐	☐	☐	☐
15. How run-down did you feel on average?.....	☐	☐	☐	☐	☐
16. How fatigued were you on average?.....	☐	☐	☐	☐	☐
Sleep Disturbance **In the past 7 days**	**Very poor**	**Poor**	**Fair**	**Good**	**Very good**
17. My sleep quality was.....	☐	☐	☐	☐	☐

In the past 7 days	**Not at all**	**A little bit**	**Some what**	**Quite a bit**	**Very much**
18. My sleep was refreshing.....	☐	☐	☐	☐	☐
19. I had a problem with my sleep	☐	☐	☐	☐	☐
20. I had difficulty falling asleep	☐	☐	☐	☐	☐
Ability to Participate in Social Roles and Activities	**Never**	**Rarely**	**Some times**	**Usually**	**Always**
21. I have trouble doing all of my regular leisure activities with others.....	☐	☐	☐	☐	☐
22. I have trouble doing all of the family activities that I want to do	☐	☐	☐	☐	☐
23. I have trouble doing all of my usual work (include work at home)	☐	☐	☐	☐	☐
24. I have trouble doing all of the activities with friends that I want to do…….	☐	☐	☐	☐	☐
Pain Interference **In the past 7 days…**	**Not at all**	**A little bit**	**Some what**	**Quite a bit**	**Very much**
25. How much did pain interfere with your day to day activities?	☐	☐	☐	☐	☐
26. How much did pain interfere with work around the home?	☐	☐	☐	☐	☐
27. 1 How much did pain interfere with your ability to participate in social activities?.....	☐	☐	☐	☐	☐

28. How much did pain interfere with your household chores?	☐	☐	☐	☐	☐
<u>Pain Intensity</u> **In the past 7 days…**					
29. How would you rate your pain on average?.....	☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ 0 1 2 3 4 5 6 7 8 9 10 **No pain** **Worst imaginable pain**				



APPENDIX E

PROMIS-29 Thai version

แบบสอบถามข้อมูลการวัดผลลัพธ์โดยผู้ป่วย

คำชี้แจง: โปรดตอบคำถามหรือข้อความแต่ละข้อ โดยทำเครื่องหมายในช่องสี่เหลี่ยมของแต่ละแถวเพียงช่องเดียว

ความสามารถทางกายภาพ	**ไม่มีความยากลำบาก**	**มีความยากลำบากเล็กน้อย**	**มีความยากลำบากบ้าง**	**มีความยากลำบากมาก**	**ไม่สามารถทำได้**
1. ท่านสามารถทำงานบ้าน เช่น กวาดบ้านหรือทำงานบ้านบริเวณรอบตัวบ้าน ได้หรือไม่ …….	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
2. ท่านสามารถเดินขึ้นและลงบันไดด้วยความเร็วปกติได้หรือไม่ …….	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
3. ท่านสามารถที่จะเดินเล่นเป็นเวลาอย่างน้อย 15 นาทีได้หรือไม่ …….	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
4. ท่านสามารถไปทำธุระและซื้อของได้หรือไม่ …….	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
ความวิตกกังวล ในช่วง 7 วันที่ผ่านมา…	**ไม่เคย**	**แทบจะไม่เคย**	**บางครั้ง**	**บ่อยครั้ง**	**ตลอดเวลา**
5. ข้าพเจ้ารู้สึกกลัว	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

6. ข้าพเจ้ารู้สึกยากที่จะจดจ่ออยู่กับสิ่งอื่นนอกเหนือจากความวิตกกังวลของข้าพเจ้า …….	□ 1	□ 2	□ 3	□ 4	□ 5
7. ความวิตกกังวลครอบงำข้าพเจ้า …….	□ 1	□ 2	□ 3	□ 4	□ 5
8. ข้าพเจ้ารู้สึกไม่สบายใจ …….	□ 1	□ 2	□ 3	□ 4	□ 5
<u>ภาวะซึมเศร้า</u> ในช่วง 7 วันที่ผ่านมา…	**ไม่เคย**	**แทบจะไม่เคย**	**บางครั้ง**	**บ่อยครั้ง**	**ตลอดเวลา**
9. ข้าพเจ้ารู้สึกไร้ค่า	□ 1	□ 2	□ 3	□ 4	□ 5
10. ข้าพเจ้ารู้สึกว่าทำอะไรไม่ได้เลย ……	□ 1	□ 2	□ 3	□ 4	□ 5
11. ข้าพเจ้ารู้สึกซึมเศร้า	□ 1	□ 2	□ 3	□ 4	□ 5
12. ข้าพเจ้ารู้สึกสิ้นหวัง…….....	□ 1	□ 2	□ 3	□ 4	□ 5
<u>ความเหนื่อยล้า</u> ในช่วง 7 วันที่ผ่านมา…	**ไม่เลย**	**เล็กน้อย**	**ปานกลาง**	**ค่อนข้างมาก**	**มากที่สุด**
13. ข้าพเจ้ารู้สึกล้า …….	□ 1	□ 2	□ 3	□ 4	□ 5
14. ข้าพเจ้ามีปัญหาในการ<u>เริ่ม</u>ทำสิ่งต่างๆ เพราะข้าพเจ้ารู้สึกเหนื่อย …….	□ 1	□ 2	□ 3	□ 4	□ 5

