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Effects of kinesiotaping added to a rehabilitation program for patients with rotator cuff tendinopathy: protocol for a single-blind randomised controlled trial addressing symptoms, functional limitations, and underlying deficits

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1 **Effects of kinesiotaping added to a rehabilitation program for patients with**
2 **rotator cuff tendinopathy: protocol for a single-blind randomised controlled**
3 **trial addressing symptoms, functional limitations, and underlying deficits**

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20 **ABSTRACT**

21
22 **Introduction:** Rotator cuff tendinopathy (RCTe) is the most frequent cause of shoulder pain,
23 resulting in considerable losses to society and public resources. Muscle imbalance and inadequate
24 sensorimotor control are deficits often associated with RCTe. Kinesiotaping (KT) is widely used by
25 clinicians for rehabilitation of RCTe. While previous studies have examined the immediate effects
26 of KT on shoulder injuries or the effects of KT as an isolated method of treatment, no published
27 study has addressed its mid- and long-term effects when combined to a rehabilitation program for
28 patients with RCTe. The primary objective of this randomised controlled trial (RCT) will be to
29 assess the efficacy of therapeutic KT, added to a rehabilitation program, in reducing pain and
30 disabilities in individuals with RCTe. Secondary objectives will look at the effects of KT on the
31 underlying factors involved in shoulder control, such as muscular activity, acromiohumeral distance
32 (AHD), and range of motion (ROM).

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34 **Methods and analysis:** A single-blind RCT will be conducted. Fifty-two participants, randomly
35 allocated to one of two groups (KT or no-KT), will take part in a 6-week rehabilitation program.

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The KT-group will receive KT added to the rehabilitation program, whereas the no-KT group will receive only the rehabilitation program. Measurements will be taken at baseline, week-3, week-6, week-12 and 6-month. Primary outcomes will be symptoms and functional limitations assessed by the DASH questionnaire. Secondary outcomes will include shoulder ROM, AHD at rest and at 60° of abduction, and muscle activation during arm elevation. The added effects of KT will be assessed through a 2-way ANOVA for repeated measures.

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Ethics and Dissemination: Ethics approval was obtained from the Ethics Committee of Quebec Rehabilitation Institute (IRDPQ) of the Center Integrated University Health and Social Services (CIUSSS-CN). Results of this protocol will be disseminated through international publications in peer-reviewed journals, in addition to international conference presentations.

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Trial registration number: Protocol registered at ClinicalTrials.gov (NCT02881021) on August 25, 2016.

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Keywords: elastic tape, kinesiology taping, physiotherapy, rotator cuff, shoulder pain, tendon injuries.

Strengths and limitations of this study

- To our knowledge, this study will be the first randomised controlled trial to assess the mid- and long-term effects of kinesiотaping added to a conventional rehabilitation program for patients with a rotator cuff tendinopathy.
- Underlying mechanisms that could explain the possible effects of kinesiотaping will be analysed.
- Because our standardized rehabilitation program parallels those in current existence in a clinical setting, our results can be directly applied to clinical practice.
- Methods to reduce the risk of bias will be implemented throughout the study, which includes a statistically justified sample size, methodological rigor, blinding, randomisation, and adequate concealment of group allocation.
- This study will result in high-level evidence on the addition of kinesiотaping to a conventional rehabilitation program for this population.
- Results will help to build a solid framework of evidence for the use of kinesiотaping within a clinical setting.
- While patients will be blinded to the treatment provided to the other group, it is not feasible to blind the experimental group due to the nature of their own allocated treatment.
- A sham kinesiотaping (placebo group) will not be included as previous literature has shown that establishing a sham taping protocol is problematic. Kinesiотaping applied over the skin could potentially produce some proprioceptive stimuli which may act as confounding factor.

INTRODUCTION

Shoulder pain is a very common musculoskeletal (MSK) disorder affecting a large portion of the population. With point prevalence ranging from 6.9% to 26%,^[1] it is estimated that one in three persons will have at least one episode of shoulder pain within their lifetime.^[2, 3] Rotator cuff tendinopathy (RCTe) is the most common pathology of the shoulder,^[4, 5] with up to 50% of rendered diagnoses.^[5, 6]

RCTe is a broad term encompassing several diagnoses related to painful signs and symptoms in the subacromial structures (subacromial bursa, rotator cuff [RC] tendons and long head of the biceps tendon).^[7-11] It is frequently termed impingement syndrome, based on the underlying mechanism that includes encroachment of the subacromial space soft tissues underneath the coracoacromial arch, secondary to a dynamic narrowing of the subacromial space, as the arm is elevated.^[12, 13]

While there are no consensuses on the specific etiological mechanisms of RCTe,^[14, 15] glenohumeral and scapular kinematics alterations have been suggested as instigators of the dynamic narrowing of the subacromial space.^[16-19] A lack of coordination and an imbalance between RC and scapulothoracic muscle activations could explain these kinematics alterations. The muscular balance between deltoid and RC muscles is crucial to maintaining the glenohumeral joint function,^[20] keeping a stabilizing congruency between the humeral head and the glenoid fossa; however, this dynamic interplay appears to be compromised in individuals with RCTe.^[21]

Reduction of these deficits is the key to returning to a proper shoulder neuromuscular control^{22,23} leading to the resolution of pain and restoration of function.^[22, 23] Therefore, many rehabilitation programs include interventions such as mobilisation with movements (MWM)^[24] and with exercises,^[25, 26] movement training,^[27] and strengthening exercises.^[28] These interventions improve the neuromuscular control of the shoulder and concomitantly decrease symptoms and functional limitations.^[27, 29, 30] In addition, taping techniques have been considered an interesting option to improve shoulder control^[31] and hence to reduce the deficits associated with RCTe.^[31] Taping techniques such as kinesiotaping (KT) are now widely used in clinical settings for rehabilitation of shoulder disorders. The rationale behind its functioning is based on the lifting effects of epidermis layers and papillary dermis,^[32] caused by micro-convolutions formed on the taped skin. Wrinkles generated by the KT are believed to increase the interstitial space, leading to an increase in blood and lymph flow, while facilitating pressure release on underlying soft tissues. Consequently, vascular networks in deep vessels under the skin are increased, reducing swelling and inflammation in injured tissues.^[33-42] The KT is also argued to contribute to pain relief by producing increased stimulation of cutaneous mechanoreceptors,^[43] that likely improves the proprioceptive feedback and thereby provides muscle activation.^[33, 44]

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2 111 Combination of these effects is thought to provide support to the joint during functional
3 112 movements.[33, 45] Considering all of these potential benefits, the KT method has been widely
4 113 used in clinical practice; however, its functional underlying mechanism are still hypothetical,[35,
5 114 46-48] and its clinical efficacy has not been thoroughly ascertained.

6 115 While some clinical trials have investigated the effects of KT on MSK disorders,[49-56]
7 116 including shoulder injuries,[24, 26, 32, 38, 42, 47, 48, 57-61] systematic reviews have consistently
8 117 pointed out that not enough evidence is available to conclude on the efficacy of KT on MSK
9 118 conditions.[62-67] Recently, Desjardins-Charbonneau et al (2015)[62] examined six randomised
10 119 controlled trials (RCT)[24-26, 42, 47, 58] (n=360) specifically addressing RCTe. Their meta-
11 120 analysis findings showed that KT might be effective in immediately increasing pain-free flexion
12 121 and abduction range of motion (ROM). However, most published studies on KT has presented a
13 122 high risk of bias, tested KT as an isolated method of treatment (when it is used in combination with
14 123 other modalities in the clinics), or only looked at the immediate or short-term effects of KT.[26, 38,
15 124 42, 47] Therefore, additional high-quality evidence is required to better guide health professionals
16 125 on the use of KT in the rehabilitation of individuals with RCTe.
17 126

127 **Objectives and hypotheses**

128 The primary objective of this single-blind RCT is to evaluate the added effects of
129 therapeutic KT to a rehabilitation program focusing on sensorimotor training to reduce symptoms
130 and functional limitations of individuals with RCTe. The secondary objective is to evaluate the
131 effects of KT on variables related to shoulder control, such as muscular activity, acromiohumeral
132 distance (AHD) and ROM, in attempting to identify the underlying effects of KT. Our hypothesis is
133 that both groups will achieve a mean improvement superior to the clinically important difference
134 (CID) of the Disabilities of the Arm, Shoulder, and Hand questionnaire (DASH) after the
135 rehabilitation program, as both groups will receive the same program that has been shown to be
136 effective for this population.[27] However, based on findings of previous studies that have shown
137 immediate and short-term effects of KT, the positive outcome of rehabilitation in terms of reduction
138 in symptoms and functional limitations will be obtained faster for the patients allocated to the KT-
139 group. This RCT is registered on ClinicalTrials.gov (NCT02881021).

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METHODS AND ANALYSIS

Study design

This single-blind parallel group RCT will include a 6-week rehabilitation program and five evaluation sessions (baseline, week-3, week-6, week-12, and 6-months) over six months. All evaluations will be carried out at the Center for Interdisciplinary Research in Rehabilitation and Social Integration (CIRRS) in Québec City, Canada.

Participants will take part in the baseline evaluation. After providing written informed consent, eligibility criteria will be assessed. Thereafter, eligible participants will complete a sociodemographic questionnaire, followed by the evaluation of the primary (DASH questionnaire), and secondary outcomes (Brief Pain Inventory [BPI] and the Western Ontario Rotator Cuff Index [WORC] questionnaires, shoulder ROM, AHD, muscle activity). Participants will then be randomly allocated to one of two groups (KT or No-KT), and take part in their assigned 6-week intervention: *experimental group* (KT-group - KT application will be added to the rehabilitation program), and *control group* (No-KT group - only the rehabilitation program, without any KT). An allergy testing to KT will be conducted specifically for patients allocated to the experimental group.

The three self-reported questionnaires (DASH, BPI, WORC) will be re-evaluated at week-3 (mid-point of the rehabilitation program), week-6 (end of the rehabilitation program), week-12, and 6-months after baseline evaluation. These follow-up evaluations are planned to assess progression in terms of symptoms and functional limitations throughout the study, allowing to establish whether an intervention leads to a faster and/or more lasting improvement than the other. Shoulder ROM, AHD, and muscle activity will be re-evaluated only at the end of the rehabilitation program (week-6). At the end of the rehabilitation program, participants will be asked to evaluate the change in their condition since the first physiotherapy session, using a Global Rating of Change (GRC) question.

