ศึกษาเปรียบเทียบประสิทธิผลระหว่างการทำกายภาพบำบัดร่วมกับการใช้ยาต้านการอักเสบกับการใช้ยาต้านการอักเสบอย่างเดียวในผู้ป่วยเอ็นข้อไหล่อักเสบ

นางกิ่งแก้ว ปาจรีย์

วิทยานิพนธ์นี้เป็นส่วนหนึ่งของการศึกษาตามหลักสูตรปริญญาวิทยาศาสตรมหาบัณฑิต
สาขาวิชาการพัฒนาสุขภาพ หลักสูตรการพัฒนาสุขภาพ
คณะแพทยศาสตร์ จุฬาลงกรณ์มหาวิทยาลัย
ปีการศึกษา 2544

ISBN 974-03-0724-8

EFFECTIVENESS OF PHYSICAL THERAPY IN COMBINATION WITH NSAIDs AND NSAIDs ALONE IN PATIENTS WITH ADHESIVE CAPSULITIS

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A Thesis Submitted in Partial Fulfillment of the Requirements

for the Degree of Master of Science in Health Development

Health Development Programme

Faculty of Medicine

Chulalongkorn University

Academic Year 2001

ISBN 974-03-0724-8

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กิ่งแก้ว ปาจรีย์: ศึกษาเปรียบเทียบประสิทธิผลระหว่างการทำกายภาพบำบัดร่วมกับการใช้ยาต้านการอักเสบกับการใช้ยาต้านการอักเสบอย่างเดียวในผู้ป่วยเอ็นข้อไหล่อักเสบ
(EFFECTIVENESS OF PHYSICAL THERAPY IN COMBINATION WITH NSAIDs AND NSAIDs ALONE IN PATIENTS WITH ADHESIVE CAPSULITIS)
อาจารย์ที่ปรึกษา: ร.ศ.นพ.สมรัตน์ จารุลักษณานันท์, พ.บ., วว. (วิสัญญีวิทยา), M.Sc.,
อาจารย์ที่ปรึกษาร่วม: ร.ศ.นพ.โชคชัย เมธีไตรรัตน์, พ.บ., วว. (โสต นาสิก ลาริงซ์วิทยา) M.Sc.
78 หน้า, ISBN 974-03-0724-8

รายงานนี้เป็นการศึกษาเปรียบเทียบประสิทธิผล ระหว่างการทำกายภาพบำบัดร่วมกับการใช้ยาต้านการอักเสบ กับการใช้ยาต้านการอักเสบอย่างเดียวในผู้ป่วยเอ็นข้อไหล่อักเสบ โดยดูการเปลี่ยนแปลงของคะแนนจากแบบสอบถาม The Shoulder Pain and Disability Index (ภาคภาษาไทย) รูปแบบการวิจัยเป็นการทดลองแบบสุ่มและใช้กลุ่มเปรียบเทียบ เริ่มด้วยการคัดเลือกผู้ป่วยที่มีปัญหาข้อไหล่อักเสบตามเกณฑ์ที่กำหนดแล้วสุ่มให้รับการรักษาแบบใดแบบหนึ่งเป็นเวลา 3 สัปดาห์ ให้กลุ่มควบคุมรับประทานยา Ibuprofen ขนาด 400 มก. วันละ 3 เวลาหลังอาหาร กลุ่มที่ศึกษาได้รับยา ibuprofen ขนาดเท่ากับกลุ่มควบคุม ร่วมกับการทำกายภาพบำบัดที่โรงพยาบาล สัปดาห์ละ 3 ครั้ง แต่ละครั้งเริ่มด้วยการให้ short wave diathermy นาน 20 นาที ตามด้วยการดัดข้อไหล่มากน้อยตามแนวทางมาตรฐาน ในวันที่ไม่ได้มารับการรักษาที่โรงพยาบาล ผู้ป่วยต้องบริหารข้อไหล่ด้วยตนเองตามที่ได้รับคำแนะนำ ผู้ป่วยทั้งสองกลุ่มได้คำขอร้องมิให้รับการรักษาด้วยวิธีอื่นนอกจาก acetaminophen และหยุดยาดังกล่าว 48 ชั่วโมงก่อนพบแพทย์ มีการประเมินผลเมื่อสิ้นสุดสัปดาห์ที่สาม ตัวแปรที่ใช้วัดประกอบด้วย การเปลี่ยนแปลงคะแนนจากการตอบแบบสอบถาม The Shoulder Pain and Disability Index (ภาคภาษาไทย), พิสัยการเคลื่อนไหวของข้อ, ภาวะแทรกซ้อน, จำนวนยาแก้ปวดที่รับประทาน, ผลการรักษาโดยรวม และความพึงพอใจในการรักษา เมื่อนำตัวแปรของผู้ป่วยทั้งสองกลุ่มมาเปรียบเทียบด้วยวิธี intention to treat analysis จำนวน จำนวนผู้ป่วยที่นำมาวิเคราะห์รวมทั้งสิ้น 96 ราย แบ่งเป็นกลุ่มควบคุม 45 รายและกลุ่มศึกษา 47 ราย ผลการวิเคราะห์พบว่ากลุ่มควบคุมมีคะแนนเฉลี่ยดีขึ้น 10.4 คะแนน (ส่วนเบี่ยงเบนมาตรฐาน = 13.6 คะแนน) กลุ่มศึกษามีคะแนนเฉลี่ยดีขึ้น 19.4 คะแนน (ส่วนเบี่ยงเบนมาตรฐาน = 15.8 คะแนน) กลุ่มศึกษามีคะแนนเฉลี่ยดีขึ้นมากกว่ากลุ่มควบคุม 9.0 คะแนน (ร้อยละ 95 ของความเชื่อมั่น: 2.9 -15.1 คะแนน, ค่าพี = 0.004) สำหรับตัวแปรอื่น ๆ พบว่ากลุ่มศึกษามีการเปลี่ยนแปลงในทางดีขึ้นมากกว่ากลุ่มควบคุมอย่างมีนัยสำคัญทางสถิติเกือบทุกตัวแปร ยกเว้นความสามารถในการกางไหล่และจำนวนยาแก้ปวดที่ใช้ ภาวะแทรกซ้อนจากการทำรักษานั้นมีเพียงเล็กน้อยและไม่รุนแรง

ข้อมูลที่ได้จากการศึกษานี้แสดงถึงประสิทธิผลของการทำกายภาพบำบัดในผู้ป่วยเอ็นข้อไหล่อักเสบว่าสามารถช่วยให้ผู้ป่วยมีอาการปวดไหล่ลดลง มีพิสัยของการเคลื่อนไหวข้อไหล่ดีขึ้น ปัญหาในการทำกิจวัตรประจำวันลดลง มีความก้าวหน้าในการรักษาโดยรวม และมีความพึงพอใจต่อผลการรักษามากกว่ากลุ่มควบคุมอย่างมีนัยสำคัญทางสถิติ ผลการรักษาดังกล่าวน่าจะช่วยสนับสนุนให้แพทย์ตัดสินเลือกใช้วิธีการรักษาทางกาย-ภาพบำบัดมาร่วมในการรักษาผู้ป่วยเอ็นข้อไหล่อักเสบต่อไป

ภาควิชา การพัฒนาสุขภาพ ลายมือชื่อนิสิต .....
สาขาวิชา การพัฒนาสุขภาพ ลายมือชื่ออาจารย์ที่ปรึกษา .....
ปีการศึกษา 2544 ลายมือชื่ออาจารย์ที่ปรึกษาร่วม .....

437 54213 30, MAJOR: RESEARCH DEVELOPMENT
KEY WORDS: PHYSICAL THERAPY/ NON-STEROIDAL ANTI-INFLAMMATORY AGENTS/ IBUPROFEN/ ADHESIVE CAPSULITIS/ RANDOMISED CONTROLLED TRIAL.

KINGKAEW PAJAREYA: EFFECTIVENESS OF PHYSICAL THERAPY IN COMBINATION WITH NSAIDs AND NSAIDs ALONE IN PATIENTS WITH ADHESIVE CAPSULITIS.
THESIS ADVISOR: ASSOCIATED PROFESSOR SOMRAT CHARULUXANANAN, M.D., and M.SC.
THESIS CO-ADVISOR: ASSOCIATED PROFESSOR CHOCKCHAI METHEETRAIRUT, M.D., and M.SC. 78 PAGES. ISBN 974-03-0724-8

This study was aimed to compare the effectiveness of the treatment regimen between combined technique of PT programme plus ibuprofen and ibuprofen alone for the treatment of adhesive capsulitis in terms of pain reduction and functional recovery measured by the change in The Shoulder Pain and Disability Index (the SPADI). The study design was randomised controlled trial. Ninety-six patients were diagnosed as adhesive capsulitis in outpatient clinic, Department of Rehabilitation Medicine and Department of Orthopaedic Surgery, Siriraj Hospital who met the eligibility criteria were randomly allocated to have a 3-week treatment protocol. The control group (n=48) had ibuprofen 400 mg three times daily. The study group (n=48) had ibuprofen 400 mg three times daily plus PT programme. PT programme was carried out 3 times a week. Each session comprised of short wave diathermy (20 minutes), mobilisation and passive glenohumeral joint stretching exercises to patients' tolerance. (On the day the patients did not receive hospital-based PT programme, they were encouraged to perform self-exercise.) All of the subjects were asked to receive no other adjuvant therapy during the study except oral acetaminophen. They were asked to stop acetaminophen 48 hours before next follow-up. At the end of the third week, The outcomes of each group were compared by in intention to treat analysis. The number of subjects included to the analysis was 45 from the control group and 47 from the study group. It was found that means (SD) of the improvement in the SPADI score of the study group and the control group were 19.4 (15.8) and 10.4 (13.6) respectively. The study group had mean improvement in the SPADI score 9 points more than control (95% CI: 2.9-15.1 points, p = 0.004). The differences in improvement of secondary outcome were in the same direction except the improvement in abduction and the amount of analgesic use, which the differences between the two groups were not significant different. The adverse reactions were generally mild and the compliance of treatment protocol was acceptable. There were few programme deviations.

The results of this study gave us evidence to support the use of adjunctive physical therapy for patients with adhesive capsulitis.

Department	HEALTH DEVELOPMENT	Student's signature	
Field of study	HEALTH DEVELOPMENT	Advisor's signature	
Academic year	2001	Co-advisor signature	

ACKNOWLEDGEMENT

This work cannot be finished without help from many people. I would like to thank the staffs of The Department of Rehabilitation Medicine, Siriraj Hospital especially Dr. Navaporn Chadchavalpanichaya, Miss Somluck Painmanakit, Miss Chanjira Kaidwan, Miss Patcharin Puttaruksa, and Mrs. Yananee Wongsaranuchit who help me in carrying out this projects. I also expressed my sincere thank to my advisor, Associate Professor Somrat Charuluxananan, my co-advisor, Associate Professor Chockchai Metheetrairut and Mr. Suthipol Udompanturak for their vulnerable suggestions and critics.

Finally and mostly apparently most important, I would like to thank the patients with adhesive capsulitis who had participated in this study.

CONTENTS

CONTENTS (CONTINUED.)

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LIST OF TABLES

LIST OF FIGURES

LIST OF ABBREVIATION

CI	Confidence Interval
NSAIDs	Non-steroidal Anti-inflammatory Drugs
PT	Physical Therapy
SD	Standard Deviation
SDQ	Shoulder Disability Questionnaire
SPADI	Shoulder Pain and Disability Index
SRM	Standardised Response Mean
VAS	Visual Analogue Scale

CHAPTER 1

BACKGROUND AND RATIONALE

Painful shoulder joint is one of the common problems in rheumatologic, orthopedic and rehabilitation clinics. The prevalence in the general population may be as high as 6-11% in patients under the age of 50 years, increasing to 16-25 % in the elderly. (1-2) The survey in the outpatient clinic, Department of Rehabilitation Medicine, Siriraj Hospital showed that the prevalence rate was 8.7% in the elderly patients. (3)

The term 'frozen shoulder' has been applied to the conditions when the shoulder is working less than its optimal length. However, the correct term for the true global decrease in shoulder range of motion is adhesive capsulitis, related to surgical findings of actual adherence of the capsule to the humeral head. (4-5)

Clinical course of adhesive capsulitis is divided into three stages; painful stage, adhesive stage and recovery stage. (6) The painful stage involves gradual increase in pain and stiffness and lasts between three and eight months. History of minor strain may be noted. The patients usually note a decreased ability to reach their back to fasten the garment or remove a wallet from a back trouser pocket. Sleep may be interrupted if the patient rolls on the involved shoulder. The physical examination during the painful stage of adhesive capsulitis may reveal muscle spasm and diffuse tenderness about the glenohumeral joint and deltoid muscle. In longstanding cases, disuse atrophy of the shoulder girdle may be resulted. Passive and active ranges of motion in all planes of the

shoulder movements are lost. The adhesive stage involves increasing stiffness with diminishing pain. Pain decreases at night and discomfort occurs at the extreme of motions, although movement is dramatically decreased. This stage lasts four to six months. Minimal pain and severe restriction characterize the final stage.

