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Effect of extracorporeal shock wave combined with Kinesio taping on upper limb function during individuals with biceps brachii tendinopathy : protocol for a double-blind, randomised controlled trial

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ABSTRACT

Introduction Long head of biceps brachii tendinopathy (LHBT) is characterised by persistent pain and disability of shoulder joint, impairing patients' quality of life. Extracorporeal shock wave therapy (ESWT) is a non-invasive treatment, which promotes tissue regeneration and repair. However, ESWT has a side effect that often causes short-term pain and swelling in the treatment area. It is known that the effects of Kinesio taping (KT) on relieving swelling and pain. Due to insufficient clinical evidence from current limited studies, this randomised controlled study aims to explore the effects of ESWT combined with KT on upper limb function during individuals with LHBT.

Methods and analysis A 2×2 factorial design, double-blind, randomised controlled trial will be conducted. A total of 144 participants will be randomly allocated into one of four groups (KT+ESWT, KT+sham ESWT, sham KT+ESWT or sham KT+sham ESWT) to participate in a 4-week treatment programme. Measurements will be taken at pretreatment (baseline), immediately after treatment and 6 weeks after treatment. The primary endpoint will be the Constant-Murley score (CMS), the secondary endpoints will include the pain Numerical Rating Scale, range of motion, pressure pain threshold and soft tissue hardness of biceps, speed test and global rating of change. Repeated measures analysis of variance will be used to compare differences among the effects of different interventions.

Ethics and dissemination Ethics approval was obtained from the Ethics Committee of the Shanghai Sixth People's Hospital Affiliated to Shanghai Jiao Tong University School of Medicine. In addition to international conference reports, findings will be disseminated through international publications in peer-reviewed journals.

Trial registration number ChiCTR2100051324.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ To our knowledge, this study is the first randomised controlled trial that explores the effect of extracorporeal shock wave therapy combined with Kinesio taping on upper limb function during patients with long head of biceps brachii tendinopathy.
⇒ In the whole process, each combination can be comprehensively analysed using the 2×2 factorial design method.
⇒ Methods to reduce the risk of bias will be implemented throughout the study, which include a statistically justified sample size, methodological rigour, blinding, randomisation and adequate concealment of group allocation.
⇒ Although patients will be blinded to the treatment provided, blinding therapists are not feasible due to the nature of the treatment.

INTRODUCTION

Long head of biceps brachii tendinopathy (LHBT) is caused mostly from repeated sliding and friction of the long head of the biceps tendon in the intertubercular groove. This abnormal phenomenon causes congestion, oedema and synovial layer aseptic inflammation of biceps tendon, eventually leading to tendon sheath stenosis, thickening and adhesion.[1–3] The incidence of LHBT is second only to rotator cuff disease and subacromial impingement,[4 5] associated with persistent pain and disability of shoulder joint.[6] Failure to treat timely may lead to shoulder periarthritis, affecting quality of daily life for patients.[7]

Conservative management including exercise, manual therapy, non-steroidal anti-inflammatory drugs and patient education is recommended,[4 5 8] but there is still lack of established guidelines for physical therapy. Currently, due to the property of non-invasive and convenient, extracorporeal shock wave

therapy (ESWT) has been used widely in clinical rehabilitation practice for patients with LHBT. During 'Expert Consensus on Extracorporeal Shock Wave Therapy for Musculoskeletal Disorders,' the evidence level for the treatment of LHBT with ESWT was categorised as 1b, accompanied by a grade A recommendation.[9] ESWT could produce energy by rapid or extreme compression of the medium caused by vibration and high-speed movement, leading to considerable changes in physical properties, such as pressure, temperature and density. As for the impact on human body, it could stimulate the release of growth hormones, promote microangio genesis and achieve tissue regeneration and repair.[9] It has been confirmed the effects of ESWT in promoting fracture healing,[10] treating avascular necrosis of the femoral head,[11] calcified tendinitis of the shoulder joint, long head tendinitis of the biceps, external epicondylitis of the humerus and plantar fasciitis.[12–16] Compared with traditional surgery, ESWT has the advantages of no hospitalisation, less postoperative pain, less complications, low treatment risk and high cure rate.[9] However, ESWT has side effects, improper treatment will cause local tissue subcutaneous bleeding, resulting in swelling, ecchymosis and pain.[17]

On the other hand, Kinesio taping (KT) is characterised by its elasticity, maintaining the flexibility of joints on the basis of fixation.[18] It has been shown that KT has unique effects of relieving pain,[19–21] improving joint range of motion (ROM),[22] promoting lymphatic circulation,[23 24] enhancing proprioception[25] and improving postural control.[26] A meta-analysis indicates that KT, as an adjunctive therapeutic modality, is beneficial for alleviating pain associated with shoulder disorders.[27]

As mentioned above, ESWT and KT both could achieve therapeutic effects in the treatment of chronic musculoskeletal pain and inflammation disorders, such as external humeral epicondylitis, knee osteoarthritis and plantar fasciitis[28–30]; moreover, their combination may achieve a better synergistic effect.[19 31] However, given lack of consensus on method for the treatment of LHBT-related chronic pain,[32] few studies have reported the clinical effect of ESWT and KT on LHBT individuals. Therefore, high-quality evidence-based reference for clinical practice is required for LHBT individuals.

Objectives and hypotheses

This double-blind randomised controlled trial primarily aims to explore the effect of ESWT combined with KT on upper limb function during patients with LHBT. Results would provide the best physical therapy evidence-based guidance for the treatment of pain symptoms and functional limitations in patients with LHBT tendinitis. Our hypothesis is, compared with the other group, patients who received ESWT combined with KT intervention would show superior improvement in speed tests, Constant-Murley scores and pain scores at the end of the treatment. KT would help compensate for local swelling and pain caused by ESWT, and their combination will have a more positive rehabilitation effect.

METHODS AND ANALYSIS

Study design

This double-blind, 2×2 factorial design randomised controlled trial will involve 4 weeks of treatment and three assessments (baseline, immediately after treatment and 6 weeks after treatment) (figure 1). All assessments will be conducted in the Department of Rehabilitation Medicine, Shanghai Sixth People's Hospital Affiliated to Shanghai Jiao Tong University School of Medicine, Shanghai, China. The participants will be screened for inclusion and exclusion criteria, then eligible participants will complete a sociodemographic questionnaire, following by evaluation of Constant-Murley score, pain Numerical Rating Scale (NRS), ROM, pressure pain threshold and soft tissue hardness of biceps, speed test and global rating of change. Afterwards, participants will be randomly assigned into one of following four groups: KT+ESWT, KT+sham ESWT, sham KT+ESWT or sham KT+sham ESWT.

Immediately and 6 weeks after treatment, participants will be invited to return the hospital to complete the above measurements, including Constant-Murley score, pain NRS, ROM, pressure pain threshold and soft tissue hardness of biceps, speed test with shoulder function. In addition, patients will be asked to use the Global Ratings of Change Questionnaire to assess their improvements compared with baseline.

Participants

A total of 144 participants, aged between 18 and 65 years old, diagnosed with LHBT will be recruited. To be eligible, participants will have to meet the following criteria: (1) persistent pain of anterior shoulder; (2) decreased ROM and strength of the affected limb compared with the healthy side; (3) speed test (sensitivity 0.61, specificity 0.71)[33] positive signs; (4) obvious tenderness of intertubercular groove during resistance flexion of supinated forearm; (5) receive no treatment including drugs or physical therapy within 2 weeks before participating this experiment. The participants will be excluded if they meet the following criteria: (1) severe adhesive, injuries of shoulder joint, such as fractures; (2) acute onset of severe medical diseases, local skin infection, coagulopathy or fever; (3) long-term use of hormones or immunosuppressants due to autoimmune diseases or other reasons; (4) contraindications to ESWT such as haemorrhagic disease or thrombus and (5) allergy to KT. Patients or the public will be not involved in the design, or conduct, or reporting, or dissemination plans of our research.

