

Effect of Self-Compassion Training Combined With Core Stability Exercise For Patients With Non-Specific Chronic Low Back Pain: Study Protocol For A Randomized Controlled Trial

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Abstract

Background: Non-specific chronic low back pain (NCLBP) has a high incidence, which has a significant impact on a patient's body and mind, and is a common condition affecting people's quality of life. Core Stability Exercise (CSE) is a modestly effective treatment for NCLBP; however, NCLBP has only been shown to be a useful treatment option in the short-term. Many clinical practice guidelines recommend the use of a biopsychosocial framework to guide management of NCLBP. Self-Compassion Training (SCT) is a promising psychotherapy treatment option for NCLBP; however, there is still a lack of research on CSE combined with SCT. In this study, we will seek to determine whether CSE combined with SCT is an effective treatment option for patients with NCLBP compared to CSE alone.

Methods: In this study, we will randomize 60 adults with NCLBP to a combined SCT and CSE arm or a CSE alone arm (30 participants per group). Both interventions will consist of four weekly 1.5-hour group sessions of CSE supplemented by home practice. The combined group protocol also includes 2 hours of SCT before CSE. Interviewers masked to the treatment assignments will assess outcomes at 4 and 12 weeks post-randomization. The primary outcomes will be back pain disability (based on the Roland-Morris Disability Questionnaire) and Pain intensity (NRS; average pain, worst pain, average pain) at 12 weeks.

Discussion: If SCT is found to enhance the effectiveness of CSE for patients with chronic back pain, the results of the study may promote the development of mind–body therapies for chronic low back pain.

Trial registration: The trial was prospectively registered with the Chinese Clinical Trials Registry Number: ChiCTR2100042810 .Registered on 21 Jan 2021.

Introduction

Background and rationale {6a}

Low back pain is a very common condition that occurs to people in different regions (developed and developing countries) and at different ages (from children to the elderly)^[1]. According to the 2019 Global Burden of Disease study, low back pain was identified as one of the main conditions affecting the health level of young and middle-aged people^[2]. The most common form of low back pain is non-specific low back pain. This term is used when the pathoanatomical cause of the pain cannot be determined^[3]. Non-specific chronic low back pain (NCLBP), defined as pain lasting for 12 weeks or longer^[3], can cause not only physical suffering, but also psychological and social problems^[5]. Although there is a vast range of physical and psychological therapies to treat NCLBP, the social burden associated with NCLBP has been increasing^[6].

The lumbar multifidus (LM) and transversus abdominis (TrA) are deep stabilizing spinal muscles that play crucial roles in the lumbar spine^[7]. Studies have reported that there is significant atrophy, fat

infiltration, and/or decrease in activation of the TrA and LM muscles in individuals with NCLBP^[8-9]. Core stability exercises (CSEs) can increase the activation of LM and TrA and have been proven useful for treating NCLBP^[10]. However, patients with NCLBP exhibit poor adherence to exercise training without supervision, leading to poor efficiency^[10]. Another study found only a weak relationship between the improvement in voluntary TrA activation and the improvement in some aspects of the clinical status after various programmes of exercise therapy^[13]. In addition to core muscles, low back pain may be related to psychological factors, such as perceptions of back pain, depression, fear of activity, and pain self-efficacy^[14]. Additionally, there are many proven effective psychotherapy methods for treating NCLBP, such as Mindfulness-Based Stress Reduction (MBSR). Relevant trials have suggested that MBSR may be an effective treatment option for patients with chronic low back pain^[15-17]. Self-compassion has been proposed as a key mediator of mindfulness-based interventions^[18]. An exploratory pilot study suggested that brief self-compassion training (SCT) could help people with NCLBP by reducing clinical pain intensity and disability and increase trait self-compassion and interoceptive awareness^[19]. Importantly, SCT can increase the practice of health promoting behaviors^[20]. Therefore, the addition of SCT to CSE may improve the treatment effect of low back pain. However, there is still a lack of relevant evidence about the integration of SCT and CSE to treat NCLBP.

