
The Effects of Parent-Child Activity Program on Physical Activity of Children With Cancer

March 31, 2024

Dear children and parents:

The School of Nursing of Sun Yat-sen University sincerely invites you to participate voluntarily The Effects of Parent-Child Activity Program on Physical Activity of Children With Cancer experiment.

The conduct of this study has been approved by the Nursing Ethics Committee of the School of Nursing, Sun Yat-sen University (approval number: L2023SYSU-HL-020).

In order to give you a further understanding of the trial, the investigator will provide the following details of the trial to you. If you have any questions, you can contact the investigator (address: School of Nursing of Sun Yat-sen University; Contact number: _____; contacts: _____).

1. Instructions for participation in the clinical study

(I) Rights of the subject

(1) The life, health, privacy and dignity of the subjects are protected by national laws. In this study, subject rights, safety and health exceeded the interests of science and society.

(2) The subject has the right to withdraw from the study at any stage of the study without discrimination or retaliation, and the medical treatment and rights will not be affected. Once the subject is ready to withdraw, the investigator should be informed because the investigator will provide the best withdrawal method to the subject.

(3) During the study, the subject can have the information about him at any time. All study data are owned by the investigator and will be treated strictly confidential. When required, subjects may consult the study investigator or call the Ethics Committee office.

(4) In the course of the study, the subject receives the treatment, the sponsor shall give relevant compensation according to law.

(II) Research Purpose:

(1) Describe the status of body mass index, body fat, muscle, physical activity, physical activity self-efficacy, physical activity enjoyment, family support and parents' physical activity of children with cancer, and analyze the influencing factors of physical activity of children with cancer;

(2) Construct a parent-child activity intervention program suitable for children with cancer based on adolescents with the Youth Physical Activity Promotion Model;

(3) To explore the effect of the parent-child activity program in children with cancer based on the Youth Physical Activity Promotion Model of adolescents on body mass index, body fat, muscle, physical activity, physical activity self-efficacy, physical activity enjoyment, family support and the physical activity of parents of children with cancer.

(III) Study process:

(1) Term of the study: 2023.9.1 to 2024.12.31

(2) Potential inspection operation: no.

(3) Group status: at least 27 cases in the intervention group and the control group.

(iv) Possible adverse reactions or possible adverse events in the study and their countermeasures:

(1) Although the safety of the study protocol for pediatric subjects has been verified, accidents such as falls, bumps, and bleeding may still occur due to the particularity of physical activity.

Countermeasures: The researchers have been strictly trained to accurately assess the health status of the subjects and timely treatment, and teach the parents common first aid skills;

(2) Due to the severe symptoms and signs caused by the primary disease and treatment of cancer, the subjects may feel fatigue, physical exhaustion, increased pain, or have complications such as infection and bleeding during the study.

Countermeasures: The researchers have strictly trained and explained the relevant assessment methods to the parents of the children. Both the researchers and their parents can respond accurately. If they feel unwell, they can withdraw from the study in time;

(3) Some of the study may cause subjects.

Countermeasures: The researchers have been strictly trained to fully explain, reassure and refer the subjects to the corresponding specialist

medical staff if necessary.

(V) Statement made by the investigator

(1) During the study, the investigators will strictly follow the Declaration of Helsinki.

(2) The investigator will conduct the study in strict accordance with the plan approved by the ethics committee.

2. Statement of informed consent made by the subject

(1) I (referring to the subject, the same below) have carefully read and been familiar with all the contents of the aforementioned "Instructions for participating in clinical studies", and I have obtained a full and detailed explanation of the study.

(2) The investigator has given me sufficient time to consider whether I am willing to participate in the study.

(3) In the process of fulfilling the obligation of notification, the researcher adopts the language and words that he can understand.

(4) I will voluntarily participate in this study on the premise of full understanding and knowledge.

(5) Once the trial begins, I am willing to actively cooperate with the completion of this study, and fully cooperate with various projects on time according to the time points required by the study.

(6) I guarantee to provide personal data with the investigator and state my

medical history (including allergy history).

3. This informed consent form is effective after being signed (or signed) by the subject and the investigator.

4. After signing this informed consent form, the subject and the investigator will complete the study following the relevant requirements.

5. If important new data involving the study or changes to the study plan are found, the investigator must submit a written modification of the informed consent form to the Ethics Committee for approval and obtain the subject's consent again.

6. This informed consent form is made in duplicate, with the subject and the investigator keeping one copy each.

Child Signature:

Parent Signature:

Contact number:

Investigator Signature:

Contact number:

Date: