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# 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

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3 1 **Rotator cuff unloading versus loading exercise program in the**  
4 **conservative treatment of patients with rotator cuff tear: Protocol of a**  
5 **randomized controlled trial**  
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## 16 ABSTRACT

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

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

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

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

40 **Trial registration number:** NCT03962231

41 **Keywords:** physical therapy, rehabilitation, impingement syndrome.

### 42 **Strength and limitations of the study:**

43 - This study is a unique randomized controlled trial that compares rotator cuff  
44 loading *versus* unloading exercises on clinical aspects in patients with rotator  
45 cuff tears.  
46

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

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

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

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

## 55 INTRODUCTION

56 Rotator cuff disease is one of the most common musculoskeletal  
57 disorders in the adult population. Rotator cuff tears are highly prevalent, from  
58 22% at the age of 65 years, to more than 62% in a population over 80 years  
59 old,<sup>1</sup> and appear to be an age-related finding on diagnostic imaging. The  
60 supraspinatus tendon is the most commonly affected tendon due to its  
61 anatomical location, tensile and compressive overload,<sup>2</sup> vascular changes and  
62 degeneration process associated with aging.<sup>3</sup> Although degenerative rotator  
63 cuff tears are not necessarily symptomatic,<sup>4-6</sup> a significant proportion of these  
64 injuries cause pain and disability of the patient over time. This condition may  
65 have a high impact in social life and can be associated to chronic pain,  
66 weakness, and dysfunction of the upper extremities.<sup>7</sup>

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

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

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

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56 88 **METHODS AND ANALYSIS**7  
8 89 **Study Design**

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10 90 The study will be a 2-arm, prospectively registered randomized controlled  
11 91 trial with a blinded assessor. The trial has been designed according to the  
12 92 Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT)  
13 93 and Consolidated Standards of Reporting Trials (CONSORT) guidelines.

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18 94 **Study Setting**

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20 95 The study will be conducted at the Laboratory of Analysis and  
21 96 Intervention of the Shoulder Complex at XXXX.

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24 97 **Eligibility Criteria**

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27 98 A physical therapist with seven years of clinical experience will determine  
28 99 whether or not patients will be eligible to participate in the study. Individuals of  
29 100 both sexes, older than 55 years, with shoulder pain and atraumatic  
30 101 supraspinatus tendon tear documented with magnetic resonance imaging or  
31 102 ultrasound, at least 90° of active arm elevation will participate in the study.

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36 103 The exclusion criteria will include individuals with history of trauma  
37 104 related to the onset of symptoms; history of clavicle, scapula and/or humerus  
38 105 fracture; pain related to the cervical spine; previous shoulder surgery;  
39 106 glenohumeral arthritis; inflammatory arthritis; adhesive capsulitis and cognitive  
40 107 disorders.

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45 108 Individuals will be discontinued from the study if they present fractures,  
46 109 surgeries, musculoskeletal injuries or neurological diseases that prevent  
47 110 attendance at sessions, or get corticosteroid injection at the shoulder complex  
48 111 during the treatment or follow-up periods. Any additional event, as adverse  
49 112 effects, or use of ice and hot pack during the course of the study will be  
50 113 registered. Individuals who will be excluded, discontinued, or who will complete  
51 114 study follow-up with remaining shoulder symptoms will receive written and  
52 115 verbal information about shoulder pain management and exercises.

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## 117 **Procedure**

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

## 128 **Outcome measures**

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

### 134 **Quality of Life**

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

### 141 **Pain**

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



## 147 Function of the Upper Limbs

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

## 155 Fear Avoidance Beliefs

156 The Fear Avoidance Beliefs Questionnaire (FABQ-Brazil)<sup>21</sup> will be used  
157 to measure fear avoidance. The FABQ-Brazil is a 6-item questionnaire that  
158 comprises 2 subscales physical activity and work activities. Each item is  
159 scored on a 7-point scale ranging from "strongly agree" to "strongly disagree".  
160 The final scores range from 0 to 42 for physical activity subscale and from 0 to  
161 24 for work activities subscale<sup>21</sup>. Higher scores indicate higher beliefs in fear  
162 and avoidance.<sup>22</sup> It has been currently used in patients with shoulder pain.<sup>23–25</sup>

## 163 Kinesiophobia

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

## 169 Pain Catastrophizing

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

## 174 Muscle Strength

175 Strength of the shoulder abductors<sup>30</sup>, external and medial rotators<sup>31,32</sup>  
176 (Figure 2) will be measured using a hand-held dynamometer (Lafayette

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2  
3 177 Instrument Company, Lafayette, IN, USA). A submaximal repetition of each test  
4  
5 178 will be performed for familiarization. Next, three 5-second repetitions with a  
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7 179 1min-rest interval between repetitions will be performed. The order of the tests  
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9 180 will be randomized.

## 10 181 Range of Motion

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13 182 Range of motion of active arm elevation in the sagittal and scapular  
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15 183 planes as well as the painful arcs will be assessed using a digital  
16  
17 184 inclinometer<sup>33,34</sup> (AcumarTM Lafayette Instrument Company, Lafayette, IN).  
18  
19 185 Individuals will be asked to elevate their arm in the standing position.

## 20 186 Satisfaction

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23 187 The Global Rating of Change Scale<sup>35</sup> will be used to assess patient's  
24  
25 188 satisfaction with the treatment. It is a 15-point numeric scale ranging from -7  
26  
27 189 (vastly worse) to 0 ("unchanged") to +7 ("vastly better"). Higher scores indicate  
28  
29 190 better satisfaction. Participants will respond to the following question: "How  
30  
31 191 satisfied are you with your shoulder?" Nothing, a little, moderately or totally are  
32  
33 192 the answer options to assess satisfaction.

## 34 193 Random Allocation

35  
36 194 Patients will be randomly assigned to one of the two groups: Rotator Cuff  
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38 195 Unloading Group or Rotator Cuff Loading Group. Randomization will be  
39  
40 196 computer based and carried out at a 1:1 ratio according to a random sequence  
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42 197 generated by the website <http://www.randomization.com>, stratified by sex and  
43  
44 198 age. An independent researcher, not involved in the treatment or assessment,  
45  
46 199 will perform the randomization process and prepare the sealed opaque  
47  
48 200 envelopes with group allocation consecutively numbered. The envelopes will be  
49  
50 201 securely stored and will be opened in sequence to reveal group allocation prior  
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52 202 to the first treatment session by the researcher responsible for the treatments.

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## 54 204 Blinding

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56 205 The assessor will be blinded to treatment group assignment and the  
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58 206 patients will be treated individually and blinded to the study hypothesis.

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## 208 **Interventions**

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

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

### 221 **Rotator Cuff Unloading Exercise Program**

222 Patients in this group will perform 4 exercises: semi-closed kinetic chain  
223 elevation, deltoid reeducation,<sup>37</sup> assisted arm elevation, and for scapular  
224 control.<sup>38,39</sup> The exercises and their progressions are described in the Appendix.

### 225 **Rotator Cuff Loading Exercise Program**

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

## 229 **Participant Timeline**

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

## 231 **Sample Size**

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

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3 238 groups: Rotator Cuff Unloading Exercise Program (n = 39) and Rotator Cuff  
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5 239 Loading Exercise Program (n = 39).  
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### 7 240 **Data management, monitoring and sharing**

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9 241 All data from recruitment, characteristics of the individuals who will  
10 242 complete or dropout the study will be entered into an electronic form by the  
11 243 researchers, and the integrity and validity of the data will be verified.  
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13 244 Identification of possible patients will be done only by the researchers. The  
14 245 research team is trained to address the eligibility criteria during the contact  
15 246 about survey made by e-mail, phone calls and messages. Also, the team is  
16 247 trained about how and when to contact them for follow-up and data collection.  
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18 248

19 249 The results of this article will be shared (text, tables, figures, appendices)  
20 250 immediately after publication. No interim analyses have been planned. To  
21 251 request data you will need to sign a data access agreement and the request  
22 252 can be made by e-mail. The changes made to the protocol will be  
23 253 communicated to ethics committee and also be included in the clinical trial  
24 254 register.  
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### 32 254 **Patient and Public Involvement**

