

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

Letter of information and consent: Version 11

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STOP SUGARS NOW Study

Principal Investigator: Dr. John L Sievenpiper

Version 11: Updated 20-Aug 2019

LETTER OF INFORMATION AND CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Full Study Title: A randomized controlled trial of the effect of replacing sugar-sweetened beverage with non-nutritive sweetened beverage or water on gut microbiome and metabolic outcomes: Strategies To Oppose SUGARS with Non-nutritive sweeteners Or Water (STOP SUGARS NOW) study.

INTRODUCTION

You are being asked to consider taking part in a research study. Before agreeing to take part in this research 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 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 study with your family doctor, a family member or close friend. If you decide to take part in the study, it is important for your safety and for the conduct of the study that you are as accurate as possible about your health history and any medications you are taking. This studying is being conducted as part of two graduate students' projects supervised by Dr. Sievenpiper, a staff physician at St. Michael's Hospital.

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Conflicts of Interest: Dr. John Sievenpiper and Dr. Lawrence Leiter are employees of the University of Toronto and St. Michael's Hospital. Dr. Sievenpiper functions as has received research funding, travel funding, honoraria and/or speaker fees from a broad range of food companies, agricultural trade groups, non-governmental organizations, and/or governmental agencies (please see the online conflicts of interest for details). There are, however, no conflicts, financial or otherwise that are related to this study or its outcome. They have no other conflicts of interest to report. The study staff have no conflicts of interest to report.

Study Funder: This study is being funded by a government sponsor: the Canadian Institutes of Health Research (CIHR).

PURPOSE OF THE RESEARCH

The rate of diabetes and obesity continue to grow in the world and it remains one of the most important prevention and treatment challenges in healthcare. To help with this, health experts recommend lowering the amount of sugar in the diet, especially from sugar-sweetened beverages (SSBs), such as pop or soda. One way to do this is by replacing SSBs with another drink. Current guidelines recommend water instead of non-nutritive sweetened beverages (NSBs) as the best replacement for SSBs. Since water may not be accepted as a replacement, NSBs such as diet pops or diet sodas are a sweeter alternative. Some recent research studies looked at saccharine, a calorie-free sweetener not found in NSBs. The studies found that saccharine might have a negative effect on blood sugar by changing gut bacteria in humans. It is currently not known if replacing SSBs with NSBs (which contain low-calorie sweeteners other than saccharine) or water will have any effect on the human gut microbiota and any future diabetes risk. This study will contribute to knowledge that will inform dietary guidelines and public policy on the best possible replacement for SSBs. It may also shed light on the potential harmful effects of NSBs and if the replacement of SSBs by NSBs or water is similar with respect to their effect on gut bacteria and diabetes risk.

WHY IS THIS STUDY BEING DONE?

As of now, there are no randomized controlled trials in humans looking at the effect of replacing SSBs with NSBs or water on human gut bacteria and sugar digestion and metabolism. This study is being done to find out if NSBs or water are the best replacement for SSBs. This study also hopes to find out if NSBs or water have beneficial effects on gut health and blood sugar response compared to SSBs.

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

- You are under 18 years old or are older than 75 years old
- You do not drink regular pop daily
- You are pregnant or breast feeding, or planning on becoming pregnant throughout the study

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- Regularly use medication (except birth control or use of medications such as Advil or Tylenol on an as-needed basis)
- You have used an antibiotic in the last 3 months
- You take supplements or vitamins as deemed unsuitable for the study by the investigators
- You have been diagnosed with diabetes, uncontrolled blood pressure, liver disease, uncontrolled hyperthyroidism/hypothyroidism (over or under active thyroid gland), chronic infections, lung disease, cancer/malignancy, psychiatric illness, have digestive tract issues, or any other major illnesses
- You have had previous bariatric (weight-loss) surgery
- You have had any major surgeries in the past 6 months
- You are a smoker
- You drink more than 3 alcoholic drinks per day
- You regularly use recreational drugs
- You do not have a family doctor
- You plan on making major dietary or physical activity changes over the study duration

WHAT WILL HAPPEN DURING THIS STUDY?

