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

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2.1 Experience and Training in Human Research ethics

☑corporate in post-graduate curriculum

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4. **Background & Rationale**

There was high incidence of shoulder pain in population with occupationally related to repetitive overhead position or work in the awkward position. This was evident especially when involving with sustained shoulder rotation position, lifting heavy loads or using vibratory tools. The shoulder pain was reported to be the third most common problem reported on musculoskeletal disorder after back and knee pain, approximately 16% to 21% of the population. Its prevalence in persons 60 years and older is 34%.

Based on the literature review, shoulder function is related to the postural problem and scapulo-humeral kinematics. The main mechanism of shoulder impingement syndrome is related to the narrowing of subacromial space which leads to a compressive and shear forces to the structures below that space.

The common intervention of the shoulder impingement syndrome is conventional physical therapy that consists of stretching, modality, education and passive mobilization. Manual therapy and exercises are necessary to treat the patient with the shoulder impingement syndrome. Specific exercises focus on the biomechanical aspect such as postural correction exercise.

The current manual therapy technique, the mobilization with movement which is posterolateral glide using the treatment belt, might help the physical therapist give more stable pull action, while the other hand on the scapula to assist the movement and give a direction of proper biomechanics. Some studies showed different results and limitation of the method of applying the mobilization with movement technique. Previous studies investigated the effects of mobilization with movement in the patients with shoulder dysfunction and/or shoulder impingement syndrome. A case report conducted by DeSantis and Hasson applied the mobilization with movement, other manual therapy, modalities, and therapeutic exercise to a male patient with shoulder impingement syndrome. The results showed that the mobilization with movement may be an effective treatment intervention for the patient.

Another study conducted by Tey et al evaluated the immediate effects of mobilization with on shoulder range of motion and pressure pain threshold in people with painful limitation of shoulder movement. The results showed that the mobilization with movement reduced pain and improved range of motion.

Moreover, a randomized controlled trial conducted by Delgado et al showed that the short-term effects of mobilization with movement was effective to decrease pain intensity and increase shoulder range of motion. However, Guimarães et al compared the immediate effects of mobilization with movement with sham technique on shoulder range of motion, muscle strength and function in the patients with shoulder impingement syndrome. The results showed that the mobilization with movement was no more effective than sham technique in improving shoulder external rotation and abduction, pain and function. These different results lead this study to compare the effects of adding mobilization with movement on the conventional treatment.

Several outcomes have been commonly investigated in the shoulder impingement syndrome-related previous research, for example, pain intensity, shoulder range of motion, muscle strength, and shoulder function. The pain intensity was usually assessed using the visual analogue scale. The shoulder range of motion was assessed using a bubble inclinometer, the shoulder muscle strength, and function were investigated using hand held dynamometer (HHD) and a self-reported questionnaire e.g. shoulder pain and disability index, respectively.

Since the postural correction exercise is commonly applied in the conventional physical therapy, neck and shoulder posture can be assessed using photogrammetry measurement. The neck and shoulder posture can be generally assessed by measuring the craniovertebral angle and shoulder angles, respectively.

5. Objective of the Study

5.1 General Objective

To compare the effects of 4-week conventional physical therapy treatment (conventional group) with the conventional program and the addition of the mobilization with movement (mobilization with movement group) on pain intensity, shoulder , cervical and shoulder postures, shoulder muscle strength, and shoulder function in the patients with shoulder impingement syndrome.

5.2 Specific Objective

1) To compare the pain intensity between the conventional and the mobilization with movement groups at baseline, after intervention at week 1, week 2, week 3, and week 4.

2) To compare the shoulder range of motion between the conventional and the mobilization with movement groups at baseline, after intervention at week 1, week 2, week 3, and week 4.

3) To compare the craniovertebral angle and shoulder angles between the conventional and the mobilization with movement groups at baseline, after intervention at week 2, and week 4.

