Randomized Controlled Trial

A subsidized healthy food prescription program for adults with type 2 diabetes who are experiencing food insecurity: Protocol for a randomized controlled trial, modelling and implementation studies

Additional file 1: Participant consent form for the randomized controlled trial

CONSENT TO PARTICIPATE IN RESEARCH

TITLE: Helping Albertans manage their diabetes with a subsidized healthy food prescription program

SPONSOR: University of Calgary

FUNDER: Alberta Innovates

INVESTIGATORS: Dr. Dana Olstad, (403) 210-8673
Dr. David Campbell, (403) 210-9511

INTRODUCTION

Researchers from 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 agree to take part. If you would like more detail about something mentioned here, or information not included here, please ask. Take the time to read this form carefully. You will receive a copy of this form.

You were identified as a possible participant in this study because your healthcare provider noted you may be interested in receiving a food subsidy. Your participation in this research study is voluntary.

WHY IS THIS STUDY BEING DONE?

Diabetes is a serious health issue in Alberta. Because healthy foods often cost more than less healthy foods, many people with diabetes are unable to afford healthy foods in Alberta. Eating healthy food can help people with diabetes to manage their blood sugars and improve their health.

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HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

We will be asking people from about 5 communities in Alberta to be in the study. All participants are recruited through the University of Calgary.

- For the subsidy part of the study, participants are:
  - 404 patients with type 2 diabetes and experiencing food insecurity
- For other parts of the study, our participants are:
  - 30 primary care clinic staff will take a survey at the beginning and end of the study to tell us about their experiences
  - 60 patients with type 2 diabetes and food insecurity will take part in interviews
  - Participants in the subsidy group will take a brief survey at the end of the study
  - 12 members of a study advisory board will take part in meetings that are recorded, and interviews

HOW LONG WILL I BE IN THIS STUDY?

You will be in the study for 6 months. Data collection takes about 90 minutes each time - 90 minutes at the beginning and another 90 minutes at 6 months.

If you are in the subsidy group, you will use the subsidy during your regular grocery shopping trips.

WHAT WILL I HAVE TO DO?

To take part in the study, we are asking for some data. First, we are asking you:

1. To take online surveys
   a. The first survey asks questions about you and your health. It takes about 25 minutes
   b. The second survey asks about what you ate in a day. This is called a diet recall.
      i. We are asking you to enter 2 diet recalls that take about 20 minutes each
      ii. The first one will be right after you finish the health survey
      iii. The second one will be 2-5 days later
      iv. And don't worry! We will make sure you know what to do and when by sending emails and calling you.
      v. We also have a study helpline you can call – **1-833-879-1931**
2. Give blood and urine samples which allows us to test your blood sugar levels, kidney function and other measures of your health
   a. This will be done at a community lab location
   b. If you have any questions about these tests, please ask
3. Have physical measurements collected
   a. The measurements we are asking for are your height, weight, waist circumference, blood pressure, and heart rate

4. You will also be given a healthy food prescription that someone from your clinic will talk with you about.

Then, once all of this is done, you will be randomly assigned to the subsidy group or the comparison group. This is done by a computer using a program that assigns the groups randomly. The research team does not have a role in this. If you have any questions about randomization, please ask.

If you are assigned to the comparison group, we will ask you to do the surveys, blood and urine samples, and physical measurements again in 6 months.

If you are assigned to the subsidy group, you will be given a subsidy each week for 6 months. The subsidy will be used to buy healthy foods at a local supermarket. If you are assigned to this group, a researcher will call you to go over the details. At the end of the 6 months, we will ask you to do the surveys, blood and urine samples, and physical measurements again.

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

You do not have to pay for anything to take part in the study. As a thank you for your time, you will receive a cash payment for finishing data collection, which includes the surveys, blood and urine samples, and physical measurements.

The amount you will be given is $100 for both times you finish data collection – at the beginning and 6 months later. This means that you will get a **total of $200** for finishing all your data collection for the study.

Because the surveys are online, we need to make sure we can contact you for data collection at 6 months. Two weeks before this, we will contact you using the information we have for you. If you respond and let us know the best way to reach you, you will be entered into a draw for **1 of 3 $50 cash gifts**. If we can't get in touch with you, we will contact your clinic and ask them to get in touch with you. If you let them know the best way to reach you, you will be entered into the draw.

