Informed Consent Form (Guardian Version)

Project Name: Research on Early Warning and Intervention Mechanisms for Foot Health Risks in Children and Adolescents

Version number and date of informed consent form: V1.1/2024-05-21

Applicant: Southern Hospital of Southern Medical University

Dear subject guardian:

We invite your child to participate in a study that has been reviewed and approved by the Medical Ethics Committee of Southern Hospital, Southern Medical University. Before you make a decision, we hope you can understand the reasons for conducting this study and what it requires you to do. Your participation in this study is purely voluntary, which means you can choose to participate or not. The research team will explain this information disclosure to you and answer any questions you may have. If you have any questions, please feel free to ask us. Welcome to discuss this study and the information contained in this document with your partner, family, friends, and doctors who are close to you.

After considering all the information related to this study and all your questions have been answered, if the subject agrees to participate, the research team will ask you to sign an informed consent form and indicate the date (at the end of this document) before proceeding with any study related procedures.

1. Research background

The arch of the foot is in a critical developmental stage before the age of 12, and a stable arch structure is formed during adolescence. Some children may experience abnormal foot posture such as flat feet, and some may not be able to self heal during adolescence, resulting in gait problems that may affect the stress on the knee joints, spine, etc., leading to problems such as adolescent scoliosis and increased risk of spinal degeneration in adulthood.

Gait analysis is a routine detection method for ankle diseases, which can provide diagnostic support for ankle diseases, even hip, knee, and spinal diseases. In addition to the commonly used optical dynamic capture and other methods to collect gait

information in clinical practice, this study also extensively used wireless wearable sensors (ankle rings). The devices have been verified for consistency and safety, and will not cause harm to the human body. They can effectively measure gait parameters of children for a long time.

Therefore, this study will investigate the impact of foot problems on children's growth and development, joint and spinal health by collecting information on abnormal foot posture and gait in children and adolescents.

2. research objective

This clinical study is a prospective intervention study. We plan to recruit 1000 participants aged 6-18, and use sensors to collect all-weather gait data and record foot pain occurrences 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 8 weeks of intervention, analyze and compare the differences in dynamic and static foot posture between the intervention group and the observation group. Select 120 participants aged 8-10 for an observational study on the correlation between foot development and bone age development. Select 30 participants aged 8-10 years for an observational study of gait dynamics using optical motion capture.

3. Introduction to research equipment (or diagnostic and therapeutic techniques)

1) wearable sensor

Using Huawei S-TAG foot ring, matching system HarmonyOS 2+/Android 6.0+/iOS 9.0+; IP68 (GB/T 4208-2017), waterproof rating of 50 meters; Bluetooth: BT 5.0 transmits data; Running scenario 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.

Figure 1 S-TAG Wearable Sensor

2) Optical motion capture

The passive optical motion capture system uses a floodlight sphere attached to various parts of the human body as marker points, and the motion capture camera performs spatial positioning and records the motion trajectory. 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.

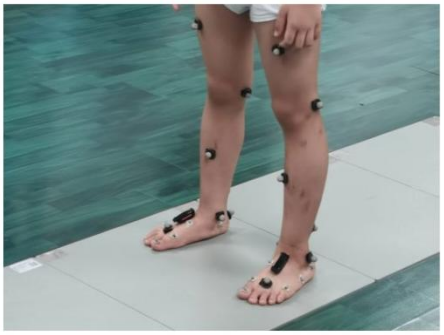

Figure 2 Optical motion capture device

3) Vertical Rhythm Training Platform

Whole body vibration (WBV) is a safe and reliable mature training technique that has been widely used in space exploration to maintain the muscle health of astronauts for a long time without gravity. The WBV vertical motion table used in this study has been tested by researchers and has ensured safety and reliability.

Figure 3 WBV Vertical Rhythm Training Platform

4) Traditional Chinese Medicine Practice Training

Traditional Chinese Medicine (TCM) exercises, including the Yi Jin Jing and Ba Duan Jin, are recommended by national professional institutions for gymnastics training suitable for children and adolescents. They are safe and effective, and have been widely promoted in primary and secondary schools across the country.

