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Effect of RUSI-based core stability exercise on chronic non-specific low back pain patients: study protocol for a randomised controlled trial

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ABSTRACT

Introduction Low back pain (LBP) is one of the most highly prevalent pain both in developed countries and low-income and middle-income countries. Despite increasing healthcare resources and numerous treatment methods for LBP, the efficacy of these therapeutic strategies is still uncertain. Recently, core stability exercise (CSE) is popularly applied as a preventive or rehabilitative method in the treatment of LBP. However, the adequate activation of the local muscle systems of CSE needs further optimisation and quantification. This trial aims to investigate the feasibility and efficacy of CSE monitored by real-time ultrasound image (RUSI) on LBP individuals.

Methods and analysis Forty subjects with chronic non-specific LBP (CNLBP), aged from 20 to 50 years, will be randomly allocated into two groups using sealed, consecutively numbered opaque envelopes: (1) study group (SG): CSE monitored by RUSI and (2) control group (CG): identical CSE without monitoring. Interventions will last 30 mins, two times a week for 8 weeks. The primary outcomes include pain intensity, disability and quality of life, and the secondary outcomes will be the postural control static stability, onset timing of trunk muscles activation, ultrasound images of muscle thickness and surface electromyography (sEMG) signal of muscle activities. Outcome measures will be collected at baseline, 4 and 8 weeks during training, and at 6 months follow-up. Data will be collected and analysed by an assessor blinded to group allocation. Effect sizes and mixed-model repeated measures analysis of variance (2 groups×4 time points) will be calculated.

Ethics and dissemination This protocol and informed consent has been approved by the Institutional Research Ethics Committee of the First Affiliated Hospital, Sun Yat-sen University (Approval number: [2020] 254-1). The findings of this study will be disseminated to participants through social networks and will be submitted to peer-reviewed journals and scientific conferences.

Trial registration number Chinese Clinical Trial Registry (ChiCTR2000034498).

Strengths and limitations of this study

► This randomised controlled trial is the first attempt to systematically investigate the efficiency of the real-time ultrasound image-based core stability exercise in individuals with chronic non-specific low back pain (CNLBP).
► This study will show the effect of short-term and medium-term applications of core stability exercise (CSE) combined with real-time biofeedback in individuals with CNLBP, which could be a more effective method to treat LBP patients.
► Outcome measures include various aspects of LBP problems (pain intensity, functional disability, quality of life and quantitative indicators such as electromyography, ultrasound, etc).
► There is no standardised intervention protocol for use of CSE therapy in LBP subjects.
► Restriction to the age range of participants may limit the generalisability of the findings.

significant burden on social economy, which is related to increased direct (eg, medical care) and indirect costs (such as sick leave and social productivity).[3 4] Therefore, finding effective treatments for chronic non-specific LBP (CNLBP) is a major challenge for clinicians and researchers, and of great importance for patients with LBP.

Various rehabilitation and treatment methods including electrical stimulation, massage, acupuncture and motor control training have been used to the management of LBP patients.[5–8] However, the effectiveness of these treatment programmes is still questionable and uncertain. In the last few years, core stability exercise (CSE) has been reported to be important in the management of LBP, not only for the prevention and reduction back pain and disability but also for improving spinal stability and flexibility.[9]

Core stability is defined as the ability to maintain a stable neutral zone of the spine. According to the function and activity, the

INTRODUCTION

Non-specific low back pain (LBP) is one of the most common musculoskeletal pain over the world and affects 85%–90% of the population at some point in their life.[1 2] LBP causes a

core muscles can be categorised into two main groups. The global or superficial muscles are the primer movers of the trunk. The local or deep muscles provide a stiffening effect on the lumbar spine through attaching to the thoracolumbar fascia and play important roles in the segmental stability.[10][11] However, patients with LBP demonstrate defection in these local muscles, such as atrophy, fat infiltration and preferential activation delay which makes anticipatory postural adjustment (APA) difficult and eventually result in damage to the spine.[12–14]

