

Study Protocol

STUDY ID: SH-RCT-ARCR-01

**Home-based Rehabilitation with a novel digital biofeedback system
versus conventional home-based rehabilitation after Arthroscopic
Rotator Cuff Repair: a randomized controlled trial**

Document Version: 2.0

Date: 06/14/2018

Sponsor: SWORD Health, SA

Revision History

Version	Date	Description	Author
1.0	02/03/2017	Original	J.G & F.C.
2.0	06/14/2018	Content revision	S.L.

Principal Investigator

Fernando Emanuel Dias Correia

Largo Prof. Abel Salazar

4099-001 Porto

Contact: 966557789

E-mail: fanacorreia@gmail.com

Co-Investigators

António Rosmaninho Seabra

Rua Sarmento Beires 153

4250-449 Porto

Email: rosmaninho.seabra@hospitaldaprelada.pt

Sara Raquel Luís

Rua de Sá da Bandeira, nro 651 1º direito

4000-437 Porto

Contact: 914710560

E-mail: sararluis@gmail.com

Investigation Centers

Hospital da Prelada - Dr. Domingos Braga da Cruz

Rua Sarmento Beires 153

4250-449 Porto

Version 2.0

Date: 06/14/2018

1. Introduction

Shoulder pain is highly prevalent, being the third main complaint in primary care settings.¹⁻³ In fact, in developed countries, 1% of adults are expected to consult primary care at some point in life due to shoulder pain.¹

Problems in the rotator cuff tendons are very common,⁴⁻¹⁰ mainly after the 4th decade of life,^{1,11} and more than 80% of the population over 70 years,¹² and it is estimated that 65 to 70% of all shoulder pain complaints involve these structures.^{1,4}

Rotator cuff tendinopathy is preceded with tendon disorganization and thickening that leads to a reduction of its physical properties, and in more severe cases leads to tendon rupture.¹⁰ Rotator cuff tears disrupt shoulder kinematics,^{1,4,13} and usually lead to loss of function, dyskinesia, pain and stiffness,^{10,14,15} with a consequent negative effect on the individual's function and therefore quality of life.^{13,16}

Rotator cuff tears are the most common cause of pain and loss of function in overhead activities,^{17,18} representing a huge burden for healthcare systems, insurance companies and employers alike.^{1,19} Symptoms may vary according to size, location or type of tear, with some people maintaining asymptomatic while others may have significant levels of pain, as well as loss of function and strength.^{1,7} In fact, from 5 to 40% of people with asymptomatic shoulders may have full-thickness rotator cuff tears.^{1,2}

Since conservative treatment is not always effective,^{1,20} rotator cuff repairs are commonly used surgical procedures^{1,4,25,26,10,15,17,20-24} and a procedure that is becoming more frequent in advanced ages.^{22,27}

Rehabilitation plays an essential role in the recovery of rotator cuff repair,^{8–10,13,15,20,28–31} and should be customized to the patients characteristics and needs.^{15,18,20,32} Different aspects must be taken into consideration for functional recovery, such as age, activity levels, extent and location of the tear, duration of symptoms, prior muscle atrophy or fatty infiltration and concomitant pathologies.^{10,17,20,23,24,31,33}

The primary goal of the rehabilitation is to relieve pain, restore function, range of motion, strength,^{4,20,29,31,34–36} balancing the need of protecting the repair and the need of mobilization to avoid stiffness and restore normal function and kinematics.^{15,20,30,31,37,38} This balance, however, is very delicate, as re-tears or failed healing are very common after surgery^{22,25,27,39}, and therefore therapies must focus on improving function without compromising the healing process.^{15,27,31}

Assure an early passive range of motion is recommended by many authors to prevent stiffness, one of the most frequent complications after rotator cuff repairs^{15,37,38,40–42} as well as joint adhesions and further tendon degradation. Conversely, longer immobilization periods can promote tendon healing and reduce the rates of re-tear.^{32,37,38,43} There is no consensus on this matter, with an immobilization period of 6 weeks being the most common period advised.^{20,28} However, several studies found no differences between them in function, pain, ROM or re-tears ratio, concluding that early mobilization may be beneficial.^{22,23,28,30,34,37,38,40,41} Furthermore, some studies demonstrate that early initiation of rehabilitation with active exercise does not appear to affect patient-reported pain and disability outcomes in a short (≤ 3 months), mid (6

SH-RCT-ARCR-01 Study Protocol

months) or long-term period (≥ 12 months).^{8,9,36} Still, even within the early mobilization group, there is no consensus on how early should the mobilization begin - since day one to 2 days after, 1 week after, 5 weeks after.^{4,28,41}

Apart from the discussion between early or late passive mobilization, there is also no consensus on which rehabilitation programs are better.^{8–10,15,17,26,38} Several studies and systematic reviews have been published on the subject, focusing mainly on the times of progression.^{4,8,40–42,44,45,23,28–30,32,34,37,38} These studies all define a four-stage process consisting of: a) immobilization, b) passive range of motion; c) active range of motion and d) strengthening, with variable times of progression.^{9,15,20,28,33} The total duration of the rehabilitation process is also variable, with some studies stating that it might take up to 6-12 months to regain full strength.^{4,33,35}

Regarding rehabilitation setting, some studies suggest that home-based therapy, based on exercise, could be as effective as clinic-based interventions.^{21,26,46,47} This is in line with the recent trends in healthcare delivery, away from inpatient care and towards home-based care with the intent of improving cost-effectiveness.

Given the high incidence and prevalence of shoulder rotator tears, and the associated morbidity, which represents a huge economic burden^{3,16,48} it is essential to ensure the access to cost-effective rehabilitation.⁴⁷ In this regard, digital health solutions that empower patients, maximize engagement and allow home-based rehabilitation without the need for constant therapist supervision, could improve effectiveness and lower the cost of rehabilitation.

SH-RCT-ARCR-01 Study Protocol

SWORD Health has developed a novel digital biofeedback system for home-based physical rehabilitation (SWORD Phoenix®). Using inertial motion trackers, this system digitizes patient motion and provides real-time feedback on performance through a mobile app. It also includes a web-based platform that allows the clinical team to prescribe, monitor and adapt the rehabilitation process remotely. This way, the system allows patients to perform independent rehabilitation sessions at home without the need for constant therapist supervision, ensuring remote monitoring throughout the rehabilitation program.

