BMJ Open

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Journal:	*BMJ Open*
Manuscript ID	bmjopen-2017-017951
Article Type:	Protocol
Date Submitted by the Author:	30-May-2017
Complete List of Authors:	de Oliveira, Fabio; Universite Laval Faculte de medecine; CIRRIS - Center for Interdisciplinary Research in Rehabilitation and Social Integration, CIUSSS-CN de Fontenay, Benoît; CIRRIS - Center for Interdisciplinary Research in Rehabilitation and Social Integration, CIUSSS-CN Bouyer, Laurent; Universite Laval Faculte de medecine, Department of Rehabilitation; CIRRIS - Center for Interdisciplinary Research in Rehabilitation and Social Integration, CIUSSS-CN Desmeules, François; Université de Montreal, School of Rehabilitation; Maisonneuve-Rosemont Hospital Research Center, Orthopaedic Clinical Research Unit Roy, Jean-Sebastien; Universite Laval Faculte de medecine, Department of Rehabilitation; CIRRIS - Center for Interdisciplinary Research in Rehabilitation and Social Integration, CIUSSS-CN
Primary Subject Heading:	Rehabilitation medicine
Secondary Subject Heading:	Sports and exercise medicine, Occupational and environmental medicine
Keywords:	elastic tape, kinesiology taping, physiotherapy, rotator cuff, shoulder pain, tendon injuries

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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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- and long-term effects when combined to a rehabilitation program 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 program, 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 program.

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 60º of abduction, and muscle activation during arm elevation. The added effects of KT will be assessed through a 2-way ANOVA for repeated measures.

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.

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

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 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.
- 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 kinesiotaping to a conventional rehabilitation program for this population.
- Results will help to build a solid framework of evidence for the use of kinesiotaping 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 kinesiotaping (placebo group) will not be included as previous literature has shown that establishing a sham taping protocol is problematic. Kinesiotaping 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]

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

While some clinical trials have investigated the effects of KT on MSK disorders,[49-56] including shoulder injuries,[24, 26, 32, 38, 42, 47, 48, 57-61] systematic reviews have consistently pointed out that not enough evidence is available to conclude on the efficacy of KT on MSK conditions.[62-67] Recently, Desjardins-Charbonneau et al (2015)[62] examined six randomised controlled trials (RCT)[24-26, 42, 47, 58] (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 has 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.[26, 38, 42, 47] 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 program 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 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 program, as both groups will receive the same program that has been shown to be effective for this population.[27] However, based on findings of previous studies that have shown immediate and short-term effects of KT, the 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. This RCT is registered on ClinicalTrials.gov (NCT02881021).

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 (CIRRIS) 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

50%;[70] e) history of glenohumeral luxation in the last 12 months or any fracture to the shoulder girdle; f) shoulder pain reproduced by cervical movements; g) clinical sign of full-thickness tears of any RC muscles identified by lag signs:[71] 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).[72]

Randomization, blinding and allocation concealment

An independent assessor, not involved in data collection, will generate the randomization list using a computer random-number generator, prior to the initiation of the study. A block randomization 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, randomization 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 program (independent variable)

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

Sensorimotor training. Shoulder control exercises with progressive complexity in terms of movement plane, ROM, speed, and resistance will be the basis of this rehabilitation program. 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.[27, 28] 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).[28] When the exercises will be executed properly, participants will perform them at home, in three sets of 10 repetitions a day. Once participants reach adequate control during arm elevation, goal-directed reaching tasks will be performed to retrain movements requiring upper limb coordination. Work- 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, whether the ligamentous and capsular restraints are identified during the initial evaluation.[29, 30, 73-75] Once its necessity is confirmed, each technique will be performed three times for approximately 60-sec, with a between-set rest interval of 30-sec.[75]

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 30 seconds each.

Strengthening. Free weights, extremities weight, and resistance elastic tube will be used to strengthen RC muscles and scapular stabilizers.[27, 28] Exercises will progress according to the following phases: (a) phase 1, humerus in a neutral position to improve the depression function; (b) phase 2, ascending arm movements; (c) phase 3, higher-level exercises, including trunk strengthening.[30] The number of repetitions will vary from one to three sets of 10 to 30, progressing gradually. Patients will begin using a light resistance elastic band (yellow non-latex TheraBand™, Hygenic Corp, Akron, OH, USA),[76] 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 one week as requirements to advance to phase 3.

Patient education. General guidance will be 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 instructions regarding preferred shoulder positioning during sleep, work, and daily and sports activities.[77]

Kinesiotaping techniques

The skin will firstly be properly cleaned with isopropyl alcohol. Kinesio® Tex Classic will be applied using a combination of techniques designed for RCTe and underlying symptoms (Figure 1).[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.[24, 37] A second strip (I-shape) will be applied for functional correction, recommended for multiaxial shoulder instability, with severe tension (50–75%), from 7–10 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, 78] 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 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 (KTAI). As a fundamental practice, a gradual weaning will permit patients to readapt to the normal feedback condition.[79] 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 primary outcomes are the symptoms and functional limitations assessed using the *Disabilities of the Arm, Shoulder, and Hand (DASH)* questionnaire.[80] The secondary outcome is shoulder control, described as ROM, AHD and muscle activity. Global Rating of Change (GRC) will be also assessed.

Primary outcome

The DASH is a 30-item self-report questionnaire, designed to measure physical disability and symptoms of upper limbs disorders,[80-82] through a scale ranging from 0 to 100 (most severe disability).[81, 82] 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 (five items); and their impact on social activities, sleep, work, self-image (four items).[81] The DASH has an excellent reliability (ICC=0.96), it is

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

Secondary outcomes

Symptoms and Functional limitations

As DASH has few questions related to pain, the BPI,[84, 85] 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).[84, 85] In addition, as the DASH is not specific for the shoulder or for RC disorders, the WORC index[86] will also be filled out. The WORC[86] 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.[83, 86]

Range of motion (ROM)

Limited and painful ROM is often observed in patients with RCTe.[87, 88] In addition, KT has been shown to be effective in restoring pain-free ROM.[26, 42] 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]).[89] All measurements will be taken with patients standing. Participants will perform two repetitions for each movement. A 5-sec 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.

Acromiohumeral distance (AHD) and muscle activity

Kinesiotaping has been shown to lead to an immediate increase in AHD in healthy individuals.[46, 90] 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.[27, 91]

First, two measures of AHD with shoulder at rest will be taken using an ultrasound scanner (Logic *e*9, GE Healthcare, Milwaukee, WI, USA) with a 6-15MHz linear array probe (model ML6-15-D).[27, 91] Thereafter, participants will perform two vertical abductions (frontal planes) at 60º. During this arm elevation, muscle activity of four shoulder muscles (upper trapezius, infraspinatus,

middle and anterior deltoid) will be recorded using surface electromyography (Trigno™ Wireless EMG system, Delsys Inc., Boston, MA, USA). At the end-point of movement (60° of abduction), the ultrasonographic image of the AHD will be recorded. These measurements (muscle activity and US) 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 60º, 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 x 20 mm x 5 mm) will be placed on the muscle belly, parallel to the direction of the muscle fibers. The EMG-sensor placements will be defined in accordance with the Surface EMG for Noninvasive Assessment of Muscles (SENIAM) guidelines.[92] For the infraspinatus muscle, the EMG-sensor will be placed 3-4 cm below and parallel to the scapular spine, over the infrascapular 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 at halfway between its insertion and the acromion.[92] No reference electrode will be used since this sensor already uses a 2-level single-differential method to minimize artifacts and baseline noise contamination through 4-parallel bars with their center 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 pre-amplified at the skin surface (300x gain, common mode rejection ratio [CMRR] 92dB at 60Hz) 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.[93] Raw EMG data will be stored on a computer for offline analysis. Prior to analysis, recorded signals will be band-pass 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-sec time-window and 0.05 of window overlap. EMG

amplitude data will then be normalized to a reference condition, where patients will raise their arm at 60º of scaption for 5-sec, with no load. Two trials will be performed for each arm, and the average of the RMS values will be used for normalization.

Global Rating of Change (GRC)

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-points scale (ICC = 0.90),[69, 94, 95] designed to report changes in clinical status over time as the perception of outcome after treatment.[69, 94] Since patients generally feel satisfied with their improvements when reaching +4 GRC score,[95, 96] we determined a priori that participants who will rate their perceived recovery at +4 *"moderately better or greater"* will be categorized as having a successful outcome.[27, 30] Then, results from GRC will be dichotomized 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; α=0.05, effect size=0.79, power [1-β]=0.82, SD=14.17 DASH points,[48] CID=12.4 DASH points),[97] 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 six 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, in 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 randomized treatment assignment. Therefore, noncompliance, protocol deviation, and withdrawal will all be ignored in the primary analyses. All dropouts and their underlying reasons will be reported.[98] Additionally, "per-protocol" analysis (i.e., the analysis will be restricted to participants who adhered perfectly 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 programs will be recorded.

