

BMJ Open Effects of kinesiotaping added to a rehabilitation programme 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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ABSTRACT

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

Methods and analysis A single-blind RCT will be conducted. Fifty-two participants, randomly allocated to one of two groups (KT or no-KT), will take part in a 6-week rehabilitation programme. The KT group will receive KT added to the rehabilitation programme, whereas the no-KT group will receive only the rehabilitation programme. Measurements will be taken at baseline, week 3, week 6, week 12 and 6 months. Primary outcomes will be symptoms and functional limitations assessed by the Disabilities of the Arm, Shoulder and Hand 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 two-way analysis of variance for repeated measures.

Ethics and dissemination Ethics approval was obtained from the Ethics Committee of Quebec Rehabilitation Institute of the Centre Integrated University Health and Social Services. Results will be disseminated through international publications in peer-

Strengths and limitations of this study

- To our knowledge, this is the first randomised controlled trial to assess the mid-term and long-term effects of kinesiotaping added to a conventional rehabilitation programme 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 rigour, 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.

reviewed journals, in addition to international conference presentations.

Trial registration number Protocol was registered at ClinicalTrials.gov (NCT02881021) on 25 August 2016. The WHO Trial Registration Data Set can also be found as an online supplementary file.

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 proposed 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} In addition, hormonal dysregulation and metabolic diseases have been suggested as a possible contributors for RC injuries due to a possible influence on the biology of tendons and hence in the biomechanical properties of the musculoskeletal system.^{14,15}

While there is no consensus on the specific aetiological mechanisms of RCTe,^{16,17} glenohumeral and scapular kinematics alterations have been suggested as instigators of the dynamic narrowing of the subacromial space.¹⁸⁻²¹ A lack of coordination and an imbalance between RC and scapulothoracic muscle activations could explain these kinematics alterations.²² The muscular balance between deltoid and RC muscles is crucial to maintaining the glenohumeral joint function,^{22,23} keeping a stabilising congruency between the humeral head and the glenoid fossa; however, this dynamic interplay appears to be compromised in individuals with RCTe.^{22,24}

Reduction of these deficits is the key to returning to a proper shoulder neuromuscular control leading to the resolution of pain and restoration of function.^{25,26} Therefore, many rehabilitation programmes include interventions such as mobilisation with movements²⁷ and with exercises,^{28,29} movement training,³⁰ and strengthening exercises.³¹ These interventions improve the neuromuscular control of the shoulder and concomitantly decrease symptoms and functional limitations.^{30,32,33} In addition, taping techniques have been considered an interesting option to improve shoulder control and hence to reduce the deficits associated with RCTe.³⁴ Taping techniques such as kinesiotaping (KT) are now widely used in clinical settings for rehabilitation of shoulder disorders. The proposed rationale behind its functioning is based on the lifting effects of epidermis layers and papillary dermis,³⁵ caused by microconvolutions 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.^{36,37} The KT is also argued to contribute to pain relief by producing increased stimulation of cutaneous mechanoreceptors,³⁸ which likely improves the proprioceptive feedback and thereby provides muscle activation.³⁹ Combination of these effects is suggested to provide support to the joint during functional movements. Considering all of these

potential benefits, the KT method has been widely used in clinical practice; however, its functional underlying mechanisms are still hypothetical, and its clinical efficacy has not been thoroughly ascertained.

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

Objectives and hypotheses

The primary objective of this single-blind RCT is to evaluate the added effects of therapeutic KT to a rehabilitation programme focusing on sensorimotor training to reduce symptoms and functional limitations of individuals with RCTe. The secondary objective is to evaluate the effects of KT on variables related to shoulder control, such as muscular activity, acromiohumeral distance (AHD) and ROM, in attempting to identify the underlying effects of KT. Our hypothesis is that both groups will possibly achieve a mean improvement superior to the clinically important difference (CID) of the Disabilities of the Arm, Shoulder and Hand questionnaire (DASH) after the rehabilitation programme, as both groups will receive the same programme that has been shown to be effective for this population.³⁰ However, based on findings of previous studies that have shown immediate and short-term effects of KT, it is likely that positive outcome of rehabilitation, in terms of reduction in symptoms and functional limitations, will be obtained faster for the patients allocated to the KT group.

