BMJ Open

Rotator cuff unloading versus loading exercise program in the conservative treatment of patients with rotator cuff tear: Protocol of a randomized controlled trial

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2020-040820
Article Type:	Protocol
Date Submitted by the Author:	29-May-2020
Complete List of Authors:	Ribeiro, Larissa; Universidade Federal de São Carlos Centro de Ciências Biológicas e da Saúde, Department of Physical Therapy Cools, Ann; Universiteit Gent, Camargo, Paula; Universidade Federal de São Carlos Centro de Ciências Biológicas e da Saúde, Department of Physical Therapy
Keywords:	REHABILITATION MEDICINE, Shoulder < ORTHOPAEDIC & TRAUMA SURGERY, PAIN MANAGEMENT

I, the Submitting Author has the right to grant and does grant on behalf of all authors of the Work (as defined in the below author licence), an exclusive licence and/or a non-exclusive licence for contributions from authors who are: i) UK Crown employees; ii) where BMJ has agreed a CC-BY licence shall apply, and/or iii) in accordance with the terms applicable for US Federal Government officers or employees acting as part of their official duties; on a worldwide, perpetual, irrevocable, royalty-free basis to BMJ Publishing Group Ltd ("BMJ") its licensees and where the relevant Journal is co-owned by BMJ to the co-owners of the Journal, to publish the Work in this journal and any other BMJ products and to exploit all rights, as set out in our licence.

The Submitting Author accepts and understands that any supply made under these terms is made by BMJ to the Submitting Author unless you are acting as an employee on behalf of your employer or a postgraduate student of an affiliated institution which is paying any applicable article publishing charge ("APC") for Open Access articles. Where the Submitting Author wishes to make the Work available on an Open Access basis (and intends to pay the relevant APC), the terms of reuse of such Open Access shall be governed by a Creative Commons licence – details of these licences and which Creative Commons licence will apply to this Work are set out in our licence referred to above.

Other than as permitted in any relevant BMJ Author's Self Archiving Policies, I confirm this Work has not been accepted for publication elsewhere, is not being considered for publication elsewhere and does not duplicate material already published. I confirm all authors consent to publication of this Work and authorise the granting of this licence.

Rotator cuff unloading *versus* loading exercise program in the conservative treatment of patients with rotator cuff tear: Protocol of a randomized controlled trial

Larissa Pechincha Ribeiro, PT, MS[1], Ann Cools, PT, PhD[2], Paula Rezende Camargo, PT, PhD[1, *]

[1] Laboratory of Analysis and Intervention of the Shoulder Complex, Department of Physical Therapy, Universidade Federal de São Carlos, São Carlos, Brazil.

[2] Ghent University, Faculty of Medicine and Health Sciences, Department of Rehabilitation Sciences and Physical Therapy, Ghent, Belgium.

* Corresponding Author at:

Departamento de Fisioterapia, Universidade Federal de São Carlos, (+55) 16-33066695; Rodovia Washington Luiz, Km 235, CEP:13.565-905, São Carlos, SP, Brazil; Email address: prcamargo@ufscar.br

ABSTRACT

Introduction: Atraumatic and degenerative rotator cuff tears are common in individuals over 55 years of age. This condition can have a high impact on social life and is associated with chronic pain, weakness and dysfunction of the upper limb. There is evidence that conservative approaches should be the first treatment option. Conservative treatment usually addresses a variety of therapeutic behaviors without providing scientific arguments for the choice and progression of exercises.

Objective: To compare the effects of two different exercise programs based on the load of the rotator cuff on a population with shoulder pain and rotator cuff tears.

Methods and analysis: This is a controlled, randomized, blinded clinical trial. Seventy-eight individuals with shoulder pain and presence of atraumatic and degenerative rotator cuff tear will participate and will be randomly distributed between two groups. The primary outcome will be quality of life (WORC index), and secondary outcomes will include pain, function (DASH), fear avoidance beliefs (FABQ-Brazil), kinesiophobia (Tampa Scale), pain catastrophizing scale, muscle strength of abductors, lateral and medial rotators of the shoulder, range of motion of arm elevation and patient satisfaction. The treatment will be performed for 12 weeks (2x/week) acording to the selected group (Rotator Cuff Unloading x Rotator Cuff Loading Exercise Program).

Ethics and dissemination: The study protocol was approved by the Institutional Review Board. The findings of the trial will be disseminated through peer-reviewed journals and scientific conferences.

Trial registration number: NCT03962231

Keywords: physical therapy, rehabilitation, impingement syndrome.

Strength and limitations of the study:

- This study is a unique randomized controlled trial that compares rotator cuff loading *versus* unloading exercises on clinical aspects in patients with rotator cuff tears.

- The results of this study will likely contribute to the physical therapy's decision-making on exercise prescriptions to individuals with rotator cuff tears.

- This study is randomized, prospectively registered, concelead allocation, with blinded evaluators and intention-to-treat approach.

- The results of this study cannot be extrapolated to individuals with massive rotator cuff tears.

- The results of this study cannot be extrapolated to individuals with traumatic rotator cuff tear and to those who already undergone surgical repair.

INTRODUCTION

Rotator cuff disease is one of the most common musculoskeletal disorders in the adult population. Rotator cuff tears are highly prevalent, from 22% at the age of 65 years, to more than 62% in a population over 80 years old,[1] and appear to be an age-related finding on diagnostic imaging. The supraspinatus tendon is the most commonly affected tendon due to its anatomical location, tensile and compressive overload,[2] vascular changes and degeneration process associated with aging.[3] Although degenerative rotator cuff tears are not necessarily symptomatic,[4–6] a significant proportion of these injuries cause pain and disability of the patient over time. This condition may have a high impact in social life and can be associated to chronic pain, weakness, and dysfunction of the upper extremities.[7]

The health care system usually deals with increasing expenses for rotator cuff surgery.[8–11] In addition, shoulder dysfunction is associated with high societal cost and patient burden. A recent systematic review with meta-analysis has supported that conservative approaches should be the first-line treatment for individuals with rotator cuff tears.[12] The rationale for this is that both surgical and non-surgical approaches improve function and pain in patients with tears of the rotator cuff.

The current gap in literature consists of the lack of knowledge on which exercises are the best to perform in this population: either exercises to strengthen the remaining muscle fibers of the rotator cuff (loading the rotator cuff), or exercises focusing on strengthening the other shoulder muscles, whilst decreasing the tension on the rotator cuff muscles (unloading the rotator cuff). At present, both exercise types are combined in most existing treatment programs,[13,14] or rotator cuff tension is not taken into consideration during exercise selection.

The aim of this study will be to compare the effects of a rotator cuff unloading exercise program compared to a rotator cuff loading exercise program on quality of life, pain, function, fear avoidance beliefs, kinesiophobia, pain catastrophizing, strength, range of motion and satisfaction with treatment in patients with shoulder pain and rotator cuff tear.

METHODS AND ANALYSIS

Study Design

The study will be a 2-arm, prospectively registered randomized controlled trial with a blinded assessor. The trial has been designed according to the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) and Consolidated Standards of Reporting Trials (CONSORT) guidelines.

Study Setting

The study will be conducted at the Laboratory of Analysis and Intervention of the Shoulder Complex at XXXX.

Eligibility Criteria

A physical therapist with seven years of clinical experience will determine wether or not patients will be eligible to participate in the study. Individuals of both sexes, older than 55 years, with shoulder pain and atraumatic supraspinatus tendon tear documented with magnetic resonance imaging or ultrasound, at least 90° of active arm elevation will participate in the study.

The exclusion criteria will include individuals with history of trauma related to the onset of symptoms; history of clavicle, scapula and/or humerus fracture; pain related to the cervical spine; previous shoulder surgery; glenohumeral arthritis; inflammatory arthritis; adhesive capsulitis and cognitive disorders.

Individuals will be discontinued from the study if they present fractures, surgeries, musculoskeletal injuries or neurological diseases that prevent attendance at sessions, or get corticosteroid injection at the shoulder complex during the treatment or follow-up periods. Any additional event, as adverse effects, or use of ice and hot pack during the course of the study will be registered. Individuals who will be excluded, discontinued, or who will complete study follow-up with remaining shoulder symptoms will receive written and verbal information about shoulder pain management and exercises.

Procedure

The participants will be recruited through flyers placed at the University, outpatient clinics and community. Advertisements in local radio, and online resources (eg, university intranet and social media) will also be used for recruitment of patients. All eligible participants will receive information about the study and will sign an informed consent form before participation. The assessor will collect the baseline data prior to randomization, after the 12-week intervention period and 1 month after the end of treatment (follow-up). Satisfaction will only be assessed after the 12-week intervention period and at follow-up. Figure 1 brings the flow diagram of the study.

Outcome measures

The primary outcome measure will be quality of life. The secondary outcomes will be pain, function, fear avoidance beliefs, kinesiophobia, pain catastrophizing, strength, range of motion and satisfaction with treatment. All scales and questionnaires have been translated and cross-culturally adapted into Brazilian Portuguese.

Quality of Life

The WORC (The Western Ontario Rotator Cuff Index) assesses quality of life in individuals with rotator cuff disease.[15] It has 21 questions in five domains: pain and physical symptoms (6 questions), sports and recreation (4 questions), work (4 questions), lifestyle (4 questions), and emotional state (3 questions). The total score ranges from 0 to 2100. Higher scores indicate worse quality of life. It is a reliable instrument.[16]

Pain

The 11-point numerical pain rating scale will be used to assess current level of shoulder pain at rest, during arm movement, and the greatest and lowest level of shoulder pain in the last week.[17] The score ranges from 0 (no pain) to 10 (worst possible pain). This scale is reliable and valid for individuals with shoulder pain.[18]

Function of the Upper Limbs

The DASH (Disabilities of the Arm, Shoulder, and Hand) questionnaire will be used to assess upper limb function.[19] It contains 30 questions that include items related to physical function, symptoms, and social function. Each question has 5 possible answers ranging from “No difficulty” to “Unable”, and is scored on a 5-point rating scale. The maximum score is 100, which indicates the worst possible condition.[20] This questionnaire has been shown to be reliable.[19]

Fear Avoidance Beliefs

The Fear Avoidance Beliefs Questionnaire (FABQ-Brazil)[21] will be used to measure fear avoidance. The FABQ-Brazil is a 6-item questionnaire that compromises 2 subscales physical activity and work activities. Each item is scored on a 7-point scale ranging from "strongly agree" to "strongly disagree". The final scores range from 0 to 42 for physical activity subscale and from 0 to 24 for work activities subscale[21]. Higher scores indicate higher beliefs in fear and avoidance.[22] It has been currently used in patients with shoulder pain.[23–25]

Kinesiophobia

The Tampa Kinesiophobia Scale assesses the individual's fear of movement and the fear of pain recurrence.[26] It has 17 questions that address pain and symptom intensity. The final score ranges from 17 to 68 points. Higher scores indicate higher kinesiophobia.[26] It has been used in individuals with shoulder pain and has good reliability.[23]

Pain Catastrophizing

This scale contains 13 items divided into 3 domains: helplessness, magnification and rumination. Total scores ranges from 0 to 52. Higher values indicate higher degree of catastrophic thoughts.[27] It has been currently used in patients with shoulder pain.[28,29]

Muscle Strength

Strength of the shoulder abductors[30], external and medial rotators[31,32] (Figure 2) will be measured using a hand-held dynamometer (Lafayette

Instrument Company, Lafayette, IN, USA). A submaximal repetition of each test will be performed for familiarization. Next, three 5-second repetitions with a 1min-rest interval between repetitions will be performed. The order of the tests will be randomized.

Range of Motion

Range of motion of active arm elevation in the sagittal and scapular planes as well as the painful arcs will be assessed using a digital inclinometer[33,34] (AcumarTM Lafayette Instrument Company, Lafayette, IN). Individuals will be asked to elevate their arm in the standing position.

Satisfaction

The Global Rating of Change Scale[35] will be used to assess patient's satisfaction with the treatment. It is a 15-point numeric scale ranging from -7 (vastly worse) to 0 ("unchanged") to +7 ("vastly better"). Higher scores indicate better satisfaction. Participants will respond to the following question: "How satisfied are you with your shoulder?" Nothing, a little, moderately or totally are the answer options to assess satisfaction.

Random Allocation

Patients will be randomly assigned to one of the two groups: Rotator Cuff Unloading Group or Rotator Cuff Loading Group. Randomization will be computer based and carried out at a 1:1 ratio according to a random sequence generated by the website http://www.randomization.com, stratified by sex and age. An independent researcher, not involved in the treatment or assessment, will perform the randomization process and prepare the sealed opaque envelopes with group allocation consecutively numbered. The envelopes will be securely stored and will be opened in sequence to reveal group allocation prior to the first treatment session by the researcher responsible for the treatments.

Blinding

The assessor will be blinded to treatment group assignment and the patients will be treated individually and blinded to the study hypothesis.

Interventions

Each intervention program will consist of 24 supervised sessions, which will be executed 2 times/week for 12 weeks. Both groups will receive advice with respect to pain control, posture and range of motion. Adherence to treatment and assessment sessions will be encouraged at each session.

The exercise program for both groups will be based on a systematic review,[36] providing a continuum of exercises, from low rotator cuff to high rotator cuff load. The selected exercises for the Rotator Cuff Unloading Group will be based on a muscle activation equal to or less than 20% of the supraspinatus maximal activity.[36] The selected exercises for the Rotator Cuff Loading Group will be based on a muscle activation equal to or greater than 40% of the supraspinatus maximal activity. All exercises will be performed in 3 sets of 10 repetitions with a 1-minute interval between repetitions.

Rotator Cuff Unloading Exercise Program

Patients in this group will perform 4 exercises: semi-closed kinetic chain elevation, deltoid reeducation,[37] assisted arm elevation, and for scapular control.[38,39] The exercises and their progressions are described in the Appendix.

Rotator Cuff Loading Exercise Program

Patients in this group will perform conventional exercises focusing on external rotation, internal rotation and arm elevation. The exercises and their progressions are described in the Appendix.

Participant Timeline

The flowchart summarising procedures and patients is shown in Figure 1.

Sample Size

The sample size calculation was based on the smallest significant difference of 282.6 points from the Western Ontario Rotator Cuff Index (WORC)[40] with a standard deviation of 400 points, a power of 80%, and a significance level of 5%. WORC was selected because it evaluates the quality of life of individuals with rotator cuff disease. Accounting for a 15% dropout, 78 subjects will be included in the study, randomly allocated to two treatment

groups: Rotator Cuff Unloading Exercise Program (n = 39) and Rotator Cuff Loading Exercise Program (n = 39).

Data management, monitoring and sharing

All data from recruitment, characteristics of the individuals who will complete or dropout the study will be entered into an electronic form by the researchers, and the integrity and validity of the data will be verified. Identification of possible patients will be done only by the researchers. The research team is trained to address the eligibility criteria during the contact about survey made by e-mail, phone calls and messages. Also, the team is trained about how and when to contact them for follow-up and data collection.

The results of this article will be shared (text, tables, figures, appendices) immediately after publication. No interim analyses have been planned. To request data you will need to sign a data access agreement and the request can be made by e-mail. The changes made to the protocol will be communicated to ethics committee and also be included in the clinical trial register.

Patient and Public Involvement

The patients were not involved in the design, will not be involved in the conduction and dissemination of the research. The results will be sent by e-mail or telephone in an unscientific language so that all patients understand the study's conclusions and know how to maintain self-care.

Statistical Analysis

For data analysis, the statistical program Statistical Package for the Social Sciences version 23 will be used. Continuous data will be presented as mean, standard deviation and mean difference between groups with 95% confidence interval, and categorical by frequency and percentage. Data normality will be verified by Kolmogorov Smirnov test and observation of histograms for each variable in each group. Statistical analysis will follow the principles of intention-to-treat analysis. Linear mixed models will be used to calculate differences between groups using the terms of group interaction (Rotator Cuff Unloading Group *versus* Rotator Cuff Loading Group) versus time

(pre-treatment, 12 weeks at the end of treatment, and a month after the end of treatment) for each variable.

ETHICS AND DISSEMINATION

Ethical Aspects

This study was approved by the Human research Ethics Committee of the University (CAAE: 12899719.5.0000.5504) and prospectively registered at clinicaltrials.gov (NCT03962231) on September, 2019.

Dissemination

The study will be disseminated through publication in peer-reviewed international journals, as well as presentations at national and international conferences.

Discussion

Potential Impact and Significance of the Study

Degenerative tears in the rotator cuff is a common finding in imaging studies due to the natural aging process.[4,41] There is evidence that therapeutic exercises should be the first treatment option for these patients[14] because the surgical approach is not clinically superior than the non-surgical approach in this population.[12] Several exercise protocols have been proposed for this population.[14] However, there is no consensus on which exercises or exercise programs are the most effective. This fact challenges the physical therapist in the clinical decision-making. Thus, the results of this study will likely contribute to the physical therapy's decision-making on exercise prescriptions to individuals with rotator cuff tears.

Strengths and Weaknesses of the Study

The strength of the current study is that it is a randomized controlled trial that has been prospectively registered. Furthermore, the study includes concealed allocation and an intention-to treat approach. The sample size has been calculated to provide appropriate statistical power to detect differences between the 2 treatment programs.

The assessor responsible for collecting outcome data will be blinded to treatment group assignment. Physical therapists responsible for treatment have similar clinical experience and have been trained by the main author of the study. However, the study has some limitations. Participants and therapists cannot be blinded. Both exercise programs include home guidelines, which depend on each participant's motivation. It is not possible to predict the amount of home guidelines and cryotherapy that will be performed by each group.

Contribution to the Physical Therapy Profession and to Patients

The results of this study will provide scientific basis to support physical therapists in the treatment of individuals with rotator cuff tears, helping in the choice of exercises and their progression. In addition, the findings may also help health care providers and patients with rotator cuff tears to reduce health costs, avoiding the need for surgery and the use of analgesic drugs. Participants will be taught how to modify their daily activities by modifying the movements and postures that appear to increase shoulder symptoms. The participants also receive a series of exercises to be performed at home in the follow-up. It is expected that patients will become independent and more empowered with good quality of life and function of the upper limbs.

Finally, the findings of the current study may contribute to a better understanding of the efficacy of exercise program for individuals with rotator cuff tears.

REFERENCES

1. Teunis T, Lubberts B, Reilly BT, Ring D. A systematic review and pooled analysis of the prevalence of rotator cuff disease with increasing age. *J Shoulder Elb Surg*. 2014;23(12):1913-1921. doi:10.1016/j.jse.2014.08.001

2. Bunker T. Rotator cuff disease. *Curr Orthop*. 2002;16(3):223-233. doi:10.1054/cuor.2002.0257

3. Spargoli G. Supraspinatus Tendon Pathomechanics: a Current Concepts Review. *Int J Sports Phys Ther*. 2018;13(6):1083-1094. doi:10.26603/ijspt20181083

4. Minagawa H, Yamamoto N, Abe H, et al. Prevalence of symptomatic and asymptomatic rotator cuff tears in the general population: From mass-screening in one village. *J Orthop*. 2013;10(1):8-12. doi:10.1016/j.jor.2013.01.008

5. Moosmayer S, Tariq R, Stiris MG, Smith HJ. MRI of symptomatic and asymptomatic full-thickness rotator cuff tears: A comparison of findings in 100 subjects. *Acta Orthop*. 2010;81(3):361-366. doi:10.3109/17453674.2010.483993

6. Barreto RPG, Braman JP, Ludewig PM, Ribeiro LP, Camargo PR. Bilateral magnetic resonance imaging findings in individuals with unilateral shoulder pain. *J Shoulder Elb Surg*. 2019;28(9):1699-1706. doi:10.1016/j.jse.2019.04.001

7. Lowe CJM, Moser J, Barker K. Living with a symptomatic rotator cuff tear "bad days, bad nights": A qualitative study. *BMC Musculoskelet Disord*. 2014;15(1):1-10. doi:10.1186/1471-2474-15-228

8. Malavolta EA, Assunção JH, Beraldo RA, Pinto G de MR, Gracitelli MEC, Ferreira Neto AA. Rotator cuff repair in the Brazilian Unified Health System: Brazilian trends from 2003 to 2015. *Rev Bras Ortop (English Ed*. 2017;52(4):501-505. doi:10.1016/j.rboe.2017.06.010

9. Syed UAM, Aleem AW, Wowkanech C, et al. Neer Award 2018: the effect of preoperative education on opioid consumption in patients undergoing arthroscopic rotator cuff repair: a prospective, randomized clinical trial. *J Shoulder Elb Surg*. 2018;27(6):962-967. doi:10.1016/j.jse.2018.02.039

10. Westermann RW, Anthony CA, Bedard N, et al. Opioid Consumption After Rotator Cuff Repair. *Arthrosc - J Arthrosc Relat Surg*. 2017;33(8):1467-1472. doi:10.1016/j.arthro.2017.03.016

11. Uquillas CA, Capogna BM, Rossy WH, Mahure SA, Rokito AS. Postoperative pain control after arthroscopic rotator cuff repair. *J Shoulder Elb Surg*. 2016;25(7):1204-1213. doi:10.1016/j.jse.2016.01.026

12. Piper CC, Hughes AJ, Ma Y, Wang H, Neviaser AS. Operative versus nonoperative treatment for the management of full-thickness rotator cuff tears: a systematic review and meta-analysis. *J Shoulder Elb Surg*. 2018;27(3):572-576. doi:10.1016/j.jse.2017.09.032

13. Kuhn JE, Dunn WR, An Q, et al. Effectiveness of Physical Therapy in Treating Atraumatic Full Thickness Rotator Cuff Tears. A Multicenter Prospective Cohort Study. *J Shoulder Elb Surg*. 2013;22(10):1371-1379. doi:10.1016/j.jse.2013.01.026.Effectiveness

14. Jeanfavre M, Husted S, Leff G. Exercise Therapy in the Non-Operative Treatment of Full-Thickness Rotator Cuff Tears: a Systematic Review. *Int J Sports Phys Ther*. 2018;13(3):335-378. doi:10.26603/ijspt20180335

15. Lopes A., Standniki S., Masiero D, Carrera E., Ciconelli R., Griffin S. Tradução E Adaptação Cultural Do Worc : Um Questionário De Qualidade De Vida Para Alterações Do Manguito Rotador. *Rev bras fisioter*. 2006;(3):309-315. doi:10.1590/S1413-35552006000300010

16. Lopes AD, Ciconelli RM, Carrera EF, Griffin S, Faloppa F, Dos Reis FB. Validity and reliability of the Western Ontario Rotator Cuff Index (WORC) for use in Brazil. *Clin J Sport Med Off J Can Acad Sport Med*. 2008;18(3):266-272. doi:10.1097/JSM.0b013e31817282f4

17. Jensen MP, Turner JA, Romano JM, Fisher LD. Comparative reliability and validity of chronic pain intensity measures. *Pain*. 1999;83:157-162.

18. Mintken PE, Glynn P, Cleland JA. Psychometric properties of the shortened disabilities of the Arm, Shoulder, and Hand Questionnaire (QuickDASH) and Numeric Pain Rating Scale in patients with shoulder pain. *J Shoulder Elb Surg*. 2009;18(6):920-926. doi:10.1016/j.jse.2008.12.015

19. Orfale AG, Araújo PMP, Ferraz MB, Natour J. Translation into Brazilian Portuguese, cultural adaptation and evaluation of the reliability of the Disabilities of the Arm, Shoulder and Hand Questionnaire. *Brazilian J Med Biol Res*. 2005;38(2):293-302. doi:10.1590/S0100-879X2005000200018

20. Pamela L. Hudak, BSCPT, MSC, Peter C. Amadio, MD, Claire Bombardier, MD and the UECG (UECG). Development of an Upper Extremity Outcome Measure: The DASH (Disabilities of the Arm, Shoulder, and Head). *Am J Ind Med 291602-608 Dev*. 2017;608(1 996):527-546. doi:10.1002/(SICI)1097-0274(199606)29:6<602::AID-AJIM4>3.0.CO;2-L

21. Abreu AM de, Faria CDC de M, Cardoso SMV, Teixeira-Salmela LF. Versão brasileira do Fear Avoidance Beliefs Questionnaire. 2008;24(3):615-623. http://www.scielo.br/pdf/csp/v24n3/15.pdf.

22. Souza FS de, Marinho C da S, Siqueira FB, Maher CG, Costa LOP. Psychometric testing confirms that the Brazilian-Portuguese adaptations, the original versions of the fear-avoidance beliefs questionnaire, and the Tampa Scale of Kinesiophobia have similar measurement properties. *Spine (Phila Pa 1976)*. 2008;33(9):1028-1033. doi:10.1097/BRS.0b013e31816c8329

23. Mintken PE, Cleland JA, Whitman JM, George SZ. Psychometric Properties of the Fear-Avoidance Beliefs Questionnaire and Tampa Scale of Kinesiophobia in Patients With Shoulder Pain. *Arch Phys Med Rehabil*. 2010;91(7):1128-1136. doi:10.1016/j.apmr.2010.04.009

24. Riley SP, Tafuto V, Cote M, Brismée J-M, Wright A, Cook C. Reliability and relationship of the fear-avoidance beliefs questionnaire with the shoulder pain and disability index and numeric pain rating scale in

patients with shoulder pain. *Physiother Theory Pract*. 2018;00(00):1-7. doi:10.1080/09593985.2018.1453004

25. Woollard JD, Bost JE, Piva SR, Kelley Fitzgerald G, Rodosky MW, Irrgang JJ. The ability of preoperative factors to predict patient-reported disability following surgery for rotator cuff pathology. *Disabil Rehabil*. 2017;39(20):2087-2096. doi:10.1080/09638288.2016.1219396

26. Siqueira FB, Teixeira-Salmela LF, Magalhães LDC. Análise das Propriedades Psicométricas da Versão Brasileira da Escala Tampa de Cinesiofobia. *Acta Ortop Bras*. 2007;15(1):19-24. doi:10.1590/S1413-78522007000100004

27. Sehn F, Chachamovich E, Vidor LP, et al. Cross-Cultural Adaptation and Validation of the Brazilian Portuguese Version of the Pain Catastrophizing Scale. *Pain Med*. 2012;13(11):1425-1435. doi:10.1111/j.1526-4637.2012.01492.x

28. George SZ, Hirsh AT. Psychologic Influence on Experimental Pain Sensitivity and Clinical Pain Intensity for Patients with Shoulder Pain. *J Pain*. 2009. doi:10.1016/j.jpain.2008.09.004

29. George SZ, Staud R, Borsa PA, et al. Biopsychosocial influence on shoulder pain: Rationale and protocol for a pre-clinical trial. *Contemp Clin Trials*. 2017;56:9-17. doi:10.1016/j.cct.2017.03.005

30. Katoh M. Test-retest reliability of isometric shoulder muscle strength measurement with a handheld dynamometer and belt. *J Phys Ther Sci*. 2015;27(6):1719-1722. doi:10.1589/jpts.27.1719

31. Schrama PPM, Stenneberg MS, Lucas C, Van Trijffel E. Intraexaminer reliability of hand-held dynamometry in the upper extremity: A systematic review. *Arch Phys Med Rehabil*. 2014;95(12):2444-2469. doi:10.1016/j.apmr.2014.05.019

32. Cools AMJ, Vanderstukken F, Vereecken F, et al. Eccentric and isometric shoulder rotator cuff strength testing using a hand-held dynamometer: reference values for overhead athletes. *Knee Surgery, Sport Traumatol Arthrosc*. 2016;24(12):3838-3847. doi:10.1007/s00167-015-3755-9

33. Kolber MJ, Hanney WJ. The reliability and concurrent validity of shoulder mobility measurements using a digital inclinometer and goniometer: a technical report. *Int J Sports Phys Ther*. 2012;7(3):306-313. doi:10.3109/09593985.2011.574203

34. Kolber MJ, Vega F, Widmayer K, Cheng M-SS. The reliability and minimal detectable change of shoulder mobility measurements using a digital inclinometer. *Physiother Theory Pract*. 2010;27(2):176-184. doi:10.3109/09593985.2010.481011

35. Kamper SJ, Maher CG, Mackay G. Global Rating of Change Scales: A Review of Strengths and Weaknesses and Considerations for Design. *J Man Manip Ther*. 2014;17(3):163-170. doi:10.1179/jmt.2009.17.3.163

36. Edwards PK, Ebert JR, Littlewood C, Ackland T, Wang A. A Systematic Review of Electromyography Studies in Normal Shoulders to Inform Postoperative Rehabilitation Following Rotator Cuff Repair. *J Orthop Sport Phys Ther*. 2017;47(12):931-944. doi:10.2519/jospt.2017.7271

37. Levy O, Mullett H, Roberts S, Copeland S. The role of anterior deltoid reeducation in patients with massive irreparable degenerative rotator cuff tears. *J Shoulder Elb Surg*. 2008;17(6):863-870. doi:10.1016/j.jse.2008.04.005

38. Kibler W Ben, Sciascia AD, Uhl TL, Tambay N, Cunningham T. Electromyographic analysis of specific exercises for scapular control in early phases of shoulder rehabilitation. *Am J Sports Med*. 2008;36(9):1789-1798. doi:10.1177/0363546508316281

39. De Mey K, Danneels L, Cagnie B, Van den Bosch L, Flier J, Cools AM. Kinetic chain influences on upper and lower trapezius muscle activation during eight variations of a scapular retraction exercise in overhead athletes. *J Sci Med Sport*. 2013;16(1):65-70. doi:10.1016/j.jsams.2012.04.008

40. Gagnier JJ, Robbins C, Bedi A, Carpenter JE, Miller BS. Establishing minimally important differences for the American Shoulder and Elbow Surgeons score and the Western Ontario Rotator Cuff Index in patients

with full-thickness rotator cuff tears. *J Shoulder Elb Surg*. 2018;27(5):e160-e166. doi:10.1016/j.jse.2017.10.042

41. Fehringer E V., Sun J, VanOeveren LS, Keller BK, Matsen FA. Full-thickness rotator cuff tear prevalence and correlation with function and co-morbidities in patients sixty-five years and older. *J Shoulder Elb Surg*. 2008;17(6):881-885. doi:10.1016/j.jse.2008.05.039

Authors' contributions: Each of the authors has contributed substantially and concurs with the content in the manuscript.

Funding statement: Coordenação de Aperfeiçoamento de Pessoal de Nível Superior and Conselho Nacional de Desenvolvimento Científico e Tecnológico (144436/2019-1)

Acknowledgement: We would like to thank Coordenação de Aperfeiçoamento de Pessoal de Nível Superior and Conselho Nacional de Desenvolvimento Científico e Tecnológico (144436/2019-1) for the fellowship provided to the first author.