4) To compare the shoulder muscle strength between the conventional and the mobilization with movement groups at baseline, after intervention at week 2, and week 4.

5) To compare the shoulder pain and disability index scores between the conventional and the mobilization with movement groups at baseline, after intervention at week 2, and week 4.

6. Research Plan

6.1 Type of Research

☑Biomedical / Clinical Research

☑ Procedural / intervention

___Conventional physical therapy,_Postural correction_exercise,_&_Mobilization_with_movement_____

6.2 Subject selection and allocation

6.2.1 Inclusion criteria

1) Age 20-60 years old
2) Anterior and/or lateral shoulder pain (between acromion and glenoid)
3) Score 4-7 cm on the 0-10 visual analogue scale (VAS)

4) Experienced shoulder pain at least 3 months

5) Positive combination 2 of 3 impingement tests (Painful arc, Empty can, and External rotation test)

6) Negative at least one of rotator cuff tear test (Isometric infraspinatus and subscapularis muscle tests)

There is no different between dominant hand and non-dominant in case of functional assessment, because some of the SPADI question ask the function that required both hand activity and the severity of the involved hand). If the patient has bilateral shoulder impingement syndrome they will be excluded because if the patient had bilateral impingement syndrome, it will affect the scapular motion and scapulothoracal joint on the both sides.

6.2.2 Exclusion criteria

1) History of shoulder, cervical, or thoracic surgery
2) History of neurological conditions (stroke, brachial plexus injury)
3) Postural deformity and musculoskeletal condition that affect the shoulder movement
4) History of shoulder major trauma on the affected side (fracture, dislocation, tendon rupture and/or labral torn)
5) Having bilateral shoulder impingement syndrome
6) Recently using muscle relaxants, pain killer, or corticosteroid injection
7) Ligamentous laxity based on positive sulcus sign
8) Numbness or tingling in upper extremity
9) Systemic illness or widespread pain
10) Rheumatic disease
11) Having malfunction of rotator cuff muscle (e.g. cannot perform at all)
12) Having a passive limitation due to adhesive capsulitis
13) Positive of scapular retraction test

6.2.3 Withdrawal criteria (for individual participant)

1) Unwilling to follow the procedure
2) Unwilling to participate in this study
3) Unable to participate until the process complete
4) Participants with any uncomfortable condition can quit in any session

6.2.4 Termination criteria (for the whole research project)

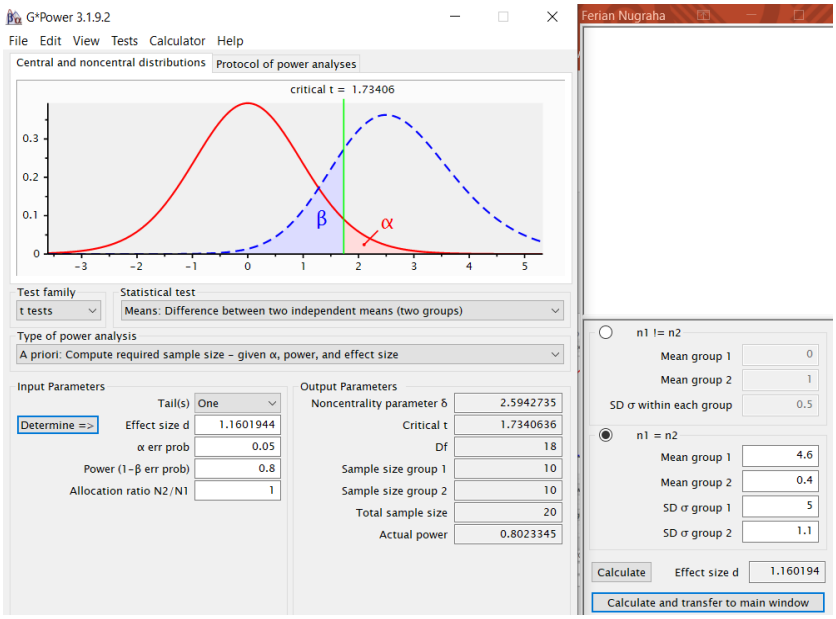
1) The methodology is harmful to the participants more than 20 % of participants
2) Researcher cannot find the patients to meet the criteria in this research

6.2.5 Subject allocation (for more than 1 arm study)

The participants will be allocated into 2 groups according to age allocation and will be randomized by sealed envelopes.

6.3 Sample size

Sample size calculation will be performed using formula for the test of different between 2 independent means.



According to the G*power 3.1.9.2 program calculation, the total of this study equal 20 subjects. Based on the previous study using the shoulder pain and disability index to measure the shoulder function, in the study of comparing the immediate effects of mobilization with movement and sham techniques. The mean (standard deviation) between group post-intervention for the mobilization with movement group was 4.6 (5.0) and that for the sham group was 0.4 (1.1) (12). In this proposed study, we need equal number of participants per group; therefore, the drop out calculation of 20% from the total participants (n = 1/1-20%). Therefore, after the ethical approval, the researcher will collect data from 24 shoulder impingement syndrome patients (12 subjects on the conventional group and 12 subjects on the mobilization with movement group).

6.4 Replacement procedure if subject withdraw from the study

☑not necessary because the number of subjects calculated already include drop out number

7. Study procedures

Assessment

1. Scapulohumeral rhythm on shoulder abduction: there should be no reverse scapulohumeral rhythm, scapular tracking will be assessed for defining the scapular motion abnormalities and glenoid rotation on the scapular abduction. If there is a presence of scapular abnormalities the patients will be assessed on the point 2 and 3.

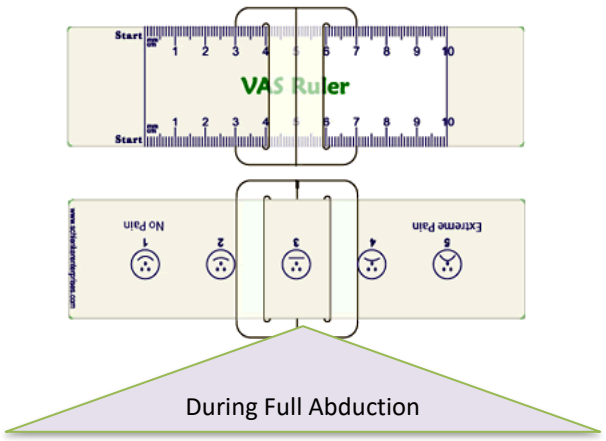
2. Scapular dyskinesis test of McClure: active shoulder flexion and abduction using 1 kg dumbbells on both hand flexion and abduction while the therapist will assess the scapular motion from behind, the result of scapular winging, shrugging or tipping will define the conventional treatment for each patient.
3. Scapula assistance test: during shoulder abduction - elevation the therapist will assist the scapular movement at the inferior angle of the shoulder blade to see which stabilizer muscles have weakness.
4. Painful arc: the pain is occurring during 60-120 degrees of shoulder abduction – elevation.
5. External rotation test: known as Infraspinatus test, the patient will perform isometric contraction of shoulder external rotation in neutral shoulder abduction.
6. Empty can test: during 90 degrees of shoulder abduction and maximally internal rotation, the test is isometric abduction while the therapist hand will resist the patient's hand.
7. Drop arm test: during 90 degrees of shoulder abduction, the therapist hand will support the patient's elbow. Next, the therapist will move the support and ask the patient to lowering the hand slowly to test the eccentric performance.
8. Lift off test: known as Subscapularis test, the patients will place their hand resting in middle lumbar region and perform the extension or lift the hand and reach to the back as far as they can.
9. Scapular retraction test: the therapist will support the scapula to retract while the will patient performs the empty can test. If the pain is reduced while performing the test, it means that the source of the pain is from the weakness of scapular stabilizer muscle only.
10. Capsulitis adhesive: the pain characteristic is stiff and painful. The patient has external rotation deficit in zero position at least 50% reduced or less than 30 degrees and loss of range of motion greater than 25% in at least 2 planes (reverse humeroscapular rhythm at shoulder abduction and flexion).