Earlier studies were shown that the adhesive capsulitis was a self-limiting condition that gradually returned to full mobility within 18 months to 3 years in most patients even without specific treatments. (5-8) However, some studies documented persistent pain and stiffness beyond 3 years. (9-11) Factors that may affect the outcomes are age (9), onset of the symptoms (12), duration of the symptoms before treatment (12-15), concomitant neck pain (12, 16), involvement of dominant side (15), association with diabetes mellitus (17) and severe limitation of movement at onset (18-19).

Several different therapeutic regimens have been used for the purpose of increasing the extent and speed of recovery. The conventional management includes patients advice, analgesics, non-steroidal anti-inflammatory drugs (NSAIDs), steroid injection and wide variety of physical therapy methods. However, there is no current consensus in favor of one form of treatment.

In primary health care, the therapy is frequently initiated with the prescription of NSAIDs. Evidences from randomised clinical trials on shoulder disorders demonstrate short-term efficacy of NSAIDs. (20-22) Systematic reviews showed that there was no strong evidence for any difference of efficacy of different NSAIDs. (23)

Various physical therapy regimens are used conventionally. The goals of the management are pain reduction, preservation of motions and ability to perform activities of daily life. Before the range of motion exercise is introduced, heat modality should be given

to increase tissue temperature and its extensibility, making passive range of motion more effective (24). Previous systematic reviews showed that there was insufficient data to draw conclusion on the effectiveness of physical therapy. (7-8) However, previous studies, which compared the efficacy of physical therapy, usually studied only one modality of physical therapy of which were far from everyday practice, for examples, ultrasound (25-26), magnetotherapy (10, 27) or mobilisation (7, 28). Only a few studies compared combined physical therapy method with control (29), corticosteroid injections (30-31).

The regimen comprising of combined technique of physical therapy and NSAIDs is commonly used in clinical practice although it has not been subjected to scientific scrutiny in randomised clinical trials despite being commonly used in shoulder disorders. In view of such a common problem, it is important to provide a balance sheet of the benefits; harms and costs for making a choice between combined treatment regimen.

CHAPTER 2

REVIEW OF RELATED LITERATURES

DEFINITION

Adhesive capsulitis is a syndrome defined by a purest sense as idiopathic painful restriction of shoulder movement that results in a global restriction of glenohumeral joint. Primary adhesive capsulitis usually develops insidiously, following minimal or no trauma. Adhesive capsulitis may also occur secondary to intrinsic shoulder pathology such as supraspinatus tendinitis or extrinsic disorders such as pulmonary disease or neuropathic conditions. (32) Some of the common terms that are synonyms for adhesive capsulitis are frozen shoulder, periarticular adhesion, and painful stiff shoulder.

EPIDEMIOLOGY

The prevalence in western general population may be as high as 6-11% in patients under the age of 50 years, increasing to 16-25 % in the elderly. (1-2) Approximately 50 % of these people consult their physicians for their shoulder complaints. The survey in the outpatient clinic, Department of Rehabilitation Medicine, Siriraj Hospital showed that the prevalence rate was 8.7% in the geriatric patients. (3)

ETIOLOGY

The exact causes of adhesive capsulitis remain unknown. Certain factors; pain, disuse, and a periarthritic personality are considered to contribute to the development of adhesive capsulitis. Pain around shoulder area whatever the source usually forces the people to protect the arm from use. Immobilization of this synovial joint has been shown to have detrimental effects on the periarticular connective tissue. (33) Some investigators proposed that psychological factors, especially depression, apathy, and emotional stress, contributed to adhesive capsulitis. Patients with periarthritic personalities have a low pain threshold; therefore any shoulder pain will probably lead to early voluntary immobilization of the extremity. (34) However, Wright and Haq found no such a personality in 186 patients with adhesive capsulitis. (35)

PATHOLOGY

Pathologic process of adhesive capsulitis primarily involved the fibrous capsule. The normally flexible capsule becomes nonelastic and shrunken. The mechanism responsible for these changes is unknown. In the early stages, the capsule becomes contracted with loss of capsular fold. In the later phases, capsular fibrosis occurs. The synovial membrane becomes thickened and hypervascular. These tissues loss their elasticity and easily tear as the humerus is rotated and abducted. The coracohumeral ligament becomes a thick and contracted cord. The subscapsularis tendon becomes also fibrotic thereby limiting external rotation. In addition to subscapularis, the supraspinatus and infraspinatus are also tight, resulting in restricted glenohumeral motion, thereby limiting downward humeral excursion. (36)

CLINICAL FEATURES

Clinical course of adhesive capsulitis is divided into three stages; painful stage, adhesive stage and recovery stage. (5) The painful stage involves gradual increase in pain and stiffness and lasts between three and eight months. History of minor strain may be noted. The patients usually note a decreased ability to reach their back to fasten the garment or remove a wallet from a back trouser pocket. Sleep may be interrupted if the patient rolls on the involved shoulder. The physical examination during the painful stage of adhesive capsulitis may reveal muscle spasm and diffuse tenderness about the glenohumeral joint and deltoid muscle. In longstanding cases, disuse atrophy of the shoulder girdle may be resulted. Passive and active ranges of motion in all planes of the shoulder movements are lost. The adhesive stage involves increasing stiffness with diminishing pain. Pain decreases at night and discomfort occurs at the extreme of motions, although movement is dramatically decreased. This stage lasts four to six months. Minimal pain and severe restriction characterize the final stage. Earlier studies were shown that the adhesive capsulitis was a self-limiting condition that gradually return to full mobility within 18 months to 3 years in most patients even without specific treatments. (5-6) However, more recent studies documented persistent pain and stiffness beyond 3 years. (10-11) Factors that may affect the outcomes are age (9), onset of the symptoms (12), duration of the symptoms before treatment (12-15), concomitant neck pain (9, 16), involvement of dominant side (15), association with diabetes mellitus (17) and severe limitation of movement at onset (18-19).

DIAGNOSIS

The diagnosis of adhesive capsulitis is primarily clinical. Radiographs are important to document secondary adhesive capsulitis. Radiograph of early adhesive capsulitis is normal. Later changes sometime show osteopenia, cyst-like changes in the humeral head and joint space narrowing. (32)

Arthrography, although invasive, is useful to document decreased joint volume. The unaffected shoulder will accommodate 20 to 30 ml. of contrast material, whereas the shoulder with adhesive capsulitis will only be able to hold 5 to 10 ml. Arthrograms may reveal an irregularity of the capsular insertion at the anatomic humeral neck and a decreased axillary fold. Arthrography should be reserved for use in patients whose diagnosis remains uncertain. (32)

Arthroscopy does not aid in the diagnosis of adhesive capsulitis itself. It was found that some MRI findings were specific and sensitive for adhesive capsulitis but the decrease in joint fluid is not appreciated. (37)

TREATMENT

Like other musculoskeletal problems, the treatment of shoulder disorders is usually aim at improvement of functional status, next to pain reduction. A wide variety of treatment modalities have been introduced, including medications, exercise therapy, corticosteroid injection and surgery. However, there is no current consensus in favor of one form of treatment.

In primary health care, the therapy is frequently initiated with the prescription of non-steroidal anti-inflammatory drugs (NSAIDs). A wide variety of NSAIDs is available to

use and new drugs are being introduced on a regular basis. NSAIDs are assumed to act by inhibiting prostaglandin synthesis, resulting in relief of pain and suppression of inflammatory process in articular and periarticular structures. In primary health care, the therapy is frequently initiated with the prescription of NSAIDs. Evidences from randomised clinical trials on shoulder disorders demonstrate short-term efficacy of NSAIDs. (20-22) Systematic reviews showed that there was no strong evidence for any difference of efficacy of NSAIDs. (23)

A systematic review of 100 trials (12,853 people) found that NSAIDs increases risk of gross hemorrhage by 0.7 % compare with placebo (95% CI: 0.1% to 1.5%). (38) A meta-analysis of 11 case-controlled studies and 1 cohort study found that ibuprofen was significantly less toxic than other NSAIDs; the 11 comparator drugs were associated with a 1.6 - 9.2 fold increase in risk of serious upper gastrointestinal complications. (39) In a randomised controlled trial of 935 patients treated with NSAIDs who had ulcers more than 10 erosions at endoscope, at 8 weeks, treatment was successful in 76% of those given omeprazole 20 mg daily, 75% given omeprazole 40 mg daily, and 71% of those given misoprostol 800 mg daily. Participants (732) in whom treatment was successful were re-randomised to maintain treatment for six months, it was found that more people remained in remission with 20 mg omeprazole (61%) than with 400 mg of misoprostol (48%), or with placebo (27%). Absolute risk reduction for omeprazole versus placebo was 34 (95% CI = 25%-43%) and number needed to treat was 3. (40)

Various physical therapy regimens are conventionally used. (41) A systematic review which demonstrated 20 randomised, controlled clinical trials of physical therapy on soft tissue shoulder disorders concluded that there is insufficient evidence to draw

conclusions on the effectiveness of low level laser therapy, heat treatment, cold therapy, electrotherapy, exercise and mobilization. (7) The adverse effects of conventional PT programme in adhesive capsulitis are rarely studied. Van der Windt reported minimal effects of heat plus range of motion exercise, mainly pain after treatment. (31)

Intra-articular corticosteroid injections are used in affected patients to relieve pain and permit more vigorous physical therapy. The usual dose is 15-40 mg of triamcenolone acetonide with 1 ml. of 1 % of lidocaine. (32) Van der Windt et al demonstrated that beneficial effects of corticosteroid injection are superior to those of physical therapy (31). However, they used relatively high dose and introduce abnormal uterine bleeding in 6 women (from 47 cases).

Manipulation under general anesthesia should be considered when the above treatments failed. It can be used in adhesive stage. During this procedure, the joint capsule and subscapular muscles are ruptured, and aggressive rehabilitation is employed to restore and maintain range of motion of shoulder. Risks of manipulation under general anesthesia include humeral fracture, dislocation and rotator cuff rupture. (42)

For patients with loss of motion refractory to close manipulation, arthroscopic capsular release has been shown to improve motion, decrease in pain, and functional improvement with minimal operative morbidity. (43)

EVALUATION OF THE TREATMENT OUTCOME

Clinical outcome data are important to determine the results of treatment. Although the patients' abilities to use their upper extremities depend on the strength and range of motion of the shoulders as modified by pain. Many investigators considered the degree of

impairment measured by range of motion as surrogate measurement for patients' improvement. (41, 44-45) However, in general, the abilities of the patients to use their shoulders are more important than the actual range of motion and the results from physical examination are usually unreliable if the pain is aggravated. It was also found that asymptomatic older people regard the function of their shoulder even though the range of motion decreases with age. (46-47)

Now it is widely accepted that the patients' subjective impression of patients' functions is the most important clinical outcomes (31, 48-49). It can be used to assess severity of the symptoms and the impact of the shoulder problems in everyday life of the patients in order to be used as a guideline for the treatment programme to focus at specific problems of each patient. Serial measurement can give us an idea of how successful our treatment programme.

Some clinical trials for shoulder disorders included an assessment of functional status of which usually consisted of a single question on the ability to perform activities of daily life. (27-29, 50)

Recently, the self-administered questionnaires were developed to allow more comprehensive assessments of shoulder functions including The Shoulder Pain and Disability Index (SPADI) (51), Shoulder Rating Questionnaire (52), and Shoulder Disability Questionnaire (SDQ) (53).