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34 255 The patients were not involved in the design, will not be involved in the  
35 256 conduction and dissemination of the research. The results will be sent by e-mail  
36 257 or telephone in an unscientific language so that all patients understand the  
37 258 study's conclusions and know how to maintain self-care.  
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### 42 259 **Statistical Analysis**

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44 260 For data analysis, the statistical program Statistical Package for the  
45 261 Social Sciences version 23 will be used. Continuous data will be presented as  
46 262 mean, standard deviation and mean difference between groups with 95%  
47 263 confidence interval, and categorical by frequency and percentage. Data  
48 264 normality will be verified by Kolmogorov Smirnov test and observation of  
49 265 histograms for each variable in each group. Statistical analysis will follow the  
50 266 principles of intention-to-treat analysis. Linear mixed models will be used to  
51 267 calculate differences between groups using the terms of group interaction  
52 268 (Rotator Cuff Unloading Group *versus* Rotator Cuff Loading Group) versus time  
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3 269 (pre-treatment, 12 weeks at the end of treatment, and a month after the end of  
4 treatment) for each variable.  
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## 7 271 **ETHICS AND DISSEMINATION**

### 9 272 **Ethical Aspects**

11  
12 273 This study was approved by the Human research Ethics Committee of  
13 the University (CAAE: 12899719.5.0000.5504) and prospectively registered at  
14 274 clinicaltrials.gov (NCT03962231) on September, 2019.  
15 275

### 17 276 **Dissemination**

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20 277 The study will be disseminated through publication in peer-reviewed  
21 international journals, as well as presentations at national and international  
22 278 conferences.  
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### 25 280 **Discussion**

#### 27 281 **Potential Impact and Significance of the Study**

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31 282 Degenerative tears in the rotator cuff is a common finding in imaging  
32 283 studies due to the natural aging process.<sup>4,41</sup> There is evidence that therapeutic  
33 284 exercises should be the first treatment option for these patients<sup>14</sup> because the  
34 285 surgical approach is not clinically superior than the non-surgical approach in this  
35 286 population.<sup>12</sup> Several exercise protocols have been proposed for this  
36 287 population.<sup>14</sup> However, there is no consensus on which exercises or exercise  
37 288 programs are the most effective. This fact challenges the physical therapist in  
38 289 the clinical decision-making. Thus, the results of this study will likely contribute  
39 290 to the physical therapy's decision-making on exercise prescriptions to  
40 291 individuals with rotator cuff tears.  
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#### 49 292 **Strengths and Weaknesses of the Study**

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51 293 The strength of the current study is that it is a randomized controlled trial  
52 294 that has been prospectively registered. Furthermore, the study includes  
53 295 concealed allocation and an intention-to treat approach. The sample size has  
54 296 been calculated to provide appropriate statistical power to detect differences  
55 297 between the 2 treatment programs.  
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3 298 The assessor responsible for collecting outcome data will be blinded to  
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5 299 treatment group assignment. Physical therapists responsible for treatment have  
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7 300 similar clinical experience and have been trained by the main author of the  
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9 301 study. However, the study has some limitations. Participants and therapists  
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11 302 cannot be blinded. Both exercise programs include home guidelines, which  
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13 303 depend on each participant's motivation. It is not possible to predict the amount  
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15 304 of home guidelines and cryotherapy that will be performed by each group.

### 16 305 Contribution to the Physical Therapy Profession and to Patients

17  
18 306 The results of this study will provide scientific basis to support physical  
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20 307 therapists in the treatment of individuals with rotator cuff tears, helping in the  
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22 308 choice of exercises and their progression. In addition, the findings may also  
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24 309 help health care providers and patients with rotator cuff tears to reduce health  
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26 310 costs, avoiding the need for surgery and the use of analgesic drugs.  
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28 311 Participants will be taught how to modify their daily activities by modifying the  
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30 312 movements and postures that appear to increase shoulder symptoms. The  
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32 313 participants also receive a series of exercises to be performed at home in the  
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34 314 follow-up. It is expected that patients will become independent and more  
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36 315 empowered with good quality of life and function of the upper limbs.

36 316 Finally, the findings of the current study may contribute to a better  
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38 317 understanding of the efficacy of exercise program for individuals with rotator cuff  
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40 318 tears.

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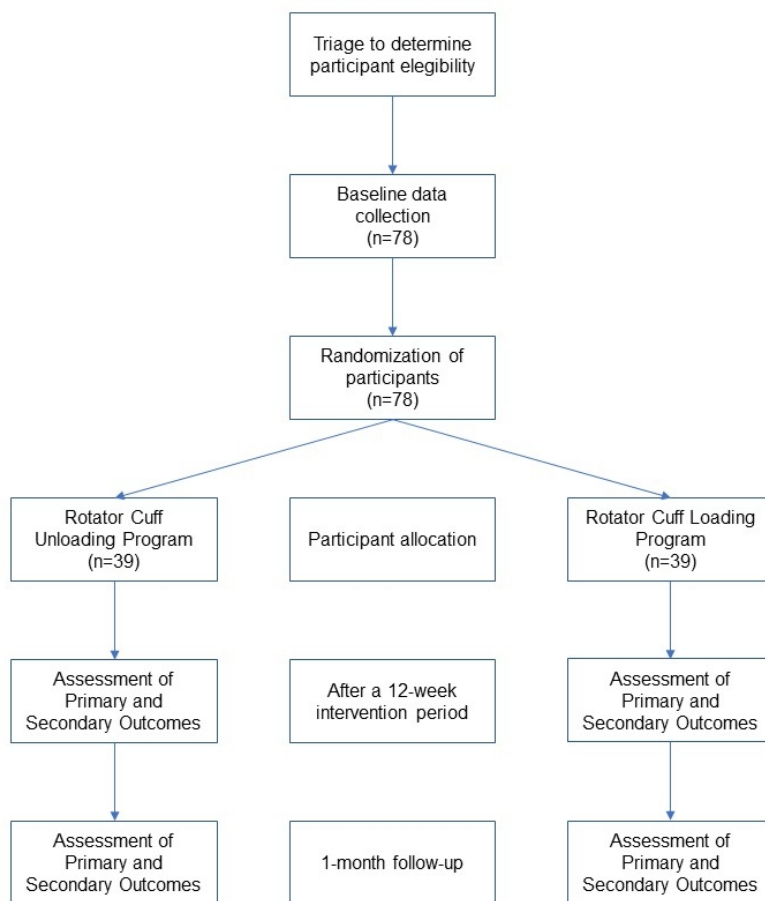


Figure 1. Study flow diagram

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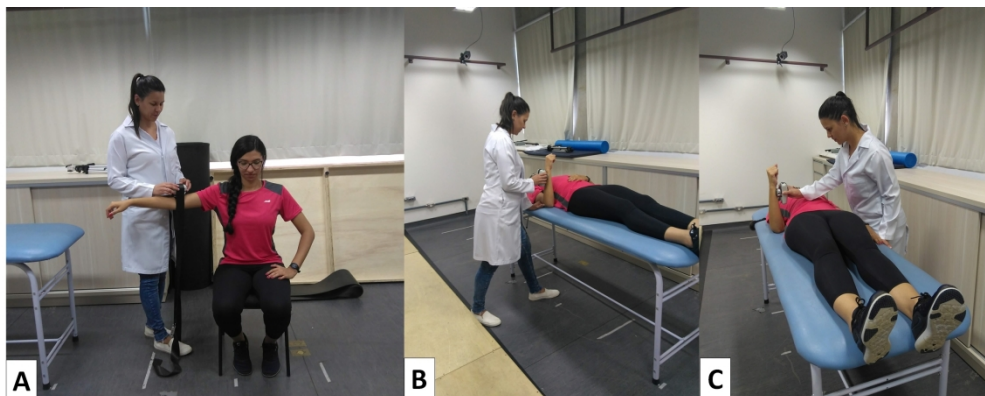




Figure 2. Muscle strength of abductors (A), external rotators (B) and internal rotators (C) of the shoulder

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## 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.		

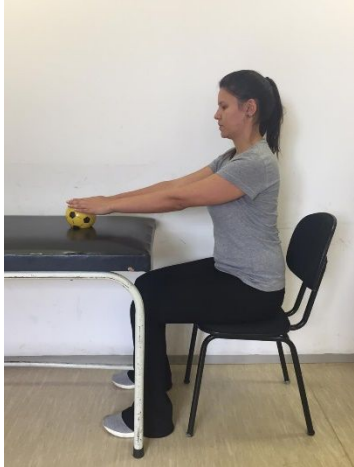


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2) Bilateral Bench Slide <90°

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 <90°

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.