2. Study Objective

The objective of the present study is to evaluate the clinical outcomes of a home-based rehabilitation program using this system against conventional home-based rehabilitation after arthroscopic rotator cuff repair. We hypothesize that the clinical outcomes of such a program will be at least similar to those of traditional rehabilitation.

3. Study Design

This study is a single-center, prospective, non-blind, parallel-group, randomized controlled trial with an active comparator.

4. System technical specifications

The version of SWORD Phoenix used in this study is composed of the following components:

- a) **Inertial motion trackers:** each one is composed of a three-axis gyroscope, three-axis accelerometer and a three-axis magnetometer, allowing 3D

Version 2.0

Date: 06/14/2018

movement analysis and quantification. The trackers communicate via Bluetooth LE with a tablet computer.

- b) **Mobile App:** a mobile app that processes the information generated by the motion trackers and provides real-time biofeedback regarding movement quality and patient performance.
- c) **Web-based Portal:** a web-based platform that allows the clinical team to prescribe motor tasks and monitor results.

Motion Trackers

The motion trackers are placed on body segments using Velcro® straps. Each motion tracker is placed in a specific position. To assist in the correct placement of the motion trackers, both the trackers and the matching straps are color-coded. In this study, the following setup will be used:

- **Red tracker:** over the sternal manubrium
- **Green tracker:** on the medium third of the external surface of the upper arm, pointing to the elbow
- **Blue tracker:** on the dorsal surface of the distal third of the forearm, pointing to the hand

Mobile App

The mobile app guides the patient in each exercise session. Before each exercise, the

patient is presented with a real-life video and audio explanation of that exercise. The execution interface is subsequently shown. This screen features: a) a posture dummy indicating correct/incorrect posture; b) a progress bar; c) a timer indicating rest time between repetitions and prompting start when rest time is over; d) a repetition counter; e) a star counter and f) a timer displaying time left to complete the exercise.

Only correctly performed repetitions count towards the repetition counter. A correct repetition is defined as a movement starting at the baseline and reaching or surpassing the specified target, without violating movement or posture constraints. In case the patient violates a movement constraint, a message is prompted showing which movement error was performed, so that the patient can correct the movement in the following attempts.

For each correct repetition, the patient earns from 1 to 3 stars, depending on how much he was able to surpass the target, as long as he has not violated any movement or posture constraints.

Web Portal

The portal is a web-based platform that allows the clinical team to create new patient profiles and create exercise sessions for each patient. When a patient performs a session, the results are uploaded to the platform and available for review. Based on this information, the clinical team can edit the parameters of each session and exercise according to patient performance and progress.

5. Study Outcomes

The assessment of the effectiveness of treatments in shoulder conditions is complex^{49,50} and should include not only the traditional clinical outcomes, such as

joint measures, but also the assessment of functional deficits, through patient reported outcome measures.⁴⁹⁻⁵¹ Lately, there has been a shift towards the latter, which are currently the primary outcomes of most research studies.⁴⁹

The Constant Shoulder Score is one of the most used outcome assessment tools worldwide,^{49,50,52,53} maybe due to the fact that it's psychometric properties have been widely studied,⁵⁰ and that it includes essential measures - physical assessment of strength and motion - as well as patient-reported function.^{49,52,53} Additionally, it is considered, in some studies, as a gold standard or "reference scale",⁵¹ and its extensive use allows for comparisons between study samples and results.⁴⁹

The DASH questionnaire also provides a very accurate assessment⁵¹ and has been recommended to be the first line of assessment in shoulder disorders, due to its high responsiveness and well-established benchmarks.⁵² The QuickDASH, its short version, with 11 items, is also validated, and its psychometric properties are very high and similar to the original long version.^{52,54} The use of QuickDASH was analysed in patients with a rotator cuff repair and was recommended to assess patients who underwent a surgery process,⁵⁴ therefore applicable in the present context.

Although the use of patient-reported outcome measures is highly recommended, conventional measures such as range of motion are still clinically relevant and critical part of shoulder assessment.^{17,52} Shoulder flexion, abduction, internal and external rotations are the mainly cited movements, although with high variability in the positions of measure.⁵²

Based on this evidence, the following outcomes will be measured:

- a) functional assessment – Constant Score
- b) patient-reported outcomes - QuickDASH

- c) range of motion of the shoulder (in degrees)

The outcome measures will be assessed pre-operatively, and then at 6, 12, 16 and 20 weeks after the surgery. In patients where a decision is made to extend the program to 24 weeks, another assessment will be made at this point.

5.1 Primary outcome

The primary outcome will be the change in patient functional assessment compared to the baseline, measured through the Constant Score.

5.2 Secondary outcomes

The secondary outcomes will be:

- The change in patient reported function in comparison to the baseline, measured by the QuickDASH score
- The change in shoulder range of motion in comparison to the baseline, measured by the shoulder flexion degree in a sitting position (in degrees)

6. Sample size estimate

Sample size estimation was performed taking into consideration the primary outcome measure – The Constant Score - and a non-inferiority scenario.

In the absence of similar studies, the calculations were made taking into account the study by Arndt *et al.* (2012)⁴⁰. This was a large study (n=100 patients) which compared two different rehabilitation protocols after ARCR and which used the same primary outcome as our study. In this study, the standard deviation of the Constant

Score at baseline was 12.0. A Minimal Clinically Important Difference (MCID) of 10.4 was considered, based on the study by Constant *et al.* (2008).⁵⁵

Considering a power of 90%, a two-sided 0.05 significance level and a 10% dropout rate, 68 patients would be necessary to detect a 10.4 points difference between the two groups.

7. Location of Recruitment

Patients will be recruited at Hospital da Prelada - Dr. Domingos Braga da Cruz.

