
Lawson Clinical Research Services

Victoria Hospital
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Canada

Letter of Information

Title: Effectiveness of a hospital based Health Initiative Program (HIP Kids) on affecting fruit, vegetable and dairy consumption among overweight children

Sponsor: Children's Health Foundation

Investigators: Dr. Cheril Clarson
Dr. Dirk Bock
Dr. Michelle Jackman

The pronouns 'you' and 'your' should be read as referring to the participant rather than the parent/guardian/next of kin who is signing the consent form for the participant.

You are being invited to participate in a research study looking at providing education to improve the health status and well being of overweight children. The purpose of this letter is to provide you with the information you require to make an informed decision on participating in this research. Please take your time to read the following information carefully.

Study Purpose

Obesity in children has been identified as a growing problem in Canada and many other countries worldwide. One in four Canadian children are now considered either overweight or obese. Significant health consequences are linked to obesity in children and adults, such as heart disease, high blood pressure, high cholesterol, diabetes, gall bladder disease, osteoarthritis, orthopaedic problems, respiratory morbidity and mortality as well as some cancers. Despite this fact, the availability of programs and services is limited, leaving a great need for programs to address childhood health and fitness. With limited resources to fund the needed services, many families have been left without the guidance and tools necessary to tackle the growing obesity epidemic.

The purpose of this study is to evaluate the effects of a hospital-based health initiative program. The program aims to decrease rate of weight gain and body mass index (BMI), increase nutritional knowledge, improve self-esteem and increase physical activity levels while decreasing screen time and healthy body image. The program also aims to improve

eating habits, including an increase in fruits and vegetable consumption and a decrease in sweetened beverages, and junk food.

Study Procedure

Paediatric specialist or dietitians from The Children's Hospital of Western Ontario will refer you to the program. The program (HIP Kids) offers healthy eating, activity and lifestyle counseling by a dietitian, a fitness specialist and a social worker. You have been referred to the program because you have been identified as being overweight and you may be at risk for developing type 2 diabetes.

You will be scheduled to attend the program every 2 weeks for 3 months and then monthly for 9 months. When you arrive for your appointment you will be asked to register on the 4th floor, PMDU, E tower, The Children's Hospital of Western Ontario.

Initial Visit will take approximately 2 hours

- Your height and weight will be taken.
- Bioelectrical Impedance Analysis (BIA) will be measured. BIA is a simple, non invasive technique for measuring body fat content.
- You will be asked to complete questionnaires (*Physical Activity, Quality of Life and Harvard Eating Survey*). This will take approximately 45 to 60 minutes to complete.
- You will be asked to wear an accelerometer for seven days. This is a small device worn on the right hip, which measures activity-related energy movement.
- DEXA scan (an x-ray used to assess body composition by measuring the amount of fat and muscle in the body).
- A fasting blood test when approximately 1-2 teaspoons of blood will be drawn for measurement of insulin, sugar, cholesterol, triglycerides, adiponectine and leptin (fat hormones), BNP (heart hormone), liver and kidney function. You will be given a sugar containing drink and two hours later another blood test (less than half a teaspoon of blood) will be taken to repeat the blood sugar measurement.
- Echocardiography (ultrasound of your heart).
- Measurement of cardiac output, which is the volume of blood pumped by the heart per minute. This is done by placing 4 electrodes on the left side of your neck and chest.
- Leonardo Mechanography - jumping plate to measure muscle strength and balance. This is a platform on which you will jump for 2 to 3 minutes and then sit up and down on a chair on the platform for another 2 to 3 minutes. You will repeat the jumping and sitting up and down on the chair twice, the whole exercise will take about 20 minutes.

Follow up Visits, every 2 weeks for 3 months and then monthly for 9 months, will take approximately 1 hour

- Bioelectrical Impedance Analysis (BIA) will be measured at 3, 6, and 9 months.

Twelve Month Visit will take approximately 1 ½ hour

- Bioelectrical Impedance Analysis (BIA) will be measured. BIA is a simple, non invasive technique for measuring body fat content.
- You will be asked to complete questionnaires (*Physical Activity, Quality of Life and Harvard Eating Survey*). This will take approximately 45 to 60 minutes to complete.

- You will be asked to wear an accelerometer for seven days. This is a small device worn on the right hip, which measures activity-related energy movement.
- DEXA scan (an x-ray used to assess body composition by measuring the amount of fat and muscle in the body).
- A fasting blood test when approximately 1-2 teaspoons of blood will be drawn for measurement of insulin, sugar, cholesterol, triglycerides, adiponectine and leptin (fat hormones), BNP (heart hormone), liver and kidney function. You will be given a sugar containing drink and two hours later another blood test (less than half a teaspoon of blood) will be taken to repeat the blood sugar measurement.
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Parents will also be asked to complete the Quality of Life Questionnaire at the Initial Visit and Twelve Month Visit.

Risks

Risks of having DEXA scan: This requires exposure to a small amount of radiation, but the risk is considered very low. The effective radiation dose from this procedure is about 0.01 mSv, which is about the same as an average person receives from background radiation in 1 day.

Risk of having an Echocardiography (ECG): the adhesive from the electrodes may cause a small rash which should disappear in a day or two.

Benefits

You may not benefit from participating in this study. However, the results of this study may lead to an improve the program methods of educating children/adolescent's eating habits, including an increase in fruits and vegetable consumption and decrease in sweetened beverages, and junk food consumption.

Participation

Participation in this study is voluntary. You may refuse to participate and there will be no effect on your future care.

Confidentiality

Your confidentiality will be maintained except where release of information is required by law. By signing the Consent Form you agree that the study coordinator, personnel involved in the study may read parts of your clinic records which are relevant to the study and share the information with those involved in conducting and analyzing the study.

Your identity will be completely protected. All data collected for this study is made anonymous by removing personal identifiers. All data is kept secure, private and confidential as per current health information legislation and data protection practices.

If the results of this study are published, your identity will remain confidential. Any identifying information will not be used in any publication or presentation. Published reports or presentations will refer to grouped data and not to any identifiable individuals.

Representatives of the University of Western Ontario Health Sciences Research Ethics Board may contact you or require access to your study related records to monitor the conduct of the research.

Your study-related records will be kept for a period of 25 years as per the Health Canada Food and Drug Regulations.

Contact for Further Information

Thank you for taking the time to read the information about this study. If you have any questions or concerns now or at any time about the study, your safety or your rights please ask your study doctor, the study staff or the contact person(s) indicated below.

If you have questions about your rights as a research participant please call Dr. David Hill, Scientific Director, c/o Lawson Health Research Institute at (519) 667-6649.

If you have any questions during the study, you may contact the study Coordinator at (519) 685-8100.

Consent Form

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I have read the Letter of Information, have had the nature of the study explained to me and I agree/I agree for my child to participate. All questions have been answered to my satisfaction. I will receive a copy of the Letter of Information and signed Consent Form.

Patient's Name (printed)

Patient's Signature/Legally Authorized Representative

Date

Person Obtaining Consent (Printed)

Person Obtaining Consent (Signature)

Date