



Mahidol University Central Institutional Review Board

Office of the President Mahidol University,

Room Number 411, 4<sup>th</sup> Floor

Tel 662 849 6224-5 FAX 662 849 6224

Ref. No. 78.0138/01597

Date November 1, 2019

Subject: Approval for Protocol Number MU-CIRB 2019/206.0608

Dear Mr. Ferian Nugraha

According to your submission your protocol entitle **"Mobilization with Movement as an Additional Treatment to Conventional Physical Therapy in Individuals with Shoulder Impingement Syndrome"** Code: MU-CIRB 2019/206.0608 to MU Central IRB for consideration. The IRB reviewed your revised protocol and granted the approval.

Please be informed that investigators subject to comply with the followings:

- 1) Conduct the research according to the approved protocol and use only the participant information sheet/informed consent form bearing the "MU-CIRB Approval stamp"
- 2) If you want to change any part of your protocol, please send the PROTOCOL AMENDMENT FORM for approval before commencing and informed research participants about the changes for their consideration in pursuing the research.
- 3) Timely report of serious adverse events to MU-CIRB and any new information that may adversely affect the safety of the subjects or the conduct of the trial.
- 4) For research that is longer than 1 year duration, please submit the annually reports to MU-CIRB within 1 month before expiration date of certificate of approval then the renew certificate of approval will be issued.
- 5) For the research that complete within 1 year, the final reports should be submitted.

Sincerely yours

A handwritten signature in blue ink, appearing to read "Rutja", is written over a faint, larger blue ink signature that is partially visible underneath.

(Professor Dr. Rutja Phuphaibul)

MU-CIRB Chair

CC To: Lect. Dr. Wunpen Chansirinukor





Mahidol University Central Institutional Review Board (MU-CIRB)

*Certificate of Approval*

Protocol No.: MU-CIRB 2019/206.0608

Title of Project: Mobilization with Movement as an Additional Treatment to Conventional Physical Therapy in Individuals with Shoulder Impingement Syndrome

Approval Includes:

- 1) Principal Investigator: Mr.Ferian Nugraha  
Affiliation: Faculty of Physical Therapy, Mahidol University  
Research Site: Esa Unggul Physical Therapy Clinic in Indonesia
- 2) Submission Form Version Received Date 11 October 2019
- 3) Protocol Version Received Date 6 August 2019
- 4) Participant Information Sheet Version Received Date 11 October 2019
- 5) Informed Consent Form Version Received Date 11 October 2019
- 6) Assessment Form Version Received Date 11 October 2019
- 7) Shoulder Pain and Disability Index Version Received Date 11 October 2019
- 8) Recruitment Material Version Received Date 11 October 2019

MU-CIRB is in Full Compliance with International Guidelines for Human Research Protection such as Declaration of Helsinki, The Belmont Report, CIOMS Guidelines and the International Conference on Harmonization in Good Clinical Practice (ICH-GCP)

*Date of Approval: 01 / November / 2019*

*Date of Expiration: 31 / October / 2020*

Signature of Chairperson: .....

(Professor Dr. Rutja Phuphaibul)

MU-CIRB Chair

Signature of Institute Representative: .....

(Professor Wachira Kochakarn)

Acting Vice President for Research and Scientific Affairs

\* See list of Co-Investigators at the back page



## List of Co – Investigators

1. Lect. Dr. Wunpen Chansirinukor
2. Assoc. Prof. Dr. Roongtiwa Vachalathiti

## All MU-CIRB Approved Investigators must comply with the Following:

1. Conduct the research according to the approved protocol.
  2. Conduct the informed consent process without coercion or undue influence, and provide the potential subjects sufficient time to consider whether or not to participate.
  3. Use only the Consent Form bearing the MU-CIRB Approval stamp.
  4. Obtain approval of any changes in research activity before commencing and informed research participants about the changes for their consideration in pursuing the research.
  5. Timely report of serious adverse events to MU-CIRB and any new information that may adversely affect the safety of the subjects or the conduct of the trial.
  6. Provide MU-CIRB the progress reports at least annually or as requested.
  7. Provide MU-CIRB the final reports when completed the study procedures.
- .....

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*MU-CIRB Address: Office of the President, Mahidol University, 4th Floor, Room Number 411  
999 Phuttamonthon 4 Road, Salaya, Nakhonpathom 73170, Thailand*

*Tel: 66 (0) 2849 6224, 6225 Fax: 66 (0) 2849 6224*

*E-mail: mucirb@gmail.com*

*Website: <http://www.sp.mahidol.ac.th>*

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Participant Information Sheet		Page 1 of 5

<b>Participant Information Sheet</b>

☐ Original      ☐ Modification

Date

...../...../.....

*In this document, there may be some statements that you do not understand. Please ask the principal investigator or his/her representative to give you explanations until they are well understood. You may bring this document home to read and consult your relatives, intimates, personal doctor or other doctors. To help your decision making in participating in the research.*

**Title of Research Project : Mobilization with movement as an additional treatment to conventional physical therapy in individuals with shoulder impingement syndrome**

**Name of Researcher : Ferian Nugraha**

**Research Site : Esa Unggul Physical therapy clinic**

**North Arjuna street number 9 RT.1/RW.2**

**Duri Kepa, Kebon Jeruk, West Jakarta 11510, Indonesia**


**Phone Number (+62 21) 5674223 ext. 286 and (+62) 81220355498 (Ferian Nugraha)**

Research objectives: This research project is conducted to compare the effects of 4-week physical therapy treatment with the same physical therapy treatment and the addition of mobilization with movement on pain intensity, shoulder range of motion, cervical and shoulder posture, shoulder muscle strength, and shoulder function in the patient with shoulder impingement syndrome.

You are invited to participate in this study because you are participant with shoulder impingement syndrome aged between 20 to 60 years old, experienced anterior and/or lateral shoulder pain at least 3 months, having the level of pain intensity from 4-7 in the visual analogue scale (score 4-7 out of 10).

Expected benefits:

- You will receive an intervention of your shoulder (physical therapy treatment, exercise, and mobilization)
- You will receive information about your impairment (pain intensity, range of motion, cervical and shoulder posture, muscle strength, and shoulder function)
- You will receive information for health promotion, home based physical therapy treatment, and injury prevention

	รับรองโดยคณะกรรมการจริยธรรมการวิจัยในคนชุดกลาง
	มหาวิทยาลัยมหิดล (MU-CIRB)
	รหัสโครงการ MU-CIRB <b>2019/206.0608</b>
	วันที่ ..... <b>- 1 พ.ค. 2562</b>



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- This study will determine the effect of adding mobilization with movement to physical therapy treatment in individuals with shoulder impingement syndrome. The findings of this study will be beneficial to physical therapy assessment and treatment of individuals with shoulder impingement syndrome.

Risk and discomfort may occur from the physical examination, exercise and measurement. You may feel some provoked pain during the examination and muscle fatigue during the exercise. However, it would be safe for your condition because the procedure of physical examination and intervention is already been proven by the previous study and have been used in clinical.

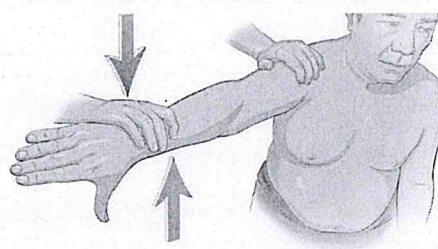
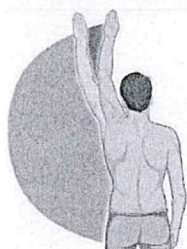
There will be approximately 24 participants in this study, and the research project will last for February 2020. Participants will get intervention for 12 sessions in 4 weeks (3 sessions/week) and will be assessed before and after treatment.

If you decide to participate in the research project, you will go through following procedures.

#### 1. Explanation research project

- 1.1 Participants will be received clear explanation of purposes, procedure, advantages and possible risk of this study.
- 1.2 Each participant will be asked to sign an informed consent after they understand and accept to participate in this study.