8. Inclusion criteria

- a) Patients over 18 and under 70 years old
- b) Shoulder pain and functional limitation with clinical examination compatible with reparable rotator cuff tear
- c) Imaging (MRI or ultrasound) evidence of rotator cuff tear (supra and/or infraspinatus tendon tear inferior to 5cm)
- d) Indication for a rotator cuff repair according to the patient's orthopedic surgeon
- e) Ability to understand simple and complex motor commands
- f) Availability of a carer to assist the patient after surgery

9. Exclusion criteria

Preoperative

- a) Patients with indication for revision cuff repair
- b) Complex cuff tears (involving subscapularis tendon or more than one tendon besides supra and infraspinatus, or massive dimension tears)

- c) Glenohumeral arthritis
- d) Irreparable tendon defect
- e) Patients with concomitant neurological disorders (ex. Stroke, Parkinson's disease, multiple sclerosis)
- f) Aphasia, dementia or psychiatric comorbidity interfering with the communication or compliance to the rehabilitation process
- g) Respiratory, cardiac, metabolic conditions or others incompatible with at least 30 minutes of light to moderate physical activity

Postoperative

- h) Irreparable tendon lesion
- i) Major medical complications occurring after surgery that prevent the discharge of the patient within 5 days after surgery
- j) Other medical and/or surgical complications that prevent the patient from complying with a rehabilitation program
- k) Blind and/or illiterate patients

10. Methods for identifying and recruiting patients

All patients admitted for rotator cuff repair during the study period will be screened for inclusion and exclusion criteria.

When a potential candidate is identified, the local investigator will approach the candidate and explain the study in detail. The prospective candidate will be given the patient information document and sufficient time to consider whether he wishes to participate in the study.

Subsequently, the prospective candidate will be given opportunity to clarify any

doubts, after which the informed consent form will be signed and dated in duplicate by the patient and the investigator. Only then will the randomization and baseline assessments be performed.

11. Patient allocation to study groups

For logistic reasons, the study will be restricted to patients living in a 20km radius around the investigation center. Patient allocation to the two groups will be performed in a random way, in a 1:1 ratio in blocks of six. This will be done using an online randomizer (<https://www.randomizer.org>).

The allocation of patients to each group will be performed centrally by one investigator - F.D.C. - and communicated to the responsible for data acquisition only after patient enrollment. This investigator will not be involved in data collection or in outcomes assessment.

12. Blinding

The nature of the study does not allow blinding of the patients regarding study groups. However, participants will be blinded to the primary and secondary outcomes being measured. All patient assessments will be performed by an investigator blinded for randomization groups. Statistical analysis will be performed blinded for randomization group.

13. Patient assessment

Patients will be assessed pre-operatively, and then at 6, 12, 16 and 20 weeks after the surgery. In patients where a decision is made to extend the program to 24 weeks,

another assessment will be made at this point. An assessment will also be made at 12 months after surgery.

13.1 Baseline assessment

Participant characterization will consist of:

- a) Demographics (gender, date of birth);
- b) Educational level (years);
- c) Affected side
- d) Injured structures
- e) Size of tear
- f) Date of surgery
- g) Comorbidities
 - a. Factors affecting tissue healing: Smoking, Diabetes, Steroid intake
 - b. Other disorders: cardiac, respiratory, hypertension
 - c. Time between diagnosis and surgery
- h) Body Mass Index
- i) Constant score
- j) QuickDASH
- k) Shoulder range of motion

13.1.1 Constant Score

The Constant Score is a functional assessment score specific to the shoulder region, that varies between 0 and 100 points, being 100 the best score possible. This total score is distributed in subjective assessments of pain and activities of

daily living (15 and 20 points, respectively) and objective measures of shoulder range of motion and strength (40 and 65 points, respectively).⁵⁵

The Constant Score is the most used instrument to assess the shoulder in Europe and its psychometric properties prove it to be a valid, reliable and responsive measure.^{56,57} Kukkonen et al. (2013)⁵⁶ determined that the Minimum Clinical Important Difference - MCID of the Constant Score for patients with arthroscopically treated rotator cuff repairs was of 10.4 points.

13.1.2. QuickDASH

The shortened version of the Disabilities of the Arm, Shoulder and Hand (QuickDASH) is an 11-item self-administered outcome measure, specific to measure disability and symptoms in individuals with musculoskeletal disorders of the upper limb.⁵⁸ Each item has a 5 option Likert scale, from “no difficulty” to “unable to do” (1 to 5), and the total raw score is obtained through the sum of the answers and then converted into a 0-100 scale with a negative orientation, in which no disability indicates a score of zero and maximum disability a score of 100, determining the functional activity level. It is an instrument widely used for clinical or research purposes and which has proven to be a valid, reliable and responsive measure.^{54,58,59} Franchioni et al. (2014)⁵⁹ have determined the MCID for the QuickDash in patients with study pain as 15.19.

13.1.3 Shoulder range of motion

The shoulder range of motion will be measured in the sitting position.

The system used in the study is a validated medical device for joint angle measurement. Therefore, shoulder range of motion will be measured automatically

SH-RCT-ARCR-01 Study Protocol

by the system.

In this study, active range of motion will be measured in the following movements:

- a) Elevation of the shoulder in the scapular plane, sitting: with the patient sitting, with the arm fully extended, have the patient actively raise the arm in the scapular plane as much as possible, with extended elbow.
- b) Sitting shoulder flexion: with the patient sitting, with the arm fully extended, have the patient actively raise the arm as much as possible, with extended elbow.
- c) Sitting Shoulder Abduction: with the patient sitting, with the arm as close as possible to the body, have the patient actively open the arm as much as possible, with extended elbow.
- d) Sitting Shoulder External Rotation: with the patient sitting with 90° bent elbow and hand pointing forward, have the patient actively rotate the arm outwards, as much as possible.

In order to achieve this, the investigator will need to:

- 1) Create a new patient in the Phoenix Portal
- 2) Prescribe these four different exercises, described above
- 3) Setup SWORD Phoenix
- 4) Ask the patient to perform five repetitions of each movement to the best of his ability, while SWORD Phoenix records movement parameters
- 5) After the session, login to the Portal, go to the session's results and click on detailed results for each exercise. Record the value of best repetition for each exercise in the patient file.