Randomisation, blinding and allocation concealment

Random numbers will be generated by using a computerised random generator by an independent assessor who will be not involved in data collection. A block

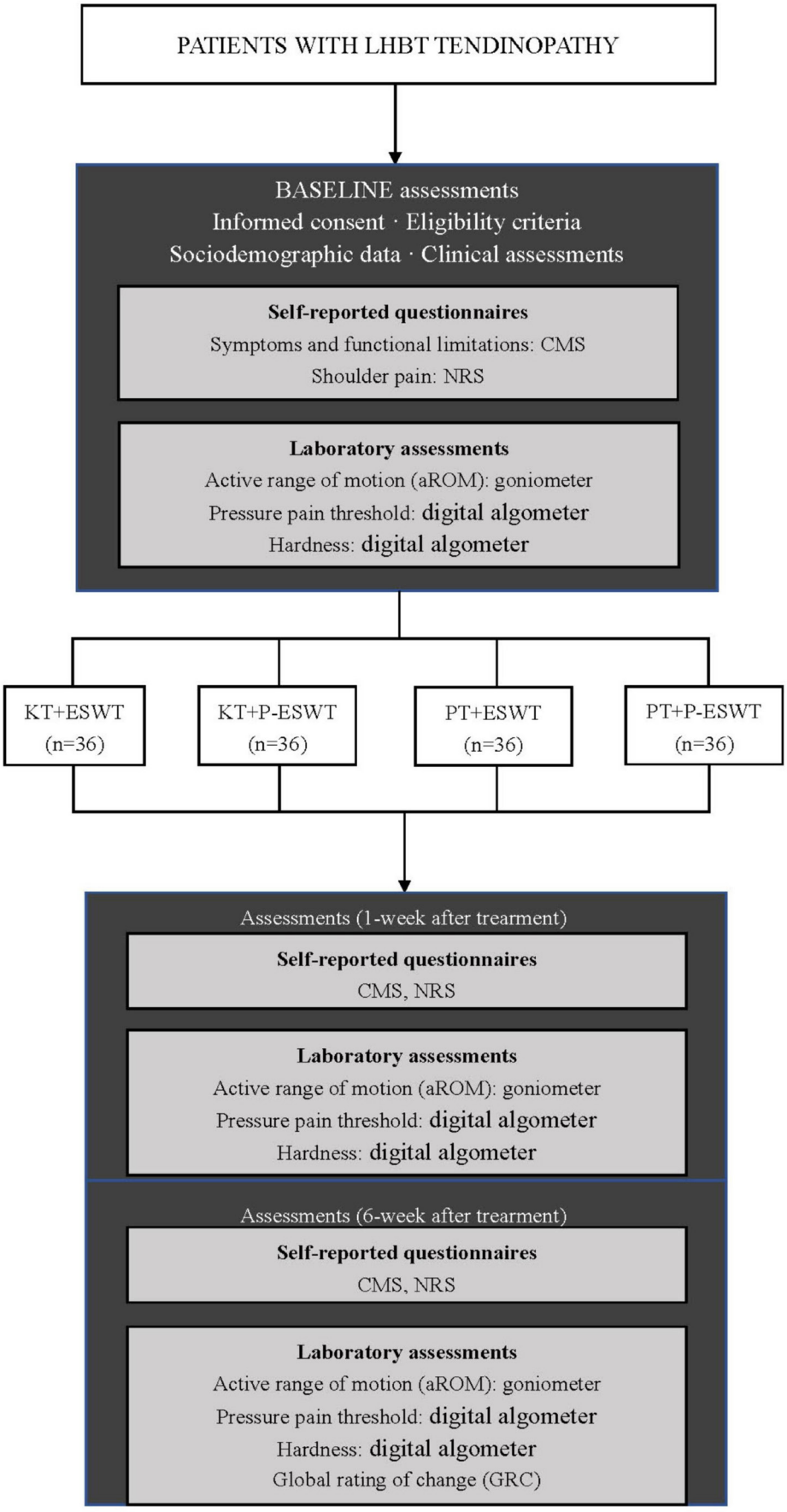

Figure 1 Schematic diagram of the study design. CMS, Constant-Murley score; ESWT, extracorporeal shock wave therapy; KT, Kinesio taping; NRS, Numerical Rating Scale; P-ESWT, placebo extracorporeal shock wave therapy; PT, placebo taping.

randomisation design (block size of 4 or 8) will be applied to ensure an equal number of participants in each group. Each participant will be assigned with a random number hidden in sealed, opaque envelopes. This envelope will be opened by a specialised physical therapist at the first therapy session. The therapists could not be blinded, but participants, researchers collecting outcome data and researchers analysing outcome data will be masked to group identity. To assess the effect of blinding, the assessors will be asked to answer a question related to their opinion of the group assignment after each follow-up assessment.

Rehabilitation programme (independent variable)

Basic treatment

All participants will receive the same standardised treatment for LHBT tendinopathy regardless of the group, including but not limited to manual therapy, strength training, health education, etc. Each patient will attend 12 physiotherapy sessions over 4 weeks (three times a week).

Manual therapy

The rehabilitation process necessitates the therapist's proficient execution of interventions aimed at restoring the normal ROM in the shoulder and elbow joints. To achieve this objective, the therapist should employ a comprehensive approach involving passive ROM exercises, manual stretches and joint mobilisation techniques.[34] During the initial evaluation, specific attention should be given to areas such as the sternoclavicular, acromioclavicular, glenohumeral and thoracic spine, where ligamentous and capsular restrictions are identified.[35] On confirming the need for these techniques, each one should be meticulously performed three times, with an approximate duration of 60 s per session. A rest interval of 30 s should be observed between sets to optimise the therapeutic outcomes.

Stretching exercises

In order to reduce tension in the tendon and musculotendinous junction, it is essential to incorporate stretching exercises that promote optimal physiological mobility of the biceps.[34] Additionally, tailored stretches should be implemented to improve the flexibility of the glenohumeral capsule and associated soft tissues, based on individual requirements. These stretching exercises will be prescribed as part of home exercise programmes during the course of treatment, with each stretch being repeated three times, held for a duration of 30 s per repetition.

Strengthening exercises

The integration of strengthening exercises serves the purpose of reestablishing muscle balance and preventing muscle atrophy. Moreover, rehabilitation should encompass drills that enhance the neurosensory properties of the joint capsule and the surrounding soft tissue.[34] To strengthen the rotator cuff muscles and scapular stabilisers, a combination of free weights, body weight and resistance elastic tubes will be used.[36] The exercise programme will follow a progressive approach divided into three phases: (1) phase 1, focusing on humerus positioning in a neutral stance to improve depression function; (2) phase 2, incorporating ascending arm movements and (3) phase 3, involving higher-level exercises including trunk strengthening. The number of repetitions will vary between one and three sets of 10–30, with a gradual progression. In phase 1, patients will initiate the exercises using a light resistance elastic band (yellow non-latex TheraBand, Hygenic, Akron, Ohio, USA).[37] As the patients demonstrate adequate progress and tolerance, they will advance to the next phase, using a medium resistance band (red and green non-latex TheraBand). It is crucial for patients to perform phase 2 exercises without exacerbating symptoms for a minimum of 1 week before progressing to phase 3. Clear verbal and written instructions regarding the prescribed home exercises will be provided to the participants.

Patient education

Comprehensive guidance will be provided to all patients in order to enhance their understanding of various aspects related to shoulder overload, pain neuroscience, pain management, posture, rehabilitation stages, graded exposure to exercise, as well as shoulder and body mechanics that may elicit pain. Moreover, verbal and written instructions will be given regarding the recommended shoulder positioning during sleep, work and daily activities, including sports.[38] Additionally, each patient will receive a dedicated notebook to document their home training sessions. After completing each home exercise, participants will be instructed to record the date, details of the exercises performed, duration of each exercise, any discomfort experienced and whether they received any additional treatments. It is important to note that if participants are concurrently undergoing other treatments during the trial period, it could impact our assessment of clinical efficacy, and therefore, we would advise them to withdraw from the study.

