LETTER OF INFORMATION AND CONSENT TO PARTICIPATE IN A RESEARCH STUDY

TITLE: **Community-integrated nutrition education to prevent type 2 diabetes in Peel: The Nourish to Flourish Program**

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INTRODUCTION

You are invited to be part of a research study. Before you decide to participate, it is important that you read and understand this research consent form. This form contains all the information you need to decide whether you want to participate in the study. If you have any questions, ask the principal investigator or study personnel. The study principal investigator is Dr. Vasanti Malik; you can find her contact information above. You should not sign this form until you are sure you understand the information. Your participation is voluntary. You might also want to discuss this study with your family doctor, a family member or close friend. If you decide to join this study, it is important that you are as accurate as possible about your health history and any medications/products (including natural health products) you are taking. This helps us keep you safe.

You are being asked to participate in a 12-month lifestyle intervention with nutrition education, and three in-person clinic visits to collect body measurements. In addition, you are being asked to complete questionnaires (demographic/lifestyle) and three 3-day food records at baseline (start of the study), 6 months and 12 months. Furthermore, you will be asked to complete a Food Frequency Questionnaire (FFQ) at baseline. You will also be asked to do a blood sample collection at a local LifeLabs clinic before the start of the intervention, at 6-months and one year thereafter. In addition, there will be an optional virtual post-implementation focus groups and interviews. All information will be stored in a secure University of Toronto online storage service. All participants will receive compensation (e.g. gift cards) for their time. All focus groups/interviews will be approximately 60-90 minutes in length and conducted by a research team member in English. Focus groups/interviews will take place online at a time that will be convenient for you. Focus groups will be recorded on Zoom. Voice recordings will be anonymized and stored on a secure University of Toronto online storage service, and transcripts will be analyzed on NVivo which is a qualitative data analysis (QDA) computer software package produced by QSR International. This completed consent form must be signed and provided to the team prior to participation in this study.

BACKGROUND

Peel has one of the highest rates of T2D in Ontario. Individuals with T2D have a higher risk of cardiovascular diseases (CVD), kidney disease, lower limb amputation and vision loss compared to the general population. Excess body weight, poor diet, and physical inactivity are key contributors to T2D risk, and are influenced by several factors including structural inequities and our built and food environments. Specific contributors in Peel include an urban design that discourages walking and a high proportion of residents with ethnic backgrounds at a higher risk of T2D. *There is an urgent need for local and practical T2D prevention strategies in Peel to ensure the health and quality of life of its residents. A healthy diet and lifestyle are important for precenting chronic diseases, such as T2D.*

The Portfolio Diet (PD) is an evidence-based healthy eating plan that has shown clinically meaningful reductions in T2D and CVD risk factors in randomized controlled trials. Several studies show benefits of the PD on lowering cholesterol, blood pressure, and likelihood of developing T2D and CVD. Given the strong scientific evidence, the PD is recommended by Diabetes Canada, the Canadian Cardiovascular Society and Obesity Canada.

An app for the PD (PortfolioDiet.app) was recently developed by our research team for translation of the PD. However, a strategy to deliver the PD at the community level has yet to be designed and evaluated. An intervention (program) that delivers tailored nutrition education based on the PD has the potential to be a successful strategy to address the T2D burden in Peel. This intervention (program) could help reduce barriers to accessing and understanding nutrition and health information, which are key elements of T2D prevention. *A critical step to ensuring the success of such an intervention (program) is engaging with community members to design an effective implementation strategy.*

The overarching aim of our proposed project is to assess the effectiveness of an intervention (program) that delivers nutrition education based on the PD on T2D risk factors. To achieve this, we have partnered with the Peel Food Action Council (PFAC) and will conduct formative work to inform the design of our study. Our research questions are about understanding the barriers and facilitators for effective implementation of the intervention (program) and evaluating the effectiveness of the intervention on T2D risk factors and identifying implementation strategies for scaling up.

OVERALL PROJECT AIMS

- Aim 1: To conduct pre-implementation focus groups and interviews with the target population to inform the design of our intervention and implementation strategy.
- Aim 2: To assess the effect of the intervention among individuals at risk for T2D on changes in body weight, waist circumference, blood pressure and diet quality after 1 year compared to baseline.
    - Aim 2.1: To assess the effect of the intervention on biomarkers of T2D risk (glucose, insulin, lipids, HbA1c) in participants after 1 year compared to baseline.
- Aim 3: To conduct post-implementation, focus groups and interviews with participants to determine the effectiveness of the intervention implementation and gather insights for scaling up.