Previous studies have reported that CSE improves spinal stability and decreases pain for individuals with lumbar instability in terms of neuromuscular control.[15][16] However, the application of CSE targeting transverse abdominis (TrA) and lumbar multifidus (LM) needs further exploration and optimisation due to the activation of local muscles that appear to be particularly difficult in LBP individuals, and also because of the difficulty to feel or palpate of the deep muscles. Studies have previously evaluated the effect of trunk stabilisation merely investigated deep muscle thickness using ultrasound or examined the changes in muscle activity using electromyography (EMG) in older or healthy subjects,[17–20] but there were few studies reported the efficiency of real-time ultrasound image (RUSI)-based CSE on LBP patients. Therefore, reliable, sensitive and non-invasive measurements are important to provide real-time and precise information of trunk muscles on specific functional tasks during CSE.[12][21] Thus, real-time display of deep muscle thickness changes monitored by ultrasound during functional re-education and training would be helpful to provide biofeedback and instruction to the therapists and patients.[22][23]

Based on the above background information, RUSI will be used to provide real-time biofeedback of observing the deep muscles morphological changes in this study. We hypothesise that, in contrast to the general CSE group, the study group (SG) monitored by RUSI will induce greater activities of TrA, and more effectively promoting trunk stability, reducing pain, and improving disability.

METHODS
Study design
To evaluate the effects of CSE monitored by RUSI on the effectiveness of LBP, a prospective two-arm randomised controlled trial will be conducted. This study will take place in an outpatient rehabilitation centre in the first affiliated hospital of Sun Yat-sen University. Participants with CNLBP will be randomly allocated into one of two groups: (a) SG: CSE monitored by RUSI to increase subjects' activity levels and (b) control group (CG): identical CSE without monitoring. All of the participants in the two groups will be treated with specified CSEs for 30 min per session, two sessions per week for up to 8 weeks. This study protocol follows the guidelines described in the 'Standard Protocol Items: Recommendations for Interventional Trials' statement.[24]

Approval and registration of the study
The study design, procedures and informed consent were approved by the Institutional Research Ethics Committee of the First Affiliated Hospital, Sun Yat-sen University (Approval number: [2020] 254–1) and was prospectively registered in the Chinese Clinical Trial Registry. We confirm that all methods are performed following the ethical standards of the Declaration of Helsinki. The subjects will be informed about the objectives and procedures of the study. When eligible for inclusion, they will be requested to sign the informed consent form.

Participant involvement
All of the participants will not be involved in the design, conduct and dissemination plans of our research. The personal data of the participants such as name, age, body mass and so on will be numerically coded and stored in a database, which can only be accessed by the researcher responsible for the randomisation and blinding process during the study. Individual evaluation results will be available to participants on completion of the trial.

Eligibility criteria
A total of 40 patients will be recruited in this study via the outpatient department of the First Affiliated Hospital, Sun Yat-sen University, flyers, and social media sites. All personal data we collected will be confidential. Inclusion criteria for the study are (a) male and female, ages between 20 and 50 years; (b) LBP for at least 3 months, but no radiculopathy, specific spinal disease, or nerve root pain[25]; (c) the scores of visual analogue scale (VAS) range from 3 to 7 and (d) body mass index (BMI) within ±10% of international standards. Exclusion criteria are a history of abdominal or spinal surgery; previous experience of ultrasound imaging evaluation on trunk muscles; comorbid health conditions that would disturb active participation in the training programmes (eg, ankylosing spondylitis, rheumatoid arthritis, fractures, tumours, systemic disease, severe neurological and psychological disorders), or pregnancy.

Sample size calculation
The sample size was defined according to the previous research results reported by Zheng et al.[23] The sample size calculation for this study is performed based on the change of the TrA activation ratio at 8-week treatment and assuming 80% power and 5% of significance to detect a significant difference of the TrA activation ratio among groups at 0.1 points, and the SD of 0.05 points. A minimal sample size of 33 patients is consequently to be included in the analysis. As a dropout rate of 20% is assumed, a total of 40 participants will be included in the study (20 in the SG, 20 in the CG).