The advantages of the multi-items functional outcome measurement compare with range of motion are (1) they are patient-centered, (2) they are more precise, multi-item format affords greater power of hypothesis testing, (3) they take less training to administer

than measuring range of motion, and it is easier and potential more reproducible than performance based measures. (48)

The Shoulder Pain and Disability Index (SPADI) is a 13 item, self-administered instrument. It was designed to identify pain and difficulty in performing activities of daily life that can be affected by shoulder problems. It was designed to measure current status and change over time. Its criterion validity was examined using active shoulder range of motion as the gold standard. The correlation between the total SPADI score and active range of motion ranged from –0.54 to –0.80. (51) The SPADI was confirmed its criterion validation by examined with generic questionnaire: Health Assessment Questionnaire (48) and with the Sickness Impact Profile (SIP) (54). The results of these studies provided support for the criterion validity of the SPADI. Roach et al provided evidences for the test-retest reliability of the total scores and score for both pain and disability sub-scales (interclass correlation coefficients = 0.64 - 0.66). Internal consistency was good with Chonbach's alpha value of 0.86 to 0.95. (51) The results of varimax rotation showed that pain and disability sub-scales were not perfectly true sub-scales. All SPADI items measure one construct, namely shoulder impairment and the correlation coefficient between pain and disability sub-scales is 0.87 (P= 0.0001). (51)

Responsiveness to change of the SPADI to the meaningful change was determined by testing the correlation of the change in the score and self-rating as improve, stable and worse. It was found that SPADI change score were significantly different between groups ($P < 0.001$). Herald and colleague compared standardized response mean (SRM) to those of the SIP. The SRM value in patients who were judged to be improved was higher for the total SPADI score (SRM=1.38) than for the SIP total

score (SRM=0.79). (54) William et al correlated the responsiveness to change of the SPADI score ($SPADI_{\Delta}$) with the overall status and showed that a $SPADI_{\Delta} > 10$ is highly specific for improvement of shoulder function with likelihood ratio for improvement = 34 (95% confidence interval: 4.8 – 238.0). (48)

The SPADI was extended its validity by changing to numeric scale 0-10 suitable for telephone administration. The VAS and numeric scaled SPADI were highly concordant (intra-class correlation coefficient = 0.86), the numeric scaled instrument yielded scores 2.5 points higher on average ($P<0.02$). (48)

CHAPTER 3

RESEARCH METHODOLOGY

3.1 RESEARCH QUESTIONS

Primary research question:

Do the patients receiving combined technique of physical therapy and NSAIDs have different mean of the SPADI score change from those who receive NSAIDs alone?

Secondary research questions:

1. Is the amount of analgesic usage different between the two groups?
2. Is the global improvement of both groups different from each other?
3. Is the mean change in range of motion of the two groups different from each other?
4. Is the patients' satisfaction of the two groups different from each other?
5. What are the adverse effects of combined technique of physiotherapy?

3.2 OBJECTIVES

Primary objective:

To compare the effectiveness of the treatment regimen, comprising combined technique of PT programme and ibuprofen with ibuprofen alone for the treatment of (primary) adhesive capsulitis in terms of pain reduction and functional recovery by measuring the change of the Shoulder Pain and Disability Index (SPADI). (51)

Secondary objectives:

1. To compare total analgesic usage between the two groups.
2. To compare the global improvement of patients with adhesive capsulitis in both treatment regimens from the view point of the patients.
3. To compare the mean change in range of motion.
4. To compare the patients' satisfaction.
5. To evaluate the adverse effects of combined technique of physical therapy.

3.3 HYPOTHESIS

Research hypothesis:

Treatment of adhesive capsulitis with combined technique of PT programme and ibuprofen yields difference in mean of the SPADI score change from ibuprofen alone.

Statistical hypothesis

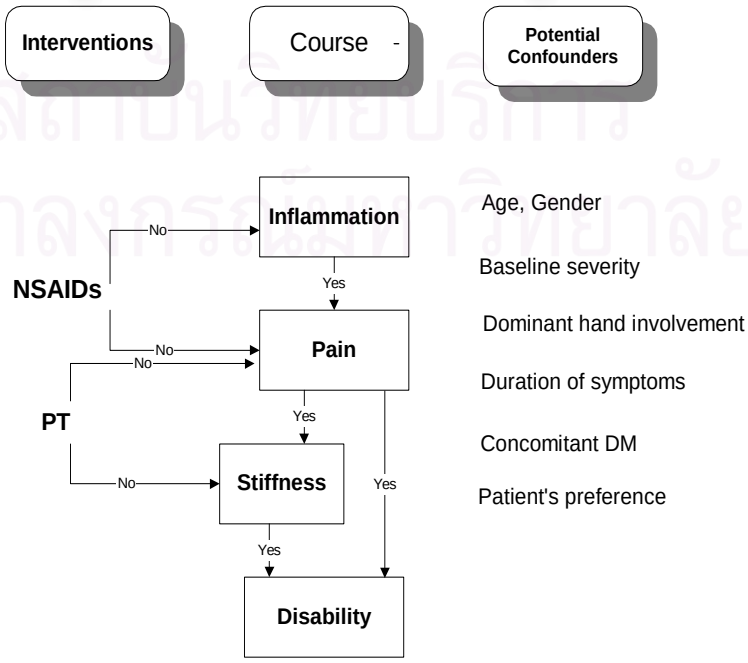
Null hypothesis $\mu_{pi} = \mu_i$

Alternative hypothesis $\mu_{pi} \neq \mu_i$

μ_{pi} : Mean of the SPADI score change in patients received PT plus ibuprofen

μ_i : Mean of the SPADI score change in patients received ibuprofen alone

3.4 CONCEPTUAL FRAMEWORK



3.5 OPERATIONAL DEFINITION

Diagnostic criteria:

Diagnostic criteria for adhesive capsulitis is based on the concept of Cyriax: Painful and limited passive glenohumeral mobility, external rotation must be relatively more restricted than abduction and internal rotation, and there must be no clear sign that the shoulder pain is caused by other conditions (i.e. painful arch, positive resistance test). (6)

The control group:

The group of patients who were randomised to have ibuprofen 400 mg three times daily

The study group:

The group of patients who were randomised to have ibuprofen 400 mg three times daily plus PT programme.

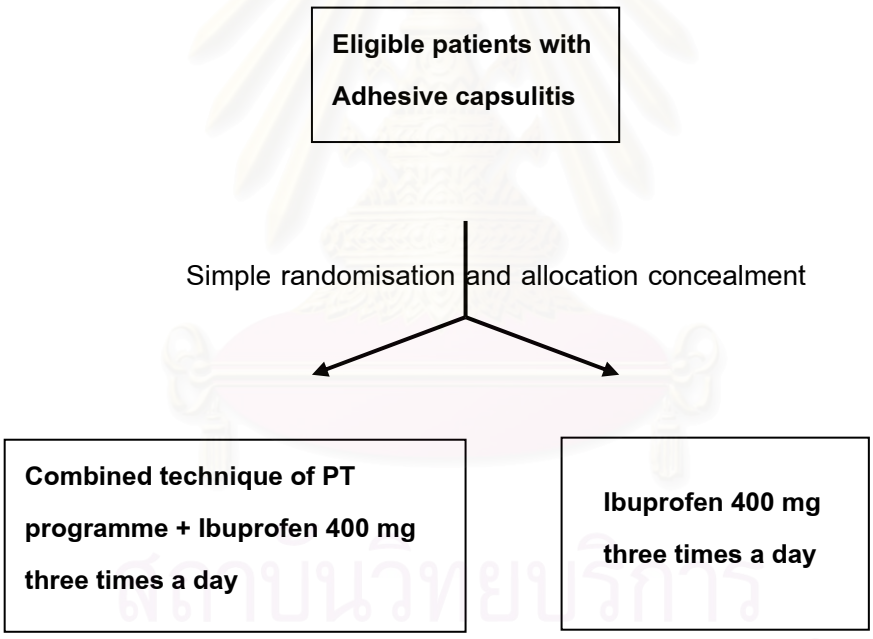
3.6 RESEARCH DESIGN

The aim of this study is to compare the effectiveness between new regimen and standard treatment. The study design that provides the strongest evidence should be a randomised controlled trial.

3.7 DESIGN JUSTIFICATION

1. Clinical trial is needed because the aim of the study is to compare the effective of two treatment regimens.
2. Randomised controlled study is needed to avoid selection bias and to make a balance of potential confounding factors between two groups.
3. Allocation concealment is needed to avoid bias of the physicians.

3.8 DESIGN OVERVIEW



3.9 POPULATION

Target Population

The target population was the patients with adhesive capsulitis whose age were at least 18 years old.

Study Population

The study population was the patients who were diagnosed as adhesive capsulitis in rehabilitation clinic and orthopedic clinic of Siriraj Hospital and met the eligibility criteria. The diagnosis of adhesive capsulitis was made according to the consensus of the two investigators.

3.10 ELIGIBILITY CRITERIA

Inclusion Criteria

1. More than 18 years old of age, both sex
2. Had shoulder complaint more than 2 weeks
3. Had no active management within 1 week
4. Had ability to read
5. Gave the consent form

Exclusion Criteria

1. Secondary adhesive capsulitis: intrinsic problems of shoulder such as history of fracture or dislocation around shoulder joint area, extrinsic causes such as neuromuscular disorders (stroke, parkinsonism), referred pain from cervical radiculopathy or patients with generalized arthritis
2. Bilateral involvement
3. Contra-indications to NSAIDs: active peptic ulcer, history of gastrointestinal hemorrhage, history of asthma or allergy to NSAIDs
4. Contraindication to deep heat modality: suspected malignancy or bleeding tendency

3.11 SAMPLE SIZE CALCULATION

The formula for calculating the sample size depended on the type of primary outcome measurement and the study design. Since the primary objective of this study was to compare two continuous independent variables. Calculation of the sample size was based on the ability to detect a clinically important difference in the mean of the SPADI score change at least 10 points between two groups.

The formula was as follow (55):

$$n = \frac{2\left[(Z_{\alpha/2} + Z_{\beta})\, \sigma_p \right]^2}{(d_s - d_c)^2}$$

α = 0.05 (type 1 error probability)

β = 0.20 (type 2 error probability)

$Z_{\alpha/2}$ = 1.96 (the value of standard normal distribution cutting of probability α / 2 at each tail)

Z_{β} = 0.84 (the value of standard normal distribution cutting of probability β in the upper tail), power of the test is 80 %.

d_s = mean change of the SPADI score in study group

d_c = mean change of the SPADI score in control group

The result of the pilot study showed that SD of the change in The SPADI results from NSAIDs and combined treatments were 15.9 and 18.2 respectively.

When σ_c was estimated from SD of the change in The SPADI results of NSAIDs and σ_s with SD of the change in The SPADI results of combined treatment and σ_p = pooled variance. When $n_c = n_s$,

$$\sigma_p = \frac{\sqrt{\sigma_s^2 + \sigma_c^2}}{\sqrt{2}}$$

$$\sigma_p = \frac{\sqrt{15.9^2 + 18.2^2}}{\sqrt{2}}$$

$$= 16.8$$

$$n \text{ (per group)} = \frac{2\left[(1.96 + 0.84)\, 16.8 \right]^2}{10^2}$$

$$= 45$$

To detect the significant difference in clinical practice, PT programme combined with ibuprofen should result in the SPADI score change at least 10 points different from ibuprofen alone, α equaled to 0.05 (two-tailed) and power of study equaled to 80 %, number of patients per group was 45. If the drop out rate was 10 %, the number per group

$$= \frac{N}{(1 - R)}$$

$$= \frac{45}{(1 - 0.1)}$$

$$= 50$$

The total sample size $= 50 \times 2$

$$= 100$$

3.12 RANDOMISATION

The patients enrolled to the study were randomly allocated to have a 3-week treatment protocol by simple randomization using random numbers table and allocation concealment.

3.13 INTERVENTION

1. Control group : ibuprofen 400 mg three times daily
2. Study group: ibuprofen 400 mg three times daily plus PT programme.

The patients who had history of peptic ulcer or problems of NSAIDs-induced dyspepsia received omeprazole 20 mg daily.

PT programme was carried out 3 times a week by each of the two research physical therapists who had been standardized their performance. Each session comprised of short-wave diathermy (20 minutes), mobilization and passive glenohumeral joint stretching exercises to patients' tolerance. On the day they did not receive hospital-based PT programme, they performed active non-assisted exercises using towel and wall (5 minutes) after applying 20 minutes hot pack. The guideline of exercise was based on Cyriax. (6) If during the passive movement the patients received pain before the therapist reached the end of range, exercise was contraindicated. If pain was experienced at the end of the range, the patient was less acute, and then the exercise was attempted.