METHODS AND ANALYSIS

Study design

This single-blind, parallel group RCT will include a 6-week rehabilitation programme and five evaluation sessions (baseline, week 3, week 6, week 12 and 6 months) over 6 months (figure 1). 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

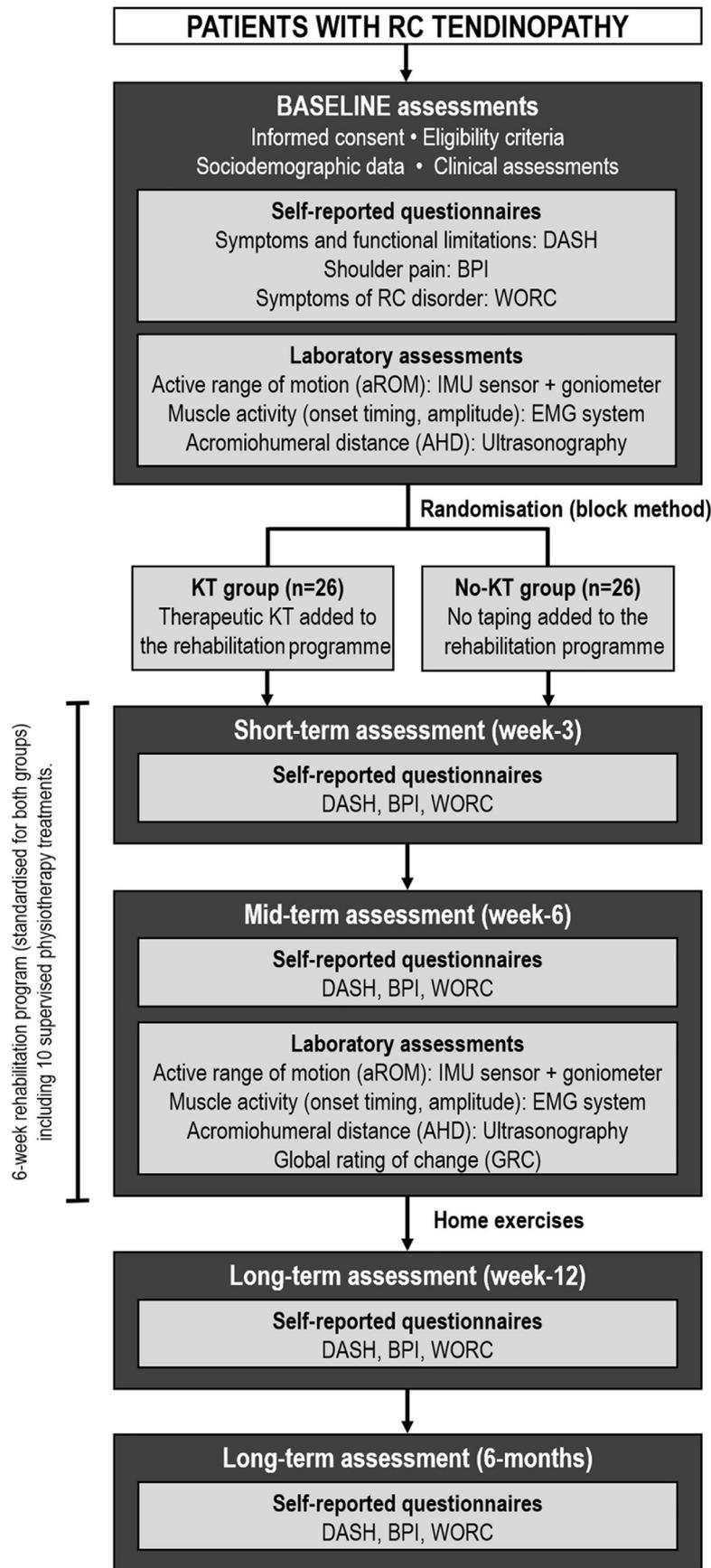


Figure 1 Schematic diagram of the study design. BPI, Brief Pain Inventory; DASH, Disabilities of the Arm, Shoulder and Hand questionnaire; EMG, electromyography; IMU, inertial measurement unit; KT, kinesiotaping; RC, rotator cuff; WORC, Western Ontario Rotator Cuff Index.

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 programme) and *control group* (no-KT group—only the rehabilitation programme, 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 (midpoint of the rehabilitation programme), week 6 (end of the rehabilitation programme), 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 programme (week 6). At the end of the rehabilitation programme, 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 signs⁶⁴; and (3) pain during resisted external rotation, abduction or empty can test (*sensitivity* 0.69, *specificity* 0.62).⁶⁴ A combination of positive results to these clinical tests has values ≥ 0.74 for sensitivity and specificity for RCTe.⁶⁵ Participants will be excluded if they have (1) an open wound that compromises KT application; (2) had a previous shoulder surgery; (3) allergy or intolerance to KT; (4) adhesive capsulitis, defined as loss of passive shoulder ROM greater than 50%⁶⁶; (5) history of glenohumeral luxation in the last 12 months or any fracture to the shoulder girdle; (6) shoulder pain reproduced by cervical movements; and (7) clinical sign of full-thickness tears of any RC muscles identified by lag signs⁶⁷: drop sign (*sensitivity* 0.73, *specificity* 0.77), external rotation sign (*sensitivity* 0.46, *specificity* 0.94) and internal rotation sign (*sensitivity* 1.00, *specificity* 0.84).⁶⁸

Randomisation, blinding and allocation concealment

An independent assessor, not involved in data collection, will generate the randomisation list using a computer random-number generator, prior to the initiation of the

study. A block randomisation design (block size of 4, 6 or 8) will be applied to ensure an equal number of participants in each group. Given that it is unknown if gender influences the physiological response to KT, randomisation will be stratified by sex. Allocation will be concealed in sealed and opaque envelopes that will be sequentially numbered. Each participant will receive an envelope that will be opened by the treating physiotherapist at the first therapy session. As it is impossible to blind participants and treating physiotherapist to KT application, a single-blind design was chosen.

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

Rehabilitation programme (independent variable)

Each patient will attend 10 physiotherapy sessions over 6 weeks (two sessions during each of the first 4 weeks, then once a week). Both KT and no-KT groups will receive the same standardised rehabilitation programme that will include sensorimotor training, manual therapy, stretching, muscular strengthening and patient education. Additionally, the participants will receive a list of four exercises, based on their individual needs, to be performed at home without supervision. The rehabilitation programme will target deficits described in patients with RCTe and will take into consideration the specific needs of each patient. The same physiotherapist will conduct all rehabilitation programme.

Sensorimotor training

Shoulder control exercises with progressive complexity in terms of movement plane, ROM, speed and resistance will be the basis of this rehabilitation programme. These exercises will be implemented aiming at the re-education of movement control to correct kinematic alterations that lead to a superior migration of the humeral head and to scapular dyskinesis, or changes in the muscle activity of shoulder muscles.^{30 69} The exercises will be performed in the frontal, sagittal and scapular planes, being graded according to resistance level (no resistance, passive, active assisted, and active with and without external resistance), and the use of feedback (with or without).⁶⁹ When the exercises will be executed properly, participants will perform them at home, in three sets of 10 repetitions a day. Once participants are able to elevate the injured arm without compensatory movements, suggesting adequate shoulder control, goal-directed reaching tasks will be performed to retrain movements requiring upper limb coordination. Work-specific or sport-specific re-education will also be performed according to participant's own activities.

Manual therapy

Joint mobilisation techniques will be applied on sternoclavicular, acromioclavicular, glenohumeral and thoracic

spine, wherever the ligamentous and capsular restraints are identified during the initial evaluation.^{32 33 70–72} Once its necessity is confirmed, each technique will be performed three times for approximately 60s, with a between-set rest interval of 30s.⁷⁰

Stretching exercises

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

Strengthening

Free weights, extremities weight and resistance elastic tube will be used to strengthen RC muscles and scapular stabilisers.^{30 69} Exercises will progress according to the following phases: (1) phase 1, humerus in a neutral position to improve the depression function; (2) phase 2, ascending arm movements; and (3) phase 3, higher level exercises, including trunk strengthening.³³ The number of repetitions will vary from one to three sets of 10–30, progressing gradually. Patients will begin using a light resistance elastic band (yellow non-latex TheraBand®, Hygenic, Akron, Ohio, USA)⁷³ in phase 1. Participants will progress to next phase when exercises are performed with medium resistance band (red and green non-latex TheraBand®). Patients should perform phase 2 without increasing symptoms for 1 week as requirements to advance to phase 3. Verbal and written instructions regarding the exercises to be performed at home will be given the participants.