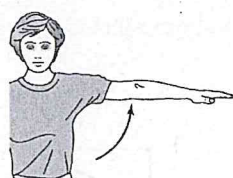
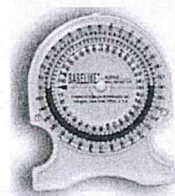
#### 2. Physical examination



The examiner will ask about your condition that might be included or excluded to this project. The examiner will ask the pain intensity during lifting the arm, and perform some physical examination related to your shoulder. The participants will be divided into 2-groups (physical therapy and mobilization with movement groups).

#### 3. Range of motion

Range of motion will be assessed by examiner and researcher in both groups of the participants.



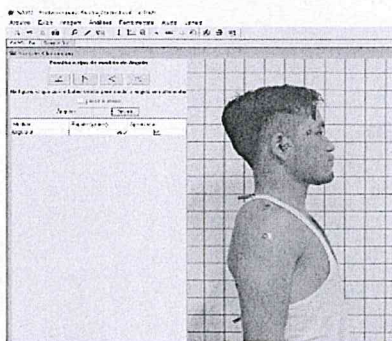
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3.1 Shoulder abduction in the standing position with an instruction to lift the arm until the pain occur or limited movement (lifting the shoulder and arm)

3.2 Shoulder rotation to internal and external in the supine position, while at the shoulder abduction and elbow flexion. The examiner will be standing beside participants and measure the range of motion using bubble inclinometer

#### 4. Cervical and shoulder postures

The photogrammetry assessments will be performed with the instruction of the participants standing facing the marker wall with relaxed posture. All of the participants will be assessed with the same procedure.



#### 5. Muscle strength

The hand held dynamometer will be used as a quantitative measurement tools for the muscle strength in kg/F. The examiner will measure the shoulder muscle for both groups.



##### 5.1 Supraspinatus muscle

The examiner will be placing the dynamometer perpendicular to your arms, the test will be performed in the supine position. You will be instructed to raise the arms (abduction) with 45° external rotation and try to push the dynamometer as hard as you can.

##### 5.2 Infraspinatus muscle

The examiner will be placing the dynamometer perpendicular with your arms, the test will be performed in the supine position. You will be instructed to externally rotate the arms in the 0° shoulder abduction with 90° elbow flexion and try to push the dynamometer as hard as you can.

##### 5.3 Subscapularis muscle



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The examiner will be placing the dynamometer perpendicular with your arms, the test will be performed in the supine position. You will be instructed to internally rotate the arms in the 90° shoulder abduction with 90° elbow flexion and try to push the dynamometer as hard as you can.

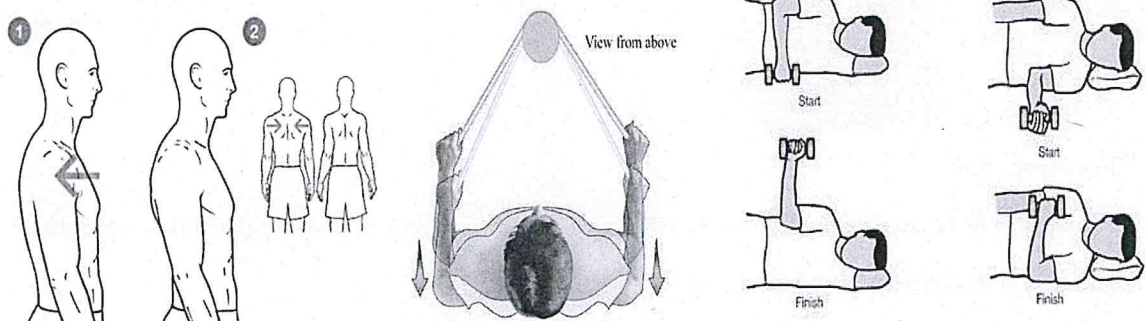
#### 5.4 Teres minor muscle

The examiner will be placing the dynamometer perpendicular with your arms, the test will be performed in the supine position. You will be instructed to externally rotate the arms in the 90° shoulder abduction with 90° elbow flexion and try to push the dynamometer as hard as you can.