Participants

Fifty-two (52) participants, aged between 18 and 65 years old, diagnosed with RCTe, will be recruited. To be eligible, participants will have to present one positive finding in each of the following categories: 1) painful arc of movement during flexion or abduction; 2) Neer (*sensitivity* 0.78, *specificity* 0.58) or Kennedy-Hawkins (*sensitivity* 0.74, *specificity* 0.57) impingement signs;^[68] and 3) pain during resisted external rotation, abduction, or empty can test (*sensitivity* 0.69, *specificity* 0.62).^[68] A combination of positive results to these clinical tests has values ≥ 0.74 for sensitivity and specificity for RCTe.^[69] Participants will be excluded if they have: a) an open wound that compromises KT application; b) had a previous shoulder surgery; c) allergy or intolerance to KT; d) adhesive capsulitis, defined as loss of passive shoulder ROM greater than

1 176 50%;[70] e) history of glenohumeral luxation in the last 12 months or any fracture to the shoulder
2 177 girdle; f) shoulder pain reproduced by cervical movements; g) clinical sign of full-thickness tears of
3
4 178 any RC muscles identified by lag signs:[71] drop sign (*sensitivity* 0.73, *specificity* 0.77), external
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6 179 rotation sign (*sensitivity* 0.46, *specificity* 0.94), and internal rotation sign (*sensitivity* 1.00, *specificity*
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8 180 0.84).[72]
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11 182 **Randomization, blinding and allocation concealment**

12 183 An independent assessor, not involved in data collection, will generate the randomization
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14 184 list using a computer random-number generator, prior to the initiation of the study. A block
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16 185 randomization design (block size of 4, 6 or 8) will be applied to ensure an equal number of
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18 186 participants in each group. Given that it is unknown if gender influences the physiological response
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20 187 to KT, randomization will be stratified by sex. Allocation will be concealed in sealed and opaque
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22 188 envelopes that will be sequentially numbered. Each participant will receive an envelope that will be
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24 189 opened by the treating physiotherapist at the first therapy session. As it is impossible to blind
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26 190 participants and treating physiotherapist to KT application, a single-blind design was chosen.

27 191 The treating physiotherapist will be unaware of the data from the outcome measures, which
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29 192 will be assessed by an evaluator blinded to the group assignment. Patients will be blinded to the
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31 193 treatment provided to the other group. To assess blinding effectiveness, the assessor will answer a
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33 194 question related to their opinion on the allocation after each of the follow-up evaluations.
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35 196 **Rehabilitation program (independent variable)**

36 197 Each patient will attend 10 physiotherapy sessions over six weeks (two sessions during each
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38 198 of the first four weeks, then once a week). Both KT and No-KT groups will receive the same
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40 199 standardized rehabilitation program that will include sensorimotor training, manual therapy,
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42 200 stretching, muscular strengthening, and patient education. Additionally, the participants will receive
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44 201 a list of four (4) exercises, based on their individual needs, to be performed at home without
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46 202 supervision. The rehabilitation program will target deficits described in patients with RCTe and will
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48 203 take into consideration the specific needs of each patient.
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50 205 **Sensorimotor training.** Shoulder control exercises with progressive complexity in terms of
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52 206 movement plane, ROM, speed, and resistance will be the basis of this rehabilitation program. These
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54 207 exercises will be implemented aiming at the re-education of movement control to correct kinematic
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56 208 alterations that lead to a superior migration of the humeral head and to scapular dyskinesis, or
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58 209 changes in the muscle activity of shoulder muscles.[27, 28] The exercises will be performed in the
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60 210 frontal, sagittal and scapular planes, being graded according to resistance level (no resistance,

211 passive, active assisted, and active with and without external resistance), and the use of feedback
212 (with or without).[28] When the exercises will be executed properly, participants will perform them
213 at home, in three sets of 10 repetitions a day. Once participants reach adequate control during arm
214 elevation, goal-directed reaching tasks will be performed to retrain movements requiring upper limb
215 coordination. Work- or sport-specific re-education will also be performed according to participant's
216 own activities.

217
218 **Manual therapy.** Joint mobilisation techniques will be applied on sternoclavicular,
219 acromioclavicular, glenohumeral, and thoracic spine, whether the ligamentous and capsular
220 restraints are identified during the initial evaluation.[29, 30, 73-75] Once its necessity is confirmed,
221 each technique will be performed three times for approximately 60-sec, with a between-set rest
222 interval of 30-sec.[75]

223
224 **Stretching exercises.** Stretches will be performed to enhance the flexibility of the glenohumeral
225 capsule and underlying soft tissues, according to individual needs. Stretches will be oriented to be
226 performed as home exercises throughout treatment, in three repetitions held for 30 seconds each.

227
228 **Strengthening.** Free weights, extremities weight, and resistance elastic tube will be used to
229 strengthen RC muscles and scapular stabilizers.[27, 28] Exercises will progress according to the
230 following phases: (a) phase 1, humerus in a neutral position to improve the depression function; (b)
231 phase 2, ascending arm movements; (c) phase 3, higher-level exercises, including trunk
232 strengthening.[30] The number of repetitions will vary from one to three sets of 10 to 30,
233 progressing gradually. Patients will begin using a light resistance elastic band (yellow non-latex
234 TheraBand™, Hygenic Corp, Akron, OH, USA),[76] in phase 1. Participants will progress to next
235 phase when exercises are performed with medium resistance band (red and green non-latex
236 TheraBand™). Patients should perform phase 2 without increasing symptoms for one week as
237 requirements to advance to phase 3.

238
239 **Patient education.** General guidance will be provided to all patients to enhance understanding of
240 shoulder overload, pain neuroscience, pain management, posture, rehabilitation stages, graded
241 exposure to exercise, shoulder and body mechanics and movements that provoke impingement,
242 besides instructions regarding preferred shoulder positioning during sleep, work, and daily and
243 sports activities.[77]

244
245 **Kinesiotaping techniques**

1 246 The skin will firstly be properly cleaned with isopropyl alcohol. Kinesio[®] Tex Classic will
2 247 be applied using a combination of techniques designed for RCTe and underlying symptoms (Figure
3 248 1).[37] The first strip will be applied in Y-shape, light tension (15-25%), surrounding the three
4 249 portion of the deltoid muscle as a group, from insertion to origin to provide inhibition and muscle
5 250 relaxation.[24, 37] A second strip (I-shape) will be applied for functional correction, recommended
6 251 for multiaxial shoulder instability, with severe tension (50–75%), from 7–10 cm above the
7 252 acromioclavicular joint to 7–10 cm below the deltoid tuberosity, passing over the supraspinatus,
8 253 trapezius, glenohumeral joint, and middle deltoid.[37] The third strip will be applied in I-shape for
9 254 mechanical correction at the glenohumeral joint, being placed with severe tension (50–75%) and
10 255 inward pressure, from coracoid process to posterior deltoid, just slightly below the coracoacromial
11 256 arch.[37, 78] The first strip will be applied in all patients of the KT-group, whereas second and third
12 257 strips will be used according to the presence of corresponding deficits observed during individual
13 258 weekly evaluations. All KT strips will be removed at the beginning of each session, and a new piece
14 259 will be applied at the end. Participants will be requested to keep the KT until the next physiotherapy
15 260 session or for a minimum of 72 hours, whichever comes first. All applications will follow the
16 261 instructions and principles described by Kase et al,[37] and will be executed by the same
17 262 physiotherapist, who is a practitioner certified by the Kinesio[®] Taping Association International
18 263 (KTAI). As a fundamental practice, a gradual weaning will permit patients to readapt to the normal
19 264 feedback condition.[79] Therefore, KT strips will be weaned gradually, according to individual
20 265 improvement, as evaluated weekly by the treating physiotherapist.
21 266

267 **Data collection**

268 Outcome measures (dependent variables)

269 The primary outcomes are the symptoms and functional limitations assessed using the
270 *Disabilities of the Arm, Shoulder, and Hand (DASH)* questionnaire.[80] The secondary outcome is
271 shoulder control, described as ROM, AHD and muscle activity. Global Rating of Change (GRC)
272 will be also assessed.

274 Primary outcome

275 The DASH is a 30-item self-report questionnaire, designed to measure physical disability
276 and symptoms of upper limbs disorders,[80-82] through a scale ranging from 0 to 100 (most severe
277 disability).[81, 82] Its items address the level of difficulty in performing, in the last week, several
278 daily activities related to upper extremity (21 items); the severity of the pain symptoms, activity-
279 related pain, tingling, weakness, and stiffness (five items); and their impact on social activities,
280 sleep, work, self-image (four items).[81] The DASH has an excellent reliability (ICC=0.96), it is

281 highly responsive following rehabilitation interventions for individuals with RCTe (effect size:
282 1.06, standardized response mean [SRM]: 1.08),[82] has a minimal detectable change (MDC) of 11
283 points and a clinically important difference (CID) of 10 points.[81, 82] The validated Canadian-
284 French version will be used (ICC=0.93; SRM=1.35; MDC=11.4 points; CID=10 points).[81-83]

285

286 Secondary outcomes

287 *Symptoms and Functional limitations*

288 As DASH has few questions related to pain, the BPI,[84, 85] specific for assessing clinical
289 pain, will also be filled out by the participants. It measures pain intensity on an 11-point numerical
290 rating scale (0-10), according to its interference with general activity, mood, walking ability, normal
291 work, relations with other people, sleep, and enjoyment of life, over the last 24 hours (ICC
292 >0.80).[84, 85] In addition, as the DASH is not specific for the shoulder or for RC disorders, the
293 WORC index[86] will also be filled out. The WORC[86] is a reliable and responsive (ICC=0.96;
294 SRM=1.54; MDC=12 points; CID=13 points) questionnaire designed to measure health-related-
295 quality-of-life in patients affected by RC injuries.[83, 86]

296

297 *Range of motion (ROM)*

298 Limited and painful ROM is often observed in patients with RCTe.[87, 88] In addition, KT
299 has been shown to be effective in restoring pain-free ROM.[26, 42] Therefore, active full and pain-
300 free ROM in shoulder elevation in the frontal (abduction) and sagittal (flexion) planes will be
301 measured using a manual goniometer. The goniometer is a reliable instrument for measuring
302 shoulder ROM (ICC flexion = 0.95 [0.89-0.98]; ICC abduction = 0.97 [0.94-0.99]).[89] All
303 measurements will be taken with patients standing. Participants will perform two repetitions for
304 each movement. A 5-sec rest will be given between each trial and 1-min between conditions. The
305 average of two trials will determine the mean ROM values for each condition.

306

307 *Acromiohumeral distance (AHD) and muscle activity*

308 Kinesiotaping has been shown to lead to an immediate increase in AHD in healthy
309 individuals.[46, 90] Therefore, AHD measurement was included as a secondary outcome of
310 shoulder control as it gives an indication of the dynamic narrowing of the subacromial space using
311 the tangential distance between humeral head bony landmarks and acromion inferior edge.[27, 91]

312 First, two measures of AHD with shoulder at rest will be taken using an ultrasound scanner
313 (Logic e9, GE Healthcare, Milwaukee, WI, USA) with a 6-15MHz linear array probe (model ML6-
314 15-D).[27, 91] Thereafter, participants will perform two vertical abductions (frontal planes) at 60°.
315 During this arm elevation, muscle activity of four shoulder muscles (upper trapezius, infraspinatus,

1
2 316 middle and anterior deltoid) will be recorded using surface electromyography (Trigno™ Wireless
3 317 EMG system, Delsys Inc., Boston, MA, USA). At the end-point of movement (60° of abduction),
4 318 the ultrasonographic image of the AHD will be recorded. These measurements (muscle activity and
5 319 US) will permit to determine the association between the presence of a dynamic narrowing of the
6
7 320 AHD and the muscular activity of key shoulder muscles.
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11 322 **Ultrasonographic recordings.** To record AHD images, the probe will be positioned on the anterior
12 323 aspect of the lateral surface of acromion along the longitudinal axis of the humerus in a coronal
13 324 plane and moved around 1 cm behind the acromion and humeral head. In this position, both
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15 325 acromion and humerus can be viewed. A strap will be used to restrain the abduction movement to
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17 326 60°, which will be confirmed using an inclinometer. Participants will be instructed to maintain the
18 327 strap slightly stretched during data collection, to maintain the angle of interest. All measurements
19 328 will be performed with patients seated up straight against the backrest of the chair. The average
20 329 over two AHD trials will be calculated for each angle examined.
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27 331 **EMG recordings.** Before measurements, the skin over upper trapezius, infraspinatus, anterior and
28 332 middle deltoid will be cleaned with isopropyl alcohol and hair will be removed, when necessary.
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30 333 Thereafter, a Trigno™ sensor (41 mm x 20 mm x 5 mm) will be placed on the muscle belly, parallel
31 334 to the direction of the muscle fibers. The EMG-sensor placements will be defined in accordance
32 335 with the Surface EMG for Noninvasive Assessment of Muscles (SENIAM) guidelines.[92] For the
33 336 infraspinatus muscle, the EMG-sensor will be placed 3-4 cm below and parallel to the scapular
34
35 337 spine, over the infrascapular fossa. For the upper trapezius, it will be placed at the midway between
36
37 338 the spine on vertebra C7 and the acromion. Over the anterior deltoid, the EMG-sensor will be
38 339 placed at one-finger width (1-2 cm) below the acromion and lateral clavicle, whereas at the middle
39 340 deltoid, it will be placed at halfway between its insertion and the acromion.[92] No reference
40
41 341 electrode will be used since this sensor already uses a 2-level single-differential method to minimize
42 342 artifacts and baseline noise contamination through 4-parallel bars with their center 10 mm apart,
43 343 and a signal bandwidth of 10-450 Hz. All EMG data will be recorded using Delsys EMGworks®
44 344 Acquisition software. The EMG signals will be pre-amplified at the skin surface (300x gain,
45 345 common mode rejection ratio [CMRR] 92dB at 60Hz) at a sampling rate of 1926 samples/s. All
46 346 electrode placements, the wireless communication, and the signal quality will be verified by visual
47 347 monitoring of signals at rest and during isometric contractions.[93] Raw EMG data will be stored
48 348 on a computer for offline analysis. Prior to analysis, recorded signals will be band-pass filtered (10-
49 349 450 Hz, fourth-order zero-lag Butterworth digital filter), full-wave rectified and smoothed using a
50 350 Root Mean Square (RMS) filter with a 0.25-sec time-window and 0.05 of window overlap. EMG
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2 351 amplitude data will then be normalized to a reference condition, where patients will raise their arm
3 352 at 60° of scaption for 5-sec, with no load. Two trials will be performed for each arm, and the
4 353 average of the RMS values will be used for normalization.
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8 355 *Global Rating of Change (GRC)*

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10 356 Participants will be asked to evaluate the change in their condition from the initial
11 357 physiotherapy session using a GRC question. The GRC is a reliable 15-points scale (ICC =
12 358 0.90),[69, 94, 95] designed to report changes in clinical status over time as the perception of
13 359 outcome after treatment.[69, 94] Since patients generally feel satisfied with their improvements
14 360 when reaching +4 GRC score,[95, 96] we determined a priori that participants who will rate their
15 361 perceived recovery at +4 “moderately better or greater” will be categorized as having a successful
16 362 outcome.[27, 30] Then, results from GRC will be dichotomized to $GRC \geq +4$ (improvement) or
17 363 $GRC < +4$ (non-improvement).
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25 365 **Sample size**

26 366 Sample size calculation is based on changes evidenced by the DASH scores for individuals
27 367 with RCTe. According to sample size calculation (G*Power 3.1.9.2; $\alpha=0.05$, effect size=0.79,
28 368 power $[1-\beta]=0.82$, SD=14.17 DASH points,[48] CID=12.4 DASH points),[97] a minimum of 22
29 369 patients are needed in each group. When adding an expected loss to follow-up of 15%, a total of 26
30 370 patients per group is required. Therefore, 52 patients with RCTe will be recruited. This sample size
31 371 is sufficient to detect the CID between the two groups.
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38 373 **Recruitment of patients**

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40 374 Fifty-two participants will be recruited. This number is feasible as a recent study from our
41 375 research team successfully recruited 30 individuals with RCTe over six months. Taking into
42 376 consideration the dropouts, we believe it is possible to recruit 26 participants over the same period.
43 377 Therefore, considering a recruitment rate of five participants per month, in average, all participants
44 378 should be enrolled in less than 11 months.
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49 380 **Withdrawal of individual participants**

50 381 Principles underlying “intention-to-treat” analysis will be followed, meaning that every
51 382 participant will be analysed according to the randomized treatment assignment. Therefore,
52 383 noncompliance, protocol deviation, and withdrawal will all be ignored in the primary analyses. All
53 384 dropouts and their underlying reasons will be reported.[98] Additionally, “per-protocol” analysis
54 385 (i.e., the analysis will be restricted to participants who adhered perfectly to the intervention as
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1 386 stipulated in the protocol) will also be performed. We believe that the combination of these
2 387 statistical strategies will increase confidence in the study results. To ensure appropriate insight of
3 388 mechanisms underlying changes in symptoms and function, only participants who completed
4 389 evaluation at week-6 will be considered for the secondary outcomes. Any harm or unintended
5 390 effects during the programs will be recorded.
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11 392 **Data integrity and analysis**

12 393 All collected data will be accessible only to the research team for audit purposes. All data
13 394 will be kept for five years after the end of the study, to ensure the completion of planned
14 395 publications. After this period, all data will be destroyed.
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20 397 **Statistical Analysis**

21 398 Basic descriptive statistics (mean and standard deviation) will be reported for each
22 399 participant's characteristic and outcome. All data will be tested to check the distributional
23 400 assumptions for the inferential statistical analyses. Baseline demographic data will be compared
24 401 using independent samples t-test and chi-square. If differences are seen in baseline characteristics,
25 402 we will apply an ANCOVA model to adjust group comparisons for confounding variables.
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30 403 The added effects of KT on the DASH, BPI, WORC and muscle activity will be examined
31 404 using a mixed design analysis of variance (ANOVA) model (Groups [KT-group, No-KT group] ×
32 405 Evaluations [Baseline, week-3, week-6, week-12, 6-months), while a 3-way ANOVA for repeated
33 406 measures (Group x Time x Angle [for AHD] or plane of movement [for ROM] will be performed
34 407 for AHD and ROM. Bonferroni adjustments for multiple comparisons will be used, and effect sizes
35 408 will also be reported (η^2). The GRC will be compared across groups using a Fischer's exact
36 409 probability test. The level of significance will be set at $p < 0.05$ for all statistical analyses.
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DISCUSSION

It is well reported that functional limitations associated with RCTe may remain for 12 months or more.[11] Personal, medical and socio-economic impacts of RCTe are well known,[1] and because RCTe results in a high rate of sick leave, assessment of the effectiveness of treatments is a priority.

Over the past few years, KT has been widely used in clinical practice; however, its effects for the rehabilitation of patients with RCTe need to be more evidenced. Despite the fact that some investigations examined the effects of KT on RCTe, no published study has, to our knowledge, addressed its mid- and long-term effects when added to a rehabilitation program, as commonly used by clinicians. Furthermore, few studies have evaluated KT efficacy as an adjunct therapeutic resource, while applying identical physiotherapy treatment for both groups (experimental and placebo/control group). This makes it difficult to ascertain causation and may compromise the evidence of the real effects of KT. Therefore, investigations with a high level of standardisation are needed to determine the scientific validity of KT efficacy for the rehabilitation of individuals with RCTe.

To our knowledge, this RCT will be the first to assess the mid- and long-term efficacy of KT added to a conventional rehabilitation program for individuals with RCTe, addressing underlying variables that could help understanding the benefits alleged for this method. Results will contribute to building robust evidence of the benefit of addition of KT in physiotherapeutic intervention for RCTe, in addition to helping to establish the best clinical treatments for this population.

ETHICS

Ethics approval was obtained from the Institutional Review Board of Quebec Rehabilitation Institute (IRDPQ) of the Center Integrated University Health and Social Services (CIUSSS-CN).

Consent

Detailed information about the research and experimental procedures will be provided to all participants before signature of the written informed consent. Participants will be requested to sign a detailed informed consent before starting any experimental procedure.

Confidentiality

All research team members will respect the data confidentiality of the patients, in agreement with the law. Patients names will be coded to keep their identity confidential; however, a list of name and respective codes will be stored in a locked and filing cabinet. All information collected during the study, including test results, will be treated as confidential. Publications related to these data will respect all principles of confidentiality.

Dissemination

Results of this protocol will be disseminated through international publication in peer-reviewed journals, in addition to international conference presentations. Participants, clinicians, and relevant research staff in the field will be informed about the results of the study.

FOOTNOTES

Contributors:

FCLO contributed to conception, design, and preparation of the procedures, data collection and will conduct the recruitment, rehabilitation program, interpretation, data analyses and writing. BPF contributed to outcomes assessments and will contribute to the analysis, and interpretation of the data. FD contributed partially to study design and will contribute to the statistical analysis. JSR and LB contributed to conception, design, and preparation of the procedures. Both authors will contribute to the analyses and interpretation of the data. JSR, LB, FD, and BPF commented on the several versions of this study protocol. All authors approved the final version of this protocol.

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Competing interests:

The authors have no relevant conflict of interests to declare.

Ethics approval:

Institutional Review Board of Quebec Rehabilitation Institute (IRDPQ) of the Center Integrated University Health and Social Services (CIUSSS-CN).

Data sharing statement:

Additional data from patients included in this study will not be available, in accordance to the principles of confidentiality of the Institutional Review Board of Quebec Rehabilitation Institute (IRDPQ).

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Box 1. Strengths and limitations of this study

- To our knowledge, this study will be the first randomised controlled trial to assess the mid- and long-term effects of kinesiotope added to a conventional rehabilitation program for patients with a rotator cuff tendinopathy.
- Underlying mechanisms that could explain the possible effects of kinesiotope will be analysed.
- Because our standardized rehabilitation program parallels those in current existence in a clinical setting, our results can be directly applied to clinical practice.
- Methods to reduce the risk of bias will be implemented throughout the study, which includes a statistically justified sample size, methodological rigor, blinding, randomisation, and adequate concealment of group allocation.
- This study will result in high-level evidence on the addition of kinesiotope to a conventional rehabilitation program for this population.
- Results will help to build a solid framework of evidence for the use of kinesiotope within a clinical setting.
- While patients will be blinded to the treatment provided to the other group, it is not feasible to blind the experimental group due to the nature of their own allocated treatment.
- A sham kinesiotope (placebo group) will not be included as previous literature has shown that establishing a sham taping protocol is problematic. Kinesiotope applied over the skin could potentially produce some proprioceptive stimuli which may act as confounding factor.



Figure 1. Kinesiotaping application. First strip (1: Y-shape surrounding deltoid muscles), second strip (2: I-shape in functional correction for multiaxial shoulder instability over the glenohumeral joint, supraspinatus, trapezius, and middle deltoid muscles), and third strip (3: I-shape in mechanical correction for glenohumeral joint).

112x149mm (72 x 72 DPI)

only



Figure 1. Kinesiotaping application. First strip (1: Y-shape surrounding deltoid muscles), second strip (2: I-shape in functional correction for multiaxial shoulder instability over the glenohumeral joint, supraspinatus, trapezius, and middle deltoid muscles), and third strip (3: I-shape in mechanical correction for glenohumeral joint).

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Figure 1. Kinesiotaping application. First strip (1: Y-shape surrounding deltoid muscles), second strip (2: I-shape in functional correction for multiaxial shoulder instability over the glenohumeral joint, supraspinatus, trapezius, and middle deltoid muscles), and third strip (3: I-shape in mechanical correction for glenohumeral joint).

112x149mm (72 x 72 DPI)

only

FIGURES

Figure 1. Kinesiotaping application. First strip (1: Y-shape surrounding deltoid muscles), second strip (2: I-shape in functional correction for multiaxial shoulder instability over the glenohumeral joint, supraspinatus, trapezius, and middle deltoid muscles), and third strip (3: I-shape in mechanical correction for glenohumeral joint).





STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

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

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	06
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	07
	2b	All items from the World Health Organization Trial Registration Data Set	02, 03
Protocol version	3	Date and version identifier	--
Funding	4	Sources and types of financial, material, and other support	05
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	05
	5b	Name and contact information for the trial sponsor	04
	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	--
	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)	--

1 **Introduction**

2				
3	Background and	6a	Description of research question and justification for undertaking the trial, including summary of relevant	9 - 10
4	rationale		studies (published and unpublished) examining benefits and harms for each intervention	
5				
6		6b	Explanation for choice of comparators	9
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8	Objectives	7	Specific objectives or hypotheses	10
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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)	11
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15	Methods: Participants, interventions, and outcomes			
16				
17	Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will	11
18			be collected. Reference to where list of study sites can be obtained	
19				
20	Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and	11, 12
21			individuals who will perform the interventions (eg, surgeons, psychotherapists)	
22				
23	Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be	12 - 14
24			administered	
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26		11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose	---
27			change in response to harms, participant request, or improving/worsening disease)	
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29		11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence	--
30			(eg, drug tablet return, laboratory tests)	
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33		11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	13 - 14
34				
35	Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood	14 - 17
36			pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg,	
37			median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen	
38			efficacy and harm outcomes is strongly recommended	
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41	Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for	11
42			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	<u>17</u>
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4	Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	<u>18</u>
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7	Methods: Assignment of interventions (for controlled trials)			
8	Allocation:			
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11	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	<u>12</u>
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17	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	<u>12</u>
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21	Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	<u>12</u>
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25	Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	<u>12</u>
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28		17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	<u>12</u>
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32	Methods: Data collection, management, and analysis			
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34	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	<u>14 - 17</u>
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40		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	<u>18</u>
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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	<u>18</u>
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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	<u>18</u>
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8		20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	<u>18</u>
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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)	<u>18</u>
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15	Methods: Monitoring			
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17	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	<u>---</u>
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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	<u>18</u>
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26	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	<u>18</u>
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29	Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	<u>18</u>
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33	Ethics and dissemination			
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35	Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	<u>21</u>
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38	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)	<u>21</u>
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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)	<u>attached</u>
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4		26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	<u>---</u>
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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	<u>21</u>
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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	<u>05</u>
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14	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	<u>21</u>
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17	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	<u>--</u>
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20	Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, health care professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	<u>21</u>
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25		31b	Authorship eligibility guidelines and any intended use of professional writers	<u>5</u>
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27		31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	<u>--</u>
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30	Appendices			
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32	Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	<u>attached</u>
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35	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	<u>--</u>
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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

Effects of kinesiotaping added to a rehabilitation program for patients with rotator cuff tendinopathy: protocol for a single-blind randomised controlled trial addressing symptoms, functional limitations, and underlying deficits

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Primary Subject Heading:	Rehabilitation medicine
Secondary Subject Heading:	Sports and exercise medicine, Occupational and environmental medicine, Evidence based practice
Keywords:	elastic tape, kinesiology taping, physiotherapy, rotator cuff, shoulder pain, tendon injuries

SCHOLARONE™
Manuscripts

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3 1 **Effects of kinesiotaping added to a rehabilitation program for patients with rotator**
4 2 **cuff tendinopathy: protocol for a single-blind randomised controlled trial**
5 3 **addressing symptoms, functional limitations, and underlying deficits**
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41 22 **ABSTRACT**
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44 26 **Introduction:** Rotator cuff tendinopathy (RCTe) is the most frequent cause of shoulder
45 27 pain, resulting in considerable losses to society and public resources. Muscle imbalance
46 28 and inadequate sensorimotor control are deficits often associated with RCTe.
47 29 Kinesiotaping (KT) is widely used by clinicians for rehabilitation of RCTe. While
48 30 previous studies have examined the immediate effects of KT on shoulder injuries or the
49 31 effects of KT as an isolated method of treatment, no published study has addressed its
50 32 mid- and long-term effects when combined to a rehabilitation program for patients with
51 33 RCTe. The primary objective of this randomised controlled trial (RCT) will be to assess
52 34 the efficacy of therapeutic KT, added to a rehabilitation program, in reducing pain and
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3 35 disabilities in individuals with RCTe. Secondary objectives will look at the effects of
4 36 KT on the underlying factors involved in shoulder control, such as muscular activity,
5 37 acromiohumeral distance (AHD), and range of motion (ROM).
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10 39 **Methods and analysis:** A single-blind RCT will be conducted. Fifty-two participants,
11 40 randomly allocated to one of two groups (KT or no-KT), will take part in a 6-week
12 41 rehabilitation program. The KT-group will receive KT added to the rehabilitation
13 42 program, whereas the no-KT group will receive only the rehabilitation program.
14 43 Measurements will be taken at baseline, week-3, week-6, week-12 and 6-months.
15 44 Primary outcomes will be symptoms and functional limitations assessed by the DASH
16 45 questionnaire. Secondary outcomes will include shoulder ROM, AHD at rest and at 60°
17 46 of abduction, and muscle activation during arm elevation. The added effects of KT will
18 47 be assessed through a 2-way ANOVA for repeated measures.
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26 49 **Ethics and Dissemination:** Ethics approval was obtained from the Ethics Committee of
27 50 Quebec Rehabilitation Institute (IRDPQ) of the Center Integrated University Health and
28 51 Social Services (CIUSSS-CN). Results will be disseminated through international
29 52 publications in peer-reviewed journals, in addition to international conference
30 53 presentations.
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36 55 **Trial registration number:** Protocol registered at ClinicalTrials.gov (NCT02881021)
37 56 on August 25, 2016. The World Health Organization Trial Registration Data Set can
38 57 also be found as a supplementary file.
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43 59 **Keywords:** elastic tape, kinesiology taping, physiotherapy, rotator cuff, shoulder pain,
44 60 tendon injuries.
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3 Strengths and limitations of this study

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- To our knowledge, this is the first randomised controlled trial to assess the mid- and long-term effects of kinesiotaping added to a conventional rehabilitation program for patients with a rotator cuff tendinopathy.
 - Underlying mechanisms that could explain the possible effects of kinesiotaping will be analysed.
 - Methods to reduce the risk of bias will be implemented throughout the study, which includes a statistically justified sample size, methodological rigor, blinding, randomisation, and adequate concealment of group allocation.
 - While patients will be blinded to the treatment provided to the other group, it is not feasible to blind the experimental group due to the nature of their own allocated treatment.
 - A sham kinesiotaping (placebo group) will not be included, as previous literature has shown that establishing a sham taping protocol is problematic.

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INTRODUCTION

65 Shoulder pain is a very common musculoskeletal (MSK) disorder affecting a
66 large portion of the population. With point prevalence ranging from 6.9% to 26%, [1] it
67 is estimated that one in three persons will have at least one episode of shoulder pain
68 within their lifetime. [2, 3] Rotator cuff tendinopathy (RCTe) is the most common
69 pathology of the shoulder, [4, 5] with up to 50% of rendered diagnoses. [5, 6]

70 RCTe is a broad term encompassing several diagnoses related to painful signs
71 and symptoms in the subacromial structures (subacromial bursa, rotator cuff [RC]
72 tendons and long head of the biceps tendon). [7-11] It is frequently termed impingement
73 syndrome, based on the proposed underlying mechanism that includes encroachment of
74 the subacromial space soft tissues underneath the coracoacromial arch, secondary to a
75 dynamic narrowing of the subacromial space, as the arm is elevated. [12, 13] In addition,
76 hormonal dysregulation and metabolic diseases have been suggested as a possible
77 contributors for RC injuries due to a possible influence on the biology of tendons and,
78 hence, in the biomechanical properties of the musculoskeletal system. [14, 15]

79 While there is no consensus on the specific etiological mechanisms of RCTe, [16,
80 17] glenohumeral and scapular kinematics alterations have been suggested as instigators
81 of the dynamic narrowing of the subacromial space. [18-21] A lack of coordination and
82 an imbalance between RC and scapulothoracic muscle activations could explain these
83 kinematics alterations. [22] The muscular balance between deltoid and RC muscles is
84 crucial to maintaining the glenohumeral joint function, [22, 23] keeping a stabilizing
85 congruency between the humeral head and the glenoid fossa; however, this dynamic
86 interplay appears to be compromised in individuals with RCTe. [22, 24]

87 Reduction of these deficits is the key to returning to a proper shoulder
88 neuromuscular control leading to the resolution of pain and restoration of function. [25,
89 26] Therefore, many rehabilitation programs include interventions such as mobilisation
90 with movements (MWM) [27] and with exercises, [28, 29] movement training, [30] and
91 strengthening exercises. [31] These interventions improve the neuromuscular control of
92 the shoulder and concomitantly decrease symptoms and functional limitations. [30, 32,
93 33] In addition, taping techniques have been considered an interesting option to improve
94 shoulder control and hence to reduce the deficits associated with RCTe. [34] Taping
95 techniques such as kinesiotaping (KT) are now widely used in clinical settings for
96 rehabilitation of shoulder disorders. The proposed rationale behind its functioning is

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3 97 based on the lifting effects of epidermis layers and papillary dermis,[35] caused by
4 98 micro-convolutions formed on the taped skin. Wrinkles generated by the KT are
5 99 believed to increase the interstitial space, leading to an increase in blood and lymph
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8 100 flow, while facilitating pressure release on underlying soft tissues. Consequently,
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10 101 vascular networks in deep vessels under the skin are increased, reducing swelling and
11 102 inflammation in injured tissues.[36, 37] The KT is also argued to contribute to pain
12 103 relief by producing increased stimulation of cutaneous mechanoreceptors,[38] that
13 104 likely improves the proprioceptive feedback and thereby provides muscle
14 105 activation.[39] Combination of these effects is suggested to provide support to the joint
15 106 during functional movements. Considering all of these potential benefits, the KT
16 107 method has been widely used in clinical practice; however, its functional underlying
17 108 mechanism are still hypothetical, and its clinical efficacy has not been thoroughly
18 109 ascertained.

110 While some clinical trials have investigated the effects of KT on MSK
111 disorders,[40-48] including shoulder injuries,[27, 29, 35, 49-57] systematic reviews
112 have consistently pointed out that not enough evidence is available to conclude on the
113 efficacy of KT on MSK conditions.[58-63] Recently, Desjardins-Charbonneau et al
114 (2015)[58] examined six randomised controlled trials (RCT)[27-29, 50, 55, 57] (n=360)
115 specifically addressing RCTe. Their meta-analysis findings showed that KT might be
116 effective in immediately increasing pain-free flexion and abduction range of motion
117 (ROM). However, most published studies on KT have presented a high risk of bias,
118 tested KT as an isolated method of treatment (when it is used in combination with other
119 modalities in the clinics), or only looked at the immediate or short-term effects of
120 KT.[29, 51, 55, 57] Therefore, additional high-quality evidence is required to better
121 guide health professionals on the use of KT in the rehabilitation of individuals with
122 RCTe.

123 124 **Objectives and hypotheses**

125 The primary objective of this single-blind RCT is to evaluate the added effects
126 of therapeutic KT to a rehabilitation program focusing on sensorimotor training to
127 reduce symptoms and functional limitations of individuals with RCTe. The secondary
128 objective is to evaluate the effects of KT on variables related to shoulder control, such
129 as muscular activity, acromiohumeral distance (AHD) and ROM, in attempting to
130 identify the underlying effects of KT. Our hypothesis is that both groups will possibly

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3 131 achieve a mean improvement superior to the clinically important difference (CID) of the
4 132 Disabilities of the Arm, Shoulder, and Hand questionnaire (DASH) after the
5 133 rehabilitation program, as both groups will receive the same program that has been
6 134 shown to be effective for this population.[30] However, based on findings of previous
7 135 studies that have shown immediate and short-term effects of KT, it is likely that positive
8 136 outcome of rehabilitation in terms of reduction in symptoms and functional limitations
9 137 will be obtained faster for the patients allocated to the KT-group.
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METHODS AND ANALYSIS

Study design

This single-blind parallel group RCT will include a 6-week rehabilitation program and five evaluation sessions (baseline, week-3, week-6, week-12, and 6-months) over six months (Figure 1). All evaluations will be carried out at the Center for Interdisciplinary Research in Rehabilitation and Social Integration (CIRRISS) in Québec City, Canada.

Participants will take part in the baseline evaluation. After providing written informed consent, eligibility criteria will be assessed. Thereafter, eligible participants will complete a sociodemographic questionnaire, followed by the evaluation of the primary (DASH questionnaire), and secondary outcomes (Brief Pain Inventory [BPI] and the Western Ontario Rotator Cuff Index [WORC] questionnaires, shoulder ROM, AHD, muscle activity). Participants will then be randomly allocated to one of two groups (KT or No-KT), and take part in their assigned 6-week intervention: *experimental group* (KT-group - KT application will be added to the rehabilitation program), and *control group* (No-KT group - only the rehabilitation program, without any KT). An allergy testing to KT will be conducted by the treating physiotherapist specifically for patients allocated to the experimental group.

The three self-reported questionnaires (DASH, BPI, WORC) will be re-evaluated at week-3 (mid-point of the rehabilitation program), week-6 (end of the rehabilitation program), week-12, and 6-months after baseline evaluation. These follow-up evaluations are planned to assess progression in terms of symptoms and functional limitations throughout the study, allowing to establish whether an intervention leads to a faster and/or more lasting improvement than the other. Shoulder ROM, AHD, and muscle activity will be re-evaluated only at the end of the rehabilitation program (week-6). At the end of the rehabilitation program, participants will be asked to evaluate the change in their condition since the first physiotherapy session, using a Global Rating of Change (GRC) question.

Participants

Fifty-two (52) participants, aged between 18 and 65 years old, diagnosed with RCTe, will be recruited. To be eligible, participants will have to present one positive finding in each of the following categories: 1) painful arc of movement during flexion or abduction; 2) Neer (*sensitivity* 0.78, *specificity* 0.58) or Kennedy-Hawkins

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3 173 (*sensitivity* 0.74, *specificity* 0.57) impingement signs;^[64] and 3) pain during resisted
4 174 external rotation, abduction, or empty can test (*sensitivity* 0.69, *specificity* 0.62).^[64] A
5 175 combination of positive results to these clinical tests has values ≥ 0.74 for sensitivity and
6 176 specificity for RCTe.^[65] Participants will be excluded if they have: a) an open wound
7 177 that compromises KT application; b) had a previous shoulder surgery; c) allergy or
8 178 intolerance to KT; d) adhesive capsulitis, defined as loss of passive shoulder ROM
9 179 greater than 50%;^[66] e) history of glenohumeral luxation in the last 12 months or any
10 180 fracture to the shoulder girdle; f) shoulder pain reproduced by cervical movements; g)
11 181 clinical sign of full-thickness tears of any RC muscles identified by lag signs:^[67] drop
12 182 sign (*sensitivity* 0.73, *specificity* 0.77), external rotation sign (*sensitivity* 0.46, *specificity*
13 183 0.94), and internal rotation sign (*sensitivity* 1.00, *specificity* 0.84).^[68]
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185 **Randomization, blinding and allocation concealment**

186 An independent assessor, not involved in data collection, will generate the
187 randomization list using a computer random-number generator, prior to the initiation of
188 the study. A block randomization design (block size of 4, 6 or 8) will be applied to
189 ensure an equal number of participants in each group. Given that it is unknown if
190 gender influences the physiological response to KT, randomization will be stratified by
191 sex. Allocation will be concealed in sealed and opaque envelopes that will be
192 sequentially numbered. Each participant will receive an envelope that will be opened by
193 the treating physiotherapist at the first therapy session. As it is impossible to blind
194 participants and treating physiotherapist to KT application, a single-blind design was
195 chosen.

196 The treating physiotherapist will be unaware of the data from the outcome
197 measures, which will be assessed by an evaluator blinded to the group assignment.
198 Patients will be blinded to the treatment provided to the other group. To assess blinding
199 effectiveness, the assessor will answer a question related to their opinion on the
200 allocation after each of the follow-up evaluations.

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202 **Rehabilitation program (independent variable)**

203 Each patient will attend 10 physiotherapy sessions over six weeks (two sessions
204 during each of the first four weeks, then once a week). Both KT and No-KT groups will
205 receive the same standardized rehabilitation program that will include sensorimotor
206 training, manual therapy, stretching, muscular strengthening, and patient education.