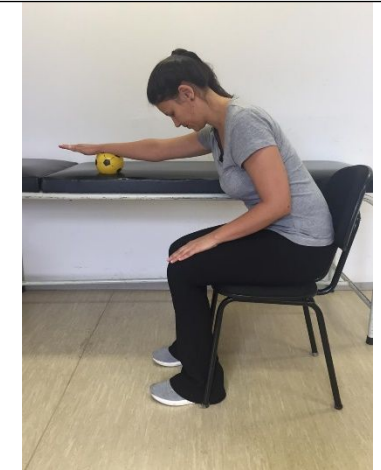


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4) Unilateral Bench  
Slide >90°

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.

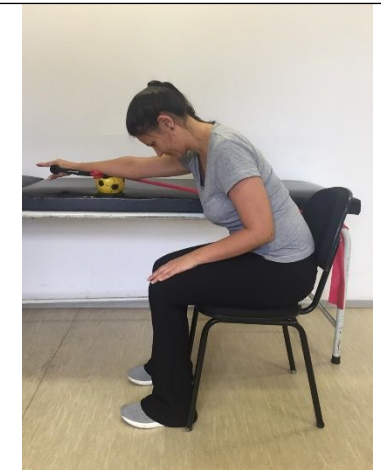


5) Unilateral Bench  
Slide > 90° + Resistance

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).

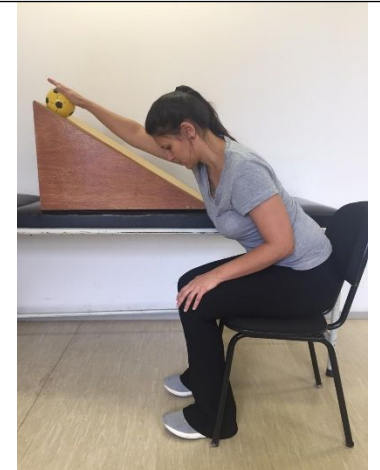
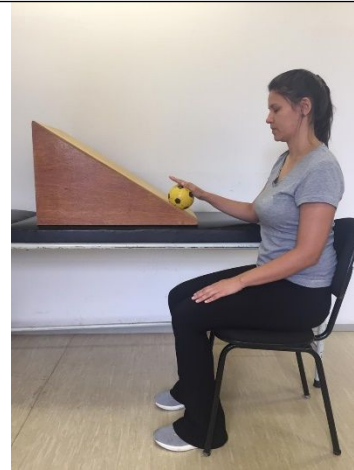


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6) Inclined Bench Slide

Patient sitting beside to the treatment table, and supporting the hand on the ball. The ball will be on an inclined surface at 45°. Elbow will be flexed and arm at the side of the trunk.

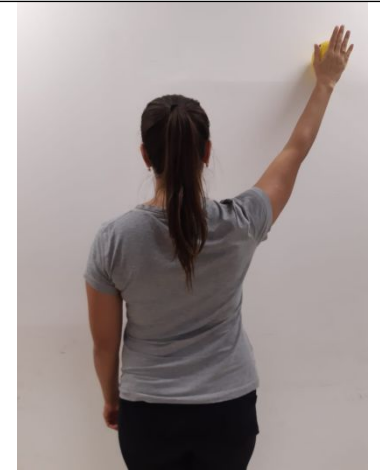
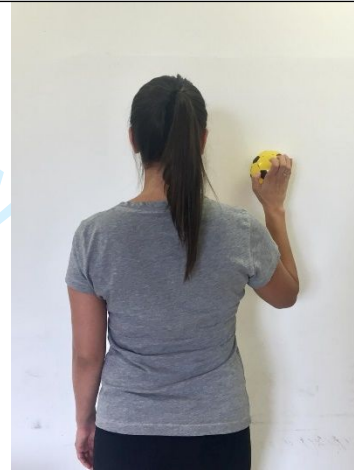
Slide the hand over the ball, moving hand and trunk forward until elbow is extended.  
\*progression: yellow, red, green and blue elastic band (Theraband).




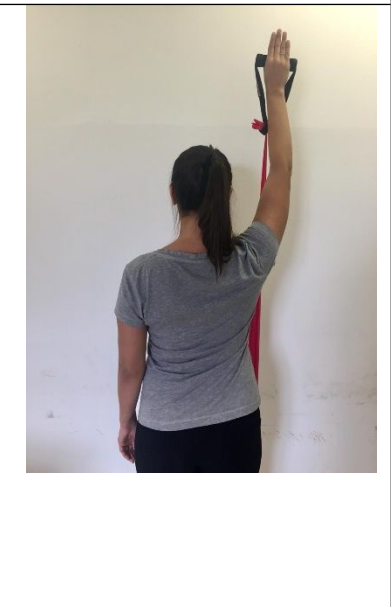


7) Wall Slide

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.




<p>1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19</p> <p>8) Wall Slide + Resistance</p>	<p>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.</p>	<p>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).</p>		
<p>20 21 22 23 24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46</p> <p>9) Wall Slide + Resistance + Open Chain</p>	<p>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.</p>	<p>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).</p>		

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**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 90° 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 90° 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 90° flexion	The unaffected arm will first assist elbow extension of the affected arm keeping the shoulder at 90° of flexion. Next, the		

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	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 90° flexion holding a toning ball.	The unaffected arm will first assist elbow extension of the affected arm keeping the shoulder at 90° 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 90° of flexion. Next, the		

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	will be at 90° 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 60° of trunk inclination, hand of the unaffected shoulder holds the affected arm. Initially elbow at 90° 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 90° of flexion. Next, the affected shoulder perform flexion without assistance and weight.		
6) Seated + Weight	Patient with 60° trunk inclination, elbow of the affected side at 90° flexion and arm at the side of the	The unaffected arm will first assist elbow extension of the affected arm keeping the shoulder at 90° 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 90° 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.		

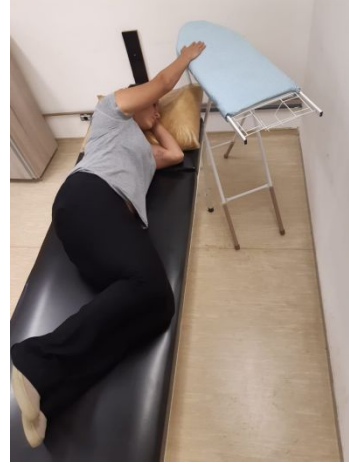


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2) Side Lying Elevation

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.

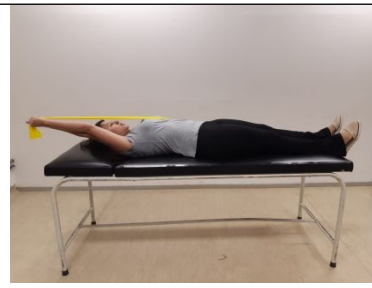
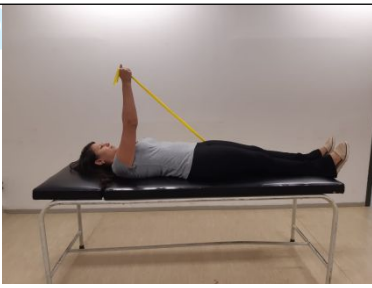
Patient slides the hand over the flat surface raising his arm with the elbow slightly bent.





3) Supine Band

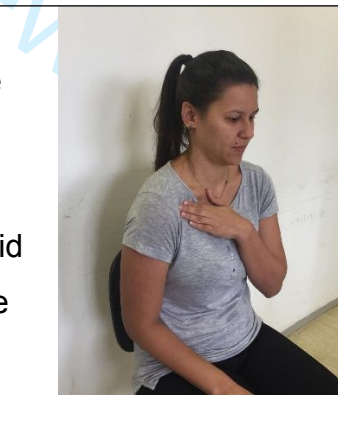
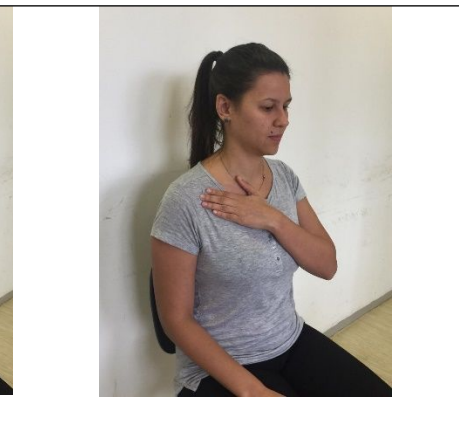
Patient in supine, holding a yellow elastic band with both hands. Unaffected shoulder remains at the side of the body and affected shoulder with 90° flexion.