Kinesio taping

Prior to taping, target area will be removed hair and sterilised with an alcohol-based cotton pad. A 10-year experienced therapist has attended the Medicine Kinesiology Taping Course Training and certified by 'KT Tape China Training Centre' (not involved in the recruitment and evaluation) will conduct all taping application (Kinesio Tex Gold, 5 cm×5 m, USA) (figure 2).[39] All applications will follow the principles and instructions described by Kase *et al*.[18] Participants sit with the affected arm abduction of approximately 45°, elbow joint extend and palm forward. The first strip will be used through 'Y' shape, the anchor point fixes on the radial tuberosity, the two tails extend along the long head and short head of the biceps with a natural tension, end at the coracoid process and acromion, respectively. The term 'natural tension' refers to applying no external tension to the tape. The second

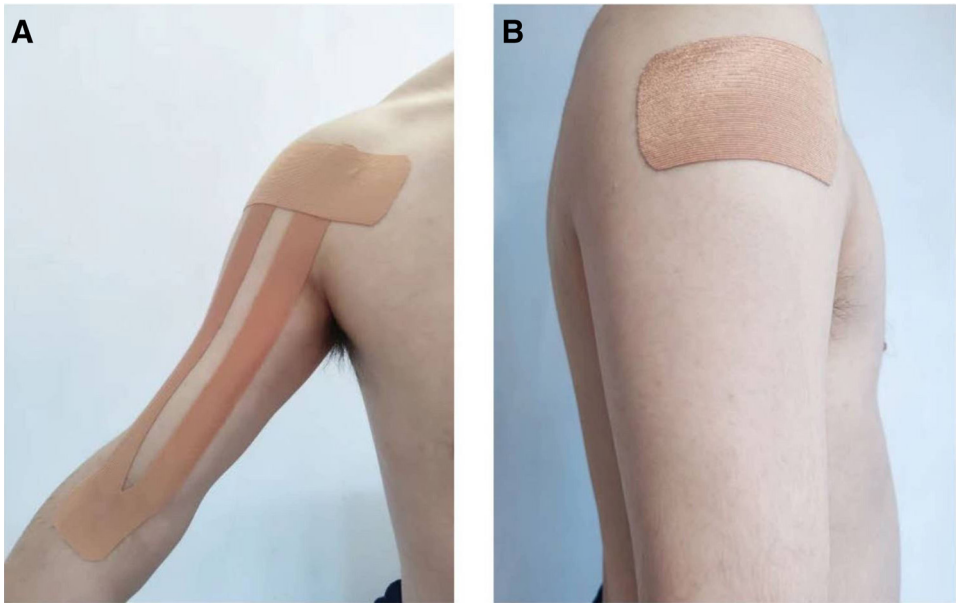

Figure 2 Demonstration of Kinesio taping (KT) application. (A) KT group, the first strip was used through 'Y' shape, the anchor point was fixed on the radial tuberosity, and the two tails extended along the long head and short head of the biceps with a natural tension of 10%–15%, ended at the coracoid process and acromion, respectively. The second strip was used through 'I'-shape according to space correction method. The middle segment was laterally fixed to the intertubercular sulcus with a large tension, two ends were extended with natural tension. (B) Placebo KT group, a strip was used to wrap the humeral head from back to front at the pain site without tension. *The person depicted is not a patient and was taken with the participants' knowledge. The individual in the picture does not need to be shown.

strip will be used through 'I'-shape. The middle segment of 'I' strip fix laterally to the intertubercular sulcus with a large tension, two ends extend with natural tension.

For placebo taping, a strip will be used to wrap the humeral head from back to front at the pain site without tension. All KT tapes will be removed before each ESWT treatment, reattached after the ESWT treatment. Participants will be required to keep taping duration for at least 72 hours.