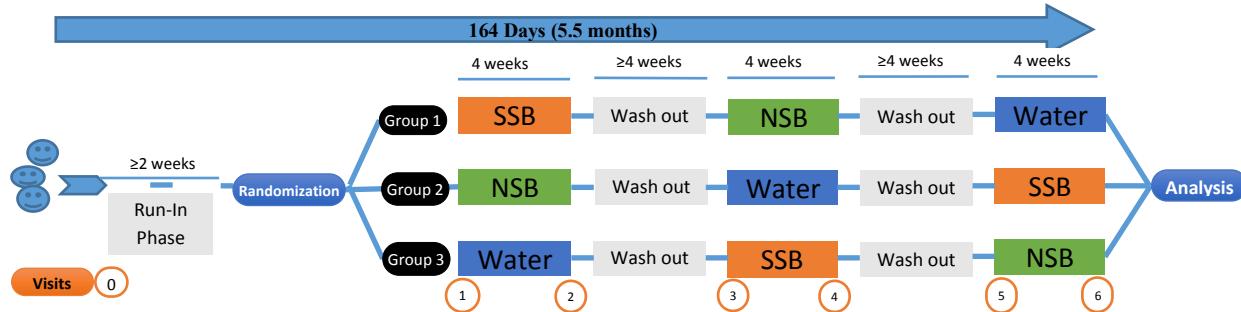
If you choose to join this study you will first attend an in-person screening visit to see if you are eligible to participate. At the screening visit we will measure your height, weight, waist circumference, and blood pressure. You will be asked to provide contact information to contact your primary care physician (family doctor) so you can discuss any potential results with them (e.g. high blood pressure). You will also be asked a few questions about your diet, demographic information (such as your ethnicity, education, and employment), personal information (such as your address and email address), and your health. You do not have to provide your email address to be part of the study. If you qualify to participate based on the screening visit, you will be enrolled in the study.

Once enrolled in the study, you will be asked to log your SSB consumption for two-weeks as part of the study run-in. You will then be asked to attend six study visits at the Clinical Nutrition and Risk Factor Modification Centre at St. Michael's Hospital. Study staff will instruct you on how to collect urine for 24 hours and how to collect a stool sample; the supplies for this will be shipped to your house a few days before your study visit. You will bring in the samples the following morning at your study visit. These visits will take place in the morning after a 10-12 hour overnight fast. Each visit will take 3 to 3.5 hours and will involve drinking a 75 g oral glucose tolerance test (OGTT, which is a sugar drink) and blood samples. Weight, blood pressure and waist circumference will be measured at each visit. Questionnaires on your diet, physical activity, symptoms and sleep quality will also be given at each visit.

This study is a randomized crossover clinical trial with three treatments (SSB, NSB, water). Crossover design means that you will be asked to participate in each treatment for 3 different 4-week periods in a random order (determined by chance). There will be at least four weeks between study treatments to make sure that the drink has cleared from your body before giving the next treatment. During this time, you will be asked to return to your usual SSB intake. The different study drinks are described in the table included at the end of this consent form (**Appendix 1**). An example of what the randomization may look like for you is also included (**Figure 1**).

An example of what the visits and sugar drink sequence may look like is outlined in **Figure 1**. You will be asked to replace your usual SSB intake with the treatment drink (SSB, NSB, or water) for a four-week period. For example, if you drink 2 regular Pepsi every day, then you will be asked to drink 2 Pepsi as your SSB for 4-weeks, 2 Diet Pepsi as your NSB for 4-weeks, and 2 waters for 4-weeks. You will be asked to choose only one type of beverage. If you currently consume NSBs you'll be asked to stop consumption except during the NSB trial phase. Please remember the sequence below may not be the sequence you will receive. Each study visit will be at least 4 weeks apart.

Figure 1: Overview of the study visits and phase.*



*All possible groups are not shown.

STUDY VISITS

For your convenience, a table summarizing the study visits and outlining the study procedures that will happen at each visit is included at the end of the consent form.

Run-in phase

If you are eligible to participate, after the screening visit you will be asked to participate in a minimum 2-week run-in phase to allow you to collect information on beverage consumption.

Study Visits:

There are 6 study visits. You will be instructed on how to collect a 24-hour urine sample and stool sample and kits to do so will be shipped to your house a few days before your visit. You will also be asked to complete a weighed three-day diet record during the week before your visit. This will include weighing your food with a provided scale and recording your dietary intake using Nutritics, a nutrition software available for use on smartphones (a paper form of the three-day diet record will be provided if you do not have access to a smartphone or prefer not to use the application). A registered dietitian will instruct you on how to complete this. For your visit, you will be asked to come in a fasted (10-12 hours) state for your visit. You will hand in your stool and urine sample and the following will be measured:

Body measures including body weight, waist circumference, and blood pressure.