Data integrity and analysis

All collected data will be accessible only to the research team for audit purposes. All data will be kept for five 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 standard deviation) 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 chi-square. If differences are seen in baseline characteristics, we will apply an ANCOVA 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 3-way ANOVA for repeated measures (Group x Time x 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 also be reported ($\eta 2$). The GRC will be compared across groups using a Fischer'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 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.

Funding:

This work was supported by the Coordenação de Aperfeiçoamento de Pessoal de Nível Superior (CAPES). FCLO receives a doctoral scholarship from the Brazilian Government through the Science without Borders program in association with the Coordenação de Aperfeiçoamento de Pessoal de Nível Superior – CAPES. JSR and FD are supported by salary awards from the Fonds de Recherche Québec-Santé (FRQS) and the Canadian Institutes of Health Research (CIHR).

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).

REFERENCES

1. Struyf, F., et al., *A Multivariable Prediction Model for the Chronification of Non-traumatic Shoulder Pain: A Systematic Review.* Pain Physician, 2016. **19**(2):1-10.
2. Luime, J.J., et al., *Prevalence and incidence of shoulder pain in the general population; a systematic review.* Scand J Rheumatol, 2004. **33**(2):73-81.
3. Peek, A.L., C. Miller, and N.R. Heneghan, *Thoracic manual therapy in the management of non-specific shoulder pain: a systematic review.* J Man Manip Ther, 2015. **23**(4):176-87.
4. Chard, M.D., et al., *Shoulder disorders in the elderly: a community survey.* Arthritis Rheum, 1991. **34**(6):766-9.
5. van der Windt, D.A., et al., *Shoulder disorders in general practice: incidence, patient characteristics, and management.* Ann Rheum Dis, 1995. **54**(12):959-64.
6. van der Windt, D.A., et al., *Shoulder disorders in general practice: prognostic indicators of outcome.* Br J Gen Pract, 1996. **46**(410):519-23.
7. Andres, B.M. and G.A. Murrell, *Treatment of tendinopathy: what works, what does not, and what is on the horizon.* Clin Orthop Relat Res, 2008. **466**(7):1539-54.
8. Desmeules, F., et al., *The efficacy of therapeutic ultrasound for rotator cuff tendinopathy: A systematic review and meta-analysis.* Phys Ther Sport, 2015. **16**(3):276-84.
9. Hanratty, C.E., et al., *The effectiveness of physiotherapy exercises in subacromial impingement syndrome: a systematic review and meta-analysis.* Semin Arthritis Rheum, 2012. **42**(3):297-316.
10. Littlewood, C., et al., *Exercise for rotator cuff tendinopathy: a systematic review.* Physiotherapy, 2012. **98**(2):101-9.
11. van der Heijden, G.J., *Shoulder disorders: a state-of-the-art review.* Baillieres Clin Rheumatol, 1999. **13**(2):287-309.
12. Bigliani, L.U. and W.N. Levine, *Subacromial impingement syndrome.* J Bone Joint Surg Am, 1997. **79**(12):1854-68.
13. Neer, C.S., 2nd, *Impingement lesions.* Clin Orthop Relat Res, 1983(173):70-7.
14. de Witte, P.B., et al., *Study protocol subacromial impingement syndrome: the identification of pathophysiologic mechanisms (SISTIM).* BMC Musculoskelet Disord, 2011. **12**:282.
15. Lopes, A.D., et al., *Visual scapular dyskinesis: kinematics and muscle activity alterations in patients with subacromial impingement syndrome.* Arch Phys Med Rehabil, 2015. **96**(2):298-306.
16. Ludewig, P.M. and T.M. Cook, *Alterations in shoulder kinematics and associated muscle activity in people with symptoms of shoulder impingement.* Phys Ther, 2000. **80**(3):276-91.
17. McClure, P.W., L.A. Michener, and A.R. Karduna, *Shoulder function and 3-dimensional scapular kinematics in people with and without shoulder impingement syndrome.* Phys Ther, 2006. **86**(8):1075-90.
18. Michener, L.A., P.W. McClure, and A.R. Karduna, *Anatomical and biomechanical mechanisms of subacromial impingement syndrome.* Clin Biomech, 2003. **18**(5):369-79.
19. Seitz, A.L., et al., *Mechanisms of rotator cuff tendinopathy: intrinsic, extrinsic, or both?* Clin Biomech, 2011. **26**(1):1-12.
20. Umer, M., I. Qadir, and M. Azam, *Subacromial impingement syndrome.* Orthop Rev, 2012. **4**(2):e18.
21. Myers, J.B., et al., *Rotator cuff coactivation ratios in participants with subacromial impingement syndrome.* Journal of Science and Medicine in Sport, 2009. **12**(6):603-608.
22. Myers, J.B., C.A. Wassinger, and S.M. Lephart, *Sensorimotor contribution to shoulder stability: effect of injury and rehabilitation.* Man Ther, 2006. **11**(3):197-201.
23. Zanca, G.G., B. Gruninger, and S.M. Mattiello, *Effects of Kinesio taping on scapular kinematics of overhead athletes following muscle fatigue.* J Electromyogr Kinesiol, 2015.

24. Djordjevic, O.C., et al., *Mobilization with movement and kinesiotaping compared with a supervised exercise program for painful shoulder: results of a clinical trial.* J Manipulative Physiol Ther, 2012. **35**(6):454-63.
25. Kaya Karas, O., et al., *The effects of Kinesio Taping® on activity and participation in children with unilateral spastic cerebral palsy: Two blind-randomized control trials.* Developmental Medicine and Child Neurology, 2014. **56**:63-64.
26. Şimşek, H.H., et al., *Does Kinesio taping in addition to exercise therapy improve the outcomes in subacromial impingement syndrome? A randomized, double-blind, controlled clinical trial.* Acta Orthop Traumatol Turc, 2013. **47**(2):104-10.
27. Savoie, A., et al., *Effects of a movement training oriented rehabilitation program on symptoms, functional limitations and acromiohumeral distance in individuals with subacromial pain syndrome.* Man Ther, 2015. **20**(5):703-708.
28. Roy, J.S., et al., *Effect of motor control and strengthening exercises on shoulder function in persons with impingement syndrome: a single-subject study design.* Man Ther, 2009. **14**(2):180-8.
29. Michener, L.A., M.K. Walsworth, and E.N. Burnet, *Effectiveness of rehabilitation for patients with subacromial impingement syndrome: a systematic review.* J Hand Ther, 2004. **17**(2):152-164.
30. Tate, A.R., et al., *Comprehensive impairment-based exercise and manual therapy intervention for patients with subacromial impingement syndrome: a case series.* J Orthop Sports Phys Ther, 2010. **40**(8):474-93.
31. Mottram, S.L., *Dynamic stability of the scapula.* Man Ther, 1997. **2**(3):123-131.
32. Cubala, A., et al., *Use of the Kinesio Taping method in painful shoulder syndrome.* Medical and Biological Sciences, 2012. **26**(4):71-76.
33. Aarseth, L.M., et al., *Kinesio Tape and Shoulder-Joint Position Sense.* J Athl Train, 2015. **50**(8):785-91.
34. Aguilar-Ferrándiz, M.E., et al., *A randomized controlled trial of a mixed Kinesio taping-compression technique on venous symptoms, pain, peripheral venous flow, clinical severity and overall health status in postmenopausal women with chronic venous insufficiency.* Clin Rehabil, 2014. **28**(1):69-81.
35. Artioli, D. and G. Bertolini, *Kinesio taping: application and results on pain: systematic review.* Fisioter. Pesqui, 2014. **21**(1):94-99.
36. Halseth, T., et al., *The effects of kinesio taping on proprioception at the ankle.* J Sports Sci Med, 2004. **3**(1):1-7.
37. Kase, K., J. Wallis, and T. Kase, *Clinical therapeutic applications of the Kinesio taping method*. 1st ed. 2003, Tokyo.
38. Kaya, E., M. Zinnuroglu, and I. Tugcu, *Kinesio taping compared to physical therapy modalities for the treatment of shoulder impingement syndrome.* Clin Rheumatol, 2011. **30**(2):201-7.
39. Murray, H. and L. Husk, *Effect of kinesiotaping on proprioception in the ankle.* J Orthop Sports Phys Ther, 2001(31):A37.
40. Oliveira, F.C., *Uma fita: Por quê e para que usam fitas coladas na pele?*, in *Revista Tênis*. 2013: São Paulo.
41. Paoloni, M., et al., *Kinesio Taping applied to lumbar muscles influences clinical and electromyographic characteristics in chronic low back pain patients.* Eur J Phys Rehabil Med, 2011. **47**(2):237-44.
42. Thelen, M.D., J.A. Dauber, and P.D. Stoneman, *The clinical efficacy of kinesio tape for shoulder pain: a randomized, double-blinded, clinical trial.* J Orthop Sports Phys Ther, 2008. **38**(7):389-95.
43. Drouin, J.L., et al., *The effects of kinesiotape on athletic-based performance outcomes in healthy, active individuals: a literature synthesis.* J Can Chiropr Assoc, 2013. **57**(4):356-65.
44. Lin, J.J., C.J. Hung, and P.L. Yang, *The effects of scapular taping on electromyographic muscle activity and proprioception feedback in healthy shoulders.* J Orthop Res, 2011. **29**(1):53-7.