The affected shoulder performs flexion with elastic band while the other shoulder remains at the side of the trunk.





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<p>4) Bar Assisted Standing</p>	<p>Patient standing holding a bar</p>	<p>Unaffected shoulder assists the arm elevation using a bar.</p>		
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Exercises for Scapular Control and progressions				
Exercise	Initial Position	Performance	Initial Position	Final Position
<p>1) Scapular Orientation Exercise</p>	<p>Patient sitting, places index finger on the coracoid process of the affected shoulder.</p>	<p>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</p>		

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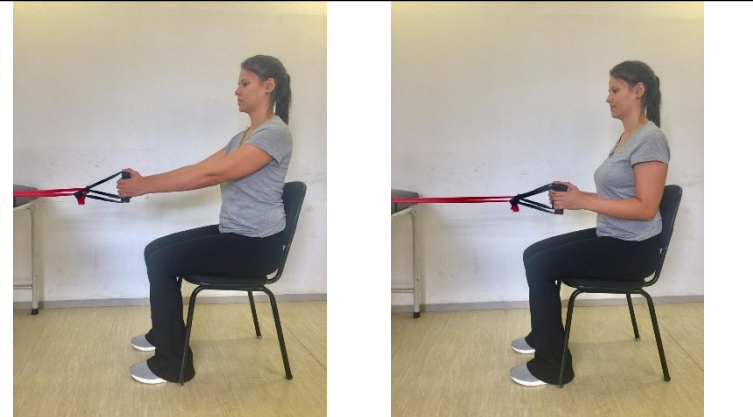
		scapula into a little hook behind.	
2) Inferior Glide	Patient sitting beside the treatment table, with affected shoulder in abduction close to 90°. A ball will be on the treatment table and the fist.	Patient will perform a pressure with the fist in the direction of arm adduction and instructed to inferiorly 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.	

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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

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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 90° 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 90° 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 90° and

The patient will perform external rotation and abduction of the shoulder, thus performing a external


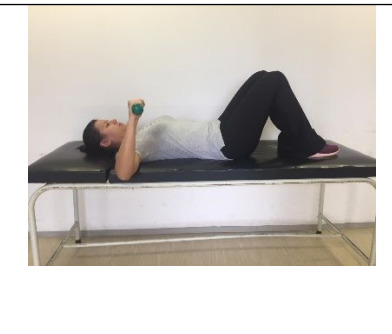




holding an elastic band by hand. rotation in the diagonal direction.  
\* progression: yellow, red and green elastic band (Theraband).



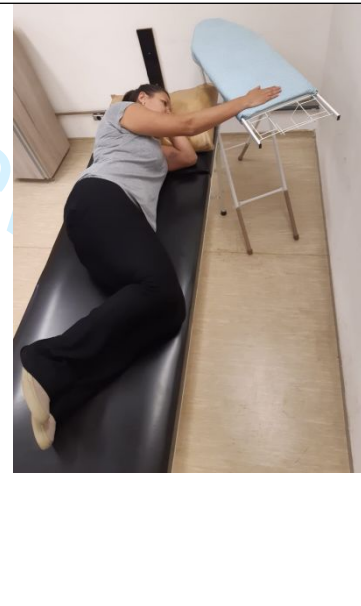
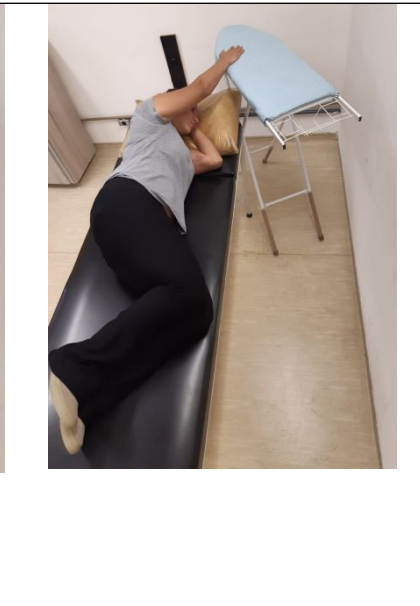
**Focus on Internal Rotation and progressions**

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 90° 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).		

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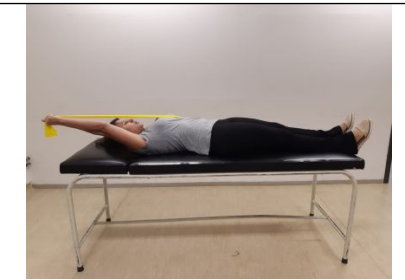


<p>2) Sitting Internal Rotation</p>	<p>Patient in supine with affected shoulder in 90° abduction and elbow in 90° flexion holding a dumbbell in hand.</p>	<p>Patient will perform internal rotation of the shoulder and return to the initial position. * progression: 1kg, 2kg and 3kg dumbbell.</p>		
<p>3)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

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





<p>1) Therapist Assisted Elevation</p>	<p>Patient in supine with elbow at 90° flexion and shoulder at the side of the trunk. Therapist holds the forearm on the affected side of the patient.</p>	<p>Therapist assists shoulder flexion during the concentric and eccentric phases.</p>		
<p>2) Side Lying Elevation</p>	<p>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.</p>	<p>Patient slides the hand over the flat surface raising the arm with the elbow slightly bent.</p>		



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

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 90° 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.		



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
<b>Administrative information</b>			
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

1 **Introduction**

2

3 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

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6 6b Explanation for choice of comparators 3

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8 Objectives 7 Specific objectives or hypotheses 3

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10 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

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14 **Methods: Participants, interventions, and outcomes**

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16 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

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19 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

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22 Interventions 11a Interventions for each group with sufficient detail to allow replication, including how and when they will be administered 8

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25 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

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28 11c Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests) 4

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31 11d Relevant concomitant care and interventions that are permitted or prohibited during the trial 4

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34 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

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40 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

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1	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
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4	Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	5
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6 **Methods: Assignment of interventions (for controlled trials)**

7 Allocation:

10	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
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16	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
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20	Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	7
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24	Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	7
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27		17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	7
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31 **Methods: Data collection, management, and analysis**

33	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
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38		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
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1	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
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5	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
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8		20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	NA
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10		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
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14	<b>Methods: Monitoring</b>			
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16	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
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22		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
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25	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
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28	Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	No
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32	<b>Ethics and dissemination</b>			
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34	Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	No
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37	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
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1	Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	5
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4		26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	NA
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7	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
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10	Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	18
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13	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
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16	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
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20	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
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24		31b	Authorship eligibility guidelines and any intended use of professional writers	9
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26		31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	9
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29	<b>Appendices</b>			
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31	Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	Ok
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34	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
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\*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”](https://creativecommons.org/licenses/by-nc-nd/3.0/) 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:	<i>BMJ Open</i>
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
<b>Primary Subject Heading</b>:	Rehabilitation medicine
Secondary Subject Heading:	Evidence based practice
Keywords:	REHABILITATION MEDICINE, Shoulder < ORTHOPAEDIC & TRAUMA SURGERY, PAIN MANAGEMENT

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Manuscripts





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3 1 **Rotator cuff unloading versus loading exercise program in the**  
4 **conservative treatment of patients with rotator cuff tear: Protocol of a**  
5 **randomized controlled trial**  
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9 4 Larissa Pechincha Ribeiro, PT, MS<sup>1</sup>, Ann Cools, PT, PhD<sup>2</sup>, Paula Rezende  
10 5 Camargo, PT, PhD<sup>1</sup>, \*  
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## 16 ABSTRACT

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

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

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

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

40 **Trial registration number:** NCT03962231

41 **Keywords:** physical therapy, rehabilitation, impingement syndrome.