15. โดยเฉลี่ยแล้ว ท่านรู้สึกอิดโรยมากเพียงใด …….	□ 1	□ 2	□ 3	□ 4	□ 5
16. โดยเฉลี่ยแล้ว ท่านรู้สึกล้ามากเพียงใด …….	□ 1	□ 2	□ 3	□ 4	□ 5
<u>การรบกวนการนอนหลับ</u> ในช่วง 7 วันที่ผ่านมา…	**แย่มาก**	**แย่**	**ปานกลาง**	**ดี**	**ดีมาก**
17. คุณภาพการนอนหลับของข้าพเจ้า …….	□ 5	□ 4	□ 3	□ 2	□ 1
ในช่วง 7 วันที่ผ่านมา…	**ไม่เลย**	**เล็กน้อย**	**ปานกลาง**	**ค่อนข้างมาก**	**มากอย่างยิ่ง**
18. การนอนหลับทำให้ข้าพเจ้าสดชื่น …….	□ 5	□ 4	□ 3	□ 2	□ 1
19. ข้าพเจ้ามีปัญหาการนอนหลับ …….	□ 1	□ 2	□ 3	□ 4	□ 5
20. ข้าพเจ้านอนหลับยาก …….	□ 1	□ 2	□ 3	□ 4	□ 5
<u>ความสามารถในการมีบทบาทและเข้าร่วมกิจกรรมทางสังคม</u>	**ไม่เคย**	**แทบจะไม่เคย**	**บางครั้ง**	**บ่อยครั้ง**	**ตลอดเวลา**
21. ข้าพเจ้ามีปัญหาในการทำกิจกรรมยามว่างตามปกติทุกกิจกรรมกับคนอื่นๆ …….	□ 5	□ 4	□ 3	□ 2	□ 1
22. ข้าพเจ้ามีปัญหาในการทำกิจกรรมกับครอบครัวทุกกิจกรรมที่ข้าพเจ้าต้องการทำ …….	□ 5	□ 4	□ 3	□ 2	□ 1

23. ข้าพเจ้ามีปัญหาในการทำงานตามปกติทุกงานของข้าพเจ้า (รวมทั้งการทำงานที่บ้าน) …….	□ 5	□ 4	□ 3	□ 2	□ 1
24. ข้าพเจ้ามีปัญหาในการทำกิจกรรมกับเพื่อนทุกกิจกรรมที่ข้าพเจ้าต้องการทำ …….	□ 5	□ 4	□ 3	□ 2	□ 1
<u>การรบกวนจากอาการปวด</u> ในช่วง 7 วันที่ผ่านมา…	**ไม่เลย**	**เล็กน้อย**	**ปานกลาง**	**ค่อนข้างมาก**	**มากอย่างยิ่ง**
25. อาการปวดรบกวนกิจวัตรประจำวันของท่านมากเพียงใด …….	□ 1	□ 2	□ 3	□ 4	□ 5
26. อาการปวดรบกวนการดูแลบ้านมากเพียงใด …….	□ 1	□ 2	□ 3	□ 4	□ 5
27. อาการปวดรบกวนความสามารถของท่าน ในการเข้าร่วมกิจกรรมทางสังคมมากเพียงใด …….	□ 1	□ 2	□ 3	□ 4	□ 5
28. อาการปวดรบกวนการทำงานบ้านของท่านมากเพียงใด …….	□ 1	□ 2	□ 3	□ 4	□ 5

ความรุนแรงของอาการปวด ในช่วง 7 วันที่ผ่านมา...	
โดยเฉลี่ยแล้วท่านประเมินอาการปวดของท่านในระดับใด	☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ 0 1 2 3 4 5 6 7 8 9 10 ไม่ปวด ปวดมากที่สุดเท่าที่จะจินตนาการได้

APPENDIX F

7-point global perceived effect scale Thai version

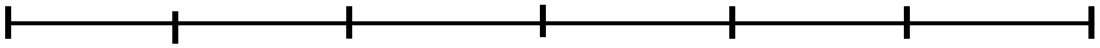
คำชี้แจง: โปรดวงกลมตัวเลขที่บ่งชี้ว่าโดยทั่วไป **ท่านรู้สึกการเปลี่ยนแปลงโดยรวมอย่างไร** เมื่อเทียบกับ**สี่สัปดาห์**ที่แล้ว (โดยระบุระดับที่เปลี่ยนแปลง โดย 1 หมายถึง ดีขึ้นอย่างมาก 4 หมายถึง ไม่เปลี่ยนแปลง และ 7 หมายถึง แย่ลงอย่างมาก)

หมายเหตุ

การตอบแบบประเมินของท่าน จะไม่มีผลกระทบต่อการรักษาหรือวิธีการรักษาที่ท่านได้รับอยู่ไม่ว่าทางใดก็ตาม

<u>คำชี้แจง</u>: โปรดตอบคำถามแต่ละข้อ โดยวงกลมตัวเลขแต่ละแถวเพียงช่องเดียว

1. ท่านคิดว่า **ความสามารถทางกายภาพ** (เช่น กวาดบ้าน ทำสวน เดินไปซื้อของ เป็นต้น) ของท่านเปลี่ยนแปลงไปอย่างไร เมื่อเทียบกับ 4 สัปดาห์ที่ผ่านมา



1	2	3	4	5	6	7
ดีขึ้นอย่างมาก	ดีขึ้นปานกลาง	ดีขึ้นเล็กน้อย	ไม่เปลี่ยนแปลง	แย่ลงเล็กน้อย	แย่ลงปานกลาง	แย่ลงอย่างมาก

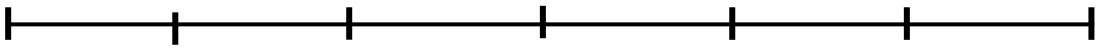
2. ท่านคิดว่า **ความวิตกกังวล** ของท่านเปลี่ยนแปลงไปอย่างไร เมื่อเทียบกับ 4 สัปดาห์ที่ผ่านมา

1	2	3	4	5	6	7
ดีขึ้นอย่างมาก	ดีขึ้นปานกลาง	ดีขึ้นเล็กน้อย	ไม่เปลี่ยนแปลง	แย่ลงเล็กน้อย	แย่ลงปานกลาง	แย่ลงอย่างมาก