At the start, all of the eligible patients received an information sheet containing advice on protection of the shoulder from vigorous activities such as pushing and pulling. They were encouraged to use their arms in normal fashion for reaching and other activities of daily life.

The interventions were stop before the end of the study if:

1. The patients rated themselves as complete recovery.
2. The patients rated themselves as much worse.
3. There was any serious complication such as gastrointestinal hemorrhage.
4. The patients decided to withdraw from the study.

Co-intervention

All of the subjects were asked to receive no other adjuvant therapy during the study except oral acetaminophen (up to 2 g/ day). They were asked to stop acetaminophen 48 hour before next follow-up. The total number of the pills left was recorded. All of the patients were asked to record if there was other additional treatment. The physicians in this study were blinded to avoid bias while they gave patients' instruction of shoulder care and during follow-up period.

Contamination

Regarding the problem of contamination, the research assistance arranged an appointment to make sure that the participants in each group did not meet the other group in order to avoid instruction of exercise technique from the study group to the control group.

Compliance

Before asking for informed consent, the patients were carefully selected to reduce the risk of non-compliance. The patients were asked whether they could come to hospital regularly or not. For each patient, the detail of actual therapy he/she received was recorded. All of the patients were asked to record total number of NSAIDs and analgesics usage.

3.14 VARIABLES

Administrative variables

1. Name
2. Identification number
3. Address and telephone number

Baseline variables

1. Age (year)
2. Gender (male/ female)
3. Duration of disability; $<$ 6 weeks, $\geq$ 6 weeks but $<$ 12 weeks, $\geq$ 12 weeks
4. Dominant/ non dominant extremity involvement
5. Association with neck pain
6. Association with diabetes mellitus
7. The Shoulder Pain and Disability Index Score
8. Patient's preference as randomisation (Yes, No)

Primary outcome variable:

The change of the Shoulder Pain and Disability Index (the SPADI) score over time was calculated for each patient by subtracting the result at baseline from the follow-up at the end of 3rd week. Before measuring, the instrument was assessed for its reliability, validity, and applicability. Some modifications were carried out according to the suggestion from the content experts and the results of the pilot test (see the details in appendix).

Secondary outcome variables:

1. Total number of analgesic usage

   The number of analgesic usage was calculated from the number prescribed pill minus the number of pill left.

2. The global measure of improvement

   Recovery from baseline was recorded at the end of 3rd week by the patients on a six point Likert Scale; “complete recovery, much improve, little improve, not change, little worse, much worse”.

3. Range of motion (ROM)

   Range of motion of the shoulder joint was measured with a goniometer by a blinded investigators according to the method advocated by Clarke. (9) The goniometer was attached by Velcro strap to the upper arm with the patients sitting upright for total abduction. Shoulder external rotation was assessed in

sitting position with the shoulder in 90 degree of abduction and the goniometer attached to the dorsal aspect of the forearm. The measurements were performed twice, and if they differed by more than 5 % they were repeated once more and the means of the closest two observations were taken. Internal rotation range was assessed by measuring the distance between the spine of C7 and tip of thumb with the arm fully internal rotated. The inter-rater reliability was carried out before the beginning of the study (see details in appendix).

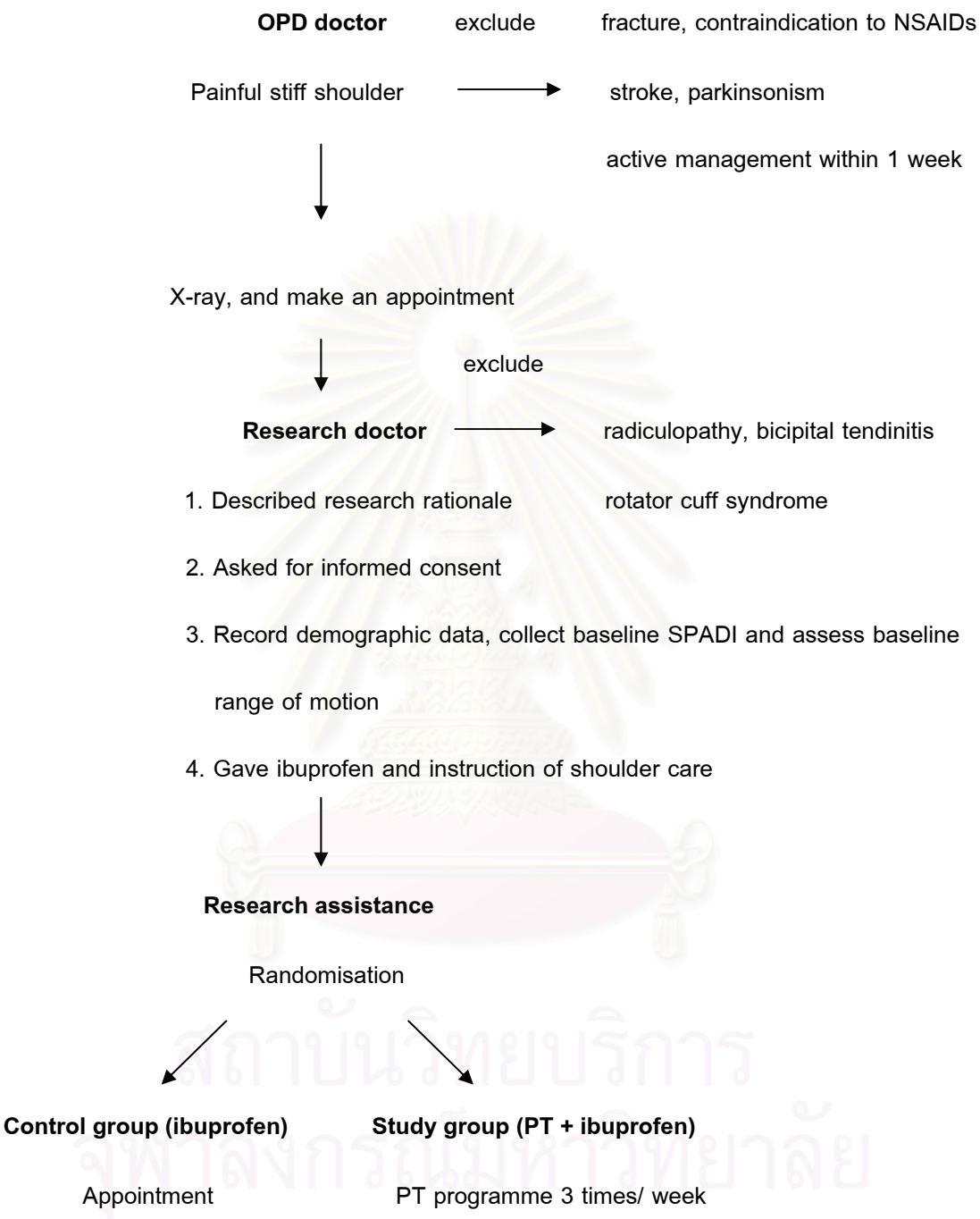
4. The patients' satisfaction

At the end of 3rd week, the questionnaire was added one question concerning the patients' satisfaction on the treatment regimens by a four point Likert scale "very satisfied, moderately satisfied, unsatisfied, very unsatisfied".

5. Adverse reactions

The patients and the blinded investigators elicited report of the adverse effects of PT programme. The patients who received PT programme were asked to record whether they have more pain that persisted more than 2 hours after treatment or more disability in the next morning or not. At each follow-up, the blinded investigator asked all of the patients "Have the trial drugs and/or treatment programme upset you any way?" and looked for any signs of echymosis and burn during range of motion evaluation.

3.15 RESEARCH ADMINISTRATION



1st week follow-up: evaluated any complication of treatment

3rd week follow-up: reassessed SPADI, global rating of improvement, range of motion, complications, total number of NSAIDs and acetaminophen usage, patients' satisfaction

3.16 DATA COLLECTION

After the eligible patients signed the consent forms, they were asked to complete their baseline data and the SPADI questionnaire after having some instruction. At the end of 1st week, the patients were asked whether they have any problems from the treatment of this protocol. At the end of the study, they completed the questionnaire again including any complication occurred, their overall improvement and their satisfaction regarding the treatment programme. Range of motion was assessed at baseline and the end of treatment.

3.17 DATA ANALYSIS

Intention to treat analysis was used to evaluate a statistical difference between two groups. All baseline data and outcome variables were analyzed by computer programme SPSS version 9.0.

3.18 ETHICAL CONSIDERATION

1. The interventions in this study had been conventional used. The evidence from previous studies showed their benefit more than harm.
2. The complications of the treatment regimens were prevented by carefully selected the cases and strictly performed within the standard regimen.
3. The research proposal was submitted to the hospital ethics committee and written approval was received before the beginning of the study.

4. The information about the study was described to the patients before asking to sign the consent form. The information included the details of the interventions, potential adverse effects, and measures for prevention and treatment of the adverse effects (see details in the appendix).
5. The patients knew that they had right to withdraw from the study without interference with their regular care.

CHAPTER 4

RESULTS

4.1 PATIENTS ACCOUNTING

From March, 2001 to September, 2001, there were 210 patients with adhesive capsulitis consulted orthopedic clinic of the Siriraj Hospital, a total of 96 patients with adhesive capsulitis who fulfilled the eligibility criteria and willing to join this study. Of the 114 subjects not recruited, 78 were due to inconvenience (They lived far away from Bangkok so they were inconvenient to go to the Siriraj Hospital to receive treatment or to be followed up as schedule), 21 had secondary adhesive capsulitis, 10 had contra-indication for NSAIDs, and 5 had bilateral involvement. The number of subjects dropped out from the study were 3 from control group and 1 from study group. The detail of total cases recruited, randomisation and dropped out were demonstrated in figure 4.1.

4.2 BASELINE DATA AND BASELINE COMPARISON

The total cases included in the analysis were 45 and 47 for the control and study group respectively. The details of baseline characteristic were shown in table 4.1.

Figure 4.1 Summary data for study recruitment and completion.

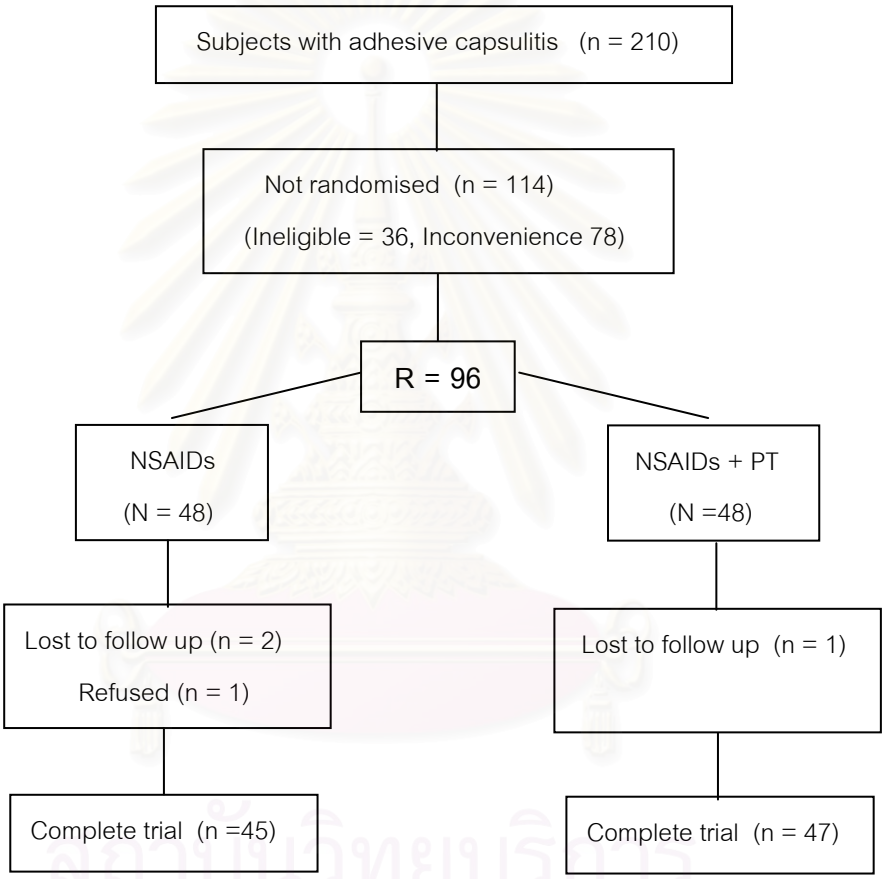


Table 4.1 Baseline characteristics of patients with adhesive capsulitis by group.