WHAT WILL I NEED TO DO FOR THIS STUDY?

We are inviting you to participate in Aim 2, 2.1 and 3 for this study. This will involve:

1. **Participation in a 12-month lifestyle intervention with nutrition education*:***
    - Virtual education sessions will be led by a dietitian/diabetes educator and based on the Portfolio Diet (PD). The PD is a healthy eating plan that promotes 5 cholesterol-

lowering foods (nuts, viscous fiber, plant protein, plant sterols, and monounsaturated oils).
    - Community gardening sessions will be led by the Peel Food Action Council (PFAC) and take place across different sites within the Peel Region.
    - Participants will be given the PortfolioDiet.app, an interactive dashboard app for goal setting and tracking, that features recipes and tips.
    - Participants will be invited to a WhatsApp Community Chat to stay motivated and engaged with the study throughout the year.
    - Participants will be given a home body weight scale for personal weight tracking and motivation.
2. **Attend 3 in-person clinic visits to collect body measurements and complete questionnaires (demographic/lifestyle) at the University of Toronto Mississauga Campus, at baseline, 6 months and 12 months in a community setting facilitated by PFAC.**
    - Body measurements include body weight (primary outcome), waist circumference, blood pressure and diet quality after 1 year from baseline using a one-group pretest-posttest design.
3. **Complete 1 Food Frequency Questionnaire (FFQ), and 3 three-day food records using the Keenoa App at baseline, 6 months and 12 months**
4. **Blood sample collection at a local LifeLabs clinics before the start of the intervention, at 6-months and one year thereafter** (baseline and 1-year after the intervention) to collect biomarkers of T2D risk (glucose, insulin, lipids, HbA1c).
5. **Participate in virtual post-implementation focus groups and interviews (approximately 60-90 minutes)** to determine the effectiveness of the intervention implementation and gather insights for scaling up. Participants who participate in a focus group/interview will receive a $25 gift card.

Kindly be advised that only a subset of participants will receive invitations to participate in a post-implementation focus groups or interviews (#5 as listed above). To express your interest in potentially being selected for these activities, please indicate by checking the boxes below:

☐ **YES, I would like to be contacted to participate in a post-implementation focus group or interview**

PARTICIPANT RECRUITMENT

You have been recruited for this study as you are an Adult (40 years of age or over) without chronic conditions, who have overweight and a high waist circumference plus one self-reported T2D risk factor (e.g. family history, ethnicity) and have access to a smartphone or internet, are not participating in another trial, and a risk score of 21 or above using the CANrisk T2D screening tool (https://health.canada.ca/apps/canrisk-standalone/pdf/canrisk-en.pdf).

BENEFITS & RISKS

The risks involved in this study are minimal. Despite this, there is still a possibility that you may experience different risks as a result of participation in this study, however, steps will be taken to minimize and manage these risks, as outlined below. In addition, to make sure you are safe, it is important that you are honest about your health history and any medications (including any natural health products) you are taking. It is also important that you follow the instructions in order to prevent any unnecessary harm to you if you decide to participate in this study.

Psychological/emotional risks (e.g., feeling uncomfortable, embarrassed, or upset): There is a possibility of psychological/emotional risks when participants complete the focus group/interview sessions as participants will be asked to share their personal opinions on the different aspects of the study. To minimize this risk, the questions asked during these sessions will not be of a sensitive matter and will be reviewed by a community advisory committee comprising of Peel community members. Participants may also experience psychological/emotional risks when answering the questionnaires, and/or completing the anthropometric and blood pressure measurements. However, the questionnaires, anthropometric and blood pressure measurements are non-invasive and will be measured by trained staff in a private setting to prevent these risks. In addition, participants might experience psychological/emotional risks when having difficulty adhering to the Portfolio Diet. While this is unlikely, participants will be encouraged to report any adverse events, and support will be provided to them should they experience psychological/emotional risks. Participants will be provided with resources should they experience any psychological/emotional risks. Such as resources outlined in the Canadian Mental Health Association Peel Dufferin website: https://cmhapeeldufferin.ca/programs-services

Physical risks (e.g., any bodily contact or administration of any substance): There is a possibility of physical risks when participants undergo a blood test to measure biomarkers of T2D risk. However, blood tests will be completed at local Life Labs clinics by a trained Life Labs professional who will take every precaution to keep participants safe and to minimize the possibility of any physical risks. To minimize physical harm while gardening, participants will be instructed to work at their own pace and be provided with gardening gloves/hats and have access to water.