3. ท่านคิดว่า **ภาวะซึมเศร้า** ของท่านเปลี่ยนแปลงไปอย่างไร เมื่อเทียบกับ 4 สัปดาห์ที่ผ่านมา

1	2	3	4	5	6	7
ดีขึ้นอย่างมาก	ดีขึ้นปานกลาง	ดีขึ้นเล็กน้อย	ไม่เปลี่ยนแปลง	แย่ลงเล็กน้อย	แย่ลงปานกลาง	แย่ลงอย่างมาก

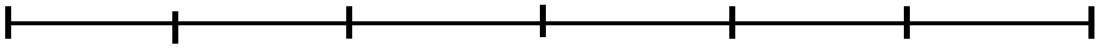
4. ท่านคิดว่า **ความเหนื่อยล้า** ของท่านเปลี่ยนแปลงไปอย่างไร เมื่อเทียบกับ 4 สัปดาห์ที่ผ่านมา



1	2	3	4	5	6	7
ดีขึ้นอย่างมาก	ดีขึ้นปานกลาง	ดีขึ้นเล็กน้อย	ไม่เปลี่ยนแปลง	แย่ลงเล็กน้อย	แย่ลงปานกลาง	แย่ลงอย่างมาก

<u>คำชี้แจง</u>: โปรดตอบคำถามแต่ละข้อ โดยวงกลมตัวเลขแต่ละแถวเพียงช่องเดียว

5. ท่านคิดว่า **การรบกวนการนอนหลับ** ของท่านเปลี่ยนแปลงไปอย่างไร เมื่อเทียบกับ 4 สัปดาห์ที่ผ่านมา

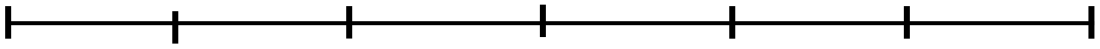


1	2	3	4	5	6	7
ดีขึ้นอย่างมาก	ดีขึ้นปานกลาง	ดีขึ้นเล็กน้อย	ไม่เปลี่ยนแปลง	แย่ลงเล็กน้อย	แย่ลงปานกลาง	แย่ลงอย่างมาก

6. ท่านคิดว่า **ความสามารถในการมีบทบาทและการเข้าร่วมกิจกรรมทางสังคม** ของท่านเปลี่ยนแปลงไปอย่างไร เมื่อเทียบกับ 4 สัปดาห์ที่ผ่านมา

1	2	3	4	5	6	7
ดีขึ้นอย่างมาก	ดีขึ้นปานกลาง	ดีขึ้นเล็กน้อย	ไม่เปลี่ยนแปลง	แย่ลงเล็กน้อย	แย่ลงปานกลาง	แย่ลงอย่างมาก

7. ท่านคิดว่า **ความรบกวนจากอาการปวด** ของท่านเปลี่ยนแปลงไปอย่างไร เมื่อเทียบกับ 4 สัปดาห์ที่ผ่านมา



1	2	3	4	5	6	7
ดีขึ้นอย่างมาก	ดีขึ้นปานกลาง	ดีขึ้นเล็กน้อย	ไม่เปลี่ยนแปลง	แย่ลงเล็กน้อย	แย่ลงปานกลาง	แย่ลงอย่างมาก

หมายเหตุ

การตอบแบบประเมินของท่าน จะไม่มีผลกระทบต่อการรักษาหรือวิธีการรักษาที่ท่านได้รับอยู่ไม่ว่าทางใดก็ตาม

APPENDIX G

Roland Morris Disability Questionnaire Thai version

แบบทดสอบภาวะทุพพลภาพโรแลนด์-มอริส สำหรับประเมินในผู้ป่วยปวดหลัง

คำชี้แจง: เมื่อปวดหลังท่านอาจพบว่าท่านปฏิบัติกิจวัตรประจำวันได้ค่อนข้างลำบาก ข้อความข้างล่างนี้ผู้ป่วยปวดหลังทั่วไปมักพูดเพื่อบอกอาการเมื่อเขาปวดหลัง ถ้าข้อความใดต่อไปนี้ตรงกับอาการที่ท่านมีอยู่ในวันนี้ กรุณาเขียนเครื่องหมาย √ ลงใน ☐ หน้าข้อความนั้น และถ้าข้อความใดไม่ตรงกับอาการของท่านในวันนี้ โปรดเว้นว่างไว้ และอ่านข้อความถัดไป

