# Effects of eight-week therapy using a spinal mobilization apparatus on pain and muscle fatigue in subjects with non-specific low back pain: a protocol for a single-center randomized controlled trial

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**Study Protocol**

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# Abstract

**Background:** Long-term clinical practice has found that there are still some deficiencies in freehand joint loosening. Due to the therapist's lack of anatomical knowledge and treatment experience, and incorrect wrist joints, wrist and other parts of the force during the treatment, the incidence of wrist and lower back pain produced by the therapist has significantly increased. The purpose of the feasibility study is to observe the effects of spinal mobilization apparatus combined with sling exercise training on pain and muscle fatigue in patients with non-specific low back pain.

**Methods:** This pilot study will recruit 82 eligible patients with non-specific lower back pain from Ningbo Rehabilitation Hospital. Patients who are re-elected to this study will be randomly assigned to the intervention group in a 1:1 ratio to receive spinal mobilization apparatus and sling exercise training on top of completing conventional rehabilitation therapy, while the control group will receive sling exercise training on top of conventional rehabilitation therapy. Primary and secondary indicators were tested at the 0-week, 8-week and 3-month follow-up phases, respectively. The Japanese Orthopaedic Association (JOA) scale was used for the primary observation and the visual analogue scale (VAS) score, core group endurance test (CET) for the secondary indicators, intra-abdominal pressure (IAP), surface electromyographic (SMEG) measurement of core muscle fatigue, musculoskeletal ultrasound measurement of diaphragm thickness (DT), range of motion (ROM) and the activity of daily life (ADL).

**Discussion:** This pilot study will determine the feasibility of conducting a full randomized controlled trial protocol to assess the effectiveness of spinal mobilization apparatus combined with sling exercise training compared to sling exercise training alone in improving low back pain and muscle fatigue in patients with non-specific lower back pain, providing preliminary clinical evidence of the efficacy of the combined therapy in improving low back pain and muscle fatigue in patients with non-specific lower back pain.

**Trial registration:** This trial was first registered on Chinese Clinical Trial Register, ChiCTR2100042333 on 19 January 2021.


# Introduction

Nonspecific low back pain (NLBP) is a general term for back pain that is characterized by neither definite histopathological changes nor objective examination to determine the potential cause [1]. One study reported that the use of health care facilities by patients with chronic low back pain has risen every year between 1990 and 2015, with to a 54% increase in the number of patients with disabilities [2]. NLBP is generally manifested as persistent or recurrent episodes of low back pain, excluding local specific and nerve root lesions, such as the spasticity of lumbar muscle caused by bilateral spinal tension imbalance, low back muscle strain, myofascial pain syndrome, etc. [3]. It not only affects the health and quality of life of sufferers, but also increases social costs [3]. In view of the common nature of NLBP and its harm

to health, how to effectively treat NLBP has been a research hotspot in the fields of rehabilitation and sports medicine.

Existing studies, however, have suggested that inactivation or prolonged activation of the core muscles is one of the important causes of lumbar instability [4]. Exercise therapy has been recognized as the mainstream treatment to improve the clinical symptoms of patients with low back pain [5]. Above of the Sling exercise training, as a new exercise therapy method, has aroused extensive interest in rehabilitation and sports medicine both at home and abroad in improving the neuromuscular function of patients with low back pain [6, 7]. On the one hand, some studies have confirmed that the effect of Sling exercise training for the treatment of low back pain is significantly superior to conventional rehabilitation training [8]. On the other hand, Sling exercise training can strengthen and train the core muscle group, so as to better improve the body's core stability [9]. It should be noted that there are limitations to various treatments and training for NLBP, including acupuncture or massage therapy, that nevertheless can significantly improve the symptoms of low back pain and muscle spasticity in patients [10, 11]. These methods are relatively simple but their effects on patients with chronic NLBP are limited.

Studies have shown that level 1–2 manipulation of joints is more significant for improving the pain status of patients with low back pain, and level 3–4 manipulation of joints is more significant for improving the joint movement limitation of patients with low back pain [12, 13]. However, long-term clinical practice has found that there are still some deficiencies in freehand joint loosening. Due to the therapist's lack of anatomical knowledge and treatment experience, and incorrect wrist joints, waist and other parts of the force during the treatment, the incidence of wrist and lower back pain produced by the therapist has significantly increased. Our research team developed a spinal joint loosening instrument, which was designed strictly according to the treatment parameters of spinal mobilization. Based on previous clinical practice, it was found that the force was more permeable and even than that produced by manipulation looseness. After the loosening of the spinal joints, the stiffness of the lumbar spine is significantly reduced, and the tension of the back muscles is also improved. Therefore, the purpose of this study will be to investigate the effects of a spinal mobilization apparatus combined with sling exercise training on pain and muscle fatigue in patients with NLBP.

# Methods/design

### Aims and hypotheses

A total of 82 subjects will be enrolled in a single-center randomized controlled trial. This study will be conducted in Ningbo Rehabilitation Hospital from March 2021 to March 2023. Subjects with NLBP will be recruited from both outpatient and inpatient departments at Ningbo Rehabilitation Hospital and randomly divided into the intervention group and the control group in a 1:1 ratio. Two groups of subjects will receive conventional rehabilitation treatment, the intervention group will be treated with the spinal mobilization apparatus combined with sling exercise training and the control group will only be treated with sling exercise training. The treatment time on the spinal mobilization apparatus will be 20 min, and the sling

exercise training time 20 min, 5 times a week for 8 weeks. The main indicators will be the Japanese Orthopaedic Association (JOA) scale, and secondary indicators will include the visual analogue scale (VAS) score, core group endurance test, intra-abdominal pressure, surface electromyographic (SMEG) measurement of muscle fatigue, musculoskeletal ultrasound measurement of diaphragm thickness, range of motion and activity of daily life. All evaluations will be performed at baseline, 8 weeks and during 3 months follow-ups. The flow chart of the trial design is shown in Fig. 1. The design of the trial protocol is based on the standard protocol project: 2013 statement of the intervention trial (SPIRIT) (Fig. 2).

### Primary and secondary outcome measurements

In the proposed trial, the JOA scale will be used as the main evaluation index to assess a subject's subjective symptoms, signs, daily living ability and bladder function. Similarly, three levels of clinical efficacy will be used to evaluate the effects before and after treatment namely: complete response (CR), partial response (PR) and no response (NR). The ranked data will be used to define the main observation indicators.

Secondary observation indicators will include the VAS score, core group endurance test, intra-abdominal pressure, SMEG test for muscle fatigue, musculoskeletal ultrasound for diaphragm thickness, range of motion and activity of daily life. The main indicators and secondary indicators will be evaluated as listed in Table 1.

### Main outcome measurement

An experienced physician will assess lumbar function using the JOA scale. Primary evaluators will be assessed at baseline, 8 weeks and during a 3-month follow-up. The assessments will include subjective symptoms, signs, daily activity and bladder function, with the highest total score being 29 points and the lowest score 0 points. The lower the score, the greater the dysfunction [14, 15].

We will use JOA scale and traditional Chinese medicine (TCM) symptom diagnostic efficacy criteria to evaluate the efficacy before and after treatment [16]. The criteria will be as follows:

**CR:** 60% ≤ improvement rate < 95%, the symptoms of lumbago and leg pain basically disappeared, straight leg elevation test above 50°, general waist function is ok, does not affect daily work and life.

**PR:** 26% ≤ improvement rate < 60%, the symptoms of lumbago and leg pain were alleviated, the function of waist activity was improved, and the daily work and life were affected to some extent.

**NR:** improvement rate < 25%, no improvement in symptoms or signs.

### Secondary outcome measurement

Secondary indicators will include other relevant assessment indicators, such as the VAS score, core group endurance test, intra-abdominal pressure, SMEG test for muscle fatigue, musculoskeletal ultrasound for diaphragm thickness, range of motion and activity of daily life. An experienced physician will be responsible for evaluating secondary measures at baseline, 8 weeks and at 3 months follow-ups.

The VAS score will be used to evaluate the improvement of patients' lumbar pain function before and after treatment and at the 3 months follow-ups, with a total score range of 10–0 for painless and 10 for severe pain [17, 18]. The higher the score, the more obvious the pain will be.

The core muscle endurance test will be divided into two parts [19]: Static endurance tests of the abdominal muscles and lower back muscles, respectively. The specific test methods will be as follows: 1) Abdominal static muscle endurance test: During the test, subjects will be required to touch the knee joint with their fingers, lie on their back, bend their knees 90° and record the test time with a stopwatch; 2) Back static muscle endurance test: Subjects will be placed in the supine position, with the anterior iliac ridge as the dividing line. During the test, patients will be required to put their hands behind their head, raise their upper body and maintain it in the horizontal position, and record the time with a stopwatch.

With Chattanooga (New Jersey, USA) as a stabilizer, intra-abdominal pressure will be measured [20, 21]. In the trial, 4 conventional training exercises will be employed and the abdominal pressure of the waist measured. The observation index will be the value of intra-abdominal pressure. Specific test methods will be:

1) The subject in the prone position. The initial value of the pressure biofeedback instrument will be 70 mmHg and placed in $L_{2-4}$. The abdomen will be contracted with the greatest strength until the pointer shows a stable value, and the pressure value measured and recorded.