Blood tests will be done to measure the levels of glucose and insulin in your blood, your risk of diabetes, and risk of heart disease. You will have 6 blood samples taken every 30 minutes over a 2.5 hour period. Each blood sample will require 2 tubes (15 ml=1 tbsp) of blood. You will have a catheter in your arm for the entire 2.5 hour period in which blood will be drawn. Your arm will be wrapped in a heating blanket during the testing to keep your arm warm (which allows for

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faster blood draws). Once the blood is taken, a lab technician will process the blood samples. The samples will be analyzed at St. Michael's Hospital. Once the blood tests are complete you will be provided a light breakfast.

Any remaining blood samples will be stored for future analysis at the University of Toronto and only the study investigators and study staff will have access to the blood samples. The study investigators may do analysis in the future on biomarkers of diabetes and heart disease. Biomarkers are characteristics (e.g., cholesterol levels in the blood) that are measured and evaluated as indicators of normal biological processes or disease processes. The blood will be used to analyze these markers related to bone turnover, blood lipids, inflammation, and nutrient status. There will be a separate consent form for use of blood for future analyses, you may refuse to sign it and still participate in the study.

Questionnaires: You will be asked questions on your diet (review of weighed three-day diet record, cravings and satiety questionnaire), symptoms, medications, physical activity, and study beverage use.

Study Beverages: At the beginning of all 3 treatments, you will be given 1 weeks' worth of beverages to take home; the beverages for the remaining 3 weeks will be delivered to your home.

Washout period:

At the end of the first two treatments, the wash-out phase of at least 4 weeks will start for which you will be asked to go back to your usual beverage intake. No beverages will be provided by the study during the wash-out phase. The study coordinator will call you near the middle and near the end of each phase to remind you of your next study visit. Reminders will also be sent via email, with your consent.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

We plan to recruit 81 participants for this study. Participation for each individual will last approximately six months, depending on your availability for study visits. The entire study is expected to take about four years to complete and the results should be known in late 2021.

OPTIONAL RESEARCH ACTIVITIES

Optional MRI procedure

In addition to the main study, there is an optional study procedure in which you are being asked to consider taking part. The procedure is an MRI, which will be looked at as a sub-study. The procedure and consent to participate in it is described in detail in another consent form.

Future Use of samples

We would also like to ask that you consider allowing us to store your samples for use in the future. We plan on setting up a bank of biological samples (e.g. urine, feces, and blood) for new tests that are discovered to learn more about risks and biomarkers of diabetes and heart disease. You will be given a separate document that will describe this optional storage and seek your consent to participate. You do not need to agree to the optional storage and use of your samples in order to take part in this study.

As part of the long-term banking, we are asking you to consider taking part in optional genetic testing. This is an optional research component and we will seek your consent to participate. You do not need to agree to the optional genetic testing in order to take part in this study or the long-term sample banking.

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

The known risks of the study are outlined below. However, the study may involve risks which are not currently known.

Blood Sample: After providing a blood sample, you may experience redness or puffiness at the site where the catheter or needle is inserted. As with any puncture of the skin there is a small risk of infection associated with breaking the skin. If you do not like having your blood taken, you may feel uncomfortable, anxious or upset. In addition, because all study blood samples will be provided in the fasted state, you may feel uncomfortable, anxious or upset secondary to fasting. A healthcare professional and study staff will be there to assist you should you experience any of these symptoms. Blood samples are taken by a Registered Nurse and blood samples are used only for purposes of this research study.

OGTT: You may feel unwell or nauseous after drinking the OGTT due to the amount of sugar in the drink, this is normal. If you do experience any of these symptoms, please let the study staff know.

Stool sample collection: The risks of collecting stool samples includes contamination of skin, clothing, and food with feces. Contamination with food could lead to food borne illness. The stool collection kit is designed so that samples can be collected without touching the stools – however, there is a small chance this may occur. Please wash your hands after collecting your stool sample. The stool sample should be placed in the provided zip lock bag, labeled, and kept in your home freezer.