    Positive of the test from the points 7 to 10 will be excluded because of the pain may occur from others region or not only from the subacromial region.

The therapist (AH) and (FN) will examine all the participants. Both of them are professional physical therapy practitioners at Esa Unggul physical therapy clinic with more than 4 years working experience. The therapist (AH) is certified upper and lower orthopedic manual physical therapy (physical therapy advancement seminars APTA) and the therapist (FN) is certified A and B Mulligan practitioner.

Research Equipment

1. Visual analogue scale



The pain will be measured during the shoulder abduction because the provocation of the impinged structure is high on the range of 60 to 120 degrees. The therapist will ask the patient to rate the pain on the VAS scale from 0 to 10.

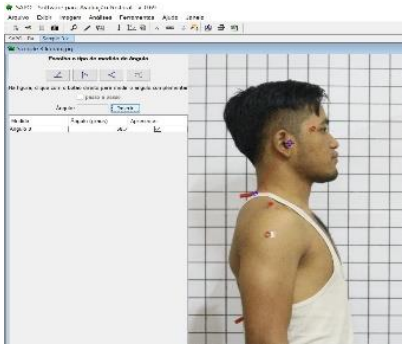
2. Bubble inclinometer (Baseline. USA)

The therapist will put the inclinometer on the upper arm and set the marker to the edge of the bubble. The patient will perform shoulder abduction on standing position, internal rotation and external rotation on the supine position with 90 degrees shoulder abduction and elbow flexion.

3. Canon EOS M 10 (Canon. Japan) and tripod

The camera and tripod will be set up on the postural assessment room, the range of the tripod and camera will be set on maximum zoom and 4 meters from the patient. The height of the tripod will be adjusted depending on the patient's height ranging from 130 to 150 cm.

4. Postural assessment software (SAPO ver. 0.69 BMC Brazil)

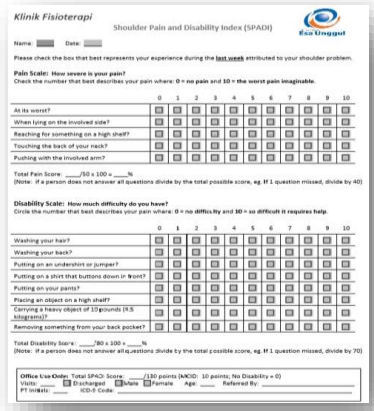


The therapist will ask the patient to stand beside the grid line and face the marker on the wall. The results of the photograph will be inputted to the software and the examiner will mark the degree of cervical angle and sagittal shoulder posture.

5. Hand held dynamometer (Micro FET2, Hoggan. USA)

The therapist will place the dynamometer on the arm and ask the patient to push against the therapist's hand to test the isometric contraction prior to each muscle. The test is performed to measure abductor and external rotator muscles.

6. Shoulder pain and disability index (SPADI) questionnaire


Klinik Fisioterapi

Shoulder Pain and Disability Index (SPADI)

Eka Unggul

Name: 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?	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
When lying on the involved side?	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Reaching for something on a high shelf?	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Touching the back of your neck?	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Pushing with the involved arm?	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

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?	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Washing your back?	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Putting on an undershirt or jumper?	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Putting on a shirt that buttons down in front?	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Putting on your pants?	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Placing an object on a high shelf?	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Carrying a heavy object of 10 pounds (4.5 kilograms)?	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Removing something from your back pocket?	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

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: ____

The therapist will ask the patient to rate the pain and shoulder disability on the SPADI questioner, the therapist will explain how to rate and measure the score. If the patient does not understand the question, the examiner will help until the patient can understand.