☐ 1. ฉันต้องพักอยู่ที่บ้านเกือบตลอดเวลาเพราะปวดหลัง

☐ 2. ฉันเปลี่ยนท่าทางบ่อย ๆ เพื่อช่วยให้หลังของฉันสบายขึ้น

☐ 3. ฉันเดินช้าลงกว่าปกติเพราะปวดหลัง

☐ 4. ฉันหยุดทำงานต่าง ๆ ที่ฉันมักทำในบ้านเพราะปวดหลัง

☐ 5. ฉันต้องยึดเกาะราวบันไดขณะเดินขึ้นบันไดเพราะปวดหลัง

☐ 6. อาการปวดหลังทำให้ฉันต้องลงนอนพักบ่อย ๆ

☐ 7. อาการปวดหลังทำให้ฉันต้องหาที่จับยึดเพื่อพยุงตัวลุกจากที่นั่ง

☐ 8. ฉันแต่งตัวช้ากว่าปกติเพราะปวดหลัง

☐ 9. ฉันต้องอาศัยผู้อื่นทำสิ่งต่าง ๆ ให้เพราะฉันปวดหลัง

☐ 10. ฉันยืนได้ไม่นานเพราะปวดหลัง

☐ 11. ฉันลุกจากเก้าอี้ลำบากเนื่องจากปวดหลัง

☐ 12. เนื่องจากปวดหลัง ฉันพยามยามไม่ก้มตัวไปข้างหน้า

☐ 13. ฉันรู้สึกปวดหลังมากเกือบตลอดเวลา

☐ 14. ฉันพลิกตัวบนเตียงลำบากเพราะปวดหลัง

☐ 15. ฉันรู้สึกไม่อยากกินอาหารเมื่อปวดหลัง

☐ 16. ฉันใส่ถุงเท้า รองเท้าลำบากขึ้นเพราะปวดหลัง

☐ 17. ฉันเดินได้ไม่ไกลเพราะปวดหลัง

☐ 18. ฉันนอนไม่ค่อยหลับเพราะปวดหลัง

☐ 19. เนื่องจากปวดหลัง ฉันต้องขอให้ผู้อื่นช่วยฉันแต่งตัว

☐ 20. ฉันนั่งเกือบตลอดทั้งวันเพราะปวดหลัง

☐ 21. ฉันพยายามไม่ทำงานบ้านที่หนัก ๆ เพราะปวดหลัง

☐ 22. เนื่องจากปวดหลัง ฉันหงุดหงิดและอารมณ์เสียกับผู้คนรอบข้างง่ายกว่าปกติ

☐ 23. ฉันเดินขึ้นบันไดช้ากว่าปกติเพราะปวดหลัง

☐ 24. ฉันนอนอยู่บนเตียงเกือบตลอดเวลาเพราะปวดหลัง

APPENDIX H

Information sheet

ข้อมูลสำหรับกลุ่มประชากรหรือผู้มีส่วนร่วมในการวิจัย

ชื่อโครงการวิจัย การปรับข้ามวัฒนธรรม ความน่าเชื่อถือ และความเที่ยงตามโครงสร้างของแบบประเมิน UW Pain Appraisal Scale, UW Pain-Related Self-Efficacy Scale, และ Patient-Reported Outcomes Measurement Information System-29 ฉบับภาษาไทย

ชื่อผู้วิจัย ดร. รสลัย กัลยาณพจน์พร **ตำแหน่ง** ผู้ช่วยศาสตราจารย์
ผู้ร่วมวิจัย 1. ศ. ดร. ประวิตร เจนวรรธนะกุล
2. Prof. Dr. Mark P. Jensen
3. Prof. Helena Correia
4. นิสิตหลักสูตรวิทยาศาสตรมหาบัณฑิต สาขาวิชากายภาพบำบัด
สถานที่ติดต่อผู้วิจัย (ที่ทำงาน) ภาควิชากายภาพบำบัด คณะสหเวชศาสตร์ จุฬาลงกรณ์มหาวิทยาลัย
โทรศัพท์ (ที่ทำงาน) 0 2218 3767 ต่อ 205 **โทรศัพท์มือถือ** 08 6990 3775 **E-mail :** rotsalai.k@chula.ac.th

เรียน ผู้มีส่วนร่วมในการวิจัยทุกท่าน

"กรุณาใช้เวลาในการอ่านข้อมูลต่อไปนี้อย่างละเอียดรอบคอบ
และสอบถามข้อมูลเพิ่มเติมหรือข้อมูลที่ไม่ชัดเจนได้ตลอดเวลา"

ท่านเป็นหนึ่งในอาสาสมัครที่ได้รับเชิญให้เข้าร่วมการวิจัยจำนวน 250 คน อายุ 18 ปีขึ้นไป

วัตถุประสงค์งานวิจัย ทดสอบความน่าเชื่อถือ และความเที่ยงตามโครงสร้างของแบบสอบถามผลกระทบของอาการปวด แบบสอบถามความสามารถในการควบคุมอาการปวด และแบบสอบถามข้อมูลการวัดผลลัพธ์โดยผู้ป่วย

สถานที่ดำเนินการวิจัย หน่วยปฏิบัติการบริการวิทยาศาสตร์สุขภาพ คณะสหเวชศาสตร์ จุฬาฯ และโรงพยาบาลในกรุงเทพมหานครและปริมณฑล

วิธีการดำเนินการวิจัย เมื่อท่านตกลงเข้าร่วมการศึกษา ท่านจะได้รับการปฏิบัติตามขั้นตอนดังนี้

1. ผู้วิจัยจะอธิบายให้ท่านทราบเกี่ยวกับขั้นตอนการวิจัยทั้งหมด และจะให้ท่านลงชื่อยินยอมเข้าร่วมการวิจัย
2. ท่านจะได้รับการคัดกรองโดยผู้วิจัยจะให้ท่านตอบแบบสอบถามเกี่ยวกับข้อมูลพื้นฐาน (เช่น อายุ น้ำหนัก ประวัติการเจ็บป่วย เป็นต้น) เพื่อตรวจสอบคุณสมบัติของท่านตามเกณฑ์การคัดเข้าและเกณฑ์การคัดออกข้างต้นให้ตรงตามข้อกำหนดของงานวิจัย ดังนี้

   เกณฑ์การคัดเข้า
   - มีสัญชาติไทย โดยสามารถเข้าใจและสื่อสารภาษาไทยได้
   - อายุมากกว่า 18 ปี
   - มีอาการปวดหลังส่วนล่างเรื้อรังอย่างน้อย 3 เดือน และในระยะเวลา 6 เดือนที่ผ่านมามีจำนวนวันที่มีอาการปวดรวมกันได้อย่างน้อย 3 เดือน