Figure 4 Traditional Chinese Medicine Practice Training

5) Bone age testing

The bone age photography adopts a dual energy X-ray bone age analyzer, which has extremely low radiation levels, equivalent to taking a plane for two minutes or walking in sunlight for 20 minutes, without causing harm to the human body.

Figure 5 Dual energy X-ray bone age analyzer

6) Bone density testing

The bone density is measured using an ultrasonic bone densitometer, which can be used to detect the bone density of the heel bone in children without radiation or trauma.

Figure 6 Ultrasonic bone densitometer

4. Research process

1) How many people will participate in this study?

This clinical study is a prospective intervention study. In the first phase, approximately 1000 people will participate in the study conducted at Southern Hospital of Southern Medical University. In the second and third phases, 120 and 30 people will be invited to participate, respectively.

2) What will be required to participate in the research?

Before the start of the study: In order to check whether the children are suitable to participate, this study will register their basic information and relevant medical history. The results of the screening checks and/or related issues will help researchers determine whether you can continue with this study. If you do not meet the relevant standards, you cannot continue to participate in this study, and the researchers will notify you as soon as possible.

■ Phase 1 experiment

Recruitment target: 1000 children aged 6-18

This study will last for 4-8 weeks. Before the study begins, researchers will

guide you to wear wearable devices for children and collect gait data for the next 4 weeks, with daily daytime wear exceeding 8 hours. When the device's battery level is low, it should be charged in a timely manner during the nighttime rest period to ensure that the wearable device can be used daily. When children experience foot pain, they should promptly report it to researchers. Children with foot pain will be added to the observation group, exercise intervention group, or WBV intervention group according to their wishes for a 4-week intervention. After the intervention, we will analyze the improvement of children's dynamic and static foot posture.

Phase 2 experiment

Recruitment target: 120 children aged 8-10 years old

This study does not involve any disease specific interventions and all examinations will be completed on the same day. The selected children must be accompanied by their guardians and arrive at the research site on time. On the same day, we need to collect data on the growth and development of the children's feet and bones. The testing content includes physical examination of foot posture, 3D foot scan, foot X-ray, bone age, bone density ultrasound, traditional Chinese medicine body mass table, saliva gene analysis, body fat test, etc.

■ **Third stage experiment**

Recruitment target: 30 children aged 8-10 years old

This study does not involve any disease specific intervention behaviors, and all observations will be completed on the same day. The selected children will undergo MRI scans to obtain MRI images of their feet and waist before the study, which will be used to establish a finite element musculoskeletal model (non-invasive, radiation free). The researchers will arrange the testing time and location in advance and notify the guardian. Children must arrive at the research site on time accompanied by their guardians. Researchers will conduct optical motion capture studies on the process of children's walking, traditional Chinese medicine exercise training, and WBV vertical rhythm training. Children will be marked with reflective balls attached to their bodies, and the entire process of their movements will be recorded by cameras. The data obtained from motion capture will be used for virtual simulation model building and

finite element analysis to dynamically analyze the joint and muscle states of children during the motion process. During the testing period, the facial recognition characteristics of children will be kept confidential.

3) What tests and evaluations will be conducted in this study?

After providing written informed consent, you will undergo some tests, examinations, and procedures during this study. If you have any doubts about any of these tests, please discuss with the research doctor. Regarding the testing and procedures of this study, we would like to provide you with the following explanation:

• Demographic data: Researchers will collect personal information about children, such as date of birth and ethnic background.

Basic health condition: Height and weight: The child's height and weight will be measured, and relevant medical history will be understood.

Body fat analysis: Evaluate the muscle/fat ratio and distribution of children through bioelectrical impedance.

• Static assessment: 3D foot morphology scanning, X-ray, ultrasound, magnetic resonance imaging, etc

• Dynamic evaluation: Research doctors will collect gait parameters of children through wearable sensors and optical motion capture.