2) The subject in the supine position. Asked to bend the hip and knee, adduction of unilateral upper limb to body side, and hold the pressure biofeedback instrument on the other side. Bend the hip and bend the knee of both lower limbs. The initial value of the pressure biofeedback instrument will be 40 mmHg and placed at position $L_{2-4}$.

3) The subject in the supine position. Adduction on one side of the upper limb to the body side, with the pressure biofeedback instrument on the other side of the upper limb, accompanied by lower limb flexion and hip flexion (90º), on the other side of the lower extremity adduction flat, and placed at the $L_{2-4}$, pressure of the biofeedback instrument with starting value of 40 mmHg, back in the greatest contraction, until the pointer displays a stable value, measure and record the pressure value.

4) The test subjects' shoulder joint undergoes forward flexion, that is, under the prone position, accompanied by the unilateral upper limb forward extension parallel to the spine and raised, the other side upper limb adduction to the body side, and both lower limbs adduction flat. The initial value of the pressure biofeedback instrument will be 70 mmHg and placed in $L_{2-4}$. The abdomen will be contracted with the greatest force until the pointer shows a stable value, and the pressure value measured and recorded.

In the proposed trial, SMEG signal indicators will be used to select the latency difference values of root mean square (RMS), median frequency (MF) and mean power frequency (MPF) of the multifidus muscle and trans-abdominis muscle [22–24]. Noraxon's 10-channel wireless SMEG analysis system (signal:

TeleMyo DTS) and its own signal acquisition system will be adopted as appropriate. SMEG signals of the multifidus muscle and transverse abdominis will be measured.

5) Electrode placement: The location of the electrode will be determined according to the anatomical position of the muscle and the muscle fiber trend as well as on reports in the literature. The location of the electrode will be recorded: multifidus muscle (2 cm between the spines of $L_{4-5}$); Transverse abdominis (about 2c m medial to the intersection of the vertical line of the anterior superior iliac spine and the costal margin); the highest point of the left and right eminence of the erector spinalis muscle ($T_{12}$ to $L_1$). Before placing the electrode, the corresponding skin will be disinfected with alcohol to resist resistance. The sequence of placement of the 4 electrodes will be as follows: (1) the left multifidus muscle; (2) the right multifidus muscle; (3) the left erector spine muscle; (4) the right erector spinalis muscle. The sequence of placement of the 4 electrodes will be: (1) the left multifidus muscle; (2) the right multifidus muscle; (3) the left transverse abdominis; (4) the right transverse abdominis muscle. The SMEG signal test will be divided into two components:

The first step will be the prone and back lift test:

The second step will be the plank support test. The patient tries his best to perform the plank support until the hip drops more than 1 cm, and then monitoring ceases. The SMEG signals on the surface of the multi-splitters and transverse abdominis muscles on both sides of the trunk of the patient will be monitored through blue-tooth connected electrode sensors, and the MF and MPF values of the SMEG recorded during the contraction process of the multi-splitters and transverse abdominis muscles.

A Toshiba high frequency ultrasound (APLIO-SSA770, Japan) system will be used with an ultrasonic probe frequency of 7.5–14 Hz to measure the thickness of the $L_{4-5}$ segment multifidus muscle. All tests measurements will be taken by a formally trained doctor [25, 26]. The thickness of multifidus muscle will be determined by taking 3 pictures at a time and then calculating the mean value. The specific experimental steps will be as follows: the subject will be placed in the prone position; a pillow placed on the abdomen to avoid excessive spine flexion; the subject will be asked to put both upper limbs on the side of the body; at the same time place the pillow on the calf, put the knee joint in a comfortable position. (2) Position the body surface with both hands to mark the $L_{4-5}$ vertebral spinous process with a pen. The thickness of the multifidus muscle on both sides of the vertebral body will be measured by placing the ultrasonic high-frequency probe at the mark of $L_{4-5}$. Measurement of transverse abdominis muscle thickness: The subject will lie prone on the treatment bed, exposing the abdominal skin, the probe being positioned at the intersection of the axillary front and the level of the navel, and perpendicular to the skin. The subject will be asked to perform the action of pulling in the abdomen and levelling the anus, while maintaining smooth breathing and measure the thickness of the transverse abdominis will be measured. Measurement of the thickness of the erector spine muscle: the subject will be in the prone position, lying on the side of the upper limb, with the lower back muscle relaxed. At the bilateral level of the third lumbar spine, the highest point of the muscle, about 2 cm from the spinous process, is the erect spinal muscle. A conventional two-dimensional ultrasound cross section will be employed to examine the

muscle abdominis of the erector spine muscle. The longitudinal section will be rotated 90° along the direction of the muscle bundle to observe the muscle echo and muscle fiber movement. The SWE mode will be selected and set to 20 × 20 mm. The square examination box will be located 1–3 cm from the skin surface (depending on the thickness of the subject fat layer) and we will wait for about 5 s until the color in the box is evenly filled, and then the image will be frozen. The Q-Box function starts. The left and right sides will be measured 3 times and the average value calculated. **Note**: The muscle thickness of the erector spine muscle, transverse abdominis muscle, and multifidus muscle will be measured on both sides.

The lumbar flexion and extension angles will be measured with a protractor [27, 28]. The subject will be placed in the standing position with the spinous process of the 5th lumbar spine as the axis, the vertical line with the ground as the fixed arm, and the line between the 7th cervical spine and the 5th lumbar spine as the mobile arm. The range of motion of the joint in spinal flexion and extension will be measured using a protractor.

Quality of life will be assessed using the SF-36 Health Survey summary [29]. The eight aspects related to quality of life are physiological function (PF), role physical (RP), physiological pain (BP), general health (GH), vitality (VT), social function (SF), emotional function (RE) and mental health (MH). PF, RP, BP and GH represent physical health, while VT, SF, RE and MH represent mental health. The scores will range from 0 to 100, with higher scores indicating better health.

Table 1
An evaluation list of major and minor indicators

| Assessment | Baseline | 8 weeks | Follow-up (3 month) |
|---|---|---|---|
| **Primary outcome** | | | |
| JOA scale | | | |
| **Secondary outcomes** | | | |
| Visual analogue scale (VAS) | | | |
| Range of motion (ROM) | | | |
| SF-36 health survey summary | | | |
| Diaphragm thickness (DT) | | | |
| Intra-abdominal pressure (IAP) | | | |
| Core group endurance tests (CET) | | | |
| **Surface electromyography (SMEG)** | | | |
| 1. Mean power frequency (MPF) | | | |
| 2. Power frequency (PF) | | | |
| 3. Root mean square (RMS) values | | | |

### Adverse event collection procedure

The lead investigator will promptly report, manage, and document any adverse events and procedures that may occur during the trial. An 8-week clinical intervention will be required to determine the cause of adverse events during the trial and to ensure that the safety, health and legal rights of the subjects are effectively protected. Serious adverse events will be referred to the project manager within 24 h. The Ethics Committee of Ningbo college of health sciences and the Clinical Trial Office of Ningbo Rehabilitation Hospital will jointly put forward rationalization proposals.

### Trial setting

The Ningbo Rehabilitation Hospital will undertake the study. Rehabilitation therapists (including physiotherapists and occupational therapists) will provide a comprehensive rehabilitation program, in which subjects enrolled in the trial will receive motor therapy, manual therapy, physical factor therapy (low frequency, medium frequency, high frequency ultrashort wave and light therapy) and traditional rehabilitation.

### Inclusion and exclusion criteria

### Inclusion criteria

(1) Medical history: Most of the subjects will have a history of acute lumbar pain and chronic low back pain;

(2) Symptoms: The subjects lower back pain will be obviously diffuse and have unclear locations. It will often be accompanied by hip discomfort and pain in the back of the thigh, but the range will generally not be more than the knee joint;

(3) Signs: Increased muscle tension in the lower back, bands and nodules reached in the muscles, accompanied by low back pain. The physiological radian of the waist decreases or even disappears, and the spine process can be touched, and the range of waist movement is obviously limited.

(4) Imaging examination: no obvious abnormalities found, part of the spine has rotational scoliosis, and the pelvis was not ascending or of equal width. Physiological radian change, lumbar vertebra bone hyperplasia.

(5) No relevant treatment had been given in the past two weeks;

(6) Patients voluntarily will participate in this trial, agree and sign informed consent;

(7) Aged between 18 and 65 years.

If the above conditions are met, subjects will be included in the trial.

**Exclusion criteria**

(1) Failure to meet the above diagnostic or inclusion criteria;

(2) Failure to cooperate with examination and treatments;

(3) Receive other treatments during the trial;

(4) Imaging findings of root compression, accompanied by symptoms of corresponding innervated muscles and sensory areas;

(5) Patients with tumor, mandatory spondylitis, tuberculosis, fracture, etc. detected after laboratory results;

(6) Critically ill patients: recent unstable blood pressure control and women's pregnancy; patients with an abnormal coagulation function;

(7) Severe skin injury or skin disease in the manipulation region;

Any one of the above items meant a subject was excluded from the trial.

**Study population and recruitment**

In the trial, the aim will be to enroll 82 subjects aged 18–65 years with NLBP in the Ningbo Rehabilitation Hospital from March 2021 to March 2023. First, prior to the start of the trial, a resident will inform potential subjects that they can participate in the trial according to the inclusion criteria, explain its purpose and provide feedback. Second, the main investigator will introduce the specific reason for the trial according to the inclusion and exclusion criteria. The subjects will be informed of the risks and advantages of the trial. Third, if a subject is to participate, the main investigator will be required to provide more detailed information in response to questions raised by a subject. Finally, if the subject wishes to participate in the trial, they and their family members must sign informed consent anonymously.

## Randomization and blinding

### Randomization

The CW will be responsible for the assignment order of subjects. The CW and FMY will be responsible for the inclusion of subjects and JWY will assign subjects to the intervention group. In the early stages when no subjects will have participated in the trial, a statistician will be responsible for generating a table of random numbers using SPSS ver. 20.0 software (IBM Corp., Armonk, NY, USA). Subjects will be randomly assigned to the intervention group and the control group in a 1:1 ratio. A list of random numbers will be placed in an opaque envelope. The sequencing of the trial will be conducted by a research assistant who is not participating in it. Specific requirements will include that the research assistant shall not participate in the process of trial recruitment, intervention, outcome assessment or statistical analyses. When subjects meet the inclusion criteria a research assistant will inform participating therapists of the intervention and the assigned results will be communicated to enrolled subjects (intervention group and control group).

### Blinding

Subjects will be randomly assigned through a random code generated by IBM SPSS statistical software, ensuring that the evaluator was blind. Only the principal investigator will know the order of the random codes and the results evaluator will be blind. Similarly, the outcome evaluator and the caregiver will not change the information exchanged during the trial and the outcome evaluator will not be allowed to ask for specific information about the intervention. In the trial, only the evaluator will be blind, so un-blindness will not be an issue.

### Intervention

Both groups will be treated with conventional rehabilitation therapy. The intervention group (IG) will be treated with the spinal mobilization apparatus combined with sling exercise training and the control group (CG) will be instructed in sling exercise training, 5 times a week, for a total of 8 weeks. It should be noted that the spinal mobilization apparatus has been awarded a utility model invention patent (patent number: ZL 201820437008.8). An experienced therapist will be responsible for completing the training and treatment to ensure consistency with the trial protocol. At the same time, manipulative therapy and rehabilitation training will adopted, which will not have any side effects on the subjects participating. However, during the course of the trial if the subject's physical condition deteriorated, the medical

expenses incurred in treatment and evaluation will be covered by National Health Insurance. All subjects participating in the trial will receive comprehensive rehabilitation treatment at Ningbo Rehabilitation Hospital including exercise therapy, acupuncture massage, physical factor therapy and so on. The frequency, duration and intensity of comprehensive rehabilitation will be the same for both groups.

### Control group

In addition to receiving conventional rehabilitation treatment, subjects in the control group will only need to complete sling exercise training [30]. Sling exercise training will include[31]: 1) supine bilateral training using narrowband inelastic rope hanging double lower limbs respectively; wide band elastic rope suspension will be used in the lumbosacral area. The subject will be asked to pull in their abdomen and levitate the anus, raise the pelvis, cooperate with breathing training, maintain the posture until they experience a little fatigue or pain and rest for 30 s, and then proceed to the next set of training for a total of 5 repetitions; 2) Unilateral strengthening training in the supine position: the lower limbs will be suspended by narrow band elastic ropes and inelastic ropes respectively, and the lumbosacral region suspended using a wide band elastic rope. The subjects will be instructed to carry out the previous step of training and repeat it on the other side; 3) Prone position training: will use elastic rope suspension at the waist, and use non-elastic rope suspension on both sides of the lower extremities, upper arm elbow joints for support on the treatment bed, requiring the subject to coordinate breathing, abdominal and anal lifting and hip clamping, requiring the pelvis and trunk to be raised when doing plank support, or do body bending. According to the subjects functional level, the above training will gradually increase the difficulty of shaking and moving the suspension position. 20 min/time, once a d, 5 d a week, course of treatment 8 weeks. Sling exercise training for all control groups will be performed by two experienced therapists separately. All the exercise programs are illustrated in Fig. 3.

### Intervention group

The intervention group will be treated with sling exercise training combined with spinal mobilization apparatus. The sling exercise training and conventional rehabilitation treatment will be the same for the control group, and the specific treatment procedure of the spinal joint loosening apparatus will be as follows. First, the subject will lie prone on the treatment bed in a comfortable position. A physiotherapist will determine the lesion and muscle areas that need to be relaxed through rehabilitation assessment. Next, the treatment parameters of the robotic arm will be adjusted, and then a 5 to 10 min lower back muscle relaxation program will be started. A laser will be used to locate the muscle segments that need to be relaxed. Then, the mechanical pressure on the arm will be reduced until the head is fully applied to the skin, changed to the "slow down" mode, and subjects asked to relax (slow their breathing rates). If the subject has mild acid distension, they should stop pressing their head and slow down. This position is the end of mobilization and we will record the pressure weight of the head at this time. The set pressure displacement, click "Settings", and the displacement will become yellow, then click on the button on the "slow", according to the requirements of the reaction of subjects with joint mobilization determine appropriate increase displacement (general control in 1 ~ 5 mm), start recording, this position is the press the start bit, then click "Settings", and the displacement with a yellow into primary colors. Parameters:

treatment time (including total time: that is, a treatment unit of time; mobilization time refers to the press time, every time a 6 ~ 10 times pressure will be selected, and each applied for 30 ~ 60 s). The tentative time (refers to the press after 30 ~ 60 s of the time duration of the machine, generally 60 s), cycle times (refers to the treatment frequency, average 6 ~ 10 times repeated). All settings by be adjusted by the subject. In case of discomfort, the subject can press an abort treatment button.

## Sample size

Figure 1 shows a standard detailed flow chart of the trial with reference to the (CONSORT) reporting criteria. Subjects who met the inclusion and exclusion criteria were randomly allocated to two groups prior to enrolment in this study. Namely, the intervention group and the control group, with the intervention group (n = 41),and the control group (n = 41). As no previous clinical studies related to this topic have been conducted. Therefore, it was not possible to carry out sample size calculations by determining clinical power and effect size. As this study was a pilot study, we decided to keep the various numbers at 41, i.e. a total of 82.Statistical analysis

In the proposed trial, the main indicator will be the JOA scale, which will be divided into three grades, CR, PR and NR according to the change values at baseline, 8 weeks and at 3 month follow-up, respectively expressed as the adoption rates and percentages. Comparison of efficiency between the two groups will be performed using the $X^2$ test. The overall efficacy evaluation and efficacy evaluation methods will also be used. The calculation formula will be: Effective = (excellent + effective)/total cases × 100%. The secondary indicator (e.g., VAS score, core group endurance test, intra-abdominal pressure, SMEG test for muscle fatigue, musculoskeletal ultrasound for diaphragm thickness, range of motion, and daily quality of life are all continuous data. If they are in line with a normal distribution, repeated measurement MANOVA of 2 groups * 3 times points will be used, and post-test will be performed by the LSD or SNK methods. If the data does not conform to a normal distribution, a nonparametric test will be employed. The significance level will be set as $P < 0.05$.

This trial will use the intention-to-treat (ITT) method, including the final analysis set (the only) and per protocol (PP). FAS will refer to data sets that are obtained from all random subjects to eliminate the least and fair data. PP is sometimes referred to as "effective case" and "effective sample collection", which is an analysis set of the total subset. PP often refers to the collection of valid cases and valid samples, and it is also the analysis set of the whole subset. Consistency evaluation will also be employed as it is frequently used to evaluate the efficacy of treatment for subjects [32].

## Monitoring

To ensure the quality of the randomized controlled trial, this study will be conducted at Ningbo Rehabilitation Hospital. We will upload the data onto the Chinese clinical trial registration website, so as to facilitate the management team to find problems, timely checks and potential data analysis for errors. The clinical trial center office of the ethics committee of Ningbo college of health sciences will have the opportunity to obtain the results of the mid-term trial and make a decision. A qualified clinical specialist will also be invited to monitor the RCT.

### Trial quality control

The principal researchers, CW and FMY, will be responsible for the formulation of the study protocol while JWY will be responsible for the coordination (collation and completing the collection and analysis of data). SSX will be responsible for the overall quality control of the test process. MM and QQ will be responsible for database management and data development. FMY will be responsible for establishing the test quality management committee.

### Researcher training

All researchers participating in the trial will have good clinical expertise, qualifications and strong research capabilities. All subjects in the trial will receive unified training before starting it. After training, all researchers will become fully familiar with the purpose of the clinical study, including the trial plan, observational indicators and case report forms (CRF). Each researcher will publish an "investigator's manual" for reference.

### Data management

This project will be carried out in strict accordance with the phase plan of the experiment. Data will be recorded in the CRF table after baseline, 8 weeks and for the 3 month follow-ups and data in the CRF table will be input into Excel by CW and FMY and stored in a single folder. We will also set up a data management team consisting of two people, one responsible for identifying problems and correcting errors, and the other for the accuracy of data checking.

