Clinical research protocol

Project Name: Early warning and intervention mechanism of foot health risk in children and adolescents

Scheme version number/date: V1.0/2024-04-22

Leader Unit/Main Researcher: NA

Leader's Unit Address: NA

Research Department/Principal Investigator: Department of Traditional Chinese Medicine Orthopedics, Southern Hospital, Southern Medical University/Chen Chao

Applicant/Address: Southern Medical University Southern Hospital/1838 Guangzhou Avenue North, Guangzhou City

Summary of research proposal

Scheme Name	Early warning and intervention mechanism of foot health risk in children and adolescents
Application unit	Southern Medical University Southern Hospital
Main researchers	Chen Chao
Team leader unit	N/A
Research object	Children aged 6-18
research objective	Main objective: To construct a foot health risk warning model based on wearable sensors. Secondary objective: To explore the correlation between children's foot health and musculoskeletal development
Research Group	Observation group, WBV intervention group, martial arts intervention group
research design	This clinical study is a prospective intervention study. Plan to recruit 1000 individuals aged 6-18.First, we collected gait data using sensors and recorded the occurrence of foot pain for the next 4 weeks. Children with foot pain will be enrolled in the observation group, exercise intervention group, or WBV intervention group according to their wishes. After 4 weeks of intervention, analyze and compare the dynamic and static foot movements between the intervention group and the observation group.Select 120 participants aged 8-10 for foot development in the second stage.Observational study on the correlation with bone age development. In the third stage, 30 participants aged 8-10 years were selected for an observational study of gait dynamics using optical motion capture.
Research period	From January 1, 2024 to December 31, 2027
sample size	1000
Inclusion Criteria	Agree to participate in the study, and the legal representative voluntarily signs the informed consent form Children and adolescents aged 6-18 with typical development, regardless of gender

Exclusion criteria	Except for flat feet, there are other congenital deformities of the lower limbs or spine that affect foot posture. In addition to flat feet, there are other muscle, nerve, and bone diseases that affect foot posture. The researchers have determined that they are not suitable to participate in this study
Effectiveness analysis	Main efficacy indicators: Motional foot posture improvement (push off phase foot flip angle) Secondary efficacy indicators: Static foot posture improvement (foot posture index FPI-6)
Security analysis	The detection equipment and methods used in this study mainly include harmless optical motion capture, structured light 3D scanning, wearable sensors, and bioelectrical resistance body composition analysis; X-ray, bone age, ultrasound and other imaging tests are all operated by professional technicians, and the collection environment and methods meet safety requirements; The intervention method is non pharmacological therapy, which is harmless to the human body; The data acquisition and analysis process strictly follows privacy protection regulations,and there is no security risks.
statistical analysis	Analysis set: Use the full analysis set for statistical analysis. Full analysis set (FAS): Includes all enrolled subjects who have received at least one non pharmacological intervention and have measurable baseline foot injury. Sample size determination: According to epidemiological surveys, the incidence of foot pain events in children is about 12%, and it is determined based on similar studies. Statistical analysis: SPSS 25.0 statistical analysis software will be used for statistical analysis
follow-up	Feedback on foot pain events; Execution of martial arts training and vertical rhythm training; The efficacy and adverse reactions of martial arts training and vertical rhythm training.
Statistical methods	The method used is independent sample t-test to analyze gait parameters of normal and poor foot postures, and repeated measures ANOVA to analyze gait and foot posture parameters before and after intervention.
Expected progress	Starting from January 2024 to December 2024, recruit phase one participants and initiate the study Screening of Phase II subjects and conducting experiments from January 2025 to December 2025

	Screening of Phase III subjects and conducting experiments from January 2026 to December 2027

List of abbreviations and definitions of terms

abbreviation	definition
WBV	Whole Body Vibration Training: The subject is placed on a vibration platform that provides vertical sinusoidal vibrations to the body, stimulating receptors and causing neuromuscular excitation.
IMU	Inertial Measurement Unit: including gyroscope and accelerometer.

Experimental Procedure Table

project	baseline	Phase I		Phase II	Phase III
		Asymptomatic	Foot pain intervention		
informed consent	√	√	√	√	√
Inclusion/exclusion criteria	√	√	√	√	√
physical examination	√	√	√	√	√
Foot pain VAS score	√	√	√		
All-weather sensors		√	√		
WBV Training			√		
TCM training			√		
3D foot scan		√	√	√	√
Foot X-ray in weight-bearing position				√	
Analysis of Traditional Chinese Medicine Tongue Images				√	
Body fat measurement				√	
Saliva gene analysis				√	
Wrist bone age				√	
Bone density ultrasound				√	
Magnetic resonance imaging scan					√
Gait optical action capture					√
Surface electromyography collection					√
Foot pressure test					√

1. Research background

1.1 research meaning

Foot injury is one of the most common motor system diseases in children, and the most common clinical manifestation is foot pain. At present, there are few reports on the incidence of foot pain in Chinese children. Foreign studies have shown that the incidence of foot pain in children and adolescents is as high as 10% -15%, accompanied by the risk of foot injury and foot deformity. Our preliminary research found the same pattern, with the highest proportion of foot pain among children aged 6-11 in Foshan reaching 12.67%, and the proportion of foot pain gradually increases with age. Among young people who frequently suffer from ankle sprains, about 25% have long-term ankle instability, making ankle injuries a common disease among adolescents and children.

In recent years, the implementation of the "double reduction" policy has encouraged children to increase their physical activity, with the aim of enhancing their physical fitness. However, due to inadequate prevention and control measures, there have been more cases of ankle injuries in children in clinical practice. There are 250 million children in China, and the estimated total number of foot injuries is 20-30 million. As age increases, the risk of foot injury and its complications increases, with approximately 24% of adults having experienced foot injury or foot disease [3,4]. The underdevelopment of children's feet, abnormal foot shape, and uneven lower limb force lines are important structural causes of foot injuries in children. As a result, abnormal foot movement posture is the dynamic cause of foot injuries. Failure to correct abnormal foot movement posture in a timely manner after causing foot injury will further lead to multi joint posture abnormalities, causing a vicious cycle of secondary injury, ultimately affecting limb and trunk force lines, and causing damage to knee joints, hip joints, and spine [5,6]. Partial injuries can cause serious consequences, such as cartilage damage to the talus, and may even lead to talus necrosis, endangering children's health [7]. Early detection and intervention of foot injuries in children are important tasks to ensure their healthy development.

Due to children's weak ability to express illnesses, foot pain is often concealed, making it difficult for parents to detect potential foot diseases in their children. The symptoms of childhood foot disease are different from those of adults, and the clinical manifestations are more diverse, including walking on tiptoes, unwillingness to walk, limping, and inability to keep up with peers [8-10]. Therefore, it is particularly crucial to monitor objective indicators related to children's foot injuries and rehabilitation through certain methods, rather than relying on children's expressions or waiting for visual signs to appear [11]. In clinical practice, the detection of foot movement posture can analyze the causes and risks of foot injuries, and is also an important method for judging the effectiveness of rehabilitation interventions. Commonly used systems include high-speed plantar pressure systems, optical motion capture systems, etc. The principle is to obtain detailed posture characteristics of the foot during movement for analysis. When movements exceeding physiological limits are detected, it can confirm the source of clinical injuries and monitor the process of injury recovery [12-14].

However, the drawbacks of these methods are complex operation, high cost, and the ability to perform very low frequency breakpoint detection. They are often used for simple observation of clinical diagnosis and treatment processes after foot injuries have occurred, and cannot actually predict and

prevent the occurrence of injuries in advance. It is even more difficult to control the risk of foot injuries and rehabilitation processes in large-scale children. Therefore, we used Huawei HUAWEI S-TAG inertial sensors to observe the foot posture characteristics of children with foot injuries in the early stage. In the study, it was found that the static and dynamic foot posture of children are closely related to foot pain, mainly due to the significant difference in the angle of calcaneus valgus and the swing angle of the longitudinal axis of the foot during gait (toe push off phase) between normal children and children with foot pain. Based on the above, this project focuses on the research of neural network models for key rehabilitation nodes in the core content of foot injury risk prediction, WBV intervention process, and exercise intervention process. Inertial sensors are used to observe foot posture data 24/7, and regular features in gait before injury and during rehabilitation process are mined. Neural network algorithms are used to construct algorithm models, and recognition and evaluation models are established for earlier "compensated", "decompensated", and "key rehabilitation node" gaits before injury. Prompt for decompensated gait before injury occurs, thereby achieving early warning and monitoring of the rehabilitation process before injury occurs. The prediction accuracy of this model approaches the real world infinitely as the amount of training data continues to increase.

