Informed Consent Form · Information Sheet

Dear Volunteer:

We sincerely invite you to participate in the study titled “Effects of Proprioceptive Neuromuscular Facilitation (PNF) Combined with Spiral Stabilization (SPS) Spiral Muscle Chain Training on Spinal Curvature Abnormalities in Children.” This study has been reviewed and approved by the Biomedical Research Ethics Committee of Nanjing Normal University. The implementing unit for this exercise-intervention study is the School of Physical Education and Sports Science, Nanjing Normal University. Before you decide whether to take part, please read the following information carefully. It will help you understand the study, why it is being conducted, the procedures and duration, and the possible benefits, risks, and discomforts. If you wish, you may discuss it with your guardian, or ask the researchers to explain anything to help you make a decision. This process is called “informed consent.”

You may decide independently whether to participate. To help you understand the study content and what it requires of you, please take some time to read the following carefully. If you have any questions, you may ask the researcher who is responsible for informing you. Once you understand the study and agree to participate, we will ask you to sign this document. We will provide you with a copy of the signed document for your records.

I. Background, Purpose, and Study Procedures/Duration

1. Disease burden and current treatment status

Spinal curvature abnormalities refer to developmental deformities in which the spinal curvature exceeds the normal physiological range. They mainly include congenital, pathological, idiopathic, and postural types. Clinical presentations include lumbar lordosis, thoracic kyphosis, flat back, and scoliosis. Patients often present with asymmetric imbalance of the shoulder-girdle, pelvic-girdle, and trunk muscles, which can lead to adaptive changes of the spine, neck and back pain, limited activity, and cardiopulmonary function problems. These conditions tend to occur at younger ages, be more complex, and progress rapidly, becoming important risk factors affecting adolescents’ physical and mental health.

At present, there are many exercise-intervention models and methods for spinal curvature abnormalities. When a single intervention is applied to a specific population, its effect on maintaining paraspinal muscle strength may be limited and the sustained therapeutic effect may be relatively low. Both PNF and SPS adopt three-dimensional self-correction techniques to stabilize posture, prevent or limit the progression of idiopathic scoliosis and reduce reliance on braces, help restore the natural physiological curvature of the spine, and restore optimal gait coordination and stability, thereby providing natural movement stability for healthy individuals. International studies have shown that the special movement therapy of PNF can produce immediate effects on trunk rotation angle and spinal rotational flexibility in patients with idiopathic scoliosis. SPS training has also been shown to have significant effects in treating scoliosis, demonstrating scientific validity.

2. Study objectives

This study focuses on children and adolescents with spinal curvature abnormalities. Using PNF and SPS as exercise-intervention methods, we will explore and compare the effects of PNF therapy and SPS training, examine their additive effects in spinal curvature abnormalities, and promote high-quality spinal health management in adolescents. The results will provide references for comprehensive screening and monitoring and for developing and promoting school-based corrective exercises.

3. Study timeline and expected number of participants

In the preliminary stage, volunteers with spinal abnormalities will be recruited as participants and will undergo a secondary screening based on study indicators. It is expected that 45 participants will be enrolled. The study is expected to run continuously for 2 months. During the intervention, practice is expected to occur 3 times per week (every other day), with each session lasting 10–30 minutes. Because of the nature of the study, noticeable improvements in indicators may appear only after long-term exercise therapy. If you are interested in participating in exercise-intervention research for spinal curvature abnormalities, please first consider whether the study schedule is suitable for you.

II. Who is eligible for this study?

If you wish to participate, the principal investigator will first ask you to sign the informed consent form, and then you will undergo relevant screening examinations to ensure you meet the enrollment criteria (meet inclusion criteria and do not meet exclusion criteria). The instruments and costs related to the trial examinations will be covered by the School of Physical Education and Sports Science, Nanjing Normal University. Only after your results meet the enrollment requirements may you join the study.

Inclusion criteria (all of the following):

1 Age 10–14 years.

2 Meets the diagnostic criteria for spinal curvature abnormalities.

3 In scoliosis screening, classified as postural imbalance (positive body balance test or forward-bend test, or ATR ≥ 5°, but ATR < 5° on scoliometer measurement after the spinal movement test) or scoliosis (ATR measurement after the spinal movement test: 5° ≤ ATR < 10°).

4 In sagittal curvature screening, classified as postural imbalance or abnormal sagittal curvature (abnormal findings on general lateral inspection but negative prone test; kyphosis angle < 20°; or kyphosis angle > 40° with a positive prone test).

5 Able to complete PNF therapy and SPS training as required.

6 Not wearing a brace and has not undergone surgery.

The scope and boundaries for screening will follow the “Key Points of Screening Techniques for Spinal Curvature Abnormalities” in the Technical Guideline for Prevention and Control of Spinal Curvature Abnormalities in Children and Adolescents (2021) issued by the National Health Commission, with screening primarily focused on scoliosis.

