UNIVERSITY OF CALGARY

RESEARCH INFORMATION SHEET

Name of Study: **Effect of Prebiotic Fibre on Glycemic Control, Gut Microbiota, and Intestinal Permeability in Newly Diagnosed (<12 months) Type 1 Diabetes**

Who is Eligible: Adults that have been newly diagnosed with Type 1 Diabetes within the previous 12 months

Brief Description:

Can taking a prebiotic fiber supplement improve diabetes control and prolong honeymoon?

If you are interested in joining this study or would like more information please contact Tetsuro Okada at:
403-955-7758 or **tetsuro.okada@albertahealthservices.ca**

Can taking a prebiotic fiber supplement improve diabetes control and prolong honeymoon?

Your child could be part of this study if:

- Diagnosed with type 1 diabetes in the past 12 months
- 18 years of age or older

This study involves:

- Taking a fiber supplement for 6 months
- Completing questionnaires
- Blood, urine and stool samples at baseline, 3 months and 6 months to coordinate with usual blood tests for diabetes

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Poster Version Date: Version 3.0, January 27, 2022

This study has been approved by the University of Calgary Conjoint Health Research Ethics Board (Ethics ID # REB21-0852*)*

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UNIVERSITY OF CALGARY
CONSENT TO PARTICIPATE IN RESEARCH

TITLE: Effect of Prebiotic Fibre on Glycemic Control, Gut Microbiota, and Intestinal Permeability in Newly Diagnosed (<12 months) Type 1 Diabetes

SPONSOR: University of Calgary

FUNDER: Canadian Institutes of Health Research

INVESTIGATORS: Dr. Raylene Reimer, Dr. Carol Huang, Dr. Josephine Ho, Dr. Sonia Butalia. Phone number: 403-220-8218.

INTRODUCTION

Dr. Raylene Reimer, and associates from the Diabetes Centre Calgary and the Department of Medicine at the University of Calgary are conducting a research study.

This consent form is only part of the process of informed consent. It should give you the basic idea of what the research is about and what your participation will involve. If you would like more detail about something described here, or information not included here, please ask. Take the time to read this carefully and to understand any accompanying information. You will receive a copy of this form for your records.

You were identified as a possible participant in this study because you have been diagnosed with type 1 diabetes in the last 12 months. Your participation in this research study is voluntary.

WHY IS THIS STUDY BEING DONE?

The purpose of this research study is to determine whether a dietary fibre supplement can improve glucose control (highs and lows in blood glucose) in persons who have been diagnosed with type 1 diabetes within the past 12 months. Prebiotic fibre is a unique type of dietary fibre with the potential to be an inexpensive, low-risk treatment addition for type 1 diabetes. The fibre may improve blood glucose control through changes in gut microbiota (bacteria), gut permeability (leaky gut), and inflammation. The gut microbiota is increasingly recognized as a contributor to various diseases in people. Both animal and human studies found a difference in gut bacteria profiles

between those that develop diabetes from those that did not develop diabetes. Prebiotic fibre may help correct defects in the gut microbiota associated with type 1 diabetes. Prebiotic fibre has also been shown to improve blood glucose levels and reduce inflammation markers in the body. A small initial study in children with type 1 diabetes showed that prebiotic fibre could increase C-peptide levels in the blood, which is a marker that reflects the ability of the pancreas to still produce some insulin. The study also showed that prebiotic fibre might be able to reduce episodes of hypoglycemia (low blood sugar).

The current study is a larger scale version of the small initial study. In this study we will recruit patients from the Diabetes Centre Calgary and randomize (like a flip of a coin) participants with type 1 diabetes to receive either the prebiotic fibre powder or a non-active ingredient (placebo). This study is double-blinded (researchers and participants don't know who is receiving the fibre or placebo). This blinding can be broken should an emergency arise and you or your treating physician requires the information.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

About 144 people will take part in this study in Alberta and Saskatchewan. About 100 people will take part in this study through the University of Calgary.

WHAT WILL HAPPEN IF I TAKE PART IN THIS STUDY?

At Baseline Visit:

1. **Questionnaire** (age, gender, diagnosis details including date of type 1 diabetes diagnosis, current medications, other medical conditions, number of episodes of severe hypoglycemia and diabetic ketoacidosis since diagnosis of type 1 diabetes). Some of this information will be collected from your medical chart since it may be a lot of details to remember.
2. **Measurements** (height, weight)
3. **Surveys** that include a Fear of Hypoglycemia survey, Quality of Life survey, and a 24-Hour Diet Record
4. **Continuous blood glucose monitoring** will be done for a minimum of 3 weeks prior to your baseline visit. A Dexcom G6 will be provided to you if you do not have one. The data from your continuous glucose monitor and your self-monitored blood glucose logs will be collected at your clinic visit.
5. **Blood sample** coordinated with usual diabetes clinic bloodwork (HbA1c, inflammatory markers). Results from the HbA1c test will be collected from your medical chart.
6. **Gut leakiness test.** You will consume a regular evening meal and then 3 hours prior to bedtime drink a solution containing lactulose (5g), mannitol (2g) and 3-O-methylglucose (5g) in 200 mL of water. All urine for the following 12h will be collected in a storage container and you will bring the container to the clinic within 24 hours.

7. **Meal tolerance test.** You will arrive to clinic fasted. You will get special instructions about diet and insulin dosing before the test. To make the blood sampling easier for the test, an intravenous needle and plastic tube (IV) will be placed in your vein. The IV will be kept in place during the test so you only get poked once. One blood sample (one teaspoon of blood) will be taken through the IV. You will then drink a meal replacement beverage (like “Boost”). Additional blood samples will be drawn through the IV at regular intervals for 2 hours to measure glucose and hormones that tell us how well your body is making insulin (C-peptide, glucose, insulin, proinsulin).
8. **Stool sample** will be collected at home. Two tablespoons of stool will be placed in a pre-labelled sterile conical tube, placed in a plastic bag and stored in your home freezer (-20°C). Stool samples will be brought to the laboratory on ice within 1 week from collection and stored at -80°C until analysis.

At Randomization:

1. You will be randomized to receive either placebo (maltodextrin) or prebiotic fibre (oligofructose-enriched inulin) for 6 months.
2. Both prebiotic fibre and placebo come in a powder form.
3. You will be instructed to mix the powder with 250 mL water until dissolved. We suggest taking it with the evening meal.
    i. For the first 3 weeks, you will be asked to only take half of the dose in order to minimize potential intestinal side effects (e.g. increased gas) and then you will take the full dose for the remainder of the 6 month study.
    ii. You will be asked to record any diabetes related adverse reactions (i.e. severe hypoglycemia and diabetic ketoacidosis).
    iii. At the end of the 6 months, you will be asked to return any remaining packets of placebo or prebiotic in order to assess for compliance.

After 3 months (half-way through the study):

- You will be asked to repeat all the tests and surveys that were done at baseline.

After 6 months (end of study):

- You will be asked to repeat all the tests and surveys that were done at baseline.

Telephone contact from a member of the research team will occur twice a month to encourage you to take the study product every day and for recording of any reactions, especially hypoglycemia and intestinal symptoms (i.e. gas, bloating, change in stool frequency or quality).

WHAT WILL HAPPEN WHEN I AM FINISHED THE STUDY?

When you complete the study, you will continue to see your usual diabetes doctor for your regular care. If the fibre proves to be beneficial and you were randomly assigned to

the placebo, you will be offered a supply of the fibre to try on your own. There are no tests associated with you using the fibre after the study.

HOW LONG WILL I BE IN THIS STUDY?

The study will include a minimum of four visits over the course of 6 months. Taking into account the screening visit, baseline visit and visits at 3 and 6 months as well as filling out the questionnaires and tests at home, it is estimated that you will spend at least 15 hours over the next 6 months on this study.

ARE THERE ANY POTENTIAL RISKS OR DISCOMFORTS THAT I CAN EXPECT FROM THIS STUDY?