   เกณฑ์การคัดออก
   - มีประวัติพยาธิสภาพที่รุนแรงในบริเวณกระดูกสันหลังส่วนเอวที่ได้รับการวินิจฉัยโดยแพทย์ เช่น เนื้องอก มะเร็ง ไขสันหลังอักเสบ เป็นต้น
   - มีปัญหาสายตา หรือการเขียนที่ส่งผลกระทบต่อการตอบแบบสอบถาม
3. ผู้วิจัยจะขอให้ท่านที่ผ่านเกณฑ์การคัดเข้าและเกณฑ์การคัดออกเข้าร่วมการวิจัย 4 วัน คือ
   1) **วันที่ 1** ใช้เวลาประมาณ *50* นาที ท่านจะได้รับการร้องขอให้ตอบแบบสอบถาม จำนวน *7* ฉบับ คือ
      - แบบสอบถามข้อมูลพื้นฐาน (เช่น อายุ น้ำหนัก ประวัติการเจ็บป่วย เป็นต้น) จำนวน 5 ข้อ
      - แบบสอบถามผลกระทบของอาการปวด จำนวน 6 ข้อ
      - แบบสอบถามความสามารถในการควบคุมอาการปวด จำนวน 6 ข้อ

- แบบสอบถามข้อมูลการวัดผลลัพธ์โดยผู้ป่วย จำนวน 29 ข้อ
- แบบสอบถามพฤติกรรมที่เกี่ยวข้องกับอาการปวดหลัง จำนวน 16 ข้อ
- แบบสอบถาม SF-36 สำหรับประเมินสุขภาพในผู้ป่วยปวดหลัง จำนวน 36 ข้อ
- *แบบทดสอบภาวะทุพพลภาพโรแลนด์-มอริส สำหรับประเมินในผู้ป่วยปวดหลัง จำนวน 24 ข้อ*

2) **วันที่ 2 (ถัดจากวันที่ 1 เป็นเวลา 1 สัปดาห์)** ใช้เวลาประมาณ 25 นาที ท่านจะได้รับการร้องขอให้ตอบแบบสอบถาม จำนวน 4 ฉบับ คือ
   - ระดับการเปลี่ยนแปลงของอาการในภาพรวม จำนวน 1 ข้อ
   - แบบสอบถามผลกระทบของอาการปวด จำนวน 6 ข้อ
   - แบบสอบถามความสามารถในการควบคุมอาการปวด จำนวน 6 ข้อ
   - แบบสอบถามข้อมูลการวัดผลลัพธ์โดยผู้ป่วย จำนวน 29 ข้อ
3) **วันที่ 3 (ถัดจากวันที่ 1 เป็นเวลา 4 สัปดาห์)** ใช้เวลาประมาณ *35* นาที ท่านจะได้รับการร้องขอให้ตอบแบบสอบถาม จำนวน *5* ฉบับ คือ
   - ระดับการเปลี่ยนแปลงของอาการในภาพรวม จำนวน 1 ข้อ
   - แบบสอบถามผลกระทบของอาการปวด จำนวน 6 ข้อ
   - แบบสอบถามความสามารถในการควบคุมอาการปวด จำนวน 6 ข้อ
   - แบบสอบถามข้อมูลการวัดผลลัพธ์โดยผู้ป่วย จำนวน 29 ข้อ
   - *แบบทดสอบภาวะทุพพลภาพโรแลนด์-มอริส สำหรับประเมินในผู้ป่วยปวดหลัง จำนวน 24 ข้อ*
4) *วันที่ 4 (ถัดจากวันที่ 1 เป็นเวลา 8 สัปดาห์)* *ใช้เวลาประมาณ 35 นาที ท่านจะได้รับการร้องขอให้ตอบแบบสอบถาม จำนวน 5 ฉบับ คือ*
   - *ระดับการเปลี่ยนแปลงของอาการในภาพรวม จำนวน 1 ข้อ*
   - *แบบสอบถามผลกระทบของอาการปวด จำนวน 6 ข้อ*
   - *แบบสอบถามความสามารถในการควบคุมอาการปวด จำนวน 6 ข้อ*
   - *แบบสอบถามข้อมูลการวัดผลลัพธ์โดยผู้ป่วย จำนวน 29 ข้อ*
   - *แบบทดสอบภาวะทุพพลภาพโรแลนด์-มอริส สำหรับประเมินในผู้ป่วยปวดหลัง จำนวน 24 ข้อ*

4. ผู้วิจัยจะขอเบอร์โทรศัพท์และที่อยู่ของท่านเพื่อนัดหมายในการส่ง และรับแบบสอบถามกลับคืนสำหรับวันที่ 2, วันที่ 3 และวันที่ 4 กับท่าน และใช้สำหรับการติดต่อเพื่อการวิจัยนี้เท่านั้น เมื่อเสร็จสิ้นการวิจัย ข้อมูลที่เกี่ยวข้องกับท่านจะถูกลบทำลาย

ความเสี่ยงที่เกี่ยวข้องกับการศึกษาวิจัยนี้

ท่านจะไม่มีความเสี่ยงใดจากการเข้าร่วมการวิจัยนี้ การเข้าร่วมงานวิจัยมีความเสี่ยงน้อยมาก แต่อาจรบกวน เวลาส่วนตัวหรือเวลาในการทำกิจกรรมประจำวันของท่านบ้าง

ประโยชน์ที่ท่านจะได้รับ

ท่านจะได้รับการประเมินผลกระทบของอาการปวด ความสามารถในการควบคุมอาการปวด และสุขภาพในผู้ป่วยปวดหลัง ในการนี้ผู้วิจัยจะแจ้งผลการประเมินพร้อมทั้งคำแนะนำให้ผู้เข้าร่วมการวิจัยทราบในวันที่ 2 ของการวิจัย

ค่าชดเชยการเสียเวลา

ท่านจะได้รับค่าชดเชยการเสียเวลาในแต่ละวันที่เข้าร่วมการวิจัย คือ วันที่ 1 จำนวน 200 บาท วันที่ 2, วันที่ 3 และวันที่ 4 จำนวน 100 บาทต่อวัน