Randomisation and blinding
Immediately after inclusion and baseline assessment, subjects will be randomised into one of the two groups by an investigator who is not involved in the recruitment or other study procedures of the patients. The randomisation
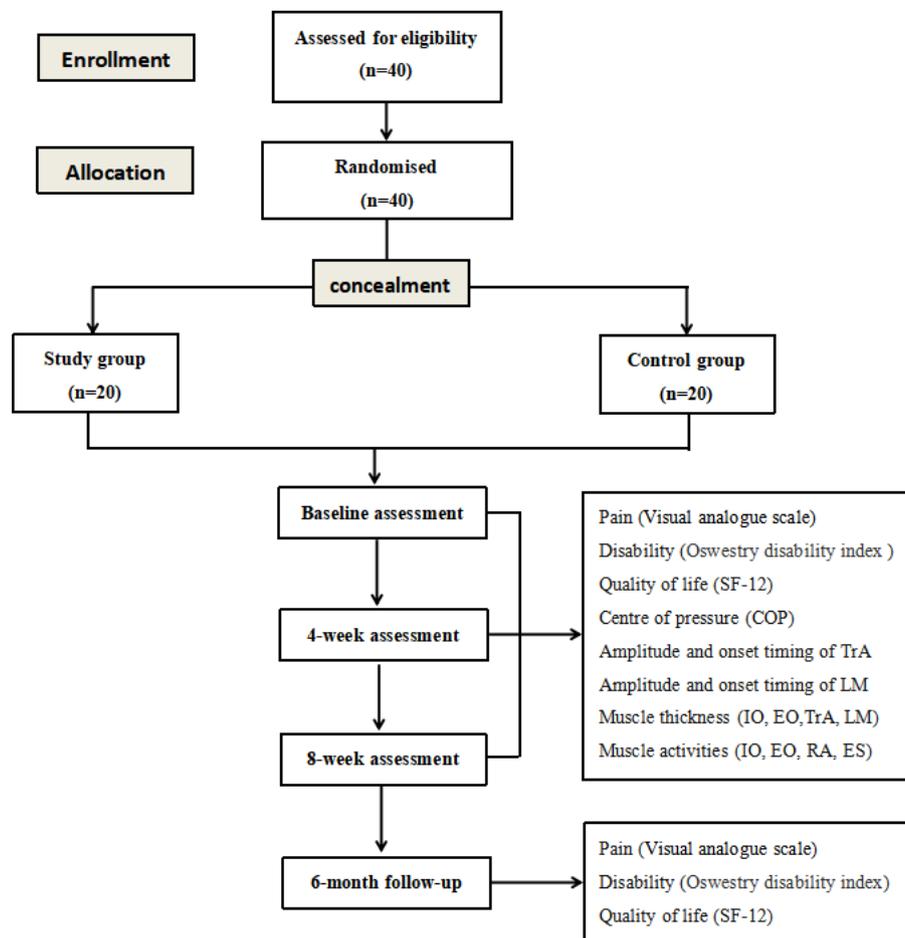
Figure 1 Flow diagram of the study. CSE, core stability exercise; EO, external oblique; IO, internal oblique; LM, lumbar multifidus; RA, rectus abdominis; SF-12, 12-Item Short-Form Health Survey; TrA, transverse abdominis; ES, erector spinae.

sequence is generated relying on a computer-generated randomization schedule (www.randomization.com). The allocation of subjects will be concealed by using consecutive numbered, sealed and opaque envelopes.[26] The study assessor will be blinded to the allocated groups of the patients. However, it will not be possible for the therapist or the patients to be blinded. The flow of the study is summarised in figure 1.