The fibre can sometimes cause intestinal side effects (e.g. gas, bloating, change in stool, mild abdominal pain). For the first three weeks, you will be asked to only take half of the dose in order to minimize potential side effects and then take the full dose for the remainder of the 6 month study. You could have discomfort and/or a bruise when you get your blood drawn but these would be brief and transient. There is a minimal chance of infection. The Meal Tolerance Test requires drinking a product which contains milk and soy ingredients. If you have a known allergy to either of these ingredients, please let us know.

Reproductive risks:

The fibre being tested in this study is a food ingredient and does not pose a risk to a developing fetus but pregnancy changes many of the things we are testing in this study (example gut bacteria). Therefore, if you become pregnant, we would need to withdraw you from the study.

ARE THERE ANY POTENTIAL BENEFITS IF I PARTICIPATE?

If you agree to participate in this study, there may or may not be a direct medical benefit. Your type 1 diabetes may be improved during the study but there is no guarantee that this research will help. The information we get from this study may help us to provide better treatments in the future for patients with type 1 diabetes.

WHAT OTHER CHOICES DO I HAVE IF I CHOOSE NOT TO PARTICIPATE?

If you chose not to take part in this study, you will receive the usual standard of care from your medical team. You will continue to have regular treatments through the diabetes clinic and your usual diabetes team. Participation in this study is voluntary and you may withdraw from it at any time without jeopardizing your health care.

CAN I STOP BEING IN THE STUDY?

Yes. You can decide to stop at any time. Tell the study investigator if you are thinking about stopping or decide to stop. If you stop, you will continue your regular diabetes care with your diabetes doctor.

CAN THE RESEARCHERS REMOVE ME FROM THIS STUDY?

The researchers may end your participation in this study for a number of reasons, such as if your safety and welfare are at risk, if you do not follow instructions or if you miss scheduled visits. The researchers or the study sponsor might also decide to stop the study at any time.

If you decide to stop being in the study, or are removed from the study, or the study is stopped the researcher will ask you to have a brief telephone conversation with the research coordinator.

WHAT IF RESEARCHERS DISCOVER SOMETHING ABOUT ME?

During the study, the researchers could learn something about you that they didn't expect. For example, the researchers may find out that you have another medical condition. The researchers will consult with medical experts as needed to evaluate the findings and will then share these results with you. You will be helped with arranging appropriate follow up and care.

I consent for the researchers to share findings with me:

- ❑ YES
- ❑ NO

WITHDRAWAL OF STUDY DATA

If you decide to stop being in the study, or are removed from the study, or the study is stopped, the data collected about you up to that point will remain part of the study because withdrawal of data in clinical trials could bias results.

WILL I BE PAID FOR PARTICIPATING, OR DO I HAVE TO PAY FOR ANYTHING?

You will be reimbursed for the cost of parking at each study visit. A $25 Chapters or Amazon gift card will be given to you when you complete the study to thank you for your participation.

WILL INFORMATION ABOUT ME AND MY PARTICIPATION BE KEPT CONFIDENTIAL?

The researchers will do their best to make sure that your private information is kept confidential, unless required by law. Information about you will be handled as confidentially as possible, but there is always the potential for an unintended breach of privacy. The research team will handle data according to the Data Management Plan as outlined below:

Only the researchers and designated research assistants will have access to the information collected. All identifiable information about you will be replaced with a study code. A master list linking the study code and your identifiable information will be kept separate from the research data. All paper files will be kept in locked offices at the Diabetes Centre Calgary and/or University of Calgary. All data will be password protected and stored on a University of Calgary server.

Authorized representatives from the University of Calgary and the Conjoint Health Research Ethics Board may look at your research records held at the University of Calgary for quality assurance purposes. By signing this form you are authorizing such access.

HOW LONG WILL INFORMATION FROM THE STUDY BE KEPT?