Objectives {7}

To help enrich relevant research, we will conduct a randomized trial to evaluate the effectiveness of SCT in combination with CSE compared to CSE alone for the treatment of NCLBP. Our hypothesis is that SCT can reduce the negative emotions of patients with NCLBP and increase their adherence to CSE, thus achieving relief of pain intensity and disability.

Trial design {8}

The trial was designed as a randomized, controlled, observer and patient-blinded trial with two parallel groups. Randomization will be performed as block randomization with a 1:1 allocation. The control group will receive CSE only while the interventional group will receive a combination of CSE and SCT. Participants will be asked to complete a follow-up assessment at weeks 4 (post-treatment), and 12 (primary end point) after randomization (Figure 1).

The trial protocol will be conducted and reported according to the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT 2013)^[21]. The study was prospectively registered with the Chinese Clinical Trials Registry, Number: ChiCTR2100042810 (1/21/2021).

Methods: Participants, Interventions, And Outcomes

Study setting {9}

The study site is located in the outpatient Department of Rehabilitation of the First Affiliated Hospital of Sun Yat-sen University, and participants in Guangzhou will be mainly recruited for intervention.

The form of intervention will be group intervention with 10 participants per intervention group.

Eligibility criteria {10}

Participants aged 18 to 60 years whose back pain has persisted for at least 12 weeks, and are interested in participating the trial will be recruited. Table 1 lists the exclusion criteria and the rationale for each criterion. The main screening criteria will be included in the registration questionnaire. We will contact possible eligible participants by telephone or WeChat, and invited them to the hospital for final inclusion.

Table 1. Exclusion criteria

Exclusion criteria	Rationale
Low back pain has lasted <3 months	Not NCLBP
There were clear "red flag signs" (unilateral leg pain and numbness consistent with nerve distribution, intermittent claudication, weight loss without obvious cause, nighttime pain,trauma etc.) ⁸	Our interventions may not be effective
The history of spinal surgery	Back problem is complicated by medical or medicolegal issues
A score <4 on Roland-Morris Low Back Pain and Disability Questionnaire (RMDQ)	Back pain too mild to detect improvement
Patients who practice meditation regularly(weekly) in past 3 months;	Possible bias due to current or recent interventions
Patients who participated in courses relating to Core Stability Exercises in the past 3 months	Possible bias due to current or recent interventions
Conditions that may be uncontrolled for self-compassion meditation (e.g., psychosis, major depression or anxiety, current self-harm or suicidal ideation)	Condition would make it difficult to control or cause harm to participants
Unable to independently complete Chinese language questionnaires	Condition would make it difficult to communicate

Who will take informed consent? {26a}

A study researcher (ZFM) will introduce the trial to potential participants and discuss the trial with them. If the patient agrees, the researcher will obtain a written consent form stating that the patients are willing to participate in the trial.

Additional consent provisions for collection and use of participant data and biological specimens {26b}

Additional fMRI and musculoskeletal ultrasound will be needed to assess changes in brain function and muscle structure function that are not harmful to the patient's body.

Interventions

Explanation for the choice of comparators {6b}

CSE is the traditional treatment for low back pain. However, many patients have poor adherence to exercise training without supervision. One of the aims of the study is to demonstrate that SCT can improve CSE adherence. Its selection as a comparator is therefore justified.

Intervention description {11a}

We will randomize participants with NCLBP into two groups: an intervention group receiving SCT + CSE, and a control group receiving CSE alone. Both interventions consisted of four weekly 1.5-hour group sessions of CSE supplemented by home practice. The combined group protocol also includes 2-hours of SCT before CSE. The intervention will take place on Saturday and Sunday.