Exclusion criteria (any of the following):

1 Congenital scoliosis caused by skeletal developmental dysplasia during the fetal period.

2 Neuromuscular scoliosis caused by conditions such as muscular dystrophy, poliomyelitis sequelae, or cerebral palsy.

3 Neurofibromatosis with scoliosis, where growth of neurofibromas compresses and destroys surrounding tissues causing scoliosis.

4 Spondylolisthesis with scoliosis caused by congenital vertebral pars defects.

5 Degenerative scoliosis caused by severe degenerative changes of intervertebral discs and facet joints and reduced intervertebral stability.

6 Other systemic diseases not suitable for exercise therapy, such as cardiovascular disease or respiratory dysfunction.

7 ATR ≥ 10°.

8 Unable to complete simple exercise movements.

III. What will you be required to do if you participate?

If you decide to participate, you must sign this informed consent form and accept the relevant laboratory examinations and other screening tests. Signing this informed consent form does not necessarily mean you will be able to participate; only those who pass screening according to the inclusion/exclusion criteria may be enrolled. This study plans to include 45 volunteers with spinal curvature abnormalities (no restriction on sex), divided into three groups: PNF therapy group (PNF only), SPS training group (SPS only), and a combined group (both methods). The exercise-intervention methods used by each group are different, and the time involved differs. If you are enrolled, you may be randomly assigned to one of the groups. The specific group assignment will be determined after the first measurement of physical indicators.

Once enrolled in this study, please be sure to:

1 Follow the researcher’s instructions, answer questions about your health truthfully, do not conceal congenital bone diseases or a history of sports injuries, and cooperate with the secondary screening.

2 Strictly follow the researcher’s requirements during the trial, actively cooperate with training and data collection; report promptly if you take any medications.

3 During the study, inform the researcher truthfully of any abnormal reactions during training (e.g., pain) and any changes in your health condition, whether favorable or unfavorable.

4 During the trial period, you may not participate in any other drug clinical trials.

5 Whether or not you feel it is related to the exercise training in this study, please inform the researcher of all discomfort symptoms that occur.

6 If at any time you wish to stop participating in the study, please inform the researcher.

7 If any of the following occurs, the researcher may discontinue your participation in the study at any time:

1) An adverse event or serious adverse event occurs, and the researcher believes it may affect trial results or that it is not appropriate to continue.

2) Poor compliance, including but not limited to repeatedly missing study visits, not cooperating with the researcher to carry out exercise training, or training time seriously not meeting requirements; the researcher believes it may affect trial results or that it is not appropriate to continue.

3) Other circumstances that may affect the safety evaluation; the researcher believes that withdrawal is in the participant's best interest or that it is not appropriate to continue the trial.

The specific study procedures are as follows:

During screening, the researcher will conduct an interview and record your medical history, and perform screening related to spinal health. You will undergo assessments including body balance parameters, Angle of Trunk Inclination (ATI), and evaluation of spinal curvature in the sagittal plane, to diagnose spinal curvature abnormalities and determine whether you are suitable to participate based on the exclusion criteria.

If you are enrolled, you will also participate in the Biering–Sorensen Test (B-S) to measure surface electromyography (sEMG) of trunk extensor muscles. Based on the above results, the researcher will allocate participants equally into three groups. After confirming you meet the requirements for the experimental intervention, each group (15 participants per group) will carry out a 2-month exercise intervention. After the final exercise training session, the researcher will arrange a final post-intervention data collection, after which the study will end.

IV. Possible adverse reactions, risks, discomfort, and inconvenience

This study may involve certain risks of sports-related injury. If you feel unwell, you may withdraw from the study at any time. During the trial, if any significant new research findings or risks may affect your decision on whether to continue, we will inform you in a timely manner. Any new findings related to the trial will be communicated to you as soon as possible. You may discuss this information and your health condition with trusted physicians, teachers, friends, or family members to decide whether to participate.

V. Benefits and costs of participation

1. Benefits of participation

Participants may benefit in terms of health, improve exercise awareness, learn PNF methods and SPS spiral muscle chain training movements, receive a spinal health assessment report, and carry out targeted spinal training to improve postural abnormalities.

2. Costs and compensation

All study-related examination expenses will be covered by the sponsor. By participating, you can receive a free spinal examination, thereby gaining a more comprehensive understanding of your spinal health status.

As a volunteer participating in this study, in recognition of your contribution, you will receive certain compensation. If you meet the study requirements and complete the entire study,

you will receive the corresponding incentive/reward item upon completion of the study.