13.2 Assessments at 6, 12, 16, 20 (and/or 24) weeks after surgery and assessment

12 months after surgery

These assessments will include:

- a) Constant score
- b) QuickDASH
- c) Shoulder range of motion (as described for the baseline assessment)

14. Intervention

Both study groups will receive early-onset home-based rehabilitation for 20 weeks, starting two weeks after surgery.²⁸ This program can be extended for another 4 weeks if necessary.

The experimental group will perform daily home-based rehabilitation sessions using SWORD Phoenix, under remote monitoring by a physiotherapist, as well as home one-to-one physiotherapy sessions, with decreasing periodicity depending on program stage.

The conventional rehabilitation group will receive home-based rehabilitation provided by a physiotherapist, 3 times a week, for 1 hour. Patients will also be instructed to perform additional unsupervised sessions in at least two other days of the week. Compliance to these additional sessions is not mandatory, but patients will be asked to fill in a diary regarding these extra-sessions.

The intervention arm, additionally to the one-to-one sessions, will perform daily home-based rehabilitation sessions using the system alone, under remote monitoring

SH-RCT-ARCR-01 Study Protocol

by a physiotherapist. Patients will be instructed to perform exercise sessions at least 5 times per week, but compliance to that frequency is not mandatory per protocol. The number of sessions, daily adherence and total training time will be registered automatically by the system and will be made available through the Web Portal, from where it can be transcribed to each patient file. When required, additional visits or telephone calls for technical assistance can be performed by the physical therapist. These will be registered as such in the patient file.

In the absence of a gold standard, the rehabilitation protocols were designed taking into account: a) a recent systematic review on the subject;⁴ b) a review of the concepts and evidence-based guidelines on this subject by van der Meijden *et al.* (2012)¹⁵; c) an overview of systematic reviews comparing early and conservative rehabilitation²⁸ and d) the protocol of the Massachusetts General Hospital for rehabilitation after rotator cuff repair.

The rehabilitation program will be based on the principles outlined in the following tables 1-4. In any case, these protocols can be tailored to the patient's specific needs, according to the assessment of the orthopedic surgeon and the physical therapist.

Table 1. Immediate Post-op Phase

Rotator cuff repair program: Immediate Post-op Phase (weeks 0 to 2) - Immobilization period	
Goals	Precautions
Control pain and swelling	
Protect the rotator cuff repair	Do not lift the operated arm
Protect wound healing	
Prevent shoulder stiffness	
Intervention	
Conventional PT group	Experimental Group
Use of a sling during the day and during the night until week 4	
Ice pack application to the operated shoulder for 15 minutes if necessary to reduce pain and swelling several times per day	
Promote the active movement of fingers, hand and elbow to increase circulation	
Gentle pendulum exercises for three to five minutes every one to two hours	

Table 2. Phase 1 of the rehabilitation program (weeks 2 to 4)

Rotator cuff repair program: Phase 1 - Immobilization period	
Goals	Precautions
Control pain and swelling	
Protect the rotator cuff repair	Do not lift the operated arm
Protect wound healing	
Prevent shoulder stiffness	
Intervention	
Conventional PT group 2 weeks 2 face-to-face sessions per week	Experimental Group 2 weeks: 1 face-to-face session per week Daily sessions with SWORD Phoenix
Ice pack application on the shoulder for 15 minutes to reduce pain and swelling	Intervention of the Control Group + SWORD Phoenix Exercises: - Scapula Elevation - Scapula Protraction - Scapula Retraction - Elbow Flexion - Forearm Supination - Forearm Pronation - Pendular Exercises
Active mobilization exercises of the scapula, elbow, forearm and hand	
Pendular exercises	
Drainage massage, when needed	

Table 3. Phase 2 of the rehabilitation program (weeks 5 to 7/9)

Rotator cuff repair program: Phase 2 - passive mobilization	
Goals	Precautions
Maintain integrity of the repair Avoid overstress healing tissue Gradually increase soft passive range of motion Diminish pain and inflammation Prevent muscular inhibition Begin early shoulder motion Reach 120° passive scapular mobility Reach 40° passive external rotation Reach 120° passive shoulder flexion	No active elevation for the first six weeks No lifting of objects No excessive stretching or sudden movements No supporting of body weight by hands Avoid resisted exercises and exercises in coronal plane abduction No mobilization of the shoulder for flexion on the scapular plane (20° to 30°) between 60° and 110° if rotator tear suture Avoid shoulder external rotation until the 8 th week if shoulder instability
Intervention	
Conventional PT group 5 weeks 3 face-to-face sessions/week	Experimental Group 5 weeks:2-2-2-1 face-to-face sessions* daily sessions with SWORD Phoenix
Ice pack application on the shoulder for 15 minutes to reduce pain and swelling Sub-maximal isometric strengthening: internal and external rotation at neutral Start soft passive ROM movements: - Limit lying internal rotation to 30° in the scapular plane (20° to 30°) - Lying external rotation to 60° in the scapular plane (20° to 30°) - Lying shoulder flexion in the scapular plane (20° to 30°) When passive ROM starts to improve, progress to soft active-assisted exercises (lying flexion, external and Internal rotation) Exercises: Ball squeezes, AROM for elbow, forearm and hand, scapular elevation and retraction	Intervention of the Control Group + SWORD Phoenix Exercises: - Scapula Elevation - Scapula Protraction - Scapula Retraction - Elbow Flexion - Forearm Supination - Forearm Pronation

Legend: * progressing to 1 session/week when possible

Patients may progress to the next phase after completing all passive range of motions of the shoulder described with no pain associated.