Self-Compassion Training (SCT)

Two hours of SCT will begin in a group counseling room in the hospital. This intervention is adapted from our previous study^[22] with some minor modifications based on the characteristics of NCLBP. During the intervention, group leaders will introduce information about self-compassion and guided participants through a series of practices. Participants will also be encouraged to do home practices following the guidelines provided by the group leaders. Psycho-education about self-compassion will be provided in the first session and a few practices to improve participants' awareness of stress (e.g, observing body sensations under NCLBP) will be presented. The second session will seek to advance participants' understanding of self-compassion using exercises that savored the experience accompanied by self-compassion practices (e.g., affectionate breathing meditation). The third session will focus on guiding participants to meet stress with self-compassion (e.g., loving-kindness meditation for ourselves). In the last session, participants will discuss and review their experience during the intervention with the group and make plans for future self-compassion practice (Table 2). SCT will be co-led by two graduate students in counseling psychology who have an adequate theoretical understanding of self-compassion and practiced mindfulness and self-compassion themselves. The whole intervention process will be supervised by a counseling psychologist (WYY).

Core Stability Exercise(CSE)

Group core stabilization training of 1.5 hours will be conducted under the supervision and guidance of a professional physical therapist. The Anyoukang (AUK,V1.0) sports training system will be used for on-site teaching. After the training, homework will be arranged for the subjects using the AUK Sports Training System. The participants will be asked to complete at least three training sessions per week with a training time of 20 to 30 min per session^[23], and to complete the daily training diary after training. The overall training lasted for 4 weeks. The first week will be spent mainly teaching the participants stretching exercises. In the second week, low-difficulty strength training will be added on top of the stretching training. In the third week, the participants will be taught more difficult strength training. In the last week, according to the actual condition of the participants, a set of exercise programs suitable for them will be determined (see Table 2 and Fig. 2). The program will be led by two professional physiotherapists with at least five years of experience (Liu Shufeng and Zheng Yiyi).

Table 2
Content of Core Stability Exercise and Self-Compassion Training class sessions

Session	Core Stability Exercise		Self-Compassion Training	
	Theme	Content	Theme	Content
1	Stretching exercise	<ul style="list-style-type: none"> • Rolling spine exercise • Lumbar rotation • lumbar extension • Cat stretch 	Back to body sensations	<ul style="list-style-type: none"> • Self-introduction • Body scan meditation • Introduction about self-compassion • Self-compassion touch
2	Add simple core strength exercise	<ul style="list-style-type: none"> • Hollowing training • Hip bridge • Simplified Bird dog • Half plank 	Experience compassion	<ul style="list-style-type: none"> • The relationship between the three emotional systems (threat system, drive-reward system, soothing system) and self-compassion; • Affectionate breathing; • Compassionate image
3	Add intensive core strength exercise	<ul style="list-style-type: none"> • inverted bicycle ride • Hip-single leg support • Bird dog • Dead bug 	Self-compassion under pressure	<ul style="list-style-type: none"> • Discussion about home practice; • Inner child; • Self-compassion writing
4	Summary	Develop personalized exercise programs	On the road	<ul style="list-style-type: none"> • Brief loving-kindness meditation; • Self-compassion phrases; • Review and Share; • Wishing bottle.

Criteria for discontinuing or modifying allocated interventions {11b}

Excessive exercise or Inadequate warm-up will cause muscle pain. In the event this happens, the participant should be told to reduce the intensity of the exercise or to rest for a few days.

Strategies to improve adherence to interventions {11c}

In addition to face-to-face therapy to improve adherence to interventions, the participants will be asked to keep a diary after exercise, and they will be reminded every day through an electronic questionnaire.

Relevant concomitant care permitted or prohibited during the trial {11d}

Relevant concomitant care and interventions(e.g, massage, physiotherapy or medicine) are prohibited during the trial. This can affect the accuracy of treatment outcomes.

Provisions for post-trial care {30}

If participants are injured as a result of this study, they may receive free treatment and/or compensation in accordance with Chinese law in case of injury in connection with this clinical study.

Outcomes {12}

Participants will complete outcomes at baseline, mid-treatment, post-treatment, and at 12-week follow-up. The primary time point will be 12 weeks after randomization. Baseline data collection included demographic and clinical characteristics, such as gender, age, work status, height, weight, education, treatment history, and medical history. Participants scanned the QR code to complete the questionnaire by themselves (wenjuanxing).