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3 207 Additionally, the participants will receive a list of four (4) exercises, based on their
4 208 individual needs, to be performed at home without supervision. The rehabilitation
5 209 program will target deficits described in patients with RCTe and will take into
6 210 consideration the specific needs of each patient. The same physiotherapist will conduct
7 211 all rehabilitation programs.
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13 213 **Sensorimotor training.** Shoulder control exercises with progressive complexity in
14 214 terms of movement plane, ROM, speed, and resistance will be the basis of this
15 215 rehabilitation program. These exercises will be implemented aiming at the re-education
16 216 of movement control to correct kinematic alterations that lead to a superior migration of
17 217 the humeral head and to scapular dyskinesis, or changes in the muscle activity of
18 218 shoulder muscles.[30, 69] The exercises will be performed in the frontal, sagittal and
19 219 scapular planes, being graded according to resistance level (no resistance, passive,
20 220 active assisted, and active with and without external resistance), and the use of feedback
21 221 (with or without).[69] When the exercises will be executed properly, participants will
22 222 perform them at home, in three sets of 10 repetitions a day. Once participants are able to
23 223 elevate the injured arm without compensatory movements, suggesting adequate
24 224 shoulder control, goal-directed reaching tasks will be performed to retrain movements
25 225 requiring upper limb coordination. Work- or sport-specific re-education will also be
26 226 performed according to participant's own activities.
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38 228 **Manual therapy.** Joint mobilisation techniques will be applied on sternoclavicular,
39 229 acromioclavicular, glenohumeral, and thoracic spine, wherever the ligamentous and
40 230 capsular restraints are identified during the initial evaluation.[32, 33, 70-72] Once its
41 231 necessity is confirmed, each technique will be performed three times for approximately
42 232 60-sec, with a between-set rest interval of 30-sec.[70]
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48 234 **Stretching exercises.** Stretches will be performed to enhance the flexibility of the
49 235 glenohumeral capsule and underlying soft tissues, according to individual needs.
50 236 Stretches will be oriented to be performed as home exercises throughout treatment, in
51 237 three repetitions held for 30 seconds each.
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56 239 **Strengthening.** Free weights, extremities weight, and resistance elastic tube will be
57 240 used to strengthen RC muscles and scapular stabilizers.[30, 69] Exercises will progress
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3 241 according to the following phases: (a) phase 1, humerus in a neutral position to improve
4 242 the depression function; (b) phase 2, ascending arm movements; (c) phase 3, higher-
5 243 level exercises, including trunk strengthening.[33] The number of repetitions will vary
6 244 from one to three sets of 10 to 30, progressing gradually. Patients will begin using a
7 245 light resistance elastic band (yellow non-latex TheraBand™, Hygenic Corp, Akron, OH,
8 246 USA),[73] in phase 1. Participants will progress to next phase when exercises are
9 247 performed with medium resistance band (red and green non-latex TheraBand™).
10 248 Patients should perform phase 2 without increasing symptoms for one week as
11 249 requirements to advance to phase 3. Verbal and written instructions regarding the
12 250 exercises to be performed at home will be given the participants.
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252 **Patient education.** General guidance will be verbally provided to all patients to
253 enhance understanding of shoulder overload, pain neuroscience, pain management,
254 posture, rehabilitation stages, graded exposure to exercise, shoulder and body
255 mechanics and movements that provoke impingement, besides verbal and written
256 instructions regarding preferred shoulder positioning during sleep, work, and daily and
257 sports activities.[74]
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259 **Kinesiotaping techniques**

260 The skin will firstly be properly cleaned with isopropyl alcohol. Kinesio® Tex
261 Classic will be applied using a combination of techniques designed for RCTe and
262 underlying symptoms (Figure 2).[37] The first strip will be applied in Y-shape, light
263 tension (15-25%), surrounding the three portion of the deltoid muscle as a group, from
264 insertion to origin to provide inhibition and muscle relaxation.[27, 37] A second strip (I-
265 shape) will be applied for functional correction, recommended for multiaxial shoulder
266 instability, with severe tension (50–75%), from 7–10 cm above the acromioclavicular
267 joint to 7–10 cm below the deltoid tuberosity, passing over the supraspinatus, trapezius,
268 glenohumeral joint, and middle deltoid.[37] The third strip will be applied in I-shape for
269 mechanical correction at the glenohumeral joint, being placed with severe tension (50–
270 75%) and inward pressure, from coracoid process to posterior deltoid, just slightly
271 below the coracoacromial arch.[37, 75] The first strip will be applied in all patients of
272 the KT-group, whereas second and third strips will be used according to the presence of
273 corresponding deficits observed during individual weekly evaluations. All KT strips
274 will be removed at the beginning of each session, and a new piece will be applied at the

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3 275 end. Participants will be requested to keep the KT until the next physiotherapy session
4 276 or for a minimum of 72 hours, whichever comes first. All applications will follow the
5 277 instructions and principles described by Kase et al,[37] and will be executed by the
6 278 same physiotherapist, who is a practitioner certified by the Kinesio[®] Taping Association
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8 279 International (KTAI). As a fundamental practice, a gradual weaning will permit patients
9 280 to readapt to the normal feedback condition.[76] Therefore, KT strips will be weaned
10 281 gradually, according to individual improvement, as evaluated weekly by the treating
11 282 physiotherapist.
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18 284 **Data collection**

19 285 Outcome measures (dependent variables)

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21 286 The outcomes data will be collected by the same assessor, not involved in any
22 287 other process of the study. The primary outcomes are the symptoms and functional
23 288 limitations assessed using the *Disabilities of the Arm, Shoulder, and Hand (DASH)*
24 289 questionnaire.[77] The secondary outcomes are the BPI, WORC index, and shoulder
25 290 control, described as ROM, AHD and muscle activity. Global Rating of Change (GRC)
26 291 will be also assessed.
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33 293 Primary outcome

34 294 *Symptoms and functional limitations*

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36 295 The DASH is a 30-item self-report questionnaire, designed to measure physical
37 296 disability and symptoms of upper limbs disorders,[31, 77, 78] through a scale ranging
38 297 from 0 to 100 (most severe disability).[31, 78] Its items address the level of difficulty in
39 298 performing, in the last week, several daily activities related to upper extremity (21
40 299 items); the severity of the pain symptoms, activity-related pain, tingling, weakness, and
41 300 stiffness (five items); and their impact on social activities, sleep, work, self-image (four
42 301 items).[78] The DASH has an excellent reliability (ICC=0.96), it is highly responsive
43 302 following rehabilitation interventions for individuals with RCTe (effect size: 1.06,
44 303 standardized response mean [SRM]: 1.08),[31] has a minimal detectable change (MDC)
45 304 of 11 points and a clinically important difference (CID) of 10 points.[31, 78] The
46 305 validated Canadian-French version will be used (ICC=0.93; SRM=1.35; MDC=11.4
47 306 points; CID=10 points).[31, 78, 79]
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58 308 Secondary outcomes
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309 *BPI and WORC index*

310 As DASH has few questions related to pain, the BPI,[80, 81] specific for
311 assessing clinical pain, will also be filled out by the participants. It measures pain
312 intensity on an 11-point numerical rating scale (0-10), according to its interference with
313 general activity, mood, walking ability, normal work, relations with other people, sleep,
314 and enjoyment of life, over the last 24 hours (ICC >0.80).[80, 81] In addition, as the
315 DASH is not specific for the shoulder or for RC disorders, the WORC index[82] will
316 also be filled out. The WORC is a reliable and responsive (ICC=0.96; SRM=1.54;
317 MDC=12 points; CID=13 points) questionnaire designed to measure health-related-
318 quality-of-life in patients affected by RC injuries.[79, 82]

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320 *Range of motion (ROM)*

321 Limited and painful ROM is often observed in patients with RCTe.[83, 84] In
322 addition, KT has been shown to be effective in restoring pain-free ROM.[29, 57]
323 Therefore, active full and pain-free ROM in shoulder elevation in the frontal
324 (abduction) and sagittal (flexion) planes will be measured using a manual goniometer.
325 The goniometer is a reliable instrument for measuring shoulder ROM (ICC flexion =
326 0.95 [0.89-0.98]; ICC abduction = 0.97 [0.94-0.99]).[85] All measurements will be
327 taken with patients standing. Participants will perform two repetitions for each
328 movement. A 5-sec rest will be given between each trial and 1-min between conditions.
329 The average of two trials will determine the mean ROM values for each condition.

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331 *Acromiohumeral distance (AHD) and muscle activity*

332 Kinesiotaping has been shown to lead to an immediate increase in AHD in
333 healthy individuals.[86, 87] Therefore, AHD measurement was included as a secondary
334 outcome of shoulder control as it gives an indication of the dynamic narrowing of the
335 subacromial space using the tangential distance between humeral head bony landmarks
336 and acromion inferior edge.[30, 88]

337 First, two measures of AHD with shoulder at rest will be taken using an
338 ultrasound scanner (Logic e9, GE Healthcare, Milwaukee, WI, USA) with a 6-15MHz
339 linear array probe (model ML6-15-D).[30, 88] Thereafter, participants will perform two
340 vertical abductions (frontal planes) at 60°. During this arm elevation, muscle activity of
341 four shoulder muscles (upper trapezius, infraspinatus, middle and anterior deltoid) will
342 be recorded using surface electromyography (Trigno™ Wireless EMG system, Delsys