Interventions
All participants will be randomly allocated into one of two groups (all of the subjects will receive the same CSE training with or without real-time biofeedback). Interventions will last 30 min per session and will happen two times a week for 8 weeks. The therapist will demonstrate and explain a modified CSE training plan (shown in table 1) to the subjects in the two groups based on the previous studies.[23 27] They will also be instructed not to initiate any intervention while during the study. In the first 4 weeks, the participants will be asked to finish primary training, and in the next 4 weeks, they will be required to finish superior training using a sling setting. During training, RUSI will be used to provide real-time feedback in the SG to guarantee the correct contraction of the trunk muscles. The real-time biofeedback using RUSI will be maintained

throughout the whole training process. The activities of the superficial muscles, such as RA, are not allowed to be more intense than those of the deep muscles namely TrA during exercise. The protocol of CSE training programmes is shown in table 1 and the placement of the EMG electrode and the ultrasound transducer for real-time biofeedback and examination are shown in table 2 concerning the recommendation by SENIAM and the method applied in previous studies.[23 28–30]

Data collection
Data collection will occur at baseline, 4, 8 weeks and 6 months follow-up. During training, all data will be recorded and saved into the trial database. Participants will also be asked to complete follow-up over the telephone by one of the researchers. If participants do not complete the evaluation within 2 days of the scheduled date, they will receive a message reminder or will be contacted by one of the study researchers.

Primary outcome measures
Pain
Self-reported pain will be investigated using the VAS. The VAS is a tool with a 10 cm ruler and the participants will be asked to rate their pain intensity by moving the marker

Table 1 Description of the core stability exercise protocol

Week	Core stability exercise
1–4	**Low-load exercises (mat exercises)** 1. Train TrA muscle activation in a supine/prone lying position without spinal and pelvic movements for 10 s with 10 repetitions, while keeping respiration normal (abdominal drawing-in manoeuvre, ADIM). 2. Train LM muscle activation in a prone lying position. Raise the contralateral arm/leg while performing the ADIM for 10 s with 10 repetitions. 3. Perform ADIM in a crook lying position with hips at 45° and knees at 90°. Then abduct one (right/left) leg to 45° of hip abduction and sustain for 10 s. 4. Train ADIM in a crook lying position with hips at 45° and knees at 90° as described previously. Then slide one leg down until the knee is straight, maintain it for 10 s, and then slide it back up to the starting position. 5. Perform ADIM and raise the buttocks off a couch from a crook lying position until the shoulders, hips and knees are in straight alignment. Keep the position for 10 s and then lower the buttocks back down to the couch with 10 repetitions. 6. Perform ADIM and raise the buttocks off a couch from a crook lying position until the shoulders, hips and knees are in straight alignment, then straighten one (right/left) leg. Sustain this posture for 10 s and then back up to the starting position with 10 repetitions. 7. Perform ADIM and raise one (right/left) leg from a four-point kneeling position and maintain the trunk in a neutral position. Sustain the posture for 10 s and then back up to the starting position with 10 repetitions. 8. Perform ADIM and raise one (right/left) arm and contralateral leg from a four-point kneeling position and maintain the trunk in a neutral position. Sustain the position for 10 s and then return to the starting position with 10 repetitions.
5–8	**High-load exercises (sling exercises)** 1. Lay supine on the treatment bench with arms cross over the chest, the hips and knees bent to 90°. The knees and ankle joints were placed into two slings per leg. Perform ADIM, then raise the buttocks off the bench while maintaining straight alignment of the knees, hips and shoulders. Hold this position for 10 s with 10 repetitions and then will be instructed to lower back to the starting position. 2. Lay supine on the treatment bench with arms cross over the chest, the hips and knees bent to 90°. One leg remains in the slings and the other leg was not in the sling. Hold the leg at the same level as the other, perform ADIM, and then raise the buttocks off the bench while maintaining straight alignment of the knees, hips and shoulders. Keep this position for 10 s and then will be instructed to lower back to the starting position. 3. Lay supine on the treatment bench with arms cross over the chest with the ankle joints placed into one sling per leg. Perform ADIM, then raise the buttocks off the bench while maintaining straight alignment of the ankles, knees, hips and shoulders. Hold this position for 10 s with 10 repetitions and then will be instructed to lower back to the starting position. 4. Lay supine on the treatment bench with arms cross over the chest and one ankle joint placed in a sling. Hold the other leg at the same level as the one suspending in the sling. Perform ADIM, then raise the buttocks off the bench while maintaining straight alignment of the ankles, knees, hips and shoulders. Hold this position for 10 s with 10 repetitions and then will be instructed to lower back to the starting position. 5. Lay supine on the treatment bench with arms cross over the chest. The head is placed into one sling, the chest into a wider sling and the knees and ankle joints are placed into two slings. A height-adjustable bench was lowered until the subject hung with the whole body weight in the sling system. Perform ADIM, place the subject's pelvis in a neutral position between the knee and shoulder for 10 s with 10 repetitions and then will be instructed to lower back to the starting position. 6. Lay prone on the treatment bench with arms cross over the chest. The head is placed into one sling, the chest into a wider sling and the knees and ankle joints are placed into two slings. The bench is lowered until the subject hung with the whole body weight in the sling system. Perform ADIM, place the subject's pelvis in a neutral position between the knee and shoulder for 10 s and then will be instructed to lower back to the starting position.