45. Cools, A.M., et al., *Does taping influence electromyographic muscle activity in the scapular rotators in healthy shoulders?* Man Ther, 2002. **7**(3):154-62.
46. Luque-Suarez, A., et al., *Short term effects of kinesiotaping on acromiohumeral distance in asymptomatic subjects: a randomised controlled trial.* Man Ther, 2013. **18**(6):573-7.
47. Shakeri, H., et al., *Clinical effectiveness of kinesiological taping on pain and pain-free shoulder range of motion in patients with shoulder impingement syndrome: a randomized, double blinded, placebo-controlled trial.* Int J Sports Phys Ther, 2013. **8**(6):800-10.
48. Shakeri, H., et al., *Therapeutic Effect of Kinesio-taping on Disability of Arm, Shoulder, and Hand in Patients with Subacromial Impingement Syndrome: A Randomized Clinical Trial.* J Nov Physiother, 2013. **3**(4):1-5.
49. Kaplan, Ş., et al., *Short-Term Effects of Kinesio Taping in Women with Pregnancy-Related Low Back Pain: A Randomized Controlled Clinical Trial.* Med Sci Monit, 2016. **22**:1297-301.
50. El-Abd, A.M., A.R. Ibrahim, and H.M. Hel-Hafez, *Efficacy of kinesio taping versus postural correction exercises on pain intensity and axioscapular muscles activation in mechanical neck dysfunction: a randomized blinded clinical trial.* J Sports Med Phys Fitness, 2016.
51. Coskun Benlidayi, I., et al., *Kinesio Taping for temporomandibular disorders: Single-blind, randomized, controlled trial of effectiveness.* J Back Musculoskelet Rehabil, 2016.
52. Kelle, B., R. Güzel, and H. Sakallı, *The effect of Kinesio taping application for acute non-specific low back pain: A randomized controlled clinical trial.* Clin Rehabil, 2015. **30**(10):997-1003.
53. Cho, H.-y., et al., *Kinesio taping improves pain, range of motion, and proprioception in older patients with knee osteoarthritis: a randomized controlled trial.* Am J Phys Med Rehabil, 2015. **94**(3):192-200.
54. Saavedra-Hernández, M., et al., *Short-term effects of kinesio taping versus cervical thrust manipulation in patients with mechanical neck pain: a randomized clinical trial.* J Orthop Sports Phys Ther, 2012. **42**(8):724-30.
55. Castro-Sánchez, A.M., et al., *Kinesio Taping reduces disability and pain slightly in chronic non-specific low back pain: a randomised trial.* J Physiother, 2012. **58**(2):89-95.
56. González-Iglesias, J., et al., *Short-term effects of cervical kinesio taping on pain and cervical range of motion in patients with acute whiplash injury: a randomized clinical trial.* J Orthop Sports Phys Ther, 2009. **39**(7):515-21.
57. Arab, A.M., *A Randomized Clinical Trial of Kinesio-Taping on DASH in Patients with Subacromial Impingement Syndrome.* J Nov Physiother, 2013. **3**(4):169.
58. Hsu, Y.H., et al., *The effects of taping on scapular kinematics and muscle performance in baseball players with shoulder impingement syndrome.* J Electromyogr Kinesiol, 2009. **19**(6):1092-9.
59. Kim, S.Y., et al., *Kinesio Taping improves shoulder internal rotation and the external/internal rotator strength ratio in patients with rotator cuff tendinitis.* Isokinetics and Exercise Science, 2014. **22**:259-263.
60. Oliveira, V.M.A.d., et al., *Efeito do Kinesio Taping na dor e discinesia escapular em atletas com síndrome do impacto do ombro.* Revista Dor, 2013. **14**:27-30.
61. Shaheen, A.F., A.M. Bull, and C.M. Alexander, *Rigid and Elastic taping changes scapular kinematics and pain in subjects with shoulder impingement syndrome; an experimental study.* J Electromyogr Kinesiol, 2015. **25**(1):84-92.
62. Desjardins-Charbonneau, A., et al., *The Efficacy of Taping for Rotator Cuff Tendinopathy: A Systematic Review and Meta-Analysis.* Int J Sports Phys Ther, 2015. **10**(4):420-33.
63. Montalvo, A.M., E.L. Cara, and G.D. Myer, *Effect of kinesiology taping on pain in individuals with musculoskeletal injuries: systematic review and meta-analysis.* Phys Sportsmed, 2014. **42**(2):48-57.
64. Morris, D., et al., *The clinical effects of Kinesio(R) Tex taping: A systematic review.* Physiother Theory Pract, 2013. **29**(4):259-70.

65. Mostafavifar, M., J. Wertz, and J. Borchers, *A systematic review of the effectiveness of kinesio taping for musculoskeletal injury.* Phys Sportsmed, 2012. **40**(4):33-40.
66. Parreira, P.d.C.S., et al., *Current evidence does not support the use of Kinesio Taping in clinical practice: a systematic review.* J Physiother, 2014. **60**(1):31-9.
67. Williams, S., et al., *Kinesio taping in treatment and prevention of sports injuries: a meta-analysis of the evidence for its effectiveness.* Sports Med, 2012. **42**(2):153-64.
68. Alqunaee, M., R. Galvin, and T. Fahey, *Diagnostic accuracy of clinical tests for subacromial impingement syndrome: a systematic review and meta-analysis.* Arch Phys Med Rehabil, 2012. **93**(2):229-36.
69. Michener, L.A., et al., *Reliability and diagnostic accuracy of 5 physical examination tests and combination of tests for subacromial impingement.* Arch Phys Med Rehabil, 2009. **90**(11):1898-903.
70. Siegel, L.B., N.J. Cohen, and E.P. Gall, *Adhesive capsulitis: a sticky issue.* Am Fam Physician, 1999. **59**(7):1843-52.
71. Hertel, R., et al., *Lag signs in the diagnosis of rotator cuff rupture.* J Shoulder Elbow Surg, 1996. **5**(4):307-13.
72. Miller, C.A., G.A. Forrester, and J.S. Lewis, *The validity of the lag signs in diagnosing full-thickness tears of the rotator cuff: a preliminary investigation.* Arch Phys Med Rehabil, 2008. **89**(6):1162-8.
73. Mulligan, B., *Manual Therapy: Nags, snags*. 4th Edition ed. MWMs etc. 1999: Plane View Services.
74. Teys, P., L. Bisset, and B. Vicenzino, *The initial effects of a Mulligan's mobilization with movement technique on range of movement and pressure pain threshold in pain-limited shoulders.* Man Ther, 2008. **13**(1):37-42.
75. Conroy, D.E. and K.W. Hayes, *The effect of joint mobilization as a component of comprehensive treatment for primary shoulder impingement syndrome.* J Orthop Sports Phys Ther, 1998. **28**(1):3-14.
76. Andersen, L.L., et al., *Validity and reliability of elastic resistance bands for measuring shoulder muscle strength.* Scand J Med Sci Sports, 2016.
77. McClure, P.W., et al., *Shoulder function and 3-dimensional kinematics in people with shoulder impingement syndrome before and after a 6-week exercise program.* Phys Ther, 2004. **84**(9):832-48.
78. Kase, K., H. Tatyusuki, and O. Tomoki, *KinesioTM taping perfect manual*. 2nd ed. Development of KinesioTM tape. 1996, Tokyo.
79. Goldwasser, R.S. and C.M. David, *Weaning from mechanical ventilation: let's perform a strategy.* Rev Bras Ter Intensiva, 2007. **19**(1):107-12.
80. Hudak, P.L., P.C. Amadio, and C. Bombardier, *Development of an upper extremity outcome measure: the DASH (disabilities of the arm, shoulder and hand) [corrected]. The Upper Extremity Collaborative Group (UECG).* Am J Ind Med, 1996. **29**(6):602-8.
81. Durand, M.J., et al., *The cross-cultural adaptation of the DASH questionnaire in Canadian French.* J Hand Ther, 2005. **18**(1):34-9.
82. Roy, J.S., J.C. MacDermid, and L.J. Woodhouse, *Measuring shoulder function: a systematic review of four questionnaires.* Arthritis Rheum, 2009. **61**(5):623-32.
83. St-Pierre, C., et al., *Reliability, validity, and responsiveness of a Canadian French adaptation of the Western Ontario Rotator Cuff (WORC) index.* Journal of Hand Therapy, 2015. **28**(3):292-299.
84. Tan, G., et al., *Validation of the Brief Pain Inventory for chronic nonmalignant pain.* J Pain, 2004. **5**(2):133-7.
85. Tatham, B., et al., *The efficacy of exercise therapy in reducing shoulder pain related to breast cancer: a systematic review.* Physiother Can, 2013. **65**(4):321-30.