### 42 **Strength and limitations of the study:**

43 - This study is a unique randomized controlled trial that compares rotator cuff  
44 loading *versus* unloading exercises on clinical aspects in patients with rotator  
45 cuff tears.  
46

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

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

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

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

## 55 INTRODUCTION

56 Rotator cuff disease is one of the most common musculoskeletal  
57 disorders in the adult population. Rotator cuff tears are highly prevalent, from  
58 22% at the age of 65 years, to more than 62% in a population over 80 years  
59 old,<sup>1</sup> and appear to be an age-related finding on diagnostic imaging. The  
60 supraspinatus tendon is the most commonly affected tendon due to its  
61 anatomical location, tensile and compressive overload,<sup>2</sup> vascular changes and  
62 degeneration process associated with aging.<sup>3</sup> Although degenerative rotator  
63 cuff tears are not necessarily symptomatic,<sup>4-6</sup> a significant proportion of these  
64 injuries cause pain and disability of the patient over time. This condition may  
65 have a high impact in social life and can be associated to chronic pain,  
66 weakness, and dysfunction of the upper extremities.<sup>7</sup>

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

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

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

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3 87 rotator cuff exercise program will produce better outcomes in the follow-up as  
4  
5 88 regeneration of the rotator cuff is very unlikely in degenerative rotator cuff tears.  
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7 89

## 8 90 **METHODS AND ANALYSIS**

### 91 **Study Design**

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

### 96 **Study Setting**

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

### 100 **Eligibility Criteria**

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

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

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

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3 117 study follow-up with remaining shoulder symptoms will receive written and  
4  
5 118 verbal information about shoulder pain management and exercises.  
6  
7 119

## 8 120 **Procedure**

9  
10 121 The participants will be recruited through flyers placed at the University,  
11 122 outpatient clinics and community. Advertisements in local radio, and online  
12 123 resources (eg, university intranet and social media) will also be used for  
13 124 recruitment of patients. All eligible participants will receive information about the  
14 125 study and will sign an informed consent form before participation. The assessor  
15 126 will collect the baseline data prior to randomization, after the 12-week  
16 127 intervention period and 1 month after the end of treatment (follow-up).  
17 128 Satisfaction will only be assessed after the 12-week intervention period and at  
18 129 follow-up. Figure 1 brings the flow diagram of the study.  
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## 28 131 **Outcome measures**

29 132 The primary outcome measure will be quality of life. The secondary  
30 133 outcomes will be pain, function, fear avoidance beliefs, kinesiophobia, pain  
31 134 catastrophizing, strength, range of motion and satisfaction with treatment. All  
32 135 scales and questionnaires have been translated and cross-culturally adapted  
33 136 into Brazilian Portuguese.  
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### 40 137 **Quality of Life**

41  
42 138 The WORC (The Western Ontario Rotator Cuff Index) assesses quality  
43 139 of life in individuals with rotator cuff disease.<sup>15</sup> It has 21 questions in five  
44 140 domains: pain and physical symptoms (6 questions), sports and recreation (4  
45 141 questions), work (4 questions), lifestyle (4 questions), and emotional state (3  
46 142 questions). The total score ranges from 0 to 2100. Higher scores indicate worse  
47 143 quality of life. It is a reliable instrument.<sup>16</sup>  
48  
49  
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53

### 54 144 **Pain**

55  
56 145 The 11-point numerical pain rating scale will be used to assess current  
57 146 level of shoulder pain at rest, during arm movement, and the greatest and  
58 147 lowest level of shoulder pain in the last week.<sup>17</sup> The score ranges from 0 (no  
59  
60

1  
2  
3 148 pain) to 10 (worst possible pain). This scale is reliable and valid for individuals  
4  
5 149 with shoulder pain.<sup>18</sup>

#### 6 7 150 Function of the Upper Limbs

8  
9 151 The DASH (Disabilities of the Arm, Shoulder, and Hand) questionnaire  
10 152 will be used to assess upper limb function.<sup>19</sup> It contains 30 questions that  
11 153 include items related to physical function, symptoms, and social function. Each  
12 154 question has 5 possible answers ranging from "No difficulty" to "Unable", and is  
13 155 scored on a 5-point rating scale. The maximum score is 100, which indicates  
14 156 the worst possible condition.<sup>20</sup> This questionnaire has been shown to be  
15 157 reliable.<sup>19</sup>

#### 16 17 158 Fear Avoidance Beliefs

18  
19 159 The Fear Avoidance Beliefs Questionnaire (FABQ-Brazil)<sup>21</sup> will be used  
20 160 to measure fear avoidance. The FABQ-Brazil is a 6-item questionnaire that  
21 161 comprises 2 subscales physical activity and work activities. Each item is  
22 162 scored on a 7-point scale ranging from "strongly agree" to "strongly disagree".  
23 163 The final scores range from 0 to 42 for physical activity subscale and from 0 to  
24 164 24 for work activities subscale<sup>21</sup>. Higher scores indicate higher beliefs in fear  
25 165 and avoidance.<sup>22</sup> It has been currently used in patients with shoulder pain.<sup>23-25</sup>

#### 26 27 166 Kinesiophobia

28  
29 167 The Tampa Kinesiophobia Scale assesses the individual's fear of  
30 168 movement and the fear of pain recurrence.<sup>26</sup> It has 17 questions that address  
31 169 pain and symptom intensity. The final score ranges from 17 to 68 points. Higher  
32 170 scores indicate higher kinesiophobia.<sup>26</sup> It has been used in individuals with  
33 171 shoulder pain and has good reliability.<sup>23</sup>

#### 34 35 172 Pain Catastrophizing

36  
37 173 This scale contains 13 items divided into 3 domains: helplessness,  
38 174 magnification and rumination. Total scores ranges from 0 to 52. Higher values  
39 175 indicate higher degree of catastrophic thoughts.<sup>27</sup> It has been currently used in  
40 176 patients with shoulder pain.<sup>28,29</sup>

#### 41 42 177 Muscle Strength

1  
2  
3 178 Strength of the shoulder abductors<sup>30</sup>, external and medial rotators<sup>31,32</sup>  
4  
5 179 (Figure 2) will be measured using a hand-held dynamometer (Lafayette  
6  
7 180 Instrument Company, Lafayette, IN, USA). A submaximal repetition of each test  
8  
9 181 will be performed for familiarization. Next, three 5-second repetitions with a  
10  
11 182 1min-rest interval between repetitions will be performed. The order of the tests  
12  
13 183 will be randomized.

#### 14 184 Range of Motion

15  
16 185 Range of motion of active arm elevation in the sagittal and scapular  
17  
18 186 planes as well as the painful arcs will be assessed using a digital  
19  
20 187 inclinometer<sup>33,34</sup> (Acumar™ Lafayette Instrument Company, Lafayette, IN).  
21  
22 188 Individuals will be asked to elevate their arm in the standing position.

#### 23 24 189 Satisfaction

25  
26 190 The Global Rating of Change Scale<sup>35</sup> will be used to assess patient's  
27  
28 191 satisfaction with the treatment. It is a 15-point numeric scale ranging from -7  
29  
30 192 (vastly worse) to 0 ("unchanged") to +7 ("vastly better"). Higher scores indicate  
31  
32 193 better satisfaction. Participants will respond to the following question: "How  
33  
34 194 satisfied are you with your shoulder?" Nothing, a little, moderately or totally are  
35  
36 195 the answer options to assess satisfaction.

#### 37 196 Random Allocation

38  
39  
40 197 Patients will be randomly assigned to one of the two groups: Rotator Cuff  
41  
42 198 Unloading Group or Rotator Cuff Loading Group. Randomization will be  
43  
44 199 computer based and carried out at a 1:1 ratio according to a random sequence  
45  
46 200 generated by the website <http://www.randomization.com>, stratified by sex and  
47  
48 201 age. An independent researcher, not involved in the treatment or assessment,  
49  
50 202 will perform the randomization process and prepare the sealed opaque  
51  
52 203 envelopes with group allocation consecutively numbered. The envelopes will be  
53  
54 204 securely stored and will be opened in sequence to reveal group allocation prior  
55  
56 205 to the first treatment session by the researcher responsible for the treatments.