The development of arch morphology from physiologically flexible flat feet in children is a necessary process for growth and development. The "Ling Shu" records: "The kidneys originate from gushing springs, and the gushing springs are also in the heart of the feet." Traditional Chinese medicine believes that "kidney qi begins at the foot of the foot," and the filling of kidney qi has an important impact on the growth and development of children. Delayed growth and development in children and insufficient kidney qi in adults are often treated with Yongquan acupoint or foot massage. The development time of the arch of the foot is consistent with the theory in "Su Wen" about kidney qi, which states that "when a woman is seven years old, her kidney qi is abundant and her teeth are longer; when a husband is eight years old, his kidney qi is solid and his teeth are longer." Boys usually develop their arch of the foot about a year later than girls. Around the age of 7, children's foot structures develop fully and their gait approaches that of adults, with over half of them developing arch shapes; 7-12 years old is an important stage for children's arch development, during which most children will gradually develop arch shape. Our team completed a foot health screening project for 10000 children in Sanshui District, Foshan City in 2022, and found that about 20% of children were still left with flat feet at the age of 12, which can be considered as "delayed arch development". Domestic and foreign studies have shown that arch development is a part of the human body's maturation process. Children with delayed arch development have a shorter average height, higher obesity rates, and weaker physical abilities. By detecting the development of children's arch morphology, it is expected to bring new research ideas and diagnosis and treatment plans for promoting height in children and preventing obesity in adolescents. Therefore, exploring the relationship between delayed arch development and abnormal growth and development is in line with the requirements of "Healthy China 2030" and reflects the concept of "great health" and the important research content of the concepts of "health" and "prevention of illness". Another objective of this study is to observe the relationship between arch development and growth development in children.

1.2 Current research status at home and abroad

Epidemiological progress of flat feet in children

The normal development of the foot during childhood, especially the development of the arch, is extremely important for the activity and function of the adult foot [15]. The foot undergoes different changes in morphological structure and function during childhood. Among them, the development of the arch follows certain morphological rules at different ages: within a few weeks after birth, the arch is filled with thick fat pads and disappears; Subsequently, as gross motor development progresses, the function of the feet gradually becomes apparent; The transition stage from 3 to 4 years old is usually characterized by flexible flat feet, during which the arch of the foot begins to develop. However, due to the insufficient strength of various tissues such as foot muscles, tendons, and ligaments to meet the pressure caused by children's functional activities, it is easy to cause arch deformation, which is an inevitable transition stage in the growth and development process of some children's bodies. The age of 6 is a critical period for the development of the arch of the foot [16], during which ossification is incomplete and plasticity is strong, making it an important stage for the formation of stable joints and strong arches. At the age of 13-14, children's arches stop developing due to the maturation of their bones during puberty.

Abnormal arch development can lead to flat feet and other deformities in children [17], posing a threat to their health. Some patients may persist into adolescence and adulthood. Foreign studies have shown that flat feet are a common foot deformity in children, mainly characterized by the collapse or flattening of the medial longitudinal arch (MLA) of the foot, usually accompanied by abduction of the forefoot, inversion of the midfoot, eversion of the hindfoot, abduction of the tarsal joint, and eversion of the subtalar joint. Due to factors such as urbanization, premature/inappropriate shoe wearing, overweight/obesity, excessive/insufficient exercise, and excessive joint laxity, the risk of developing flat feet increases [18,19]. According to the impact of age on flatfoot in foreign children, it is estimated that approximately 45% of preschool children and 15% of older children (with an average age of 10 years) suffer from flatfoot [20]. There are significant differences in the estimated prevalence of flatfoot among foreign epidemiology, ranging from 0.6-77.9% [20]. Although there are different estimates of the prevalence of flatfoot in children.There is a consensus that the incidence of flatfoot disease is inversely proportional to the age of children. The overall incidence of flat feet among 3226 children aged 7-12 in Shanghai, China is 56.1%, and the incidence gradually decreases with age [21]. The detection rate of flat feet is still 13% even at the age of 12. Lin et al. used a gait analysis system to study 377 children aged 2-6 years. The detection rates of moderate flat feet were 43%, 31%, 24%, and 19%, respectively; The detection rates of severe flat feet are 14%, 9%, 4%, and 2%, respectively.

The hazards of poor foot posture and foot pain

When children stand with flat feet, there is no good support at the bottom of the foot, resulting in the inner edge being close to the ground and unable to provide cushioning, which can easily lead to fatigue and foot pain. Long term development can have adverse effects on the joints and muscles of the foot, which may lead to foot injury/foot disease. Abnormal foot movement posture can cause further multi joint posture abnormalities after causing foot injury, leading to a vicious cycle of secondary injury and ultimately affecting limb and trunk lines of force,causing damage to the knee joint, hip joint, and spine [23,24]. Partial injuries can cause serious consequences, such as cartilage damage to the talus, and may even lead to talus necrosis, endangering children's health [25].

Research shows that 1/4 of children have experienced pain in their skeletal muscle system, with over 1% of children seeking medical help each year due to musculoskeletal issues in their feet. Foot pain is the most common musculoskeletal problem in the age group of 10-13 years old [26, 27]. In current research, foot pain in children is often overlooked because it is believed to be less common than foot pain in adults. However, the definition of pediatric foot pain may be broader than that of adult foot pain. In most cases, pain is not often reported as the chief complaint of foot symptoms in children. On the contrary, parents may notice their children limping, walking on their toes, preferring to be held instead of walking, unable to keep up with their peers, or frequently complaining of muscle fatigue in their feet. In clinical clinics, 30% of children and adolescents seek treatment for pain related conditions [28,29].

Intervention methods for children with flat feet

Most flexible flat feet do not require formal treatment, preventive treatment is sufficient, including appropriate exercise, a balanced diet, and suitable shoes. Patients with mild flat feet and mild pain are recommended to undergo conservative treatment, including orthopedic arch foot pads, orthopedic shoes, foot orthotics, and ankle function training. If conservative treatment is ineffective, surgical options should be considered, including joint reconstruction, joint fusion, and joint immobilization. Generally, combined surgical treatment should be performed after fully understanding the cause.

In non-surgical treatment, orthopedic insoles/shoes/foot orthotics are the most commonly used means, which integrate the morphological development laws of children's feet, arch development mechanisms, bone growth characteristics, foot shape characteristics, and gait characteristics. The design principles include adjusting the force points on the sole of the foot and dispersing foot pressure; Support the arch of the foot and improve cushioning ability; Improve lower limb line of force, provide stability and support; Improving proprioceptive experience and enhancing foot comfort, among other aspects; Flat feet in children can have effective preventive and rehabilitation functions [30]. However, studies have shown that orthopedic insoles/shoes or foot orthotics have limited effectiveness in improving children's flexible flat feet [20]. In practical applications, children have poor compliance due to discomfort in wearing/dressing, and due to rapid growth, they have to replace frequently, which limits long-term portable applications due to high prices.

Secondly, children with flat feet usually undergo ankle function training such as plantar muscle strength training, proprioceptive training, and balance training. However, traditional rehabilitation training is usually conducted in hospital rehabilitation departments, with high requirements for movements and postures, dry and repetitive training, poor child compliance, poor tracking of training effects outside of hospitals, and inability to quantify training, which also limits its application in home rehabilitation scenarios.