Extracorporeal shock wave therapy

A 5-year experienced therapist certified by International Society of Physical and Rehabilitation (not involved in the recruitment and evaluation) will conduct all ESWT application. The radial and pneumatic ballistic shock wave device, Swiss DolorClast Smart (EMS Electro Medical Systems, Nyon, Switzerland) will be used with medium energy density of 0.12–0.25 mJ/mm^2, using the 'radial' (blue) handpiece with the 15 mm applicator, radial extracorporeal shock waves were applied at a frequency of 8 Hz, each impact point was 2000 times, about 5 min.[9] The ESWT treatment will be performed once a week, four times in total.[9] Placebo ESWT will employ a silicone pad for energy isolation; however, patients will still be able to hear the sound of the shock waves, experience a slight tingling sensation on the skin, but without energy transmission.

Ultrasound-guided localisation

An experienced doctor who is registered and certified to practice medical imaging and radiotherapy (not involved in the recruitment and evaluation) will conduct all ultrasound-guided application. PHILIPSiU22 Doppler ultrasound diagnostic instrument will be used, high-frequency of probe will be 7.5–13.0 MHz. Patients sit, the upper arm was naturally lowered, the elbow was bent 90°, the forearm was rotated externally and the palm was up, ensure intertubercular groove of the humerus and the biceps longus tendon face forward. The ultrasound sleeve probe is disposable, and 2% povidone iodine will be used as ultrasound coupler. The transducer frequency was chosen based on the depth of the individual anatomic structure. According to previous studies,[40] on the transverse scanning of proximal humerus, the probe was placed at right angles to the tendon sheath, the brachial bicipital groove and the biceps brachii tendon could be seen clearly. The tendon appears as an echogenic ellipse within the groove, as the treatment region, the inflammatory fluid presents as a hypoechoic area.[41]

Data collection

Outcome measures (dependent variables)

Outcome data will be collected by the same assessor who is not involved in any other process of the study. The primary outcome will be Constant-Murley scores. Secondary outcomes will include the pain NRS, ROM, pressure pain threshold and soft tissue hardness of biceps, speed test and global rating of change.

Primary outcome

Constant-Murley scores

The European Society for Shoulder and Elbow Surgery promotes usage of the Constant-Murley score as the gold standard for a comprehensive and comparable assessment of shoulder function.[42] Constant-Murley score is also one of the most commonly used scoring systems in follow-up of shoulder injury.[43]

Constant-Murley score is a 100-point scale, which is divided into four subscales: pain (15 points), activities of daily living (20 points), strength (25 points) and ROM: forward flexion, external rotation, shoulder abduction and internal rotation (40 points). These parameters define the degree of pain and the ability of the patient to perform normal daily activities.[44] Pain and activity of daily living (ADL) questions will be answered by the patient, ROM and strength assessment were completed by the therapist.[45] Higher scores indicate better functional quality.[46] The minimum score important difference was 17.[47] Participants will be expected to complete Constant-Murley score for 5–7 min.[48] It has been demonstrated that Constant-Murley score is a reliable (intraclass correlation coefficient, ICC=0.80–0.87) and responsive (effect size (ES)=0.59) tool for assessing the impact of shoulder interventions. The test was shown to be responsive to improvements after shoulder interventions to detect a variety of shoulder disorders. Several studies confirmed good reproducibility, responsiveness and construct validity of the score.[46] During this protocol, Constant-Murley scores (Chinese version) will be used. It has been demonstrated that the Chinese translational version of CMS questionnaire harboured good internal consistency (Cronbach's α=0.739) and test–retest reliability (ICC=0.827).[49]

Secondary outcomes

Secondary outcome measures will include the pain NRS, ROM, pressure pain threshold and soft tissue hardness of biceps, speed test and global rating of change with shoulder function.

Pain

NRS 0–10 version (Chinese version) will be used to assess shoulder pain intensity respectively during rest, exercise and night sleep, with 0 indicating 'no pain', 1–3 indicating 'mild pain', 4–6 indicating 'moderate pain' and 7–10 indicating 'severe pain'.[50] NRS (Chinese version) has been demonstrated to be a reliable and valid tool for assessing pain intensity during Chinese clinical musculoskeletal settings.[50–52] The ICCs of NRS (Chinese version) were proved to be high.[50–52]

Range of motion

A manual goniometer will be used to measure a pain-free ROM of shoulder joint abduction and flexion when patients stand upright. 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)).[53] The average values of the three measurements determines mean ROM value for each intervention condition.

