St. Michael's

Inspired Care. Inspiring Science.

A randomized controlled trial of the effect of replacing sugar-sweetened beverages with non-nutritive sweetened beverages or water on gut microbiome and metabolic outcomes: Strategies To OPpose SUGARS with Non-nutritive sweeteners Or Water trial

NCT03543644

MRI ICF

August 20, 2019

LETTER OF INFORMATION AND CONSENT TO PARTICIPATE IN A RESEARCH SUB-STUDY

You are being asked to consider taking part in a research sub-study. Before agreeing to take part in this research sub-study, it is important that you read the information in this research consent form. It includes details we think you need to know in order to decide if you wish to take part in the sub-study. If you have any questions, ask the study doctor or study staff. You should not sign this form until you are sure you understand the information. All research is voluntary. You may also wish to discuss the sub-study with your family doctor, a family member or close friend. If you decide to take part in the sub-study, it is important for your safety and for the conduct of the sub-study that you are as accurate as possible about your health history and any medications you are taking.

Title of Research Sub-study: Strategies To OPpose SUGARS with Non-nutritive Sweeteners Or Water (STOP SUGARS NOW) Trial (REB# 17-292)
-MRI Testing Component (optional)

Consent for this section of the sub-study is optional but we hope it is of sufficient interest to allow all those who enroll in the main study to also be included in this "sub-study."

BACKGROUND AND PURPOSE

The MRI sub-study is **an optional** component of the study in which you have enrolled as a participant. Its purpose is to see if sugar-sweetened beverages (SSB), non-nutritive sweetened beverages (NSB), or water consumption has an effect on calf and liver fat. Thirty (30) of the participants in the STOP SUGARS NOW study will be asked to participate in the MRI sub-study.

You **cannot** participate in this sub-study if you meet any one of the following conditions:

- Any condition or circumstance which would prevent you from having an MRI (e.g. having prostheses or metal implants, tattoos, or claustrophobia)

WHAT WILL HAPPEN DURING THIS SUB-STUDY?

You will be asked to have a 30-45-minute body scan by magnetic resonance imaging (MRI). An MRI is a large tube-shaped magnet that uses the magnets and radio waves to take pictures of your body's insides. This sub-study will not add additional visits to the main study, only an additional 30 - 45 minutes per visit.

SUB-STUDY VISITS

Medical imaging: Your liver and calf muscle fat will be measured by a 30-45 minute MRI body scan. Please refer to "Risk or Harms" section for more information.

HOW MANY PEOPLE WILL TAKE PART IN THE SUB-STUDY?

We plan to recruit 30 participants from the main study to take part in sub-study.

WHAT ARE THE RISKS OR HARMS OF PARTICIPATING IN THIS SUB-STUDY?

Risks associated with the MRI procedure:
Metal Objects: Before being enrolled in this sub-study, you must fill out an MRI screening form and have an interview with a nurse or technologist in order to find out if the MRI scan is safe for you. Please ensure that all of your questions/ concerns are answered prior to signing the consent form. The MRI scanner is a powerful magnet. Any metal objects you are carrying or wearing must be

removed prior to the MRI scan to avoid potential severe injury. Metal objects (e.g., hair barrettes, oxygen bottles) can be strongly attracted to the MRI magnet becoming projectiles and can cause serious injury to anyone in the MRI scanner room. The screening process and safety training of MRI personnel will help avoid injury due to projectiles.

Implants: The magnet may cause metal or implants inside your body to heat up or move leading to potentially serious injury or death. The magnet may also affect some electronic or magnetic devices. Let the doctor/nurse/technologist know if you have a pacemaker, aneurysm clips, cochlear implants, a neuro-stimulator, metal implants, an implanted drug infusion device, or any other implants. Many of these devices are dangerous if getting an MRI and you will not be eligible to participate.

If you have any metal in your eyes, you will not be able to go into the MRI. If you think that there is even the slightest chance that you may have some metal in your eyes (e.g., from your current or previous line of work), please inform the researcher and/or the MRI technologist and an x-ray of your eyes will be performed to make sure it is safe for you to go into the MRI.

Magnetic Fields: To date, there are no known long-term health risks from the magnetic field or radio waves from the magnetic resonance imaging (MRI) scanner. The "static" magnetic fields are not known to cause serious health risks. The "switched" magnetic fields may cause sensations of warmth, seeing spots or tingling. These sensations occur only rarely, and are always temporary. The magnetic fields are kept at low levels to help prevent these side-effects. Fans are used to provide cooling within the MRI bore.

Noise: MRI scanning produces a loud noise that could cause temporary hearing damage if appropriate sound protection is not used or does not remain in place. You will be given ear plugs or headphones in order to protect your ears.

Confined Space: The MRI magnet is shaped like a long tube and may cause some people to feel cramped. If you feel anxious in confined spaces you may not want to participate in the sub-study. If you decide to participate and begin to feel anxious within the MRI magnet, you can tell the MRI technologist to stop the scan.

WHAT ARE THE BENEFITS OF PARTICIPATING IN THIS SUB-STUDY?

There is no direct benefit for you to participate in this sub-study; however, the results of this sub-study will contribute to the growing literature on alternatives to SSBs.

HOW WILL MY INFORMATION BE KEPT CONFIDENTIAL?

The study personnel will make every effort to keep your personal health information private and confidential in accordance with all applicable privacy legislation, including the Personal Health Information Protection Act (PHIPA) of Ontario. Any health information that is recorded for study purposes will be de-identified by using a unique study identification number instead of any identifying information. The principal investigator at St. Michael's Hospital is in control of the key that links your study number to you personally.

Any information containing personal information will be securely stored in a locked cabinet and room within the hospital. Data relating to your MRI data will also be securely stored in a locked cabinet within the Clinical Nutrition and Risk Factor Modification Centre, St. Michael's Hospital; separate from your personal information. Electronic files containing personal health information will be stored securely on hospital or institutional network at St. Michael's Hospital. No information identifying you will be allowed off site in any form.

NEW INFORMATION ABOUT YOUR HEALTH (INCIDENTAL FINDINGS)

The study doctor does not have any plans to include information regarding your participation in this study in your medical chart. As this is an exploratory study, the results of the MRI are not being reviewed by a radiologist (doctor specializing in looking at medical imaging), and will not have any medical relevance the results of this study will not be disclosed to you or your doctor.

CAN PARTICIPATION IN THIS SUB-STUDY END EARLY?

Your participation in this sub-study is voluntary and optional and if you choose not to participate, you and your family will continue to have access to customary care at St. Michael's Hospital. You will also be able to continue participating in the main study.

RESEARCH ETHICS BOARD CONTACT

If you have any questions regarding your rights as a research participant, you may contact Dr. David Mazer, Chair, Unity Health Toronto Research Ethics Board (REB)at 416-864-6060 ext. 2557, during business hours.

The Research Ethics Board is a group of scientists, medical staff, and individuals from other backgrounds (including law and ethics) as well as members from the community. The committee is established by the hospital to review studies for their scientific and ethical merit. The Board pays special attention to the potential harms and benefits involved in participation to the research participant, as well as the potential benefit to society. The committee is also required to do periodic review of ongoing research studies. As part of this review, someone may contact you from the Research Ethics Board to discuss your experience in the research study.

STUDY CONTACTS

If you have any questions for the principal investigator, please contact Dr. John Sievenpiper at 416-867-3732 between 9am and 5pm Monday to Friday. Voicemail is available on this phone line. Messages are only picked up by Dr. Sievenpiper.

The study coordinator will be available to answer your questions regarding the study between 9am and 5pm Monday to Friday. Please call the following number to speak to the study coordinator: 416-867-7460 ext. 48216. Voicemail is available on this phone line.

DOCUMENTATION OF INFORMED CONSENT

STOP SUGARS NOW Trial: MRI Sub-Study

General Declaration of Consent

The research sub-study has been explained to me, and my questions have been answered to my satisfaction. I have been informed of the alternatives to participation in this sub-study. I have the right not to participate and the right to withdraw without affecting the quality of medical care at St. Michael's Hospital for me and for other members of my family. As well, the potential harms and benefits (if any) of participating in this research sub-study have been explained to me. I have been told that I have not waived my legal rights nor released the investigators, sponsors, or involved institutions from their legal and professional responsibilities. I know that I may ask now, or in the future, ask any questions I have about the sub-study. I have been told that records relating to me and my care will be kept confidential and that no information will be disclosed without my permission unless required by law. I have been given sufficient time to read the above information.

I consent to participate. I have been told I will be given a signed copy of this consent form.

_____	_____	_____
Name of Participant (Please Print)	Signature of Participant	Date (Day/ Month/ Year)

I confirm that I have explained the nature and purpose of the sub-study to the participant named above. I have answered all questions asked about the sub-study.

_____	_____	_____
Name & Position of Person Conducting Consent Discussion	Signature of Person Conducting Consent Discussion	Date (Date/ Month/ Year)