Research progress on whole-body vibration training

Whole Body Vibration Training (WBVT) transmits mechanical vibration stimulation through a vibration platform to induce neuromuscular excitation, and has been validated by numerous studies to enhance lower limb muscle strength, increase bone density, and improve functional activity in different age groups [31]. Compared with traditional clinical methods, it has the advantages of high compliance, quantifiability, good interactive experience, low cost, and rich application scenarios. In the future, scalable virtual reality interaction will have both practical and entertaining effects, making it an excellent choice for children's rehabilitation training. At present, most studies on WBV generally focus on the overall posture of the whole body [32,33,34], and training the feet in different postures is rare [35]. In addition to the influence of body position, different vibration parameters including vibration frequency, amplitude, vibration mode, etc. can also affect the acceleration transfer and muscle activation effect of WBV [36] [32,34,37]. However, currently there is still a lack of recommended optimal training schemes, especially quantitative WBV training schemes for the feet. Swing board training can assist in the re education of the sensory motor system by improving proprioceptor function and restoring normal

neuromuscular feedback circuits. It is commonly used for proprioceptive and balance training in patients with ankle sprains, functional ankle instability, and other conditions. In 2012, Kiers et al. [39] proposed that training only on unstable surfaces is not sufficient to stimulate ankle proprioceptors. He emphasized that muscle bundles are highly sensitive to vibration stimuli, and muscle bundles are key to ankle proprioceptive and overall body orientation. Marin and Hazell [40] demonstrated that the combination of unstable surfaces and WBV can increase the electromyographic activity of lower limb and trunk muscles to maintain balance. Similarly, patients with knee osteoarthritis also showed improvement in proprioception after WBV training on a balance board. Rendo [41], Cloak [42], and others studied the positive effects of this combined training on balance function and postural stability in patients with CAI. Ray et al. found that WBV can improve posture stability when the environment is more challenging. When the parameters of the platform are more challenging, it has a lasting impact on balance, lasting for 20 minutes. However, in less challenging environments, this effect disappears faster, 10-20 minutes. These research results indicate that vibration can be studied as an auxiliary tool to provide more effective balance function training for children with flat feet. Previous studies have lacked observation on the therapeutic effect of WBV on flat feet in children, so it is necessary to conduct relevant research.

Progress in the study of martial arts

The Yi Jin Jing originated from ancient guidance techniques and is one of the important traditional Chinese rehabilitation techniques. In clinical practice, Yi Jin is often used to treat bone and joint diseases. By adjusting muscles and treating bones, it achieves a balance between the body's muscles and bones, effectively improving the functions of the cardiovascular, respiratory, exercise, endocrine, and immune systems [44,45]. Research has shown that elderly patients with skeletal muscle atrophy can significantly improve their balance and walking stability after continuous exercise of the Yi Jin Jing, effectively preventing falls and post fall injuries [46]. In addition, when treating primary fibromyalgia syndrome, Yijin Jing can significantly alleviate pain symptoms [47]. According to the perspective of modern rehabilitation studies, the Yi Jin Jing not only provides comprehensive training, but also Includes strength training for the feet. Therefore, the Yi Jin Jing is one of the methods for treating children's foot pain, preventing the risk of joint injuries, enhancing children's physical fitness, and improving muscle strength. It should be promoted and encouraged for children to train. However, currently there is still a lack of quantitative indicators for the therapeutic efficacy and mechanism of Yijin Jing in treating foot pain and foot diseases. Therefore, combining wearable inertial sensors to evaluate the risk of foot pain and injury can provide a true and objective quantitative evaluation of the effectiveness of the Yi Jin Jing in improving children's foot symptoms and function, which can provide important data basis for future research and promotion of the Yi Jin Jing. Research has shown that Yijin Jing can improve sub-health neck fatigue in primary and secondary school students, and help prevent the occurrence of spinal diseases in middle school students [48, 49]. At present, there is no research on the effectiveness of traditional Chinese medicine techniques in treating flat feet in children, so it is necessary to conduct research in this area.

2. research objective

2.1 Main purpose

Constructing a foot health risk warning model based on wearable sensors

2.2 Secondary purpose

Exploring the correlation between children's foot health and musculoskeletal development;

3. Study endpoint:

3.1 Primary endpoint indicator

If a wearable sensor gait detection is completed for 4 weeks and a foot pain event is reported, gait data collection can be stopped.

3.2 Secondary endpoint indicators

After the occurrence of foot pain events, a 4-week observation or intervention was conducted under the guidance of researchers, and the evaluation of the improvement of dynamic and static foot posture was ultimately completed.

4. experimental design

4.1 overall design

This clinical study is a prospective intervention study. We plan to recruit 1000 participants aged 6-18,Over the next 4 weeks, sensors were used to collect gait data and record the occurrence of foot pain. Children with foot pain will be enrolled in the observation group, exercise intervention group, or WBV intervention group according to their wishes. After 4 weeks of intervention, analyze and compare the differences in dynamic and static foot posture between the intervention group and the observation group. In the second stage, 120 participants aged 8-10 were selected for an observational study on the correlation between foot development and bone age development, and all levels were completed on the day of the study. In the third stage, 30 participants aged 8-10 years were selected for an observational study of gait dynamics using optical motion capture. Complete all levels of the day.

4.2 Randomization and blinding

4.2.1 randomization

In the first stage of this study, it is expected that about 12% of the children will experience foot pain, and eligible/ineligible patients will be enrolled according to their willingness to join the observation group, WBV intervention group, or gongfa intervention group, with at least 34 cases in each group, and no randomization will be conducted.

4.2.2 Blind state/Breaking blindness

This study will not be conducted in a blinded manner.

5. Subject population

The subjects of this study are children and adolescents aged 6-18 years old.

5.1 Diagnostic criteria: Foot pain diagnosis is based on facial VAS score, foot posture evaluation is based on foot posture index, foot 3D scanning and weight-bearing position foot X-ray, plantar soft tissue development evaluation is based on plantar ultrasound, bone growth and development evaluation is based on left wrist bone age, gene analysis uses saliva samples, traditional Chinese medicine syndrome analysis uses the Four Diagnostic and Traditional Chinese Medicine Tongue Image Intelligent Analysis System, gait and training motion dynamics analysis uses optical motion capture combined with virtual simulation technology, etc.

5.2 Inclusion criteria:

1) Agree to participate in the study, and the legal representative voluntarily signs the informed consent form

2) Children and adolescents aged 6-18 with typical development, regardless of gender

5.3 Exclusion criteria

1) Besides flat feet, there are other congenital deformities of the lower limbs or spine that affect foot posture

2) History of muscle, nerve, and bone diseases that affect foot posture, except for flat feet

3) According to the researcher's judgment, it is not suitable to participate in this study

5.4 Exit criteria

All enrolled subjects have the right to withdraw from this study at any time.

Participants who withdraw from the study for any reason must record their reasons, including the following:

1) The subject withdraws the informed consent form;

2) Subject lost to follow-up;

3) The legal representative of the subject refuses to continue the follow-up visit;

4) The researchers believe that for other reasons, the subjects are not suitable to continue participating in this study;

Participants who withdraw from the study midway are considered dropout samples. When the subject falls off, efforts should be made to obtain as much as possible contact, complete the evaluation project, and fill out the research summary page.

5.5 Termination criteria

Termination criteria (terminated if any of the following criteria are met):

1) Serious safety issues occurred during the experiment;

2) Significant errors were found in the clinical trial protocol during the trial;

3) The ethics committee requests the termination of the experiment;

6. Research instruments

1) Height and weight measurement: using ultrasonic ranging and pressure sensors

2) Body fat analysis: using bioelectrical impedance method to analyze the muscle fat ratio of the human body

3) Foot 3D scanner: using structured light, Class 2M, harmless to the human body and eyes

4) S-TAG all-weather wearable sensor: using inertial measurement unit (IMU), including gyroscope and accelerometer

5) VICON optical motion capture system: (produced by Oxford Metrics Limited, UK), sampling frequency 100Hz; Mainly including hardware and software facilities, the hardware part includes 8 cameras, MX components, PC host, information conversion box, calibration T-frame, reflective marker ball, and other accessories; The software part mainly consists of VICON Nexus software.