Study Drinks: We do not anticipate any side effects from the study drinks.

WHAT ARE THE BENEFITS OF PARTICIPATING IN THIS STUDY?

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

WHAT OTHER CHOICES ARE THERE?

You are under no obligation to participate in this study. As this study is not looking at alternatives to treatment, the alternative to participating in this study is to not participate in the study.

HOW WILL MY INFORMATION BE KEPT CONFIDENTIAL?

This section describes how your personal health information and study data and samples will be accessed, disclosed, and stored during this study. All persons involved in the study are committed to respecting your privacy. Other than the individuals or groups described in this section, no persons will have access to your personal health information without your consent, unless required by law.

Personal health information is any information that could be used to identify you and includes your name, address, date of birth, and new or existing medical records, including types, dates, and results of medical tests or procedures.

Study data is any information about you that is generated by and/or collected for this study. It does not include any identifying information.

Study samples are any biologic (e.g. blood, stool) samples that are taken from you for use in this study.

Representatives of Unity Health Toronto Research Ethics Board (REB) may look at your personal health information to check that the information collected for the study is correct and to make sure the study followed the required laws and guidelines:

Protecting Your Privacy

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.

All information gathered during this study will be held in strict confidence. Study documents containing personal information will be securely stored in a locked cabinet and room within the hospital. Data collection forms 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.

You will also be asked to complete a cheque requisition/remuneration form however your personal information will be collected for the sole purpose of processing your compensation and reimbursement. The accounting department of the University of Toronto will also receive a copy of the cheque requisition/remuneration form in order to process the cheque/remuneration. Their department will retain this information as per their requirements.

Study Biologic Sample Storage and Retention

Samples will be kept in Toronto, Ontario at either St Michael's Hospital or the University of Toronto for 10 years following studying completion to complete all analysis as outlined in this consent form. After the 10 years they will be destroyed according to St Michael's Hospital guidelines. The study investigator will ensure that your samples are kept in a freezer in a locked room. Only study staff and students will have access to these samples. The samples will have your unique study identification number instead of any identifying information. If you consent (in a separate consent form) to have your samples kept for long-term use, they will then be kept for longer than the 10 years.

Nutritics Software/ Libro App

Nutritics, a nutrition software available for use on smartphones, will be used to collect diet records. No identifiable information will be inputted into this system. We will be creating logins for each participant. Nutritics complies with the General Data Protection Regulation ((EU) 2016/679).

Please note that the online survey is hosted by Nutritics, which stores survey data on servers located in Ireland. You do not need to provide an email address to create an account. Your information may be processed in and transferred or disclosed to countries in which Nutritics's affiliates are located and in which their service providers are located or have servers, which may transfer your data to servers in other countries for storage. The data may be subject to foreign laws such as the USA PATRIOT Act that allows authorities access to the records of internet service providers.

Nutritics may collect Personal Data from their Clients in order to provide their Services. Information is collected in two ways: (1) when you provide it directly to Nutritics, and (2)

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passively through technology such as "cookies". "Cookies" are a feature of web browser software that allows web servers to recognize the computer used to access a website. Information gathered through cookies and web-server log files may include information such as the date and time of visits, the pages viewed, IP addresses, links to/from any page, and time spent on the site.

Data containing personal information will be kept in within the Clinical Nutrition and Risk Factor Modification Centre, St. Michael's Hospital, for up to 10 years and then securely destroyed.

Risks of a Privacy Breach

It is important to understand that despite the protections described in this section being in place, there continues to be the risk of an unintentional release of information. The chance that personal information or study data will be accidentally released or accessed without authorization is small.

NEW INFORMATION ABOUT YOUR HEALTH (INCIDENTAL FINDINGS)

The tests or procedures that we do during this study might reveal medical information about you that is not part of the objectives of this study but may be relevant to your health. This type of medical information is called an incidental finding. Some incidental findings could be related to treatable conditions or they could be related to factors that may affect your current or future health care. The study doctor does not have any plans to include information regarding your participation in this study in your medical chart. However, if any incidental findings are discovered and you seek further care for these findings, these will be included in your medical records (which may include information regarding your participation in the study). New findings or information that would warrant the research team to disclose your information to individuals outside the research team (i.e. your family doctor) will primarily relate to blood pressure test results.