Intervention

1. Conventional physical therapy

In the conventional physical therapy, the procedure of intervention depends on the patient's condition (tailor made). After the physical examination every patient will be assessed based on the assessment list and will be treated based on the intervention that they needed. The conventional physical therapy includes muscle stretching, passive mobilization, postural correction exercise, home based exercise and education.

No	Exercise Purpose	Type of exercise	Dose
1	Proprioception and joint sense recognition	Scapular Retraction	Frequency: 3x/week, Intensity: 3 sets, Time: 6' contraction, 6' rest, Repetition: 10x
2	Middle trapezius, lower trapezius & serratus anterior	Y to I Exercise	Frequency: 3x/week, Intensity: 2 sets, Time: 20' contraction, 10' rest, Repetition: 8x

3	Co-contraction of shoulder muscle	Shoulder retraction pull back with elastic resistant	Frequency: 3x/week, Intensity: 2 sets, Time: 20' contraction, 10' rest, Repetition: 8x
4	Supraspinatus	Seated full can	Frequency: 3x/week, Intensity: 2 sets, Weight: 60-80% 10RM, 1:1 rest interval, Repetition: 8x
5	Teres minor and infraspinatus	Side lying external rotation	Frequency: 3x/week, Intensity: 2 sets, Weight: 60-80% 10RM, 1:1 rest interval, Repetition: 8x
6	Upper trapezius stretch	Sitting stretch	Frequency: 3x/day, Intensity: 2 sets, Time: 30'stretch, Repetition: 3x
7	Pectoralis minor stretch	Wall corner stretch	Frequency: 3x/day, Intensity: 2 sets, Time: 30'stretch, Repetition: 3x
8	Posterior capsule stretch	Arm adducted across body	Frequency: 3x/day, Intensity: 2 sets, Time: 30'stretch, Repetition: 3x

Each patient will exercise based on the number in the aforementioned Table which is programmed based on the examination.

The therapist (E) who will give the conventional physical therapy is a professional practitioner at Esa unggul physical therapy clinic Jakarta with more than 5 years working experience. He is certified level 1 sport physical therapist (APA) and a former official physical therapist for Indonesia national team (basketball 3x3, mini soccer, football and wheelchair basketball Paralympic).