• Bone age assessment: Research doctors use a mobile wrist bone age monitor to determine children's bone age

Saliva gene analysis: By collecting saliva from children's mouths and analyzing genomic data

Traditional Chinese Medicine constitution assessment: Analyze the TCM constitution classification by filling out scales and observing tongue images.

4) How long will this study last?

The first phase of this study is expected to last for 4-8 weeks, while the second and third phases will be completed on the day of the study. You can choose to

withdraw from the study at any time without any punishment and without losing any benefits you should have received. However, if you decide to withdraw from this study during the research process, we encourage you to consult with your doctor first. Considering your security concerns, it is possible that a relevant check will be conducted after exiting.

5. Risk and/or discomfort

This study does not pose any health risks. However, there may be risks in terms of information security. We will do our best to protect the information you provide from being leaked, however, we cannot guarantee absolute security of the information. Some of the questions we asked you in this study may make you feel uncomfortable, and you can refuse to answer such questions. At the same time, you can rest at any time during the research process. You can withdraw from this study at any time during the research.

The risk of subject privacy leakage: In the motion capture test data, there are facial data of children and personal contact information of children and their guardians. To minimize the leakage of privacy information, all personal data of the subjects were anonymized and analyzed. A single testing process may take 1-2 hours.

The imaging examination in this study will not cause any harm to children. The X-rays and bone age shots used have minimal radiation, equivalent to taking a two minute flight or a 20 minute walk in sunlight.

6. What are the benefits of participating in research?

Participating in this study may not bring you direct medical benefits. But we hope that your participation will help to enhance our understanding of children's foot health knowledge and provide more information for the diagnosis and treatment of related diseases in the future.

7. Alternative treatment options

Children with flat feet generally do not require special intervention in clinical practice, and they can lead a normal life. If symptoms such as foot pain worsen, they can seek medical attention at the hospital on their own.

8. The use of research results and the confidentiality of personal information

When the study is completed, we will analyze the data. You will have the opportunity to learn about the research results. You can inquire with your research doctor about the research results and ask them to provide an explanation. The results of this study may also be published in journals and presented at conferences, but will not contain any information that may identify you.

To ensure privacy, records or samples published for research purposes will not include your name or other identifying information. On the contrary, your information will only be identified by one code. Only research doctors and authorized personnel can associate this code with your name through a list, which will be securely stored at the research center.

In order to ensure that the research is conducted correctly at the research center, if necessary, the sponsor, ethics review committee, and government regulatory authorities may access your information in accordance with regulations. They are bound by confidentiality obligations and will not infringe upon your privacy.

9. Research related new information

During the research period, if there are any changes in the research procedure, newly discovered side effects, or significant circumstances that may affect your health or willingness to participate, the research team will notify you and your child. The research doctor will immediately notify you and discuss with you whether your child wishes to continue participating in this study.

10. Regarding research expenses, compensation, and damages

1) The cost of drugs and related examinations used in the research institute

You do not need to bear any costs to participate in this study. You will receive all research checks and procedures free of charge.

2) Compensation for participation in research

This study may have 2-3 on-site follow-up or testing sessions, and some participants may not have been followed up. Each on-site follow-up or test will receive a transportation compensation of 50 yuan, which will be distributed in cash after the last follow-up of the subjects. If the subjects choose to withdraw midway, compensation will be based on the number of completed follow-up visits.

3) Compensation for damages

If you suffer damage due to participating in the research, you can receive free treatment provided by Southern Hospital of Southern Medical University and will be compensated according to law.

11. Rights and Responsibilities of Participants

1) Your rights

Throughout the entire process of participating in the research, you were voluntary. If you and the child decide not to participate in this study, it will not affect the other treatments that the child should receive. If you and your child decide to participate, you will be required to sign this written informed consent form. You and the child have the right to withdraw from the trial at any stage without discrimination or unfair treatment, and the corresponding medical treatment and rights of the child shall not be affected.