86. Kirkley, A., C. Alvarez, and S. Griffin, *The development and evaluation of a disease-specific quality-of-life questionnaire for disorders of the rotator cuff: The Western Ontario Rotator Cuff Index.* Clin J Sport Med, 2003. **13**(2):84-92.
87. Kocyigit, F., et al., *Kinesio taping or just taping in shoulder subacromial impingement syndrome? A randomized, double-blind, placebo-controlled trial.* Physiother Theory Pract, 2016. **32**(7):501-8.
88. Dejaco, B., et al., *Eccentric versus conventional exercise therapy in patients with rotator cuff tendinopathy: a randomized, single blinded, clinical trial.* Knee Surg Sports Traumatol Arthrosc, 2016.
89. Kolber, M.J. and W.J. Hanney, *The reliability and concurrent validity of shoulder mobility measurements using a digital inclinometer and goniometer: a technical report.* Int J Sports Phys Ther, 2012. **7**(3):306-13.
90. Harput, G., et al., *Acute effects of scapular kinesiotaping on shoulder rotator strength, range of motion and acromiohumeral distance in asymptomatic overhead athletes.* J Sports Med Phys Fitness, 2016.
91. Desmeules, F., et al., *Acromio-humeral distance variation measured by ultrasonography and its association with the outcome of rehabilitation for shoulder impingement syndrome.* Clin J Sport Med, 2004. **14**(4):197-205.
92. Hermens, H.J., et al., *Development of recommendations for SEMG sensors and sensor placement procedures.* J Electromyogr Kinesiol, 2000. **10**(5):361-74.
93. Roy, J.S., H. Moffet, and B.J. McFadyen, *Upper limb motor strategies in persons with and without shoulder impingement syndrome across different speeds of movement.* Clinical Biomechanics, 2008. **23**(10):1227-1236.
94. Jaeschke, R., J. Singer, and G.H. Guyatt, *Measurement of health status. Ascertaining the minimal clinically important difference.* Control Clin Trials, 1989. **10**(4):407-15.
95. Kamper, S.J., C.G. Maher, and G. Mackay, *Global rating of change scales: a review of strengths and weaknesses and considerations for design.* J Man Manip Ther, 2009. **17**(3):163-70.
96. Hung, C.J., et al., *Scapular kinematics and impairment features for classifying patients with subacromial impingement syndrome.* Man Ther, 2010. **15**(6):547-51.
97. Faul, F., et al., *G*Power 3: a flexible statistical power analysis program for the social, behavioral, and biomedical sciences.* Behav Res Methods, 2007. **39**(2):175-91.
98. Gupta, S.K., *Intention-to-treat concept: A review.* Perspect Clin Res, 2011. **2**(3):109-12.

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 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.
- 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 kinesiotaping to a conventional rehabilitation program for this population.
- Results will help to build a solid framework of evidence for the use of kinesiotaping 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 kinesiotaping (placebo group) will not be included as previous literature has shown that establishing a sham taping protocol is problematic. Kinesiotaping applied over the skin could potentially produce some proprioceptive stimuli which may act as confounding factor.

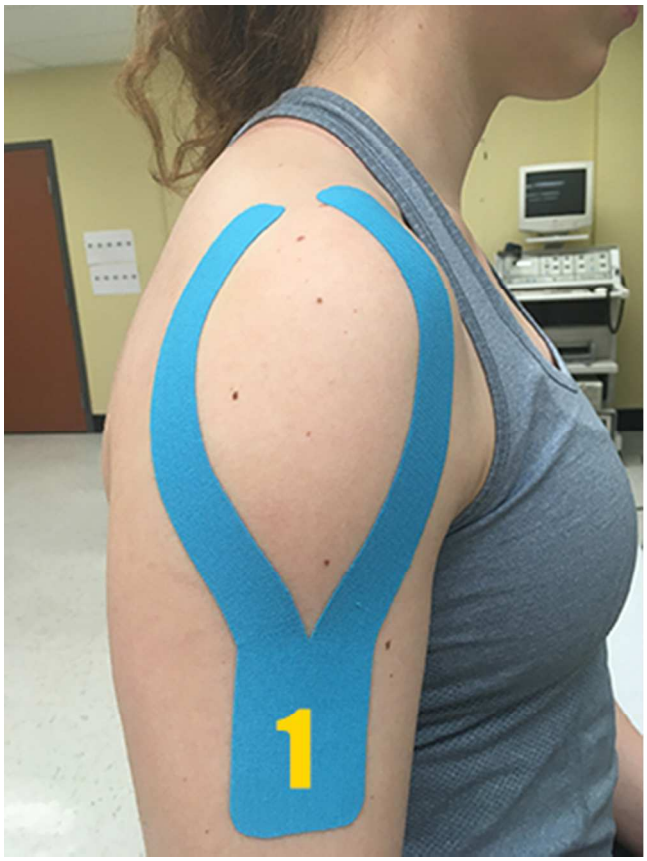
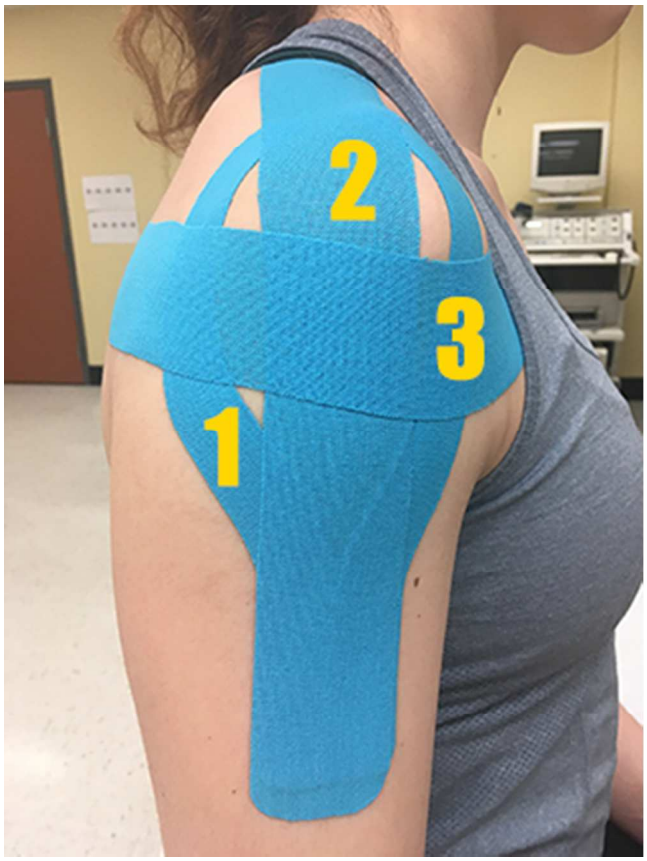


Figure 1. Kinesiotaping application. First strip (1: Y-shape surrounding deltoid muscles), second strip (2: I-shape in functional correction for multiaxial shoulder instability over the glenohumeral joint, supraspinatus, trapezius, and middle deltoid muscles), and third strip (3: I-shape in mechanical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

112x149mm (72 x 72 DPI)

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)



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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).

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)	--

Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	9 - 10
	6b	Explanation for choice of comparators	9
Objectives	7	Specific objectives or hypotheses	10
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	11
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	11
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	11, 12
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	12 - 14
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	---
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	--
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	13 - 14
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	14 - 17
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	11

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	17
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	18
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	12
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	12
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	12
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	12
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	12
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	14 - 17
	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	18

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	18
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	18
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	18
	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)	18
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	---
	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	18
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	18
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	18
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	21
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)	21

Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	attached
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	---
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	21
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	05
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	21
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	--
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	21
	31b	Authorship eligibility guidelines and any intended use of professional writers	5
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	--
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	attached
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	--

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

BMJ Open

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

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2017-017951.R1
Article Type:	Protocol
Date Submitted by the Author:	19-Jul-2017
Complete List of Authors:	de Oliveira, Fabio; Universite Laval Faculte de medecine; CIRRIS - Center for Interdisciplinary Research in Rehabilitation and Social Integration, CIUSSS-CN de Fontenay, Benoît; CIRRIS - Center for Interdisciplinary Research in Rehabilitation and Social Integration, CIUSSS-CN Bouyer, Laurent; Universite Laval Faculte de medecine, Department of Rehabilitation; CIRRIS - Center for Interdisciplinary Research in Rehabilitation and Social Integration, CIUSSS-CN Desmeules, François; Université de Montreal, School of Rehabilitation; Maisonneuve-Rosemont Hospital Research Center, Orthopaedic Clinical Research Unit Roy, Jean-Sebastien; Universite Laval Faculte de medecine, Department of Rehabilitation; CIRRIS - Center for Interdisciplinary Research in Rehabilitation and Social Integration, CIUSSS-CN
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

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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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- and long-term effects when combined to a rehabilitation program 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 program, 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 program. 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-months. Primary outcomes will be symptoms and functional limitations assessed by the DASH questionnaire. Secondary outcomes will include shoulder ROM, AHD at rest and at 60º of abduction, and muscle activation during arm elevation. The added effects of KT will be assessed through a 2-way ANOVA for repeated measures.

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 will be disseminated through international publications in peer-reviewed journals, in addition to international conference presentations.

Trial registration number: Protocol registered at ClinicalTrials.gov (NCT02881021) on August 25, 2016. The World Health Organization Trial Registration Data Set can also be found as a supplementary file.

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

Strengths and limitations of this study

- 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.

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 etiological 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 stabilizing 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 programs include interventions such as mobilisation with movements (MWM)[27] 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 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.[36, 37] The KT is also argued to contribute to pain relief by producing increased stimulation of cutaneous mechanoreceptors,[38] that 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 mechanism 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 (2015)[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 program 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 program, as both groups will receive the same program 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 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 (CIRRIS) 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

(*sensitivity* 0.74, *specificity* 0.57) impingement signs;[64] 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: 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 50%;[66] e) history of glenohumeral luxation in the last 12 months or any fracture to the shoulder girdle; f) shoulder pain reproduced by cervical movements; g) clinical sign of full-thickness tears of any RC muscles identified by lag signs:[67] 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]

Randomization, blinding and allocation concealment

An independent assessor, not involved in data collection, will generate the randomization list using a computer random-number generator, prior to the initiation of the study. A block randomization 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, randomization 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 program (independent variable)

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

Additionally, the participants will receive a list of four (4) exercises, based on their individual needs, to be performed at home without supervision. The rehabilitation program 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 programs.

Sensorimotor training. Shoulder control exercises with progressive complexity in terms of movement plane, ROM, speed, and resistance will be the basis of this rehabilitation program. 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- 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 60-sec, with a between-set rest interval of 30-sec.[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 30 seconds each.

Strengthening. Free weights, extremities weight, and resistance elastic tube will be used to strengthen RC muscles and scapular stabilizers.[30, 69] Exercises will progress

according to the following phases: (a) phase 1, humerus in a neutral position to improve the depression function; (b) phase 2, ascending arm movements; (c) phase 3, higher-level exercises, including trunk strengthening.[33] The number of repetitions will vary from one to three sets of 10 to 30, progressing gradually. Patients will begin using a light resistance elastic band (yellow non-latex TheraBand™, Hygenic Corp, Akron, OH, 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 one 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]

Kinesiotaping techniques

The skin will firstly 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 7–10 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 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 (KTAI). 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 *Disabilities of the Arm, Shoulder, and Hand (DASH)* questionnaire.[77] The secondary outcomes are the BPI, WORC index, and shoulder control, described as ROM, AHD and muscle activity. Global Rating of Change (GRC) will be also 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 (five items); and their impact on social activities, sleep, work, self-image (four items).[78] The DASH has an excellent reliability (ICC=0.96), it is highly responsive following rehabilitation interventions for individuals with RCTe (effect size: 1.06, standardized response mean [SRM]: 1.08),[31] has a minimal detectable change (MDC) of 11 points and a clinically important difference (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 index[82] 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 (ROM)

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-sec 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.

Acromiohumeral distance (AHD) and muscle activity

Kinesiotaping 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 (Logic *e*9, GE Healthcare, Milwaukee, WI, USA) with a 6-15MHz linear array probe (model ML6-15-D).[30, 88] Thereafter, participants will perform two vertical abductions (frontal planes) at 60º. During this arm elevation, muscle activity of four shoulder muscles (upper trapezius, infraspinatus, middle and anterior deltoid) will be recorded using surface electromyography (Trigno™ Wireless EMG system, Delsys

Inc., Boston, MA, USA). At the end-point of movement (60° of abduction), the ultrasonographic image of the AHD will be recorded. These measurements (muscle activity and US) 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 60º, 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 x 20 mm x 5 mm) will be placed on the muscle belly, parallel to the direction of the muscle fibers. The EMG-sensor placements will be defined in accordance with the Surface EMG for Noninvasive Assessment of Muscles (SENIAM) guidelines.[89] For the infraspinatus muscle, the EMG-sensor will be placed 3-4 cm below and parallel to the scapular spine, over the infrascapular 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 at halfway between its insertion and the acromion.[90] No reference electrode will be used since this sensor already uses a 2-level single-differential method to minimize artifacts and baseline noise contamination through 4-parallel bars with their center 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 pre-amplified at the skin surface (300x gain, common mode rejection ratio [CMRR] 92dB at 60Hz) 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 band-pass 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-sec time-window and 0.05 of window overlap. EMG amplitude data will then be normalized to a reference condition, where patients will raise their arm at 60º of scaption for 5-sec, with no load. Two trials will be performed for each arm, and the average of the RMS values will be used for normalization.

Global Rating of Change (GRC)

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-points 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 categorized as having a successful outcome.[30, 33] Then, results from GRC will be dichotomized 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; α=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 six 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, in 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 randomized treatment assignment. Therefore, noncompliance, 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 (i.e., 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 programs will be recorded.

Data integrity and analysis

All collected data will be accessible only to the research team. All data will be kept for five 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 standard deviation) 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 chi-square. If differences are seen in baseline characteristics, we will apply an ANCOVA 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 3-way ANOVA for repeated measures (Group x Time x 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

(η2). The GRC will be compared across groups using a Fischer'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 socio-economic impacts of RCTe are well known,[1, 22] 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.

Strength and limitations of this study

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. Because our standardized rehabilitation program 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 rigor, 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 (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. 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

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 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.

Funding:

This work was supported by the Coordenação de Aperfeiçoamento de Pessoal de Nível Superior (CAPES). FCLO receives a doctoral scholarship from the Brazilian Government through the Science without Borders program in association with the Coordenação de Aperfeiçoamento de Pessoal de Nível Superior – CAPES. JSR and FD are supported by salary awards from the Fonds de Recherche Québec-Santé (FRQS) and the Canadian Institutes of Health Research (CIHR).

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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REFERENCES

1. Struyf F, Geraets J, Noten S, Meeus M, Nijs J. A Multivariable Prediction Model for the Chronification of Non-traumatic Shoulder Pain: A Systematic Review. Pain Physician, 2016; 19(2):1-10.
2. Luime JJ, Koes BW, Hendriksen IJ, Burdorf A, Verhagen AP, Miedema HS, Verhaar JA. Prevalence and incidence of shoulder pain in the general population; a systematic review. Scand J Rheumatol, 2004; 33(2):73-81.
3. Peek AL, Miller C, Heneghan NR. Thoracic manual therapy in the management of non-specific shoulder pain: a systematic review. J Man Manip Ther, 2015; 23(4):176-87.
4. Chard MD, Hazleman R, Hazleman BL, King RH, Reiss BB. Shoulder disorders in the elderly: a community survey. Arthritis Rheum, 1991; 34(6):766-9.
5. van der Windt DA, Koes BW, de Jong BA, Bouter LM. Shoulder disorders in general practice: incidence, patient characteristics, and management. Ann Rheum Dis, 1995; 54(12):959-64.
6. van der Windt DA, Koes BW, Boeke AJ, Deville W, de Jong BA, Bouter LM. Shoulder disorders in general practice: prognostic indicators of outcome. Br J Gen Pract, 1996; 46(410):519-23.
7. Andres BM, Murrell GA. Treatment of tendinopathy: what works, what does not, and what is on the horizon. Clin Orthop Relat Res, 2008; 466(7):1539-54.
8. Desmeules F, Boudreault J, Roy JS, Dionne C, Fremont P, MacDermid JC. The efficacy of therapeutic ultrasound for rotator cuff tendinopathy: A systematic review and meta-analysis. Phys Ther Sport, 2015; 16(3):276-84.
9. Hanratty CE, McVeigh JG, Kerr DP, Basford JR, Finch MB, Pendleton A, Sim J. The effectiveness of physiotherapy exercises in subacromial impingement syndrome: a systematic review and meta-analysis. Semin Arthritis Rheum, 2012; 42(3):297-316.
10. Littlewood C, Ashton J, Chance-Larsen K, May S, Sturrock B. Exercise for rotator cuff tendinopathy: a systematic review. Physiotherapy, 2012; 98(2):101-9.
11. van der Heijden GJ. Shoulder disorders: a state-of-the-art review. Baillieres Clin Rheumatol, 1999; 13(2):287-309.
12. Bigliani LU, Levine WN. Subacromial impingement syndrome. J Bone Joint Surg Am, 1997; 79(12):1854-68.
13. Neer CS 2nd. Impingement lesions. Clin Orthop Relat Res, 1983; (173):70-7.
14. Frizziero A, Vittadini F, Gasparre G, Masiero S. Impact of oestrogen deficiency and aging on tendon: concise review. Muscles Ligaments Tendons J, 2014; 4(3):324-8.
15. Oliva F, Piccirilli E, Berardi AC, Frizziero A, Tarantino U, Maffulli N. Hormones and tendinopathies: the current evidence. Br Med Bull, 2016; 117(1):39-58
16. de Witte PB, Nagels J, van Arkel ER, Visser CP, Nelissen RG, de Groot JH. Study protocol subacromial impingement syndrome: the identification of pathophysiologic mechanisms (SISTIM). BMC Musculoskelet Disord, 2011; 12:282.
17. Lopes AD, Timmons MK, Grover M, Ciconelli RM, Michener LA. Visual scapular dyskinesis: kinematics and muscle activity alterations in patients with subacromial impingement syndrome. Arch Phys Med Rehabil, 2015; 96(2):298-306.
18. Ludewig PM, Cook TM. Alterations in shoulder kinematics and associated muscle activity in people with symptoms of shoulder impingement. Phys Ther, 2000; 80(3):276-91.
19. McClure PW, Michener LA, Karduna AR. Shoulder function and 3-dimensional scapular kinematics in people with and without shoulder impingement syndrome. Phys Ther, 2006; 86(8):1075-90.

20. Michener LA, McClure PW, Karduna AR. Anatomical and biomechanical mechanisms of subacromial impingement syndrome. Clin Biomech (Bristol, Avon), 2003; 18(5):369-79.

21. Seitz AL, McClure PW, Finucane S, Boardman ND 3rd, Michener LA. Mechanisms of rotator cuff tendinopathy: intrinsic, extrinsic, or both? Clin Biomech (Bristol, Avon), 2011; 26(1):1-12.

22. de Oliveira FCL, Bouyer LJ, Ager AL, Roy JS. Electromyographic analysis of rotator cuff muscles in patients with rotator cuff tendinopathy: A systematic review. J Electromyogr Kinesiol, 2017; 35:100-14.

23. Umer M, Qadir I, Azam M. Subacromial impingement syndrome. Orthop Rev (Pavia), 2012; 4(2):e18.

24. Myers JB, Hwang JH, Pasquale MR, Blacburn JT, Lephart SM. Rotator cuff coactivation ratios in participants with subacromial impingement syndrome. Journal of Science and Medicine in Sport, 2009; 12(6):603-8.

25. Myers JB, Wassinger CA, Lephart SM. Sensorimotor contribution to shoulder stability: effect of injury and rehabilitation. Man Ther, 2006; 11(3):197-201.

26. Zanca GG, Gruninger B, Mattiello SM. Effects of Kinesio taping on scapular kinematics of overhead athletes following muscle fatigue. J Electromyogr Kinesiol, 2016; 29:113-20.

27. Djordjevic OC, Vukicevic D, Katunac L, Jovic S. Mobilization with movement and kinesiotaping compared with a supervised exercise program for painful shoulder: results of a clinical trial. J Manipulative Physiol Ther, 2012; 35(6):454-63.

28. Kaya Karas O, Turker D, Karayazgan S, Kerem-Gunel M, Baltaci YG, Atasavun Uysal S. The effects of Kinesio Taping® on activity and participation in children with unilateral spastic cerebral palsy: Two blind-randomized control trials. Dev Med Child Neurol, 2014; 56:63-4.

29. Şimşek HH, Balki S, Keklik SS, Ozturk H, Elden H. Does Kinesio taping in addition to exercise therapy improve the outcomes in subacromial impingement syndrome? A randomized, double-blind, controlled clinical trial. Acta Orthop Traumatol Turc, 2013; 47(2):104-10.

30. Savoie A, Mercier C, Desmeules F, Fremont P, Roy JS. Effects of a movement training oriented rehabilitation program on symptoms, functional limitations and acromiohumeral distance in individuals with subacromial pain syndrome. Man Ther, 2015; 20(5):703-8.

31. Roy JS, MacDermid JC, Woodhouse LJ. Measuring shoulder function: a systematic review of four questionnaires. Arthritis Rheum, 2009; 61(5):623-32.

32. Michener LA, Walsworth MK, Burnet EN. Effectiveness of rehabilitation for patients with Subacromial impingement syndrome: a systematic review. J Hand Ther, 2004; 17(2):152-64.

33. Tate AR, McClure PW, Young IA, Salvatori R, Michener LA. Comprehensive impairment-based exercise and manual therapy intervention for patients with subacromial impingement syndrome: a case series. J Orthop Sports Phys Ther, 2010; 40(8):474-93.

34. Mottram SL. Dynamic stability of the scapula. Man Ther, 1997; 2(3):123-31.

35. Cubala A, Sniegocki M, Hoffman J, Ratuszek D, Jurkiewicz T, Molski P, Nowacka A, Dzierzanowski M. Use of the Kinesio Taping method in painful shoulder syndrome. Medical and Biological Sciences, 2012; 26(4):71-6.

36. Aguilar-Ferrándiz ME, Castro-Sánchez AM, Matarán-Peñarrocha GA, Guisado-Barrilao R, García-Rios MC, Moreno-Lorenzo C. A randomized controlled trial of a mixed Kinesio taping-compression technique on venous symptoms, pain, peripheral venous flow, clinical severity and overall health status in postmenopausal women with chronic venous insufficiency. Clin Rehabil, 2014; 28(1):69-81.

37. Kase K, Wallis J, Kase T. Clinical therapeutic applications of the Kinesio taping method. 1st ed. 2003, Tokyo.

38. Drouin JL, McAlpine CT, Primak KA, Kissel J. The effects of kinesiotape on athletic-based performance outcomes in healthy, active individuals: a literature synthesis. J Can Chiropr Assoc, 2013; 57(4):356-65.

39. Lin JJ, Hung CJ, Yang PL. The effects of scapular taping on electromyographic muscle activity and proprioception feedback in healthy shoulders. J Orthop Res, 2011; 29(1):53-7.

40. Castro-Sanchez AM, Lara-Palomo IC, Mataran-Penarrocha GA, Fernandez-Sanchez M, Sanchez-Labraca N, Arroyo-Morales M. Kinesio Taping reduces disability and pain slightly in chronic non-specific low back pain: a randomised trial. J Physiother, 2012; 58(2):89-95.

41. Cho HY, Kim EH, Kim J, Yoon YW. Kinesio taping improves pain, range of motion, and proprioception in older patients with knee osteoarthritis: a randomized controlled trial. Am J Phys Med Rehabil, 2015; 94(3):192-200.

42. Coskun Benlidayi I, Salimov F, Kurkcu M, Guzel R. Kinesio Taping for temporomandibular disorders: Single-blind, randomized, controlled trial of effectiveness. J Back Musculoskelet Rehabil, 2016; 29(2):373-80.

43. El-Abd AM, Ibrahim AR, Hel-Hafez HM. Efficacy of kinesio taping versus postural correction exercises on pain intensity and axioscapular muscles activation in mechanical neck dysfunction: a randomized blinded clinical trial. J Sports Med Phys Fitness, 2016.

