HMC RESEARCH PROTOCOL

Study Title:	**To develop and validate a structured exercise protocol and to assess its effectiveness in patients with sub acromial impingement syndrome**
Principal Investigator:	Reshma Shashank Gurav Physiotherapy Specialist Female Outpatient Department –Bin Omran Qatar Rehabilitation Institute

Contents

1. Synopsis

Shoulder impingement syndrome (SIS) is responsible for 44% to 60% of medical consultations related to shoulder pain with an approximate prevalence of 70-200 per 1000 adults, which implies a remarkable use of health care resources. The cost for society is high and patients with shoulder disorders account for 20% of all disability due to musculoskeletal disorder. The underlying mechanisms are thought to include inflammation, degeneration of the tendons or bursa, dysfunctional scapulothoracic and glenohumeral mechanics, debilitated scapular musculature, joint capsule irregularities, postural abnormalities of the neck and shoulder, and morphological abnormalities of the relevant skeletal elements.

There is a need for well-designed structured exercise program in detail considering content, dosage and progression to guide treatment for patients with sub acromial pain. The purpose of this study is to develop and validate a structured exercise protocol and to assess its effectiveness in patients with sub-acromial impingement syndrome. Through the extensive literature review, the exercise program would be proposed. We will develop and evaluate a structured exercise programs for sub acromial impingement syndrome using an expert consensus Delphi-based survey technique. A randomized controlled trial will be conducted. Group A (Experimental Group) will receive structured exercises for twelve weeks and Group B (control group) will receive conventional exercise program for 12 weeks. Evaluation of the participant will be done at the baseline using Constant Murley Score, shoulder pain and disability Index (SPADI). Shoulder range of motion, shoulder muscles extensibility will be assessed and scapulothoracic ratio will be calculated and documented. T-FAST test will be conducted to score the patients functional performance. Assessment will be done at baseline, 3, 6, 9, and 12 weeks in both the groups. At the end of the study the data will be collected, coded and tabulated using descriptive and inferential statistics.

2. Abbreviations and Acronyms

1. Shoulder impingement syndrome (SIS): The inflammation and irritation of the rotator cuff tendons as they pass through the sub acromial space, resulting in pain, weakness, and reduced range of motion within the shoulder.

2. TIDieR: Template for intervention description and replication

3. Physiotherapeutic Exercises: - Exercise is a type of physical activity consisting of planned, structured, and repetitive bodily movement done to improve and/or maintain one or more components of physical fitness

4. SPADI: The Shoulder Pain and Disability Index is a self-administered questionnaire that consists of two dimensions, one for pain and the other for functional activities.

5. VAS: The visual analogue scale (0–10) is used to assess the patient's perceived pain intensity at rest, during arm activity and at night during the previous 24 hours at each follow-up.

6. TFast: Timed Functional Arm and Shoulder Test is a sensitive test to detect differences in functional performance between age groups, demonstrates adequate reliability, and feasibility in a symptomatic patient group

3. Introduction / Background

Shoulder pain is the second most common problem among the general population reporting musculoskeletal pain. Values between 6.9 to 26% have been reported for point prevalence and 7 to 67% for lifetime prevalence. The pain is often of long duration and only 50% of patients report recovery after 18 months. Shoulder impingement syndrome (SIS) is responsible for 44% to 60% of medical consultations related to shoulder pain with an approximate prevalence of 70-200 per 1000 adults, which implies a remarkable use of health care resources. The cost for society is high and patients with shoulder disorders account for 20% of all disability due to musculoskeletal disorder[1].

Many terms have been used to describe sub acromial pain and pathology, including sub acromial impingement syndrome, rotator cuff tendinopathy, sub acromial bursitis, supraspinatus tendinosis, and rotator cuff syndrome. The variety in diagnostic labels reflects the uncertainty regarding the pathogenesis. The most common source of pain appears to be the sub acromial bursa and the rotator cuff with the diagnostic label sub acromial impingement syndrome (SIS). SIS refers to the pain that arises when structures in the sub acromial space (primarily the rotator cuff tendons and the sub acromial bursa) are impinged between the humeral head and the acromion mainly during arm activity above the horizontal plane [2]. This syndrome is a multifactorial condition where intrinsic and extrinsic mechanisms of rotator cuff pathology are the two main factors. The most common deficits are alterations in scapulothoracic kinematics, humeral head displacement within the glenoid cavity and increased elevation and retraction of the clavicle in the sternoclavicular joint during arm elevation.

The underlying mechanisms are thought to include inflammation and/or degeneration of the tendon(s) or bursa (e), dysfunctional scapulothoracic and glenohumeral mechanics, debilitated scapular and/or rotator cuff musculature, joint capsule irregularities, postural abnormalities of the neck and/or shoulder, and morphological abnormalities of the relevant skeletal elements [3]. Repetitive activity, particularly during overhead work, heavy lifting and forceful work, as well as working in an awkward posture increases the risk of shoulder disorders. During arm elevation, the scapula must externally rotate, upwardly torque and tilt posteriorly. Abnormal scapular kinematics is common in SIS and may include reduced upward rotation and external rotation of the scapula, along with increased elevation and retraction of the clavicle, although increased upward rotation of the scapula has also been noted[4].

Intrinsic factors affect tendon morphology and performance over time. These factors are influenced by genetic predisposition, age related changes, poor vascularity, biological alterations and mechanical properties where the physiological limit of the rotator cuff tendons are surpassed.

Extrinsic factors relate to anatomical structure and biomechanical alterations causing mechanical compression. Biomechanical alterations refer to the superior translation of humeral head and altered scapulohumeral kinematics, which is often caused by a weakness and imbalance of the rotator cuff musculature, and/or tendons opposing superiorly directed shifts as well as postural dysfunction. This can present as external impingement with narrowing of the sub acromial space or internal impingement within the glenohumeral joint space[4].

Alterations in shoulder kinematics are often observed among patients with SIS. Postural dysfunction relating to increased flexion and kyphosis of the thoracic spine cause alignment impairments which interfere with shoulder kinematics. These kinematic alterations contribute to narrowing of the sub acromial space (external impingement) which can affect biceps tendons, rotator cuff tendons, sub acromial bursa and sub tendinous bursa increasing the risk of joint inflammation and tears[3].