WHAT WILL HAPPEN WHEN I AM FINISHED THE INTERVENTION?

You will continue to receive treatment from your health care provider as normal.

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

We do not expect this study will harm you. Some of the questions in the online survey may cause you to feel anxious or upset. You can answer only those questions you are comfortable with.

Because of COVID, we completely understand that you may be nervous to meet with someone for the samples, and physical measurements because of COVID. We want to assure you that your safety is of the utmost importance to us. We are following all guidance from Alberta Health Services. This includes masks, gloves, face shields, and stringent cleaning. We will make

sure to physically distance when possible as well. We are also making sure we follow the current rules and will make all changes required by Alberta Health Services.

ARE THERE ANY POTENTIAL BENEFITS IF I PARTICPATE?

This study may or may not benefit you directly. You may learn more about eating healthy or getting better access to food. The results of this study will help us understand if a subsidy helped people with diabetes access healthy food. The knowledge we gain may help more people in the future.

WHAT HAPPENS IF MY BLOOD AND URINE TESTS SHOW SOMETHING ABOUT ME?

Your blood and urine samples will be tested by your community lab for things like A1C. Your results will be reviewed by the research team to identify any tests that may be outside the accepted range. We would like to share such results with your healthcare provider so they can follow-up with you. If you agree to this, please check the box below.

☐ I consent for the research team to share blood and urine test results with my healthcare provider.

CAN I STOP BEING IN THE STUDY OR BE REMOVED FROM THE STUDY?

Yes. Participating is completely up to you. You can choose not to participate at this time.

If you decide to take part but change your mind later, you can withdraw at any time without any consequences. To be removed, please call 1-833-879-1931.

If your eligibility changes, you may be removed from the study. A researcher will talk with you if this happens. If any new information becomes available that may affect your willingness to take part, a researcher will contact you immediately.

CAN MY STUDY DATA BE WITHDRAWN?

If you are no longer taking part in the study, the data collected about you so far will remain part of the study. This is because taking any data out may cause problems with the results.

WILL INFORMATION ABOUT ME AND MY PARTICIPATION BE KEPT CONFIDENTIAL?

Yes. The research team will make sure that your private information is kept private.

All data from the study will be stored on protected and secure University of Calgary servers. Data will not be stored on personal computers. Only research team members will have access to your personal information such as your name. This information will never be directly linked to your data. Your data will be identified by a study ID number only.

Your participation in this study will never be revealed. If we publish the results, they will be anonymous and will not include any personal information.

HOW LONG WILL MY STUDY DATA BE KEPT?

Your personal information (e.g., name) will be deleted when the study is finished. Your data will be kept until the results are published, or for five years, whichever is later. It will then be deleted. During this time, any other use of your data must have your consent and ethics approval.

WHAT ELSE DO I NEED TO KNOW?

Your blood and urine samples will be sent to Alberta Precision Laboratories and DynaLife for testing. Once the tests are complete, the samples will be carefully disposed of by the lab staff. The research team will never have access to the samples. We will only receive the test results. Your samples will be labeled with your study ID number only. No other information or data about you will be shared.

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

If you think you have been injured because taking part in the study, please let us know.

If you do suffer injury as a result of participating in this study, no compensation will be provided to you by Alberta Innovates, the University of Calgary, Alberta Health Services, or the researchers. You still have all your legal rights. Nothing said in this consent form alters your right to seek damages.

WHO DO I CONTACT IF I HAVE QUESTIONS?

The Research Team: You may contact Dr. Dana Olstad at (403) 210-8673 or Dr. David Campbell at (403) 210-9511 with any questions or concerns about 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.

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 consequences for you.**

You have a right to have all of your questions answered before deciding and have the right to leave the study at any time.

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HOW DO I INDICATE MY AGREEMENT TO PARTICIPATE?

Your signature on this form indicates that you understand the information about participating in this study and agree to be 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

☐ By checking this box and typing my name and the date below, I am electronically signing this consent form.

Participant's Name	*Date (yy/m/d)*
Investigator/Delegate's Name	*Date (yy/m/d)*
Witness' Name	*Date (yy/m/d)*

The University of Calgary Conjoint Health Research Ethics Board has approved this research study.

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