Values are numbers (percentages) unless indicated otherwise.

Variables	**The control group** (n = 45)	**The study group** (n = 47)	**Mean difference (95 %CI)**
Mean (SD) of age (years)	56.9 (9.9)	56.1 (10.7)	0.9 (-3.4 to 5.2)
Gender; male	11 (24.4%),	18 (38.3%),	
female	34 (75.6%)	29 (61.7%)	
Duration of disability;			
- < 6 weeks	5 (11.1%)	8 (17.7%)	
- ≥ 6 weeks < 12 weeks	26 (57.8%)	22 (46.8%)	
- ≥ 12 weeks	14 (31.1%)	17 (36.2%)	
Dominant arm involvement	24 (53.3%)	24 (51.1%)	
Causes; minor trauma	11 (24.4%),	13 (27.6%),	
unknown	34 (75.6%)	34 (72.3%)	
Associated with neck pain	8 (17.8%)	8 (17.0%)	
Associated with DM	8 (17.8%)	5 (10.6%)	
Patient's preference as randomisation	41 (91.1%)	37 (78.7%)	

Table 4.1 Baseline characteristics of patients with adhesive capsulitis by group.

Values are numbers (percentages) unless indicated otherwise. (Continued)

Variables	The control group (n = 45)	The study group (n = 47)	Mean difference (95 %CI)
Mean (SD) of the SPADI score*	50.6 (16.6)	54.9 (21.3)	-0.4 (-12.2 to 3.4)
Range of motion			
- Mean (SD) glenohumeral Abduction (degree)	120.8 (25.1)	118.6 (25.1)	2.2 (-8.2 to 12.6)
- Mean (SD) glenohumeral External rotation (degree)	74.0 (18.0)	75.0 (23.0)	2.9 (-4.0 to 9.9)
- Mean (SD) of distance Between thumb and tip of C7 spine (cm.)**	38.0 (16.5)	43.0 (14.0)	-2.2 (-6.7 to 2.3)

* Pain and disability as rated on the SPADI score in which scores range from 0–130; the higher scores indicate more severe pain and disability.

** Internal rotation was quantified by measuring distance between thumb and tip of C7 spine in hand behind back position

All of the categorical baseline variables were compared between the two groups by using Chi square and Fisher's exact test. It was shown that the proportions of subjects regarding to sex, dominant arm involvement, cause of disability, duration of

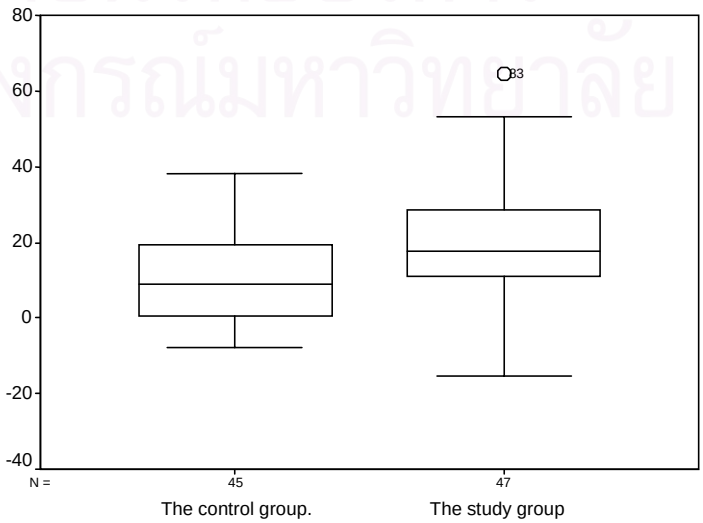
disability, associated with neck pain, association with diabetes, and patients' preference were not different between two groups (table 4.1). All of the continuous baseline variables were tested for their distributions with one sample Kolmorogov-Smirnov test. It was found that all of them were normality distributed. Then Student t – test was used to find if there was any difference in baseline between the two groups. It was found that there was no statistical difference (table 4.1).

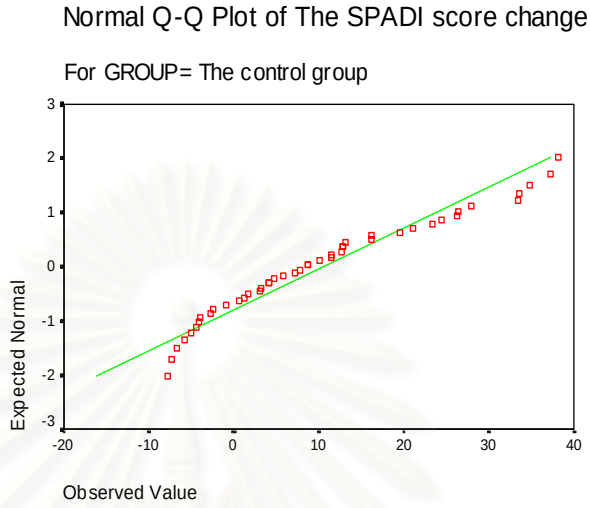
4.3 COMPARING OUTCOME VARIABLES

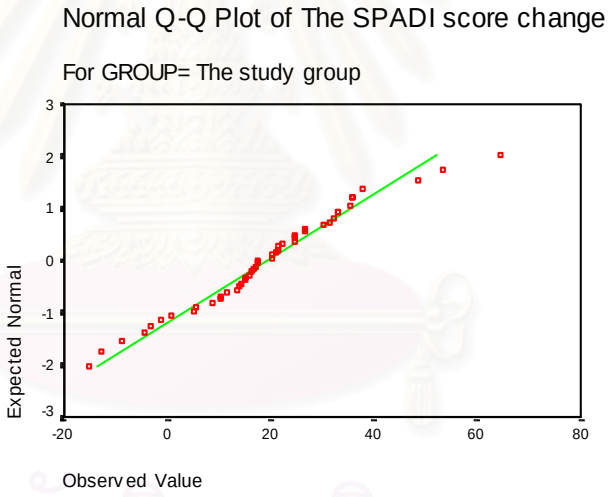
4.3.1 PRIMARY OUTCOME VARIABLE

The change of the SPADI score of each subject was obtained by extracted his/ her follow-up score from the baseline score. The data of the two groups were tested for normality using box plot, Q-Q plot and one sample Kolmorogov-Smirnov test. The result was acceptable with significant level more than 0.05.

Figure 4.2 Box plot of the SPADI score improvement by treatment groups.







Since the assumption of normal distribution could be held, the parametric statistical method was used for further analysis. The mean (standard deviation) changes of the scores of the study group and the control group were points 19.4 (15.8) and 10.4 (13.6) points, respectively. The magnitudes of change of both groups were compared by using Student's t-test for independent variable (table 4.2).

It was shown that the subjects in the study group had mean of improvement more than the control group significantly (p = 0.004). The magnitude of difference was 9.0 points (95% CI was 2.9 points to 15.1 points) (table 4.2).

Table 4.2 Mean (SD) improvement in continuous outcome variables of patients with adhesive capsulitis and differences between two groups.

Variables	The control group (n = 45)	The study group (n = 47)	Difference (95% CI)	P value
Improvement in SPADI score	10.4 (13.6)	19.4 (15.8)	9.0 (2.9 to 15.1)	0.004
Improve in external rotation (degree)	18.4 (15.8)	25.6 (14.6)	7.3 (1.0 to 13.6)	0.024
Improvement in abduction (degree)	17.6 (17.2)	24.5 (20.5)	6.9 (-1.0 to 14.8)	0.085
Improvement in internal rotation (cm.)	4.5 (6.1)	7.37 (7.2)	2.9 (0.1 to 5.6)	0.040
Number of analgesic use (tablet)	12.4 (14.2)	13.5 (17.1)		0.889*

* The number of analgesic use was non-gaussian-distribution, non-parametric test was used.

4.3.2 SECONDARY OUTCOME VARIABLES

For secondary outcome variables, number of analgesic use and range of motion improvement (glenohumeral abduction, external rotation and internal rotation) were continuous data. All of these variables were tested for their distribution. It was found that the improvements in range of motion were normally distributed. Then the mean of range of motion improvement between the two groups could be tested with Student's t-test. On contrary, the amounts of analgesic use of both groups were tested with Mann-Whitney U test due to the fact that it was not normally distributed.

Regarding to range of motion, the mean improvement of glenohumeral external rotation between the two groups was significantly different ($p = 0.024$). The study group had mean improvement 7.3 degrees (95% CI was 1.0 degree to 13.6 degrees) more than control (table 4.2).

For glenohumeral abduction, the mean improvement in the study group was 6.9 degrees more than control (95% CI was -1.0 degree to 14.8 degrees) but the difference was not statistical significant ($p = 0.085$).

Distance between thumb to tip of C7 spine (cm.) was used to quantify glenohumeral internal rotation. The analysis showed that the study group had more improvement than the control group significantly ($p = 0.040$). The magnitude of difference was 2.9 centimeters (95% CI was 0.1 cm. to 5.6 cm.).

Because the test for normality showed that number of analgesic use was not normally distributed, the difference between the two groups was tested with

Man-Whitney U test. It was found that the medians of analgesic use between the groups were not statistical different (p = 0.889).

Table 4.3 Number (percentage) of subjects with adhesive capsulitis who rated their global improvement and satisfaction between groups by treatment

Variables	The control group (n = 45)	The study group (n = 45)	P value
Global rating of improvement:			
- Complete recovery	9 (20.0%)	15 (31.9%)	
- Much improve	8 (17.8%)	17 (36.2%)	
- Little improve	16 (35.4%)	10 (21.3%)	
- Not change	10 (22.2%)	3 (6.4%)	0.004
- Little worse	2 (4.4%)	2 (4.6%)	
- Much worse	0 (0.0%)	0 (0.0%)	
Satisfaction ;			
- Very satisfied	19 (42.22%)	39 (89.98%)	
- Moderately satisfied	19 (42.22%)	7 (14.89%)	
- Unsatisfied	4 (8.89%)	1 (2.23%)	< 0.001
- Very unsatisfied	3 (6.67%)	0 (0.0%)	

For ordinal secondary outcomes, Man-Whitney U test was used to compare the results between the two groups. It was found that the subjects who received physical therapy incombination with NSAIDs rated their improvement and satisfaction better than the subjects who received NSAIDS alone significantly (table 4.3).

4.4 COMPLICATIONS OF TREATMENT

Patients in the study group reported a total of 10 episodes of pain that persisted more than 2 hours after treatment from 4 subjects. There were no other complications recorded (table 4.4). Regarding to NSAIDs, 13 subjects (13.5%) had gastrointestinal side effects; the number of those who had severe dyspepsia and had to stop NSAIDs was 5 (5.2%). There was 1 report (1.0%) about severe edema and 1 case (1.0%) with severe headache, which rapidly subsided after the drug, was discontinued.

Table 4.4 Complications of PT in patients with adhesive capsulitis.

Complications	Number of episodes(percentage) (n = 364)
Pain persisted more than 2 hours after treatment	10 (2.8%)
Marked increase disability in the next morning	0 (0.0%)
Echymosis or burn around shoulder region	0 (0.0%)

4.5 COMPLIANCE AND CO-INTERVENTION

About three forth of subjects of both groups took NSAIDs as prescribed (table 4.5). The reasons why some of the subjects had less NSAIDs than the others were due to gastrointestinal discomfort, forgetful or misunderstanding about the schedule.

In the study group, there were 6 cases who had hospital-based PT less than 6 sessions. Main reasons were problems of accessibility. There were 6 cases who performed home programme exercise less than 3 sessions per week.

Two cases from the control group reported that they had additional treatment; 1 had Chinese herbal medicine and 1 had analgesic from private clinic. No patient in the control group had hospital-based PT or home exercise therapy for their shoulder.

Table 4.5 Compliance and co-intervention in patients with adhesive capsulitis by treatment received. Values are numbers (percentages).