Considering all these biomechanical alterations, exercise therapy remains principal intervention in the management of sub acromial shoulder pain. Exercise therapy is always prioritized as the primary treatment. Physiotherapists often tailor rehabilitation programs to correct movement deficits, postural dysfunction and or muscles weakness/imbalance to improve characteristics of the sub acromial space.

Conclusions from various systematic reviews suggest that physiotherapy interventions, combining different methods or techniques like manual therapy, electrotherapy that seems to be of additional benefit. Although there is evidence to suggest exercise interventions can reduce shoulder impingement symptoms, there is minimal evidence of these interventions changing movement patterns of the scapula.

Ludewig and Braman also highlighted the need to link exercise regimes with changes in scapular movement patterns and regaining motor control. The scapula plays several key roles to optimize the function of the shoulder, providing a position of support and a motion for stability. Its position facilitates optimal muscle activation and strength development, and force and energy transfer through the kinetic chain, while its dynamic motion maximizes glenohumeral (G-H) concavity/compression kinematics and G-H stability, maximizes G-H range of motion, and minimizes humeral impingement. Studies have accurately documented the composite 3-dimensional scapular motions necessary to optimize the roles[1].

Numerous systematic reviews have been undertaken in relation to the various plausible interventions including exercise and multimodal physiotherapy but many are emphasizing on strengthening exercise program [5]. According to the literature review, the mainstay of exercise program includes phase wise strength and endurance program. Whereas considering the role of scapulothoracic joint, motor control in initial phase of sub acromial impingement has the priority. Several studies have reported aberrant scapular muscle activities in patients with

subacromial pain. Correction of scapular alignment with respect to scapulothoracic and glenohumeral mechanism with diagnosing the cause and identifying the source or affected structure is of utmost importance [6].

Need of the Study

Recent systematic review and meta-analysis conducted by Louis Pieter and Jeremy Lewis in 2020 concluded that continued research is needed to more fully understand the uncertainty around the optimal type, dose, and duration of exercise for sub-acromial shoulder pain.

All the meta-analysis conducted conclude that strengthening and endurance exercises are recommended but the type of exercises are not mentioned and not much emphasis on regaining scapular motor control.

Thus, nearly all current systematic reviews emphasize the need for more high quality trials of physiotherapy interventions to optimize the dosimetry of exercise program.

There is a need for well-designed structured exercise program in detail considering content, dosage and progression to guide treatment for patients with sub acromial pain. This demands developing a specific guidance on how exercise interventions should be reported in clinical trials depending on what structure is affected in intrinsic and extrinsic mechanisms of subacromial impingement syndrome.

The term conventional physiotherapy is uninterpretable and inconclusive especially because there is presumption of how exactly the exercise program is formed. Many of the exercise program do not provide adequate information of what and why interventions are used. There are many varieties of exercises with different rationale and techniques. Hence, it is mandatory to have an adequate description of techniques making up the intervention and rationale for dosage is essential i.e. the number of sessions, intensity, and duration of intervention as per the TIDieR checklist (Template for Intervention description and replication).

Involvement of shoulder rehabilitation experts in developing the template through an international Delphi consensus project will accelerate this project.

Structured exercise regime for SIS would consist of exercises based on movement dysfunctions and biomechanical derangements commonly seen in patients with impingement. These patients tend to have anterior tipping and downward rotation of scapula along with internally rotated humeral head. Correction of the biomechanical faults would off load the sub acromial space and reduce the pain. The technique used to correct the biomechanics is called "load modification or Shoulder symptom modification process" And involves 4 techniques:

1. Alterations to thoracic kyphosis
2. Scapular positioning techniques
3. Humeral head positioning procedures
4. Pain and symptom neuromodulation procedure.

Exercise protocol based on these 4 categories will help produce a better treatment outcome as compared to conventional Physiotherapy treatment.

If a standardized exercise program based on latest evidence designed to enable implementation into clinical practice is proved effective, the need for surgery might decrease and it will help the patients to regain the shoulder functions and improve the physical activities as well as quality of life.

Evaluation and implementation of physical activity and exercise research would be greatly facilitated if exercise programs and their components were comprehensively reported in clinical trials in a standardized way.

The proposed exercise program will provide explicit data about whether exercises are generic or individualized, the type of exercise equipment used, the exercise starting position and the program starting point, the degree of load or resistance, rules for exercise progression, motivation and adherence strategies, and exercise duration, repetitions, sets and sequence.

4. Objectives

Research Question

Is there a difference in the effectiveness of structured exercise program as compared to conventional exercise program on pain, range of motion and functions in patients with sub acromial impingement?

Hypothesis

Null Hypothesis (H0):

There will be no difference in the effectiveness of structured exercise program and conventional exercise program in the individuals with sub acromial pain.

Alternative Hypothesis (H1):

There will be significant difference in the effectiveness of structured exercise program and conventional exercise program in the individuals with sub acromial pain.

Aim and objectives

Aim- To develop and validate a structured exercise protocol and to assess its effectiveness in patients with sub-acromial impingement syndrome.

Objectives-

Phase 1:

1. To develop and validate a structured exercise program

Phase 2:

Primary Objectives: -

1. To evaluate efficacy of structured exercises on pain, range of motion and shoulder functions using Constant Murley score and Shoulder Pain and Disability Index (SPADI) and functional performance using timed functional arm and shoulder test.

2. To compare the effectiveness of structured exercises and conventional exercises on pain, range of motion and shoulder functions using Constant Murley score and Shoulder Pain and Disability Index (SPADI) and functional performance in patients with sub acromial impingement syndrome.

5. Indicate if this is a retrospective data review

This is a prospective study

6. Study Methodology

Objective 1: Development of a structured exercise program in patients with sub acromial impingement syndrome.

1. Through the extensive literature review, the exercise program would be proposed as per the rationale of altered biomechanics and structures affected in sub acromial impingement syndrome.

2. The structured exercises program will be developed in systematic way to describe intervention, inclusive of rationale (why); materials that were used (what); procedures (what); how, where, when, how much, and by whom training will be provided, how it will be tailored and modified and how well planned it will be.