56 206

#### 57 58 207 Blinding



1  
2  
3 208 The assessor will be blinded to treatment group assignment and the  
4  
5 209 patients will be treated individually and blinded to the study hypothesis.  
6  
7 210

## 8 9 211 **Interventions**

10  
11 212 Each intervention program will consist of 24 supervised sessions, which  
12  
13 213 will be executed 2 times/week for 12 weeks. Both groups will receive advice  
14  
15 214 with respect to pain control, posture and range of motion. Adherence to  
16  
17 215 treatment and assessment sessions will be encouraged at each session.

18  
19 216 The exercise program for both groups will be based on a systematic  
20  
21 217 review,<sup>36</sup> providing a continuum of exercises, from low rotator cuff to high rotator  
22  
23 218 cuff load. The selected exercises for the Rotator Cuff Unloading Group will be  
24  
25 219 based on a muscle activation equal to or less than 20% of the supraspinatus  
26  
27 220 maximal activity.<sup>36</sup> The selected exercises for the Rotator Cuff Loading Group  
28  
29 221 will be based on a muscle activation equal to or greater than 40% of the  
30  
31 222 supraspinatus maximal activity. All exercises will be performed in 3 sets of 10  
32  
33 223 repetitions with a 1-minute interval between repetitions.

### 33 224 **Rotator Cuff Unloading Exercise Program**

34  
35  
36 225 Patients in this group will perform 4 exercises: semi-closed kinetic chain  
37  
38 226 elevation, deltoid reeducation,<sup>37</sup> assisted arm elevation, and an exercise for  
39  
40 227 scapular control.<sup>38,39</sup> The exercises and their progressions are described in the  
41  
42 228 Appendix.

### 43 229 **Rotator Cuff Loading Exercise Program**

44  
45  
46 230 Patients in this group will perform conventional exercises focusing on  
47  
48 231 external rotation, internal rotation and arm elevation. The exercises and their  
49  
50 232 progressions are described in the Appendix.

## 51 233 **Participant Timeline**

52  
53 234 The flowchart summarising procedures and patients is shown in Figure 1.

## 55 235 **Sample Size**

56  
57  
58 236 The sample size calculation was based on the smallest significant  
59  
60 237 difference of 282.6 points from the Western Ontario Rotator Cuff Index

1  
2  
3 238 (WORC)<sup>40</sup> with a standard deviation of 400 points, a power of 80%, and a  
4  
5 239 significance level of 5%. WORC was selected because it evaluates the quality  
6  
7 240 of life of individuals with rotator cuff disease. Accounting for a 15% dropout, 78  
8  
9 241 subjects will be included in the study, randomly allocated to two treatment  
10  
11 242 groups: Rotator Cuff Unloading Exercise Program (n = 39) and Rotator Cuff  
12  
13 243 Loading Exercise Program (n = 39).

#### 14 244 **Data management, monitoring and sharing**

15  
16 245 All data from recruitment, characteristics of the individuals who will  
17  
18 246 complete or dropout the study will be entered into an electronic form by the  
19  
20 247 researchers, and the integrity and validity of the data will be verified.  
21  
22 248 Identification of possible patients will be done only by the researchers. The  
23  
24 249 research team is trained to address the eligibility criteria during the contact  
25  
26 250 about survey made by e-mail, phone calls and messages. Also, the team is  
27  
28 251 trained about how and when to contact them for follow-up and data collection.

29 252 The results of this article will be shared (text, tables, figures, appendices)  
30  
31 253 immediately after publication. No interim analyses have been planned. To  
32  
33 254 request data you will need to sign a data access agreement and the request  
34  
35 255 can be made by e-mail. The changes made to the protocol will be  
36  
37 256 communicated to ethics committee and also be included in the clinical trial  
38  
39 257 register.

#### 40 258 **Patient and Public Involvement**

41  
42 259 The patients were not involved in the design, will not be involved in the  
43  
44 260 conduction and dissemination of the research. The results will be sent by e-mail  
45  
46 261 or telephone in an unscientific language so that all patients understand the  
47  
48 262 study's conclusions and know how to maintain self-care.

#### 49 263 **Statistical Analysis**

50  
51  
52 264 For data analysis, the statistical program Statistical Package for the  
53  
54 265 Social Sciences version 23 will be used. Continuous data will be presented as  
55  
56 266 mean, standard deviation and mean difference between groups with 95%  
57  
58 267 confidence interval, and categorical by frequency and percentage. Data  
59  
60 268 normality will be verified by Kolmogorov Smirnov test and observation of

1  
2  
3 269 histograms for each variable in each group. Statistical analysis will follow the  
4  
5 270 principles of intention-to-treat analysis. Linear mixed models will be used to  
6  
7 271 calculate differences between groups using the terms of group interaction  
8  
9 272 (Rotator Cuff Unloading Group *versus* Rotator Cuff Loading Group) versus time  
10  
11 273 (pre-treatment, 12 weeks at the end of treatment, and a month after the end of  
12  
13 274 treatment) for each variable.

## 14 275 **ETHICS AND DISSEMINATION**

### 16 276 **Ethical Aspects**

17  
18  
19 277 This study was approved by the Human research Ethics Committee of  
20  
21 278 the University (CAAE: 12899719.5.0000.5504) and prospectively registered at  
22  
23 279 clinicaltrials.gov (NCT03962231) on September, 2019.

### 24 280 **Dissemination**

25  
26  
27 281 The study will be disseminated through publication in peer-reviewed  
28  
29 282 international journals, as well as presentations at national and international  
30  
31 283 conferences.

## 32 284 **DISCUSSION**

### 34 285 **Potential Impact and Significance of the Study**

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36  
37 286 Degenerative tears in the rotator cuff is a common finding in imaging  
38  
39 287 studies due to the natural aging process.<sup>4,41</sup> There is evidence that therapeutic  
40  
41 288 exercises should be the first treatment option for these patients<sup>14</sup> because the  
42  
43 289 surgical approach is not clinically superior than the non-surgical approach in this  
44  
45 290 population.<sup>12</sup> Several exercise protocols have been proposed for this  
46  
47 291 population.<sup>14</sup> However, there is no consensus on which exercises or exercise  
48  
49 292 programs are the most effective. This fact challenges the physical therapist in  
50  
51 293 the clinical decision-making. Thus, the results of this study will likely contribute  
52  
53 294 to the physical therapy's decision-making on exercise prescriptions to  
54  
55 295 individuals with rotator cuff tears.

### 56 296 **Strengths and Weaknesses of the Study**

57  
58 297 The strength of the current study is that it is a randomized controlled trial  
59  
60 298 that has been prospectively registered. Furthermore, the study includes

1  
2  
3 299 concealed allocation and an intention-to treat approach. The sample size has  
4  
5 300 been calculated to provide appropriate statistical power to detect differences  
6  
7 301 between the 2 treatment programs.  
8

9 302 The assessor responsible for collecting outcome data will be blinded to  
10 303 treatment group assignment. Physical therapists responsible for treatment have  
11 304 similar clinical experience and have been trained by the main author of the  
12 305 study. However, the study has some limitations. Participants and therapists  
13 306 cannot be blinded. Both exercise programs include home guidelines, which  
14 307 depend on each participant's motivation. It is not possible to predict the amount  
15 308 of home guidelines and cryotherapy that will be performed by each group.  
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20

### 21 309 Contribution to the Physical Therapy Profession and to Patients

22  
23  
24 310 The results of this study will provide scientific basis to support physical  
25 311 therapists in the treatment of individuals with rotator cuff tears, helping in the  
26 312 choice of exercises and their progression. In addition, the findings may also  
27 313 help health care providers and patients with rotator cuff tears to reduce health  
28 314 costs, avoiding the need for surgery and the use of analgesic drugs.  
29 315 Participants will be taught how to modify their daily activities by modifying the  
30 316 movements and postures that appear to increase shoulder symptoms. The  
31 317 participants also receive a series of exercises to be performed at home in the  
32 318 follow-up. It is expected that patients will become independent and more  
33 319 empowered with good quality of life and function of the upper limbs.  
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41 320 Finally, the findings of the current study may contribute to a better  
42 321 understanding of the efficacy of exercise program for individuals with rotator cuff  
43 322 tears.  
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3 324 **Contributorship statement:** All authors (LPR, AC and PRC) were equally  
4  
5 325 responsible for outlining the conception and protocol design. LPR, AC and PRC  
6  
7 326 drafted the work, revised it critically for important intellectual content, and  
8  
9 327 approved the final version.