#### 6. Shoulder function

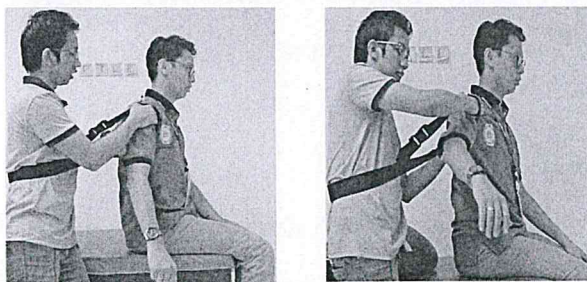
The examiner will explain each item in the shoulder pain and disability index, how to score the condition, and how to measure the total score. The participants will be asked to fill in the questionnaire before the treatment.

#### 7. Physical therapy treatment



Physical therapist (E) will give the intervention based on the participant condition related to the results of physical examination. The intervention will be tailor made to each participant, the intervention includes stretching, passive joint mobilization, and postural correction exercise. The physical therapy session will be taking 45 to 60 minutes and you can make an appointment to the researcher for the schedule.

#### 8. Mobilization with movement



Physical therapist (S) will give the mobilization with movement. The physical therapist will perform posterior lateral glide, therapeutic belt will be used and the therapist will ask you to move in the specific pain free range of motion. The intervention will be taking 10 to 15 minutes.



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This study has no payment and you do not need to pay for any expenses in the study. Participants in this research will have appointments for 12 sessions (3 times/week). If the participants meet criteria, they will participate in this research project and follow the research procedure.

If any unanticipated event occurs during the assessment or the treatment, you have to inform the researcher as soon as possible. If you have questions about the research protocol, you can contact Mr. Ferian Nugraha (+62) 81220355498 24 hours day. According to medical standards, person who is responsible for unanticipated events from research is Mr. Ferian Nugraha and will be responsible for all medical expenses during the protocols.

If relevant information arises about benefits and risks of the research project, the researcher will inform the subject immediately and without concealment.

Participant private information will be kept confidential, it will not be individually disclosed, but will be disseminated as part of the overall results. Individual information, however, may be examined by groups of persons e.g. funding organizations, the ethics committee.

Participant have the right to withdraw from the project at any time without prior notice. And the refusal to participate or the withdrawal from the research project will not at all affect the proper service that the subject will receive.

On the condition that you are not treated as indicated in this information sheet, you can contact the Chair of Mahidol University Central Institutional Review Board (MU-CIRB) at the office of MU-CIRB, Research Administration Division, Office of the President, Mahidol University, Tel 66-2-8496224-5, Fax 66-2-8496224. I thoroughly read the details in this document.

Signature..... Participant

(.....)

Date...../...../.....







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## Informed Consent Form

Date...../...../.....

My name is....., aged.....years, address.....  
road/street.....sub-district/tambon.....district/amphur.....  
Province.....postal code.....tel.number.....

I hereby express my consent to participate as a subject in the research project entitled *mobilization with movement as an additional treatment to conventional physical therapy in individuals with shoulder impingement syndrome*.

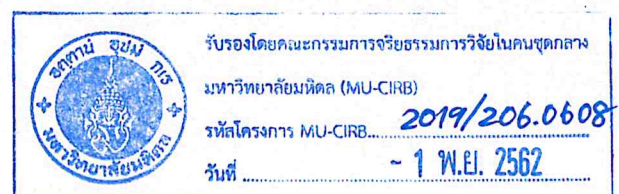
In so doing, I am informed of the research project's origin and purposes; its procedural details to carry out or to be carried out; its expected benefits and risks that may occur to the participants, including methods to prevent and handle harmful consequences; and remuneration, and expense. I thoroughly read the detailed statements in the information sheet given to research participants. I was also given explanations and my questions were answered by the head of the research project without anything concealed hidden.

I therefore consent to participate as a subject in this research project.

I am aware of my right to further information concerning benefits and risks from the participation in the research project and my right to withdraw or refrain from the participation anytime without any consequence on the service or health care I am to receive in the future. I consent to the researchers' use of my private information obtained in this research, but do not consent to an individual disclosure of private information. The information must be presented as part of the research results as a whole.