3.Structured exercise program will be formed as per the guidelines of TIDieR items which will include the name of the intervention; intervention rationale for essential elements; intervention materials and details about how to access them; description of the intervention procedures; details of intervention providers; mode of delivery of intervention; location of intervention delivery and key infrastructure; details about the number, duration, intensity, and dose of intervention sessions; details of any intervention tailoring; any intervention modifications throughout the study; and details of intervention assessment, monitoring, and level achieved.

4. Exercise protocol based on following four categories will be proposed to correct the biomechanics as per "load modification or Shoulder symptom modification process"

1. Pain and symptom neuromodulation procedure.

2. Scapular positioning techniques

3. Humeral head positioning procedures

4. Alterations to thoracic kyphosis.

This intervention will be based on shoulder kinetic control, load modification exercises and lumbopelvic stabilization with core stability exercises which is not a part of conventional exercise program for shoulder impingement syndrome patients.

Retraining exercises for scapular control

1.	Dissociate flexion to 90°.	5-10 repetitions x2.
2.	Dissociate abduction to 90°+ rotation timing	5-10 repetitions x2
3.	Dissociate medial rotation – supine arm abducted 90°	5-10 repetitions x2
4.	Dissociate lateral rotation – standing arm by side	5-10 repetitions x2
5.	Dissociate extension to 15° + rotation timing	5-10 repetitions x2
6.	Dissociate lateral rotation – prone arm overhead (wrist lift)	5-10 repetitions x2
7.	Dissociate medial rotation – prone arm overhead (elbow lift).	5-10 repetitions x2
8.	Full range overhead movement – flexion and abduction	5-10 repetitions x2

The exercises to be performed at the PT clinic 2 times a week combined with home exercises twice daily.

Retraining exercise for glenohumeral control

1.	Dissociate lateral rotation – standing arm by side.	5-10 repetitions x2
2.	Dissociate medial rotation – supine arm abducted 90°.	5-10 repetitions x2
3.	Dissociate extension to 15°.	5-10 repetitions x2
4.	Dissociate lateral rotation – prone wrist lift.	5-10 repetitions x2
5.	Dissociate medial rotation – prone elbow lift.	5-10 repetitions x2

The exercises to be performed at the PT clinic 2 times a week combined with home exercises twice daily.

Hook-lying Stabilization Progression

1.	Neutral position	5-10 repetitions x2
2.	Hook-lying with Arm Movements	5-10 repetitions x2
3.	Bent Knee to Side	5-10 repetitions x2
4.	Heel Slides	5-10 repetitions x2
5.	Bent Knee Leg Lift (small steps)	5-10 repetitions x2
6.	Alternate Arm and Leg Marching	5-10 repetitions x2
7.	Curl-up	5-10 repetitions x2
8.	Curl-up with Rotation	5-10 repetitions x2

The exercises to be performed at the PT clinic 2 times a week combined with home exercises twice daily.

Hands and Knees Stabilization Progression

1.	Neutral Position	5-10 repetitions x2
2.	Rocking Forward and Backward	5-10 repetitions x2
3.	Arm Slide and Reach	5-10 repetitions x2
4.	Leg Slide and Reach	5-10 repetitions x2
5.	Opposite Arm and Leg Slide and Reach	5-10 repetitions x2

The exercises to be performed at the PT clinic 2 times a week combined with home

exercises twice daily.

Face-down Stabilization Progression

1.	Neutral Position	5-10 repetitions x2
2.	Face-down One-arm Lift	5-10 repetitions x2
3.	Face-down Knee Bend/Lift	5-10 repetitions x2
4.	Face-down Arm/Leg Lift	5-10 repetitions x2

The exercises to be performed at the PT clinic 2 times a week combined with home exercises twice daily.

Bridging Stabilization Progression

1.	Basic Bridge	5-10 repetitions x2
2.	Bridge with Arm Lift	5-10 repetitions x2
3.	Bridge with Leg Lift,	5-10 repetitions x2

The exercises to be performed at the PT clinic 2 times a week combined with home exercises twice daily.

The grid of exercise with dosimetry will be constructed as per the experts' opinion in first round of Delphi and will be finalized in further rounds by following TIDieR checklist (Template for Intervention description and replication).

Phase 2: The newly developed structured exercise protocol will be implemented in patients with subacromial impingement syndrome.

Random allocation of subjects who meet inclusion and exclusion criteria and give consent for the study will be allocated to either of the two groups by table of random sequence generation generated by Graph Pad.

Patients will be "randomized" into one of two treatment groups. Patients blinding is not needed, as they will be in either of the group.

- Patients will be put into a group by chance. Neither patients nor the researchers choose which group they will be in. Patients will have equal chance of being placed in a specific group.
- Allocation will be done by an independent person who is not aware of the aim and objectives of the study thus assigning participants into interventional group A and interventional group B.
- Co-investigator will do the follow up assessments hence blinding of principal investigator will be possible.

Group A (Experimental Group) will receive structured exercises for 12 weeks and
Group B (control group) will receive conventional exercise program for 12 weeks.
The treatment protocol will be given approximately for two days per week for twelve weeks. But the actual treatment frequency and duration after finalization of new protocol.
The treatment protocol will be participant specific and progression will be made according to the participant's performance.
Assessment will be done at baseline, 3, 6, 9, and 12 weeks in both the groups.

In the literature review, previous studies have mentioned feasible duration of approximately 12 weeks with twice or thrice sessions in a week. However, this will be finalized after development and validation of exercise program with consensus of experts.

The patient's treatment will continue even after12 weeks if needed.

Type of Study Design: An experimental study.

Sampling Method: Random allocation method

Study Setting: Musculoskeletal Physiotherapy OPD

Duration of study: 3 years

Calculation of sample size-

Phase 1:

Eight to ten experts in the field of shoulder rehabilitation with minimum 10 years of clinical experience will be recruited for Delphi method.

Pilot testing of structured exercise program: Pilot testing will be done on 8 patients in experimental group and 8 patients in control group.

Phase 2:

Sample size was determined using the estimates of mean and standard deviation values from literature.

Reference: Debashree Mitra, P.K Mitra et al. Effect of Specific Exercise Program and Conventional Exercise Protocol on Pain and Disability in Patients with Subacromial Impingement Syndrome. International Journal of Health Sciences and Research. 2019; 9 (8):132-139.