Primary outcomes

The primary outcomes are disability associated with low back pain and pain intensity.

(1)Back pain disability:

Back pain disability will be assessed using the Roland Morris disability questionnaire (RMDQ; scale 0–24; higher scores indicate greater functional limitation)^[24].

(2)Pain intensity

Pain intensity will be assessed with the Numeric Rating Scale (NRS), which measures mean pain intensity during the last week (scale 0–10, higher scores indicate greater pain intensity)^[25]. We selected three NRS types: average NRS (average pain intensity over the last week), current NRS (current pain intensity), and most severe NRS (most severe pain intensity over the last week)^[17].

Secondary outcomes

The secondary outcomes will be measured using questionnaires, such as pain intensity, psychological status, and general health status. The functional change in lumbar core muscles after intervention will also be evaluated.

(1)Anxiety and Depression Symptoms

Anxiety will be measured with the 7-item Generalized Anxiety Disorder scale (GAD-7; range, 0–21; higher scores indicate greater severity)^[26]. Depressive symptoms will be assessed with the Patient Health Questionnaire-9 (PHQ-9; range, 0–27; higher scores indicate greater severity)^[26].

(2)Quality of life

Quality of life will be assessed with the 36-item Short Form Health Survey (SF-36), which evaluates health-related quality of life and is analyzed into 2 main domains, the physical component and the mental component^[28].

(3)Patient satisfaction:

Patient satisfaction will be assessed using the patient satisfaction questionnaire. This is a simple questionnaire asking patients how satisfied they are with their treatment with answers rated from 1 to 5 using the following criteria: 1 = satisfied, 2 = just a little satisfied, 3 = neither satisfied nor dissatisfied, 4 = just a little dissatisfied, 5 = dissatisfied.

(4)Brain function assessment

All imaging data will be acquired at the East Campus of Sun Yat-sen University using a 3.0-T MRI scanner (Siemens 3T Prismas). Each participant will lay supine with their head snugly fixed with pillows and foam pads to reduce head motion. Participants will be asked to close their eyes and rest comfortably throughout the scans without moving or falling asleep. Functional MRI data will be acquired using a T2*-weighted, single-shot, gradient-recalled echo planar imaging sequence with the following parameters: TR/TE = 2000/30 ms; field of view (FOV) = 224mmx224mm; matrix size = 64x63; flip angle = 90°; 3.5mmx3.5mm in-plane resolution; slice thickness = 3.5mm; 33slices; slice gap = 0.7mm.

(5)Lumbar core muscles function assessment

TrA and LM muscle thickness will be directly measured by ultrasound, and the thickness change rate between the contractile and resting state will be calculated to predict postural stability from the perspective of muscle morphology^[29].

Images of the LM and TrA will be acquired in B-mode with a portable ultrasound machine (KONICA MINOLTA Inc, SONIMAGE HS1, Japan). Images of the resting and contractile state of the TrA and LM at the L4 level will be taken by a physician familiar with musculoskeletal ultrasound. The average resting and contractile thickness of the TrA and LM will be calculated using Image J software (Media Cybernetics, Silver Spring, USA). The following calculation formula of muscle contraction rate will be used: contraction rate = (average contraction thickness - average resting thickness)/average resting thickness ×100%.

Potential mediators

The clinical effect of low back pain may be mediated by different variables, and the effects of all potential mediators on outcomes will be explored in both treatment groups. The potential mediators of

outcome will be assessed at baseline, and at 2, 4, and 12 weeks after randomization with brief screening questions for pain catastrophizing, as well as pain acceptance, self-compassion, and self-efficiency.

(1) Pain catastrophizing

Pain catastrophizing will be assessed with the Pain Catastrophizing Scale (PCS). PCS consists of 13 items, and each item will be answered with a numeric value between 0 and 4; 0 corresponded to “not at all,” and 4 corresponded to “all the time”. Higher scores indicate a higher level of pain catastrophizing^[30].