LM, lumbar multifidus; TrA, transversus abdominis.

indicating his or her intensity of pain. The VAS was horizontally positioned with the extremes labelled 'least possible pain' and 'worst possible pain'.[31] VAS will be assessed in all-time points (ie, baseline, 4 weeks, 8 weeks and 6 months follow-up).

Disability
The Oswestry disability index (ODI) is a scale containing 10 sections, each section rated on a 0–5 scale, the greater number represents greater disability. Relative values will be shown as total score/total possible score ×100%.[31] Participants will be asked to select the items that describe the degree of disability on the day of the evaluation.

Health-related quality of life
The quality of life is evaluated by the 12-Item Short-Form Health Survey (SF-12).[32 33] SF-12 consists of eight health scales namely physical or social functioning,

role limitations due to physical or emotional problems, bodily pain, general health, vitality and perceived mental health. Raw scores in the eight domains are combined transformed into physical and mental health composite scores, which both range from 0 (lowest) to 100 (highest). Higher scores represent better health and well-being.

Secondary outcome measures
Postural control: static stability
The centre of pressure (COP) sways parameters will be evaluated on a Balancing Instrument (Prokin 254P, TecnoBody Company, Italy) to assess the balance performance during quiet standing.[34–36] To assess postural stability in bipedal stance, the individuals will be asked to stand statically in a standardised position on the platform with their arms at their sides and eyes (open or closed) looking straight at the computer screen. To assess static

Table 2 Placement of the electromyography electrodes and ultrasound transducer

Muscle	Electrode placement location
Transversus abdominis/internal oblique (TrA/IO)	Along either side of the course of the underlying muscle fibres and centred 2 cm cephalic to the pubic bone, just lateral to the midline, and parallel to the superior pubic ramus
External oblique (EO)	Halfway between the iliac crest and the twelfth rib at a slightly oblique angle
Rectus abdominis (RA)	2 cm lateral to the umbilicus
Erector spinae (ES)	2–3 cm lateral to the L3 level
Lumbar multifidus (LM)	A line from posterior superior iliac spine to the spinous process interval between L1 and L2, at the level of L5 spinous process (about 2 cm from the posterior midline)
Muscle	**Ultrasound transducer placement location**
TrA/IO/EO	Along the midaxillary line at the level of the umbilicus
LM	2 cm lateral to the L4 spinous process

stability in a monopedal stance, subjects will be asked to stand on one leg while the other leg is flexed off the floor with their arms crossover the chest. All tests will maintain 30 s with two repetitions. During the measurement, the COP sway area (mm^2) and sway length (mm) will be recorded to evaluate the static balance and stability.