Using the formula

$$n = \frac{2\,(Z_\alpha + Z_\beta)^2\,[s]^2}{d^2}$$

Where Zα is the z variate of alpha error i.e. a constant with value 1.96, Zβ is the z variate of beta error i.e. a constant with value 0.84.

Minimally clinical difference was calculated by dividing the individual patient change score by the square root of the SEM. The RCI was considered to confer a true change when it is more than 1.96 (95 % confidence) (the *z*-score corresponding to the desired level of significance).

(Reference: Allen JC. Sample Size Calculation for Two Independent Groups: A Useful Rule of Thumb. Proceedings of Singapore Healthcare 2011:20(2);138-40)

Approximate estimates:

1. 80% power
2. Type I error to be 5%
3. Type II error to be 20%
4. True difference of atleast 0.31 units between the groups (SPADI)
5. Pooled standard deviation of 0.48

Substituting the values,

$$n = \frac{2\,(2.8)^2\,[0.48]^2}{(0.31)^2}$$

n = 37.31

Approximately 38 to 40 subjects / patients per group should complete the study at the endpoint follow up

For follow-up studies, to avoid loss by loss to follow up / attrition, kindly consider recruiting 5-25% more subjects so that even after attrition, we would be able to achieve the required minimum sample size.

Also taking into consideration the attrition to be 15%

n= N / (1-0.15)

n = 38

(1-0.05)

= 44.70

Approximately 45 subjects / patients per group need to be recruited in the present study

Assessment will be done at baseline, 3, 6, 9, and 12 weeks in both the groups, which will help to detect the changes in outcome measures at, frequent intervals.

Out of the five outcome measures,

- Constant Morley part A and SPADI are patient reported scales
- T Fast is functional test
- Constant Murley and Scapulothoracic measuresment are ROM assessments

15% attrition is considered while computing the sample size.

7. Study Population and Study Setting/ Location

Study Setting: Outpatient Physiotherapy Units- Orthopedics

Qatar Rehabilitation Institute

Inclusion Criteria

1. Age group between 18-60 years
2. Symptoms for more than three weeks
3. Main complaints in the gleno humeral joint region or the proximal arm
4. Presence of one of the following signs indicating SAIS: Neer impingement test, Hawkins-Kennedy impingement test, painful arc with active abduction or flexion.

Pain with one of the following resistance tests: external rotation, internal rotation, abduction

Exclusion Criteria

1. Severe pain; pain is > 7/10 on NRS (0 = no pain)
2. Shoulder surgery on affected shoulder
3. Traumatic shoulder dislocation/ fracture within the past 3 months
4. Previous rehabilitation for this episode of shoulder pain
5. Reproduction of shoulder pain with active or passive cervical motion
6. Systemic inflammatory joint disease
7. Global loss of passive shoulder ROM, indicative of adhesive capsulitis
8. Full-thickness rotator cuff tear
9. Incompetent adults
10. Subjects unable to consent
11. patients who are unfit to undergo the suggested exercises as per the protocol.

8. Study procedures

Phase 1: Development of a structured exercise program in patients with sub acromial pain

We will develop and evaluate a structured exercise programs for sub acromial impingement syndrome using an expert consensus with Delphi-based survey technique.

Modified Delphi technique

- Eight to ten experts in the field of Musculoskeletal physiotherapy with focus on shoulder rehabilitation with minimum 10 years of clinical experience will be recruited for Delphi method. Experts are defined as individuals involved in the conception, design, conduct, teaching or analysis of exercise interventions.
- Sixty percent experts will be from physiotherapy discipline and forty percent would be orthopedic surgeons. There are no laypersons.
- Experts who respond to pre-Delphi invitations will be chosen to participate in the first round.
- The participant information sheet will be provided to the experts and consent will be obtained after they are willing to participate.
- Experts will be provided the facility to complete it over several sessions and to allow reviewing their answers before final submission of their responses.
- In the first round, participants will be asked to rank the importance of items they will also be asked to provide recommendations regarding any additions and/or deletions to the list of proposed items and for any other comments/suggestions.

- Only those who complete round one will be invited to participate in round two. De-identified results comprising overall scores for each item and narrative summary of findings, comments and suggestions will be sent to each panel member after the first round. In a second round, all ambiguous items or proposals driven by comments of the first round and concerning exclusion, aggregation or retention of items, together with any new potential items identified from the first round, will be included in the second survey.
- The final exercise protocol will be distributed to the panel members for final approval with decision rules for each item and guidance on how some information may best be presented and elaboration and explanatory document will be developed.
- Following the second round, a ranking of item importance will be made to rationalize the number of items and model this according to the CONSORT Statement and TIDieR Checklist for consistency. Synthesis of comments and further additions and deletions will be made until there is final majority agreement. It is anticipated that three rounds will be required. Rounds will continue until consensus is achieved. More than 80% of response rate will be acceptable in Delphi study.
- Results from the final round will be summarized and distributed to the entire group for final remarks. The final document, including all phase wise exercises will be accepted and research team will validate it.

- Pilot testing of a newly developed exercise program will be done on eight patients in experimental group and eight patients in control group. Response of the patients (self-reported parameters – such as ease of doing it etc.) will be checked.
- Evaluation of the patients will be done at the baseline using Constant Murley Score, shoulder pain and disability Index (SPADI). Shoulder range of motion, shoulder muscles extensibility will be assessed and scapulothoracic ratio will be calculated and documented. T-FAST test will be conducted to score the patients functional performance.

STUDY PROCEDURE: -

Phase 2:

A randomized controlled trial will be conducted as per the guidelines/statement given by CONSORT 2010 (Consolidated Standards of Reporting Trials).

Evaluation of the participant will be done at the baseline using Constant Murley Score, shoulder pain and disability Index (SPADI). Shoulder range of motion, shoulder muscles extensibility will be assessed and scapulothoracic ratio will be calculated and documented. T-FAST test will be conducted to score the patients functional performance.

specified timeframes for phase 1 and phase 2

Sr. No.	Task	Timeline
1.	Phase 1: developing and validating the structured exercise program	6 months
2.	Pilot phase	6 months

3.	Phase 2: RCT, implementation of exercise program	2 years

Outcome measures:

1. Constant–Murley Score

This score is a shoulder-specific assessment tool containing objective measures (range of movement and shoulder strength) and subjective measures (activity of daily living and pain). The maximum is 100 points and indicates excellent shoulder function.

