

#### 1. Title of research

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

#### 2. Principal Investigator

Reshma Shashank Gurav, Physiotherapy Specialist, Female Outpatient Physiotherapy -Bin Omran, Qatar Rehabilitation Institute.

#### 3. Why are we inviting you to join this research?

The investigator at Qatar Rehabilitation Institute, Physiotherapy Department is conducting this research.

We are inviting you to join because we are investigating:

- 1- The new exercise program for shoulder pain
- 2- To check the pain, movements and shoulder functions after treatment in new exercise program and in conventional group.

## 4. What should you know about this research?

- We will explain the research to you
- Whether or not you join is your decision (you can accept or refuse no matter who is inviting you to participate)
- Please feel free to ask questions or mention concerns before deciding, or during or after the research
- You can say yes but change your mind later
- We will not hold your decision against you

## 5. Who can you talk to?

If you have questions or concerns, or if you think the research has hurt you, talk to the research team at:

Reshma Gurav, mobile # 55023509, Email: RGurav@hamad.qa, Sadia Kazi <u>SKazi1@hamad.qa</u> Manisha Shenoy- MShenoy@hamad.qa

If you have questions about your rights as a volunteer, or you want to talk to someone outside the research team,

please contact:

• HMC-IRB Office at 4025 6410 (from Sunday to Thursday between 7:00am-3:00pm) or email at irb@hamad.qa

### 6. Why are we doing the research?

We are doing this research with intention that if the new exercise program based on latest evidence is proved effective, the need for surgery might decrease and help patients to get back shoulder functions and improve the physical activities as well as quality of life.

#### 7. How long will the research take?

We think that you will be in the research 12 weeks.

We expect the research to last for 3 years.

#### 8. How many people will take part?

We plan to study 90 people.

#### 9. What happens if you take part?

If you agree to join, we will ask you to do the following:

If you agree to join, we will ask you to do the following:

You will be tested for shoulder pain by using testing methods and according to the randomization you will be provided treatment modality.

- Treatment will be provided for approximately 12 weeks.
- Re-checking every 5th session.
- Study will continue for 24 sessions.
- Total duration of the schedule will be 2 years.

You will be "randomized" into one of 2 treatment groups.

Randomization means that you are put into a group by chance. It is like flipping a coin. Neither you nor the researchers choose which group you will be in. You will have equal chance of being place in a specific group.

# 10. Could the research be bad for you?

There is possibility of increase in shoulder pain after exercises.



#### 11. Could the research be good for you?

By participating in this study, you may have possible cure or improvement in your condition. However, there is no guarantee that you will receive direct health benefit from being in this study. Your participation in this study may not be directly beneficial, however the results obtained of this study may prove useful in further studies or research in patients with shoulder pain.

# 12. What happens to information about you?

We will make efforts to secure information about you. This includes using a code to identify you in our records instead of using your name. We will not identify you personally in any reports or publications about this research. We cannot guarantee complete secrecy, but we will limit access to information about you. Only people who have a need to review information will have access. These people might include:

- Members of the research team and medical research center representative whose work is related to the research or to protecting your rights and safety
- Representatives of the Ministry of Public Health Qatar and HMC who make sure the study is done properly and that your rights and safety are protected.

#### 13. What if you don't want to join?

You can say "No" and we will not hold it against you.

## 14. What if you join but change your mind?

You can stop participating at any time and we will not hold it against you.

We will tell you about any new information that might affect your health or welfare, or might affect your willingness to continue in the research.

However, if you stop you should know that you should continue your home exercise program

If you stop participating, we cannot delete information that we have already collected about you.

# 15. What else should you know?

This research is funded by Medical Research Center.

The analysis of data and results of the study will be shared with Maharashtra University of Health Sciences, India.

If you are injured as a direct result of research procedures, contact the investigator and appropriate care will be made available at HMC.



Signature Page for Capable Adult
Volunteer
I voluntarily agree to join the research described in this form.
Printed Name of Volunteer
Signature of Volunteer Date
Person Obtaining Consent
<ul> <li>I document that:</li> <li>I (or another member of the research team) have fully explained this research to the volunteer.</li> <li>I have personally evaluated the volunteer's understanding of the research and obtained their voluntary agreement.</li> </ul>
Printed Name of Person Obtaining Consent
Signature of Person Obtaining Consent  Date
Witness (if applicable)
I document that the information in this form (and any other written information) was accurately explained to the volunteer, who appears to have understood and freely given Consent to join the research.
Printed Name of Witness
Signature of Witness Date