6) Vertical Rhythm Platform (WBV): Adjustable frequency, 3mm vertical synchronous vibration

7) Traditional Chinese Medicine Tongue Analysis System: An Image Recognition and Analysis System Based on Artificial Intelligence

8) Bone age DR system: using lead plates with micro radiation protection for movable wrist measurement

9) Bone density ultrasound: measurement with a fully dry (no temperature control device required) oil bag probe, bidirectional ultrasound transmission and reception. No radiation, suitable for testing various populations (children, pregnant women, adults, and elderly). It is recommended to test within the age range of 3-100 years old (actual testing can be conducted within 0-100 years old).

7. Research methods and steps

As this is an experimental study, researchers will select the children to be included according to the research protocol. Researchers will inquire about the medical history of the child's guardian and conduct a physical examination of the child to determine their eligibility based on inclusion and exclusion

criteria. The guardian of the child must sign the latest IRB/IEC approved informed consent form (ICF) before conducting data collection. The frequency and duration of visits shall be determined by the doctor in accordance with the usual practice of the research plan.

7.1 Screening period:

All subjects are required to complete screening period related examinations before enrollment and be screened according to inclusion and exclusion criteria.

1) Sign informed consent form

2) Record demographic data: date of birth, gender, initials;

3) Anthropometry: including height, weight, and length of both lower limbs

① Measurement of length of both lower limbs

Measurement position: supine position, lower limbs extended, pelvis in neutral position, hip joint in neutral position.

Measurement method: Use a soft tape to measure the shortest distance from the anterior superior iliac spine to the medial malleolus, measure the left and right legs separately, and record the results in the test registration form.

② height

Measurement method: The subject stands barefoot in a "upright" position, with their heels, sacrum, and shoulder blades tightly against the wall. The measurer can stand on either side of the person being measured, adjust their head to the lowest point between the upper edge of the tragus and the lower edge of the eye socket, and start the height measuring device to measure their height.

Measurement requirements: The height should be measured barefoot each time, using the same measuring instrument at the same time (more accurately in the morning), with the same person measuring as much as possible, and the body posture should be consistent before and after. Each measurement of height requires two consecutive measurements with a 30 second interval. The results of the two measurements should be roughly the same, and the error in height should not exceed 0.5 centimeters.

③ weight

Testing method: Wear lightweight clothing, stand barefoot, naturally on an electronic weight scale, measure weight twice in a row with a 30 second interval. The results of the two measurements should be roughly the same, and the error in weight should not exceed 0.5KG.

4) Facial VAS score for foot pain

The subjects represent the degree of foot pain by selecting the corresponding pattern on the scale.

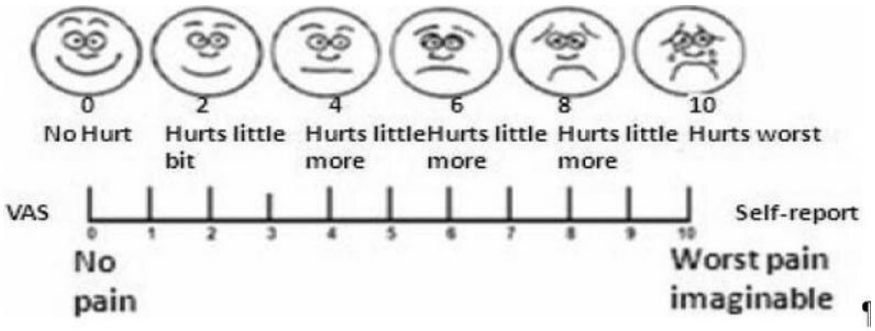

Figure 1 Facial VAS score for children: representing foot pain by selecting the corresponding pattern on the scale degree

7.2 Phase One

We plan to recruit 1000 participants aged 6-18 to record their basic health status and static foot posture at baseline.Subsequently, sensors were used to collect gait data for more than 8 hours per day for the next 4 weeks, and all enrolled children wore wearable sensors in their daily lives. The obtained data is uploaded to the cloud server through a mobile application, and remote monitoring and daily event recording are achieved by uploading the data through the APP. When subjects experience foot pain events, they should promptly report to the researchers through the APP. After determining foot pain based on VAS scores, the subjects with foot pain will be enrolled in the observation group, exercise intervention group, and WBV intervention group according to their wishes. Children in the observation group should rest according to medical advice and not participate in sports activities. Children in the intervention group received WBV vertical rhythm or exercise training programs under the guidance of researchers' follow-up. The follow-up time is once a week, and the training lasts for a total of 4 weeks. Using a self-developed app for researchers to remotely monitor and guide children's training movements, and track training progress.

The device uses Huawei S-TAG foot rings, matched with HarmonyOS 2+/Android 6.0+/iOS 9.0+systems; IP68 (GB/T 4208-2017), waterproof rating of 50 meters; Bluetooth: BT 5.0 transmits data; Running Scene

Battery life: Run for 1 hour per day, run 5 days a week, leave it still when not in use, and have a battery life of 30 days.

（1） WBV Vertical Rhythm Training Standard Process: Children enrolled in the study will be trained at home using vertical rhythm equipment under the guidance of researchers and parental supervision. WBV training lasts for 4 weeks, five days a week, with 15 minutes of training per day. Each movement lasts for 30 seconds, and there is a 30 second break between groups.

（2） Standard process for traditional Chinese medicine exercise training: Children enrolled in the group will undergo exercise training under the supervision of their parents, following the teaching of a self-developed APP. The Yi Jin Jing training will last for 4 weeks, five days a week, with 15 minutes of training per day. There will be a total of 12 exercises, each lasting 1 minute, with a 15 second break between groups.

Figure 2 S-TAG Wearable Sensor

7.3 Phase 2

120 children aged 8-10 years were selected for an observational study on foot development and growth development, without grouping, and no intervention procedures were performed in this stage of the study. The following is the collected data:

Foot three-dimensional morphology: Using harmless and radiation free structured light three-dimensional scanning to obtain foot three-dimensional morphology parameters. The subject stood barefoot on a 3D foot scanner and tested their left and right feet separately.

Figure 3 Schematic diagram of 3D scanning of foot morphology

1) Static foot posture: FPI-6 foot posture index, weight-bearing position foot X-ray

2) Bone age analysis: using lead plates with micro radiation to protect the movable wrist and measure bone age

3) Bone density analysis: Measurement of bone density in the calcaneus using musculoskeletal ultrasound

4) Genomic grouping: Collecting saliva from children for whole genome analysis

5) Body fat analysis: Evaluating body fat ratio using bioelectrical impedance method

6) Traditional Chinese Medicine Constitution Evaluation: Using the Traditional Chinese Medicine Body Mass Scale combined with tongue image analysis, "Classification and Identification of Traditional Chinese Medicine Constitution in Children in Guangdong Province" (T/GDACM 0112-2022)

7.4 Phase Three

Select 30 children aged 8-10 for laboratory testing. This stage is an observational study without grouping.

Passive optical motion capture system, using a floodlight sphere attached to various parts of the human body as marker points, driven by motion capture the camera for spatial positioning and record the motion trajectory. The ground reaction force of gait is obtained through the plantar pressure plate. The surface muscle activation force is collected through a 16 channel Delsys surface electromyography testing system: Noraxon bipolar disposable surface electromyography electrodes are used, with a distance of 20mm between the electrodes. Used to collect the maximum voluntary contraction (MVC) of 4 hip and knee muscles and 11 ankle muscles of the subjects, as well as the muscle strength change curves and maximum force values during training, with a frequency set at 1000 Hz for model validation.

This technology is mature, with high accuracy, high sampling rate, and wireless, non luminous, non heating, non radiative, and non-invasive detection. Motion capture systems have provided comprehensive solutions for nearly a thousand users worldwide, widely used in fields such as motion analysis and animation production.

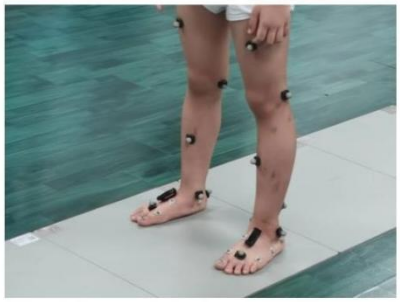

Figure 4 Optical motion capture device

The collected actions are as follows:

1) Gait analysis: Children walk 10 meters on the plantar pressure plate at their own pace and collect dynamic parameters during the gait process.

2) Analysis of martial arts movements: Children stand on a plantar pressure plate and collect dynamic parameters of the training movements of the Yi Jin Jing.

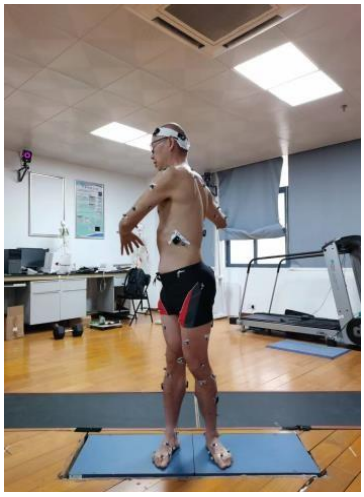

Figure 5 Schematic diagram of optical motion capture in traditional Chinese medicine exercises

3) Analysis of WBV Vertical Rhythm Training Actions: The subjects stand on a vertical rhythm platform, adopt different heel lifting or squatting postures, maintain static posture for 30 seconds, and collect dynamic parameters during the period.

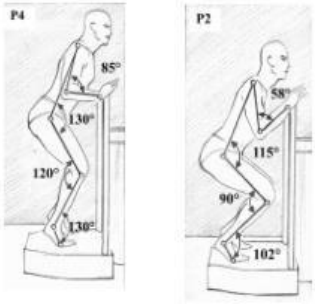

Figure 6 Schematic diagram of WBV rhythm training

Finite element analysis: Reconstruct muscle bone models from Dicom format files of children's MRI scans, and use the muscle activation force obtained from motion capture parameters in virtual simulation as boundary conditions for finite element analysis of structural stress in areas such as the feet and waist.

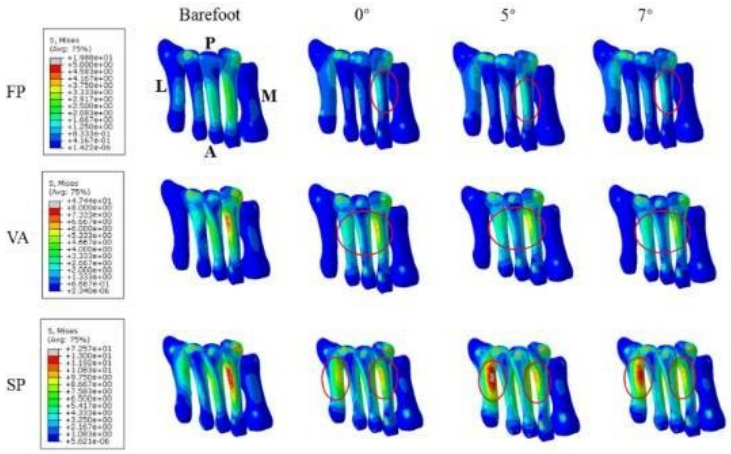

Figure 7 Schematic diagram of finite element analysis

8. evaluating indicator

The first stage is a prospective intervention study, in which children who experience foot pain events are trained and intervened until the end of a 4-week intervention period, and the evaluation of efficacy indicators is considered the endpoint of the rehabilitation study. The second and third stages are observational studies, where participants' participation in laboratory testing on the same day is considered the endpoint.

8.1 Main efficacy indicators

Dynamic Foot Posture: Gait Push Off Period Foot Outward Angle

Capture the angle of foot valgus during gait push off period through wearable devices, and compare the difference between the values after intervention and before intervention.

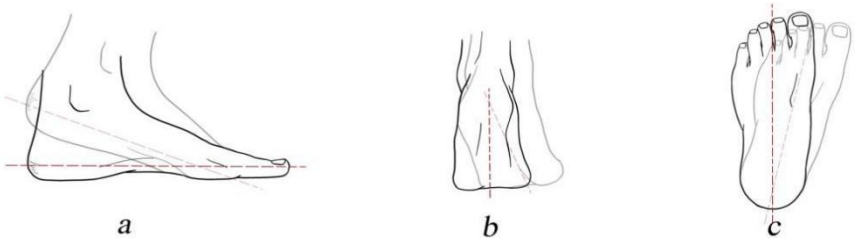

Figure 8 Schematic diagram of wearable sensor dynamic foot axis

The red dashed line represents the longitudinal axis of the foot, and through wearable sensors, the angle of this axis relative to the reference axis during the stance phase of gait can be calculated.

8.2 Secondary efficacy indicators

Static foot posture is evaluated using the Foot Posture Index FPI-6.

The FPI score should be an integer between -12 and 12, with $12 \geq FPI \geq 8$ indicating severe pronation posture, $8 > FPI \geq 4$ indicating mild pronation posture, $-12 \geq FPI \geq -8$ indicating severe supination posture, $-8 > FPI \geq -4$ indicating mild supination posture, and $4 > FPI > -4$ indicating neutral posture.

9. Safety monitoring, reporting, and medical treatment

9.1 Definition of Adverse Events (AE)

Adverse events refer to any adverse medical events that occur after a patient or subject receives a drug, which may not necessarily be causally related to the treatment. Therefore, adverse events can be any adverse signs (including abnormal laboratory results), symptoms, or diseases that are temporally related to the use of the study drug, regardless of whether a causal relationship with the study drug is considered. Adverse events include Serious Adverse Events (SAEs) and Non Serious Adverse Events.

9.2 SAE Definition

SAE refers to medical events that occur during clinical trials that require hospitalization or prolonged hospitalization, disability, affect work ability, endanger life or death, or cause congenital malformations. Including the following medical events:

1） Events leading to death;

2） Life threatening events (defined as the risk of immediate death for the subject at the time of the event);

3） Events that require hospitalization or prolonged hospitalization;

4） Events that can lead to permanent or severe disability/functional impairment/affect work ability;

5） Congenital abnormalities or birth defects;

Other important medical events (defined as events that endanger the subjects or require intervention to prevent any of the above situations from occurring).

9.3 Adverse event recording, collection, reporting, and handling

9.3.1 Definition of Adverse Events (AE):

AE is any adverse medical event that occurs in clinical research subjects and is time related to the use of research treatment interventions, regardless of whether it is considered related to the

research treatment interventions. Therefore, AE can be any adverse and unexpected signs (including abnormal laboratory results), symptoms, or signs that are time-dependent with the use of research treatment interventions, condition or disease (new or aggravated).

Definition of Serious Adverse Event (SAE):

SAE refers to medical events that occur during clinical research that require hospitalization or prolonged hospitalization, disability, affect work ability, endanger life or death, or cause congenital malformations. Including the following medical events:

1) events leading to death;

2) Life threatening events (defined as the risk of immediate death for the subject at the time of the event);

3) Events that require hospitalization or prolonged hospitalization;

4) Events that can lead to permanent or severe disability/functional impairment/affect work ability;

5) Congenital abnormalities or birth defects;

Other important medical events (defined as events that endanger the subjects or require intervention to prevent any of the above situations from occurring).

Definition of Suspected and Unexpected Serious Adverse Reaction (SUSAR):

Suspected and unexpected serious adverse reactions that exceed the nature and severity of the clinical presentation beyond existing information such as the investigational drug investigator's manual, marketed drug instructions, or product characteristic summaries

9.3.2 Collection, reporting, and processing of AE

All adverse events related to the operating procedures specified in the trial protocol that occur between the signing of the informed consent form and the administration of the investigational drug must be recorded in the APP database.