The CMS scale assesses four aspects related to shoulder pathology; two subjective: pain and activities of daily living (ADL) and two objectives: range of motion (ROM) and strength. The subjective components can receive up to 35 points and the objective 65, resulting in a possible maximum total score of 100 points (best function). Pain and ADL are answered by the patient; ROM and strength require a physical evaluation and are answered by the physiotherapist.

Questions and measurements are standardized according to the original description by Constant and Murley.

2. Pain perception

The visual analogue scale (VAS; 0–10) is used to assess the patient's perceived pain intensity at rest, during arm activity and at night during the previous 24 hours at each follow-up.

3. Shoulder Pain and Disability Index (SPADI)

The Shoulder Pain and Disability Index (SPADI) is a self-administered questionnaire that consists of two dimensions, one for pain and the other for functional activities. The pain dimension consists of five questions regarding the severity of an individual's pain. Functional activities are assessed with eight questions designed to measure the degree of difficulty an individual has with various activities of daily living that require upper-extremity use. The SPADI takes 5 to 10 minutes for a patient to complete and is the only reliable and valid region-specific measure for the shoulder.

4. Timed Functional Arm and Shoulder Test

Description of the Timed Functional Arm and Shoulder Test.

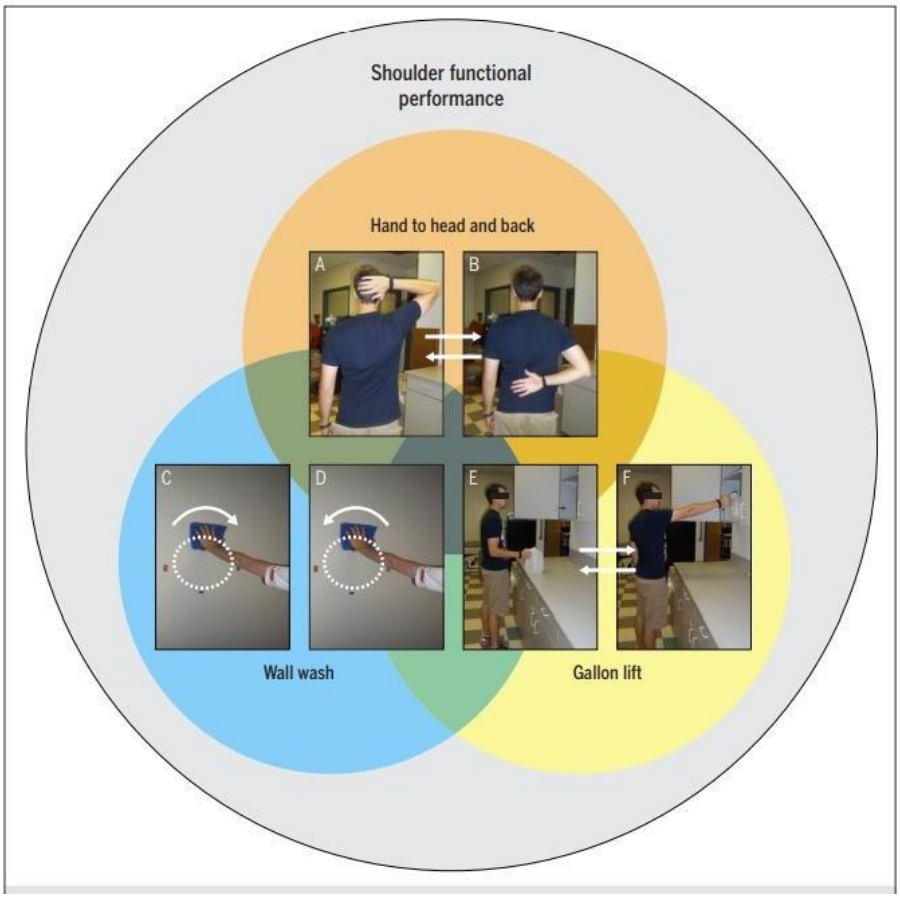
Hand to head and back: This test is timed for 30 seconds. Each time the patient touches the back of his or her head, it counts as 1 repetition. Begin with the unaffected arm or dominant arm at the side of the body.

Reach up and touch the back of the head (A). Any part of the hand touching the head is acceptable. Ideally, the full palm should be touching. After the patient touches the back of the head, bring the arm down and place the dorsal surface of the hand on the small of the back (B). Repeat the motion for the duration of the test.

\Wall wash outward and inward: This test is timed for 60 seconds in each direction. The center of the circle should be at the shoulder height of the patient. Measure 6 inches up, down, left, and right to mark off a 12-inch-diameter circle. Begin the test with the hand on the top mark. Keeping the hand in full contact with the wall, rotate internally (inward) so that the towel/hand touches each of the 4 marks (C). Each time the hand passes the top mark, it counts as 1 rotation. Record the score.

For the outward wall-wash motion, begin the test with the hand on the top mark. Keeping the hand in full contact with the wall, rotate externally (outward) so that the towel/hand touches each of the 4 marks (D). Each time the hand passes the top mark, it counts as 1 rotation. Record the score.

Gallon-jug lift: This test is timed for 30 seconds. Starting counter height should be 36 inches, and the shelf should be 20 inches above the counter (56 inches off the floor). Begin with a full gallon jug on the counter (E). Lift the jug to touch the shelf and return to start (F). Every time the jug touches the shelf, it counts as 1 repetition. Record the score.



5. Scapulothoracic ratio Measurement

Two inclinometers will be used to measure humeral elevation and scapular upward rotation in 30, 60 and 90 degrees of arm elevation during flexion and abduction. Using an electromagnetic tracking system, Johnson et al. (2001) validated use of the inclinometer to quantify scapular upward rotation associated with varying amounts of humeral elevation (r ¼ 0.66e0.89) with good Intraclass correlation coefficient (ICC ¼ 0.86e0.91) for measurement of scapular upward rotation.