สิทธิของอาสาสมัคร

การเข้าร่วมในโครงการศึกษาวิจัยครั้งนี้เป็นไปด้วยความ**สมัครใจ** ท่าน**มีสิทธิถอนตัว**ออกจากการศึกษาวิจัยในครั้งนี้ได้ทุกเวลา โดยไม่จำเป็นต้องแจ้งเหตุผลของการถอดถอน และจะไม่มีภาระผูกพันต่อไปในอนาคต ทั้งนี้ จะไม่มีผลกระทบทั้งในทางใดๆ ต่อท่าน

การเปิดเผยข้อมูล

ข้อมูลส่วนตัว และข้อมูลอื่นๆ ที่อาจนำไปสู่การเปิดเผยตัวของท่านจะได้รับการปกปิด ยกเว้นว่าได้รับคำยินยอมจากท่าน ข้อมูลของท่านจะถูกเก็บไว้เป็นความลับเฉพาะคณะผู้วิจัย ผู้กำกับดูแลการวิจัย ผู้ตรวจสอบ และคณะกรรมการพิจารณาจริยธรรม และจะเปิดเผยเฉพาะในรูปที่เป็นสรุปผลการวิจัย ดังนั้น ข้อมูลที่เกี่ยวข้องกับท่านจะเก็บ**เป็นความลับ** หากมีการเสนอผลการวิจัยจะเสนอเป็นภาพรวม ข้อมูลใดที่สามารถระบุถึงตัวท่านได้จะไม่ปรากฏในรายงาน

หากท่านมีข้อสงสัยให้สอบถามเพิ่มเติมได้โดยสามารถติดต่อผู้วิจัยได้ตลอดเวลา และหากผู้วิจัยมีข้อมูลเพิ่มเติมที่เป็นประโยชน์หรือโทษเกี่ยวกับการวิจัย ผู้วิจัยจะแจ้งให้ท่านทราบอย่างรวดเร็ว

หากท่านไม่ได้รับการปฏิบัติตามข้อมูลดังกล่าวสามารถร้องเรียนได้ที่

คณะกรรมการพิจารณาจริยธรรมการวิจัยในคน กลุ่มสหสถาบัน ชุดที่ 1 จุฬาลงกรณ์มหาวิทยาลัย
254 อาคารจามจุรี 1 ชั้น 2 ถนนพญาไท เขตปทุมวัน กรุงเทพฯ 10330
โทรศัพท์/โทรสาร 0-2218-3202 E-mail: eccu@chula.ac.th

เอกสารที่โครงการวิจัย 117.1/61
วันที่รับรอง: 3 มิ.ย. 2562
วันหมดอายุ 2 มิ.ย. 2563

APPENDIX I

Consent form

หนังสือแสดงความยินยอมเข้าร่วมการวิจัย

ทำที่.....

วันที่.....เดือน.....พ.ศ. .....

เลขที่ ประชากรตัวอย่างหรือผู้มีส่วนร่วมในการวิจัย.....

ข้าพเจ้า ซึ่งได้ลงนามท้ายหนังสือนี้ ขอแสดงความยินยอมเข้าร่วมโครงการวิจัย

ชื่อโครงการวิจัย การปรับข้ามวัฒนธรรม ความน่าเชื่อถือ และความเที่ยงตามโครงสร้างของแบบประเมิน UW Pain Appraisal Scale, UW Pain-Related Self-Efficacy Scale, และ Patient-Reported Outcomes Measurement Information System-29 ฉบับภาษาไทย

ชื่อผู้วิจัย ผู้ช่วยศาสตราจารย์ ดร. รสลัย กัลยาณพจน์พร และคณะ

ที่อยู่ที่ติดต่อ ภาควิชากายภาพบำบัด คณะสหเวชศาสตร์ จุฬาฯ

โทรศัพท์ที่ทำงาน 0 2218 3767 ต่อ 205 โทรศัพท์มือถือ 08 6990 3775 E-mail: rotsalai.k@chula.ac.th

ข้าพเจ้า **ได้รับทราบ**รายละเอียดเกี่ยวกับที่มาและวัตถุประสงค์ในการทำวิจัย รายละเอียดขั้นตอนต่างๆ ที่จะต้องปฏิบัติหรือได้รับการปฏิบัติ ความเสี่ยง/อันตราย และประโยชน์ซึ่งจะเกิดขึ้นจากการวิจัยเรื่องนี้ โดยได้อ่านรายละเอียดในเอกสารชี้แจงผู้เข้าร่วมการวิจัยโดยตลอด **และได้รับคำอธิบาย**จากผู้วิจัย **จนเข้าใจเป็นอย่างดี**แล้ว

ข้าพเจ้า**จึงสมัครใจ**เข้าร่วมในโครงการวิจัยนี้ ตามที่ระบุไว้ในเอกสารชี้แจงผู้เข้าร่วมการวิจัย โดยข้าพเจ้ายินยอมตอบแบบสอบถามจำนวน *7* ฉบับในการเข้าร่วมการวิจัย 4 วัน ซึ่งห่างกัน 1 *หรือ 4* สัปดาห์ โดยวันที่ 1 ใช้เวลาประมาณ *50* นาที และวันถัดไปใช้เวลาประมาณ *35* นาที

ข้าพเจ้ามีสิทธิ**ถอนตัว**ออกจากการวิจัยเมื่อใดก็ได้ตามความประสงค์ **โดยไม่ต้องแจ้งเหตุผล** ซึ่งการถอนตัวออกจากการวิจัยนั้นจะไม่มีผลกระทบในทางใดๆ ต่อข้าพเจ้าทั้งสิ้น