(2) Pain acceptance

Pain acceptance will be measured with the Chronic Pain Acceptance Questionnaire-8 (CPAQ-8). The outcome represents the mental influence of pain. Two factors are contained in the scale: activity engagement and pain willingness. Higher scores indicate higher levels of pain acceptance^[31].

(3) Self-efficiency

Self-efficiency will be assessed with the Pain self-efficiency questionnaire (PSEQ). The PSEQ consists of 10 items and assesses the extent to how confident the participant is in performing a range of certain activities using a 7-point Likert scale, with 0 denoting no confidence at all and 6 denoting complete confidence. A higher total score after adding up the score of each item, indicates stronger confidence in mastering self-efficiency^[32].

(4) Self-compassion

Self-compassion will be measured with the Self-Compassion Scale (SCS). The scale is used to assess the degree that one realizes their suffering and wants to soothe oneself. The scale consists of 26 items measured on a 5-point scale with 1 = almost never and 5 = almost always; a higher score indicates a higher level of self-compassion^[33].

Intervention-related information

Intervention-related information will be evaluated by class attendance, adverse events, and exercise adherence. Class attendance will be assessed. by class records. Exercise adherence and adverse events will be recorded using the home practice diary.

Participant timeline {13}

Table 3
Content of Baseline and Follow-up Questionnaires

MEASURES	Baseline	Week		
		1-4	4	12
BASELINE CHARACTERISTICS				
Patient characteristics (age,gender,education, work status, BMI,pain duration)	X			
PRIMARY OUTCOME				
Back pain disability (RMDQ)	X		X	X
Pain intensity (NRS; average pain, worst pain, average pain)	X		X	X
SECONDARY OUTCOMES				
Quality of life (SF-36)	X		X	X
Depression (PHQ-9)	X		X	X
Anxiety (GAD-7)	X		X	X
Patient satisfaction			X	
Brain function assessment	X		X	X
Musculoskeletal assessment	X		X	X
Potential mediators				
Pain catastrophizing (PCS)	X		X	X
Pain acceptance (CAPQ-8)	X		X	X
Pain self-efficiency questionnaire (PSEQ)	X		X	X
Self-compassion (SCS)	X		X	X
Intervention-related information				
Class attendance			X	
Exercise adherence			X	X
Adverse events			X	X

Sample size {14}

Sample size calculation will be based on the primary outcome and RMDQ. For CSE, a mean difference of 1.6 for disability with a standard deviation of 2.0 has been found according to our previous study on exercise for lower back pain (not yet published). For SCT, a mean difference of 3.35, with a standard

deviation of 2.5 has been found according to a recent study^[19]. We assume that there will be more significant functional changes in the combined group with a mean difference in the RMDQ score of 4 points (SD = 3.0). To detect this difference at 12 weeks with a two-sided significance level (alpha) of 0.05 and a power of 90% with equal allocation to two arms would require 25 participants in each arm of the trial. To allow for 15% drop out, 30 will be recruited per arm, for a total of 60.

Recruitment {15}

Participants will be recruited in three waves of 20 participants each. Recruitment will be advertised in notices posted in the clinic and on a social network platform (Wechat). The main inclusion and exclusion criteria will be included in our registration questionnaire. Possible eligible participants will be invited to come to the hospital for a physical examination and baseline assessment. Eligible participants will be assigned a number according to the sequence of their arrival at the hospital and a to the research assistant (YJJ) for random grouping. Participants will be informed of the time of treatment after baseline assessment, so that the participants could arrange the time. Treatment content will be announced 3 days before the start of intervention.

Assignment of interventions: allocation

Sequence generation {16a}

For the randomization, a simple block randomization process was conceived and will be implemented by a trial assistant (Yang Jiajia). After eligibility is confirmed, every participant will be assigned a unique number as an identifier. Sequence generation will be achieved using the IBM Statistical Package for Social Sciences (SPSS) Version 23 software, and stratified with a 1:1 allocation random block size of 10. The randomization list reports a progressive randomization number for randomized participants (from 1 to 20), and the treatment (A or B) will be assigned for each of the participant.