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13  
14 330 interest in any matter included in this manuscript.

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19  
20 333 (144436/2019-1).

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22  
23 334 **Data sharing statement:** All data (especially from potential or enrolled  
24  
25 335 participants) collected during the trial will be entered into an electronic form by  
26  
27 336 those responsible and maintained confidential before, during and after the trial  
28  
29 337 by encoding participant's name. Any changes made to the protocol will be  
30  
31 338 reported to the ethics committee and included in the clinical trial register. The  
32  
33 339 results of this article will be shared (text, tables, figures, appendices)  
34  
35 340 immediately after publication. Upon completion of the study, supported data will  
36  
37 341 be available upon request. Requests for data or any form of analysis should be  
38  
39 342 directed to [prcamargo@ufscar.br](mailto:prcamargo@ufscar.br).

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5 505 Figure 1. Study flow diagram.  
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8 506 Figure 2. Muscle strength of abductors (A), external rotators (B) and internal  
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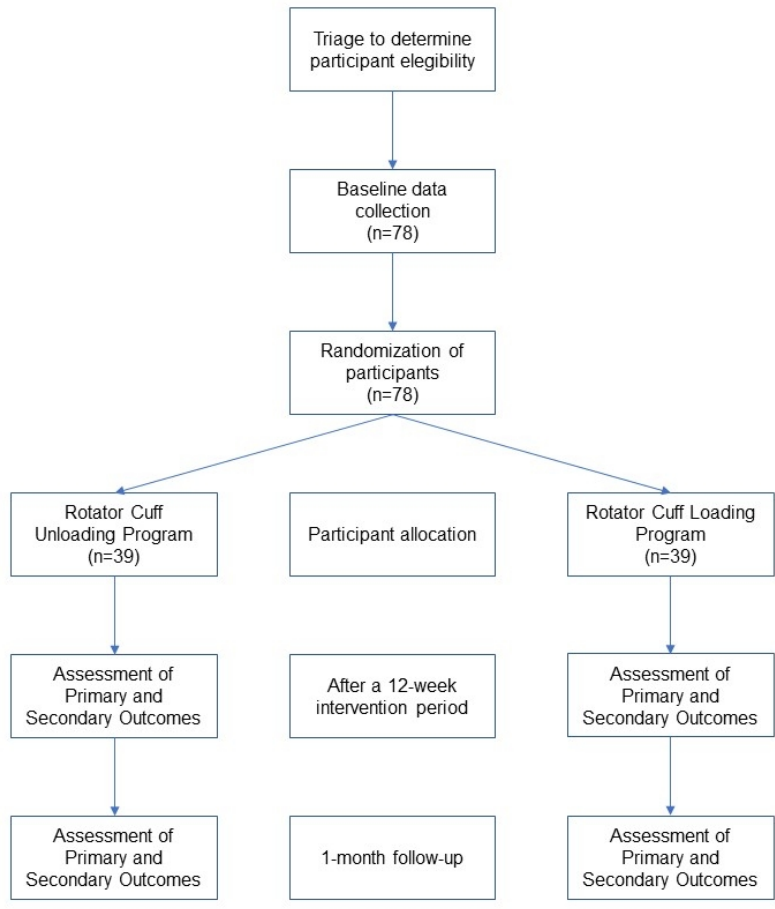


Figure 1. Study flow diagram  
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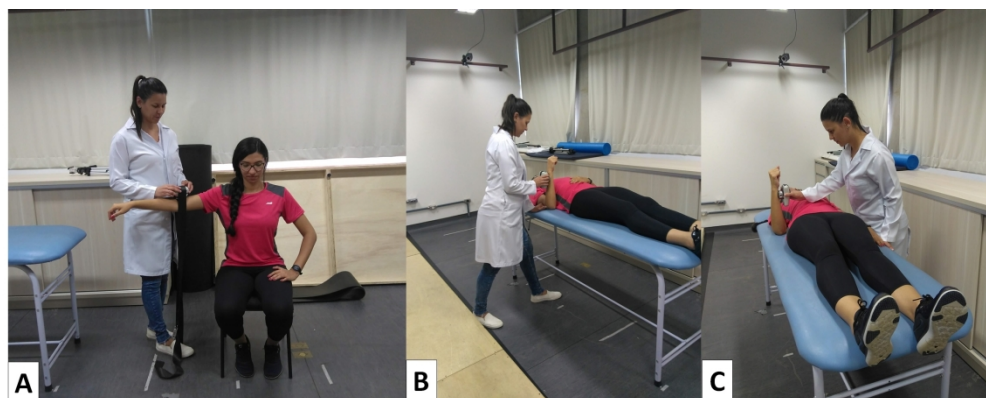


Figure 2. Muscle strength of abductors (A), external rotators (B) and internal rotators (C) of the shoulder



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**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.		

<p>1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19</p> <p>2) Bilateral Bench Slide &lt;math&gt;&lt;90^\circ&lt;/math&gt;</p>	<p>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.</p>	<p>Slide the hands over the ball, moving it forward until the elbow is extended, and shoulder flexed &lt;math&gt;&lt;90^\circ&lt;/math&gt;. Keep the trunk straight.</p>		
<p>20 21 22 23 24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46</p> <p>3) Unilateral Bench Slide &lt;math&gt;&lt;90^\circ&lt;/math&gt;</p>	<p>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.</p>	<p>Slide the hand over the ball, moving it forward until the elbow is extended. Keep the trunk straight.</p>		



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4) Unilateral Bench  
Slide >90°

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.

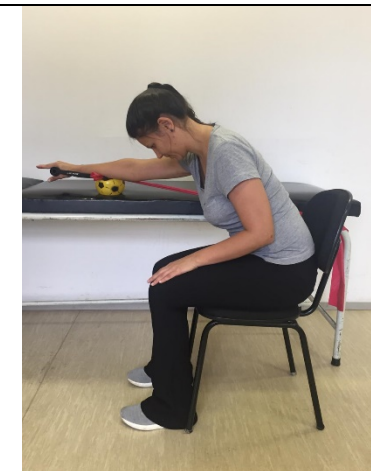
Slide the hand over the ball and incline the trunk forward until the elbow is extended.


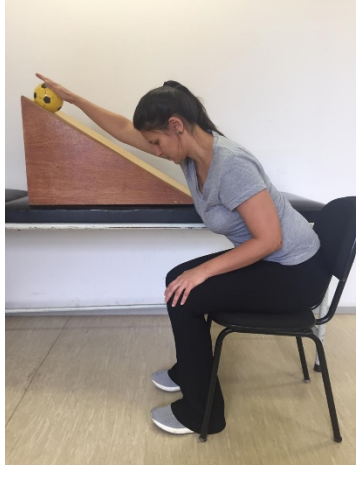




5) Unilateral Bench  
Slide > 90° + Resistance

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 45°. 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.		

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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).



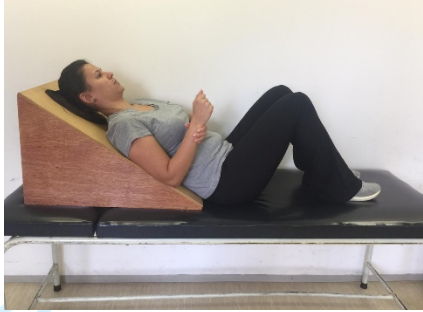



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Anterior Deltoid Reeducation and progressions				
Exercise	Position	Performance	Initial Position	Final Position
1) Passive Elevation	Patient in supine, hand of the unaffected arm holds the wrist of affected arm. Elbow will be at 90° flexion and the arm at the side of the trunk.	The unaffected arm will first assist elbow extension of the affected arm keeping the shoulder at 90° 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 90° flexion	The unaffected arm will first assist elbow extension of the affected arm keeping the shoulder at 90° of flexion. Next, the		

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	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 90° flexion holding a toning ball.	The unaffected arm will first assist elbow extension of the affected arm keeping the shoulder at 90° 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 90° of flexion. Next, the		