Treatment actually received	The control group (N = 45)	The study group (N = 47)
Take NSAIDs less than 70% of prescribed	12 (26.6%)	13 (27.6%)
Received PT less than 6 sessions	-	6 (12.8%)
Perform home exercise less than 3 sessions per week	-	6 (12.8%)
Other additional treatment	2 (4.4%)	0 (0.0%)

4.6 SUMMARY OF THE RESULTS

At the end of 3rd week, mean improvement of the SPADI score of patients who received combined technique of physical therapy was 9.0 points more than patients who received NSAIDs alone with 95% confidence interval from 2.9 points to 15.1 points. Regarding to the secondary outcomes, the difference in improvement was in the same direction for all outcome measures except amount of analgesic use of which the difference between the two groups was not statistical significant. Adverse reactions were generally mild and compliance of treatment protocol was acceptable. There were few programme deviations.

CHAPTER 5

DISCUSSION

DESIGN OF THE STUDY

The design of this study was a conventional randomised controlled trial in that all eligible patients were randomised. There were no significant different between the two groups for any variable at entry, which suggests that the randomisation of 92 cases was successful.

Because of inclusion criteria, the subjects in this study exhibited a specific range of shoulder disorders. We limited enrollment to one specific type of shoulder disorders to make sure that my results are easily applicable to patients with primary adhesive capsulitis. Inter-observer (2 clinicians) reliability for diagnosis was acceptable. There was some variation in subjects' age (range 36-81); the means and standard deviations of both groups were similar.

The external validity was enhanced to facilitate the implementation of the findings to every practice in rehabilitation field. First, to ensure that the intervention used resemble those carried out in routine care. Second, at the beginning of the study, three 5-years experienced physical therapists were standardised their performances to the Cyriax's technique (6) enhancing internal validity of the study.

Outcome measurements encompassed a range of important aspects associated with patient-centered multi-items functional outcome measure, one global impression of improvement and patients satisfaction. To use a broad range of outcome

measurements including a standardised shoulder scoring system (The SPADI) which evaluated pain and disabilities in common activities of daily life established validity and enabled other researchers and clinicians to compare the results.

Because of the nature of treatment used in this study, it was not possible to keep the subjects blinded as to the experimental condition for each subject. Since the primary outcome were subjective measurement, it was probably direct influenced by the subjects preconceived idea regarding the effectiveness of intervention (56) and patients' preferences can be an important determinant of the outcomes (57). Participants who were randomised to their treatment of choice may have a better outcome irrespective of the physiological effects of the intervention. The Placebo treatment, which theoretically would have alleviated this threat to internal validity, was not convenient in this study. Therefore, the differences of primary outcome between the two groups in this study could be due to placebo effects. This problem may be partly ameliorated because the patients' treatment preferences were elicited after randomisation. Because it was found that the patients in the control group had tendency to prefer their allocated treatment more than the patients in the study group. Then it was unlikely that the difference of primary outcome at the end of this study was due to patients' preference.

In addition, range of motion evaluation was added as an objective measurement that assessed by a blinded investigator to reduce observer bias. It was found that there was correlation between the improvement in SPADI score and improvement in range of motion. Pearson correlation coefficients between the improvement in SPADI score and improvement in glenohumeral joint abduction,

external rotation and internal rotation were 0.36 ($p < 0.001$), 0.11 ($p = 0.286$), and 0.35 ($p = 0.001$) respectively. In addition, the error in range of motion measurement was minimised by standardising the performance in evaluation and controlling the analgesic use before assessment.

RESULTS OF THE STUDY

The primary objective of this study is to compare the effectiveness of treatment regimen, comprising combined technique of PT programme and NSAIDs with NSAIDs alone for the treatment of (primary) adhesive capsulitis.

The hypothesis of this study, using experimental design, was not rejected because the results of the study demonstrates that physical therapy in-combination with ibuprofen aimed at reduced pain and disability resulted in more improvement in a variety of outcome measures, compared with ibuprofen alone, over a 3-week period. The study group reported more decrease in The Shoulder Pain and Disability Index score; more perceived global improvement and satisfaction as well as more improvement in glenohumeral external and internal rotations.

No difference was found in the improvement of glenohumeral abduction and numbers of analgesic use. However, the difference between means of improvement in abduction showed trend that favored study group.

The results of this study is different from previous studies that made systematic reviews concluded that there was insufficient data to draw the conclusion on the effectiveness of PT. (7-8) The reasons were due to the fact that PT regimen in this study comprised of important components. Deep heat modality was introduced in order to increase tissue temperature and its extensibility, making passive range of

motion more effective. (24) After that mobilisation and passive range of motion exercise were carried out. To avoid problems of accessibility and make the patients more convenience, the patients were instructed to carry out home programme on the day they did not receive hospital-based PT programme. They were advised to use superficial heat modality to decrease pain and reduced muscle spasm in stead of deep heat modality before they performed self-exercise to maintain or increase range of motion exercise.

Regarding the range of motion, the study group had mean improvement in external rotation 7.3 degrees more than control (95% CI was 1.0 degree to 13.6 degrees, p = 0.024), mean improvement in abduction 6.9 degrees more than control (95% CI was -1.0 degree to 14.8 degrees, p = 0.085) and mean improvement in internal rotation (quantified by distance between thumb to tip of C7 spine) 2.9 centimeters more than control (95% CI was 0.1 cm. to 5.6 cm., p = 0.040). It would seem, therefore, confirm that physical therapy is recommended adjunct to NSAIDs for patients with adhesive capsulitis.

The protocol deviation in this study may have an effect on the results. The difference of the outcome at the end of this study should be more elicited if there was no protocol deviation. The patients of the study group received treatment less than the schedule (six cases had hospital-based PT less than and 6 cases performed home programme exercise less than 3 sessions per week), while the subjects of the control group received treatment more than the schedule (one case had Chinese herbal medicine and 1 case had analgesic from private clinic).

Because only one subject in the study group and 3 subjects in the control group were unavailable for reassessment, represent a dropout rate of just 4.3 %, differences between the two groups at the end of the study can not be attributed to follow-up bias. This negligible number can be explained by the restriction of enrollment to patients willing to adhere to the allocated treatment and to complete follow-up.

Distinguishing between clinical and statistical significance is an important aspect. A mean improvement in the Shoulder Pain and Disability Index of the study group, which was about 2 times, more than the control group can be considered to have clinical significance.

Although the differences in 7.3 degrees external rotation improvement, 6.9 degrees abduction improvement and 2.9 centimeters internal rotation improvement might not be considered to have clinical significance. The patients in the study group rated their global impression of improvement and their satisfaction in the results of treatment better than the control group.

IMPLICATIONS OF THE RESULTS

Up to date, no other published study has described the positive effects of PT technique similar to everyday practice in-combination with NSAIDS compare with NSAIDs alone. The results of this study suggest that we should prescribe PT adjunct to NSAIDs for treating patients with adhesive capsulitis.

SUGGESSION

Because combined technique of physical therapy needs wide variety of resources such as people, time, facilities and equipment. It is rationale to carry out further study to evaluate economic aspect of the study to provide a balance sheet of the benefits; harms and costs for making choice between combined treatment regimen. If combined technique of physical therapy is not cost-effective. Home-programme physical therapy should be alternative interventions to be studied in further trial. Because it was shown that many patients in this study still had disability from shoulder joint problems at the end of the study. Longer follow-up period should be carried out to give us more information regarding to the treatment outcomes. However, it is unethical to give the treatment modalities for the patients who did not response to. The treatment should be modified from the previous regimens but the analysis of long term results should base on intention to treat analysis because the reasons for modifying treatments were strongly related to the results of allocated interventions.

CHAPTER 6

CONCLUSION

This randomised controlled trial demonstrated that the treatment regimen comprising with combined technique of PT programme and ibuprofen yielded more beneficial effects than the usage of ibuprofen alone for the treatment of (primary) adhesive capsulitis. At the end of 3rd week, mean improvement of the SPADI score of patients who received combined technique of physical therapy was 9.0 points more than patients who received NSAIDs alone with 95% confidence interval from 2.9 points to 15.1 points. Regarding to secondary outcomes, the difference in improvement was in the same direction for all outcome measures except amount of analgesic use of which the difference between the two groups was not statistical significant. Adverse reactions were generally mild and compliance of treatment protocol was acceptable. There were few co-interventions and there was no contamination recorded.

The results of this study gave us evidence to support the use of adjunctive physical therapy for patients with adhesive capsulitis.

Further study is recommended to evaluate economic aspect of the treatment regimen with longer follow-up period that may give us more information regarding to the treatment outcomes.

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Appendices

ข้อมูลที่ผู้ป่วยควรทราบ (Patients Information Sheet)

ชื่อโครงการวิจัย การศึกษาเปรียบเทียบประสิทธิผลระหว่างการทำกายภาพบำบัดร่วมกับการใช้ยาต้านการอักเสบ กับการใช้ยาต้านการอักเสบอย่างเดียวในผู้ป่วยเอ็นข้อไหล่อักเสบ

สถานที่ทำการวิจัย คณะแพทยศาสตร์ศิริราชพยาบาล

ผู้ทำการวิจัย รองศาสตราจารย์แพทย์หญิงกิ่งแก้ว ปาจรีย์

อาจารย์ที่ปรึกษา รองศาสตราจารย์นายแพทย์สมรัตน์ จารุลักษณานันท์

ข้อมูลทั่วไป

เอ็นข้อไหล่อักเสบเป็นปัญหาที่สำคัญของผู้สูงอายุ ทำให้เกิดอาการเจ็บปวดและเป็นอุปสรรคต่อการทำกิจวัตรประจำวัน ต้องใช้เวลาในการรักษาต่อเนื่องนานหลายสัปดาห์ การรักษาที่นิยม ได้แก่ การใช้ยาต้านการอักเสบ และการทำกายภาพบำบัด ร่วมกับการปฏิบัติตนอย่างถูกต้อง โดยหลีกเลี่ยงการใช้ข้อไหล่อย่างหักโหม

ข้อมูลของโครงการ

การศึกษาวิจัยนี้เป็นการทดลองเพื่อเปรียบเทียบประสิทธิผลระหว่างการทำกายภาพบำบัดร่วมกับการใช้ยาต้านการอักเสบ กับการใช้ยาต้านการอักเสบอย่างเดียวในผู้ป่วยเอ็นข้อไหล่อักเสบ โดยใช้กลุ่มตัวอย่างเป็นผู้ป่วยที่มีปัญหาเอ็นข้อไหล่อักเสบประมาณ 100 ราย ผู้ป่วยแต่ละรายจะถูกสุ่มเข้ารับการรักษาวิธีใดวิธีหนึ่งเป็นเวลาติดต่อกัน 3 สัปดาห์ การวัดผลทำได้โดยเปรียบเทียบผลการตอบแบบสอบถามและการตรวจร่างกายก่อนและหลังการรักษา

ประโยชน์ของการทำวิจัย

ข้อมูลที่ได้จากการวิจัยจะช่วยให้แพทย์สามารถให้คำแนะนำแก่ผู้ป่วยในการเลือกวิธีการรักษาได้อย่างเหมาะสมต่อไป

ความไม่สะดวกที่อาจจะเกิดจากการศึกษาวิจัย

ผู้ป่วยจะได้รับการขอร้องให้มาพบแพทย์ตรงเวลาที่นัดอีก 2 ครั้ง หลังจากการพบกันครั้งแรก และขอร้องไม่ให้รับการรักษาเพิ่มเติมด้วยวิธีอื่นใดในระหว่าง 3 สัปดาห์ที่อยู่ในช่วงการวิจัยนี้ ผู้ที่ถูกสุ่มให้รับการรักษาด้วยการทำกายภาพบำบัดร่วมด้วย ต้องไปรับการทำกายภาพบำบัดที่โรงพยาบาลสัปดาห์ละ 3 ครั้ง อย่างไรก็ตามผู้ป่วยมีสิทธิ์อันสมบูรณ์ที่จะยกเลิกข้อตกลงนี้ โดยที่การตัดสินใจยกเลิกดังกล่าวไม่ทำให้ผู้ป่วยเสียสิทธิ์ในการรับการรักษาพยาบาลที่ถูกต้องตามมาตรฐาน

ท่านจำเป็นต้องเข้าร่วมในการศึกษาวิจัยนี้หรือไม่

การเข้าร่วมในการศึกษาวิจัยเป็นไปโดยความสมัครใจ แพทย์มีหน้าที่ต้องให้ดูแลรักษาท่านอย่างดีที่สุด ไม่ว่าท่านจะตัดสินใจเข้าร่วมโครงการหรือไม่

แพทย์ที่ท่านสามารถติดต่อได้

ท่านสามารถสอบถามรายละเอียดเพิ่มเติมได้จากรองศาสตราจารย์แพทย์หญิงกิ่งแก้ว ปาจรีย์ ใบประกอบวิชาชีพเวชกรรม เลขที่ 12084 หมายเลขโทรศัพท์ 0-2419-7504, 0-2411-4536

แบบยินยอมเข้าร่วมโครงการวิจัย

วันที่.....