Pressure pain threshold and hardness

A reliable,[54 55] digital algometer (OE-220, ITO, Tokyo, Japan) will be used to measure pain pressure threshold (kg/cm^2) and tissue hardness (N/cm^2) at tender points. The pressure pain thresholds will be applied at 50 kPa/s until the onset of pain, with a stimulation area of 1 cm^2. Participants will be asked to respond as long as they feel pain, corresponding algometer force (N) will be recorded as pressure pain thresholds.

A tissue harness algometer will be used.[21 56] Hardness test will be conducted by increasing the pressure slowly and evenly until the digital display automatically outputted the value (N).

Speed test

We will carry out a special test-speed test (sensitivity 0.61, specificity 0.71).[33] During this test, participants will be instructed to supinate the forearm, extend the elbow and bend the affected arm forward 90°. The tester will apply resistance and ask participants to continue to bend the forearm forward. If participants reported pain at the long head tendon of the biceps (intertubercular sulcus), indicating that speed test is a positive sign.

Global rating of change

Participants will be asked to complete a global rating of change (GRC) question to assess changes in their intervention. GRC is a reliable 15-point scale (ICC=0.90) which is designed to report changes in clinical status over time as perceptions of post-treatment outcomes.[57–59] Considering that patients are generally satisfied with their improvement when their GRC score reaches+4, we will predetermine that participants who rated their perceived recovery score as +4 would be classified as having a successful outcome.[36] Therefore, the GRC results will be classified as GRC≥+4(improvement) and GRC<+4 (no improvement).[60]

Sample size

In this study, 2×2 factorial design analysis of variance (ANOVA) will be used to estimate sample size. According to G-Power software, under the condition of ES of 0.25, α level of 0.05 and power of 0.8 and considering 10% drop-out rate, the total sample size was calculated to be at least 144 people, with 36 people in each group.

Recruitment of patients

A total of 144 participants will be recruited in this study, and this number is feasible because the number of emergency outpatient visits in our hospital exceeded 5 million in recent 5 years and the number of outpatient visits in our department exceeded 150 000 each year. Therefore, all participants are expected to be recruited within 15 months, average 10 participants per month.

Withdrawal of individual participants

The researchers will document the weekly treatment dosage through participant diaries and conduct phone communication with participants who have not adhered to the treatment schedule, ensuring the completion of treatment as protocol and recording the reasons and frequency of any deviations from the experimental protocol. Each participant will be analysed according to randomised treatment assignment, following the basic principles of 'intention-to-treat' analysis. All drop-out participants and their underlying causes will be reported. The combination of these statistical strategies would increase the confidence in the findings and ensure proper understanding of the underlying mechanisms of symptom and functional changes. Any injuries or accidental effects during the intervention will be recorded.

Patient and public involvement

None.

Data integrity and analysis

All collected data will be used for the research team only and stored for 5 years. After the planned publication of the study, all data will be destroyed.

Statistical analysis

Demographic characteristics and baseline descriptive statistics for each participant will be reported as mean±SD ($\bar{x} \pm S$) or median (quartile). SPSS V.26.0 will be used for statistical analysis. Shapiro-Wilk (S-W) test and Levene test will be used to determine whether variables fitted normal distribution and variance homogeneity, respectively. Non-normally distributed data will be performed Mann-Whitney U test. One-way ANOVA will be used to determine differences in demographic data among different groups. Intervention effects will be examined using a two-way (experimental condition by time) mixed ANOVA with repeated measures, incorporating covariates including age, gender and disease progression for potential confounding factors. The significance level will be set at $p<0.05$. The 95% CI and ES will be reported. The reported *F*-values and df were obtained after the Huynh-Feldt correction when Mauchly's test of sphericity indicated a violation of the sphericity assumption. Partial eta squared (η_p^2) will be used to express ES. Small ES will be defined as $0.01 \leq \eta_p^2 < 0.06$, medium ES will be defined as $0.06 \leq \eta_p^2 < 0.14$ and large ES will be defined as $\eta_p^2 \geq 0.14$.[61]

To address potential participant drop-outs, the data will be analysed using the intention-to-treat analysis approach. This method includes all randomised participants, regardless of whether they completed the intervention or not. Participants who withdrew from the intervention will be contacted promptly to investigate the reasons and encouraged to continue providing measurements to minimise data loss. In cases where participants could not be followed up or left the group, their last available data will be used to fill in missing information for the intention-to-treat analysis.