ข้าพเจ้าได้รับคำรับรองว่า ผู้วิจัยจะปฏิบัติต่อข้าพเจ้าตามข้อมูลที่ระบุไว้ในเอกสารชี้แจงผู้เข้าร่วมการวิจัย และข้อมูลใดๆ ที่เกี่ยวข้องกับข้าพเจ้า **ผู้วิจัยจะเก็บรักษาเป็นความลับ** โดยจะนำเสนอข้อมูลการวิจัยเป็นภาพรวมเท่านั้น ไม่มีข้อมูลใดในการรายงานที่จะนำไปสู่การระบุตัวข้าพเจ้า หลังเสร็จสิ้นการวิจัย ผู้วิจัยจะทำลายข้อมูลใดๆ ที่สามารถระบุถึงตัวข้าพเจ้าได้ทั้งหมด

หากข้าพเจ้าไม่ได้รับการปฏิบัติตรงตามที่ได้ระบุไว้ในเอกสารชี้แจงผู้เข้าร่วมการวิจัย ข้าพเจ้าสามารถร้องเรียนได้ที่คณะกรรมการพิจารณาจริยธรรมการวิจัยในคน กลุ่มสหสถาบัน ชุดที่ 1 จุฬาลงกรณ์มหาวิทยาลัย 254 อาคารจามจุรี 1 ชั้น 2 ถนนพญาไท เขตปทุมวัน กรุงเทพฯ 10330 โทรศัพท์/โทรสาร 0-2218-3202 **E-mail: eccu@chula.ac.th**

ข้าพเจ้าได้ลงลายมือชื่อไว้เป็นสำคัญต่อหน้าพยาน ทั้งนี้ข้าพเจ้าได้รับสำเนาเอกสารชี้แจงผู้เข้าร่วมการวิจัย และสำเนาหนังสือแสดงความยินยอมไว้แล้ว

ลงชื่อ.....

(.....)

ผู้วิจัยหลัก

ลงชื่อ.....

(.....)

ผู้มีส่วนร่วมในการวิจัย

ลงชื่อ.....

(.....)

พยาน

เอกสารการพิจารณาจริยธรรมการวิจัยในคน กลุ่มสหสถาบัน ชุดที่ 1

เอกสารโครงการวิจัย 117.1/61

วันที่รับรอง : 3 มิ.ย. 2562

วันหมดอายุ 2 มิ.ย. 2563

APPENDIX J

Certificate of approval

AF 02-12

The Research Ethics Review Committee for Research Involving Human Research Participants, Health Sciences Group, Chulalongkorn University
Jamjuree 1 Building, 2nd Floor, Phyathai Rd., Patumwan district, Bangkok 10330, Thailand,
Tel/Fax: 0-2218-3202, 0-2218-3409 E-mail: eccu@chula.ac.th

COA No. 153/2019

Certificate of Approval

Study Title No. 117.1/61 (1) : CROSS-CULTURAL ADAPTATION, RELIABILITY, AND CONSTRUCT VALIDITY OF THE THAI VERSION OF THE UW PAIN APPRAISAL SCALE, UW PAIN-RELATED SELF-EFFICACY SCALE, AND PATIENT-REPORTED OUTCOMES MEASUREMENT INFORMATION SYSTEM-29

Principal Investigator : ROTSALAI KANLAYANAPHOTPORN, Ph.D.

Place of Proposed Study/Institution : Faculty of Allied Health Sciences, Chulalongkorn University

The Research Ethics Review Committee for Research Involving Human Research Participants, Health Sciences Group, Chulalongkorn University, Thailand, has approved constituted in accordance with Belmont Report 1979, Declaration of Helsinki 2013, Council for International Organizations of Medical Sciences (CIOM) 2016, Standards of Research Ethics Committee (SREC) 2013, and National Policy and guidelines for Human Research 2015.

Signature: Prida Tasanapradit
(Associate Prof. Prida Tasanapradit, M.D.)
Chairman

Signature: Nuntaree Chaichanawongsaroj
(Assistant Prof. Nuntaree Chaichanawongsaroj, Ph.D.)
Secretary

Date of Approval : 3 July 2019 Approval Expire date : 2 July 2020

The approval documents including;

1) Research proposal
2) Participant Information Sheet and Consent Form
3) Researcher
4) Questionnaire

117.1/61
- 3 JUL 2019
- 2 JUL 2020

The approved investigator must comply with the following conditions:

1. *The research/project activities must end on the approval expired date of the Research Ethics Review Committee for Research Involving Human Research Participants, Health Sciences Group, Chulalongkorn University (RECCU). In case the research/project is unable to complete within that date, the project extension can be applied one month prior to the RECCU approval expired date.*
2. *Strictly conduct the research/project activities as written in the proposal.*
3. *Using only the documents that bearing the RECCU's seal of approval with the subjects/volunteers (including subject information sheet, consent form, invitation letter for project/research participation (if available).*
4. *Report to the RECCU for any serious adverse events within 5 working days*
5. *Report to the RECCU for any change of the research/project activities prior to conduct the activities.*
6. *Final report (AF 02-14) and abstract is required for a one year (or less) research/project and report within 30 days after the completion of the research/project. For thesis, abstract is required and report within 30 days after the completion of the research/project.*
7. *Annual progress report is needed for a two- year (or more) research/project and submit the progress report before the expire date of certificate. After the completion of the research/project processes as No. 6.*

APPENDIX K

Certificate of approval

กรมการแพทย์
โรงพยาบาลเลิดสิน

เอกสารรับรองโครงการวิจัย

เลขที่หนังสือ ๑๑๖

คณะกรรมการจริยธรรมการวิจัยในมนุษย์ โรงพยาบาลเลิดสิน ได้พิจารณาโครงการนี้ เมื่อวันที่ ๒๙ เมษายน ๒๕๖๒ ตามหลักมาตราฐานสากล แล้วเห็นว่า โครงการนี้ควรได้รับการรับรองจริยธรรมการวิจัยในมนุษย์

ชื่อโครงการ (สุดท้าย) การตอบสนองของแบบประเมิน Patient Reported Outcomes Measurement Information System-29 (PMOMIS-29) ฉบับภาษาไทย ในผู้ป่วยที่มีอาการปวดหลังส่วนล่างเรื้อรัง

หัวหน้าโครงการ : นางสาวกรกนก พูนก

รหัสโครงการ (สุดท้าย) : .....๖๒๐๙๒.....Version.....๒.....Date.....๒๙ เมษายน ๒๕๖๒.....

