Short-term effects of gene-physical activity interaction on obesity and related metabolic indicators in children: a randomized controlled trial

1-February-2022

Informed Consent

Dear Volunteer:

The dramatic increase in childhood obesity has been recognized as one of the most serious but preventable global public health challenges. Engaging children in moderate to vigorous physical activity (MVPA) is important in addressing obesity. According to the World Health Organization (WHO) recommendations, children aged 5-17 years need to engage in MVPA for 60 minutes per day; however, only about one-third of children in China meet the recommended standard of at least 60 minutes of MVPA per day. Therefore, there is an urgent need for a large number of MVPA intervention programs in schools in China and around the world. However children with different genetic characteristics may derive different benefits from MVPA, suggesting an interaction between genes and physical activity on obesity. This research project has been reviewed by the Medical Ethics Committee of China Medical University. You decide voluntarily to participate or not. Before deciding, please read the following carefully, and if you have any questions please do not hesitate to ask.

I. Purpose of the study:

The aim of this study was to investigate the short-term effects of gene-physical activity interactions on childhood obesity.

II.Content and Steps of the Study:

Participants will start by receiving a questionnaire containing basic information about the participant, self-reported general health status, a dietary frequency

questionnaire, and a physical activity questionnaire. In addition to the questionnaire, the community physician will measure the participant's height, weight, waist circumference, hip circumference, and abdominal fat thickness, and 3-4 ml of venous blood will be collected by a health care professional.

Each participant will then be randomly assigned to either the intervention group or the control group. Participants in the intervention group were required to wear a physical activity accelerometer, while those in the control group were not instructed in any way, and the intervention was guided by the school physical education teacher and parents. At the end of the intervention, all participants' height, weight, waist circumference, hip circumference, and abdominal fat thickness were measured again by the community doctor, and the participants in the intervention group turned in their physical activity accelerometers.

All the processes of this study were conducted according to SOP standards, so please do not worry.

III. What is required of you in the study?

In this study, we need to collect your basic, dietary and physical activity information, measure your body dimensions and body composition data and collect 3-4 ml of venous blood. During the intervention period, if you are a participant in the intervention group, you will be required to wear a physical activity accelerometer and follow the instructions of your school teacher and parents to complete the physical activity intervention.

IV. Possible Risks, Discomfort, and Management of Participation in the Study

During venous blood collection, you may be at risk for transient pain, localized bruising and swelling, black or blue markings, fainting, or infection at the site of the blood draw. In addition, wearing a physical activity accelerometer can cause some inconvenience. Please contact the researcher promptly if you experience any discomfort during the intervention.

V. Possible Benefits and Compensation for Participating in the Study

If you agree to participate in this study, all physical tests in the program are free checkups without any payment; participants in the intervention group may achieve weight loss, and in order to protect the rights and interests of the control group, the control group will also undergo the physical exercise intervention at the end of the study.

VI. Voluntary participation/withdrawal from the study

Participation in this study is voluntary. You may refuse to participate or withdraw from the study at any time.

VII. Confidentiality of personal information

All personal information collected during the study will be kept strictly confidential and will not be disclosed. The researchers, members of the Ethics Committee and relevant management departments have the right to review your information records within the scope permitted by law. Your personal information will not be independently disclosed in any research reports and publications about the project.

Declaration of Consent by Subject and Supervisor

(When participants do not have the capacity to give informed consent)

1. I have carefully read the above description of the study and have had the opportunity to discuss and ask questions about the study with the investigator. All my questions were answered to my satisfaction.

2. I am aware of the possible risks and benefits to my ward of participating in this study and I understand that participation is voluntary. I acknowledge that there has been sufficient time to consider this and understand that:

(1) I am free to ask for information about the study at any time;

(2) My ward can withdraw from the study at any time without discrimination or retaliation, and that medical treatment and benefits will not be affected.

In conclusion, I have decided to agree to participate in this study and am willing to cooperate in the completion of this study as required by the study protocol.

Participant's Signature: Date: Phone:

Signature of guardian: Relationship to participant:

Date: Phone:

I have fully explained and justified to this participant the purpose of this study, the operational procedures, and the possible risks and benefits of the participant's participation in the program, and have answered to the participant's satisfaction all relevant questions.

Signature of researcher: Date: Phone: