Dietary intervention for low free sugars in children with non-alcoholic fatty liver disease: a randomized controlled trial

12-January-2018

Informed consent form

Dear volunteers,

The proportion of overweight and obesity in follow-diagnosed children has increased globally, and non-alcoholic fatty liver disease (NAFLD) has become the most common chronic liver disease in children. The high prevalence of NAFLD is strongly associated with unhealthy dietary patterns and life behaviors, especially with free sugar intake. Developing randomized controlled trials focusing entirely on nutrients in a low-free sugar diet is essential to extend their definition and quality and to support guidelines. This study is to clarify whether a dietary intervention program with low free sugar can improve hepatic steatosis in children with nonalcoholic fatty liver disease. This research project has passed the review by the Medical Ethics Committee of China Medical University. You voluntarily decide whether to participate or not. Before deciding, please read the following carefully and if you have any questions.

1. purpose of research:

This study aims to investigate whether hepatic steatosis in children with nonalcoholic fatty liver disease.

2. Study Content and Steps:

Participants will receive a questionnaire from their basic information, self-reported general health status, eating frequency questionnaire, and physical activity questionnaire. In addition to the questionnaire, the community physician will measure participants' height, weight, waist circumference, fatty liver, and 3-4ml venous blood collected by professional providers.

Each participant will then be randomly assigned to either the intervention group or the control group. Participants in the intervention group should evaluate the dietary conditions by the nutritionist, and the clinicians should give the medication treatment plan based on the test results of the study subjects, and conduct multidisciplinary joint diagnosis and treatment education in the NAFLD clinic to form a health education prescription; then conduct the second and third intervention after 3 months.

All the procedures of this study were conducted according to the SOP criteria, please don't worry.

3. What is you cooperation in the study

This study needs to collect your basic, dietary and physical activity information, measure your body dimensions and body composition data, and collect 3-4ml of venous blood. During the intervention period, if you are a participant in the intervention group, the diet status will be assessed by the dietitian, and the clinician will give the medication treatment plan based on the laboratory test results of the study subjects.

4. Possible risks, discomfort, and management methods for participation in the study

During venous blood collection, you may have risks of blood drawing such as temporary pain, local blue swelling, black or blue marks, fainting or infection of the blood drawing site.

4. Possible benefits and compensation for participating in the study

If you agree to participate in this study, all physical tests in the project are free with no fees; participants in the intervention group may achieve weight loss. In order to protect the rights of the control group, the control group will also undergo physical exercise intervention at the end of the study.

6. Voluntary participation / withdrawal from the study

Participation in this study is on a voluntary basis and you may refuse to participate or withdraw from the study at any time.

7. Confidentiality of personal information

All personal information collected during the study period will be kept strictly confidential and not publicly available. Researchers, ethics committee members and relevant authorities have the right to review your information records to the extent permitted by law. Your personal information will not be publicly disclosed in any research reports and publications on this project.

8. Contact information

Contact person: Mr.Zhou Tel.: 18900918195. If you have any comments on the project, please contact the Ethics Committee (contact 024-31939080).

Subject and guardian consent statement

(When the participant is not able to give informed consent)

1．I have read the above introduction to this study carefully and have the opportunity to discuss and ask questions with the investigators about this study. All the questions I have asked were answered satisfactorily.

2．I know that participating in this study may cause risks and benefits to my ward, and I know that participating in the study is voluntary. I confirm that I have enough time to consider this and understand that:

（1） I can consult and study the relevant problem information at any time;

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

Finally, I have decided to agree to participate in this study, and I am willing to cooperate with the completion of this study according to the requirements of the study protocol.

Participant signature: Date: Telephone:

Guardian Signature: Relationship with Participants: Date: Telephone:

I have fully explained and explained to the participant the purpose of the study, the operation process and the possible risks and benefits of the participant in the project, and answered all relevant questions with satisfaction from the participant.

Investigator Signature: Date: Tel:

Contact person: Mr.Zhou Tel.: 18900918195