ชื่อโครงการวิจัย การศึกษาเปรียบเทียบประสิทธิผลระหว่างการทำกายภาพบำบัดร่วมกับการใช้ยาต้านการอักเสบ กับการใช้ยาต้านการอักเสบอย่างเดียวในผู้ป่วยเอ็นข้อไหล่อักเสบ

ผู้ทำการวิจัย รองศาสตราจารย์แพทย์หญิงกิ่งแก้ว ปาจรีย์ ใบประกอบวิชาชีพเวชกรรม เลขที่ 12084 หมายเลขโทรศัพท์ที่ติดต่อได้ 0-2419-7504, 0-2411-4536

วัตถุประสงค์ เพื่อเปรียบเทียบประสิทธิผลระหว่างการทำกายภาพบำบัดร่วมกับการใช้ยาต้านการอักเสบ กับการใช้ยาต้านการอักเสบอย่างเดียวในผู้ป่วยเอ็นข้อไหล่อักเสบ

รายละเอียดที่จะปฏิบัติต่อผู้เข้าร่วมวิจัย

ผู้เข้าร่วมวิจัยจะได้รับการสุ่มให้เข้ารับการรักษาวิธีใดวิธีหนึ่งเป็นเวลา 3 สัปดาห์ ผู้ที่อยู่กลุ่มยาต้านอักเสบจะได้รับยาต้านการอักเสบไปรับประทานที่บ้าน และกลับมาพบแพทย์เมื่อครบ 1 สัปดาห์ และ 3 สัปดาห์ ผู้ที่อยู่กลุ่มกายภาพบำบัดร่วมกับยาต้านการอักเสบต้องมาทำกายภาพบำบัดที่โรงพยาบาลร่วมกับการรับประทานยา โดยมาทำสัปดาห์ละ 3 ครั้ง แต่ละครั้งใช้เวลาประมาณ 1 ชั่วโมง การวัดผลทำโดยเปรียบเทียบผลการตอบแบบสอบถามและการตรวจร่างกายก่อนและหลังการรักษา

ประโยชน์และผลข้างเคียงที่จะเกิดแก่ผู้สมัครเข้าร่วมวิจัย

สิ่งที่ผู้เข้าร่วมวิจัยจะได้รับนอกเหนือจากการรักษาด้วยวิธีมาตรฐาน คือถ้ามีการตรวจเพิ่มเติมด้วยวิธีการเอกซเรย์ข้อไหล่และการเจาะเลือดเพื่อตรวจเช็คเบาหวาน โดยผู้เข้าร่วมวิจัยไม่ต้องเสียค่าใช้จ่าย ในกรณีที่ผู้เข้าร่วมวิจัยมีอาการเสียดท้องจากยาต้านการอักเสบ จะได้รับยาที่ใช้แก้ไขอาการดังกล่าวโดยไม่คิดมูลค่าเช่นกัน ผลข้างเคียงที่อาจเกิดขึ้น ได้แก่ ผู้ป่วยบางรายอาจมีอาการจุกเสียดภายหลังรับประทานยา บางรายอาจมีอาการขัดยอกหลังทำกายภาพบำบัด อย่างไรก็ตามผลข้างเคียงที่อาจเกิดขึ้นนั้นไม่แตกต่างจากผลข้างเคียงที่เกิดจากการรักษาที่ใช้เป็นประจำ เนื่องจากวิธีการรักษาที่ใช้ในการศึกษาวิจัยนี้เป็นวิธีการที่ใช้อยู่ตามปกติ ถ้าคณะผู้วิจัยพบว่ามีภาวะแทรกซ้อนรุนแรงจากการรักษา เช่น ปวดท้องรุนแรง หรือมีเลือดออกจากทางเดินอาหาร จะแจ้งให้ผู้เข้าร่วมวิจัยทราบทันทีเพื่อยกเลิกการวิจัย และคณะผู้วิจัยจะรับผิดชอบในการรักษาภาวะดังกล่าวจนหายเป็นปกติ

<u>การรับฟังการชี้แจง</u>

ข้าพเจ้า (นาย/ นาง/ น.ส).....นามสกุล.....อายุ.....ปี
ที่อยู่.....โทรศัพท์.....

ได้รับทราบรายละเอียดของโครงการวิจัย เรื่องการเปรียบเทียบประสิทธิผลของการใช้ยาต้านการอักเสบกับการใช้ยาต้านการอักเสบควบคู่กับการทำกายภาพบำบัดในผู้ป่วยเอ็นข้อไหล่อักเสบ และข้าพเจ้าเข้าใจวัตถุประสงค์ของการวิจัย วิธีการ ประโยชน์และผลข้างเคียงอันอาจเกิดต่อตัวข้าพเจ้าเองทุกประการ

ข้าพเจ้ามีสิทธิ์ที่จะงดการเข้าร่วมโครงการวิจัยโดยมิต้องแจ้งให้ทราบล่วงหน้า และการงดเข้าร่วมโครงการนี้จะไม่มีผลกระทบต่อการได้รับบริการ หรือการรักษาที่ข้าพเจ้าจะได้รับแต่อย่างใด

ข้าพเจ้าได้รับทราบจากผู้วิจัยว่าจะไม่มีการเปิดเผยข้อมูลหรือผลการวิจัยของข้าพเจ้าเป็นรายบุคคลต่อสาธารณชน และใช้ข้อมูลที่ได้เพื่อเป็นประโยชน์ทางการแพทย์ การเปิดเผยข้อมูลเกี่ยวกับข้าพเจ้าต่อหน่วยงานต่างๆ กระทำได้เฉพาะกรณีที่จำเป็นด้วยเหตุผลทางวิชาการหรือกฎหมายเท่านั้น ซึ่งในกรณีดังกล่าวข้าพเจ้าจะไม่เรียกร้องค่าเสียหายใดๆทั้งสิ้น ทั้งนี้ผู้กำกับดูแลการวิจัย คณะกรรมการพิจารณาจริยธรรมของโรงพยาบาล รวมทั้งตัวข้าพเจ้าเอง หรือผู้แทนตามกฎหมายของข้าพเจ้า สามารถเข้าตรวจสอบบันทึกข้อมูลทางการแพทย์ของข้าพเจ้า เพื่อเป็นการยืนยันขั้นตอนของการทำวิจัยได้ด้วย ในกรณีที่ผลงานวิจัยได้รับการตีพิมพ์ ชื่อและที่อยู่ของข้าพเจ้าจะได้รับการปกปิด

ข้าพเจ้าได้รับทราบจากผู้วิจัยว่าหากมีข้อมูลข้อมูลใหม่ ๆ ทางวิชาการ ซึ่งอาจมีผลต่อการตัดสินใจเข้าร่วมในการศึกษาวิจัยนี้ ข้าพเจ้าจะได้รับทราบจากคณะผู้ทำการวิจัยโดยไม่ชักช้า

ข้าพเจ้าได้รับทราบจากผู้วิจัยว่า หากเข้าเจ้าได้รับความผิดปกติเนื่องจากการทดลอง ข้าพเจ้าจะได้รับการคุ้มครองตามกฎหมาย และหากข้าพเจ้าได้รับการรักษาอื่น ๆ โดยมิได้ปรึกษาแพทย์ผู้รับผิดชอบโครงการวิจัยนี้ และมิได้แจ้งให้แพทย์ทราบทันทีถึงความผิดปกติที่เกิดขึ้น จะถือว่าข้าพเจ้าเป็นผู้ให้การคุ้มครองความปลอดภัยเป็นโมฆะ (ตามที่กฎหมายกำหนด)

ข้าพเจ้าได้รับทราบและได้ซักถามผู้วิจัยจนหมดข้อสงสัยและยินดีเข้าร่วมการศึกษาวิจัยครั้งนี้โดยความสมัครใจ แต่อาจถอนตัวจากการเข้าร่วมวิจัยครั้งนี้ โดยไม่ต้องแจ้งเหตุผล ข้าพเจ้าจะยอมรับสิ่งไม่พึงประสงค์ที่อาจเกิดขึ้นและจะปฏิบัติตัวตามคำแนะนำของแพทย์ทุกประการ จึงได้ลงลายมือไว้เป็นหลักฐานต่อหน้าพยาน

ลงนาม.....ผู้ยินยอม
( )
...../...../.....

ลงนาม.....ผู้วิจัย
( )
...../...../.....

ลงนาม.....พยาน
( )
...../...../.....

PATIENT RECORD FORM

แบบบันทึกของแพทย์

ชื่อ……

เคยตรวจเบาหวานหรือไม่……..ผลการตรวจ □ เป็น □ ไม่เป็น

ผลเอกซเรย์ ……..

	baseline	F/U
วันที่	……..	
abduction	……..	
external rotation	……..	
internal rotation	……..	
Echymosis	……..	
Burn	……..	

ผลข้างเคียงของการรักษา (F/U) ครั้งที่ 1…….

ครั้งที่ 2…….

ปวดท้องหรือถ่ายดำหรือไม่ (F/U) ครั้งที่ 1……

ครั้งที่ 2……

ยาเหลือ (F/U) ครั้งที่ 1……

ครั้งที่ 2……

วันที่เริ่ม Omeprazole……..…….

วันที่หยุด NSAIDs……..

ค่าใช้จ่ายของผู้วิจัย……

หมายเหตุ ……..

……

MEASUREMENT

INSTRUMENTAL DESIGN

The original version of the Shoulder Pain and Disability Index (The SPADI) was developed for use in an outpatient setting by Roach et al in 1991 at Miami School of Medicine. (51) It was designed to measure the impact of shoulder problems in term of pain and disability for both current status and change in status over time. It consists of two separate scales; one for pain and the other for functional activities, and requires 5 - 10 minutes for patients to complete.

The pain sub-scale consists of five questions regarding the severity of an individual's pain in common activity;

1. At its worse
2. When lying on the involved side
3. Reaching for something on a high shelf
4. Touch the back of the neck
5. Pushing with the involved arm

Functional activities are assessed with eight questions designed to measure the degree of difficulty an individual had with various ADL related to shoulder joint. The activities in this instrument include basic activities of daily life;

1. Washing hair
2. Washing back
3. Putting on undershirt or pullover sweater
4. Putting on the shirt that button down the front
5. Putting on the pants
6. Placing on object on high shelf

7. Carry a heavy objects of 10 pounds
8. Removing something from back pocket

Scaling of the SPADI

The SPADI scoring system is based on the assumption that the severity of pain and disability resulting shoulder pathology is a function of the number of situations in which pain and disability is experienced as well as the intensity of that experience in each situation.

All items are rated using a scale 0 - 10. The scales in the SPADI consist of horizontal lines without division or number. Verbal anchors for pain sub-scale are “no pain at all” and “worse pain imaginable,” and those for the functional activities are “no difficulty” and “so difficult it required help”. To answer the questions, the patients place a mark on each 10-cm line. The higher scale is for the more severe of the problems.

The sub-scale scores are calculated by adding the item scores for that sub-scale and dividing this number by the maximum score possible for the items that are deem applicable by the subjects. This number is then multiplied by 100. Any item marked by the patients as not applicable is not included in the maximum possible score. If the patients do not mark more than two items, no score is calculated.

The score from both sub-scales are averaged to drive a total score and change to the 0 - 100 score. Higher score indicates worse problems.

DEVELOPMENT OF THE THAI VERSION OF THE SPADI

The original version of the SPADI was translated into Thai by a physiatrist who had been working in the field for 10 years and keened in translation. The translated version was then validated by back translation into English by a professional English translator without any information regarding to this instrument.

Some modifications had been carried out according to valuable suggestion from the content experts and the results of the pilot test. The modifications were the followings.