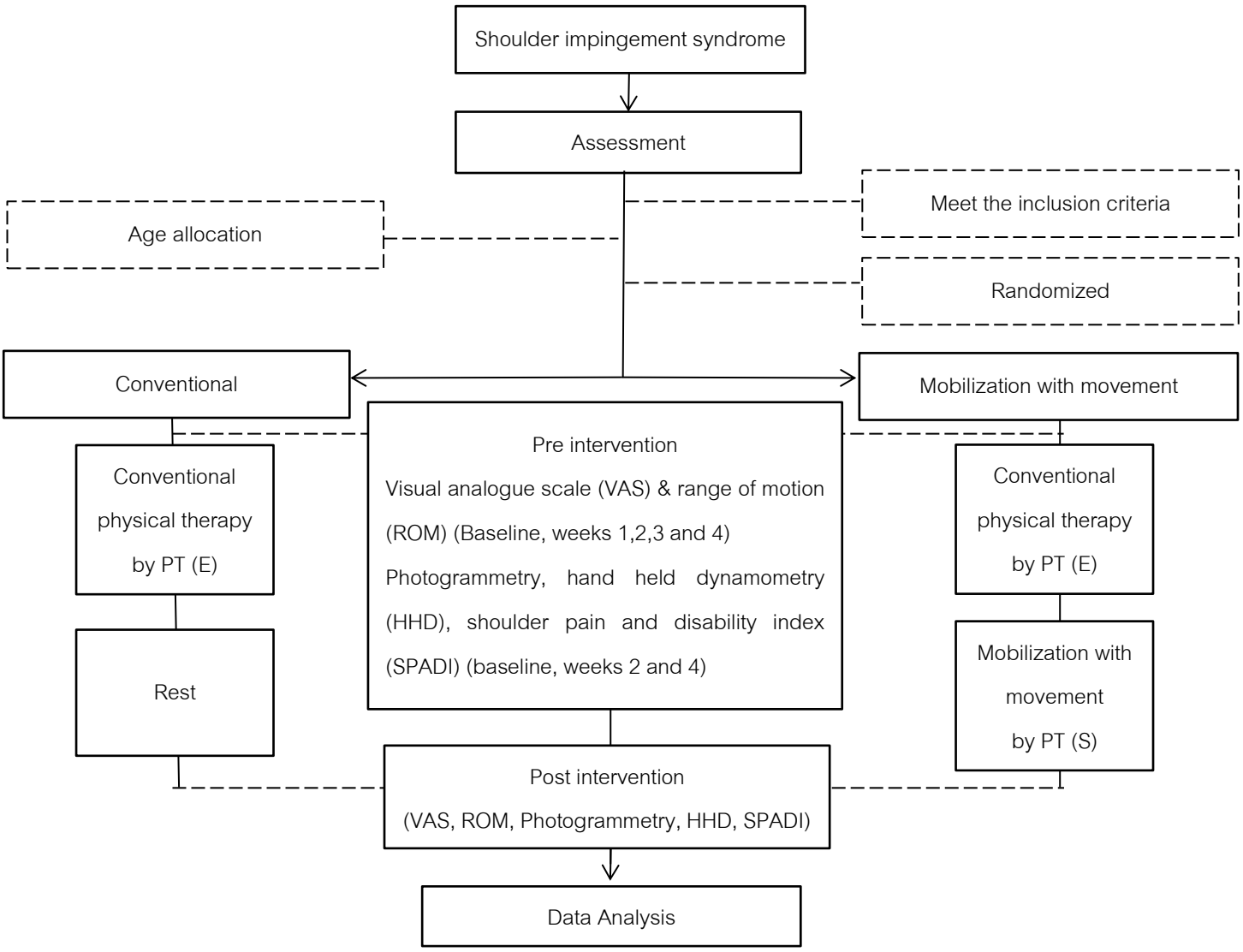
2. Mobilization with movement


The physical therapist put the treatment belt on the anterior boarder of glenohumeral joint while the other hand is on the scapula. Mobilization with movement direction is posterolateral glide with active shoulder abduction in the pain free range of motion. The direction is changing simultaneously with the glenoid and scapular movement to make sure the glide of the glenoid close to the normal movement, and the therapist hand will assist the scapular

motion. Every patient will have the same amount of glide because the therapist will use the treatment belt to perform the glide. Therefore, the force will be adjusted by the body weight and performed by the same therapist. The place of treatment will be used in only one manual therapy room with the same bed and position.

The therapist (S) who will give the mobilization with movement is a professional practitioner at Esa unggul physical therapy clinic Jakarta with more than 40 years working experience. He is certified A and B Mulligan practitioner, (spine, upper, and lower extremity) certified orthopedic manual physical therapy (APTA) and has specialist of orthopedic musculoskeletal title from Indonesian Physical Therapy Association.

Flow chart of procedure



8. Data collection process

This study will recruit shoulder patients around Jakarta city, the age between 20 and 60 years. The patients with shoulder impingement syndrome will be recruited by online brochures and leaflets.

All eligible participants will receive clear explanation of purposes, procedure, advantages and possible risk of this study. Each participant will be asked to sign an informed consent after they understand and accept to participate in this study.

Based on the assessment form, the participant will be assessed by the examiner and researcher. The participants' age will be used to grouping the participants into the conventional or mobilization with movement group. The participant will be asked to rate their pain intensity using the visual analogue scale during the maximum shoulder abduction.