Table 4. Phase 3 of the rehabilitation program (weeks 8-10 to 12-14)

Rotator cuff repair program: Phase 3 - active movements	
Goals	Precautions
Maintain integrity of the repair and avoid overstress healing tissue Gradually increase to assisted and active range of motion Progressive scapular stability Progressive functional training Restore full shoulder motion	Respect previous precautions Do soft strengthening exercises under 1,5kg Weight training precautions Avoid excessive force on the shoulder
Intervention	
Conventional PT group 5 weeks 3 face-to-face sessions/week	Experimental Group 5 weeks: 1 face-to-face session/week daily sessions with SWORD Phoenix
Gradually progress to full ROM all planes: increasing angles of abduction in external and internal rotation and lying horizontal adduction Active-assisted arm flexion, progressing to active shoulder flexion Dynamic exercises: <ul style="list-style-type: none">- Side-lying and sitting external rotation;- Side-lying and standing scaption- Prone row, T, extension and scaption- External Rotation- Wall Slide- Internal Rotation behind back- Horizontal Abduction Stretching: <ul style="list-style-type: none">- Prone extension- Lying external Rotation/with abduction- Lying/standing/sitting active-assisted Arm Elevation- Standing forward flexion ("full can") exercise- Supine Cross-Chest Stretch- Wall slide Stretch	Intervention of the Control Group + SWORD Phoenix: <ul style="list-style-type: none">- Scapula Elevation- Scapula Protraction- Scapula Retraction- Elbow Flexion- Forearm Supination- Forearm Pronation- Shoulder Flexion- Shoulder External Rotation- Shoulder Internal Rotation- Shoulder Horizontal Abduction- Arm circles with 90° flexion- Push-up against a wall

Patients may progress to the next phase after completing all active range of motions of the shoulder described with no pain associated.

Table 5. Phase 4 of the rehabilitation program (weeks 13-15 to 18-20)

Rotator cuff repair program: Phase 4 – strengthening	
Goals	Precautions
Maintain integrity of the repair and avoid overstress healing tissue Progressive rotator cuff strengthening and scapular stability Progressive functional training Re-establish dynamic shoulder stability Re-establish scapulohumeral rhythm Restore full shoulder strength Gradually begin to return to normal activity	Respect previous precautions Do soft strengthening exercises under 3,0kg Weight training precautions Avoid excessive force on the shoulder
Intervention	
Conventional PT group 6 weeks 3 face-to-face sessions/week	Experimental Group 6 weeks:1-0-1-0-1-0 face-to-face sessions daily sessions with SWORD Phoenix
Continue as above and progressively add: - Shoulder Abduction to full ROM Theraband exercises: - Standing external rotation (at 0° abduction) - Standing internal rotation (at 90°) - Standing shoulder flexion - Standing forward punch - Standing dynamic hug - Standing W's (external rotation with elbow flexion) - Standing Biceps curls - Seated row Dynamic strengthening exercises (first weeks limit resistance to max 1,5 to 2,5 kg): - Scapulohumeral rhythm exercises - Side-lying external rotation at 0° - Prone row, Scaption "Y", Extension - Standing forward flexion 1,5-2kg (scaption) - Standing external rotation at 90° abduction	Intervention of the Control Group + SWORD Phoenix exercises (adding Theraband or weight): - Scapula Elevation - Scapula Protraction - Scapula Retraction - Shoulder Flexion - Shoulder External Rotation - Shoulder Internal Rotation - Shoulder Abduction - Shoulder Horizontal Abduction - Seated Press-up - Push-up against a wall - Diagonals to flexion - Arm circles with 90° flexion - Arm circles with 90° abduction

Note: * may be less if patient is progressing well

The rehabilitation program may be extended until 24 weeks, according to the orthopaedic surgeon assessment.

Version 2.0

Date: 06/14/2018

Schedule of face-to-face sessions

The following schedule depicts the number of face-to-face sessions according to the “normal” protocol, not counting with the exceptions, ie, patient who can proceed to the following Phases earlier.

Table 4. Face-to-face session schedule

	Weeks	Conventional PT	Experimental
Immediate Post-op Phase	1	0	0
	2	0	0
Phase 1 - Immobilization Weeks 3 to 4	3	2	1
	4	2	1
Total Phase (accumulated)		4 Sessions (4)	2 Sessions (2)
Phase 2 - PROM Weeks 5 to 9	5	3	2
	6	3	2
	7	3	2
	8	3	2
	9	3	1
Total Phase (accumulated)		15 Sessions (19)	9 Sessions (11)
Phase 3 – AROM Weeks 10 to 14	10	3	1
	11	3	1
	12	3	1
	13	3	1
	14	3	1
Total Phase (accumulated)		15 Sessions (34)	5 Sessions (16)
Phase 4 – Strength Weeks 15 to 20	15	3	1
	16	3	0
	17	3	1
	18	3	0
	19	3	1
	20	3	0
Total Phase (accumulated)		18 Sessions (52)	3 Sessions (19)

15. Safety and adverse events

Patients in the active comparator group will receive face-to-face rehabilitation sessions provided by a physical therapist. Therefore, patient safety will be ensured at all times during the sessions. Patients will be able to report adverse events to their physical therapist. Moreover, the patient's orthopedic surgeon will be notified in case of detrimental clinical progression, so that the patient can be re-evaluated.

For patients in the experimental group, safety of the remote sessions will be evaluated through pain and fatigue scores (graduated from 0 to 10) collected at the end of each session. These will be presented to the patient using the mobile App and will be available for remote monitoring by their physical therapist. In case of excessive pain or fatigue, patients will be contacted by their physical therapist to ascertain the cause and change prescription if needed. Patients will also be asked to report any other adverse events to their physical therapist by telephone. Moreover, the patient's orthopedic surgeon will be notified in case of detrimental clinical progression, so that the patient can be re-evaluated.

The adverse events will be registered in the patient's file (beginning date, resolution date (if applicable), resolution state, severity).

16. Statistical analysis

To assess differences in clinical and demographic variables of the patients allocated to the two study groups, independent samples t test or Mann-Whitney U test will be used for quantitative variables. For qualitative variables, Chi-squared test or Fisher's exact test will be used.

Outcome analysis will be performed using a per-protocol analysis. The impact of the interventions in the primary and secondary outcomes will be evaluated considering

the change between baseline and week 20. Differences between the two study groups will be performed using independent samples t test or Mann-Whitney U test.

Since outcomes will be measured in several different times during the rehabilitation program, a repeated measures analysis will also be performed, using a 3x2 ANOVA with group as an independent factor and time as a within-subjects factor.