Content modifications

1. Added the phase ‘when you use the involved side’ in item 3 (reaching for something on high shelf), 4 (touching the back of the neck), 7 (washing back) and item 13 (removing something from the back pocket) due to the fact that these tasks can be completed with the other arm.
2. Changed the word ‘worse pain imaginable’ to “severe pain that can not be tolerable” because the later one seemed to make better sense in Thai language than “can not been imaginable”.
3. Item 8: Difficulty carrying heavy object

   Changed the weight of the objects 10 pounds to 3 kilograms suitable for Thai people who had smaller body build than American people.
4. Item 13: Removing something from back pocket

   Added ‘or fastening posterior hook or zip of the skirt’ as an alternative task to decrease the bias toward male patients because men usually carried item such as wallet in their back paint pocket.

TEST FOR RELIABILITY, VALIDITY, APPLICABILITY, AND PRACTICALITY

STUDY DESIGN

Descriptive cross-sectional design

METHODOLOGY AND RESULTS

Assessment of validity

1. Face validity

One physiatrist, 1 orthopaedes, 1 physical therapist and a patient who suffered from painful stiff shoulder for 2 months from Siriraj Hospital were asked to be content experts. All of these health care professionals worked in their field more than 10 years. All of the experts agreed that all items in the SPADI had face validity; they appeared to measure the pain and disability in the patients with shoulder disorders.

2. Content validity

All of the experts were asked to examine each items of the Thai Version of SPADI to determine The intra-class coefficient of each item varied from 0.75 - 1 from 4 experts. So the content validity of the Thai version of SPADI was accepted.

3. Criterion validity

To find the criterion validity, this set of questionnaire has to be compared with gold standard. Because there is no real gold standard, the Thai Version of SPADI can not be assessed in criterion validity.

4. Construct validity

The translated version was adopted from the original SPADI which had been already assessed in construct validity by operational defined and hypothetical construct, so it needed no test in its construct validity.

Assessment of reliability

The reliability assessment is a measure of consistency or degree of dependability. It can be divided into two major classes. Reproducibility, or test-retest reliability, which is a measure of stability, is the ability of a scale to give the same results when administered on separate occasions. Internal consistency, which is a measure of equivalence, is the ability of a scale to measure a single coherent concept.

Because The SPADI is self-assessment questionnaires, the test-retest for intra-rater reliability is the only method to test for stability. But in case of shoulder complaint which fluctuations over time in an episodic condition will tend to be attributed to change in condition rather than to poor repeatability.

In summary, reliability of the Thai Version of Numeric SPADI can be obtained into test for internal consistency and responsiveness to change.

1. Internal consistency

Internal consistency assesses the extent to which each item correlates with the other items and total score. Internal consistency is assessed by calculating the Chonbach's coefficient alpha for the entire scale and for each individual sub-scale.

Study population

Twenty-four literated patients who had painful stiff shoulder and consulted out- patient clinic of the Department of Rehabilitation Medicine, Siriraj Hospital were asked for participation. We excluded the patients who had severe cognitive dysfunction, the shoulder movement was prohibited, and had associated problems interfering with upper extremity functions. The patients were instructed how to use this questionnaire.

Result

The internal consistency of this questionnaire was determined by calculating the value of Chonbach's alpha. It was computed by using SPSS program version 9 for window statistical package. The results included item mean, standard deviation, item inter-correlation, item-total correlation and coefficient alpha. The mean value of inter-item correlation of 5 items in pain sub-scale was 0.80 (SD = 0.003) and the mean value of disability sub-scale was 0.51 (SD = 0.32). Test for item-total correlation in each sub-scale demonstrated that all of the items of pain sub-scale were well correlated (table A - 1) whereas most of the items in disability sub-scale had relatively lower item-total correlation especially item 10 (putting on a pant) and item 13 (removing something from back pocket) (table A - 2). The alpha coefficient of pain sub-scale (item 1-5) was 0.95 (95% CI: 0.91 to 0.98). The alpha coefficient of disability sub-scale (item 6-13) was 0.89 (95% CI: 0.81 to 0.95).

Table A - 1 Total-item statistics of 5 items in pain sub-scale

Item	Corrected item-total correlation
1	0.85
2	0.84
3	0.88
4	0.85
5	0.90

Table A - 2 Total-item statistics of 8 items in disability sub-scale

Item	Corrected item-total correlation
6	0.66
7	0.82
8	0.77
9	0.64
10	0.56
11	0.78
12	0.70
13	0.47

When the SPADI was considered as true uni-dimensional questionnaire, it was found that the mean inter-items correlation is 0.54 (SD = 0.03). Test for item-total correlation showed that all of the items are well correlated (table A - 3). The Chonbach's alpha of all items was 0.94 (95% CI: 0.90 to 0.97).

Table A - 3 Total-item statistics of all items.

Item	Corrected item-total correlation
1	0.70
2	0.76
3	0.87
4	0.83
5	0.84
6	0.58
7	0.79
8	0.84
9	0.63
10	0.48
11	0.81
12	0.64
13	0.51

3. Responsiveness to change

Responsiveness of the SPADI to the meaningful change was determined by calculating the responsiveness ratio. Gayatt et al illustrated the concept of responsiveness by analogy with signal to noise ratio. (58-59) The signal constitutes the clinical relevant changes we wish to detect. The noise represents the measurement error according to within subjects' variability unrelated to a clinical relevant change. According to Gayatt et al, the most appropriate measure of responsiveness relates a clinical relevant change to the variability of the change score in stable patients. If the responsiveness ratio is larger than 1, the mean change score in clinically improved subjects exceeds the measurement error and the measurement tool may be considered as responsiveness. (58-59)

The results from 24 subjects with painful stiff shoulder showed that the mean of The SPADI score change of clinically stable patients was 13.04 and the mean change in clinically improved patents was 22.09. The responsiveness ratio of the Thai version of the SPADI is 1.69 whereas Williams et al found that responsiveness ratio of the original English version was 1.4. (48) In summary, this study showed that the Thai Version of Shoulder Pain and Disability Index had acceptable face validity and content validity and it could be applied to Thai patients with shoulder disorders after carefully translated and minimal modification. The excellent response rate suggested that it was easily administered. The internal consistency of each sub-scale was acceptable. If the SPADI was considered as uni-dimensional questionnaire, the Chonbach's alpha of total items is 0.94 similar to the results from the original article which Chonbach's alpha equals 0.95. (48).

Range of motion (ROM) assessment

Range of motion of the shoulder joint was measured with a goniometer according to the method advocated by Clarke by blinded investigators. (9) The goniometer was attached by Velcro strap to the upper arm with the patients sitting upright for total abduction. Shoulder external rotation was assessed in sitting position with the shoulder in 90 degree of abduction and the goniometer attached to the dorsal aspect of the forearm. The measurement was performed twice, and if they differ by more than 5 degrees they will be repeated once more and the means of the closest two observations will be taken. Internal rotation range was assessed by measuring the distance between the spine of C7 and tip of index

finger with the arm fully internal rotated. The inter-rater reliability of 10 subjects was carried out. The reliability coefficient of abduction, external rotation and internal rotation were 0.98, 0.92, and 0.99 respectively.

แบบสอบถามสำหรับผู้มีอาการปวดไหล่ ครั้งที่ 1

1. ชื่อ……นามสกุล……ที่อยู่ที่ติดต่อได้…….
   ……
   โทรศัพท์……...

2. อายุ……..ปี

3. เพศ ☐ ชาย ☐ หญิง

4. ระดับการศึกษาสูงสุด

☐ ประถม ☐ ปริญญาตรี

☐ มัธยม ☐ สูงกว่าปริญญาตรี

☐ ปวส, ปวช, อนุปริญญา ☐ อื่น ๆ (ระบุ)……..

5. ท่านมีปัญหาที่ไหล่ข้างไหน ☐ ซ้าย ☐ ขวา
เป็นแขนข้างถนัดใช่หรือไม่ ☐ ใช่ ☐ ไม่ใช่

6. ท่านมีอาการมานานแค่ไหน

☐ น้อยกว่า 3 เดือน

☐ ตั้งแต่ 3 เดือน - 6 เดือน

☐ มากกว่า 6 เดือน

7. สาเหตุของอาการปวดไหล่

☐ เกิดตามหลังอุบัติเหตุเล็กน้อย ☐ จำไม่ได้ หรือไม่ทราบ

8. เมื่อเปรียบเทียบกับสัปดาห์ก่อนหรือวันก่อน ตอนนี้ปัญหาที่ไหล่ของท่านกำลัง

☐ แย่ลง ☐ คงที่ ☐ ดีขึ้น

ข้อ 1-5 กรุณาขีดกากบาทบนเส้นตรง แทนระดับความเจ็บปวดที่หัวไหล่ของท่าน ในรอบ 24 ชั่วโมงก่อนหน้านี้

1. **เมื่อตอนที่ท่านเจ็บไหล่มากที่สุด ท่านเจ็บมากแค่ไหน ?**

ไม่เจ็บเลย _____ **เจ็บมากจนทนไม่ไหว**

2. **เมื่อนอนตะแคงทับไหล่ข้างเจ็บ ท่านเจ็บที่ไหล่มากแค่ไหน ?**

ไม่เจ็บเลย_____ **เจ็บมากจนทนไม่ไหว**

3. **เมื่อเอาแขนข้างเจ็บเอื้อมหยิบของจากที่สูงระดับเหนือศีรษะท่านเจ็บไหล่มากแค่ไหน ?**

ไม่เจ็บเลย_____ **เจ็บมากจนทนไม่ไหว**

4. **เมื่อท่านยกมือข้างที่เจ็บขึ้นเกาท้ายทอย ท่านเจ็บที่ไหล่มากแค่ไหน**

ไม่เจ็บเลย _____ **เจ็บมากจนทนไม่ไหว**

5. **เมื่อท่านใช้แขนข้างเจ็บผลักหรือดันของหนักๆ ท่านเจ็บที่ไหล่มากแค่ไหน**

ไม่เจ็บเลย _____ **เจ็บมากจนทนไม่ไหว**

ข้อ 6 – 13 กรุณากากบาทบนเส้นตรงแทนความยากลำบากในการทำกิจกรรมต่างๆ ในรอบ 24 ชั่วโมงก่อนหน้านี้

6. **สระผม**

ไม่ลำบากเลย ——————————————— **ลำบากจนต้องการคนช่วย**

7. **ใช้มือข้างเจ็บถูหลัง**

ไม่ลำบากเลย ——————————————— **ลำบากจนต้องการคนช่วย**

8. **ใส่เสื้อสวมหัว**

ไม่ลำบากเลย ——————————————— **ลำบากจนต้องการคนช่วย**

9. **ใส่เสื้อแบบที่ติดกระดุมหน้า**

ไม่ลำบากเลย ——————————————— **ลำบากจนต้องการคนช่วย**

10. **สวมกางเกง**

ไม่ลำบากเลย ——————————————— **ลำบากจนต้องการคนช่วย**

11. **ใช้แขนข้างเจ็บ หยิบของขึ้นไปวางไว้บนหิ้งหรือตู้ที่อยู่เหนือศีรษะ**

ไม่ลำบากเลย ——————————————— **ลำบากจนต้องการคนช่วย**

12. .ใช้แขนข้างเจ็บหิ้วของหนัก (3 กิโลกรัม)

ไม่ลำบากเลย ———————————————— ลำบากจนต้องการคนช่วย

13. เอามือข้างเจ็บหยิบของออกจากกระเป๋ากางเกงหลัง (ผู้ชาย) หรือ รูดซิปหรือติดตะขอกระโปรงด้านหลัง (ผู้หญิง)

ไม่ลำบากเลย ———————————————— ลำบากจนต้องการคนช่วย

14. โดยสรุปท่านคิดว่าขณะนี้ ปัญหาที่หัวไหล่ของท่านเป็นอย่างไร (เฉพาะการตอบครั้งที่ 2)

ก. หายสนิทแล้ว ข. ดีขึ้นมาก ค. ดีมากพอประมาณ
ง. ดีขึ้นน้อยมาก จ. คงที่ ฉ. แย่ลง

15. โดยสรุปท่านพอใจวิธีการรักษานี้หรือไม่ (เฉพาะการตอบครั้งที่ 2)

ก. พอใจมาก ข. พอใจเล็กน้อย ค. เฉย ๆ ง. ไม่พอใจ

ข้อเสนอแนะ

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VITAE

Kingkaew Pajareya was born on March 11, 1961 in Chandhaburi province. She got medical degree from Faculty of Medicine Siriraj Hospital, Mahidol University in 1985 and Diplomate Thai Board of Rehabilitation Medicine in 1991. She enrolled in the Thai CERTC training programme in 1999 as fund by Faculty of Medicine Siriraj Hospital, Mahidol University.