The researchers intend to keep the research data and records for a minimum of five years. Data collected for this study may be shared with other researchers for future studies that are unknown at this time. Any data shared with other researchers, will not include your name or other personal identifying information. Any future use of this research data is required to undergo review by a Research Ethics Board.

WHAT OTHER THINGS SHOULD I CONSIDER BEFORE PARTICIPATION?

Use of My Specimens:

Any specimens (e.g., blood, urine, stool) obtained for the purposes of this study will become the property of the University of Calgary. Once you provide the specimens you will not have access to them. The University may share your specimens in the future with other researchers or outside institutions. Information that identifies you will not be shared with anyone outside of University of Calgary. The specimens will be used for research and such use may result in inventions or discoveries that could become the basis for new products or diagnostic or therapeutic agents. In some instances, these inventions and discoveries may be of potential commercial value and may be patented and licensed by the University. You will not receive any money or other benefits derived from any commercial or other products that may be developed from use of the specimens.

RESEARCHER CONFLICTS OF INTERESTS

The study is funded by the Canadian Institutes of Health Research which has no financial interest in its outcome. Payments are made to the University of Calgary and are used to cover the expenses of the study. The investigators do not have a financial interest in the outcomes of the study. The principal investigator, Dr. Raylene Reimer, has received a speakers honorarium in the past for a conference presentation about prebiotic fibre.

USE OF DATA AND SPECIMENS FOR FUTURE RESEARCH

My research data and/or specimens may be kept for use in future research to learn about, prevent or treat other health-related problems.

- ❑ YES
- ❑ NO

CONTACT FOR FUTURE RESEARCH

University of Calgary researchers may contact me in the future to ask me to take part in other research studies.

- ❑ YES
- ❑ NO

IF I SUFFER A RESEARCH-RELATED INJURY, WILL I BE COMPENSATED?

It is important that you tell the researchers if you believe that you have been injured because of taking part in this study. In the event that you suffer injury as a result of participating in this research, no compensation will be provided to you by the Canadian Institutes of Health Research, the University of Calgary, Alberta Health Services or the Researchers. However, you still have all your legal rights. Nothing said in this consent form alters your right to seek damages.

WHO CAN I CONTACT IF I HAVE QUESTIONS ABOUT THIS STUDY?

The Research Team:

You may contact Dr. Raylene Reimer at 403-220-8218 with any questions or concerns about the research or your participation in this study.

Conjoint Health Research Ethics Board (CHREB):

If you have any questions concerning your rights as a possible participant in this research, please contact the Chair, Conjoint Health Research Ethics Board, University of Calgary at 403-220-7990.

Public Information about this Study:

ClinicalTrials.gov is a website that provides information about federally and privately supported clinical trials. A description of this clinical trial will be available on http://www.ClinicalTrials.gov. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

HOW CAN I FIND OUT ABOUT THE STUDY RESULTS?

Once the study data is analyzed and published, the study investigators can provide you with a link to the publication.

WHAT ARE MY RIGHTS IF I TAKE PART IN THIS STUDY?

Taking part in this study is your choice. You can choose whether or not you want to participate. Whatever decision you make, there will be no penalty to you.

- You have a right to have all of your questions answered before deciding whether to take part.
- Your decision will not affect the standard medical care you receive.
- If you decide to take part, you may leave the study at any time.

HOW DO I INDICATE MY AGREEMENT TO PARTICIPATE?

Your signature on this form indicates that you have understood to your satisfaction the information regarding your participation in the research project and agree to participate as a participant. In no way does this waive your legal rights nor release the investigators or involved institutions from their legal and professional responsibilities.

SIGNATURE OF STUDY PARTICIPANT

_____
Name of Participant

_____ _____
Signature of Participant Date

SIGNATURE OF PERSON OBTAINING CONSENT

_____ _____
Name of Person Obtaining Consent Contact Number

_____ _____
Signature of Person Obtaining Consent Date

SIGNATURE OF THE WITNESS

_____
Name of Witness

_____ _____
Signature of Witness Date

A signed copy of this consent form has been given to you to keep for your records and reference.