Postural control: trunk position sense

Trunk position sense, represented by trunk reposition errors (TRE), will be evaluated with a digital inclinometer (Prokin 254P, TecnoBody Company, Italy). The subjects will be asked to stand upright in a relatively standardised position. Then the inclinometer will be placed at the level of T4, the subjects will be asked to flex the trunk approximately 30° in the sagittal plane and hold this position for 3 s to remember the position sense, then back to the starting position with two repetitions. After the initial trials, they will be asked to duplicate the previously attained position in the eye-closed condition three times and hold the position for 3 s each time. The absolute differences between the original position and the other three attempts will be calculated, and the mean of the three calculated data will be adopted to assess the trunk position sense.[37 38]

Muscle activity recorded by EMG

Trunk muscle activity will be recorded using wireless surface EMG sensors (Trigno Wireless EMG system, Delsys, Boston, USA). Careful skin preparation will be performed to increase electrode conductivity, then the sensors will be positioned and attached over the muscle belly of the right trunk muscles (shown in table 2). The

wireless EMG signals are transmitted to the EMG acquisition software via the electrodes pasted on the muscle belly, and then the raw EMG signals are processed and analysed using the EMG software (EMGworks Analysis and MATLAB) at a sampling frequency of 2000 Hz, with band-pass filtering at 15–500 Hz. Each muscle's EMG data will be high-pass filtered, low-pass filtered and rectified to calculate the linear envelope describing muscle activation. EMG data were measured for 5 s. After discarding the first and last second, the root-mean-squared, integrated EMG values and the mean power frequency and the median frequency of the three-second surface electromyography (sEMG) signals will be calculated.[39 40] All muscle EMG characteristics will be assessed at 0, 4 and 8 weeks during the study.

Muscle onset times determination

When the assessment of onset latency of the trunk muscles, subjects will be asked to perform rapid arm raises while quiet standing, which creates internal perturbations to the trunk and requires APAs. One electrode is placed over the right anterior deltoid (AD) as the prime mover. Other electrodes placements sites of the trunk muscles are shown in table 2. Participants will be instructed to stand relaxed with their feet shoulder-width apart and arms by their sides, then they will be told to flex their left shoulder as fast as possible to the level of 90 degrees with the full-extended elbow. After familiarisation, five repetitions of left shoulder flexion trials will be recorded with a random 5–10 s interval.[41 42] Participants will be instructed to 'relax and breathe' while standing between each trial. All of the trunk muscle onset latency will be calculated as the difference between absolute trunk muscle onset times and the AD onset time. Muscle activation occurred between 200 ms before AD onset and 50 ms after is regarded as anticipatory. The average muscle onset time for the five repetitions of each trunk muscle will be calculated and formed the basis for data analysis.[42]

RUSI on muscle thickness

Images of the external oblique (EO)/internal oblique (IO)/TrA and LM will be acquired with a portable ultrasound machine in B-mode (SonoSite M-Turbo, Seattle, USA) with a 6–13 MHz linear-array transducer (for abdominal muscles) or 2–5 MHz curvilinear-array transducer (for lumber muscles), automatically adjusted by the scanning depth. To avoid affecting the muscle morphology, the examiner must be careful not to compress the skin with the transducer. The positions of the transducer, the same as the monitoring sites, are shown in table 2. To avoid the influence of respiration, images will be captured at the end of exhalation. All muscle thicknesses will be measured at 0, 4 and 8 weeks during the study.[43 44] Muscle activation ratio=contraction thickness/relax thickness. Preferential activation ratio of TrA=TrA contracted/(TrA+IO+EO) contracted−TrA rest/(TrA+IO+EO) rest. A higher value of the preferential contraction ratio indicates a relatively greater change in the contraction

thickness of the TrA, whereas a lower value represents a relatively greater change in the contraction thickness of the EO and IO muscles.

Data management

All study data including the paper-based documents and electronic data will be stored at the Sun Yat-sen University for 15 years after the completion of the trial. All documents that contain participants' personal information will be identified by code number and stored separately. Only researchers involved in this study can be available to the confidential documents.

Monitoring

Because the study is not a drug trial and the sponsor or funder has no access to the raw data, a data monitoring committee will not be formed and there is no planned trial audit. Besides, there are no interim analyses and stopping guidelines due to the very low risks of adverse events and other unintended effects.