2) Your responsibility

To participate in the research, please abide by the following agreement:

According to the plan, ensure sufficient power supply for the foot ring and upload the data of the foot ring on time

According to the appointment arrangement of the researchers, lead the children to the designated location on time for the experiment

If you wish to terminate the clinical study, you can inform your study doctor at any time

- Need to provide truthful information about one's medical history and current physical condition
- Assist children in following the instructions of researchers

Assist children in informing the research doctor of any discomfort discovered during the study period.

12. Related contact information

If you have any questions related to this study, please contact Chen Chao by phone at 13580348819.

If you have any questions related to your own rights/interests, or if you would like to report any difficulties, dissatisfaction, or concerns encountered during your

participation in this study, or if you would like to provide opinions and suggestions related to this study, please contact the Medical Ethics Committee of Southern Hospital of Southern Medical University at 020-62787238 or email: nfyyec@163.com

Informed Consent Form · Consent Signature Page

Agree statement

I have read the above introduction about this study and have had the opportunity to discuss and raise questions with doctors regarding this research. All the questions I raised received satisfactory answers.

I and the participants are aware of the potential risks and benefits of participating in this study. I and the participants are aware that participating in the study is voluntary, and we confirm that we have sufficient time to consider it and understand that:

- I can consult the doctor for more information at any time.
- Participants can withdraw from this study at any time without discrimination or retaliation, and their medical treatment and rights will not be affected.

I am also aware that if a participant withdraws from this study midway, informing the doctor of any changes in their condition and completing the corresponding physical and chemical examinations will be very beneficial for the participant themselves and the entire study.

If any other medication treatment is required due to the subject's illness, I will seek the doctor's opinion in advance or truthfully inform the doctor afterwards.

I agree for the drug regulatory department, ethics committee, or sponsor representative to access the research data of the subjects.

I will receive a signed and dated copy of the informed consent form.

Finally, the participants and I decided to agree to participate in this study.

Subject Signature: _____Date: _____Contact Number:_____
Signature of guardian: _____Relationship with subject:_____
(Note: If the subject is unable to sign informed consent due to reasons such as lack/limited capacity, it shall be signed by their guardian)

Contact phone number:_____ Date: _____
Fair Witness Signature: _____Date:_____
contact number:
(Note: Only when it is possible to include participants who have the ability to read the text but are unable to read it (such as illiterate or visually impaired), a fair witness signature is required. When the witness is informed, it is best for the researcher to keep video materials as evidence of knowledge.).

I have accurately informed the subject of this document, and he/she has read this informed consent form accurately, demonstrating that the subject had the opportunity to ask questions and that he/she voluntarily agreed.

I confirm that I have explained the details of this trial to the subjects, including their rights and potential benefits and risks, and provided them with a signed copy of the informed consent form.
Researcher's Signature: _____Date: _____

Researcher's work phone number: Chen Chao 13580348819

Informed Consent Form (Minor Version, ≥ 8 years old)

Project Name: Research on Early Warning and Intervention Mechanisms for Foot Health Risks in Children and Adolescents

Version number and date of informed consent form: V1.0/2024-05-21

Applicant: Southern Hospital of Southern Medical University

Dear participant:

This is a clinical study that uses wearable devices to detect your usual walking posture, which may be related to the occurrence of foot pain. Doctors from Southern Hospital of Southern Medical University want to know if some exercise methods (such as traditional Chinese medicine fitness exercises and vibration training) can improve your walking posture. We would like to know if you are willing to participate in this study.

1、 Research objective

We collected your walking posture over a period of one month using two small smart devices installed on the shoes. If you experience symptoms such as foot pain, sprain, knee pain, etc. during this one month period, you should inform your parents or doctor in a timely manner. These symptoms may be related to your walking posture, and we will arrange some training to help you improve your foot posture. There are two main types of training: traditional Chinese medicine fitness exercises (TCM exercise training) and vibration training (WBV vertical rhythm training).

