Effects of exercise on lipids and endothelial function in youth with obesity and dyslipidemia participating in a weight loss program

Key Information:

Principal Investigator:

Jordan Sill

Contact Info:

(513) 803-4574

The following is a short summary of this study to help you decide whether to be a participant in it. More detailed information about the study is listed later in this form. This document does not replace the discussion you should have with the research team about this study including having any questions or concerns answered.

If you are 18 years and older: This is a consent form. It explains this research study. If you decide that you want to be in this research study, then you will sign this form to show that you agree to be part of this study. If you sign this form, you will receive a signed copy of it for your records.

Parents/Guardians: You have the option of having your child or teen join this research study. This is a parental permission form. It explains this research study. If you decide that your child can be in this study, you will sign this form to show that you agree. If you sign this form, you will receive a signed copy for your records.

COMBINED Parental Permission/Assent: If you are a parent or legal guardian of a child who may take part in this study, permission from you is required. The assent (agreement) of your child may also be required. When we say "you" in this form, we mean you or your child; "we" means the study doctor and other staff.

Reason for the study:

You are being asked to take part in this study because you have a BMI that is at or above the 95th percentile and are participating in the Healthworks! Structured weight loss program. The main reason for this research study is to determine how exercise affects an individual's high level of lipids (fats) in their blood and how well their blood vessels function.

Procedures:

During your participation in the study, you will be asked to wear a watch called a Garmin Vivosmart tracker. You will wear this watch for one week at a time, three separate times during the study. The watch looks very similar to a FitBit.

We'll take measurements from the Garmin tracker at every study visit and perform a Laser flow Doppler test to assess your blood flow and Veggie Meter readings to assess your vegetable intake during your baseline and 6-month follow-up visits.

You will complete all other standard-of-care Healthworks! procedures during your time in this study, including routine blood draws, mental health screenings, and physical exams. The study team will collect this information from your medical records.

It may not always be possible to align your study visit with your Healthworks visit, so you may need to come in a separate time for the study procedures to be completed.

The Twilio® text messaging platform will be used to send text message notifications and reminders during the course of study participation for your follow up visits, and daily reminders for you to record your at-home study procedures. You can opt-out from these notifications later in this consent document if you do not want to receive these reminders.

We expect each study visit to last about an hour. We expect that you will be in this research study for 6 months.

More detailed information about the study procedures can be found under ***"Detailed Procedures"***

Risks to Participate:

COMMON, SOME MAY BE SERIOUS
• Slight warmth/discomfort at the site of laser flow Doppler and Veggie Meter analyses that quickly resolve • Loss of confidentiality • Possible risks related to a blood draw include faintness, inflammation of the vein, pain, bruising, or bleeding at the site of puncture. There is also a slight possibility of infection.

More detailed information about the risks of this study can be found under ***"Detailed Risks"***

Benefits to Participate:

We cannot promise any benefits to you or others from your taking part in this research. However, the information learned in this study could benefit patients in the future.

Other Options:

Participation in research is completely voluntary. Your decision to participate or not to participate will not affect the care you receive.

Your alternative to participating in this research study is to not participate.

Cost to Participate:

You and your insurance company will be charged for the healthcare services that you would ordinarily be responsible to pay. In some cases, insurance will not pay for services ordinarily covered because these services were performed in a research study. You should check with your insurance to see what services will be covered by your insurance and what you will be responsible to pay.

Payment:

If you agree to take part in this research study, we will pay you up to $75 for your time and effort. You will receive $25 for each completed session of wearing the fitness tracker.

You (your child) will receive payment for this study in the form of an institution issued ClinCard. We will give you (your child) a handout that will explain how to use the card. Because you (your child) are being paid for your participation, Cincinnati Children's is required by the Internal Revenue Service (IRS) to collect and use your (your child's) social security number (SSN) or taxpayer identification number (TIN) to track the amount of money that we pay. You will need to complete a Federal W-9 form for this income tax reporting. This form requires your child's Social Security number. This form will be given to the Cincinnati Children's business office. It will not be kept as part of your child's study chart. If you move, you will need to complete another W-9 with an updated address.

Additional Study Information:

The following is more detailed information about this study in addition to the Key Information.

If I have Questions or would like to know about:

Who to talk to…	**You can call …**	**At …**
• Emergencies • General study questions • Research-related injuries • Any research concerns or complaints	**Principal Investigator:** **Jordan Sill, M.D.**	**Phone:** (513) 803-4574
• Your child's rights as a research participant	**Institutional Review Board** This is a group of scientists and community members who make sure research meets legal and ethical standards.	**Phone:** (513) 636-8039

Total number of participants:

We expect about 110 people will be in this research study here at Cincinnati Children's Hospital.

Detailed Procedures:

Schedule of Procedures				
	Baseline	Study Visit$^{\alpha}$	3 Months$^{\beta}$	6 Months$^{\gamma}$
Consent	X			
Demographics, medical history	X*			
Vitals	X*		X*	X*

Mental health screen	X*		X*	X*
Session with physician, dietitian, and/or exercise physiologist	X*		X*	X*
Physical exam	X*		X*	X*
Blood work	X*		X*+	X*
Laser flow Doppler & Veggie Meter	X	Xα		X
Physical activity tracker	X	Xα	X	X
Twilio Text reminder	X		X	X
*denotes Healthworks! weight management standard of care procedure + if collected α if not performed at baseline visit, must be performed within 30 days of baseline visit β must be 2-5 months after Baseline visit γ must be 5-8 months after Baseline visit				

Change of Mind/Study Withdrawal:

You can leave the research at any time; it will not be held against you. If you decide to leave the research, contact the investigator.

Detailed Risks:

Twilio Text Message Reminders : Many companies and applications on your smartphone commonly work with text platforms and cloud-based companies to send and receive information securely. We use Twilio to send you text messages. Text messaging does not provide a completely secure and confidential means of communication, and the messages are unencrypted. Twilio does encrypt your information on their servers, but no system can guarantee complete privacy. If they decide to share these data, it may no longer be covered under the privacy protections. Information that identifies you, such as your phone number, may be sent to and permanently kept by Twilio and their business associates. Information disclosed to these companies or their business partners may no longer be covered under the privacy protections.

Laser Flow Doppler: There is a small risk of discomfort from the device heating but it does not reach a temperature that could cause any damage to your skin or other tissues.

Veggie Meter: This is a low-risk, non-invasive machine. It uses a process called spectroscopy to determine your carotenoid levels. It will help us visualize your fruit and vegetable intake using light. There may be a mild finger discomfort with compression if there is improper finger placement but the study team will direct for proper usage

Blood Draw: You may experience slight bruising on your arm after the blood draw (up to 2 teaspoons will be collected, no more than with a typical blood test).

Privacy:

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete privacy. Organizations that may inspect and copy your information include the IRB and other representatives of this organization.

Samples and/or data collected for or generated from this study could be shared and used for future research. Samples and /or data may be shared with other collaborators at Cincinnati Children's and possibly with outside collaborators, who may be at another institution or for-profit company. Data and specimens will be deposited into an existing IRB-approved institutional repository for future unspecified research

If information that could identify you is removed from your information or samples collected during this research, that information or those samples could be stored and used for future research studies or distributed to another investigator for future research studies without your additional informed consent.

AUTHORIZATION FOR USE/DISCLOSURE OF HEALTH INFORMATION FOR RESEARCH

To be in this research study you must also give your permission (or authorization) to use and disclose (or share) your "protected health information" (called PHI for short).

What protected health information will be used and shared during this study?

Cincinnati Children's Hospital Medical Center (Cincinnati Children's) will need to use and share your PHI as part of this study. This PHI will come from:

- Your Cincinnati Children's medical records
- Your research records

The types of information that will be used and shared from these records include:

- Laboratory test results, diagnosis, and medications
- Reports and notes from clinical and research observations
- Imaging (like CT scans, MRI scans, x-rays, etc.) studies and reports

Who will share, receive and/or use your protected health information in this study?

- Staff at all the research study sites (including Cincinnati Children's)
- Personnel who provide services to you as part of this study
- Other individuals and organizations that need to use your PHI in connection with the research, including people at the sponsor and organizations that the sponsor may use to oversee or conduct the study.
- The members of the Cincinnati Children's Institutional Review Board and staff of the Office of Research Compliance and Regulatory Affairs.

How will you know that your PHI is not misused?

People that receive your PHI as part of the research are generally limited in how they can use your PHI. In addition, most people who receive your PHI are also required by federal privacy

laws to protect your PHI. However, some people that may receive your PHI may not be required to protect it and may share the information with others without your permission, if permitted by the laws that apply to them.

Can you change your mind?
You may choose to withdraw your permission at any time. A withdrawal of your permission to use and share your PHI would also include a withdrawal from participation in the research study. If you wish to withdraw your permission to use and share PHI you need to notify the study doctor, listed on the first page of this document, in writing. Your request will be effective immediately and no new PHI about you will be used or shared. The only exceptions are (1) any use or sharing of PHI that has already occurred or was in process prior to you withdrawing your permission and (2) any use or sharing that is needed to maintain the integrity of the research.

Will this permission expire?
Your permission will expire at the end of the study.

Will your other medical care be impacted?
By signing this document, you agree to participate in this research study and give permission to Cincinnati Children's to use and share your PHI for the purpose of this research study. If you refuse to sign this document you will not be able to participate in the study. However, your rights concerning treatment not related to this study, payment for services, enrollment in a health plan or eligibility of benefits will not be affected.

While you are participating in this research study you may not be able to access some of your health information that is related to the study. Any request for this information can be fulfilled once the study is completed.

Optional Study Reminders:

☐ I do not agree with receiving emails and/or text reminders throughout the study.

☐ I agree to receiving emails and/or text reminders throughout the study. The preferred method and information are indicated below.

☐Email address:_____

☐Phone number for text messages:_____

SIGNATURES

The research team has discussed this study with you and answered all of your questions. Like any research, the researchers cannot predict exactly what will happen. Once you have had enough time to consider whether you/your child should participate in this research, you will document your permission by signature below.

You will receive a copy of this signed document for your records.

_____
Printed Name of Research Participant

_____ _____
Signature of Research Participant Indicating Consent or Assent Date

_____ _____
Signature of Parent or Legally Authorized Representative* Date

_____
* If signed by a legally authorized representative, a description of such representative's authority must be provided

_____ _____
Signature of Individual Obtaining Consent Date