17. Potential Risks and Benefits to Participants

There are no invasive procedures involved in this research protocol and, given the nature of the intervention, no relevant risks are foreseen.

Both study groups will benefit from a 20-24 week rehabilitation program starting on week 2 after surgery. This program will be based on the latest treatment guidelines and will therefore represent the state of the art regarding rehabilitation after arthroscopic rotator cuff repairs. Thus, both study arms are likely to benefit directly from entering the study.

The experimental group will perform, in addition to the one-to-one physiotherapy sessions, a home-based program using SWORD Phoenix. This program will be tailored to their specific needs and be accompanied remotely by a physical therapist, that will have access to patient performance data, as well as pain and fatigue scores as rated by the patient at the end of each session. This allows the therapist to detect adverse events and to act promptly. In case of detrimental clinical progression, the patient's orthopedic surgeon will be notified, and the patient will be re-evaluated, to decide whether to continue the study. This ensures patients in the experimental group are not subject to greater risk.

Participants will not receive any payments or reimbursements specifically for taking part in this study.

18. Confidentiality of Personal Data

Data collection for this study was authorized by the National Commission on Data Protection, with the authorization number 5798/2018.

Personal data will only be accessible to authorized investigators in this study.

Personal data will not be entered into the database as part of this research. The clinical data collected will only be linked to the patient by a unique study number and will contain no personal identifiers. Informed consent will be obtained from participants to collect and retain this data. The data that will be used for analysis and dissemination for research purposes will be completely anonymized.

19. Ethical issues

All participants will be provided with information about the purpose and procedures of the study and will give written informed consent before inclusion.

The study was approved by the Ethics Committee of Hospital da Prelada (Authorization number 42-26/06/2018).

20. Dissemination of Results

The results of the study will be published in peer-reviewed scientific journal(s) and presented at relevant national and international meetings.

References

1. Edwards P, Ebert J, Joss B, Bhabra G, Ackland T, Wang A. Exercise Rehabilitation in the Non-Operative Management of Rotator Cuff Tears: a Review of the Literature. *Int J Sports Phys Ther.* 2016;11(2):279-301. <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4827371/>
2. Mitchell C, Adebajo A, Hay E, Carr A. Shoulder pain: Diagnosis and management in primary care. *Bmj.* 2005;330(November):331-1124. doi:10.1136/bmj.2005.052183.
3. Lewis JS. Rotator cuff tendinopathy/subacromial impingement syndrome: Is it time for a new method of assessment? *Br J Sports Med.* 2009;43(4):259-264. doi:10.1136/bjsm.2008.052183.
4. Thomson S, Jukes C, Lewis J. Rehabilitation following surgical repair of the rotator cuff: a systematic review. *Physiotherapy.* 2016;102(1):20-28. doi:10.1016/j.physio.2015.08.003.
5. Grant HJ, Arthur A, Pichora DR. Evaluation of interventions for rotator cuff pathology: A systematic review. *J Hand Ther.* 2004;17(2):274-299. doi:10.1197/j.jht.2004.02.013.
6. Littlewood C, May S, Walters S. Epidemiology of rotator cuff tendinopathy: a systematic review. *Shoulder Elb.* 2013;(December 2012):n/a-n/a. doi:10.1111/sae.12028.
7. Bey MJ, Song HK, Wehrli FW, Soslowsky LJ. Intratendinous strain fields of the intact supraspinatus tendon: The effect of glenohumeral joint position and tendon region. *J Orthop Res.* 2002;20(4):869-874. doi:10.1016/S0736-0266(01)00177-2.
8. Littlewood C, Bateman M. Rehabilitation following rotator cuff repair: a survey of current UK practice. *Shoulder Elb.* 2015;7(3):193-204. doi:10.1177/1758573215571679.
9. Ross D, Maerz T, Lynch J, Norris S, Baker K, Anderson K. Rehabilitation following arthroscopic rotator cuff repair: a review of current literature. *J Am Acad Orthop Surg.* 2014;22(1):1-9. doi:10.5435/JAAOS-22-01-1.
10. Factor D, Dale B. Current concepts of rotator cuff tendinopathy. *Int J Sports Phys Ther.* 2014;9(2):274-288.

SH-RCT-ARCR-01 Study Protocol

<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC10389083/>

11. Hawkins RJ, Morin WD, Bonutti PM. Surgical treatment of full-thickness rotator cuff tears in patients 40 years of age or younger. *J Shoulder Elbow Surg.* 1999;8(3):259-265. <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC10389083/>.

12. Tempelhof S, Rupp S, Seil R. Age-related prevalence of rotator cuff tears in asymptomatic shoulders. *J Shoulder Elb Surg.* 1999;8(4):296-299. doi:10.1016/S1058-2746(99)90148-9.

13. Jackins S. Postoperative shoulder rehabilitation. *Phys Med Rehabil Clin N Am.* 2004;15(3):643-682. doi:10.1016/j.pmr.2004.01.002.

14. Christensen BH, Andersen KS, Rasmussen S, Andreasen EL, Nielsen LM, Jensen SL. Enhanced function and quality of life following 5 months of exercise therapy for patients with irreparable rotator cuff tears - An intervention study. *BMC Musculoskelet Disord.* 2016;17(1):1-8. doi:10.1186/s12891-016-1116-6.

15. van der Meijden OA, Westgaard P, Chandler Z, Gaskill TR, Kokmeyer D, Millett PJ. Rehabilitation after arthroscopic rotator cuff repair: current concepts review and evidence-based guidelines. *Int J Sports Phys Ther.* 2012;7(2):197-218.
<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3325631/>

16. Page M, Green S, McBain B, et al. Manual therapy and exercise for rotator cuff disease (Review). *Cochrane Database Syst Rev.* 2016;(6). doi:10.1002/14651858.CD012224.www.cochranelibrary.com.

17. Mall NA, Tanaka MJ, Choi LS, Paletta GA. Factors affecting rotator cuff healing. *J Bone Jt Surg - Am Vol.* 2014;96(9):778-788. doi:10.2106/JBJS.M.00583.