Patient education

General guidance will be verbally provided to all patients to enhance understanding of shoulder overload, pain

neuroscience, pain management, posture, rehabilitation stages, graded exposure to exercise, shoulder and body mechanics and movements that provoke impingement, besides verbal and written instructions regarding preferred shoulder positioning during sleep, work and daily and sports activities.⁷⁴

KT techniques

The skin will first be properly cleaned with isopropyl alcohol. Kinesio® Tex Classic will be applied using a combination of techniques designed for RCTe and underlying symptoms (figure 2).³⁷ The first strip will be applied in Y-shape, light tension (15%–25%), surrounding the three portion of the deltoid muscle as a group, from insertion to origin to provide inhibition and muscle relaxation.^{27 37} A second strip (I-shape) will be applied for functional correction, recommended for multiaxial shoulder instability, with severe tension (50%–75%), from 7 to 10 cm above the acromioclavicular joint to 7–10 cm below the deltoid tuberosity, passing over the supraspinatus, trapezius, glenohumeral joint and middle deltoid.³⁷ The third strip will be applied in I-shape for mechanical correction at the glenohumeral joint, being placed with severe tension (50%–75%) and inward pressure, from coracoid process to posterior deltoid, just slightly below the coracoacromial arch.^{37 75} The first strip will be applied in all patients of the KT group, whereas second and third strips will be used according to the presence of corresponding deficits observed during individual weekly evaluations. All KT strips will be removed at the beginning of each session, and a new piece will be applied at the end. Participants will be requested to keep the KT until the next physiotherapy session or for a minimum of 72 hours, whichever comes first. All applications will follow the instructions and



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).

principles described by Kase *et al.*,³⁷ and will be executed by the same physiotherapist, who is a practitioner certified by the Kinesio Taping Association International. As a fundamental practice, a gradual weaning will permit patients to readapt to the normal feedback condition.⁷⁶ Therefore, KT strips will be weaned gradually, according to individual improvement, as evaluated weekly by the treating physiotherapist.

Data collection

Outcome measures (dependent variables)

The outcomes data will be collected by the same assessor, not involved in any other process of the study. The primary outcomes are the symptoms and functional limitations assessed using the DASH questionnaire.⁷⁷ The secondary outcomes are the BPI, WORC Index and shoulder control, described as ROM, AHD and muscle activity. The GRC will also be assessed.

Primary outcome

Symptoms and functional limitations

The DASH is a 30-item self-report questionnaire designed to measure physical disability and symptoms of upper limbs disorders,^{31 77 78} through a scale ranging from 0 to 100 (most severe disability).^{31 78} Its items address the level of difficulty in performing, in the last week, several daily activities related to upper extremity (21 items); the severity of the pain symptoms, activity-related pain, tingling, weakness and stiffness (5 items); and their impact on social activities, sleep, work and self-image (4 items).⁷⁸ The DASH has an excellent reliability (intraclass correlation coefficient [ICC]=0.96), is highly responsive following rehabilitation interventions for individuals with RCTe (effect size: 1.06, standardised response mean [SRM]: 1.08),³¹ has a minimal detectable change (MDC) of 11 points and has a CID of 10 points.^{31 78} The validated Canadian-French version will be used (ICC=0.93; SRM=1.35; MDC=11.4 points; CID=10 points).^{31 78 79}

Secondary outcomes

BPI and WORC Index

As DASH has few questions related to pain, the BPI,^{80 81} specific for assessing clinical pain, will also be filled out by the participants. It measures pain intensity on an 11-point numerical rating scale (0–10), according to its interference with general activity, mood, walking ability, normal work, relations with other people, sleep and enjoyment of life, over the last 24 hours (ICC >0.80).^{80 81} In addition, as the DASH is not specific for the shoulder or for RC disorders, the WORC Index⁸² will also be filled out. The WORC is a reliable and responsive (ICC=0.96; SRM=1.54; MDC=12 points; CID=13 points) questionnaire designed to measure health-related-quality of life in patients affected by RC injuries.^{79 82}

Range of motion

Limited and painful ROM is often observed in patients with RCTe.^{83 84} In addition, KT has been shown to be effective in restoring pain-free ROM.^{29 57} Therefore,

active full and pain-free ROM in shoulder elevation in the frontal (abduction) and sagittal (flexion) planes will be measured using a manual goniometer. The goniometer is a reliable instrument for measuring shoulder ROM (ICC flexion=0.95 [0.89–0.98]; ICC abduction=0.97 [0.94–0.99]).⁸⁵ All measurements will be taken with patients standing. Participants will perform two repetitions for each movement. A 5 s rest will be given between each trial and 1 min between conditions. The average of two trials will determine the mean ROM values for each condition.