เอกสารแบบยื่นขอรับการพิจารณาจริยธรรมการวิจัย (สุดท้าย) : Version ๒ Date...๒๙ เมษายน ๒๕๖๒....

โครงการวิจัย (สุดท้าย) : Version.....๒.....Date.....๒๙ เมษายน ๒๕๖๒.....

เอกสารแนะนำอาสาสมัคร (สุดท้าย) : Version.....๒.....Date.....๒๙ เมษายน ๒๕๖๒.....

เอกสารยินยอมเข้าร่วมโครงการ (สุดท้าย) : Version.....๒.....Date.....๒๙ เมษายน ๒๕๖๒.....

เอกสารแบบเก็บข้อมูล (สุดท้าย) : Version.....๒.....Date.....๒๙ เมษายน ๒๕๖๒.....

เอกสารประชาสัมพันธ์ (สุดท้าย) : Version.....-.....Date.....-.....

คณะกรรมการจริยธรรมนี้ได้จัดตั้งและดำเนินการตามหลัก GCP ระเบียบและกฎหมายที่เกี่ยวข้อง

เอกสารฉบับนี้มีผลการรับรองตั้งแต่วันที่ ๒๙ เมษายน ๒๕๖๒ จนถึงวันที่ ๒๙ เมษายน ๒๕๖๓

ลงนาม
ประธานกรรมการจริยธรรมการวิจัยในคน
(นายเอกฤทธิ์ คุณศรีรักษ์สกุล)

ลงนาม
ผู้อำนวยการโรงพยาบาลเลิดสิน
(นายสมพงษ์ ตันจริยกรณ์)

APPENDIX L

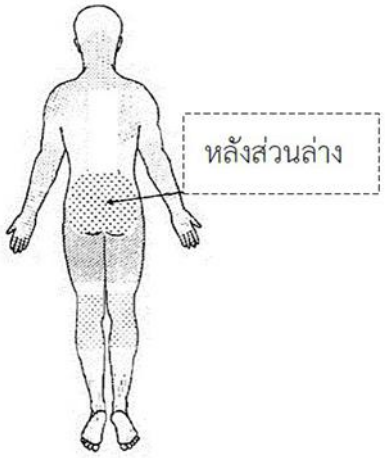
Screening questionnaire

แบบคัดกรองอาสาสมัคร

1. อายุ _____ ปี

2. อาการปวดหลังส่วนล่างของท่านอยู่ในบริเวณดังรูปขวามือ ใช่หรือไม่

( ) ใช่ ( ) ไม่ใช่



3. อาการปวดหลังส่วนล่างเป็นปัญหาต่อเนื่องสำหรับท่านมาเป็นระยะเวลานานเท่าใด

_____ ปี _____ เดือน _____ วัน

4. อาการปวดหลังส่วนล่างเป็นปัญหาต่อเนื่องสำหรับท่านบ่อยเพียงใดในระยะเวลา 6 เดือนที่ผ่านมา

( ) มีอาการทุกวัน หรือ เกือบทุกวันของระยะเวลา 6 เดือนที่ผ่านมา

( ) มีอาการเกิดขึ้นมากกว่าร้อยละ 50 ของระยะเวลา 6 เดือนที่ผ่านมา

( ) มีอาการเกิดขึ้นน้อยกว่าร้อยละ 50 ของระยะเวลา 6 เดือนที่ผ่านมา

APPENDIX M

Demographic questionnaire I

แบบบันทึกข้อมูลผู้เข้าร่วมงานวิจัย

เลขที่ประชากรตัวอย่าง _____

วันที่ตอบแบบสอบถาม : _____

1. เพศ ☐ ชาย ☐ หญิง

2. ส่วนสูง : _____ เซนติเมตร น้ำหนัก : _____ กิโลกรัม

3. ท่านเคยได้รับการตรวจวินิจฉัยอาการปวดหลังส่วนล่างโดยแพทย์หรือไม่

☐ เคย โปรดระบุการวินิจฉัยโรค :

_____

☐ ไม่เคย

4. สถานภาพการทำงาน

☐ ทำงาน โปรดระบุอาชีพ : _____

☐ ว่างงาน

5. ท่านได้รับการค่าชดเชยการรักษาอาการปวดหลังส่วนล่างหรือไม่

☐ ได้รับ

☐ ไม่ได้รับ

APPENDIX N

Demographic questionnaire II

เลขที่ประชากรตัวอย่าง _____

วันที่ตอบแบบสอบถาม : _____

1. ผู้เข้าร่วมงานวิจัย ยังคงเข้ารับการรักษาทางกายภาพบำบัดอยู่หรือไม่

❑ ใช่ ❑ ไม่ใช่

2. ในช่วงระยะเวลา 1 เดือนที่ผ่านมา สำหรับอาการปวดหลังเรื้อรังของท่าน นอกจากได้รับการรักษาทางกายภาพบำบัดแล้ว ท่านได้รับการรักษาอื่นๆร่วมด้วยหรือไม่

_____

_____

_____

3. หาก ไม่ได้ เข้ารับการรักษาทางกายภาพบำบัดแล้ว เนื่องจากเหตุผลใด

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VITA

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