Competing interests statement: We affirm that we have no financial affiliation or involvement with any commercial organization that has a direct financial interest in any matter included in this manuscript, except as disclosed in an attachment and cited in the manuscript.

Word Count: 2.458 (Unmasked version)

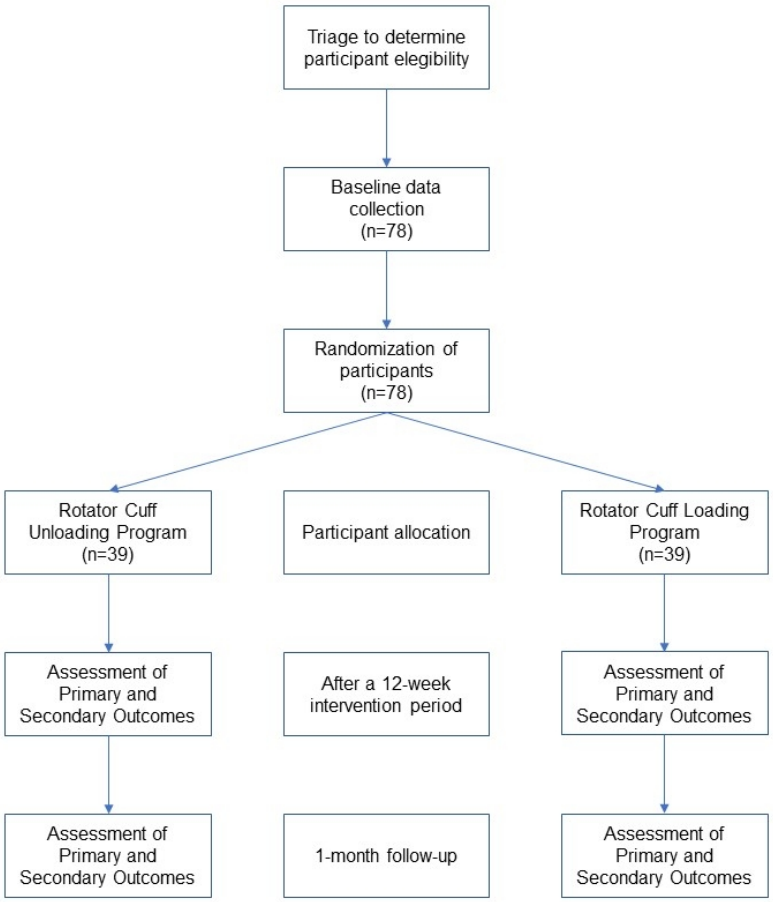


Figure 1. Study flow diagram

60x88mm (300 x 300 DPI)

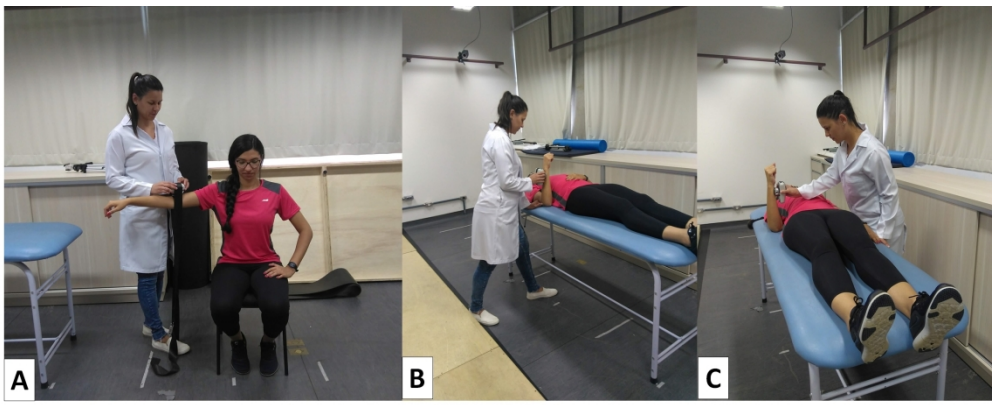
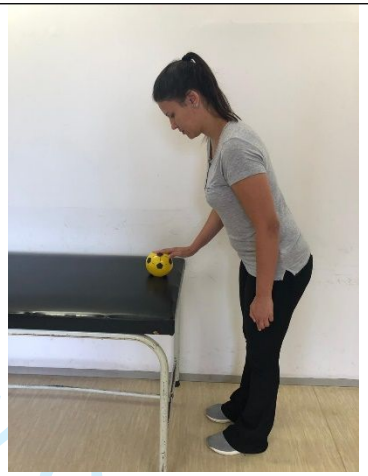


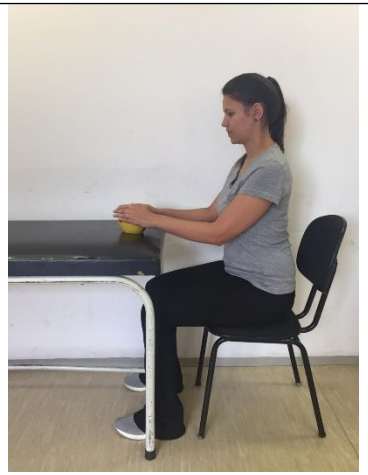
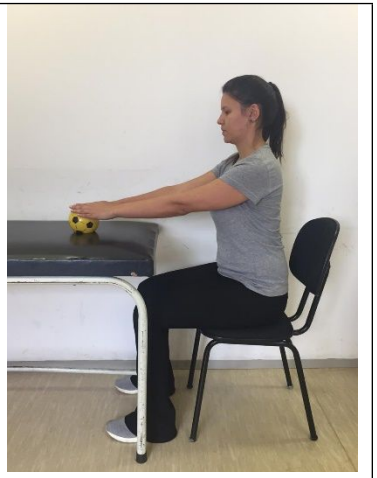
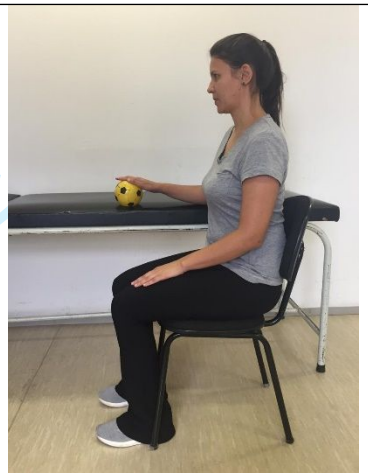
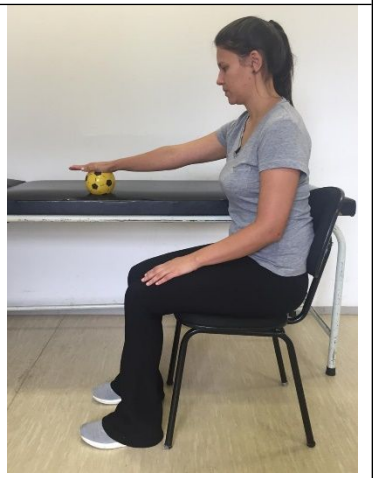
Figure 2. Muscle strength of abductors (A), external rotators (B) and internal rotators (C) of the shoulder

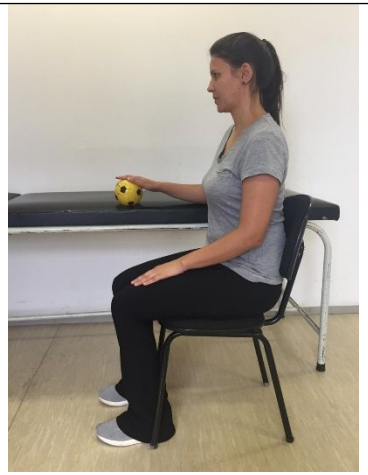
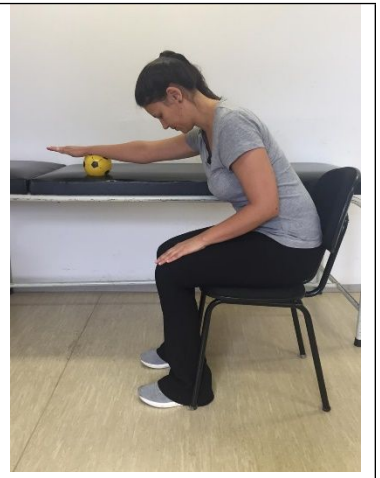
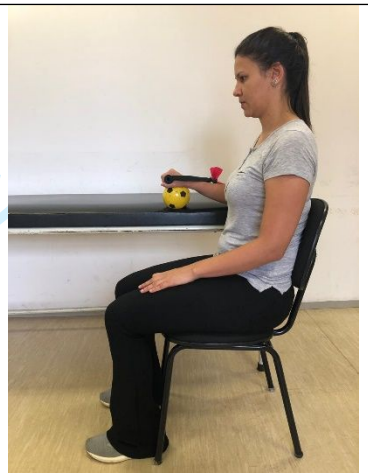
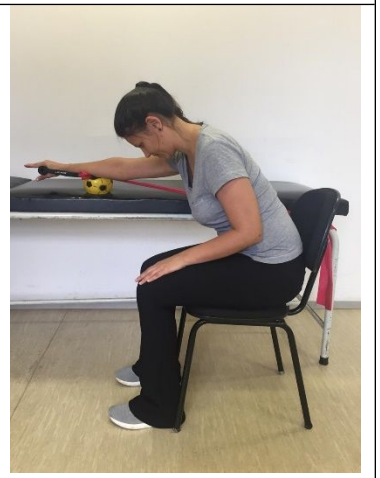
224x97mm (300 x 300 DPI)

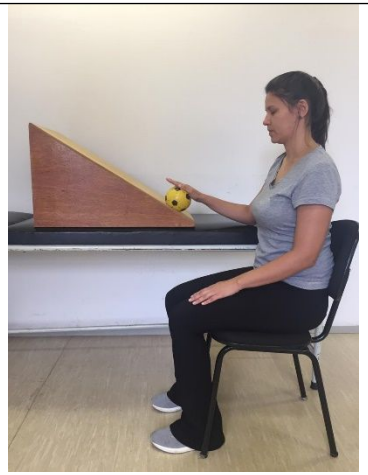
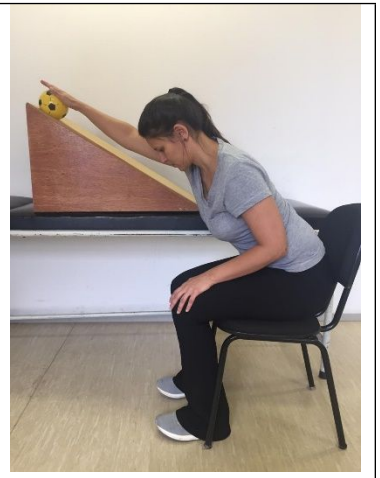
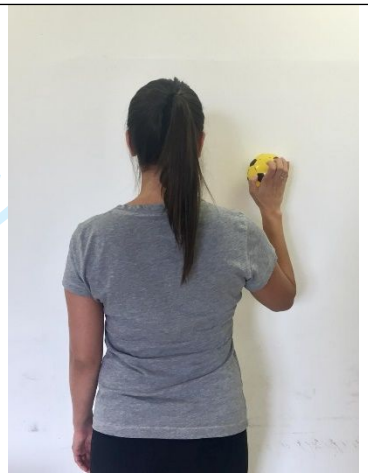
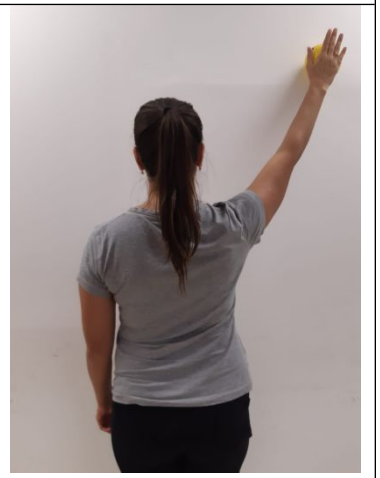
APPENDIX

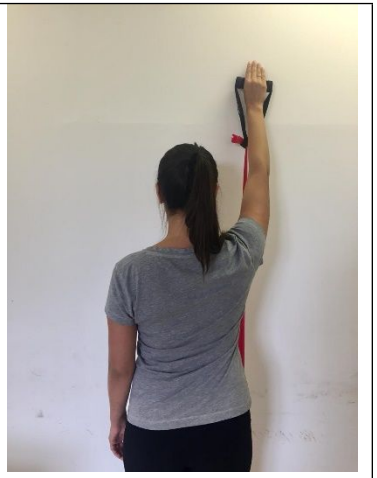
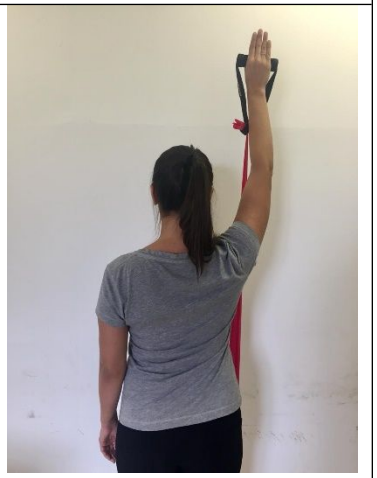
Rotator Cuff Unloading Exercise Program

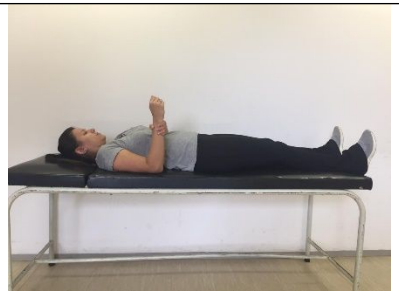
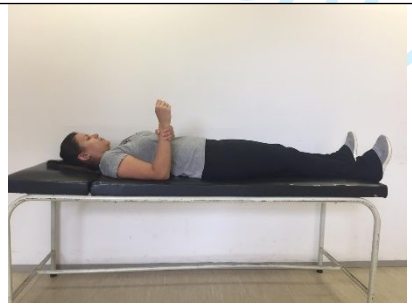
Semi-Closed Kinetic Chain Exercises and progressions				
Exercise	**Initial Position**	**Performance**	**Initial Position**	**Final Position**
1) Closed Chain Pendulum	Patient in standing position supporting the hand on a ball positioned on a treatment table with the trunk inclined.	Shoulder circular movements in scapular plane.		

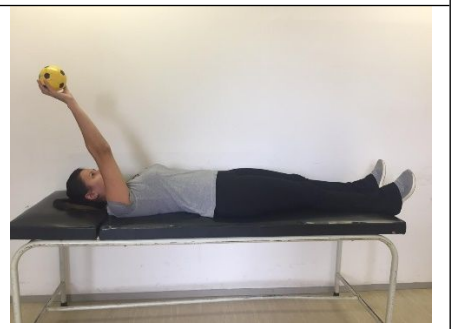
2) Bilateral Bench Slide <90º	Patient sitting in front of the treatment table supporting the hands on a ball positioned on the treatment table. Initially the elbow will be flexed and the shoulder slightly flexed.	Slide the hands over the ball, moving it forward until the elbow is extended, and shoulder flexed <90°. Keep the trunk straight.		
3) Unilateral Bench Slide <90º	Patient sitting beside to the treatment table, and supporting the hand on the ball. Initially the elbow will be flexed and the arm at the side of the trunk.	Slide the hand over the ball, moving it forward until the elbow is extended. Keep the trunk straight.		