Figure 1 S-TAG Wearable Sensor

Traditional Chinese Medicine Fitness Exercises (TCM exercises) are similar to morning exercises in schools, which can increase lower limb strength and joint stability through specific movements; Vibration training (WBV vertical rhythm training) requires you to stand on a machine and maintain a posture for a period of time.

Figure 2 Traditional Chinese Medicine Practice Training

Figure 3 WBV Vertical Rhythm Training Platform

Doctors and nurses will explain this study and answer any questions you may have. If you agree to participate in this study, they will require you to sign this consent form. Your father, mother, or family member (guardian) will sign another consent form. You can talk to them (guardians) and learn about the information provided to them by the doctor.

2、 What would happen if you participated in this study?

At the beginning of the research, there will be doctor appointments and some examinations, mainly to evaluate your growth and development, such as body fat analysis, bone age assessment, saliva gene analysis, etc; Additionally, it is possible to evaluate your walking posture. These checks are very safe and will not cause any physical damage or discomfort to you.

3、 Something that may make you feel uncomfortable, scared, or uncomfortable

For the vast majority of people, the things that require your cooperation in this study will not be uncomfortable or uncomfortable. But remember to tell your parents and doctor about any feelings you have during the study. If you feel any discomfort, you or your parents can call the doctor based on the number on the last page of this consent form.

4、 Has participating in this study been helpful to you?

You can have a clearer understanding of the health status of your feet, which may help you improve some symptoms such as foot pain, but it may not improve and we cannot guarantee it. Your participation can help doctors better understand children's foot injury issues and better treat children with related problems in the future.

5、 Participation is voluntary

Whether or not to participate in this study is up to you to decide. If you choose not to participate in this study, no one will be angry.

If you do not agree, your doctor or parents cannot force you to participate in this study. If you agree to participate in this study now and change your mind later, you can stop participating in this study. Whenever you want to withdraw from the study, just tell your doctor or your parents (legal representative). Even if you don't want to participate in this study, your doctor will still take care of you.

If you would like to inquire about ethical issues related to this study, you or your parents can call the Medical Ethics Committee of Southern Hospital of Southern Medical University at 020-62787238 or email: nfyyec@163.com

You can ask questions about what we told you. You can circle or indicate that you want to know more about the content on this consent form. If you have anything you don't understand, feel

free to ask us. We hope you can ask us questions now or later.

If you participate in this study, both you and your parents (or legal representative) must agree. But whether you are willing to participate still depends on you.

Informed Consent Form · Consent Signature Page

I have read the above introduction about this study and have had the opportunity to discuss and raise questions with doctors regarding this research. All the questions I raised received satisfactory answers. I can consult the doctor for more information at any time. I confirm that there has been sufficient time to consider and be aware of the potential risks and benefits.

I am aware that participating in research is voluntary. I am aware that I can withdraw from this study at any time without discrimination or retaliation, and my medical treatment and rights will not be affected.

I agree for the drug regulatory department, ethics committee, or sponsor representative to access the research data of the subjects. I will receive a signed and dated copy of the informed consent form.

Subject Signature: _____Date: _____ Contact Number:_____

Signature of guardian: _____Relationship with subject:_____
(Note: If the subject is unable to sign informed consent due to reasons such as lack/limited capacity, it shall be signed by their guardian)

Contact phone number:_____ Date: _____

(Children under 8 years old shall have their informed consent form signed by their legal representative, and their consent shall be obtained from themselves when they express their consent through their abilities; children and adolescents over 8 years old shall have their legal representative's consent obtained, and their consent shall also be signed by themselves.)

I have accurately informed the subject of this document, and he/she has read this informed consent form accurately, demonstrating that the subject had the opportunity to ask questions and that he/she voluntarily agreed.

I confirm that I have explained the details of this trial to the subjects, including their rights and potential benefits and risks, and provided them with a signed copy of the informed consent form.

Researcher's Signature: _____Date: _____

Researcher's work phone number: Chen Chao 13580348819