Step 1: Assessment of glenohumeral range of motion with inclinometers

- First inclinometer will be attached parallel to the humerus, just under the deltoid insertion with the use of Velcro straps.
- Standing posture and postural sway will be controlled by asking subjects to look at target approximately 2m ahead of them positioned at eye level.
- Range of motion will be documented by inclinometer in sagittal and frontal plane at glenohumeral joint in arm elevation.
- Three trials with 30 seconds rest in between the trials will be done, and means of them will be calculated.

Assessment of scapular upward rotation:

- Scapular upward rotation will be measured using a second inclinometer; this will be achieved by manually aligning the base of the inclinometer along the spine of the scapula.
- Range of scapular upward rotation will be documented by an inclinometer in the sagittal and frontal plane in arm elevation in 30, 60, 90 degrees and in the available end range.
- Three trials with 30 seconds rest in between the trials will be done, and means of them will be calculated.

Step 2: Deriving scapulohumeral ratio:

• The ratio of glenohumeral motion to scapular motion will be then calculated to derive scapulohumeral rhythm i.e. Glenohumeral motion = total shoulder motion – scapular upward rotation

• Scapulohumeral rhythm = Glenohumeral elevation / scapular upward rotation While assessing range of motion at glenohumeral joint assessment of end feel, joint reactivity and irritability will be done with Maitland concept.

The conventional exercise program for control group

Phases

Maximal protection: acute phase

Goals

- Relieve pain and inflammation
- Normalize range of motion
- Reestablish muscular balance
- Improve posture
- Patient education and avoidance of aggravating activities
- Elimination of any activity that causes an increase in symptoms

Range of motion (5-10 repetitions x2.)

- L-Bar
- Flexion
- Elevation in scapular plane
- External and internal rotation in scapular plane at 45° abduction
- Progress to 90° abduction
- Horizontal abduction/adduction
- Pendulum exercises
- Active-assisted range of motion: limited symptom-free available range of motion
- Rope and pulley
- Flexion

Joint mobilizations

- Inferior and posterior glides to the GH joint in the scapular plane
- Goal is to establish balance in the glenohumeral joint capsule

Modalities

Cryotherapy/ Hot pack 10 minutes

Strengthening exercises (10-15repetitions x 3).

- Rhythmic stabilization exercises for External rotation/ Internal rotation
- Rhythmic stabilization drills Flexion / Extension
- External rotation strengthening
- If painful, isometrics (External rotation, Internal rotation, abduction)
- Scapular strengthening

Postural exercises stretch (30 seconds stretch x 3).

- Strengthen scapular muscles (depressors, retractors, and
- protractors)
- Stretch pectoralis minor (corner stretch)
- Wall circles

Patient education

- Educate patient regarding activity level, activities
- Pathology and avoidance of overhead activity, reaching, and lifting activity
- Correct seating posture (consider lumbar roll)
- Seated posture with shoulder retraction, scapular external rotation, posterior tilting
- Consider postural shirt for patients with poor posture

Guideline for progression

- Decreased pain and/or symptoms
- Normal range of motion
- Elimination of painful arc
- Muscular balance

<u>Intermediate phase</u>

Goals

- Reestablish nonpainful range of motion
- Normalize arthrokinematics of shoulder complex
- Normalize muscular strength
- Maintain reduced inflammation and pain
- Increase activities with involved arm

Range of motion (5-10 repetitions x2.)

- L-Bar

- Flexion
- External rotation at 90° of abduction
- Internal rotation at 90° of abduction
- Horizontal abduction/adduction at 90°
- Rope and pulley
- Flexion

Joint mobilization

- Continue joint mobilization techniques to the tight aspect of the
- shoulder (especially inferior)
- Initiate self-capsular stretching
- Grades 2, 3, 4
- Inferior, anterior, and posterior glides
- Combined glides as required

Modalities (as needed)

Cryotherapy/ Hot pack 10 minutes

Ultrasound 3 MHZ /5 minutes

Postural exercises (5-10 repetitions x2.)

- Continue with stretching of pectoralis minor and strengthening scapular muscles
- Continue use of postural shirt
- Strengthening exercises
- Progress to complete shoulder exercise program
- Emphasize rotator cuff and scapular muscular training
- External rotation tubing
- Side lying external rotation
- Full can
- Shoulder abduction
- Prone horizontal abduction
- Prone shoulder extension
- Prone rowing
- Prone horizontal abduction external rotation
- Biceps/triceps
- Lower trapezius muscular strengthening
- Scapular neuromuscular exercises

Functional activities

- Gradually allow an increase in functional activities
- No prolonged overhead activities
- No lifting activities overhead

Advanced strengthening phase

Goals

Improve muscular strength and endurance

Maintain flexibility and range of motion

Maintain postural correction

Gradual increase in functional activity level

Flexibility and stretching

Continue all stretching and range-of-motion exercises

L-Bar: External rotation /internal rotation at 90° abduction

Continue capsular stretch

Maintain/increase posterior/inferior flexibility

Strengthening exercises (5-10 repetitions x2.)

- Establish patient on the fundamental shoulder exercises
- Tubing external rotation /internal rotation
- Lateral raises to 90° dumbbell
- Full can dumbbell to 90°
- Side lying External rotation
- Prone horizontal abduction
- Prone extension
- Wall slides
- Biceps/triceps
- Scapular neuromuscular control drills

Guideline for progression to phase 4

- Full, nonpainful range of motion
- No pain or tenderness
- Strength test fulfills criteria

- Satisfactory clinical examination

Return to activity phase

Goals

Unrestricted, symptom-free activity

The exercises to be performed at the PT clinic 2 times a week combined with home exercises twice daily.

Any dropouts or participants lost to follow-up will be mentioned with appropriate reasoning.

At the end of the study the data will be collected, coded and tabulated using descriptive and inferential statistics. All analysis will be done using SPSS for Windows (Version 16).

9. Study Duration and Timelines

Total duration of study: 3 years

The treatment protocol will be given for two days per week for twelve weeks.

Each treatment session will be for 45 mins.

Assessment will be done at baseline, 3, 6, 9, and 12 weeks in both the groups.

The treatment protocol will be participant specific and progression will be made according to the participant's performance.

specified timeframes for phase 1 and phase 2

Sr. No.	Task	Timeline
1.	Phase 1: developing and validating the structured exercise program	6 months
2.	Pilot phase	6 months
3.	Phase 2: RCT, implementation of exercise program	18 months

Timeline for the entire study

Sr. No.	Task	Timeline
2.	Related Literature Search	September 2022
6.	Institutional Ethical Committee Approval	October-December 2022
9.	Data Collection Post MRC Approval	February 2023-February 2025
10.	Data Presentation and Analysis	March 2025
11.	Writing Discussion and Conclusion	June 2025
12.	Preparing manuscript and publication	August 2025

10. Informed Consent

The patients who are endorsed in physiotherapy OPD will be approached to consider being a research subjects, Principal investigator will be taking informed consent from the patients. Participants can take 24-72 hours to decide on participation in research. Subjects will be screened for eligibility criteria as per the inclusion and exclusion criteria, Subjects will be enrolled in the study through simple random method.

11. Risk

Potential risks associated with this study are none or very minimal. The time required is 45 minutes is the only discomfort which will be having throughout the study. There is possibility of increase in shoulder pain after exercises which will be managed with pain relieving electrotherapeutic modalities.

The therapist will always be in the vicinity to prevent and treat the same.

12. Outcomes

The effect of structured exercises on pain, range of motion and shoulder functions using Constant Murley score and Shoulder Pain and Disability Index (SPADI) and functional performance using timed functional arm and shoulder test will be tested and compared with conventional exercise program.

13. Data Collection, Management & Confidentiality

a) Indicate below HOW study data will be collected for the proposed research.

√ ☐ Study Forms ☐ Study Database ☐ Study Web-Based/App ☐ Other

A standardized data collection tool will be developed. Variables will be designated to measure the pre specified outcomes.

The subject data will be coded by Alphanumeric notations. The subject name and the number will be coded and the subject identifier will be kept locked in the drawer. Subject identifiers- Name, HC number and Date of Birth (DOB) will not be included in the data collection sheet. Subject identifiers will be logged in the subject code and identification list.

Data collection sheet and other confidential documents will be kept inside the cupboard, which will be locked, and only Principal investigator will have the access, which will be limited to the study personal and MRC personal. Only the research team that includes the Principle investigator will have access to the data. In addition, the Medical research Centre will be having access along with the other regulatory bodies in Qatar. The study identifiers will not be shared outside the HMC except the regulatory bodies. Link between the code and Identifier will be stored in the subject code and identification list and will be destroyed after the study finishes. De-identified data will be kept for at least 5 years from the completion of the study.

14. Subject Withdrawal/ Withdrawal of Consent

The subject can request to be withdrawn from the study at any time during the study period. The PI will withdraw the subject & his/ her consent from the study and will notify the research governing bodies of this withdrawal. If subjects sustain any trauma or injury related to shoulder joint or undergoes shoulder surgery, PI may have to withdraw a subject from the study.

15. Statistical Consideration and Data Analysis

Statistical analysis:

Phase 1

In the Delphi method, the results will be analyzed independently in each round. The percentages of responses shall be calculated in categories following the consensus analysis method of most studies that also adopt the visual scale of 1–5, according to CREDES.

The percentages of agreement and disagreement shall be calculated for each of the items in the exercise protocol.

When the percentage is greater than or equal to 80%, the statement is considered to have reached (dis)agreement consensus. The items that reach consensus are excluded from the next round. Finally, those items that have not reached 80% agreement or disagreement will be included to the questionnaires of the following rounds with the modifications proposed by the panelists, if they consider it necessary.

Phase 2

Data collected will be compiled on to a MS Office excel worksheet & will be subjected to statistical analysis using an appropriate package like SPSS software.

Normality of numerical data will be checked using Shapiro – Wilk test or Kolmogorov-Smirnov test. Depending on the normality of data, statistical tests will be determined.

For a numerical continuous data following a normal distribution, inter group comparison (2 groups) will be done using t test, else a non-parametric substitute like Mann Whitney U test will be used.

Descriptive statistics like frequency (n) & percentage (%) of categorical data, mean & Standard deviation of numerical data in each group will be depicted & may be compared using chi square test or a suitable test like Fisher's exact test / McNemar test based on the data obtained.

Intra group comparisons for a numerical continuous data following a normal distribution will be done using paired t test (for 2 observations) or repeated measures ANOVA for >2 observations, else a non-parametric substitute like Wilcoxon signed rank test (for 2 observations) or Friedman's test for >2 observations will be used.

Keeping alpha error at 5% and Beta error at 20%, power at 80%, $p<0.05$ will be considered statistically significant.

For the primary end-point, namely SPADI score after 12 weeks, and for all other outcomes, a constrained linear mixed model (cLMM) will be applied in order to compare the change from baseline to 12 weeks in experimental and control group.

Principal investigator with the help of bio stastician will be carrying out the data analysis.

16. Adverse Event Reporting

All research related incidents through the OVA/Electronic Incident Reporting System no later than 24 hours for all SAE's covered in the SOP in accordance to Policy OP 4070 REPORTING OF OCCURRENCES, VARIANCES AND ACCIDENTS.

Unanticipated Problems that are serious will be reported to HMC-IRB within 7 days of the investigator becoming aware of the event.

Any other Unanticipated Problems will be reported to HMC-IRB within 14 days of the investigator becoming aware of the event.

17. Ethical Consideration

The study will be conducted in full conformance with principles of the "Declaration of Helsinki", Good Clinical Practice (GCP) and within the laws and regulations of MoPH in Qatar

18. Sponsor, Funding & Collaborator Information

Sponsor and funding: None

This is a PhD study.

The name of the research Centre: PT School and Centre, Seth G.S.Medical College and KEM Hospital, Mumbai, Maharashtra, India

19. Dissemination of Results and Publication policy

The results will be disseminated during PhD presentations at Research Centre as well as at university. Two international publication are mandatory throughout duration of PhD as per the PhD guidelines.

20. References

1. Ludewig PM, Cook TM. Alterations in shoulder kinematics and associated muscle activity in people with symptoms of shoulder impingement. Phys Ther. 2000 Mar; 80(3):276-91. PMID: 10696154.