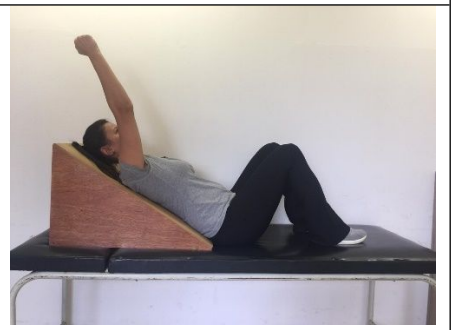
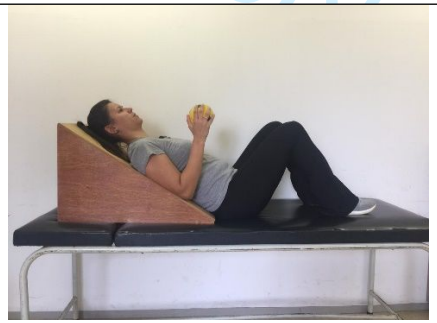
4) Unilateral Bench Slide >90º	Patient sitting beside to the treatment table, and supporting the hand on the ball. Initially the elbow will be flexed and the arm at the side of the trunk.	Slide the hand over the ball and incline the trunk forward until the elbow is extended.		
5) Unilateral Bench Slide > 90º + Resistance	Patient sitting beside to the treatment table, and supporting the hand on the ball while holding an elastic band. Initially the elbow will be flexed and the arm at the side of the trunk.	Slide the hand over the ball against resistance and incline the trunk forward until the elbow is extended. *progression: yellow, red, green and blue elastic band (Theraband).		

6) Inclined Bench Slide	Patient sitting beside to the treatment table, and supporting the hand on the ball. The ball will be on an inclined surface at 45º. Elbow will be flexed and arm at the side of the trunk.	Slide the hand over the ball, moving hand and trunk forward until elbow is extended. *progression: yellow, red, green and blue elastic band (Theraband).		
7) Wall Slide	Patient standing in front of a wall. Hand positioned on a ball or towel against the wall. Elbow will be flexed and the shoulder slightly flexed in the scapular plane.	Slide the hand over the ball or towel on the wall by moving it upward until elbow is extended in scapular plane direction.		

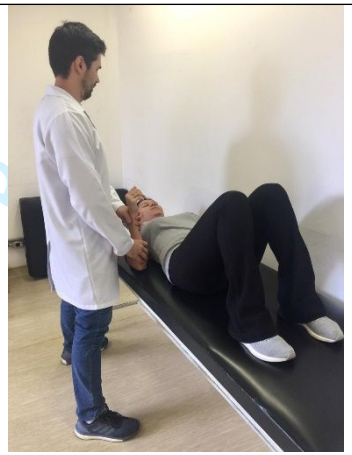
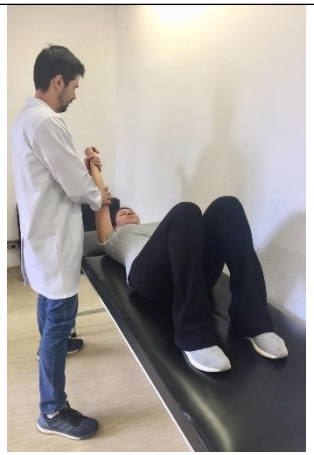
8) Wall Slide + Resistance	Patient standing in front of a wall. Hand holding an elastic band and positioned against the wall. Elbow will be flexed and the shoulder slightly flexed.	Slide the hand on the wall by moving it upward against resistance until elbow is extended. *progression: yellow, red, green and blue elastic band (Theraband).		
9) Wall Slide + Resistance + Open Chain	Patient standing in front of a wall. Hand holding an elastic band and positioned against the wall. Elbow will be flexed and the shoulder slightly flexed.	Sliding the hand on the wall by moving it upward against resistance until elbow is extended. At the end range move the hand away from the wall increasing the flexion. *progression: yellow, red, green and blue elastic band (Theraband).		

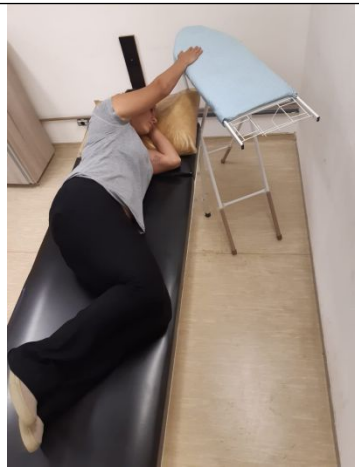
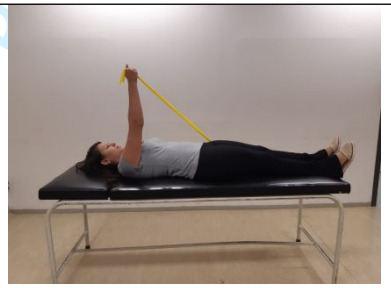
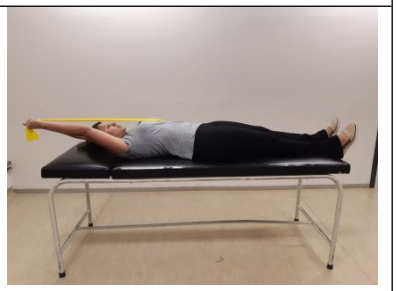
Anterior Deltoid Reeducation and progressions				
Exercise	**Position**	**Performance**	**Initial Position**	**Final Position**
1) Passive Elevation	Patient in supine, hand of the unaffected arm holds the wrist of affected arm. Elbow will be at 90º flexion and the arm at the side of the trunk.	The unaffected arm will first assist elbow extension of the affected arm keeping the shoulder at 90º of flexion. Next, the unaffected limb assists the flexion and extension of the affected shoulder during concentric and eccentric phases.		
2) Active - Weight	Patient in supine, hand of the unaffected arm holds the wrist of affected arm. Elbow will be at 90º flexion	The unaffected arm will first assist elbow extension of the affected arm keeping the shoulder at 90º of flexion. Next, the		

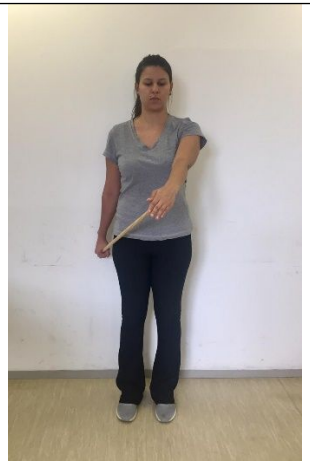
	and the arm at the side of the trunk.	affected shoulder perform flexion without assistance.		
3) Active + Weight	Patient in supine, hand of the unaffected arm holds the wrist of affected arm. Elbow will be at 90º flexion holding a toning ball.	The unaffected arm will first assist elbow extension of the affected arm keeping the shoulder at 90º of flexion. Next, the affected shoulder perform flexion without assistance with toning ball. * progression: 1kg and 2kg toning ball.		
4) Increased Trunk Inclination Angle	Patient in supine, slightly inclined trunk, hand of the unaffected arm holds the wrist of affected arm. Elbow	The unaffected arm will first assist elbow extension of the affected arm keeping the shoulder at 90º of flexion. Next, the		

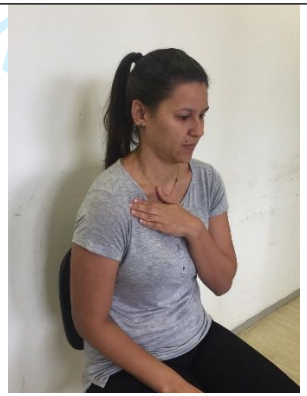
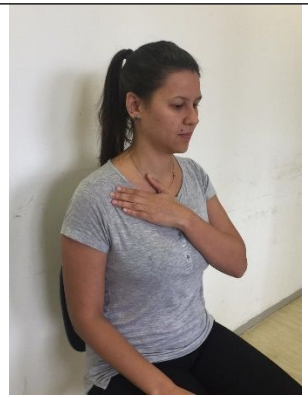
	will be at 90º flexion holding a toning ball..	affected shoulder perform flexion without assistance with toning ball.* progression: 1kg and 2kg toning ball.		
5) Seated - Weight	Patient with 60º of trunk inclination, hand of the unaffected shoulder holds the affected arm. Initially elbow at 90º flexion and arm at the side of the trunk.	The unaffected arm will first assist elbow extension of the affected arm keeping the shoulder at 90º of flexion. Next, the affected shoulder perform flexion without assistance and weight.		
6) Seated + Weight	Patient with 60º trunk inclination, elbow of the affected side at 90º flexion and arm at the side of the	The unaffected arm will first assist elbow extension of the affected arm keeping the shoulder at 90º of flexion. Next, the		

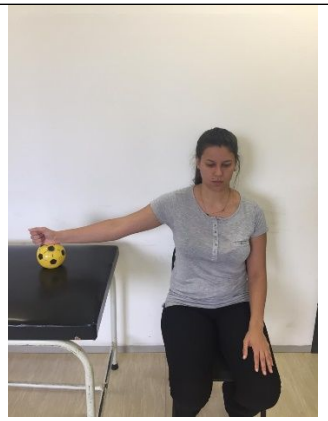
	trunk. Hand of the affected arm holds a toning ball.	affected shoulder perform flexion without assistance with toning ball.* progression: 1kg and 2kg tonning ball.

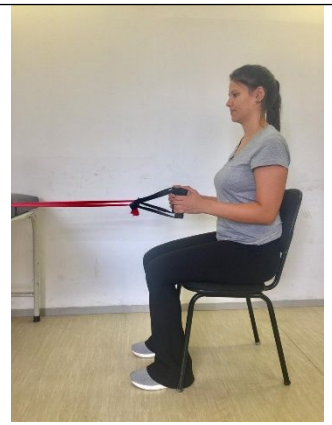
Assisted Elevation and progressions				
Exercise	**Initial Position**	**Performance**	**Initial Position**	**Final Position**
1) Therapist Assisted Elevation	Patient in supine with elbow at 90º flexion and shoulder at the side of the trunk. Therapist holds the forearm on the affected side of the patient.	Therapist assists shoulder flexion during the concentric and eccentric phases.		

2) Side Lying Elevation	Patient in side lying position, affected shoulder upwards. Support the hand on a flat surface in front of the treatment table at the same level as the height of the affected shoulder. The elbow and shoulder will be slightly flexed.	Patient slides the hand over the flat surface raising his arm with the elbow slightly bent.		
3) Supine Band	Patient in supine, holding a yellow elastic band with both hands. Unaffected shoulder remains at the side of the body and affected shoulder with 90º flexion.	The affected shoulder performs flexion with elastic band while the other shoulder remains at the side of the trunk.		

4) Bar Assisted Standing	Patient standing holding a bar	Unaffected shoulder assists the arm elevation using a bar.		

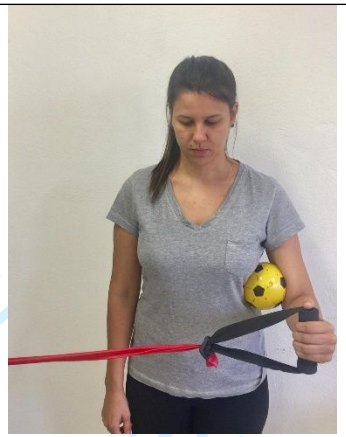
Exercises for Scapular Control and progressions				
Exercise	**Initial Position**	**Performance**	**Initial Position**	**Final Position**
1) Scapular Orientation Exercise	Patient sitting, places index finger on the coracoid process of the affected shoulder.	The patient will be instructed to move the scapula in external rotation and posterior tilt, moving the coracoid process away from the index finger or pretending to put the		

		scapula into a little hook behind.		
2) Inferior Glide	Patient sitting beside the treatment table, with affected shoulder in abduction close to 90º. A ball will be on the treatment table and the fist.	Patient will perform a pressure with the fist in the direction of arm adduction and instructed to inferiorly depress their scapula.		
3)) Low Row Static	Patient standing in front of an immovable surface and placed their hand on the anterior edge of the surface with palm facing posteriorly.	Patient will perform a shoulder extension movement against the immovable surface doing retraction and depression of the scapula.		

4) Low Row Dynamic	Patient seating holding an elastic band with shoulder flexion.	The patient will perform the movement towards shoulder extension and scapular retraction. * progression: yellow, red, green and blue elastic band (Theraband).		

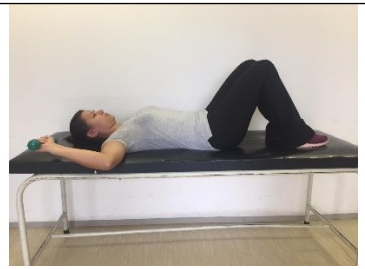
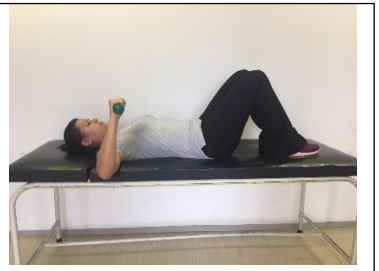
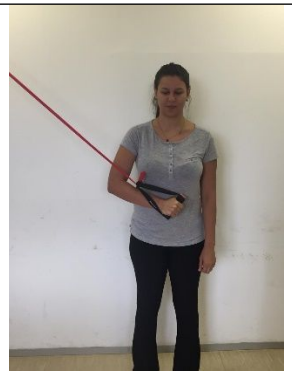
Rotator Cuff Loading Exercise Program

Focus on External Rotation and progressions				
Exercise	**Initial Position**	**Performance**	**Initial Position**	**Final Position**

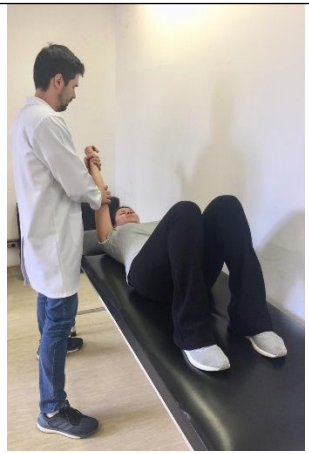
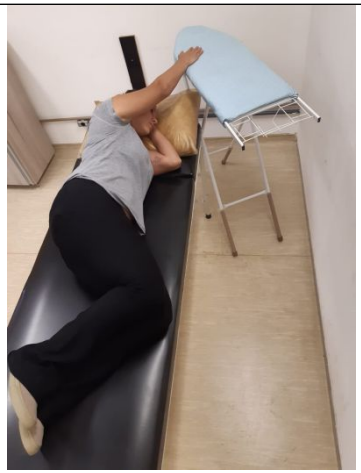
1) Side Lying External Rotation	Patient in side lying position with the affected arm upwards. Arm at the side of the trunk and elbow flexed at 90º with a dumbbell in hand.	Patient will perform external rotation of the shoulder and return to the initial position. * progression: 1kg, 2kg and 3kg dumbbell.		
2) Standing External Rotation	Patient standing with affected shoulder at the side of the trunk, elbow flexed at 90º and holding an elastic band by hand.	Patient will perform external rotation of the shoulder and return to the initial position. * progression: yellow, red and green elastic band (Theraband).		
3) External Rotation Diagonal Standing	Patient standing with affected shoulder in internal rotation, elbow flexed at 90º and	The patient will perform external rotation and abduction of the shoulder, thus performing a external		

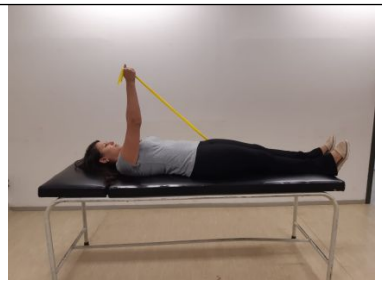
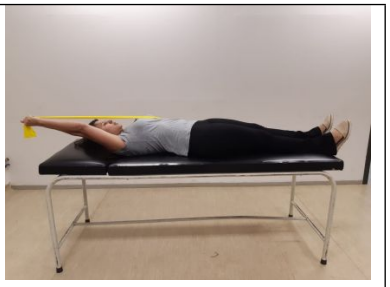
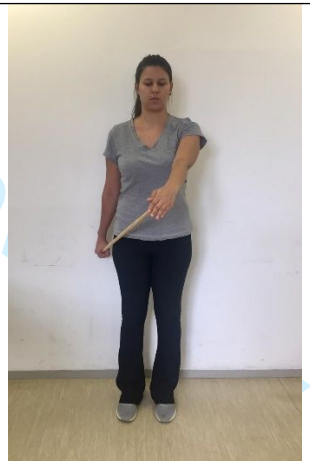
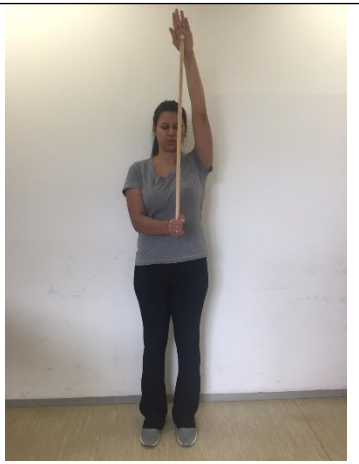
	holding an elastic band by hand.	rotation in the diagonal direction. * progression: yellow, red and green elastic band (Theraband).		