Statistical analysis

All of the statistical analyses will be based on the intention-to-treat principle and the Shapiro-Wilk test will be used to examine the normality of data distribution. Descriptive statistics including the number and proportions for categorical variables and means and SD for continuous variables will be recorded and displayed. Data are collected and analysed centrally after evaluation completion. Statistical analysis will be conducted using the SPSS V.22.0 software (IBM). Baseline demographics will be examined by descriptive statistics. Sphericity assumption will be identified by the test, and the differences of all the variables in each group will be compared using the repeated measures analyses of variance to examine intervention effects (dependent variables), with the group (SG and CG) as between-subject variable and time (0, 4, 8 weeks and 6 months of follow-up) as the within-subject variable. If a significant interactive effect of time and group exists, the post-hoc tests for multiple comparisons with Bonferroni adjustments will be adopted. The significance level is set at a priori alpha level of 0.05 for all of these tests.

Patient and public involvement

Patients and the public were not involved in the development of this study protocol. Patients presenting for treatment to our clinic or being recruited from the internet who satisfied the inclusion criteria will be recruited for the proposed randomised controlled trial (RCT). All subjects included will receive related treatments for free. If needed, trial participants will be able to obtain their individual results from the trial after the completion of the study.

DISCUSSION

The primary aim of the present study is to examine the effect of the RUSI-based CSE in individuals with CNLBP. The pain intensity of LBP patients is assessed with VAS,

the degree of disability is evaluated by ODI, and the quality of life is assessed with the SF-12. We hypothesise that CSE monitored by real-time biofeedback ultrasound will be superior compared with the CG for reducing pain, improving functional capacity as well as physical and mental health aspects.

Besides, the postural stability is examined with COP ways parameters, and the trunk position sense is represented by TRE. The effectiveness of postural control depends on the interaction between the neural and musculoskeletal systems, which is a suitable indicator for evaluating the function of the sensorimotor system. Previous studies have demonstrated that there are impaired postural control mechanisms, such as reduced postural strategy variability, increased COP sways, and difficulty in equilibrium maintenance after perturbation in subjects with CNLBP compared with healthy individuals.[45 46] In the present study, we expect that CSE with real-time biofeedback which targeted specific core muscles can improve the posture stability and position sense of the trunk.

Then, the trunk muscle onset latency in CNLBP individuals is evaluated based on the measurement of APAs during a postural task. During a rapid voluntary limb movement, the period before and up to 50 ms after the onset of the prime mover is defined as the anticipatory time window.[47] Some studies indicated that compared with healthy controls, trunk muscle onsets are delayed in people with CLBP, which cannot be classified as an anticipatory or feedforward response.[48 49] In our study, we speculate that RUSI-based core stabilising exercise will be useful to modify the delayed muscle onsets in CNLBP patients.

Finally, the trunk muscle activities are recorded by sEMG and the muscle thickness changes are measured with RUSI. Previous researches have reported that the imbalance of the trunk muscle force may lead to kinetic instability of the spine, while the weakness of local muscles, such as LM and TrA, may suboptimally load the passive tissues of the spine, contributing to the development and recurrence of LBP. Besides, the compensation activity of the superficial muscles during the process of training affects the effectiveness of CSE. Thus, muscles will be monitored under real-time biofeedback techniques to guarantee the correct training to facilitate selective activity and contraction of the TrA independently off the superficial muscles, which can be more beneficial than global exercise programmes on the restoration of deep muscles activation and strength.

Altogether, this is the first attempt to systematically investigate the efficiency of the RUSI-based core stabilising exercise in individuals with CNLBP. This trial will provide a quantitative analysis of the deep and superficial trunk muscle contraction and performance concerning changes in pain and functional status. It will provide randomised trial evidence of the clinical effectiveness of implementing RUSI biofeedback during CSE, which could potentially be a cost-effective method in clinical rehabilitation.

Ethics and dissemination

This protocol and informed consent has been approved by the Institutional Research Ethics Committee of the First Affiliated Hospital, Sun Yat-sen University (Approval number: [2020] 254–1). Participants will be informed of the study objectives, its risks and benefits, and must sign the informed consent before the study begins. Any protocol amendments will be detailed in the trial registration. Besides, the study findings will be submitted to scientific meetings and will also be published in peer-reviewed journals.

Trial status

This trial is currently recruiting participants and will require 6–8 months to complete all follow-up assessments.

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