AHD and muscle activity

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

First, two measures of AHD with shoulder at rest will be taken using an ultrasound scanner (Logiq e9, GE Healthcare, Milwaukee, Wisconsin, USA) with a 6–15 MHz linear array probe (model ML6-15-D).^{30 88} Thereafter, participants will perform two vertical abductions (frontal planes) at 60°. During this arm elevation, muscle activity of four shoulder muscles (upper trapezius, infraspinatus, middle and anterior deltoid) will be recorded using surface electromyography (EMG) (Trigno Wireless EMG system, Delsys, Boston, Massachusetts, USA). At the end-point of movement (60° of abduction), the ultrasonographic image of the AHD will be recorded. These measurements (muscle activity and ultrasonography) will permit to determine the association between the presence of a dynamic narrowing of the AHD and the muscular activity of key shoulder muscles.

Ultrasonographic recordings

To record AHD images, the probe will be positioned on the anterior aspect of the lateral surface of acromion along the longitudinal axis of the humerus in a coronal plane and moved around 1 cm behind the acromion and humeral head. In this position, both acromion and humerus can be viewed. A strap will be used to restrain the abduction movement to 60°, which will be confirmed using an inclinometer. Participants will be instructed to maintain the strap slightly stretched during data collection, to maintain the angle of interest. All measurements will be performed with patients seated up straight against the backrest of the chair. The average over two AHD trials will be calculated for each angle examined.

EMG recordings

Before measurements, the skin over upper trapezius, infraspinatus, anterior and middle deltoid will be cleaned with isopropyl alcohol and hair will be removed, when necessary. Thereafter, a Trigno sensor (41 mm × 20 mm × 5 mm) will be placed on the muscle belly, parallel to the direction of the muscle fibres. The EMG sensor placements will be

defined in accordance with the Surface EMG for Non-Invasive Assessment of Muscles guidelines.⁸⁹ For the infraspinatus muscle, the EMG sensor will be placed 3–4 cm below and parallel to the scapular spine, over the infra-scapular fossa. For the upper trapezius, it will be placed at the midway between the spine on vertebra C7 and the acromion. Over the anterior deltoid, the EMG sensor will be placed at one-finger width (1–2 cm) below the acromion and lateral clavicle, whereas at the middle deltoid it will be placed halfway between its insertion and the acromion.⁹⁰ No reference electrode will be used since this sensor already uses a two-level single-differential method to minimise artefacts and baseline noise contamination through four-parallel bars with their centre 10 mm apart, and a signal bandwidth of 10–450 Hz. All EMG data will be recorded using Delsys EMGworks Acquisition software. The EMG signals will be preamplified at the skin surface (300× gain, common mode rejection ratio 92 dB at 60 Hz) at a sampling rate of 1926 samples/s. All electrode placements, the wireless communication and the signal quality will be verified by visual monitoring of signals at rest and during isometric contractions.⁹⁰ Raw EMG data will be stored on a computer for offline analysis. Prior to analysis, recorded signals will be bandpass-filtered (10–450 Hz, fourth-order zero-lag Butterworth digital filter), full-wave-rectified and smoothed using a root mean square (RMS) filter with a 0.25 s time window and 0.05 of window overlap. EMG amplitude data will then be normalised to a reference condition, where patients will raise their arm at 60° of scaption for 5 s, with no load. Two trials will be performed for each arm, and the average of the RMS values will be used for normalisation.

Global Rating of Change

Participants will be asked to evaluate the change in their condition from the initial physiotherapy session using a GRC question. The GRC is a reliable 15-point scale (ICC=0.90)^{65 91 92} designed to report changes in clinical status over time as the perception of outcome after treatment.^{65 91} Since patients generally feel satisfied with their improvements when reaching +4 GRC score,^{92 93} we determined a priori that participants who will rate their perceived recovery at +4 '*moderately better or greater*' will be categorised as having a successful outcome.^{30 33} Then, results from GRC will be dichotomised to GRC ≥+4 (improvement) or GRC <+4 (non-improvement).