PUBLICATION OF STUDY RESULTS

It is possible that the results of this study may be published in scientific literature or presented at a conference or seminars. Confidentiality will be upheld, and no names or identifying information about study participants will be used in any publication or presentation.

STUDY REGISTRATION

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>. This Web site will not include information that can identify you. At most, the Website will include a summary of the results, when they are available. You can search this Web site at any time. The registration number for this study is *NCT03543644*.

PRIMARY CARE PHYSICIAN CONTACT

You must have a primary care physician, or family doctor, to join this study. We will collect your primary care physician information from you after signing this consent form. We will send (via fax or email) any abnormal results (i.e. abnormal blood pressure) and any other applicable health related information to your primary care physician. The 75g OGTT results will not be known until the end of the study and all study samples have been analyzed. We will include your name and full date of birth with the information sent to your family doctor but not your study identification number.

WHAT ARE THE COSTS OF PARTICIPATING IN THIS STUDY?

Participation in this study may result in additional costs due to parking or transportation. You will be reimbursed for additional transportation costs with the submission of parking receipts or request for TTC tokens. You will not be reimbursed for screening visit attendance or for your time during the run-in period.

ARE STUDY PARTICIPANTS PAID TO PARTICIPATE IN THIS STUDY?

To thank you for participating in this study, you will be given \$80 for each of the first 5 visits and \$95 for final visit. Payments will be processed at the end of every other visit (three times during the study). Your cheques will be ready for pick up approximately one month after processing (typically this will be at visit 3, visit 5, and a month after study completion). If you choose to withdraw early, you will be compensated for each visit that was completed. For example, if you complete the first 2 study visits and decide to withdraw you will receive \$160. If you complete the first 3 visits you will receive \$240. You will not be compensated for the screening visit or run-in visit.

WHAT IF I BECOME INJURED FROM PARTICIPATING IN THIS STUDY?

If you suffer an injury from participation in this study, medical care will be provided to you in the same manner as you would normally obtain any other medical treatment. In no way does signing this form waive your legal rights nor release the study investigators or involved institutions from their legal and professional responsibilities.

CAN PARTICIPATION IN THIS STUDY END EARLY?

Participating in this study is voluntary; if you decide to participate in this study, you can change your mind without giving a reason and you can withdraw at any time. Withdrawing from this study will not affect the care you receive at St. Michael's Hospital. If you choose not to participate, you and your family will continue to have the same access to care at St. Michael's Hospital as you did before. Withdrawal from the study will not affect your participation in any future studies or future interactions with the St Michael's Hospital or affiliates of this institution.

If you withdraw voluntarily from the study you are encouraged to contact the Study Coordinator at 416-867-7460 ext. 8216 or the Principal Investigator, Dr. John Sievenpiper at 416-867-3732 (Monday-Friday, 9am-5pm).

If you withdraw from the study before completing all 6 study visits, we may or may not use the data you provided to us or your blood samples. Any data or blood samples that you provided to us before you decided to withdraw will be kept for analysis. Nothing further will be collected or used.

The investigator may decide to remove you from this study for any of the following reasons:

- If you do not meet the study eligibility criteria.
- If you decide to take part in another study involving drug therapy or lifestyle therapy that may affect glucose and insulin regulation
- If you become pregnant during the study
- If you are not following the protocol
- If you do not follow the Unity Health Toronto code of conduct

If you are removed from this study, the investigator will discuss the reasons with you.

NEW FINDINGS AND INFORMATION

We may learn new things during the study that you may need or wish to know. We can also learn about things that might make you want to stop participating in the study. If so, you will be notified about any new information in a timely manner.

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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 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.

STATEMENT OF CONSENT

Study Title: A randomized controlled trial of the effect of replacing sugar-sweetened beverage with non-nutritive sweetened beverage or water on gut microbiome and metabolic outcomes: Strategies To OPpose SUGARS with Non-nutritive sweeteners Or Water (STOP SUGARS NOW) trial.

The research 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 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 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 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.

Further, I understand that by taking part in this study, I am agreeing that my family doctor will be notified about my participation in this study.

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 study to the participant named above. I have answered all questions asked about the study.

Name & Position of Person
Conducting Consent Discussion

Signature of Person
Conducting Consent Discussion

Date (Date/ Month/ Year)

Consent to be contacted for future studies

We would also like to ask that you consider providing consent to be contacted about future research studies. The information that you should consider before agreeing to this is outlined below.