VI. Measures to protect the confidentiality of personal information in this study

Information collected during your participation will be recorded in your medical history as required. Those who may access any information collected in this study include: researchers, data monitoring committees, the sponsor, other government departments in the sponsor's country, institutional review boards (IRB) or independent ethics committees (EC), and the sponsor's representatives or authorized agents. Your personal information and any information that could reveal your identity will be kept strictly confidential and will not be disclosed. If the study results are published, your identity will remain confidential. By signing this consent form, you authorize relevant research personnel and administrative bodies to review these confidential materials.

Signing this written informed consent form indicates that you authorize researchers to collect and process your personal information, including but not limited to: your date of birth, sex, age, and personal data related to your physical and psychological status, as well as any personal information and any results obtained from examinations during the study. Authorized researchers may use your personal information in the management and implementation of the study and in statistical analysis of study data. Authorized researchers will share within the study the personal information collected about you ("study data"). Only authorized researchers may link your data and contact information.

However, all of your personal data that are collected may be reviewed at the research center by the sponsor and its representatives, ethics committees, data and safety monitoring committees, and other competent authorities. The purpose of such reviews is to ensure the correct conduct of the study and/or the quality of the data.

There is no expiration date for the authorization to use your study data. However, you may withdraw your informed consent at any time in writing or orally. If you withdraw consent, authorized researchers will no longer use your study data (including information recorded in your medical history about this study) or share your data with others, unless necessary for authorized researchers to ensure the validity of the study data. Information already shared with the researchers before you withdraw consent may still be used. If you withdraw consent for the use of your study data, you cannot continue participating in this study.

Please note that the results of this study may be published in journals or presented at academic conferences in sports science, but none of your personal information will be made public.

VII. Your rights

Whether to participate in this study is entirely your decision. Throughout the entire research process, your participation is voluntary. If you decide not to participate, it will not affect any other treatment or medical observation you should receive. If you decide to participate, you will be asked to sign this written informed consent form. Even after signing, you may freely withdraw at any stage of the study, and this will not affect any other treatment you receive in the future.

Similarly, if the researchers believe that continued participation is not in your best interest, you will be withdrawn from the study. The study may need to be stopped under the following circumstances: unacceptable adverse events occur; the study is not conducted according to the protocol; incorrect enrollment; withdrawal of informed consent, etc. Without requiring your consent, the sponsor or regulatory authorities may also terminate this study during the study period. If the study is terminated early, we will notify you in a timely manner, and the researchers will provide recommendations for your next treatment plan based on your health status.

VIII. Your responsibilities

As a volunteer, you need to provide truthful information about your medical history, current physical condition, and lifestyle habits. Inform the researcher whether you have recently participated in other studies or are currently participating in other studies. Inform the researcher of any discomfort you discover during this study period. Follow the study protocol and complete the required exercise training and examinations related to data collection. Unless there is a study-related risk, do not disclose any information about the trial to others.

IX. How to obtain more information

You may ask any questions about this study at any time. The researcher will leave you his/her phone number so that you can ask questions at any time. If any important new information arises during the study that may affect your willingness to continue participating, the researchers will inform you promptly.

X. What should you do now?

Whether to participate in this study is up to you. You may discuss it with your family or friends before making a decision. Before deciding, please ask the researcher as many questions as possible until you fully understand this study.

Thank you for reading the above information. If you decide to participate in this study, the researchers will arrange all matters related to the study for you. Please keep this document.

Informed Consent Form · Consent Signature Page

Research project title: Effects of PNF Combined with SPS Spiral Muscle Chain Training on Spinal Curvature Abnormalities in Adolescents Aged 10–14

Responsible institution: School of Physical Education and Sports Science, Nanjing Normal University

Consent statement

I have read the above introduction to this study and have had the opportunity to discuss the study with the researcher and ask relevant questions. All of my questions have been answered to my satisfaction.

I understand the possible risks and benefits of participating in this study. Participation is voluntary. I confirm that I have had sufficient time to consider participation, and I understand that:

- I can consult the researcher for more information at any time.
- I can withdraw from this study at any time without discrimination or retaliation. My medical care, treatment, and rights/interests will not be affected.

I understand that if I withdraw partway through the study (especially due to training-related reasons), I should inform the researcher of any changes in my condition and complete the corresponding examinations, which will be beneficial to the study. If my condition changes and I need other treatments, I will seek the researcher's opinion beforehand or inform the researcher afterward.

I agree that the Biomedical Research Ethics Committee of Nanjing Normal University and/or the sponsor and its representatives may review my research materials. I will receive a signed and dated copy of this informed consent form.

Finally, I decide to participate in this study and will endeavor to follow the researcher's instructions.

Guardian's signature: _____

Volunteer's signature: _____

Contact phone number: _____

Date: _____ Year _____ Month _____ Day

I confirm that I have explained the details of this trial to the participant, including his/her rights and the possible benefits and risks, and have provided a signed copy of the informed consent form.

Researcher's signature: _____

Contact phone number: _____

Date: _____ Year _____ Month