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3 343 Inc., Boston, MA, USA). At the end-point of movement (60° of abduction), the
4 344 ultrasonographic image of the AHD will be recorded. These measurements (muscle
5 345 activity and US) will permit to determine the association between the presence of a
6 346 dynamic narrowing of the AHD and the muscular activity of key shoulder muscles.
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11 348 **Ultrasonographic recordings.** To record AHD images, the probe will be positioned on
12 349 the anterior aspect of the lateral surface of acromion along the longitudinal axis of the
13 350 humerus in a coronal plane and moved around 1 cm behind the acromion and humeral
14 351 head. In this position, both acromion and humerus can be viewed. A strap will be used
15 352 to restrain the abduction movement to 60°, which will be confirmed using an
16 353 inclinometer. Participants will be instructed to maintain the strap slightly stretched
17 354 during data collection, to maintain the angle of interest. All measurements will be
18 355 performed with patients seated up straight against the backrest of the chair. The average
19 356 over two AHD trials will be calculated for each angle examined.
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28 358 **EMG recordings.** Before measurements, the skin over upper trapezius, infraspinatus,
29 359 anterior and middle deltoid will be cleaned with isopropyl alcohol and hair will be
30 360 removed, when necessary. Thereafter, a Trigno™ sensor (41 mm x 20 mm x 5 mm) will
31 361 be placed on the muscle belly, parallel to the direction of the muscle fibers. The EMG-
32 362 sensor placements will be defined in accordance with the Surface EMG for Noninvasive
33 363 Assessment of Muscles (SENIAM) guidelines.[89] For the infraspinatus muscle, the
34 364 EMG-sensor will be placed 3-4 cm below and parallel to the scapular spine, over the
35 365 infrascapular fossa. For the upper trapezius, it will be placed at the midway between the
36 366 spine on vertebra C7 and the acromion. Over the anterior deltoid, the EMG-sensor will
37 367 be placed at one-finger width (1-2 cm) below the acromion and lateral clavicle, whereas
38 368 at the middle deltoid, it will be placed at halfway between its insertion and the
39 369 acromion.[90] No reference electrode will be used since this sensor already uses a 2-
40 370 level single-differential method to minimize artifacts and baseline noise contamination
41 371 through 4-parallel bars with their center 10 mm apart, and a signal bandwidth of 10-450
42 372 Hz. All EMG data will be recorded using Delsys EMGworks® Acquisition software.
43 373 The EMG signals will be pre-amplified at the skin surface (300x gain, common mode
44 374 rejection ratio [CMRR] 92dB at 60Hz) at a sampling rate of 1926 samples/s. All
45 375 electrode placements, the wireless communication, and the signal quality will be
46 376 verified by visual monitoring of signals at rest and during isometric contractions.[90]
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3 377 Raw EMG data will be stored on a computer for offline analysis. Prior to analysis,
4 378 recorded signals will be band-pass filtered (10-450 Hz, fourth-order zero-lag
5 379 Butterworth digital filter), full-wave rectified and smoothed using a Root Mean Square
6 380 (RMS) filter with a 0.25-sec time-window and 0.05 of window overlap. EMG amplitude
7 381 data will then be normalized to a reference condition, where patients will raise their arm
8 382 at 60° of scaption for 5-sec, with no load. Two trials will be performed for each arm,
9 383 and the average of the RMS values will be used for normalization.
10 384

16 385 *Global Rating of Change (GRC)*

17 386 Participants will be asked to evaluate the change in their condition from the
18 387 initial physiotherapy session using a GRC question. The GRC is a reliable 15-points
19 388 scale (ICC = 0.90),[65, 91, 92] designed to report changes in clinical status over time as
20 389 the perception of outcome after treatment.[65, 91] Since patients generally feel satisfied
21 390 with their improvements when reaching +4 GRC score,[92, 93] we determined a priori
22 391 that participants who will rate their perceived recovery at +4 “*moderately better or*
23 392 *greater*” will be categorized as having a successful outcome.[30, 33] Then, results from
24 393 GRC will be dichotomized to $GRC \geq +4$ (improvement) or $GRC < +4$ (non-
25 394 improvement).
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34 396 **Sample size**

35 397 Sample size calculation is based on changes evidenced by the DASH scores for
36 398 individuals with RCTe. According to sample size calculation (G*Power 3.1.9.2; $\alpha=0.05$,
37 399 effect size=0.79, power $[1-\beta]=0.82$, SD=14.17 DASH points,[56] CID=12.4 DASH
38 400 points),[94] a minimum of 22 patients are needed in each group. When adding an
39 401 expected loss to follow-up of 15%, a total of 26 patients per group is required.
40 402 Therefore, 52 patients with RCTe will be recruited. This sample size is sufficient to
41 403 detect the CID between the two groups.
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48 405 **Recruitment of patients**

49 406 Fifty-two participants will be recruited. This number is feasible as a recent study
50 407 from our research team successfully recruited 30 individuals with RCTe over six
51 408 months. Taking into consideration the dropouts, we believe it is possible to recruit 26
52 409 participants over the same period. Therefore, considering a recruitment rate of five
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3 410 participants per month, in average, all participants should be enrolled in less than 11
4 411 months.
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413 **Withdrawal of individual participants**

414 Principles underlying “intention-to-treat” analysis will be followed, meaning that
415 every participant will be analysed according to the randomized treatment assignment.
416 Therefore, noncompliance, protocol deviation, and withdrawal will all be ignored in the
417 primary analyses. All dropouts and their underlying reasons will be reported.[95]
418 Additionally, “per-protocol” analysis (i.e., the analysis will be restricted to participants
419 who adhered to the intervention as stipulated in the protocol) will also be performed.
420 We believe that the combination of these statistical strategies will increase confidence in
421 the study results. To ensure appropriate insight of mechanisms underlying changes in
422 symptoms and function, only participants who completed evaluation at week-6 will be
423 considered for the secondary outcomes. Any harm or unintended effects during the
424 programs will be recorded.
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426 **Data integrity and analysis**

427 All collected data will be accessible only to the research team. All data will be
428 kept for five years after the end of the study, to ensure the completion of planned
429 publications. After this period, all data will be destroyed.
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431 **Statistical analysis**

432 Basic descriptive statistics (mean and standard deviation) will be reported for
433 each participant’s characteristic and outcome. All data will be tested to check the
434 distributional assumptions for the inferential statistical analyses. Baseline demographic
435 data will be compared using independent samples t-test and chi-square. If differences
436 are seen in baseline characteristics, we will apply an ANCOVA model to adjust group
437 comparisons for confounding variables.

438 The added effects of KT on the DASH, BPI, WORC and muscle activity will be
439 examined using a mixed design analysis of variance (ANOVA) model (Groups [KT-
440 group, No-KT group] × Evaluations [Baseline, week-3, week-6, week-12, 6-months),
441 while a 3-way ANOVA for repeated measures (Group x Time x Angle [for AHD] or
442 plane of movement [for ROM] will be performed for AHD and ROM. Bonferroni
443 adjustments for multiple comparisons will be used, and effect sizes will be reported

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3 444 (η^2). The GRC will be compared across groups using a Fischer's exact probability test.

4 445 The level of significance will be set at $p < 0.05$ for all statistical analyses.

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DISCUSSION

4 448 It is well reported that functional limitations associated with RCTe may remain
5 449 for 12 months or more.[11] Personal, medical and socio-economic impacts of RCTe are
6 450 well known,[1, 22] and because RCTe results in a high rate of sick leave, assessment of
7 451 the effectiveness of treatments is a priority.

8 452 Over the past few years, KT has been widely used in clinical practice; however,
9 453 its effects for the rehabilitation of patients with RCTe need to be more evidenced.
10 454 Despite the fact that some investigations examined the effects of KT on RCTe, no
11 455 published study has, to our knowledge, addressed its mid- and long-term effects when
12 456 added to a rehabilitation program, as commonly used by clinicians. Furthermore, few
13 457 studies have evaluated KT efficacy as an adjunct therapeutic resource, while applying
14 458 identical physiotherapy treatment for both groups (experimental and placebo/control
15 459 group). This makes it difficult to ascertain causation and may compromise the evidence
16 460 of the real effects of KT. Therefore, investigations with a high level of standardisation
17 461 are needed to determine the scientific validity of KT efficacy for the rehabilitation of
18 462 individuals with RCTe.

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464 **Strength and limitations of this study**

31 465 To our knowledge, this RCT will be the first to assess the mid- and long-term
32 466 efficacy of KT added to a conventional rehabilitation program for individuals with
33 467 RCTe, addressing underlying variables that could help understanding the benefits
34 468 alleged for this method. Because our standardized rehabilitation program parallels those
35 469 in current existence in a clinical setting, it will be possible to directly apply the results to
36 470 clinical practice. Results will contribute to building robust evidence of the benefit of
37 471 addition of KT in physiotherapeutic intervention for RCTe, in addition to helping to
38 472 establish the best clinical treatments for this population. Lastly, a series of measures
39 473 such as a statistically justified sample size, methodological rigor, blinding,
40 474 randomisation, and adequate concealment of group allocation, will be implemented in
41 475 order to reduce the risk of bias.

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52 476 On the other hand, we are aware of some limitations of this study. First, while
53 477 patients will be blinded to the treatment provided to the other group, it is not feasible to
54 478 blind the experimental group due to the nature of their own allocated treatment.
55 479 Notwithstanding, a sham KT (placebo group) will not be included as previous literature

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3 480 has shown that establishing a sham taping protocol is problematic since KT applied over
4 481 the skin could potentially produce some proprioceptive stimuli, which may act as
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6 482 confounding factor.[38, 39, 41]
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For peer review only

ETHICS

This RCT is registered on ClinicalTrials.gov (NCT02881021). Ethics approval was obtained from the Institutional Review Board of Quebec Rehabilitation Institute (IRD PQ) of the Center Integrated University Health and Social Services (CIUSSS-CN).

Consent

Detailed information about the research and experimental procedures will be provided to all participants before signature of the written informed consent. Participants will be requested to sign a detailed informed consent before starting any experimental procedure.

Confidentiality

All research team members will respect the data confidentiality of the patients, in agreement with the law. Patients names will be coded to keep their identity confidential; however, a list of name and respective codes will be stored in a locked and filing cabinet. All information collected during the study, including test results, will be treated as confidential. The trial dataset will be accessible only to the research team and Ethics committee of IRDPQ for purposes of management or audit of research development. Publications related to these data will respect all principles of confidentiality.

Dissemination

Results of this protocol will be disseminated through international publication in peer-reviewed journals, in addition to international conference presentations. Participants, clinicians, and relevant research staff in the field will be informed about the results of the study.

FOOTNOTES

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Contributors:

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Funding:

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Competing interests:

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Ethics approval:

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Data sharing statement:

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FCLO contributed to conception, design, and preparation of the procedures, data collection and will conduct the recruitment, rehabilitation program, interpretation, data analyses and writing. BPF will conduct the outcomes assessments and will contribute to the analysis, and interpretation of the data. FD contributed to study design and will contribute to the statistical analysis, and interpretation of the data. JSR and LB contributed to conception, design, and preparation of the procedures. Both authors will contribute to the analyses and interpretation of the data. JSR, LB, FD, and BPF commented on the several versions of this study protocol. All authors approved the final version of this protocol.

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The authors have no relevant conflict of interests to declare.

Institutional Review Board of Quebec Rehabilitation Institute (IRDPQ) of the Center Integrated University Health and Social Services (CIUSSS-CN).