Concealment mechanism {16b}

For allocation concealment, the randomization list will be maintained by the trial assistant (YJJ) who won't participant in the entire treatment procedure.

Implementation {16c}

The trial assistant (YJJ) will generate the allocation sequence and the principal investigator (ZFM) will enroll and assign participants to the interventions.

Assignment of interventions: Blinding

Who will be blinded {17a}

This method will provide 2-blinded conditions. During the intervention, participants will only know the participants in their own treatment group and will not know the identity of participants in the other groups. Each group will receive treatment at separate times to prevent contact between participants of the two groups. The outcome assessor (LY) and data analyst (LZC) will also be blinded to the group allocation. The physiotherapists and psychologists cannot be blinded to group allocation due to the study design.

Procedure for unblinding if needed {17b}

Not applicable. There is no need for unblinding.

Data collection and management

Plans for assessment and collection of outcomes {18a}

The data will be collected by the electronic questionnaire and automatically stored in the network disk database (<https://mhlab7.wjx.cn/corlogin.aspx>). The data will be jointly managed by the research team and analyzed by the statistical analyst, who will not know the grouping situation and intervention measures.

Plans to promote participant retention and complete follow-up {18b}

At the time of baseline assessment, participants will be charged a deposit of 100 yuan, which will be returned upon completion of the follow-up. The participants must complete two follow-up visits to receive their deposit (20 yuan for the first visit and 80 yuan for the second).

Data management {19}

The electronic-questionnaire data will be stored directly in the network disk of Wenjuanxing (<https://mhlab7.wjx.cn/corlogin.aspx>). After the patient fills out the questionnaire, they will not be allowed to modify their response. The musculoskeletal ultrasound and fMRI data will be added the database by two independent researchers, and then checked by a third one. Any inconsistencies between findings must be discussed and confirmed.

Confidentiality {27}

The personal information and confidentiality of the participants will be protected before, during, and after the trial. In all the saved data, only the unique number identifier of participants will be displayed, not the name of the participants. Only the researcher knows the name corresponding to the number.

Plans for collection, laboratory evaluation and storage of biological specimens for genetic or molecular analysis in this trial/future use {33}

Not applicable. No biological samples will be collected for genetic or molecular analysis as part of this trial.

Statistical methods

Statistical methods for primary and secondary outcomes {20a}

We will use an intent-to-treat approach to analyse all available data at baseline, post-treatment, and 3 months. We will compare the baseline demographic and clinical characteristics of the groups using the independent t-test for continuous variables and chi-square tests for categorical variables. The primary endpoint is change in RMDQ during the 3 months. Analyses of the primary and secondary continuous outcome variables will be analysed using two way repeated-measures ANOVA. Effect sizes of the mean group differences will be calculated as the Cohen d. Differences with a 2-sided P-value < 0.05 will be considered significant. All data will be analysed using IBM SPSS Statistics V.22.

Interim analyses {21b}

An interim-analysis will be performed on the primary endpoint after the first cohort (n = 20) of patients have been randomized and have completed the 3 months follow-up. The interim-analysis will be performed by an independent statistician blinded to the treatment allocation and will report their findings to the project leaders (WCH and WYY). Statistical results will determine whether the trial should be continued, modified, or halted earlier.

Methods for additional analyses (e.g. subgroup analyses) {20b}

Changes in the primary outcomes (RMDQ and NRS) will be correlated with other results (deep trunk muscle function, brain function, and potential mediators) to identify the reasons behind any change in the primary outcomes.

Methods in analysis to handle protocol non-adherence and any statistical methods to handle missing data {20c}

We will use intent-to-treat approach to analyse all available data, all participants will be assessed at baseline prior to randomization, so for the missing data we will use the methods of last observation

carried forward or baseline observation carried forward to fill up.

Plans to give access to the full protocol, participant level-data, and statistical code {31 c}

According to the data sharing statement, we will deliver a completely deidentified data set to an appropriate data archive for sharing purposes no later than 3 years after the collection of the 1-year post-randomization interviews.