DISCUSSION

LHBT is one of the most common causes of shoulder pain and activity dysfunction.[6] If not treated in time, this condition may develop into periarthritis of shoulder, which will affect the patient's exercise performance and daily life.[7] Surgery is often the last option, however, in current conservative treatment, no clear recommendation has been established for the treatment of this disease and its symptoms. Therefore, diverse conservative treatment methods should be explored.

In recent years, ESWT and KT have been widely used to rehabilitate musculoskeletal diseases, but their clinical efficacy in patients with LHBT tendinitis still needs to be confirmed. To the best of our knowledge, this study is the first to explore the effect of ESWT combined with KT on upper limb function during patients with LHBT. Few studies have explored the efficacy of ESWT and KT alone and their synergistic effect, causing difficulty in determining causality and obtaining evidence that ESWT and KT really work. Therefore, we believe this RCT could provide related evidence-based references for application of ESWT combined with KT during LHBT individuals, promote related clinical rehabilitation practice.

Strengths and limitations of this study

To our knowledge, this randomised controlled trial is the first to explore the effect of ESWT combined with KT on upper limb function during patients with LHBT. This trial could help understand the claimed clinical benefits of this approach. Since our intervention protocol is similar to that in the current clinical setting, the results can be applied directly to clinical practice. This work helps establish strong evidence of the benefits of KT versus ESWT in physical therapy interventions for LHBT. Optimal clinical treatment approaches are also developed for this population. Finally, this study will take a number of measures such as statistically reasonable sample size, methodological rigour, blinding, randomisation and appropriate hidden group assignment to reduce the risk of bias.

This study also has some limitations. First, we do not consider the aetiology of LHBT and further subgroup analysis. In future research, different causes can be considered to provide more detailed evidence guidance for clinical practice. Second, we only observed the short-term and medium-term efficacy of KT combined with ESWT on LHBT tendinitis. Future studies will be needed to verify the long-term efficacy of ESWT combined with KT.

Ethics and dissemination

This randomised controlled trial is registered in the Chinese Clinical Trial Centre (ChiCTR2100051324). Ethics approval was obtained from the Ethics Committee of Shanghai Sixth People's Hospital Affiliated to Shanghai Jiao Tong University School of Medicine. In addition to the international conference report, the result of the protocol will be reported through international publications in peer-reviewed journals. The participants,

clinicians and researchers will be also informed of the results of the study.

Consent

All participants will provide detailed information about the study and experimental procedures prior to signing written informed consent. Participants will be required to sign a detailed informed consent form before starting any experimental procedures.

Confidentiality

All research team members will comply with the law and respect the confidentiality of patient data. The names of the patients will be coded to hide their identity. The name and respective codes will be stored in a locked filing cabinet. All information collected during the study period, including test results, will be treated as confidential. The trial data set will be accessible only to the study team and the Ethics Committee of Shanghai Sixth People's Hospital Affiliated to Shanghai Jiao Tong University School of Medicine for research and development management or audit purposes. Publications related to these data will respect all principles of confidentiality.

Data statement

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

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Contributors KL will contribute to conception, design and preparation of the procedures, and data collection and will conduct the recruitment, rehabilitation program, interpretation, data analyses and writing. LY will conduct the outcomes assessments and will contribute to the analysis and interpretation of the data. YZ will contribute to study design and will contribute to the statistical analysis and interpretation of the data. LH and GL will contribute to conception, design and preparation of the procedures. Both authors will contribute to the analyses and interpretation of the data. RZ, PF, YM and ZM will comment on the several versions of this study protocol. All authors will approve the final version of this protocol.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

Patient consent for publication Not applicable.

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