The record of AE should include: description of AE and all related symptoms, occurrence time, severity, duration, relevance to the investigational drug, measures taken, and final results and outcomes. The recording of AE must use medical terminology, and if the symptoms and signs of the subjects can be summarized by a common cause, the diagnostic results should be recorded as much as possible. Except for indicators related to disease progression, all clinical events and clinically significant laboratory adverse reactions can be treated according to the Common Adverse Reaction Event Evaluation Criteria (CTCAE) version 5.0. Adverse reactions caused by treatment will be recorded by researchers.

9.3.3 Collection and reporting of SAE

All SAEs that occur within 4 weeks after the subjects sign the informed consent form and complete the study, regardless of their cause or drug relevance, must be reported using the SAE

report form. If a serious adverse event (SAE) occurs, the researcher should immediately take appropriate treatment measures for the subjects to ensure their safety. At the same time, the researcher should report to the drug registration applicant, the National Medical Products Administration, the Provincial Food and Drug Administration, the ethics committee of the corresponding clinical trial center, and the Medical Department of the Health Commission and Medical Administration Bureau within 24 hours, and promptly report to the ethics committee of the leading unit. The first report should include the following information as much as possible: source of the report, name of the investigational drug, name of serious adverse event, time of occurrence, severity, duration, relevance to the investigational drug, measures taken, and outcome.

9.3.4 Criteria for determining the severity of AE

Researchers will evaluate the severity based on the five level judgment criteria developed by NCI CTCAE 5.0:

- Level 1, mild; Asymptomatic or with mild signs; For clinical or diagnostic observation only, no medical intervention is required;
- Level 2, moderate; Age appropriate daily life functions are restricted (such as cooking, shopping, making phone calls, etc.);
- Level 3, severe or medically significant but not immediately life-threatening; Causing hospitalization or prolonging hospitalization time; a disability; Restricted daily self-care activities (daily self-care activities refer to bathing, dressing, undressing, eating, toileting, taking medication, etc., but not bedridden);
- Level 4, life-threatening, requiring emergency treatment;
- Level 5, AE related deaths;

9.3.5 Other responsibilities of researchers during follow-up of serious adverse events

Researchers should conduct corresponding examinations and treatments for serious adverse events based on clinical judgment, including necessary clinical laboratory tests, physical examinations, etc. Any inspection results or other updated SAE related information must be followed up with a follow-up report, which has the same time limit and process as the initial report.

10. Test termination/suspension criteria

10.1 The applicant has the right to terminate/suspend this trial. Before terminating/suspending a clinical trial, the applicant must notify the researchers, ethics committee, and the National Food and Drug Administration, and state the reasons. After early termination/suspension of the study, resuming the study must obtain approval from the ethics committee for review;

10.2 Termination/suspension requested by the ethics committee.

11. Regulations for ending clinical trials.

The experiment ends when all participants meet the following conditions:

1） All participants in the observational study completed all data collection, and all participants in the continuous monitoring study completed data collection and reporting as required after reaching the study endpoint.

2） Or all subjects may die, be lost to follow-up, or withdraw their informed consent.

12. data management

12.1 data management

1) Researchers must ensure that the data is true, complete, and accurate;

2) When making any corrections to the experimental records, only lines should be drawn and the modified data should be annotated with reasons. The researcher should sign and indicate the date, and the original records should not be erased or covered;

3) The laboratory inspection items are complete.

12.2. Data recording and file saving

The subject data on the case report form should be recorded in the form of subject codes, and subjects can only be identified by their subject codes or their initials.

This experiment uses its own APP for data management: from data entry to source data verification requirements, to questioning and answering quality control data, and finally to data locking and export operations. After confirming that there are no doubts about the data, all parties sign the database locking application form, and the data administrator locks the database. After the database is locked, the data administrator exports the analysis database and submits it to the statistical personnel for statistical analysis. The locked data cannot be edited again. Any issues discovered after database locking can be corrected in the statistical analysis program after confirmation.

13. statistical analysis

13.1 Sample size determination

This study is divided into three stages: the first stage is a prospective intervention study, and the second and third stages are observational studies. The sample size of the experiment is mainly based on the requirements of the first stage research, calculated using PASS 15.0 software. Compare the differences in dynamic and static foot posture between the intervention group and the observation group for subjects with foot pain after 4 weeks of intervention. Require bilateral testing, with α=0.05, β=0.1, and a confidence (testing efficiency) of 1- β=90%. The expected difference in effect between the intervention group and the observation group is 0.8, so each group requires 34 people, for a total of 102 people in the three groups. According to the preliminary epidemiological investigation, the incidence of foot pain events in children is about 12%. The planned recruitment sample size is 1000 people, which can collect about 120 cases of foot pain events, meeting the sample size requirements.

13.2 Definition and selection of analysis set

Use the full analysis set for statistical analysis. Full analysis set (FAS): Includes all enrolled subjects who have received at least one non pharmacological intervention and have measurable baseline foot injury.

13.3 statistical method

Independent sample t-test was used to compare gait parameters between children with foot pain and those without symptoms, while repeated measures ANOVA was used to compare dynamic and static foot posture parameters before and after training intervention.

13.4 Statistical software and general requirements:

- All statistical analyses were conducted using SPSS 25.0 (or higher version).
- Measurement data is described using mean, standard deviation, median, maximum, and minimum values
- Count data is described using frequency and percentage

14. Experimental management

14.1 Comply with GCP requirements

Management organization and implementation of GCP:

1) Researchers should adopt standard operating procedures to implement quality control and quality assurance systems for clinical studies;

2) The original data must comply with relevant regulatory requirements;

3) The laboratory inspection results must be accurate and reliable;

4) All observations and findings used should be verified to ensure the reliability of the data;

5) Establish a complete research organization and clarify the responsibilities of personnel at all levels;

6) The main researcher is responsible for comprehensive quality control and carries out the responsibilities of personnel at all levels;

7) The main researcher is responsible for designing the research plan and informed consent form, and after the research is completed, the main researcher writes the research summary report;

8) Designated researchers are responsible for developing research implementation guidelines and SOPs, which will be used in the study;

9) Prior to the study, the research team shall organize a learning program for all participants, and all participants must undergo GCP training;

10) Physicians and nurses participating in the study must strictly comply with the protocol and follow the procedures, and are not allowed to make arbitrary changes;

11) Designated statisticians are responsible for comprehensive statistical processing of data.

14.2 Protecting the privacy of participants

All data collected by participants during the study period will be stored and analyzed in a confidential computer system. If necessary, relevant institutions may review the records to confirm the authenticity, accuracy, and completeness of the data. The information obtained from the study may also be published in academic journals, but the names of participants will not be disclosed and their privacy will be kept confidential.

Take additional preventive measures to ensure the confidentiality of documents and prevent the identification of subjects through genetic data. However, in special circumstances, some individuals may be able to view a subject's facial data and personal identification code. For example, in the event of a medical emergency, the sponsor, their representative physician, or researcher becomes aware of the situation, subject identification code and access to the subject's facial data. In addition, relevant regulatory agencies require access to relevant documents.

14.3 Problems that occurred during the experiment and their corresponding solutions

1) Revision of the protocol: After approval by the ethics committee, if the protocol needs to be revised, a "Protocol Revision Explanation" must be developed and signed by the principal investigator. The revised plan can only be made after consultation and agreement between the researcher and the drug registration applicant;

2) After the revision of the plan, it needs to be reviewed and approved by the ethics committee before it can be implemented;

3) Any participant in the experiment shall not violate the protocol.

14.4 Quality Control and Quality Assurance

14.4.1 quality assurance

The sponsor or the collaborating unit entrusted by the sponsor to be responsible for all or part of the responsibilities and tasks related to this study(including CRO, SMO, statistical units, clinical centers, etc.) should establish their own quality assurance systems, fulfill their respective responsibilities, strictly follow the clinical trial protocol, and adopt corresponding standard operating procedures to ensure the implementation of clinical trial quality control and quality assurance systems.