I have been told about the possibility of being contacted for future studies. I understand that my participation in these future studies is voluntary and my refusal to participate will not affect my participation in the main study.

I understand that if I consent to be contacted for future studies, my contact information including my name, phone number, address and hospital number will be stored securely by the study staff for this purpose. No information will be collected about me without my consent. Only Dr. Sievenpiper's research team will be contacting you. You may be contacted for studies that relate to this study's subject area. You will only be contacted over the next 10 years by telephone, mail, or email (provided you have provided us email consent).

You are not obligated to participate in any research studies that you are contacted about. If you no longer want to be contacted about future research studies, please contact the study coordinator at 416-867-7460 ext. 8216.

By signing this section of the form I am not consenting to have additional measurements taken, but are consenting to be contacted later on. If you are called for a future research study, you will still have the opportunity to decline at that time, and if you decide you are interested, you will be asked to sign a separate consent form for each individual study.

Statement of Consent – Future Contact for Research Purposes

I have read the above information, and I agree to be contacted for future research as described above.

Participant Name (print)

Participant Signature

Date

Appendix 1: Study Treatments and available beverages.

Study Group	SSBs group (drink for 4 weeks)	NSBs group (drink for 4 weeks)	Water group (drink for 4 weeks)
Treatment	355 ml can 42 grams of sugars	355 ml can 0 grams of sugar	355 ml bottles or can
Drinks to choose from	Coca-Cola Pepsi Canada Dry Ginger Ale Schweppes Ginger Ale Mountain Dew Sprite 7UP Orange Crush	Diet Coke (Aspartame, Acesulfame) Coca Cola Zero (Aspartame, Acesulfame) Diet Pepsi (Aspartame, Acesulfame) Diet Canada Dry Ginger Ale (Aspartame, Acesulfame) Diet Schweppes Ginger Ale (Acesulfame, Sucralose) Diet Mountain Dew (Aspartame, Acesulfame, Sucralose) Sprite Zero (Aspartame, Acesulfame) Diet 7UP (Aspartame, Acesulfame) Diet Orange Crush (Sucralose)	

Appendix 2: Sample schedule for the Visits at the Clinical Nutrition and Risk Factor Modification Centre

Time (approx.)	Study Task
7:45 AM	Arrive at the clinic
8:00 AM	1 st fasting blood test, body measures and questionnaires
8:30 AM	2 nd fasting blood test and drink
9:00 AM	3 rd blood test
9:30 AM	4 th blood test
10:00 AM	5 th blood test
10:30 AM	6 th blood test
10:45 AM	Snack
11:15 AM	MRI (<i>if participating in MRI sub-study</i>)
12:15 PM	Home

Appendix 3: Study Visit Timeline and Tasks (x = data collected/test required)

Phase (Length in weeks)	Screening (0)	Run-in (2 weeks)	Intervention phase 1 (4 weeks)		Wash-out (4 weeks)	Intervention phase 2 (4 weeks)		Wash-out (4 weeks)	Intervention phase 3 (4 weeks)	
Study Visit	0	No visit	Week 0 (Start)	Week 4 (End)	No visit	Week 0 (Start)	Week 4 (End)	No visit	Week 0 (Start)	Week 4 (End)
Written Informed Consent Provided	x									
Anthropometric measures										
Height	x									
Weight	x		x	x		x	x		x	x
Waist circumference	x		x	x		x	x		x	x
Blood pressure	x		x	x		x	x		x	x
Biochemical measures										
Fecal sample			x	x		x	x		x	x
24-hour urine collection (biomarkers for compliance)			x	x		x	x		x	x
Blood sample drawn			x	x		x	x		x	x
Oral Glucose Tolerance Test			x	x		x	x		x	x
Questionnaires										
Personal information	x									
Demographic Data	x									
Medical History	x									
Case Report Form (eg. medications, physical activity)	x		x	x		x	x		x	x
Beverage log	x	x	x	x	x	x	x	x	x	x
Symptoms questionnaire			x	x		x	x		x	x
Three-day diet record			x	x			x			x
Cravings/hunger/satiety questionnaires			x	x		x	x		x	x
Optional: Radiology										
Liver fat (MRS)			x	x		x	x		x	x