Potential breaches to cybersecurity during virtual sessions will be minimized by using a password protected Zoom account and potential breaches to confidentiality regarding health status or personal information will be minimized by a series of steps to maintain data security (e.g. de-identifying data, using password protected computers, and limiting data access).

The Portfolio Diet is not known to have any risks and is recommend by several health organizations for the prevention and management of T2D and CVD. The participants that we are recruiting in our study include adults (40 years of age or over) without chronic conditions who have overweight and a high waist circumference plus one self-reported T2D risk factor. We do not expect any added risks due to changes in the participant's diet and difficulty in adhering

to the Portfolio Diet. While we do not expect adverse side effects from the Portfolio Diet, we will monitor safety and adverse events during the study.

Potential breaches to cybersecurity during virtual sessions will be minimized by using a password protected zoom account and potential breaches to confidentiality regarding health status or personal information will be minimized by a series of steps to maintain data security (e.g. de-identifying data, using password protected computers, and limiting data access).

Participating in this project will be an opportunity to share feedback and recommendations to identify implementation elements to inform next steps. Our goal is to integrate this intervention into a larger T2D prevention program that will be supported by PFAC and community services and offered to community members with an elevated risk for T2D. There are no known or anticipated risks to your participation in this session. Participation in this study will not affect your access to or ability to participate in University of Toronto programs and activities.

Participants who take part in this study will be provided with compensation for their time. At each study visit, participants will be given a gift card that incrementally increases in value at each study visit.

- First study visit (month 0), participants will be given a $20 gift card.
- Second study visit (month 6) participants will be given a $30 gift card.
- Last study visit (month 12), participants will be given a $40 gift card.

In addition, participants who participate in a post-implementation focus groups/interview will receive an additional $25 gift card.

WITHDRAWAL

Participation in this study is voluntary. You may refuse to participate and/or decline to answer any question in any part of the study without negative consequences. If you wish to withdraw your information, this will be done automatically without any questions from the project team. If you choose to withdraw, all of your data collected will be deleted. The project team will not be able to withdraw information from the study after the data have been analyzed (date to be determined).

CONFIDENTIALITY

The questionnaires, anthropometric and blood pressure measurements are being conducted for the purpose of this study, and all participants will not be named.

All audio recordings will be stored on an encrypted password protected cloud server and deleted from any hard drives and personal cloud storage once transcribed. Digital identifiable focus group/interview transcripts will be stored for 7 years on password protected encrypted University of Toronto servers only accessible to the Principal Investigator. Scanned copies of consent forms will also be retained for 7 years, and hard copies will be destroyed.

Contact Information

If you have any questions about this study, please feel free to contact the Project Coordinator (NutritionResearchStudy@utoronto.ca) or discuss it with the Principal Investigator, Vasanti Malik at vasanti.malik@utoronto.ca or (416) 978-5556.

This study has been reviewed and received ethics approval from the University of Toronto (Human Study REB 00046464). If you have questions regarding your rights as a research participant, contact in the first instance:

Research Oversight and Compliance Office – Human Research Ethics Program
27 King's College Circle
Toronto, ON M5S 1A1
at ethics.review@utoronto.ca or 416-946-3273

FEEDBACK AND PUBLICATION

Results of this study may be used in publications and presentations. Your data will be handled as confidentially as possible. If results of this study are published or presented, individual names and other personally identifiable information will not be used. To minimize the risks to confidentiality, your personal information will be kept safe. We may share the data collected from you for use in future research studies or with other researchers – if data collected about you is shared, we will remove any information that could identify you before sharing it.

All participants will be able to view the results. Only aggregate findings and no individual responses will be reported. You can request the executive summary by emailing Vasanti Malik at vasanti.malik@utoronto.ca

STATEMENT OF CONSENT

I have read and understood the above information. I have received a copy of this form. I agree to participate in this study.

Name of Participant: _____

Signature of Participant: _____

Date: _____

Name of Person Obtaining Consent: _____

Signature of Person Obtaining Consent: _____

Date: _____