2. Shire AR, Stæhr TAB, Overby JB, Bastholm Dahl M, Sandell Jacobsen J, Høyrup Christiansen D. Specific or general exercise strategy for subacromial impingement syndrome-does it matter? A systematic literature review and meta-analysis. BMC Musculoskelet Disord. 2017 Apr 17; 18(1):158. doi: 10.1186/s12891-017-1518-0. PMID: 28416022; PMCID: PMC5393017.

3. Kromer TO, de Bie RA, Bastiaenen CH. Effectiveness of individualized physiotherapy on pain and functioning compared to a standard exercise protocol in patients presenting with clinical signs of subacromial impingement syndrome. A randomized controlled trial. BMC Musculoskelet Disord. 2010 Jun 9; 11:114. doi: 10.1186/1471-2474-11-114. PMID: 20534140; PMCID: PMC2889850.

4. Pieters L, Lewis J, Kuppens K, Jochems J, Bruijstens T, Joossens L, Struyf F. An Update of Systematic Reviews Examining the Effectiveness of Conservative Physical Therapy Interventions for Subacromial Shoulder Pain. J Orthop Sports Phys Ther. 2020 Mar; 50(3):131-141. doi: 10.2519/jospt.2020.8498. Epub 2019 Nov 15. PMID: 31726927.

5. Theresa Holmgren, Birgitta Öberg, Irene Sjöberg, Kajsa Johansson. Supervised strengthening exercises versus home-based movement exercises after arthroscopic acromioplasty: a randomized clinical trial. J Rehabil Med 2012:44: 12–18.

6. Theresa Holmgren, Hanna Björnsson, Birgitta Öberg, Lars Adolfsson, Kajsa Johansson. Effect of specific exercise strategy on need for surgery in patients with subacromial impingement syndrome: a randomized controlled study. BMJ 2012; 344:e787.

7. Worsley P, Warner M, Mottram S, Gadola S, Veeger HE, Hermens H, Morrissey D, Little P, Cooper C, Carr A, Stokes M. Motor control retraining exercises for shoulder impingement:

effects on function, muscle activation, and biomechanics in young adults. J Shoulder Elbow Surg. 2013 Apr; 22(4):e11-9. doi: 10.1016/j.jse.2012.06.010. Epub 2012 Sep 1. PMID: 22947240; PMCID: PMC3654498.

8. Hanratty CE, McVeigh JG, Kerr DP, Basford JR, Finch MB, Pendleton A, et al. The effectiveness of physiotherapy exercises in subacromial impingement syndrome: a systematic review and meta-analysis. Semin.Arthritis Rheum. 2012; 42:297-316.

9. Kelly SM, Wrightson PA, Meads CA. Clinical outcomes of exercise in the management of subacromial impingement syndrome: a systematic review. Clin.Rehabil. 2010; 24:99-109.

10. Abdulla SY, Southerst D, Côté P, Shearer HM, Sutton D et al.Is exercise effective for the management of sub acromial impingement syndrome and other soft tissue injuries of the shoulder? A systematic review by the Ontario Protocol for Traffic Injury Management (OPTIMa) Collaboration.

11. Başkurt Z, Başkurt F, Gelecek N, Özkan MH. The effectiveness of scapular stabilization exercise in the patients with subacromial impingement syndrome. J Back Musculoskelet Rehabil 2011; 24:173-179.

12. Bernhardsson S, Klintberg IH, Wendt GK. Evaluation of an exercise concept focusing on eccentric strength training of the rotator cuff for patients with subacromial impingement syndrome. Clin Rehabil 2011; 25:69-78.

13. Bury J, West M, Chamorro-Moriana G, Littlewood C. Effectiveness of scapula-focused approaches in patients with rotator cuff related shoulder pain: A systematic review and meta-analysis. Man Ther 2016; 25: 35-42.

14. Moezy A, Sepehrifar S, Solaymani Dodaran M. The effects of scapular stabilization based exercise therapy on pain, posture, flexibility and shoulder mobility in patients with shoulder impingement syndrome: a controlled randomized clinical trial. Med J Islam Repub Iran 2014; 28:87.

15. Shankar P, Jayaprakasan P, Devi R. Effect of scapular stabilization exercise for type 2 scapular dyskinesis in subjects with shoulder impingement. Int J Physiother 2016; 3:106-110.

16. Turgut E, Duzgun I, Baltaci G. Effects of scapular stabilization exercisen training on scapular kinematics, disability, and pain in subacromial impingement: a randomized controlled trial. Arch Phys Med Rehabil 2017; 98:1915-1923.e3

17. Hotta GH, Santos AL, McQuade KJ, de Oliveira AS. Scapular-focused exercise treatment protocol for shoulder impingement symptoms: three-dimensional scapular kinematics analysis. Clin Biomech (Bristol, Avon) 2018 ;51:76-81

18. Rizzo, J. R., Thai, P., Li, E. J., Tung, T., Hudson, T. E., Herrera, J., & Raghavan, P. (2017). Structured Wii protocol for rehabilitation of shoulder impingement syndrome: A pilot study. Annals of physical and rehabilitation medicine, 60(6), 363–370. https://doi.org/10.1016/j.rehab.2016.10.004.

19. Ravichandran H, Janakiraman B, Gelaw AY, Fisseha B, Sundaram S, Sharma HR. Effect of scapular stabilization exercise program in patients with subacromial impingement syndrome: a systematic review. J Exerc Rehabil. 2020 Jun 30; 16(3):216-226. doi: 10.12965/jer.2040256.128. PMID: 32724778; PMCID: PMC7365732.

20. Youn Hee Bae, Gyu Chang Lee, Won Seob Shin, Tae Hoon Kim, Suk Min Lee, Effect of Motor Control and Strengthening Exercises on Pain, Function, Strength and the Range of Motion of Patients with Shoulder Impingement Syndrome, Journal of Physical Therapy Science, 2011, Volume 23, Issue 4, 687-692

21. Appendices

Appendix 1: Data collection tool

Appendix 2: Informed consent document

Appendix 3: Constant Murley score

Appendix 4: SPADI.