18. Boissonnault WG, Beth Badke M, Wooden MJ, Ekedahl S, Fly K. Patient Outcome Following Rehabilitation for Rotator Cuff Repair Surgery: The Impact of Selected Medical Comorbidities. *J Orthop Sport Phys Ther.* 2007;37(6):312-319. doi:10.2519/jospt.2007.2448.

19. Mather III RC, Koenig L, Acevedo D, et al. The Societal and Economic Value of Rotator Cuff Repair. *J Bone Jt Surg.* 2013;95:1993-2000.

20. Millett PJ, Wilcox RB, O'Holleran JD, Warner JJ. Rehabilitation of the Rotator Version 2.0

Date: 06/14/2018

SH-RCT-ARCR-01 Study Protocol

Approach. *J Am Acad Orthop Surg.* 2006;14(11):599-609.

21. Dickinson RN, Kuhn JE, Bergner JL, Rizzone KH. A systematic review of cost-effective treatment of postoperative rotator cuff repairs. *J Shoulder Elb Surg.* 2017;26(5):915-922. doi:10.1016/j.jse.2017.02.009.

22. Gallagher BP, Bishop ME, Tjoumakaris FP, Freedman KB. Early versus delayed rehabilitation following arthroscopic rotator cuff repair: A systematic review. *Phys Sportsmed.* 2015;43(2):178-187. doi:10.1080/00913847.2015.1025683.

23. Lee BG, Cho NS, Rhee YG. Effect of two rehabilitation protocols on range of motion and healing rates after arthroscopic rotator cuff repair: Aggressive versus limited early passive exercises. *Arthrosc - J Arthrosc Relat Surg.* 2012;28(1):34-42. doi:10.1016/j.arthro.2011.07.012.

24. Gladstone JN, Bishop JY, Lo IKY, Flatow EL. Fatty infiltration and atrophy of the rotator cuff do not improve after rotator cuff repair and correlate with poor functional outcome. *Am J Sports Med.* 2007;35(5):719-728. doi:10.1177/0363546506297539.

25. Kluger R, Bock P, Mittlböck M, Krampla W, Engel A. Long-term Survivorship of Rotator Cuff Repairs Using Ultrasound and Magnetic Resonance Imaging Analysis. *Am J Sports Med.* 2011;39(10):2071-2081. doi:10.1177/0363546511406395.

26. Baumgarten KM, Vidal AF, Wright RW. Rotator cuff repair rehabilitation: A level I and II systematic review. *Sports Health.* 2009;1(2):125-130. doi:10.1177/1941738108331200.

27. Gulotta L V., Rodeo SA. Growth Factors for Rotator Cuff Repair. *Clin Sports Med.* 2009;28(1):13-23. doi:10.1016/j.csm.2008.09.002.

28. Mazuquin BF, Wright AC, Russell S, Monga P, Selfe J, Richards J. Effectiveness of early compared with conservative rehabilitation for patients having rotator cuff repair surgery: An overview of systematic reviews. *Br J Sports Med.* 2016;(0):1-11. doi:10.1136/bjsports-2016-095963.

29. Cuff DJ, Pupello DR. Prospective randomized study of arthroscopic rotator cuff repair using an early versus delayed postoperative physical therapy protocol. *J Shoulder Elb Surg.* 2012;21(11):1450-1455. doi:10.1016/j.jse.2012.01.025.

30. Kim YS, Chung SW, Kim JY, Ok JH, Park I, Oh JH. Is early passive motion Version 2.0
Date: 06/14/2018

SH-RCT-ARCR-01 Study Protocol

exercise necessary after arthroscopic rotator cuff repair? *Am J Sports Med.* 2012;40(4):815-821. doi:10.1177/0363546511434287.

31. Kokmeyer D, Dube E, Millett PJ. Prognosis Driven Rehabilitation After Rotator Cuff Repair Surgery. *Open Orthop J.* 2016;10(1):339-348. doi:10.2174/1874325001610010339.
32. Mollison S, Shin JJ, Glogau A, Beavis RC. Postoperative Rehabilitation After Rotator Cuff Repair: A Web-Based Survey of AANA and AOSSM Members. *Orthop J Sport Med.* 2017;5(1):1-9. doi:10.1177/2325967116684775.
33. Conti M, Garofalo R, Delle Rose G, et al. Post-operative rehabilitation after surgical repair of the rotator cuff. *Chir Organi Mov.* 2009;93 Suppl 1:S55-63. doi:10.1007/s12306-009-0003-9.
34. Klintberg I, Hultenheim ACG, Svantesson U, Styf J, Karlsson J. Early loading in physiotherapy treatment after full-thickness rotator cuff repair: A prospective randomized pilot-study with a two-year follow-up. *Clin Rehabil.* 2009;23(7):622-638. doi:10.1177/0269215509102952.
35. Rokito AS, Zuckerman JD, Gallagher MA, Cuomo F. Strength after surgical repair of the rotator cuff. *J Shoulder Elb Surg.* 1996;5(1):12-17. doi:10.1016/S1058-2746(96)80025-5.
36. Düzgün I, Baltaci G, Turgut E, Atay OA. Effects of slow and accelerated rehabilitation protocols on range of motion after arthroscopic rotator cuff repair. *Acta Orthop Traumatol Turc.* 2014;48(6):642-648. doi:10.3944/AOTT.2014.13.0125.
37. De Roo P-J, Muermans S, Maroy M, Linden P, Van den Daelen L. Passive mobilization after arthroscopic rotator cuff repair is not detrimental in the early postoperative period. *Acta Orthop Belg.* 2015;81(3):485-492. <http://www.ncbi.nlm.nih.gov/pubmed/26435245>.
38. Keener JD, Galatz LM, Stobbs-Cucchi G, Patton R, Yamaguchi K. Rehabilitation Following Arthroscopic Rotator Cuff Repair. *J Bone Jt Surgery-American Vol.* 2014;96(1):11-19. doi:10.2106/JBJS.M.00034.
39. Miller BS, Downie BK, Kohen RB, et al. When do rotator cuff repairs fail? Serial ultrasound examination after arthroscopic repair of large and massive rotator cuff tears. *Am J Sports Med.* 2011;39(10):2064-2070. doi:10.1177/0363546511413372.
40. Arndt J, Clavert P, Mielcarek P, Bouchaib J, Meyer N, Kempf JF. Immediate Version 2.0
Date: 06/14/2018

passive motion versus immobilization after endoscopic supraspinatus tendon repair: A prospective randomized study. *Orthop Traumatol Surg Res.* 2012;98(SUPPL. 6):S131-S138. doi:10.1016/j.otsr.2012.05.003.