If I feel unwell and discomfort during research procedure, I will inform the researcher as soon as possible. On the condition that I have any questions about the research procedures, or on the condition that I suffer from an undesirable side effect from this research, I can contact Mr. Ferian Nugraha, phone number (+62) 81220355498 who is 24-hour ready for contact by phone.

On the condition that I am not treated as indicated in the information sheet distributed to participants, I can contact the Chair of Mahidol University Central Institutional Review Board, (MU-CIRB) at the office of the President, Mahidol University, Tel 66-2-8496224-5, Fax 66-2-849-6224.



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I thoroughly understand the statements in the information sheet for the research subjects and in this consent form. I thereby give my signature.

Signature .....

(.....)

Participants /Proxy

Date...../...../.....

Signature .....

(.....)

Principal Investigator/Representative

Date ...../...../.....

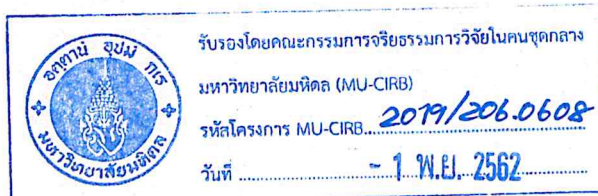
In case that the participant is illiterate, the one who read this document for the participant is (Mr./Mrs./Ms.....), who gives his/her signature as a witness.

Signature.....

(.....)

Impartial Witness

Date...../...../.....





Date \_\_\_\_\_

Code \_\_\_\_\_

Age \_\_\_\_\_ years

Gender : ☐ Male ☐ FemaleInvolved : ☐ Left ☐ Right ☐ BothDominant : ☐ Left ☐ Right

Occupation \_\_\_\_\_ Work duty \_\_\_\_\_

Sport Activity Type \_\_\_\_\_ Frequency \_\_\_\_/week

Overhead Activity \_\_\_\_\_ Frequency \_\_\_\_/week

**SUBJECTIVE:** Pain Onset \_\_\_\_\_ Pain Location \_\_\_\_\_

Pain increased during \_\_\_\_\_ decreased during \_\_\_\_\_

History \_\_\_\_\_

ADLs: \_\_\_\_\_ Tuck in shirt/bra \_\_\_\_\_ Fix hair \_\_\_\_\_

Dressing \_\_\_\_\_ Cleaning \_\_\_\_\_ Bathing \_\_\_\_\_

**OBJECTIVE:** Forward head posture ☐ Scapular winging/shrugging/tipping: R / LSpecial Test: Neer ☐ R / L External rotation test ☐ R / L Empty Can ☐ R / LPainful arc ☐ R / L Sulcus sign ☐ R / L Drop arm ☐ R / LCapsular patter ☐ R / L Reverse humeroscapular rhythm ☐ R / L

Joint play movement: \_\_\_\_\_

Glenohumeral Imbalance ☐ R / LDeltoid ☐ Supraspinatus ☐ Infraspinatus ☐ Subscapularis ☐ Teres minor ☐

Scapulothoracic Imbalance ☐ R / LUpper trapezius ☐ Middle trapezius ☐ Lower trapezius ☐ Serratus anterior ☐

Kinesio-pathologic problem \_\_\_\_\_

Posture CVA \_\_\_\_\_ ° SSP \_\_\_\_\_ ° Pain Score \_\_\_\_\_ SPADI Score \_\_\_\_\_

ROM: Shoulder ABD \_\_\_\_\_ ° ER \_\_\_\_\_ ° IR \_\_\_\_\_ °

Strength: Supraspinatus \_\_\_\_\_ kg/F Infraspinatus \_\_\_\_\_ kg/F

Postural correction exercise

No	Type of exercise	Y/N
1	Scapular Retraction	
2	Y to I Exercise	
3	Shoulder retraction pull back with elastic resistant	
4	Seated full can	
5	Side lying external rotation	
6	Sitting stretch	
7	Wall corner stretch	
8	Arm adducted across body	



## Appendix

Klinik Fisioterapi

Shoulder Pain and Disability Index (SPADI)



Code  Date:

Please check the box that best represents your experience during the last week attributed to your shoulder problem.

**Pain Scale: How severe is your pain?**

Check the number that best describes your pain where: 0 = no pain and 10 = the worst pain imaginable.

	0	1	2	3	4	5	6	7	8	9	10
At its worst?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
When lying on the involved side?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Reaching for something on a high shelf?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Touching the back of your neck?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Pushing with the involved arm?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Total Pain Score: \_\_\_\_/50 x 100 = \_\_\_\_%

(Note: if a person does not answer all questions divide by the total possible score, eg. If 1 question missed, divide by 40)

**Disability Scale: How much difficulty do you have?**

Circle the number that best describes your pain where: 0 = no difficulty and 10 = so difficult it requires help.

	0	1	2	3	4	5	6	7	8	9	10
Washing your hair?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Washing your back?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Putting on an undershirt or jumper?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Putting on a shirt that buttons down in front?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Putting on your pants?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Placing an object on a high shelf?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Carrying a heavy object of 10 pounds (4.5 kilograms)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Removing something from your back pocket?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

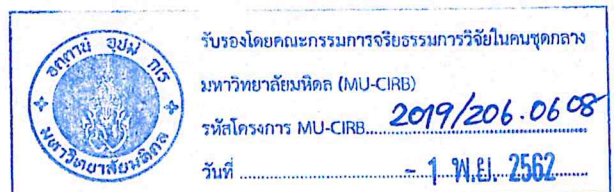
Total Disability Score: \_\_\_\_/80 x 100 = \_\_\_\_%

(Note: if a person does not answer all questions divide by the total possible score, eg. If 1 question missed, divide by 70)

Office Use Only: Total SPADI Score: \_\_\_\_/130 points (MCID: 10 points; No Disability = 0)

Visits: \_\_\_\_ ☐ Discharged ☐ Male ☐ Female Age: \_\_\_\_ Referred By: \_\_\_\_

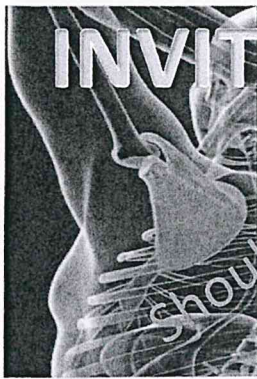
PT Initials: \_\_\_\_ ICD-9 Code: \_\_\_\_







# INVITATION



Shoulder Pain  
Come to ...  
Physiotherapy



Mahidol University  
*Wisdom of the Land*

## Entitled Project:

**MOBILIZATION WITH MOVEMENT  
AS AN ADDITIONAL TREATMENT  
TO CONVENTIONAL PHYSICAL THERAPY  
IN INDIVIDUALS WITH  
SHOULDER IMPINGEMENT SYNDROME**

### You are:

- \* 20 – 60 years old
- \* Anterior and/or lateral shoulder pain (between acromion and glenoid)
- \* Score 4-7 cm on the 0-10 visual analogue scale
- \* Shoulder pain (>3 months)
- \* Positive 2 of 3 impingement test
- \* Negative at least one of rotator test
- \* No history of surgery on shoulder, neck and upper back
- \* No major trauma on the shoulder of the affected side
- \* No passive limitation due to adhesive capsulitis
- \* No history of neurological conditions (stroke, brachial plexus injury)
- \* No rheumatological disease
- \* No bilateral shoulder impingement
- \* Negative of scapular retraction test

### Benefit:

- Physiotherapy Treatment
- Information about your condition
- Information of self-exercise and prevention
- Measurement of shoulder function and posture



### Physiotherapy Clinic

Esaunggul University gr 1  
Arjuna Utara street Number  
9, Duri Kepa, District Kb.  
Jeruk, Province Jakarta  
Barat 11510



Contact: Ferian Nugraha



feypqbd



feypqbd@yahoo.com



(+62)81-220-355-498



รับรองโดยคณะกรรมการจริยธรรมการวิจัยในคนชุดกลาง

มหาวิทยาลัยมหิดล (MU-CIRB)

รหัสโครงการ MU-CIRB 2019/206.0608

วันที่ - 1 พ.ย. 2562