### Ethics

The trial will be supported and supervised by the Ethics Committee of Ningbo college of Health Sciences (No:2020001). It will be implemented strictly in accordance with the principles of the Helsinki Declaration and Declaration and has been registered in the China Clinical Trial Registry (No: ChiCTR2100042333). All subjects participating in the trial should agree and sign informed consent form with a full understanding of the purpose and potential risks and advantages of the study. We will submit a detailed written application to the ethics committee to ensure that the members consider whether a change in the trial schedule is necessary.

## Discussion

This proposal is an assessor's blind, randomized controlled trial that will investigate the detailed effects of the 8 weeks use of a spinal mobilization apparatus on pain and muscle fatigue in subjects with NLBP. As far as we are aware, the trial will be the first to be developed according to the principles of joint mobilization and has certain innovations, the reasons being: First, the treatment efficiency will be high and the effects hopefully excellent, with the use of robot automation technology and the treatment of joint mobilization sites more accurately defined. Second, the mean power frequency values of MPF and MF in the SMEG frequency domain indexes will be used to reflect the subjects lumbar muscle fatigue, which will be more quantitative and accurate than traditional lumbar muscle endurance tests. Third, musculoskeletal ultrasound will be used to evaluate the muscle thickness of subjects, so that changes in

the cross-sectional area of muscles before and after treatment can be used visually to reflect any improvement in muscle strength. Fourth, the instrument is widely used: the operation time, frequency and displacement can be adjusted, which is suitable for different patients.

To solve the shortage of human resources: the use of an automatic treatment machine. Treatment specification: Automatic and balanced treatment by a robot can make the treatment technique more standard and the treatment technique can be fully reflected. Fifth, the clinical application of the instrument to be used will also reduce the risk of occupational diseases contracted by physiotherapists to a certain extent. For example, in clinical treatment, due to the lack of anatomical knowledge of the therapist, the relative lack of manipulative treatment experience, especially physiotherapists who do joint mobilization, wrist joint and waist and other parts at the wrong positions to exert force, will lead to a significant increase in the incidence of wrist and lower back pain [33].

To sum up, the results and practical implications of this trial may not only be beneficial to researchers and physiotherapists, but also that the innovative improvements, based on the principles of therapeutic techniques, will liberate the ‘physiotherapists' hands.

# Limitations

The potential limitations of this trial are: (1) Single and double-blind observations will not be used; (2) No biochemical indicators will be employed to reflect objectively improvements in pain function; (3) Due to the small sample size, no multi-center research method will be used to observe the specific clinical effect.

# Abbreviations

CG, control group; CR, complete response; DT, diaphragm thickness; IAP, intra-abdominal pressure; IG, intervention group; MF: median frequency; MPF, mean power frequency; NLBP, nonspecific low back pain; NR, no response; PR, partial response; RMS, root mean square; SET, sling exercise training; SLA, spinal loosening apparatus; SMEG, surface electromyography.

# Declarations


### Acknowledgements

Not applicable.


### Authors’ contributions

All authors will be responsible for the design and data analysis of the trial. In addition, SS X, MM and QQ will be responsible for data collection and statistical analysis. All the authors will participate in the writing of the manuscript. FM Y, C W and JW Y will be responsible for revising and interpreting the manuscript and authorizing its final revision. All of the authors will read and comment on the final manuscript.

### Funding

This trial will be supported by the first-class discipline of Ningbo (grant number 500/511200501).

### Availability of data and materials

The data included in this article will be presented as a peer reviewed published paper.

### Ethics approval and consent to participate

The trial will be conducted in strict accordance with the ethical principles of the Helsinki Declaration concerning human experimentation. The specific study protocol will include written informed consent from all participating subjects, which was approved and supported by the Ethics Committee of Ningbo college of health sciences (Approval No. 20200001).

### Consent for publication

Not applicable.

### Competing interests

The authors declare that they have no competing interests.