Shoulder range of motion will be assessed using the bubble inclinometer during shoulder abduction in the standing position, internal and external rotation in the supine position with 90° shoulder abduction and 90° elbow flexion. Cervical and shoulder with the instruction to the participants to stand in their relaxed posture will be recorded by photogrammetry. Muscle strength of shoulder abductors, external rotators and internal rotators will be assessed using the hand held dynamometer. The shoulder function will be recorded by the shoulder pain and disability index.

Conventional physical therapy

For the conventional group, PT (E), who has had certified level 1 sport physical therapy from Australian Physiotherapy Association and has had 5 years working experience, will treat the participants with the conventional and postural correction exercise. This therapist will be blinded by unknowing the group allocation. The participants will receive the conventional intervention, the postural correction exercise and 10 minutes rest. Then the outcome measures will be reassessed thereafter. The participants in the conventional group will receive conventional physical therapy including stretching, modality, ice, therapeutic exercise, passive mobilization, and postural correction exercise. The conventional physical therapy is adjustable or tailor made depending on the patient's specific conditions.

The therapeutic exercise has a wide variety of types and modes of exercises. The postural correction exercises consist of rotator cuff muscle strengthening with eccentric-concentric, scapular stabilization exercise, and postural awareness. In addition, these exercises include motor control therapeutic exercise for the relearn process and motor control of correct posture to change the participant's behaviour.

Mobilization with movement

For the mobilization with movement group, PT (S) will know the code to treat the participants using the conventional or mobilization with movement protocol. Moreover, this therapist will apply the mobilization with movement technique. The participants will receive the conventional intervention, the postural correction exercise and the

mobilization with movement. Then the outcome measures will be reassessed thereafter. The directions of mobilization with movement is posterolateral glide, when the participants raise their arm to perform shoulder abduction until the overhead movement. The therapist will place one hand on the participant's scapula to stabilize movement, while placing the thenar eminence of the other hand on the medial of humeral head. The treatment belt will be placed on the participant's shoulder on top of the PT (S)'s hand.

The therapist will provide sustained posterolateral and inferior glide while the participants will be asked to move the shoulder freely in the pain free angle. PT (S)'s hands will move along with the movement to sustain the glide along treatment plane with upward rotation of the scapula. The mobilization with movement dose will be 3 sets of 10 repetitions with rest interval 30 seconds between sets, twice a week for 4 weeks.

9. Outcome measurement/Data analysis

- **Primary outcome**

  Pain intensity (visual analogue scale)

  Shoulder function (shoulder pain and disability index)

- **Secondary outcome**

  (bubble inclinometer)

  Muscle strength (hand held dynamometer)

  Postural alignment (photogrammetry)

- Assessment of efficacy

The assessments that will be used in this study are standard, reliable and commonly used in the clinic. They have very low risk and are safe to be used in clinic. Moreover, the physical therapy intervention that will be used in this study are safe, proven by the previous study to treat the shoulder impingement syndrome and commonly used in the clinic.

- Assessment of safety

This study does not include any injection or invasive approach, or taking any medications and does not require any modification of patient treatment programs.

Before giving an informed consent, the participants will be asked whether they have any condition listed in exclusion criteria or any other conditions that may preclude participation in any aspect of the study.

The researcher will explain the procedure, purpose, advantages and possible risk of this study. The researcher will demonstrate each test prior to evaluation and will explain the procedures for each intervention. Moreover, the researcher will observe participants' feeling during assessment.

- Statistics to be used or process for data analysis

Data will be analysed by using SPSS version 23. The statistical significance level is set at p-value < 0.05.

- Shapiro-Wilk will be used to examine the distribution of the data
- Descriptive statistics for demographic data, mean and standard deviation for continuous, cumulative frequency for categorical and median for ordinal variables, will be calculated.
- Two-way mixed design ANOVA (two group x four time) for parametric data. If the data are significant the post hoc analysis will be performed using Bonferroni.
- Friedman test if the data are not normally distributed.