Oversight and monitoring

Composition of the coordinating centre and trial steering committee {5d}

ZFM, XWH, ZSY,WYY and WCH comprise the steering committee.

Composition of the data monitoring committee, its role and reporting structure {21 a}

A data monitoring committee will not be needed because due to the short duration of the trial and the lack of known minimal risks.

Adverse event reporting and harms {22}

In this study, physical discomfort due to exercise will be defined as an adverse event. In the treatment process, the participants will be asked to fill in a training diary every day to report their physical conditions, so as to detect adverse events and deal with them in a timely manner.

Frequency and plans for auditing trial conduct {23}

Auditing is not planned in our trial yet.

Plans for communicating important protocol amendments to relevant parties (e.g. trial participants, ethical committees) {25}

If the protocol needs major revision, we will first submit the change request to the ethics committee, and then implement the new plan after it is approved.

Dissemination plans {31 a}

The study results will be released to the participants, healthcare professionals, the public, and other relevant groups via publication.

Discussion

This trial attempts to combine SCT with CSE to improve the treatment of NCLBP. Since SCT not only relieves the negative emotions of patients with low back pain, but also promotes healthy behaviors, we think it is therefore likely to improve the effect of CSE in treating NCLBP. Face-to-face intervention will only occur once a week; the rest of the time we will use social networks to communicate with the subjects. However, due to the influence of COVID-19, our face-to-face treatment may be suspended at any time, so we will consider developing an APP for remote treatment in the future, making the treatment safer and more convenient for the participants.

Trial Status

Protocol version number: 2 (May 30, 2021)

First day of recruitment: April,15, 2021

Expected end of recruitment: October 30, 2021

Abbreviations

NCLBP: Non-specific chronic low back pain

CSE: Core Stability Exercise

SCT: Self-Compassion Training

RMDQ: Roland-Morris Disability Questionnaire

NRS: Numeric Rating Scale

LM: lumbar multifidus

TrA: transversus abdominis

MBSR: Mindfulness-Based Stress Reduction

GAD-7: 7-item Generalized Anxiety Disorder scale

PHQ-9: Patient Health Questionnaire-9

SF-36: 36-item Short Form Health Survey

PCS: Pain Catastrophizing Scale

CPAQ-8: Chronic Pain Acceptance Questionnaire-8

PSEQ:Pain self-efficiency questionnaire

SCS:Self-Compassion Scale

Declarations

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Authors' contributions {31b}

ZFM and XWH are the Chief Investigators; they conceived the study, led the proposal and protocol development.LSF and ZYY were responsible for the design and writing of Core Stability Exercise.XWH and LWJ were responsible for the design and writing of Self-Compassion Training.YJJ was responsible for the design and writing of allocation.XWH was responsible for the Selection of questionnaires.LY was responsible for the design of musculoskeletal ultrasound;ZYM and ZSY was responsible for the design of fMRI.LZC was responsible for the design of data analysis.WYY and WCH held full responsibility for this manuscript equally. All authors read and approved the final manuscript.

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Availability of data and materials {29}

Only the principal Investigators will be given access to the final trial data set.The trial data sets will be housed on web site (<https://mhlab7.wjx.cn/corplogin.aspx>),and all data sets will be password protected.

Ethics approval and consent to participate {24}

This trial has been approved and supervised by the Ethics Committee of the First Affiliated Hospital of Sun Yat-sen University. The review date is January 20, 2021, and the approval number is [2021]079.

Written, informed consent to participate will be obtained from all participants

Consent for publication {32}

Written informed consent for publication will be obtained from all participants.