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# Figures

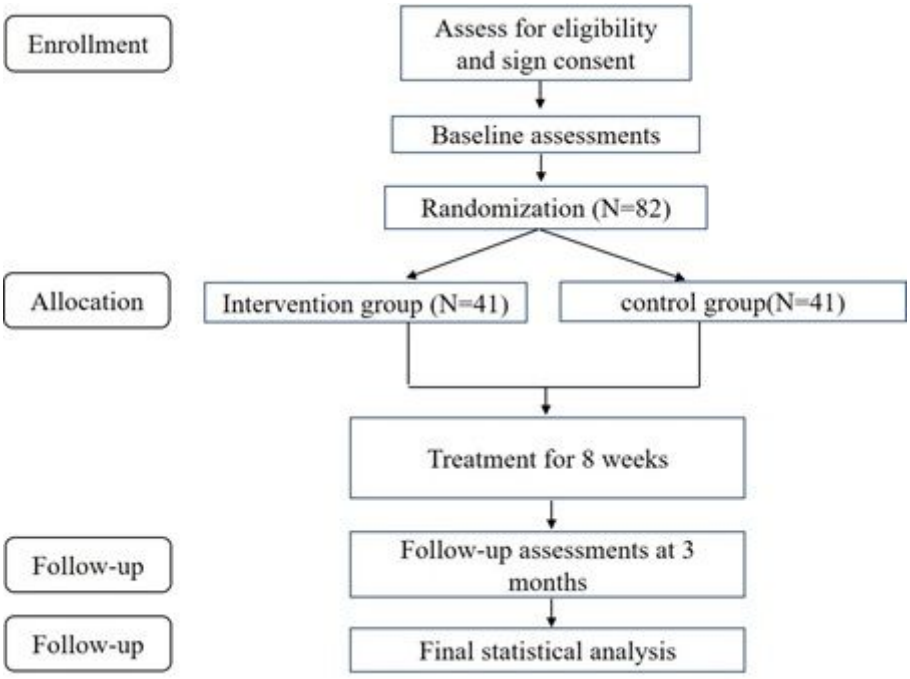



**Figure 1**

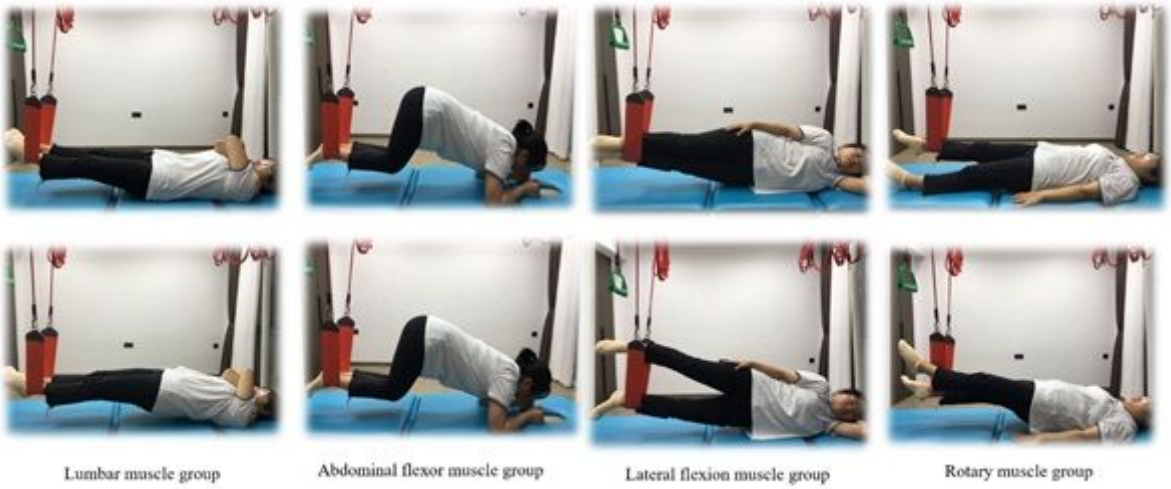
Flow chart of the trial design

| | STUDY PERIOD | | | | |
|---|---|---|---|---|---|
| | Enrolment | Baseline assessment | Allocation | Post-allocation | Follow-up |
| **Timepoint**** | *wk 0* | *wk 0* | *wk 0* | *wk 8* | 3 months |
| **ENROLMENT:** | | | | | |
| **Study information** | × | | × | | |
| **Informent consent** | × | | | | |
| **Eligibility** | × | × | × | | |
| **Allocation** | | × | | | |
| **INTERVENTIONS:** | | | | | |
| ***Spinal joint loosening apparatus (treatment)*** | | | | | |
| ***Sling exercise training(control)*** | | | | | |
| **Conventional rehabilitation training** | × | | | | |
| **ASSESSMENTS** | × | × | | × | |
| **Demographic data** | × | | | | |
| **Primary outcome:** | | × | | × | × |
| *JOA* | | | | | |
| **Secondary outcome** | | × | | × | |
| *VAS, ROM,SF-36,CET,SMEG,DT,IAP* | | | | | |
| *Adverse event* | | × | | × | × |

*Recommended content can be displayed using various schematic formats. See SPIRIT 2013 Explanation and Elaboration for examples from protocols.
**List specific timepoints in this row.

## Figure 2

Standard protocol items: recommendations for interventional trials (SPIRIT)




## Figure 3

Sling exercise training program