Focus on Internal Rotation and progressions				
Exercise	**Initial Position**	**Performance**	**Initial Position**	**Final Position**
1) Standing Internal Rotation	Patient standing with affected shoulder at the side of the trunk, elbow flexed at 90º and holding an elastic band.	Patient will perform internal rotation of the shoulder and return to the initial position. *progression: yellow, red and green elastic band (Theraband).		

2) Sitting Internal Rotation	Patient in supine with affected shoulder in 90º abduction and elbow in 90º flexion holding a dumbbell in hand.	Patient will perform internal rotation of the shoulder and return to the initial position. * progression: 1kg, 2kg and 3kg dumbbell.		
3) Internal Rotation Diagonal Standing	Patient standing with affected shoulder in 45º abduction, elbow in 90º flexion, holding an elastic band by hand.	Patient will perform internal rotation of the shoulder and return to the initial position. * progression: yellow, red and green elastic band (Theraband).		

Assisted Elevation and progression				
Exercise	**Initial Position**	**Performance**	**Initial Position**	**Final Position**

1) Therapist Assisted Elevation	Patient in supine with elbow at 90º flexion and shoulder at the side of the trunk. Therapist holds the forearm on the affected side of the patient.	Therapist assists shoulder flexion during the concentric and eccentric phases.		
2) Side Lying Elevation	Patient in side lying position, affected shoulder upwards. Support the hand on a flat surface in front of the treatment table at the same level as the height of the affected shoulder. The elbow and shoulder will be slightly flexed.	Patient slides the hand over the flat surface raising the arm with the elbow slightly bent.		

3) Supine Band	Patient in supine, holding a yellow elastic band with both hands. Unaffected shoulder remains at the side of the body and affected shoulder with 90º flexion.	The affected shoulder performs flexion with elastic band while the other shoulder remains at the side of the trunk.		
4) Bar Assisted Standing	Patient standing holding a bar.	Unaffected shoulder assists the arm elevation using a bar.		

Focus on Elevation and progressions				
Exercise	**Initial Position**	**Performance**	**Initial Position**	**Final Position**

1) Full can	Patient standing with arms at the side of the trunk.	Patient will perform shoulder abduction in the scapular plane without resistance and will return to the initial position. *progression: yellow, red and green elastic band (Theraband).		
2) Prone elevation (Blackburn exercise)	Patient in prone, shoulder off the treatment table and positioned perpendicular to the ground, with a shoulder at 90º flexion and elbow extended.	The patient will raise the arm in scapular plane and return to the initial position. * progression: 1kg, 2kg and 3kg dumbbell.		

SPIRIT
STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	2
	2b	All items from the World Health Organization Trial Registration Data Set	9, 10
Protocol version	3	Date and version identifier	9, 10
Funding	4	Sources and types of financial, material, and other support	18
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	18
	5b	Name and contact information for the trial sponsor	1
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	18
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	18

Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	3
	6b	Explanation for choice of comparators	3
Objectives	7	Specific objectives or hypotheses	3
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	4
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	4
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	4
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	8
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	4
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	4
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	4
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	5, 6, 7
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	5

Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	8, 9
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	5
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	7
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	7
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	7
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	7
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	7
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	5, 6, 7, 8, 9
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	4

Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	9
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	9
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	NA
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	9
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	9
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	9
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	9
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	No
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	No
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	No

Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	5
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	NA
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	9
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	18
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	9
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	No
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	9, 10
	31b	Authorship eligibility guidelines and any intended use of professional writers	9
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	9
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	Ok
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	No

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

BMJ Open

Rotator cuff unloading versus loading exercise program in the conservative treatment of patients with rotator cuff tear: Protocol of a randomized controlled trial

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2020-040820.R1
Article Type:	Protocol
Date Submitted by the Author:	05-Nov-2020
Complete List of Authors:	Ribeiro, Larissa; Universidade Federal de São Carlos Centro de Ciências Biológicas e da Saúde, Department of Physical Therapy Cools, Ann; Universiteit Gent, Camargo, Paula; Universidade Federal de São Carlos Centro de Ciências Biológicas e da Saúde, Department of Physical Therapy
Primary Subject Heading:	Rehabilitation medicine
Secondary Subject Heading:	Evidence based practice
Keywords:	REHABILITATION MEDICINE, Shoulder < ORTHOPAEDIC & TRAUMA SURGERY, PAIN MANAGEMENT

I, the Submitting Author has the right to grant and does grant on behalf of all authors of the Work (as defined in the below author licence), an exclusive licence and/or a non-exclusive licence for contributions from authors who are: i) UK Crown employees; ii) where BMJ has agreed a CC-BY licence shall apply, and/or iii) in accordance with the terms applicable for US Federal Government officers or employees acting as part of their official duties; on a worldwide, perpetual, irrevocable, royalty-free basis to BMJ Publishing Group Ltd ("BMJ") its licensees and where the relevant Journal is co-owned by BMJ to the co-owners of the Journal, to publish the Work in this journal and any other BMJ products and to exploit all rights, as set out in our licence.

The Submitting Author accepts and understands that any supply made under these terms is made by BMJ to the Submitting Author unless you are acting as an employee on behalf of your employer or a postgraduate student of an affiliated institution which is paying any applicable article publishing charge ("APC") for Open Access articles. Where the Submitting Author wishes to make the Work available on an Open Access basis (and intends to pay the relevant APC), the terms of reuse of such Open Access shall be governed by a Creative Commons licence – details of these licences and which Creative Commons licence will apply to this Work are set out in our licence referred to above.

Other than as permitted in any relevant BMJ Author's Self Archiving Policies, I confirm this Work has not been accepted for publication elsewhere, is not being considered for publication elsewhere and does not duplicate material already published. I confirm all authors consent to publication of this Work and authorise the granting of this licence.

Rotator cuff unloading *versus* loading exercise program in the conservative treatment of patients with rotator cuff tear: Protocol of a randomized controlled trial

Larissa Pechincha Ribeiro, PT, MS[1], Ann Cools, PT, PhD[2], Paula Rezende Camargo, PT, PhD[1, *]

[1] Laboratory of Analysis and Intervention of the Shoulder Complex, Department of Physical Therapy, Universidade Federal de São Carlos, São Carlos, Brazil.

[2] Ghent University, Faculty of Medicine and Health Sciences, Department of Rehabilitation Sciences and Physical Therapy, Ghent, Belgium.

* Corresponding Author at:

Departamento de Fisioterapia, Universidade Federal de São Carlos, (+55) 16-33066695; Rodovia Washington Luiz, Km 235, CEP:13.565-905, São Carlos, SP, Brazil; Email address: prcamargo@ufscar.br

Word Count: 2,557

ABSTRACT

Introduction: Atraumatic and degenerative rotator cuff tears are common in individuals over 55 years of age. This condition can have a high impact on social life and is associated with chronic pain, weakness and dysfunction of the upper limb. There is evidence that conservative approaches should be the first treatment option. Conservative treatment usually addresses a variety of therapeutic behaviors without providing scientific arguments for the choice and progression of exercises.

Objective: To compare the effects of two different exercise programs based on the load of the rotator cuff on a population with shoulder pain and rotator cuff tears.

Methods and analysis: This is a controlled, randomized, blinded clinical trial. Seventy-eight individuals with shoulder pain and presence of atraumatic and degenerative rotator cuff tear will participate and will be randomly distributed between two groups. The primary outcome will be quality of life (WORC index), and secondary outcomes will include pain, function (DASH), fear avoidance beliefs (FABQ-Brazil), kinesiophobia (Tampa Scale), pain catastrophizing scale, muscle strength of abductors, lateral and medial rotators of the shoulder, range of motion of arm elevation and patient satisfaction. The treatment will be performed for 12 weeks (2x/week) acording to the selected group (Rotator Cuff Unloading x Rotator Cuff Loading Exercise Program).

Ethics and dissemination: The study protocol was approved by the Institutional Review Board. The findings of the trial will be disseminated through peer-reviewed journals and scientific conferences.

Trial registration number: NCT03962231

Keywords: physical therapy, rehabilitation, impingement syndrome.

Strength and limitations of the study:

- This study is a unique randomized controlled trial that compares rotator cuff loading *versus* unloading exercises on clinical aspects in patients with rotator cuff tears.

- The results of this study will likely contribute to the physical therapy's decision-making on exercise prescriptions to individuals with rotator cuff tears.

- This study is randomized, prospectively registered, concelead allocation, with blinded evaluators and intention-to-treat approach.

- The results of this study cannot be extrapolated to individuals with massive rotator cuff tears.

- The results of this study cannot be extrapolated to individuals with traumatic rotator cuff tear and to those who already undergone surgical repair.

INTRODUCTION

Rotator cuff disease is one of the most common musculoskeletal disorders in the adult population. Rotator cuff tears are highly prevalent, from 22% at the age of 65 years, to more than 62% in a population over 80 years old,[1] and appear to be an age-related finding on diagnostic imaging. The supraspinatus tendon is the most commonly affected tendon due to its anatomical location, tensile and compressive overload,[2] vascular changes and degeneration process associated with aging.[3] Although degenerative rotator cuff tears are not necessarily symptomatic,[4–6] a significant proportion of these injuries cause pain and disability of the patient over time. This condition may have a high impact in social life and can be associated to chronic pain, weakness, and dysfunction of the upper extremities.[7]

The health care system usually deals with increasing expenses for rotator cuff surgery.[8–11] In addition, shoulder dysfunction is associated with high societal cost and patient burden. A recent systematic review with meta-analysis has supported that conservative approaches should be the first-line treatment for individuals with rotator cuff tears.[12] The rationale for this is that both surgical and non-surgical approaches improve function and pain in patients with tears of the rotator cuff.

The current gap in literature consists of the lack of knowledge on which exercises are the best to perform in this population: either exercises to strengthen the remaining muscle fibers of the rotator cuff (loading the rotator cuff), or exercises focusing on strengthening the other shoulder muscles, whilst decreasing the tension on the rotator cuff muscles (unloading the rotator cuff). At present, both exercise types are combined in most existing treatment programs,[13,14] or rotator cuff tension is not taken into consideration during exercise selection.

The aim of this study will be to compare the effects of a rotator cuff unloading exercise program compared to a rotator cuff loading exercise program on quality of life, pain, function, fear avoidance beliefs, kinesiophobia, pain catastrophizing, strength, range of motion and satisfaction with treatment in patients with shoulder pain and rotator cuff tear. We believe that the unloading

rotator cuff exercise program will produce better outcomes in the follow-up as regeneration of the rotator cuff is very unlikely in degenerative rotator cuff tears.

METHODS AND ANALYSIS

Study Design

The study will be a 2-arm, prospectively registered randomized controlled trial with a blinded assessor. The trial has been designed according to the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) and Consolidated Standards of Reporting Trials (CONSORT) guidelines.

Study Setting

The study will be conducted at the Laboratory of Analysis and Intervention of the Shoulder Complex located at the Department of Physical Therapy, Universidade Federal de São Carlos, São Carlos, Brazil.

Eligibility Criteria

A physical therapist with seven years of clinical experience will determine wether or not patients will be eligible to participate in the study. Individuals of both sexes, older than 55 years, with shoulder pain and atraumatic supraspinatus tendon tear documented with magnetic resonance imaging or ultrasound, at least 90° of active arm elevation will participate in the study.

The exclusion criteria will include individuals with history of trauma related to the onset of symptoms; history of clavicle, scapula and/or humerus fracture; pain related to the cervical spine; previous shoulder surgery; glenohumeral arthritis; inflammatory arthritis; adhesive capsulitis and cognitive disorders.

Individuals will be discontinued from the study if they present fractures, surgeries, musculoskeletal injuries or neurological diseases that prevent attendance at sessions, or get corticosteroid injection at the shoulder complex during the treatment or follow-up periods. Any additional event, as adverse effects, or use of ice and hot pack during the course of the study will be registered. Individuals who will be excluded, discontinued, or who will complete

study follow-up with remaining shoulder symptoms will receive written and verbal information about shoulder pain management and exercises.

Procedure

The participants will be recruited through flyers placed at the University, outpatient clinics and community. Advertisements in local radio, and online resources (eg, university intranet and social media) will also be used for recruitment of patients. All eligible participants will receive information about the study and will sign an informed consent form before participation. The assessor will collect the baseline data prior to randomization, after the 12-week intervention period and 1 month after the end of treatment (follow-up). Satisfaction will only be assessed after the 12-week intervention period and at follow-up. Figure 1 brings the flow diagram of the study.

Outcome measures

The primary outcome measure will be quality of life. The secondary outcomes will be pain, function, fear avoidance beliefs, kinesiophobia, pain catastrophizing, strength, range of motion and satisfaction with treatment. All scales and questionnaires have been translated and cross-culturally adapted into Brazilian Portuguese.