Competing interests {28}

The authors declare that they have no competing interests

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Figures

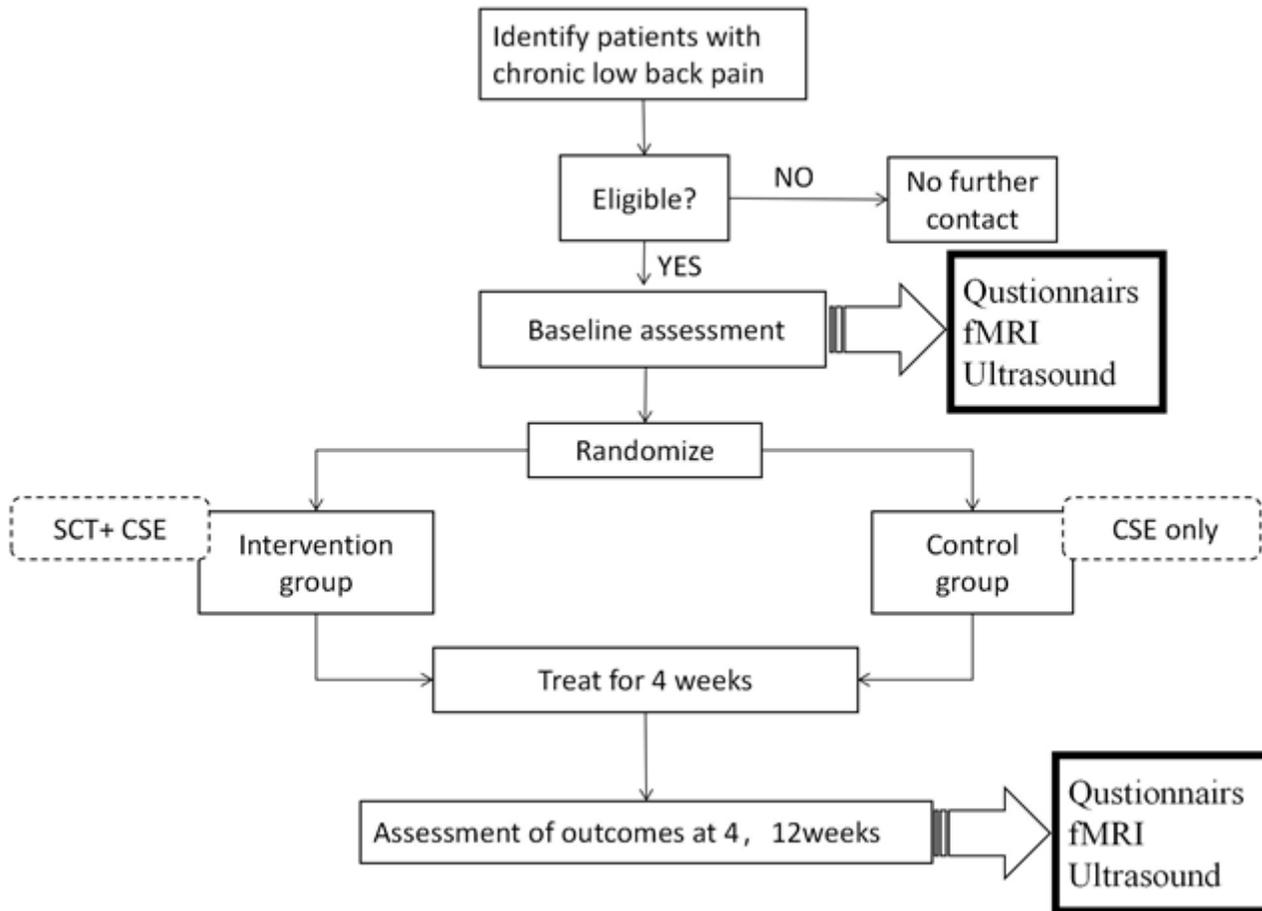


Figure 1

Flowchart of the trial protocol. SCT, Self-Compassion Training; CSE, Core Stability Exercise.



Figure 2

Exercises used in the SCE program. A. Rolling spine exercise; B. Lumbar rotation; C. lumbar extension ; D. Cat stretch; E. Hollowing training; F. Hip bridge ; G. Simplified Bird dog; H. Half plank; I. Inverted bicycle ride; J. Hip-single leg support; K. Bird dog; M. Dead bug.