Sample size

Sample size calculation is based on changes evidenced by the DASH scores for individuals with RCTe. According to sample size calculation (G*Power 3.1.9.2; $\alpha=0.05$, effect size=0.79, power (1- β)=0.82, SD=14.17 DASH points,⁵⁶ CID=12.4 DASH points),⁹⁴ a minimum of 22 patients are needed in each group. When adding an expected loss to follow-up of 15%, a total of 26 patients per group is required. Therefore, 52 patients with RCTe will be recruited. This sample size is sufficient to detect the CID between the two groups.

Recruitment of patients

Fifty-two participants will be recruited. This number is feasible as a recent study from our research team successfully recruited 30 individuals with RCTe over 6 months. Taking into consideration the dropouts, we believe it is possible to recruit 26 participants over the same period. Therefore, considering a recruitment rate of five participants per month, on average, all participants should be enrolled in less than 11 months.

Withdrawal of individual participants

Principles underlying 'intention-to-treat' analysis will be followed, meaning that every participant will be analysed according to the randomised treatment assignment. Therefore, non-compliance, protocol deviation and withdrawal will all be ignored in the primary analyses. All dropouts and their underlying reasons will be reported.⁹⁵ Additionally, 'per-protocol' analysis (ie, the analysis will be restricted to participants who adhered to the intervention as stipulated in the protocol) will also be performed. We believe that the combination of these statistical strategies will increase confidence in the study results. To ensure appropriate insight of mechanisms underlying changes in symptoms and function, only participants who completed evaluation at week 6 will be considered for the secondary outcomes. Any harm or unintended effects during the programmes will be recorded.

Data integrity and analysis

All collected data will be accessible only to the research team. All data will be kept for 5 years after the end of the study to ensure the completion of planned publications. After this period, all data will be destroyed.

Statistical analysis

Basic descriptive statistics (mean and SD) will be reported for each participant's characteristic and outcome. All data will be tested to check the distributional assumptions for the inferential statistical analyses. Baseline demographic data will be compared using independent samples t-test and χ^2 . If differences are seen in baseline characteristics, we will apply an analysis of covariance model to adjust group comparisons for confounding variables.

The added effects of KT on the DASH, BPI, WORC and muscle activity will be examined using a mixed design analysis of variance (ANOVA) model (groups [KT group, no KT group]) × evaluations [baseline, week 3, week 6, week 12, 6 months], while a three-way ANOVA for repeated measures (group × time × angle [for AHD] or plane of movement [for ROM]) will be performed for AHD and ROM. Bonferroni adjustments for multiple comparisons will be used, and effect sizes will be reported (η^2). The GRC will be compared across groups using a Fisher's exact probability test. The level of significance will be set at $p<0.05$ for all statistical analyses.

DISCUSSION

It is well reported that functional limitations associated with RCTe may remain for 12 months or more.¹¹ Personal, medical and socioeconomic impacts of RCTe are well known,¹²² 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-term and long-term effects when added to a rehabilitation programme, 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.

Strength and limitations of this study

To our knowledge, this RCT will be the first to assess the mid-term and long-term efficacy of KT added to a conventional rehabilitation programme for individuals with RCTe, addressing underlying variables that could help in understanding the benefits alleged for this method. Because our standardised rehabilitation programme parallels those in current existence in a clinical setting, it will be possible to directly apply the results to clinical practice. 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. Lastly, a series of measures such as a statistically justified sample size, methodological rigour, blinding, randomisation and adequate concealment of group allocation will be implemented in order to reduce the risk of bias.

On the other hand, we are aware of some limitations of this study. First, 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. Notwithstanding, a sham KT (placebo group) will not be included as previous literature has shown that establishing a sham taping protocol is problematic since KT applied over the skin could potentially produce some proprioceptive stimuli, which may act as confounding factor.^{38 39 41}

ETHICS

This RCT is registered on ClinicalTrials.gov (NCT02881021). Ethics approval was obtained from the Institutional Review Board of Quebec Rehabilitation

Institute (IRDPO) of the Centre Integrated University Health and Social Services.

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 data set will be accessible only to the research team and the 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.

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Contributors FCLO contributed to conception, design and preparation of the procedures, and data collection, and will conduct the recruitment, rehabilitation programme, 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. J-SR and LB contributed to conception, design and preparation of the procedures. Both authors will contribute to the analyses and interpretation of the data. J-SR, 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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