14.4.2 Quality assurance of clinical trial process

Before the initiation of clinical trials, researchers should receive training on the trial protocol to enable them to have a full understanding and recognition of the specific connotations of the clinical trial protocol and its various indicators. Quality control personnel should verify the basic conditions of clinical trials to ensure that the clinical trial conditions meet the requirements of the protocol. During the experimental process, researchers should conscientiously carry out clinical operations and other work in accordance with the institutional SOP and experimental protocol requirements, and record them truthfully, timely, completely, and standardly. Quality control personnel conduct quality checks on the experimental process and corresponding original records. After the experiment is completed, the research unit will organize the corresponding project documents, which will be checked by quality control personnel and archived for preservation. The quality assurance department of the clinical research unit conducts feasibility checks on the trials conducted. When non conformities are found, promptly notify the researchers and unit leaders to make corrections, and track the progress of the corrections.

14.4 Expected progress and completion date of clinical trials

- January 2024 to June 2024: Complete the recruitment of 1000 cases for the first phase of the study
- July 2024 to December 2025: Complete the second phase of research on 120 cases
- From January 2026 to December 2027: Complete the third phase of research on 30 cases

14.5 Responsibilities of the applicant

The applicant is responsible for initiating, applying for, and organizing this clinical trial, and providing trial funding.

The applicant selects the institution and researcher for the clinical trial, recognizes their qualifications and conditions to ensure the completion of the trial.

14.5.1 Responsibilities of Researchers

The clinical study will be conducted in accordance with the ethical, moral, and scientific principles set forth in the Helsinki Declaration and the Chinese GCP regulations, as well as the protocol design and regulations.

Researchers should be responsible for making medical decisions related to clinical trials and ensuring that subjects receive timely treatment in case of adverse events during the trial period. Researchers should be aware of the procedures and requirements for reporting SAEs, and record and report these events in accordance with the requirements.

Researchers should accurately, completely, timely, and legally load data into eCRF, and accept monitoring or inspection by supervisors or inspectors dispatched by the sponsor or CRO company, as well as inspection and inspection by drug regulatory authorities, to ensure the quality of clinical trials.

14.5.2 The method of publishing research data by the applicant

The applicant has exclusive rights to the data of this study. Unless obtaining written consent from the sponsor, individual articles should not be published before the final report of the multicenter study is completed. The applicant has the final decision-making power regarding the manuscript and publication

14.5.3 The collection, sale, export, and exit of human genetic resources shall comply with the Interim Measures for the Management of Human Genetic Resources (State Council Document No. 36 of 1998.

15. Ethics related to experiments

15.1 Ethics Committee

Before the start of the study, the researcher must submit the research protocol, informed consent form, and any other information provided to the subjects to the ethics committee for approval. Any revisions made to the experimental protocol must be approved by the ethics committee.

15.2 informed consent

Qualified researchers must provide each participant with a detailed explanation of the nature, purpose, relevant procedures, expected time, potential risks and benefits, as well as any possible discomfort of this trial in the informed consent. Each participant must be aware that participating in the trial is voluntary, and they may withdraw from the trial and withdraw their informed consent at any time without affecting their subsequent treatment or relationship with the treating physician.

The informed consent form should be provided in a standard writing format and preferably in non professional language. Each informed consent form must include all relevant information mentioned above and include a voluntary statement. The informed consent form needs to be submitted to the ethics committee for approval.

After explaining the basic content of the experiment and ensuring that each participant understands the purpose of the experiment, the researcher should require each participant to sign their name and date on the informed consent form. Participants should read and consider their statements before signing and dated, and should obtain an informed consent form for safekeeping after signing. Without obtaining informed consent and signing the informed consent form, the subjects cannot enter the trial.

15.3 other

When the subject is unable to independently participate in informed consent, a reliable and fair witness/legal representative must be present throughout the entire process of informed consent. The selection of fair witnesses/legal representatives shall not infringe upon the confidentiality rights of the subjects. After the subject's verbal consent, the fair witness/legal representative should sign and date the informed consent form to prove that the information is accurate.

16. reference

[1] Aiyer A, Hennrikus W. Foot pain in the child and adolescent. Pediatr Clin North Am. 2014;61(6):1185-1205. doi:10.1016/j.pcl.2014.08.005

[2] Lin CI, Houtenbos S, Lu YH, Mayer F, Wippert PM. The epidemiology of chronic ankle instability with perceived ankle instability- a systematic review. J Foot Ankle Res. 2021;14(1):41. Published 2021 May 28. doi:10.1186/s13047-021-00480-w

[3] Riskowski J, Dufour AB, Hannan MT. Arthritis, foot pain and shoe wear: current musculoskeletal research on feet. Curr Opin Rheumatol. 2011;23(2):148-155. doi:10.1097/BOR.0b013e3283422cf5

[4] Awale A, Hagedorn TJ, Dufour AB, Menz HB, Casey VA, Hannan MT. Foot Function, Foot Pain, and Falls in Older Adults: The Framingham Foot Study. Gerontology. 2017;63(4):318-324. doi:10.1159/000475710

[5] Chou MC, Huang JY, Hung YM, Perng WT, Chang R, Wei JC. Flat foot and spinal degeneration: Evidence from nationwide population-based cohort study. J Formos Med Assoc. 2021;120(10):1897-1906. doi:10.1016/j.jfma.2020.12.019

[6] Wyndow N, Collins NJ, Vicenzino B, Tucker K, Crossley KM. Foot and ankle characteristics and dynamic knee valgus in individuals with patellofemoral osteoarthritis. J Foot Ankle Res. 2018;11:65. Published 2018 Dec 11. doi:10.1186/s13047-018-0310-1

[7] Mendeszoon MJ, Iosue HE. Pediatric Osteochondritis Dissecans of the Talus. Clin Podiatr Med Surg. 2022;39(1):105-111. doi:10.1016/j.cpm.2021.09.005

[8] Chiodo WA, Cook KD. Pediatric heel pain. Clin Podiatr Med Surg. 2010;27(3):355-367. doi:10.1016/j.cpm.2010.03.001

[9] Engström P, Tedroff K. The prevalence and course of idiopathic toe-walking in 5-year-old children. Pediatrics. 2012;130(2):279-284. doi:10.1542/peds.2012-0225

[10] Behmaram S, Jalalvand A, Reza Jahani M. Effects of backpack-induced fatigue on gait ground reaction force characteristics in primary school children with flat-foot deformity. J Biomech. 2021;129:110817. doi:10.1016/j.jbiomech.2021.110817

[11] Costa MDC, Natour J, Oliveira HAV, Terreri MT, Len CA. Gait in children and adolescents with idiopathic musculoskeletal pain. Adv Rheumatol. 2019;59(1):7. Published 2019 Feb 12. doi:10.1186/s42358-019-0052-1

[12] Menz HB, Dufour AB, Riskowski JL, Hillstrom HJ, Hannan MT. Association of planus foot posture and pronated foot function with foot pain: the Framingham foot study. Arthritis Care Res (Hoboken). 2013; 65(12):1991-1999. doi:10.1002/acr.22079

[13] Ribeiro AP, Sacco IC, Dinato RC, João SM. Relationships between static foot alignment and dynamic plantar loads in runners with acute and chronic stages of plantar fasciitis: a

cross-sectional study. Braz J Phys Ther. 2016;20(1):87-95. doi:10.1590/bjpt-rbf.2014.0136

[14] Ursei ME, Accadbled F, Scandella M, Knorr G, Munzer C, Swider P, Briot J, Gauzy JS. Foot and ankle compensation for anterior cruciate ligament deficiency during gait in children.

Orthop Traumatol Surg Res. 2020;106(1):179-183. doi:10.1016/j.otsr.2019.07.009

[15] Chen Shanben, Bao Kun, Chen Bochang Research progress on arch development and flat feet in children [J] Journal of Clinical Pediatric Surgery, 2016,15 (06): 610-613

[16] Flat feet in children. BMJ. 1990 Dec 8;301(6764):1330-1.

[17] Han Yankun, Huo Hongfeng A study on foot shape and gait characteristics of patients with flat feet [J] Chinese Journal of Rehabilitation Medicine, 2020, 35 (04): 434-439

[18] Pauk J, Ezerskiy V, Raso JV, Rogalski M. Epidemiologic factors affecting plantar arch development in children with flat feet. J Am Podiatr Med Assoc. 2012 Mar-Apr;102(2):114-21.

[19] Jiang H, Mei Q, Wang Y, He J, Shao E, Fernandez J, Gu Y. Understanding foot conditions, morphologies and functions in children: a current review. Front Bioeng Biotechnol. 2023 Jul 19;11:1192524.

[20] Evans AM, Rome K. A Cochrane review of the evidence for non-surgical interventions for flexible pediatric flat feet. Eur J Phys Rehabil Med. 2011 Mar;47(1):69-89.

[21] Zhong Yuting, Lv Jingyi, Chen Tianwu et al. Epidemiological study on arch index and flat feet of school-age children in Shanghai [J]. China Academic Journal School Health, 2020,41 (09): 1358-1361+1364

[22] Lin CJ，LaiKA，Kuan TS，eta1．Correlating Factors and Clinical Significance of Flexible Flatfoot in Preschool Children[J]．J Pediatric Orthopaedics，2001，21：378—382．

[23] Chou MC, Huang JY, Hung YM, Perng WT, Chang R, Wei JC. Flat foot and spinal degeneration: Evidence from nationwide population-based cohort study [J]. J Formos Med Assoc. 2021, 120(10):1897-1906.

[24] Wyndow N, Collins NJ, Vicenzino B, Tucker K, Crossley KM. Foot and ankle characteristics and dynamic knee valgus in individuals with patellofemoral osteoarthritis [J]. J Foot Ankle Res. 2018, 11(1):65.

[25] Mendeszoon MJ, Iosue HE. Pediatric Osteochondritis Dissecans of the Talus [J]. Clin Podiatr Med Surg. 2022, 39(1):105-111.

[26] Tan A, Strauss VY, Protheroe J, Dunn KM. Epidemiology of paediatric presentations with musculoskeletal problems in primary care [J]. BMC Musculoskelet Disord. 2018, 19(1):40.

[27] Tian F, Guittar P, Moore-Clingenpeel M, et al. Healthcare Use Patterns and Economic Burden of Chronic Musculoskeletal Pain in Children before Diagnosis [J]. J Pediatr. 2018, 197:172-176.

[28] Elengard T, Karlsson J, Silbernagel KG. Aspects of treatment for posterior heel pain in young athletes [J]. Open Access J Sports Med. 2010, 1:223-232.

[29] Joseph AM, Labib IK. Pediatric heel pain [J]. Clin Podiatr Med Surg. 2013, 30(4):503-511.

[30] Zhang Xinyu, Xing Xinyang, Huo Hongfeng Design principles and biomechanical functions of corrective insoles [J] Chinese Journal of Tissue Engineering, 2020,24 (23): 3744-3750

[31] Cardinale M, Wakeling J. Whole body vibration exercise: are vibrations good for you? Br J Sports Med. 2005 Sep;39(9):585-9; discussion 589.

[32] Di Giminiani R, Masedu F, Tihanyi J, Scrimaglio R, Valenti M. The interaction between body position and vibration frequency on acute response to whole body vibration. J Electromyogr Kinesiol. 2013 Feb;23(1):245-51.

[33] Yang L , Gong H , Zhang M .TRANSMISSIBILITY OF WHOLE BODY VIBRATION STIMULI THROUGH HUMAN BODY IN DIFFERENT STANDING POSTURES[J]. Journal of Mechanics in Medicine & Biology, 2012, 12(3):1778-.

[34] Ritzmann R, Gollhofer A, Kramer A. The influence of vibration type, frequency, body position and additional load on the neuromuscular activity during whole body vibration. Eur J Appl Physiol. 2013 Jan;113(1):1-11.

[35] Robbins D, Goss-Sampson M. The influence of whole body vibration on the plantarflexors during heel raise exercise. J Electromyogr Kinesiol. 2013 Jun;23(3):614-8.

[36] Beerse M, Lelko M, Wu J. Acute effect of whole-body vibration on acceleration transmission and jumping performance in children. Clin Biomech (Bristol, Avon). 2021 Jan;81:105235.

[37] Zaidell LN, Pollock RD, James DC, Bowtell JL, Newham DJ, Sumners DP, Mileva KN. Lower Body Acceleration and Muscular Responses to Rotational and Vertical Whole-Body Vibration at Different Frequencies and Amplitudes. Dose Response. 2019 Jan 6;17(1):1559325818819946.

[38] Linens S W, Ross S E, Arnold B L. Wobble Board Rehabilitation for Improving Balance in Ankles With Chronic Instability[J]. Clinical Journal of Sport Medicine, 2016, 26(1): 76–82.

[39] Kiers H, Brumagne S, Van Dieen J, van der Wees P, Vanhees L. Ankle proprioception is not targeted by exercises on an unstable surface. European Journal of Applied Physiology. 2012;112(4):1577-1585.

[40] Mar ın PJ, Hazell TJ. Effects of whole-body vibration with an unstable surface on muscle activation. J Musculoskelet Neuronal Interact. 2014;14(2):213–219.

[41] Rendos N K, Jun H-P, Pickett N M, Wait Acute effects of whole body vibration on balance in persons with and without chronic ankle instability[J]. Research in Sports Medicine, 2017, 25(4): 391–407.

[42] Cloak R, Nevill A, Clarke F, Wait Vibration Training Improves Balance in Unstable Ankles[J]. International Journal of Sports Medicine, 2010, 31(12): 894–900.

[43] Ray J. THE EFFECTS OF WHOLE BODY VIBRATION VERSUS WOBBLE BOARD BALANCE EXERCISES ON DYNAMIC POSTURAL CONTROL IN RECREATIONALLY ACTIVE INDIVIDUALS WITH CHRONIC ANKLE INSTABILITY: A META-ANALYSIS[J]

[44] Fu Shifang, Li Yuetong, Ren Fengjiao, Bian Lei, Wang Yanguo. Research progress on the traditional Chinese medicine technique of Yi Jin Jing in the rehabilitation of orthopedic diseases [J]. Tianjin Journal of Traditional Chinese Medicine, 2022, 39 (05): 675-680

[45] Xie Linyan, Song Lili Research progress on the rehabilitation effect of Yijin Jing on elderly patients with chronic obstructive pulmonary disease [J] Medical Theory and Practice, 2022, 35 (22): 3806-3808+3817. DOI: 10.19381/j.issn.1001-7585.2022.2008

[46] Zhu Gaofeng, Luo Kaitao, Shen Zhifang, Qian Lifeng, Jin Yueqin, Fu Yuanxin. Effects of Guiding Technique Yi Jin Jing on Balance Function in Elderly Patients with Skeletal Muscle Reduction [J]. Zhejiang Journal of Traditional Chinese Medicine, 2018, 53 (05): 351-352

[47] Li Yutao, Niu Xiaomin, Hong Kunda, Chen Jian, Qiu Zhiwei, Jin Linglu, Zhong Weihong. Study on the Brain Mechanism of Yi Jin Jing Regulating Emotions to Relieve Chronic Pain in Knee Osteoarthritis. Chinese Journal of Rehabilitation Medicine, 2022, 37 (11): 1478-1484

[48] Wang Peng, Tang Min, Zhang Jingzhi et al. Exploring the mechanism of the seventh form of the Yi Jin Jing, "Nine Ghosts Pulling the Horse Knife," in improving sub-health neck fatigue in primary and secondary school students [J]. Journal of Traditional Chinese Medicine External Treatment, 2023, 32 (01): 128-129

[49] Yang Tao Experimental Study on the Effects of Health Qigong Yijin Jing on Spinal Function of Middle School Students [D]. Hebei Normal University, 2017