44. González-Iglesias J, Fernández-de-Las-Peñas C, Cleland JA, Hujibregts P, Del Rosario Gutiérrez-Vega M. Short-term effects of cervical kinesio taping on pain and cervical range of motion in patients with acute whiplash injury: a randomized clinical trial. J Orthop Sports Phys Ther, 2009; 39(7):515-21.

45. Kaplan S, Alpayci M, Karaman E, Cetin O, Ozkan Y, Ilter S, Sah V, Sahin HG. Short-Term Effects of Kinesio Taping in Women with Pregnancy-Related Low Back Pain: A Randomized Controlled Clinical Trial. Med Sci Monit, 2016; 22:1297-301.

46. Kelle B, Güzel R, Sakallı H. The effect of Kinesio taping application for acute non-specific low back pain: A randomized controlled clinical trial. Clin Rehabil, 2015; 30(10):997-1003.

47. Saavedra-Hernández M, Csatro-Sanchez AM, Arroyo-Morales M, Cleland JA, Lara-Palomo IC, Fernandez-de-Las-Peñas C. Short-term effects of kinesio taping versus cervical thrust manipulation in patients with mechanical neck pain: a randomized clinical trial. J Orthop Sports Phys Ther, 2012; 42(8):724-30.

48. Paoloni M, Bernetti A, Fratocchi G, Mangone M, Parrinello L, Del Pilar Cooper M, Sesto L, Santilli V. Kinesio Taping applied to lumbar muscles influences clinical and electromyographic characteristics in chronic low back pain patients. Eur J Phys Rehabil Med, 2011; 47(2):237-44.

49. Arab AM. A Randomized Clinical Trial of Kinesio-Taping on DASH in Patients with Subacromial Impingement Syndrome. J Nov Physiother, 2013; 3(4):169.

50. Hsu YH, Chen WY, Lin HC, Wang WT, Shih YF. The effects of taping on scapular kinematics and muscle performance in baseball players with shoulder impingement syndrome. J Electromyogr Kinesiol, 2009; 19(6):1092-9.

51. Kaya E, Zinnuroglu M, Tugcu I. Kinesio taping compared to physical therapy modalities for the treatment of shoulder impingement syndrome. Clin Rheumatol, 2011; 30(2):201-7.

52. Kim SY, Kang MH, Kim ER, Oh JS. Kinesio Taping improves shoulder internal rotation and the external/internal rotator strength ratio in patients with rotator cuff tendinitis. Isokinet Exerc Sci, 2014; 22:259-63.

53. Oliveira VMAd, Batista LdSP, Pitangui ACR, Araújo RCd. Efeito do Kinesio Taping na dor e discinesia escapular em atletas com síndrome do impacto do ombro. Revista Dor, 2013; 14:27-30.

54. Shaheen AF, Bull AM, Alexander CM. Rigid and Elastic taping changes scapular kinematics and pain in subjects with shoulder impingement syndrome; an experimental study. J Electromyogr Kinesiol, 2015; 25(1):84-92.

55. Shakeri H, Keshavarz R, Arab AM, Ebrahimi I. Clinical effectiveness of kinesiological taping on pain and pain-free shoulder range of motion in patients with shoulder impingement syndrome: a randomized, double blinded, placebo-controlled trial. Int J Sports Phys Ther, 2013; 8(6):800-10.

56. Shakeri H, Keshavarz R, Arab AM, Ebrahimi I. Therapeutic Effect of Kinesio-taping on Disability of Arm, Shoulder, and Hand in Patients with Subacromial Impingement Syndrome: A Randomized Clinical Trial. J Nov Physiother, 2013; 3(4):1-5.

57. Thelen MD, Dauber JA, Stoneman PD. The clinical efficacy of kinesio tape for shoulder pain: a randomized, double-blinded, clinical trial. J Orthop Sports Phys Ther, 2008; 38(7):389-95.

58. Desjardins-Charbonneau A, Roy JS, Dionne CE, Desmeules F. The Efficacy of Taping for Rotator Cuff Tendinopathy: A Systematic Review and Meta-Analysis. Int J Sports Phys Ther, 2015; 10(4):420-33.

59. Montalvo AM, Cara EL, Myer GD. Effect of kinesiology taping on pain in individuals with musculoskeletal injuries: systematic review and meta-analysis. Phys Sportsmed, 2014; 42(2):48-57.

60. Morris D, Jones D, Ryan H, Ryan CG. The clinical effects of Kinesio(R) Tex taping: A systematic review. Physiother Theory Pract, 2013; 29(4):259-70.

61. Mostafavifar M, Wertz J, Borchers J. A systematic review of the effectiveness of kinesio taping for musculoskeletal injury. Phys Sportsmed, 2012; 40(4):33-40.

62. Parreira Pdo C, Costa Lda C, Hespanhol LC, Jr., Lopes AD, Costa LO. Current evidence does not support the use of Kinesio Taping in clinical practice: a systematic review. J Physiother, 2014; 60(1):31-9.

63. Williams S, Whatman C, Hume PA, Sheerin K. Kinesio taping in treatment and prevention of sports injuries: a meta-analysis of the evidence for its effectiveness. Sports Med, 2012; 42(2):153-64.

64. Alqunaee M, Galvin R, Fahey T. Diagnostic accuracy of clinical tests for subacromial impingement syndrome: a systematic review and meta-analysis. Arch Phys Med Rehabil, 2012; 93(2):229-36.

65. Michener LA, Walsworth MK, Doukas WC, Murphy KP. Reliability and diagnostic accuracy of 5 physical examination tests and combination of tests for subacromial impingement. Arch Phys Med Rehabil, 2009; 90(11):1898-903.

66. Siegel LB, Cohen NJ, Gall EP. Adhesive capsulitis: a sticky issue. Am Fam Physician, 1999; 59(7):1843-52.

67. Hertel R, Ballmer FT, Lombert SM, Gerber C. Lag signs in the diagnosis of rotator cuff rupture. J Shoulder Elbow Surg, 1996; 5(4):307-13.

68. Miller CA, Forrester GA, Lewis JS. The validity of the lag signs in diagnosing full-thickness tears of the rotator cuff: a preliminary investigation. Arch Phys Med Rehabil, 2008; 89(6):1162-8.

69. Roy JS, Moffet H, Hebert LJ, Lirette R. Effect of motor control and strengthening exercises on shoulder function in persons with impingement syndrome: a single-subject study design. Man Ther, 2009; 14(2):180-8.

70. Conroy DE, Hayes KW. The effect of joint mobilization as a component of comprehensive treatment for primary shoulder impingement syndrome. J Orthop Sports Phys Ther, 1998; 28(1):3-14.

71. Mulligan B. Manual Therapy: Nags, snags. 4th ed. MWMs etc. 1999: Plane View Services.

72. Teys P, Bisset L, Vicenzino B. The initial effects of a Mulligan's mobilization with movement technique on range of movement and pressure pain threshold in pain-limited shoulders. Man Ther, 2008; 13(1):37-42.

73. Andersen LL, Vinstrup J, Jakobsen MD, Sundstrup E. Validity and reliability of elastic resistance bands for measuring shoulder muscle strength. Scand J Med Sci Sports, 2016; 27:887-94.

74. McClure PW, Bialker J, Neff N, Williams G, Karduna A. Shoulder function and 3-dimensional kinematics in people with shoulder impingement syndrome before and after a 6-week exercise program. Phys Ther, 2004; 84(9):832-48.

75. Kase K, Tatyusuki H, Tomoki O. KinesioTM taping perfect manual. 2nd ed. Development of KinesioTM tape. 1996, Tokyo.

76. Goldwasser RS, David CM. Weaning from mechanical ventilation: let's perform a strategy. Rev Bras Ter Intensiva, 2007; 19(1):107-12.

77. Hudak PL, Amadio PC, Bombardier C. Development of an upper extremity outcome measure: the DASH (disabilities of the arm, shoulder and hand) [corrected]. The Upper Extremity Collaborative Group (UECG). Am J Ind Med, 1996; 29(6):602-8.

78. Durand MJ, Vachon B, Hong QN, Loisel P. The cross-cultural adaptation of the DASH questionnaire in Canadian French. J Hand Ther, 2005; 18(1):34-9.

79. St-Pierre C, Dionne CE, Desmeules F, Roy JS. Reliability, validity, and responsiveness of a Canadian French adaptation of the Western Ontario Rotator Cuff (WORC) index. J Hand Ther, 2015; 28(3):292-9.

80. Tan G, Jensen MP, Thornby JI, Shanti BF. Validation of the Brief Pain Inventory for chronic nonmalignant pain. J Pain, 2004; 5(2):133-7.