Quality of Life

The WORC (The Western Ontario Rotator Cuff Index) assesses quality of life in individuals with rotator cuff disease.[15] It has 21 questions in five domains: pain and physical symptoms (6 questions), sports and recreation (4 questions), work (4 questions), lifestyle (4 questions), and emotional state (3 questions). The total score ranges from 0 to 2100. Higher scores indicate worse quality of life. It is a reliable instrument.[16]

Pain

The 11-point numerical pain rating scale will be used to assess current level of shoulder pain at rest, during arm movement, and the greatest and lowest level of shoulder pain in the last week.[17] The score ranges from 0 (no

pain) to 10 (worst possible pain). This scale is reliable and valid for individuals with shoulder pain.[18]

Function of the Upper Limbs

The DASH (Disabilities of the Arm, Shoulder, and Hand) questionnaire will be used to assess upper limb function.[19] It contains 30 questions that include items related to physical function, symptoms, and social function. Each question has 5 possible answers ranging from “No difficulty” to “Unable”, and is scored on a 5-point rating scale. The maximum score is 100, which indicates the worst possible condition.[20] This questionnaire has been shown to be reliable.[19]

Fear Avoidance Beliefs

The Fear Avoidance Beliefs Questionnaire (FABQ-Brazil)[21] will be used to measure fear avoidance. The FABQ-Brazil is a 6-item questionnaire that compromises 2 subscales physical activity and work activities. Each item is scored on a 7-point scale ranging from "strongly agree" to "strongly disagree". The final scores range from 0 to 42 for physical activity subscale and from 0 to 24 for work activities subscale[21]. Higher scores indicate higher beliefs in fear and avoidance.[22] It has been currently used in patients with shoulder pain.[23–25]

Kinesiophobia

The Tampa Kinesiophobia Scale assesses the individual's fear of movement and the fear of pain recurrence.[26] It has 17 questions that address pain and symptom intensity. The final score ranges from 17 to 68 points. Higher scores indicate higher kinesiophobia.[26] It has been used in individuals with shoulder pain and has good reliability.[23]

Pain Catastrophizing

This scale contains 13 items divided into 3 domains: helplessness, magnification and rumination. Total scores ranges from 0 to 52. Higher values indicate higher degree of catastrophic thoughts.[27] It has been currently used in patients with shoulder pain.[28,29]

Muscle Strength

Strength of the shoulder abductors[30], external and medial rotators[31,32] (Figure 2) will be measured using a hand-held dynamometer (Lafayette Instrument Company, Lafayette, IN, USA). A submaximal repetition of each test will be performed for familiarization. Next, three 5-second repetitions with a 1min-rest interval between repetitions will be performed. The order of the tests will be randomized.

Range of Motion

Range of motion of active arm elevation in the sagittal and scapular planes as well as the painful arcs will be assessed using a digital inclinometer[33,34] (AcumarTM Lafayette Instrument Company, Lafayette, IN). Individuals will be asked to elevate their arm in the standing position.

Satisfaction

The Global Rating of Change Scale[35] will be used to assess patient's satisfaction with the treatment. It is a 15-point numeric scale ranging from -7 (vastly worse) to 0 ("unchanged") to +7 ("vastly better"). Higher scores indicate better satisfaction. Participants will respond to the following question: "How satisfied are you with your shoulder?" Nothing, a little, moderately or totally are the answer options to assess satisfaction.

Random Allocation

Patients will be randomly assigned to one of the two groups: Rotator Cuff Unloading Group or Rotator Cuff Loading Group. Randomization will be computer based and carried out at a 1:1 ratio according to a random sequence generated by the website http://www.randomization.com, stratified by sex and age. An independent researcher, not involved in the treatment or assessment, will perform the randomization process and prepare the sealed opaque envelopes with group allocation consecutively numbered. The envelopes will be securely stored and will be opened in sequence to reveal group allocation prior to the first treatment session by the researcher responsible for the treatments.

Blinding

The assessor will be blinded to treatment group assignment and the patients will be treated individually and blinded to the study hypothesis.

Interventions

Each intervention program will consist of 24 supervised sessions, which will be executed 2 times/week for 12 weeks. Both groups will receive advice with respect to pain control, posture and range of motion. Adherence to treatment and assessment sessions will be encouraged at each session.

The exercise program for both groups will be based on a systematic review,[36] providing a continuum of exercises, from low rotator cuff to high rotator cuff load. The selected exercises for the Rotator Cuff Unloading Group will be based on a muscle activation equal to or less than 20% of the supraspinatus maximal activity.[36] The selected exercises for the Rotator Cuff Loading Group will be based on a muscle activation equal to or greater than 40% of the supraspinatus maximal activity. All exercises will be performed in 3 sets of 10 repetitions with a 1-minute interval between repetitions.

Rotator Cuff Unloading Exercise Program

Patients in this group will perform 4 exercises: semi-closed kinetic chain elevation, deltoid reeducation,[37] assisted arm elevation, and an exercise for scapular control.[38,39] The exercises and their progressions are described in the Appendix.

Rotator Cuff Loading Exercise Program

Patients in this group will perform conventional exercises focusing on external rotation, internal rotation and arm elevation. The exercises and their progressions are described in the Appendix.

Participant Timeline

The flowchart summarising procedures and patients is shown in Figure 1.

Sample Size

The sample size calculation was based on the smallest significant difference of 282.6 points from the Western Ontario Rotator Cuff Index

(WORC)[40] with a standard deviation of 400 points, a power of 80%, and a significance level of 5%. WORC was selected because it evaluates the quality of life of individuals with rotator cuff disease. Accounting for a 15% dropout, 78 subjects will be included in the study, randomly allocated to two treatment groups: Rotator Cuff Unloading Exercise Program (n = 39) and Rotator Cuff Loading Exercise Program (n = 39).

Data management, monitoring and sharing

All data from recruitment, characteristics of the individuals who will complete or dropout the study will be entered into an electronic form by the researchers, and the integrity and validity of the data will be verified. Identification of possible patients will be done only by the researchers. The research team is trained to address the eligibility criteria during the contact about survey made by e-mail, phone calls and messages. Also, the team is trained about how and when to contact them for follow-up and data collection.

The results of this article will be shared (text, tables, figures, appendices) immediately after publication. No interim analyses have been planned. To request data you will need to sign a data access agreement and the request can be made by e-mail. The changes made to the protocol will be communicated to ethics committee and also be included in the clinical trial register.

Patient and Public Involvement

The patients were not involved in the design, will not be involved in the conduction and dissemination of the research. The results will be sent by e-mail or telephone in an unscientific language so that all patients understand the study's conclusions and know how to maintain self-care.

Statistical Analysis

For data analysis, the statistical program Statistical Package for the Social Sciences version 23 will be used. Continuous data will be presented as mean, standard deviation and mean difference between groups with 95% confidence interval, and categorical by frequency and percentage. Data normality will be verified by Kolmogorov Smirnov test and observation of

histograms for each variable in each group. Statistical analysis will follow the principles of intention-to-treat analysis. Linear mixed models will be used to calculate differences between groups using the terms of group interaction (Rotator Cuff Unloading Group *versus* Rotator Cuff Loading Group) versus time (pre-treatment, 12 weeks at the end of treatment, and a month after the end of treatment) for each variable.

ETHICS AND DISSEMINATION

Ethical Aspects

This study was approved by the Human research Ethics Committee of the University (CAAE: 12899719.5.0000.5504) and prospectively registered at clinicaltrials.gov (NCT03962231) on September, 2019.

Dissemination

The study will be disseminated through publication in peer-reviewed international journals, as well as presentations at national and international conferences.

DISCUSSION

Potential Impact and Significance of the Study

Degenerative tears in the rotator cuff is a common finding in imaging studies due to the natural aging process.[4,41] There is evidence that therapeutic exercises should be the first treatment option for these patients[14] because the surgical approach is not clinically superior than the non-surgical approach in this population.[12] Several exercise protocols have been proposed for this population.[14] However, there is no consensus on which exercises or exercise programs are the most effective. This fact challenges the physical therapist in the clinical decision-making. Thus, the results of this study will likely contribute to the physical therapy's decision-making on exercise prescriptions to individuals with rotator cuff tears.

Strengths and Weaknesses of the Study

The strength of the current study is that it is a randomized controlled trial that has been prospectively registered. Furthermore, the study includes

concealed allocation and an intention-to treat approach. The sample size has been calculated to provide appropriate statistical power to detect differences between the 2 treatment programs.

The assessor responsible for collecting outcome data will be blinded to treatment group assignment. Physical therapists responsible for treatment have similar clinical experience and have been trained by the main author of the study. However, the study has some limitations. Participants and therapists cannot be blinded. Both exercise programs include home guidelines, which depend on each participant's motivation. It is not possible to predict the amount of home guidelines and cryotherapy that will be performed by each group.

Contribution to the Physical Therapy Profession and to Patients

The results of this study will provide scientific basis to support physical therapists in the treatment of individuals with rotator cuff tears, helping in the choice of exercises and their progression. In addition, the findings may also help health care providers and patients with rotator cuff tears to reduce health costs, avoiding the need for surgery and the use of analgesic drugs. Participants will be taught how to modify their daily activities by modifying the movements and postures that appear to increase shoulder symptoms. The participants also receive a series of exercises to be performed at home in the follow-up. It is expected that patients will become independent and more empowered with good quality of life and function of the upper limbs.

Finally, the findings of the current study may contribute to a better understanding of the efficacy of exercise program for individuals with rotator cuff tears.

Contributorship statement: All authors (LPR, AC and PRC) were equally responsible for outlining the conception and protocol design. LPR, AC and PRC drafted the work, revised it critically for important intellectual content, and approved the final version.

Competing interests statement: We affirm that we have no financial affiliation or involvement with any commercial organization that has a direct financial interest in any matter included in this manuscript.

Funding: Coordenação de Aperfeiçoamento de Pessoal de Nível Superior and Conselho Nacional de Desenvolvimento Científico e Tecnológico (144436/2019-1).

Data sharing statement: All data (especially from potential or enrolled participants) collected during the trial will be entered into an electronic form by those responsible and maintained confidential before, during and after the trial by encoding participant's name. Any changes made to the protocol will be reported to the ethics committee and included in the clinical trial register. The results of this article will be shared (text, tables, figures, appendices) immediately after publication. Upon completion of the study, supported data will be available upon request. Requests for data or any form of analysis should be directed to prcamargo@ufscar.br.

REFERENCES

1. Teunis T, Lubberts B, Reilly BT, Ring D. A systematic review and pooled analysis of the prevalence of rotator cuff disease with increasing age. *J Shoulder Elb Surg*. 2014;23(12):1913-1921. doi:10.1016/j.jse.2014.08.001

2. Bunker T. Rotator cuff disease. *Curr Orthop*. 2002;16(3):223-233. doi:10.1054/cuor.2002.0257

3. Spargoli G. Supraspinatus Tendon Pathomechanics: a Current Concepts Review. *Int J Sports Phys Ther*. 2018;13(6):1083-1094. doi:10.26603/ijspt20181083

4. Minagawa H, Yamamoto N, Abe H, et al. Prevalence of symptomatic and asymptomatic rotator cuff tears in the general population: From mass-screening in one village. *J Orthop*. 2013;10(1):8-12. doi:10.1016/j.jor.2013.01.008

5. Moosmayer S, Tariq R, Stiris MG, Smith HJ. MRI of symptomatic and asymptomatic full-thickness rotator cuff tears: A comparison of findings in 100 subjects. *Acta Orthop*. 2010;81(3):361-366. doi:10.3109/17453674.2010.483993

6. Barreto RPG, Braman JP, Ludewig PM, Ribeiro LP, Camargo PR. Bilateral magnetic resonance imaging findings in individuals with unilateral shoulder pain. *J Shoulder Elb Surg*. 2019;28(9):1699-1706. doi:10.1016/j.jse.2019.04.001

7. Lowe CJM, Moser J, Barker K. Living with a symptomatic rotator cuff tear "bad days, bad nights": A qualitative study. *BMC Musculoskelet Disord*. 2014;15(1):1-10. doi:10.1186/1471-2474-15-228

8. Malavolta EA, Assunção JH, Beraldo RA, Pinto G de MR, Gracitelli MEC, Ferreira Neto AA. Rotator cuff repair in the Brazilian Unified Health System: Brazilian trends from 2003 to 2015. *Rev Bras Ortop (English Ed*. 2017;52(4):501-505. doi:10.1016/j.rboe.2017.06.010

9. Syed UAM, Aleem AW, Wowkanech C, et al. Neer Award 2018: the effect of preoperative education on opioid consumption in patients undergoing arthroscopic rotator cuff repair: a prospective, randomized clinical trial. *J Shoulder Elb Surg*. 2018;27(6):962-967. doi:10.1016/j.jse.2018.02.039

10. Westermann RW, Anthony CA, Bedard N, et al. Opioid Consumption After Rotator Cuff Repair. *Arthrosc - J Arthrosc Relat Surg*. 2017;33(8):1467-1472. doi:10.1016/j.arthro.2017.03.016

11. Uquillas CA, Capogna BM, Rossy WH, Mahure SA, Rokito AS. Postoperative pain control after arthroscopic rotator cuff repair. *J Shoulder Elb Surg*. 2016;25(7):1204-1213. doi:10.1016/j.jse.2016.01.026

12. Piper CC, Hughes AJ, Ma Y, Wang H, Neviaser AS. Operative versus nonoperative treatment for the management of full-thickness rotator cuff tears: a systematic review and meta-analysis. *J Shoulder Elb Surg*. 2018;27(3):572-576. doi:10.1016/j.jse.2017.09.032

13. Kuhn JE, Dunn WR, An Q, et al. Effectiveness of Physical Therapy in Treating Atraumatic Full Thickness Rotator Cuff Tears. A Multicenter Prospective Cohort Study. *J Shoulder Elb Surg*. 2013;22(10):1371-1379. doi:10.1016/j.jse.2013.01.026.Effectiveness

14. Jeanfavre M, Husted S, Leff G. Exercise Therapy in the Non-Operative Treatment of Full-Thickness Rotator Cuff Tears: a Systematic Review. *Int J Sports Phys Ther*. 2018;13(3):335-378. doi:10.26603/ijspt20180335

15. Lopes A., Standniki S., Masiero D, Carrera E., Ciconelli R., Griffin S. Tradução E Adaptação Cultural Do Worc : Um Questionário De Qualidade De Vida Para Alterações Do Manguito Rotador. *Rev bras fisioter*. 2006;(3):309-315. doi:10.1590/S1413-35552006000300010

16. Lopes AD, Ciconelli RM, Carrera EF, Griffin S, Faloppa F, Dos Reis FB. Validity and reliability of the Western Ontario Rotator Cuff Index (WORC) for use in Brazil. *Clin J Sport Med Off J Can Acad Sport Med*. 2008;18(3):266-272. doi:10.1097/JSM.0b013e31817282f4

17. Jensen MP, Turner JA, Romano JM, Fisher LD. Comparative reliability and validity of chronic pain intensity measures. *Pain*. 1999;83:157-162.

18. Mintken PE, Glynn P, Cleland JA. Psychometric properties of the shortened disabilities of the Arm, Shoulder, and Hand Questionnaire (QuickDASH) and Numeric Pain Rating Scale in patients with shoulder pain. *J Shoulder Elb Surg*. 2009;18(6):920-926. doi:10.1016/j.jse.2008.12.015

19. Orfale AG, Araújo PMP, Ferraz MB, Natour J. Translation into Brazilian Portuguese, cultural adaptation and evaluation of the reliability of the Disabilities of the Arm, Shoulder and Hand Questionnaire. *Brazilian J Med Biol Res*. 2005;38(2):293-302. doi:10.1590/S0100-879X2005000200018

20. Pamela L. Hudak, BSCPT, MSC, Peter C. Amadio, MD, Claire Bombardier, MD and the UECG (UECG). Development of an Upper Extremity Outcome Measure: The DASH (Disabilities of the Arm, Shoulder, and Head). *Am J Ind Med 291602-608 Dev*. 2017;608(1 996):527-546. doi:10.1002/(SICI)1097-0274(199606)29:6<602::AID-AJIM4>3.0.CO;2-L

21. Abreu AM de, Faria CDC de M, Cardoso SMV, Teixeira-Salmela LF. Versão brasileira do Fear Avoidance Beliefs Questionnaire. 2008;24(3):615-623. http://www.scielo.br/pdf/csp/v24n3/15.pdf.