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

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the affected arm holds a toning ball.	affected shoulder perform flexion without assistance with toning ball.* progression: 1kg and 2kg toning ball.
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Assisted Elevation and progressions				
Exercise	Initial Position	Performance	Initial Position	Final Position
1) Therapist Assisted Elevation	<p>Patient in supine with elbow at 90° flexion and shoulder at the side of the trunk. Therapist holds the forearm on the affected side of the patient.</p>	<p>Therapist assists shoulder flexion during the concentric and eccentric phases.</p>		

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<p>2) Side Lying Elevation</p>	<p>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.</p>	<p>Patient slides the hand over the flat surface raising his arm with the elbow slightly bent.</p>		
<p>3) Supine Band</p>	<p>Patient in supine, holding a yellow elastic band with both hands. Unaffected shoulder remains at the side of the body and affected shoulder with 90° flexion.</p>	<p>The affected shoulder performs flexion with elastic band while the other shoulder remains at the side of the trunk.</p>		


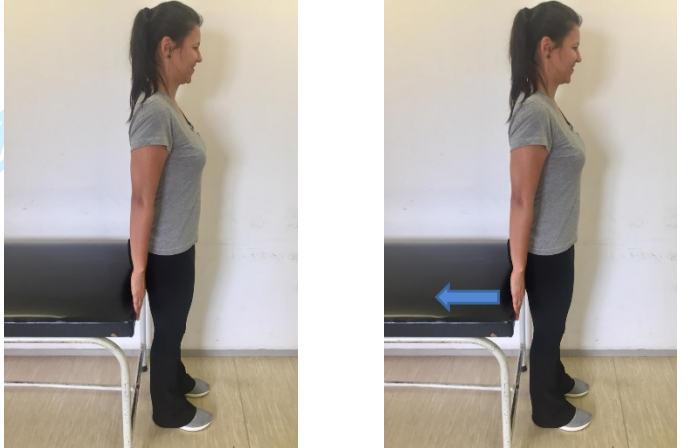


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4) Bar Assisted Standing	Patient standing holding a bar	Unaffected shoulder assists the arm elevation using a bar.		
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Exercises for Scapular Control and progressions				
Exercise	Initial Position	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		

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

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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).




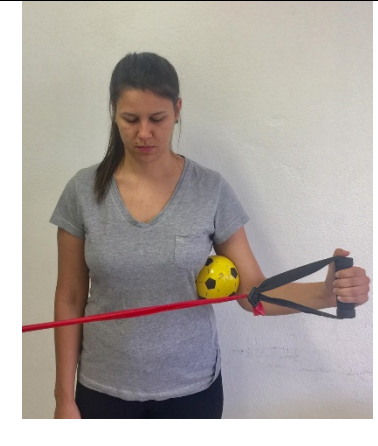

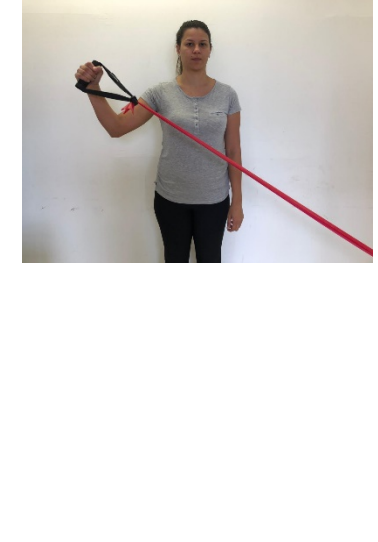
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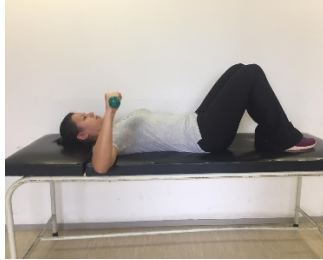
## Rotator Cuff Loading Exercise Program

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	<p>Patient in side lying position with the affected arm upwards. Arm at the side of the trunk and elbow flexed at 90° with a dumbbell in hand.</p>	<p>Patient will perform external rotation of the shoulder and return to the initial position.</p> <p>* progression: 1kg, 2kg and 3kg dumbbell.</p>		



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




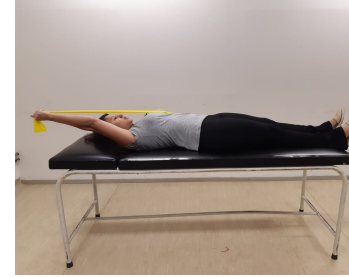
Focus on Internal Rotation and progressions				
Exercise	Initial Position	Performance	Initial Position	Final Position
1) Standing Internal Rotation	Patient standing with affected shoulder at the side of the trunk, elbow flexed at 90° and holding an elastic band.	Patient will perform internal rotation 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 90° abduction and elbow in 90° 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.		

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3) Internal Rotation Diagonal Standing	Patient standing with affected shoulder in 45° abduction, elbow in 90° 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).		
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Assisted Elevation and progression				
Exercise	Initial Position	Performance	Initial Position	Final Position
1) Therapist Assisted Elevation	Patient in supine with elbow at 90° 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.		

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<p>2) Side Lying Elevation</p>	<p>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.</p>	<p>Patient slides the hand over the flat surface raising the arm with the elbow slightly bent.</p>		
<p>3) Supine Band</p>	<p>Patient in supine, holding a yellow elastic band with both hands. Unaffected shoulder remains at the side of the body and affected shoulder with 90° flexion.</p>	<p>The affected shoulder performs flexion with elastic band while the other shoulder remains at the side of the trunk.</p>		



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

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4 2) Prone  
5 elevation  
6 (Blackburn  
7 exercise)  
8 Patient in prone, shoulder  
9 off the treatment table and  
10 positioned perpendicular  
11 to the ground, with a  
12 shoulder at 90° flexion and  
13 elbow extended.  
14 The patient will raise the  
15 arm in scapular plane and  
16 return to the initial  
17 position.  
18 \* progression: 1kg, 2kg  
19 and 3kg dumbbell.



For peer review only



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

Section/item	Item No	Description	Addressed on page number
<b>Administrative information</b>			
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

1 **Introduction**

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3 Background and 6a Description of research question and justification for undertaking the trial, including summary of relevant 3  
 4 rationale studies (published and unpublished) examining benefits and harms for each intervention  
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6 6b Explanation for choice of comparators 3  
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8 Objectives 7 Specific objectives or hypotheses 3, 4  
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10 Trial design 8 Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group),  
 11 allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory) 4  
 12  
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14 **Methods: Participants, interventions, and outcomes**

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16 Study setting 9 Description of study settings (eg, community clinic, academic hospital) and list of countries where data will 4  
 17 be collected. Reference to where list of study sites can be obtained  
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19 Eligibility criteria 10 Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and 4  
 20 individuals who will perform the interventions (eg, surgeons, psychotherapists)  
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22 Interventions 11a Interventions for each group with sufficient detail to allow replication, including how and when they will be 8  
 23 administered  
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25 11b Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose 4  
 26 change in response to harms, participant request, or improving/worsening disease)  
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28 11c Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence 4  
 29 (eg, drug tablet return, laboratory tests)  
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31 11d Relevant concomitant care and interventions that are permitted or prohibited during the trial 4  
 32

33 Outcomes 12 Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood 5, 6, 7  
 34 pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation  
 35 (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen  
 36 efficacy and harm outcomes is strongly recommended  
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38 Participant timeline 13 Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits 5  
 39 for participants. A schematic diagram is highly recommended (see Figure)  
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1	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
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4	Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	5
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6 **Methods: Assignment of interventions (for controlled trials)**

7 Allocation:

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10	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
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16	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
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20	Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	7
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24	Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	7
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27		17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	7
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31 **Methods: Data collection, management, and analysis**

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33	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
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38		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
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1	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
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5	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
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8		20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	NA
9				
10		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
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14	<b>Methods: Monitoring</b>			
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16	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
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22		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
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25	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
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28	Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	No
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32	<b>Ethics and dissemination</b>			
33				
34	Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	No
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37	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
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1	Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	5
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4		26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	NA
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7	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
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10	Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	12
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13	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
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16	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
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20	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
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24		31b	Authorship eligibility guidelines and any intended use of professional writers	9
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26		31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	9
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29	<b>Appendices</b>			
30				
31	Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	Ok
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34	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
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\*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”](https://creativecommons.org/licenses/by-nc-nd/3.0/) license.