Additional data from patients included in this study will not be available, in accordance to the principles of confidentiality of the Institutional Review Board of Quebec Rehabilitation Institute (IRDPQ).

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FIGURES

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808 **Figure 1.** Schematic diagram of the study design.

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810 **Figure 2.** Kinesiotaping application. First strip (1: Y-shape surrounding deltoid
811 muscles), second strip (2: I-shape in functional correction for multiaxial shoulder
812 instability over the glenohumeral joint, supraspinatus, trapezius, and middle deltoid
813 muscles), and third strip (3: I-shape in mechanical correction for glenohumeral joint).

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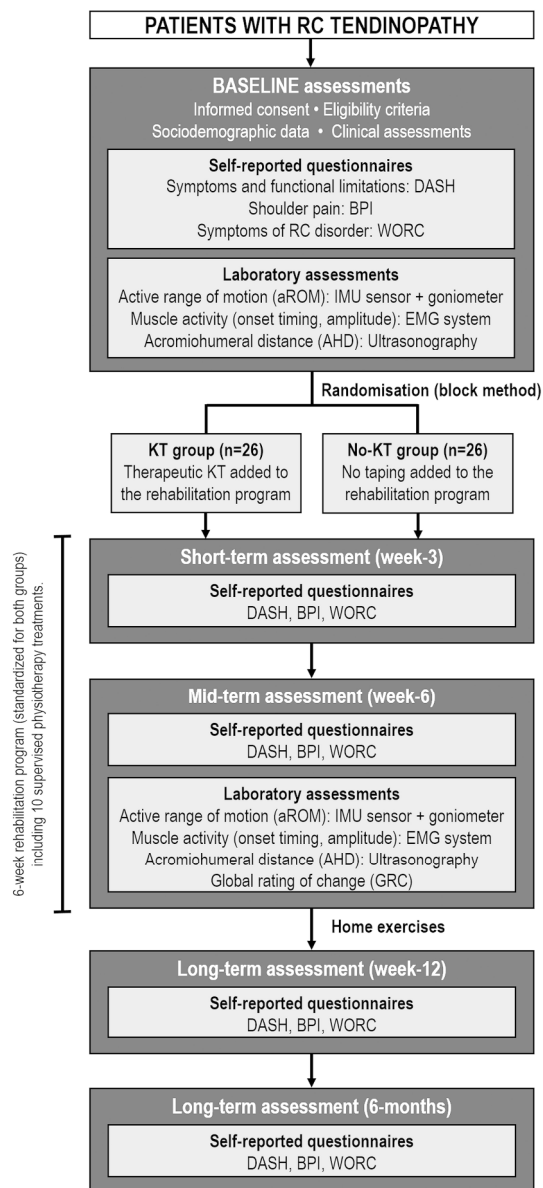


Figure 1. Schematic diagram of the study design.

199x399mm (300 x 300 DPI)

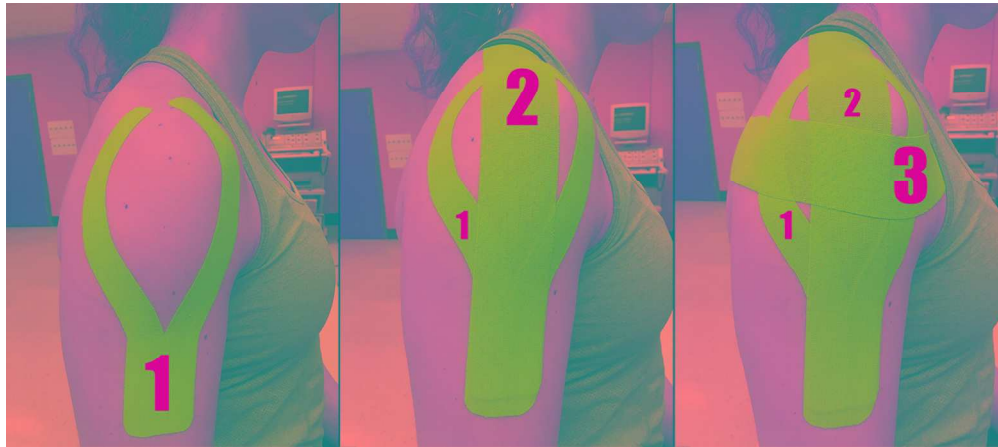


Figure 2. Kinesiotaping application. First strip (1: Y-shape surrounding deltoid muscles), second strip (2: I-shape in functional correction for multiaxial shoulder instability over the glenohumeral joint, supraspinatus, trapezius, and middle deltoid muscles), and third strip (3: I-shape in mechanical correction for glenohumeral joint).

150x66mm (300 x 300 DPI)

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World Health Organization Trial Registration Data Set

DATA CATEGORY	INFORMATION ³²
Primary registry and trial identifying number	ClinicalTrials.gov NCT02881021
Date of registration in primary registry	23 August, 2016
Secondary identifying numbers	PROJET # 2016-496
Source(s) of monetary or material support	Coordenação de Aperfeiçoamento de Pessoal de Nível Superior – CAPES/Science without Borders
Primary sponsor	Coordenação de Aperfeiçoamento de Pessoal de Nível Superior – CAPES Brazilian Government, Ministry of Education
Secondary sponsor(s)	Center for Interdisciplinary Research in Rehabilitation and Social Integration (CIRRS)
Contact for public queries	Dr. Jean-Sébastien Roy, PT, Ph.D. Phone: +1 (418) 529-9141 #6005 E-mail: jean-sebastien.roy@rea.ulaval.ca
Contact for scientific queries	Dr. Jean-Sébastien Roy, PT, Ph.D. Department of Rehabilitation, Faculty of Medicine Laval University Center for Interdisciplinary Research in Rehabilitation and Social Integration (CIRRS), CIUSS-CN Québec City, Canada
Public title	Effects of a rehabilitation program on symptoms and functional limitations in patients with rotator cuff tendinopathy: a single-blind, randomised controlled trial.
Scientific title	Effects of kinesiotaping added to a rehabilitation program for patients with rotator cuff tendinopathy: protocol for a single-blind randomised controlled trial addressing symptoms, functional limitations, and underlying deficits.
Countries of recruitment	Canada
Health condition(s) or problem(s) studied	Rotator cuff tendinopathy
Intervention(s)	Experimental group: rehabilitation programme with addition of kinesiotaping. Control group: rehabilitation programme without kinesiotaping

DATA CATEGORY	INFORMATION ³²
Key inclusion and exclusion criteria	<p>Ages eligible for study: ≥ 18 to 65 years Sexes eligible for study: both (male, female) Accepts healthy volunteers: no</p> <p><u>Inclusion criteria</u>: adult patient (≥ 18 years), unilateral rotator cuff tendinopathy, positive signs of rotator cuff tendinopathy assessed through clinical tests (arc of movement, Neer, Kennedy-Hawkins, Jobe, resisted external rotation and abduction).</p> <p><u>Exclusion criteria</u>: open wound that compromises the kinesiotaping application over the shoulder; previous shoulder surgery; allergy or intolerance to kinesiotaping; adhesive capsulitis; history of glenohumeral luxation; clinical sign of full-thickness tears of any rotator cuff muscles identified by lag signs (drop and external rotation sign).</p>
Study type	<p>Interventional Allocation: randomized Masking: single blind (subject, outcomes assessor) Primary purpose: to assess the effects of a therapeutic resource.</p>
Date of first enrolment	November 2016
Target sample size	52
Recruitment status	Recruiting
Primary outcome(s)	Symptoms and functional limitations
Key secondary outcomes	Active range of motion, rotator cuff muscle activity, acromiohumeral distance.



STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

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

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	06
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	07
	2b	All items from the World Health Organization Trial Registration Data Set	02, 03
Protocol version	3	Date and version identifier	--
Funding	4	Sources and types of financial, material, and other support	05
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	05
	5b	Name and contact information for the trial sponsor	04
	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	--
	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)	--

1 **Introduction**

2				
3	Background and	6a	Description of research question and justification for undertaking the trial, including summary of relevant	9 - 10
4	rationale		studies (published and unpublished) examining benefits and harms for each intervention	
5				
6		6b	Explanation for choice of comparators	9
7				
8	Objectives	7	Specific objectives or hypotheses	10
9				
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)	12
12				
13				
14				
15	Methods: Participants, interventions, and outcomes			
16				
17	Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will	12
18			be collected. Reference to where list of study sites can be obtained	
19				
20	Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and	12, 13
21			individuals who will perform the interventions (eg, surgeons, psychotherapists)	
22				
23	Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be	13 - 15
24			administered	
25				
26		11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose	---
27			change in response to harms, participant request, or improving/worsening disease)	
28				
29		11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence	--
30			(eg, drug tablet return, laboratory tests)	
31				
32				
33		11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	14 - 15
34				
35	Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood	16 - 19
36			pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg,	
37			median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen	
38			efficacy and harm outcomes is strongly recommended	
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41	Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for	31, figure 1
42			participants. A schematic diagram is highly recommended (see Figure)	
43				
44				

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	<u>12, 19</u>
2				
3				
4	Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	<u>19</u>
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7	Methods: Assignment of interventions (for controlled trials)			
8	Allocation:			
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10				
11	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	<u>13</u>
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17	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	<u>13</u>
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21	Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	<u>13</u>
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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	<u>13,14,16</u>
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28		17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	<u>--</u>
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31				
32	Methods: Data collection, management, and analysis			
33				
34	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	<u>14 - 17</u>
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40		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	<u>19</u>
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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	<u>20</u>
2				
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4				
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	<u>20</u>
6				
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8		20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	<u>20</u>
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)	<u>20</u>
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15	Methods: Monitoring			
16				
17	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	<u>---</u>
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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	<u>23</u>
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26	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	<u>--</u>
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29	Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	<u>23</u>
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33	Ethics and dissemination			
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35	Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	<u>23</u>
36				
37				
38	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)	<u>--</u>
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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)	<u>attached</u>
2				
3				
4		26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	<u>---</u>
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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	<u>23</u>
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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	<u>05</u>
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14	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	<u>20, 23</u>
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17	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	<u>--</u>
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20	Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, health care professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	<u>23</u>
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25		31b	Authorship eligibility guidelines and any intended use of professional writers	<u>5</u>
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27		31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	<u>--</u>
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30	Appendices			
31				
32	Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	<u>attached</u>
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35	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	<u>--</u>
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39 *It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items.
40 Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons
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