22. Souza FS de, Marinho C da S, Siqueira FB, Maher CG, Costa LOP. Psychometric testing confirms that the Brazilian-Portuguese adaptations, the original versions of the fear-avoidance beliefs questionnaire, and the Tampa Scale of Kinesiophobia have similar measurement properties. *Spine (Phila Pa 1976)*. 2008;33(9):1028-1033. doi:10.1097/BRS.0b013e31816c8329

23. Mintken PE, Cleland JA, Whitman JM, George SZ. Psychometric Properties of the Fear-Avoidance Beliefs Questionnaire and Tampa Scale of Kinesiophobia in Patients With Shoulder Pain. *Arch Phys Med Rehabil*. 2010;91(7):1128-1136. doi:10.1016/j.apmr.2010.04.009

24. Riley SP, Tafuto V, Cote M, Brismée J-M, Wright A, Cook C. Reliability and relationship of the fear-avoidance beliefs questionnaire with the shoulder pain and disability index and numeric pain rating scale in

patients with shoulder pain. *Physiother Theory Pract*. 2018;00(00):1-7. doi:10.1080/09593985.2018.1453004

25. Woollard JD, Bost JE, Piva SR, Kelley Fitzgerald G, Rodosky MW, Irrgang JJ. The ability of preoperative factors to predict patient-reported disability following surgery for rotator cuff pathology. *Disabil Rehabil*. 2017;39(20):2087-2096. doi:10.1080/09638288.2016.1219396

26. Siqueira FB, Teixeira-Salmela LF, Magalhães LDC. Análise das Propriedades Psicométricas da Versão Brasileira da Escala Tampa de Cinesiofobia. *Acta Ortop Bras*. 2007;15(1):19-24. doi:10.1590/S1413-78522007000100004

27. Sehn F, Chachamovich E, Vidor LP, et al. Cross-Cultural Adaptation and Validation of the Brazilian Portuguese Version of the Pain Catastrophizing Scale. *Pain Med*. 2012;13(11):1425-1435. doi:10.1111/j.1526-4637.2012.01492.x

28. George SZ, Hirsh AT. Psychologic Influence on Experimental Pain Sensitivity and Clinical Pain Intensity for Patients with Shoulder Pain. *J Pain*. 2009. doi:10.1016/j.jpain.2008.09.004

29. George SZ, Staud R, Borsa PA, et al. Biopsychosocial influence on shoulder pain: Rationale and protocol for a pre-clinical trial. *Contemp Clin Trials*. 2017;56:9-17. doi:10.1016/j.cct.2017.03.005

30. Katoh M. Test-retest reliability of isometric shoulder muscle strength measurement with a handheld dynamometer and belt. *J Phys Ther Sci*. 2015;27(6):1719-1722. doi:10.1589/jpts.27.1719

31. Schrama PPM, Stenneberg MS, Lucas C, Van Trijffel E. Intraexaminer reliability of hand-held dynamometry in the upper extremity: A systematic review. *Arch Phys Med Rehabil*. 2014;95(12):2444-2469. doi:10.1016/j.apmr.2014.05.019

32. Cools AMJ, Vanderstukken F, Vereecken F, et al. Eccentric and isometric shoulder rotator cuff strength testing using a hand-held dynamometer: reference values for overhead athletes. *Knee Surgery, Sport Traumatol Arthrosc*. 2016;24(12):3838-3847. doi:10.1007/s00167-015-3755-9

33. Kolber MJ, Hanney WJ. The reliability and concurrent validity of shoulder mobility measurements using a digital inclinometer and goniometer: a technical report. *Int J Sports Phys Ther*. 2012;7(3):306-313. doi:10.3109/09593985.2011.574203

34. Kolber MJ, Vega F, Widmayer K, Cheng M-SS. The reliability and minimal detectable change of shoulder mobility measurements using a digital inclinometer. *Physiother Theory Pract*. 2010;27(2):176-184. doi:10.3109/09593985.2010.481011

35. Kamper SJ, Maher CG, Mackay G. Global Rating of Change Scales: A Review of Strengths and Weaknesses and Considerations for Design. *J Man Manip Ther*. 2014;17(3):163-170. doi:10.1179/jmt.2009.17.3.163

36. Edwards PK, Ebert JR, Littlewood C, Ackland T, Wang A. A Systematic Review of Electromyography Studies in Normal Shoulders to Inform Postoperative Rehabilitation Following Rotator Cuff Repair. *J Orthop Sport Phys Ther*. 2017;47(12):931-944. doi:10.2519/jospt.2017.7271

37. Levy O, Mullett H, Roberts S, Copeland S. The role of anterior deltoid reeducation in patients with massive irreparable degenerative rotator cuff tears. *J Shoulder Elb Surg*. 2008;17(6):863-870. doi:10.1016/j.jse.2008.04.005

38. Kibler W Ben, Sciascia AD, Uhl TL, Tambay N, Cunningham T. Electromyographic analysis of specific exercises for scapular control in early phases of shoulder rehabilitation. *Am J Sports Med*. 2008;36(9):1789-1798. doi:10.1177/0363546508316281

39. De Mey K, Danneels L, Cagnie B, Van den Bosch L, Flier J, Cools AM. Kinetic chain influences on upper and lower trapezius muscle activation during eight variations of a scapular retraction exercise in overhead athletes. *J Sci Med Sport*. 2013;16(1):65-70. doi:10.1016/j.jsams.2012.04.008

40. Gagnier JJ, Robbins C, Bedi A, Carpenter JE, Miller BS. Establishing minimally important differences for the American Shoulder and Elbow Surgeons score and the Western Ontario Rotator Cuff Index in patients

with full-thickness rotator cuff tears. *J Shoulder Elb Surg*. 2018;27(5):e160-e166. doi:10.1016/j.jse.2017.10.042

41. Fehringer E V., Sun J, VanOeveren LS, Keller BK, Matsen FA. Full-thickness rotator cuff tear prevalence and correlation with function and co-morbidities in patients sixty-five years and older. *J Shoulder Elb Surg*. 2008;17(6):881-885. doi:10.1016/j.jse.2008.05.039

Legend to the figures:

Figure 1. Study flow diagram.

Figure 2. Muscle strength of abductors (A), external rotators (B) and internal rotators (C) of the shoulder.

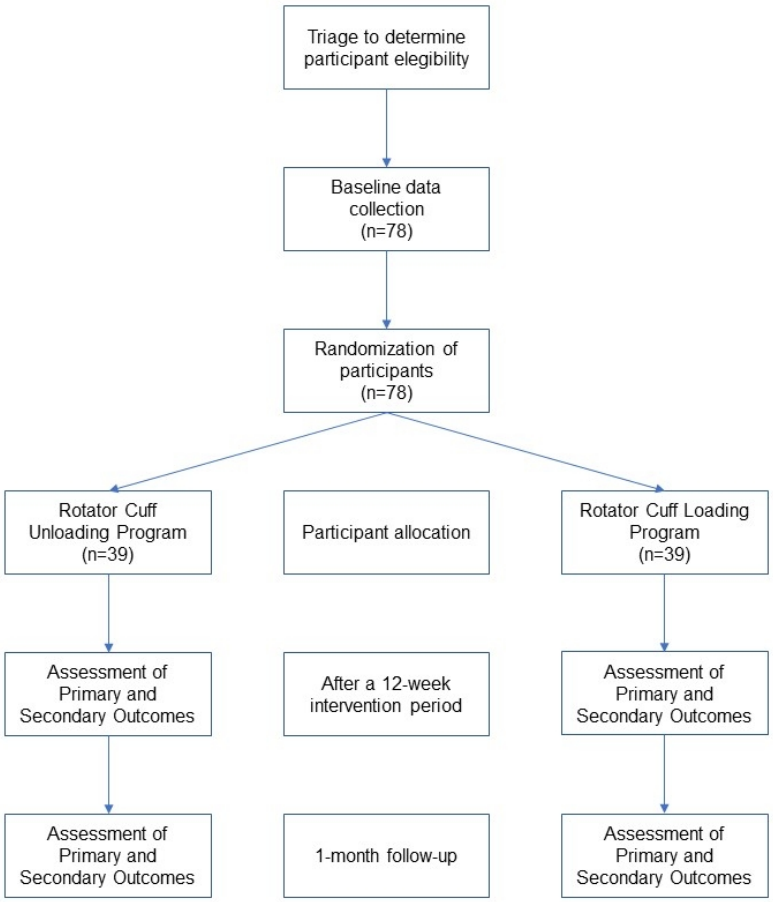


Figure 1. Study flow diagram

60x88mm (300 x 300 DPI)

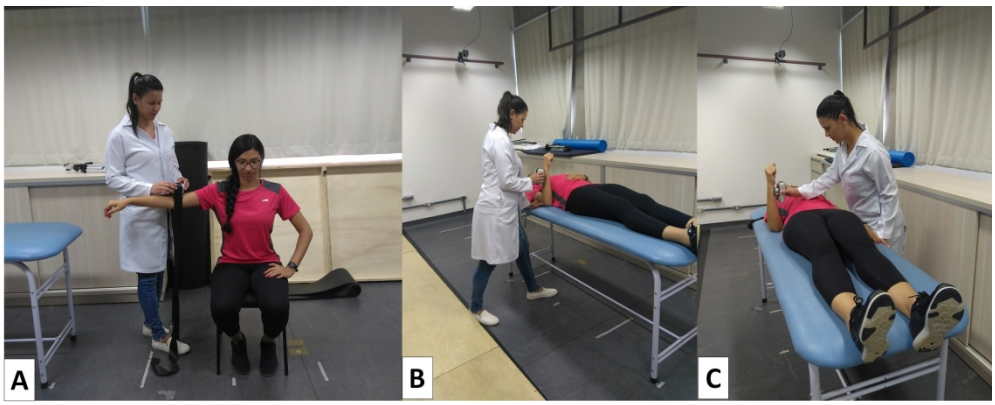


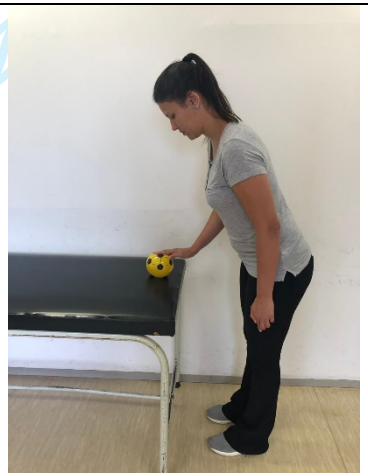
Figure 2. Muscle strength of abductors (A), external rotators (B) and internal rotators (C) of the shoulder

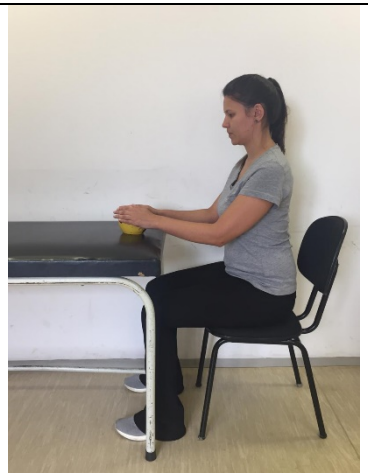
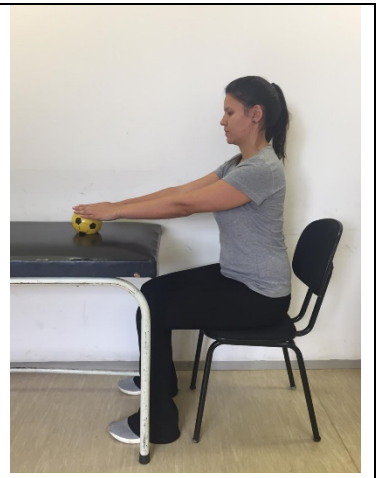
224x97mm (300 x 300 DPI)

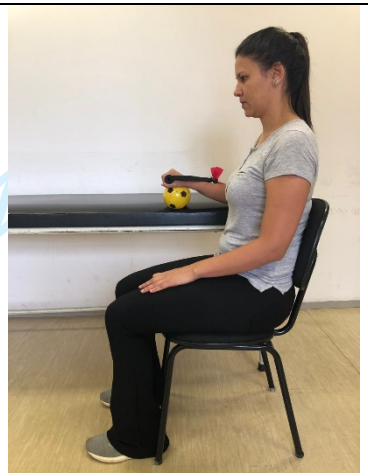
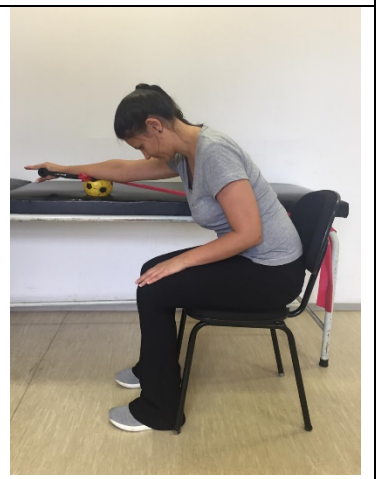
APPENDIX

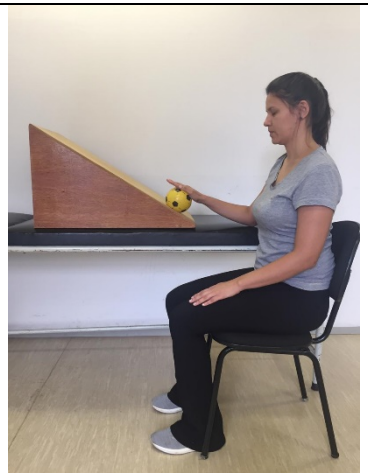
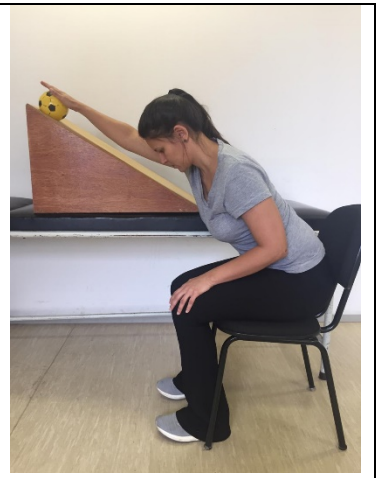
Rotator Cuff Unloading Exercise Program

Patients in this group will perform 1 exercise from each group of exercises: semi-closed kinetic chain elevation, deltoid reeducation, assisted arm elevation, and an exercise for scapular control. Exercises are grouped and described according to the level of difficulty and muscle activation. All exercises will be performed in 3 sets of 10 repetitions with a 1-minute interval between repetitions. The exercises are progressed based on the experienced pain during the program. Only in the presence of symptoms < 3 points on the 11-point numeric pain rating scale, a progression towards the next exercise or load is allowed.

Semi-Closed Kinetic Chain Exercises and progressions				
Exercise	**Initial Position**	**Performance**	**Initial Position**	**Final Position**
1) Closed Chain Pendulum	Patient in standing position supporting the hand on a ball positioned on a treatment table with the trunk inclined.	Shoulder circular movements in scapular plane.		

2) Bilateral Bench Slide <90º	Patient sitting in front of the treatment table supporting the hands on a ball positioned on the treatment table. Initially the elbow will be flexed and the shoulder slightly flexed.	Slide the hands over the ball, moving it forward until the elbow is extended, and shoulder flexed <90°. Keep the trunk straight.		
3) Unilateral Bench Slide <90º	Patient sitting beside to the treatment table, and supporting the hand on the ball. Initially the elbow will be flexed and the arm at the side of the trunk.	Slide the hand over the ball, moving it forward until the elbow is extended. Keep the trunk straight.		