41. Riboh J, Garrigues GE. Early passive motion versus immobilization after arthroscopic rotator cuff repair. *Arthrosc J Arthrosc Relat Surg.* 2014;30(8):1-9. doi:10.1016/j.arthro.2014.03.012.

42. Düzgün I, Baltaci G, Ahmet Atay Ö. Comparison of slow and accelerated rehabilitation protocol after arthroscopic rotator cuff repair: Pain and functional activity. *Acta Orthop Traumatol Turc.* 2011;45(1):23-33. doi:10.3944/AOTT.2011.2386.

43. Denard PJ, Lädermann A, Burkhardt SS. Prevention and Management of Stiffness After Arthroscopic Rotator Cuff Repair: Systematic Review and Implications for Rotator Cuff Healing. *Arthrosc J Arthrosc Relat Surg.* 2011;27(6):842-848. doi:10.1016/j.arthro.2011.01.013.

44. Koh KH, Lim TK, Shon MS, Park YE, Lee SW, Yoo JC. Effect of immobilization without passive exercise after rotator cuff repair: Randomized clinical trial comparing four and eight weeks of immobilization. *J Bone Jt Surg - Ser A.* 2014;96(6):1-9. doi:10.2106/JBJS.L.01741.

45. Mazzocca AD, Arciero RA, Shea KP, et al. The Effect of Early Range of Motion on Quality of Life, Clinical Outcome, and Repair Integrity After Arthroscopic Rotator Cuff Repair. *Arthrosc J Arthrosc Relat Surg.* 2017;33(6):1138-1148. doi:10.1016/j.arthro.2016.10.017.

46. Roddey T, Olson SL, Gartsman GM, Hanten WP, Cook KF. A Randomized Controlled Trial Comparing 2 Instructional Approaches to Home Exercise Instruction Following Arthroscopic Full-Thickness Rotator Cuff Repair Surgery. *J Orthop Sports Phys Ther.* 2002;32:548-559.

47. Hayes K, Ginn KA, Walton JR, Szomor ZL, Murrell GAC. A randomised clinical trial evaluating the efficacy of physiotherapy after rotator cuff repair. *Aust J Physiother.* 2004;50(2):77-83. doi:10.1016/S0004-9514(14)60099-4.

48. Kweon C, Gagnier JJ, Robbins CB, Bedi A, Carpenter JE, Miller BS. Surgical Versus Nonsurgical Management of Rotator Cuff Tears. *Am J Sports Med.* 2015;43(10):2368-2372. doi:10.1177/0363546515593954.

49. Wylie JD, Beckmann JT, Granger E, Tashjian RZ. Functional outcomes assessment in shoulder surgery. *World J Orthop.* 2014;5(5):623-633.

SH-RCT-ARCR-01 Study Protocol

doi:10.5312/wjo.v5.i5.623.

50. Romeo AA, Mazzocca A, Hang DW, Shott S, Bach BR. Shoulder Scoring Scales for the Evaluation of Rotator Cuff Repair. 2004; (427):107-114. doi:10.1097/01.blo.0000142624.05526.dd.
51. Skutek M, Fremerey RW, Zeichen J, Bosch U. Outcome analysis following open rotator cuff repair. Early effectiveness validated using four different shoulder assessment scales. 2000; 120:432-436.
52. Roy J-S, Esculier J-F. Psychometric evidence for clinical outcome measures assessing shoulder disorders. *Phys Ther Rev*. 2011; 16(5):331-347. doi:10.1179/1743288X11Y.0000000043.
53. Sabesan VJ, Lombardo DJ, Khan J, Wiater JM. Assessment of the optimal shoulder outcome score for reverse shoulder arthroplasty. *J Shoulder Elb Surg*. 2015; 1-7. doi:10.1016/j.jse.2015.03.030.
54. Macdermid JC, Birmingham TB, Khadilkar L, Athwall GS. Validity of the QuickDASH in Patients With Shoulder-Related Disorders Undergoing Surgery. *Journal Orthop Sport Phys Ther*. 2015; 45(1):25-36. doi:10.2519/jospt.2015.5033.
55. Constant CR, Gerber C, Emery RJH, Søjbjerg JO, Gohlke F, Boileau P. A review of the Constant score: Modifications and guidelines for its use. *J Shoulder Elb Surg*. 2008; 17(2):355-361. doi:10.1016/j.jse.2007.06.022.
56. Kukkonen J, Kauko T, Vahlberg T, Joukainen A, Aarimaa V. Investigating minimal clinically important difference for Constant score in patients undergoing rotator cuff surgery. *J Shoulder Elb Surg*. 2013; 22:1650-1655. doi:10.1016/j.jse.2013.05.002.
57. Booker S, Alfahad N, Scott M, Gooding B, Wallace WA. Use of scoring systems for assessing and reporting the outcome results from shoulder surgery and arthroplasty. *World J Orthop*. 2015; 6(2):244-251. doi:10.5312/wjo.v6.i2.244.
58. Beaton DE, Wright JG, Katz JN. Development of the QuickDASH : Comparison of Three Item-Reduction Approaches. *J Bone Jt Surg*. 2005; 87-A(5):1038-1046.
59. Franchignoni F, Vercelli S, Giordano A, Sartorio F, Bravini E, Ferriero G. Minimal Clinically Important Difference of the Disabilities of the Arm, Shoulder and Hand Outcome Measure (DASH) and Its Shortened Version Version 2.0 Date: 06/14/2018

SH-RCT-ARCR-01 Study Protocol

(QuickDASH). *J Orthop Sport Phys Ther.* 2014;44(1):30-39.

doi:10.2519/jospt.2014.4893.