81. Tatham B, Smith J, Cheifetz O, Gillespie J, Snowden K, Temesy J, Vandenberk L. The efficacy of exercise therapy in reducing shoulder pain related to breast cancer: a systematic review. Physiother Can, 2013; 65(4):321-30.

82. Kirkley A, Alvarez C, Griffin S. The development and evaluation of a disease-specific quality-of-life questionnaire for disorders of the rotator cuff: The Western Ontario Rotator Cuff Index. Clin J Sport Med, 2003; 13(2):84-92.

83. Dejaco B, Habets B, van Loon C, van Grinsven S, van Cingel R. Eccentric versus conventional exercise therapy in patients with rotator cuff tendinopathy: a randomized, single blinded, clinical trial. Knee Surg Sports Traumatol Arthrosc, 2017; 25:2051-9.

84. Kocyigit F, Acar M, Turkmen MB, Kose T, Guldane N, Kuyucu E. Kinesio taping or just taping in shoulder subacromial impingement syndrome? A randomized, double-blind, placebo-controlled trial. Physiother Theory Pract, 2016; 32(7):501-8.

85. Kolber MJ, Hanney WJ. The reliability and concurrent validity of shoulder mobility measurements using a digital inclinometer and goniometer: a technical report. Int J Sports Phys Ther, 2012; 7(3):306-13.

86. Harput G, Guney H, Toprak U, Colakoglu F, Baltaci G. Acute effects of scapular kinesiotaping on shoulder rotator strength, range of motion and acromiohumeral distance in asymptomatic overhead athletes. J Sports Med Phys Fitness, 2016.

87. Luque-Suarez A, Navarro-Ledesma S, Petocz P, Hancock MJ, Hush J. Short term effects of kinesiotaping on acromiohumeral distance in asymptomatic subjects: a randomised controlled trial. Man Ther, 2013; 18(6):573-7.

88. Desmeules F, Minville L, Riederer B, Cote CH, Fremont P. Acromio-humeral distance variation measured by ultrasonography and its association with the outcome of rehabilitation for shoulder impingement syndrome. Clin J Sport Med, 2004; 14(4):197-205.

89. Hermens HJ, Freriks B, Disselhorst-Klug C, Rau G. Development of recommendations for SEMG sensors and sensor placement procedures. J Electromyogr Kinesiol, 2000; 10(5):361-74.

90. Roy JS, Moffet H, McFadyen BJ. Upper limb motor strategies in persons with and without shoulder impingement syndrome across different speeds of movement. Clinical Biomechanics, 2008; 23(10):1227-36.

91. Jaeschke R, Singer J, Guyatt GH. Measurement of health status. Ascertaining the minimal clinically important difference. Control Clin Trials, 1989; 10(4):407-15.

92. Kamper SJ, Maher CG, Mackay G. Global rating of change scales: a review of strengths and weaknesses and considerations for design. J Man Manip Ther, 2009; 17(3):163-70.

93. Hung CJ, Jan MH, Lin YF, Wang TQ, Lin JJ. Scapular kinematics and impairment features for classifying patients with subacromial impingement syndrome. Man Ther, 2010; 15(6):547-51.

94. Faul F, Erdfelder E, Lang AG, Buchner A. G*Power 3: a flexible statistical power analysis program for the social, behavioral, and biomedical sciences. Behav Res Methods, 2007; 39(2):175-91.

95. Gupta SK. Intention-to-treat concept: A review. Perspect Clin Res, 2011; 2(3):109-12.

FIGURES

Figure 1. Schematic diagram of the study design.

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).

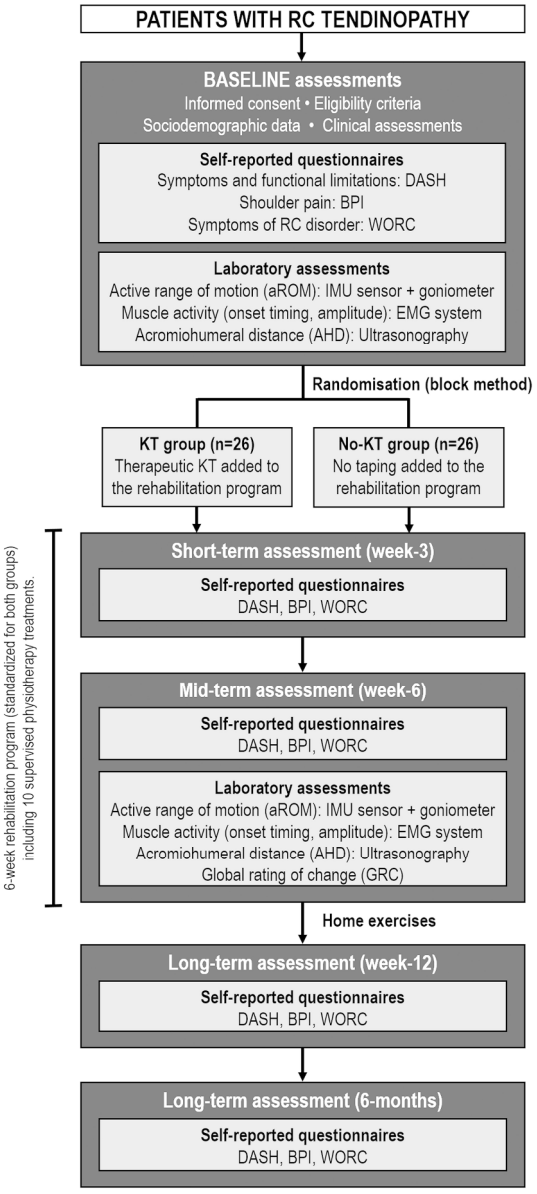

Figure 1. Schematic diagram of the study design.

199x399mm (300 x 300 DPI)

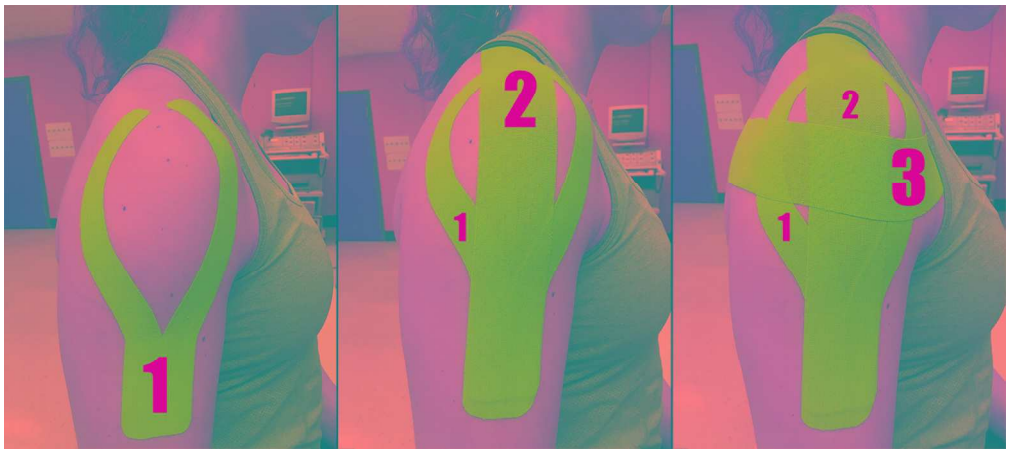

Figure 2. Kinesiotaping application. First strip (1: Y-shape surrounding deltoid muscles), second strip (2: I-shape in functional correction for multiaxial shoulder instability over the glenohumeral joint, supraspinatus, trapezius, and middle deltoid muscles), and third strip (3: I-shape in mechanical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

150x66mm (300 x 300 DPI)

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 (CIRRIS)
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 (CIRRIS), 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	Ages eligible for study: ≥18 to 65 years Sexes eligible for study: both (male, female) Accepts healthy volunteers: no Inclusion criteria: 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). Exclusion criteria: 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).
Study type	Interventional Allocation: randomized Masking: single blind (subject, outcomes assessor) Primary purpose: to assess the effects of a therapeutic resource.
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.

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)	--

Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	9 - 10
	6b	Explanation for choice of comparators	9
Objectives	7	Specific objectives or hypotheses	10
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	12
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	12
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	12, 13
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	13 - 15
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	---
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	--
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	14 - 15
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	16 - 19
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	31, figure 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	12, 19
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	19
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	13
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	13
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	13
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	13,14,16
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	--
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	14 - 17
	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	19

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	20
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	20
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	20
	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)	20
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	---
	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	23
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	--
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	23
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	23
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)	--

Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	attached
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	---
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	23
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	05
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	20, 23
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	--
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	23
	31b	Authorship eligibility guidelines and any intended use of professional writers	5
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	--
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	attached
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	--

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