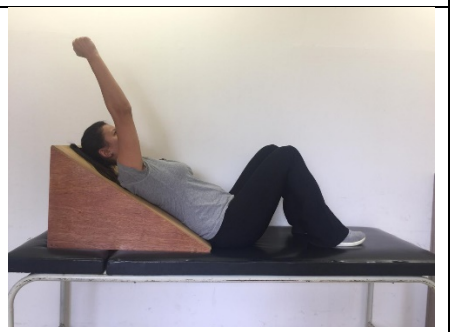
4) Unilateral Bench Slide >90º	Patient sitting beside to the treatment table, and supporting the hand on the ball. Initially the elbow will be flexed and the arm at the side of the trunk.	Slide the hand over the ball and incline the trunk forward until the elbow is extended.		
5) Unilateral Bench Slide > 90º + Resistance	Patient sitting beside to the treatment table, and supporting the hand on the ball while holding an elastic band. Initially the elbow will be flexed and the arm at the side of the trunk.	Slide the hand over the ball against resistance and incline the trunk forward until the elbow is extended. *progression: yellow, red, green and blue elastic band (Theraband).		

6) Inclined Bench Slide	Patient sitting beside to the treatment table, and supporting the hand on the ball. The ball will be on an inclined surface at 45º. Elbow will be flexed and arm at the side of the trunk.	Slide the hand over the ball, moving hand and trunk forward until elbow is extended. *progression: yellow, red, green and blue elastic band (Theraband).		
7) Wall Slide	Patient standing in front of a wall. Hand positioned on a ball or towel against the wall. Elbow will be flexed and the shoulder slightly flexed in the scapular plane.	Slide the hand over the ball or towel on the wall by moving it upward until elbow is extended in scapular plane direction.		

8) Wall Slide + Resistance	Patient standing in front of a wall. Hand holding an elastic band and positioned against the wall. Elbow will be flexed and the shoulder slightly flexed.	Slide the hand on the wall by moving it upward against resistance until elbow is extended. *progression: yellow, red, green and blue elastic band (Theraband).		
9) Wall Slide + Resistance + Open Chain	Patient standing in front of a wall. Hand holding an elastic band and positioned against the wall. Elbow will be flexed and the shoulder slightly flexed.	Sliding the hand on the wall by moving it upward against resistance until elbow is extended. At the end range move the hand away from the wall increasing the flexion. *progression: yellow, red, green and blue elastic band (Theraband).		

Anterior Deltoid Reeducation and progressions				
Exercise	**Position**	**Performance**	**Initial Position**	**Final Position**
1) Passive Elevation	Patient in supine, hand of the unaffected arm holds the wrist of affected arm. Elbow will be at 90º flexion and the arm at the side of the trunk.	The unaffected arm will first assist elbow extension of the affected arm keeping the shoulder at 90º of flexion. Next, the unaffected limb assists the flexion and extension of the affected shoulder during concentric and eccentric phases.		
2) Active - Weight	Patient in supine, hand of the unaffected arm holds the wrist of affected arm. Elbow will be at 90º flexion	The unaffected arm will first assist elbow extension of the affected arm keeping the shoulder at 90º of flexion. Next, the		

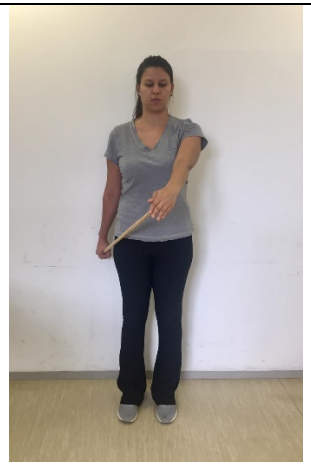
	and the arm at the side of the trunk.	affected shoulder perform flexion without assistance.		
3) Active + Weight	Patient in supine, hand of the unaffected arm holds the wrist of affected arm. Elbow will be at 90º flexion holding a toning ball.	The unaffected arm will first assist elbow extension of the affected arm keeping the shoulder at 90º of flexion. Next, the affected shoulder perform flexion without assistance with toning ball. * progression: 1kg and 2kg toning ball.		
4) Increased Trunk Inclination Angle	Patient in supine, slightly inclined trunk, hand of the unaffected arm holds the wrist of affected arm. Elbow	The unaffected arm will first assist elbow extension of the affected arm keeping the shoulder at 90º of flexion. Next, the		

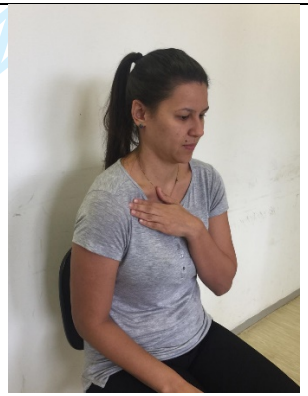
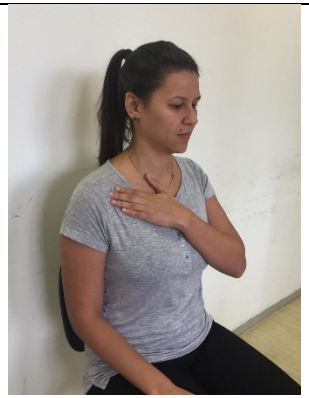
	will be at 90º flexion holding a toning ball..	affected shoulder perform flexion without assistance with toning ball.* progression: 1kg and 2kg toning ball.		
5) Seated - Weight	Patient with 60º of trunk inclination, hand of the unaffected shoulder holds the affected arm. Initially elbow at 90º flexion and arm at the side of the trunk.	The unaffected arm will first assist elbow extension of the affected arm keeping the shoulder at 90º of flexion. Next, the affected shoulder perform flexion without assistance and weight.		
6) Seated + Weight	Patient with 60º trunk inclination, elbow of the affected side at 90º flexion and arm at the side of the trunk. Hand of	The unaffected arm will first assist elbow extension of the affected arm keeping the shoulder at 90º of flexion. Next, the		

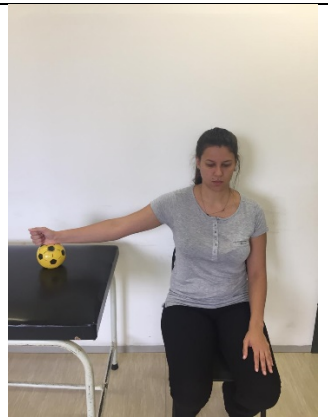
	the affected arm holds a toning ball.	affected shoulder perform flexion without assistance with toning ball.* progression: 1kg and 2kg tonning ball.

Assisted Elevation and progressions				
Exercise	**Initial Position**	**Performance**	**Initial Position**	**Final Position**
1) Therapist Assisted Elevation	Patient in supine with elbow at 90º flexion and shoulder at the side of the trunk. Therapist holds the forearm on the affected side of the patient.	Therapist assists shoulder flexion during the concentric and eccentric phases.		

2) Side Lying Elevation	Patient in side lying position, affected shoulder upwards. Support the hand on a flat surface in front of the treatment table at the same level as the height of the affected shoulder. The elbow and shoulder will be slightly flexed.	Patient slides the hand over the flat surface raising his arm with the elbow slightly bent.		
3) Supine Band	Patient in supine, holding a yellow elastic band with both hands. Unaffected shoulder remains at the side of the body and affected shoulder with 90º flexion.	The affected shoulder performs flexion with elastic band while the other shoulder remains at the side of the trunk.		

4) Bar Assisted Standing	Patient standing holding a bar	Unaffected shoulder assists the arm elevation using a bar.		

Exercises for Scapular Control and progressions				
Exercise	**Initial Position**	**Performance**	**Initial Position**	**Final Position**
1) Scapular Orientation Exercise	Patient sitting, places index finger on the coracoid process of the affected shoulder.	The patient will be instructed to move the scapula in external rotation and posterior tilt, moving the coracoid process away from the index finger or pretending to put the		

		scapula into a little hook behind.	
2) Inferior Glide	Patient sitting beside the treatment table, with affected shoulder in abduction close to 90º. A ball will be on the treatment table and the fist.	Patient will perform a pressure with the fist in the direction of arm adduction and instructed to inferiorly depress their scapula.	 
3)) Low Row Static	Patient standing in front of an immovable surface and placed their hand on the anterior edge of the surface with palm facing posteriorly.	Patient will perform a shoulder extension movement against the immovable surface doing retraction and depression of the scapula.	 

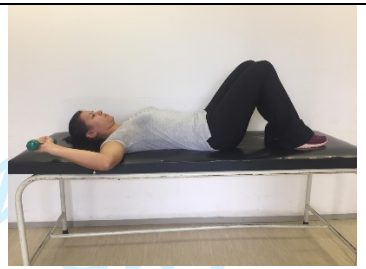
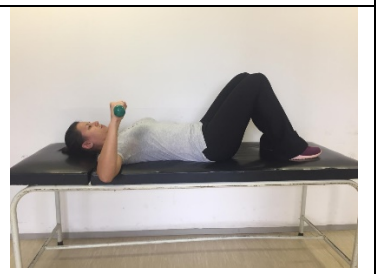
4) Low Row Dynamic	Patient seating holding an elastic band with shoulder flexion.	The patient will perform the movement towards shoulder extension and scapular retraction. * progression: yellow, red, green and blue elastic band (Theraband).		

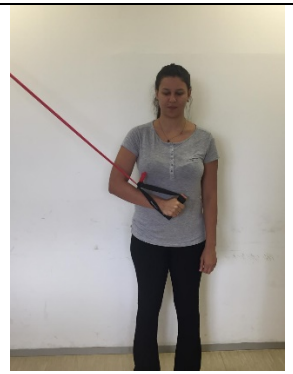
Rotator Cuff Loading Exercise Program

Patients in this group will perform 1 exercise from each group of exercises: focus on external rotation, focus on internal rotation, assisted arm elevation, and focus on active arm elevation. Exercises are grouped and described according to the level of difficulty and muscle activation. All exercises will be performed in 3 sets of 10 repetitions with a 1-minute interval between repetitions. The exercises are progressed based on the experienced pain during the program. Only in the presence of symptoms < 3 points on the 11-point numeric pain rating scale, a progression towards the next exercise or load is allowed.

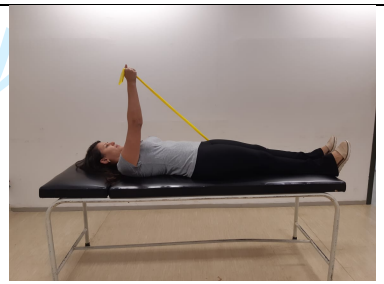
Focus on External Rotation and progressions				
Exercise	**Initial Position**	**Performance**	**Initial Position**	**Final Position**
1) Side Lying External Rotation	Patient in side lying position with the affected arm upwards. Arm at the side of the trunk and elbow flexed at 90º with a dumbbell in hand.	Patient will perform external rotation of the shoulder and return to the initial position. * progression: 1kg, 2kg and 3kg dumbbell.		

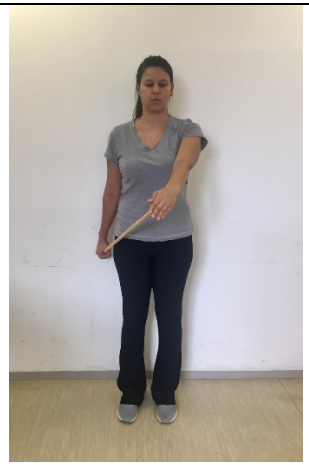
2) Standing External Rotation	Patient standing with affected shoulder at the side of the trunk, elbow flexed at 90º and holding an elastic band by hand.	Patient will perform external rotation of the shoulder and return to the initial position. * progression: yellow, red and green elastic band (Theraband).		
3) External Rotation Diagonal Standing	Patient standing with affected shoulder in internal rotation, elbow flexed at 90º and holding an elastic band by hand.	The patient will perform external rotation and abduction of the shoulder, thus performing a external rotation in the diagonal direction. * progression: yellow, red and green elastic band (Theraband).		

Focus on Internal Rotation and progressions				
Exercise	**Initial Position**	**Performance**	**Initial Position**	**Final Position**
1) Standing Internal Rotation	Patient standing with affected shoulder at the side of the trunk, elbow flexed at 90º and holding an elastic band.	Patient will perform internal rotation of the shoulder and return to the initial position. *progression: yellow, red and green elastic band (Theraband).		
2) Sitting Internal Rotation	Patient in supine with affected shoulder in 90º abduction and elbow in 90º flexion holding a dumbbell in hand.	Patient will perform internal rotation of the shoulder and return to the initial position. * progression: 1kg, 2kg and 3kg dumbbell.		

3) Internal Rotation Diagonal Standing	Patient standing with affected shoulder in 45º abduction, elbow in 90º flexion, holding an elastic band by hand.	Patient will perform internal rotation of the shoulder and return to the initial position. * progression: yellow, red and green elastic band (Theraband).		

Assisted Elevation and progression				
Exercise	**Initial Position**	**Performance**	**Initial Position**	**Final Position**
1) Therapist Assisted Elevation	Patient in supine with elbow at 90º flexion and shoulder at the side of the trunk. Therapist holds the forearm on the affected side of the patient.	Therapist assists shoulder flexion during the concentric and eccentric phases.		

2) Side Lying Elevation	Patient in side lying position, affected shoulder upwards. Support the hand on a flat surface in front of the treatment table at the same level as the height of the affected shoulder. The elbow and shoulder will be slightly flexed.	Patient slides the hand over the flat surface raising the arm with the elbow slightly bent.		
3) Supine Band	Patient in supine, holding a yellow elastic band with both hands. Unaffected shoulder remains at the side of the body and affected shoulder with 90º flexion.	The affected shoulder performs flexion with elastic band while the other shoulder remains at the side of the trunk.		

4) Bar Assisted Standing	Patient standing holding a bar.	Unaffected shoulder assists the arm elevation using a bar.		

Focus on Elevation and progressions				
Exercise	**Initial Position**	**Performance**	**Initial Position**	**Final Position**
1) Full can	Patient standing with arms at the side of the trunk.	Patient will perform shoulder abduction in the scapular plane without resistance and will return to the initial position. *progression: yellow, red and green elastic band (Theraband).		

2) Prone elevation (Blackburn exercise)	Patient in prone, shoulder off the treatment table and positioned perpendicular to the ground, with a shoulder at 90º flexion and elbow extended.	The patient will raise the arm in scapular plane and return to the initial position. * progression: 1kg, 2kg and 3kg dumbbell.		

SPIRIT
STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	2
	2b	All items from the World Health Organization Trial Registration Data Set	9, 10
Protocol version	3	Date and version identifier	9, 10
Funding	4	Sources and types of financial, material, and other support	12
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	1 and 12
	5b	Name and contact information for the trial sponsor	1
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	12
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	12

Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	3
	6b	Explanation for choice of comparators	3
Objectives	7	Specific objectives or hypotheses	3, 4
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	4
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	4
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	4
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	8
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	4
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	4
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	4
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	5, 6, 7
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	5

Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	8, 9
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	5
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	7
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	7
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	7
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	7
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	7
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	5, 6, 7, 8, 9
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	4

Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	9
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	9
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	NA
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	9
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	9
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	9
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	9
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	No
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	No
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	No

Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	5
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	NA
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	9
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	12
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	9 and 12
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	No
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	9, 10
	31b	Authorship eligibility guidelines and any intended use of professional writers	9
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	9
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	Ok
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	No

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.