Does a nutritional intervention aiming at improving diet quality initiated in early pregnancy improve glucose homeostasis in pregnant individuals at risk for gestational diabetes? A protocol for a randomized controlled trial

<u>Emilie Bernier<sup>1,2,3</sup></u>, Anne-Sophie Plante<sup>2,3</sup>, Patricia Lemieux<sup>2,4</sup>, Julie Robitaille<sup>1,2,3</sup>, Simone Lemieux<sup>1,3</sup>, Sophie Desroches<sup>1,3</sup>, Ariane Bélanger-Gravel<sup>3,5,6</sup>, Sarah Maheux-Lacroix<sup>2,4</sup>, S. John Weisnagel<sup>2,4</sup>, Suzanne Demers<sup>4</sup>, Félix Camirand Lemyre<sup>7,8</sup>, Mélanie Boulet<sup>9</sup>, Jean-Patrice Baillargeon<sup>8,10</sup>, and Anne-Sophie Morisset<sup>1,2,3</sup>

<sup>1</sup>École de Nutrition, Université Laval, Québec, QC, Canada; <sup>2</sup>Centre de Recherche du CHU de Québec-Université Laval, Québec, QC, Canada; <sup>3</sup>Centre de Recherche Nutrition, Santé et Société (NUTRISS) de l'Institut sur la Nutrition et des Aliments Fonctionnels (INAF), Université Laval, Québec, QC, Canada; <sup>4</sup>Faculté de Médecine, Université Laval, Québec, QC, Canada; <sup>5</sup>Département de Communication, Université Laval, Québec, QC, Canada; <sup>6</sup>Centre de Recherche de Recherche de l'Institut Universitaire de Cardiologie de Pneumologie de Québec, Québec, QC, Canada; <sup>7</sup>Département de Mathématiques, Université de Sherbrooke, QC, Canada; <sup>8</sup>Centre de Recherche du CHU de Sherbrooke, Sherbrooke, QC, Canada; <sup>9</sup>Centre Intégré Universitaire de Santé et de Service Sociaux de l'Estrie—CHU de Sherbrooke, Sherbrooke, QC, Canada; <sup>10</sup>Département de Médecine, Université de Sherbrooke, Sherbrooke, QC, Canada.



### Introduction

- A healthy diet during pregnancy has favorable effects on glycemic control and is associated with a lower risk of gestational diabetes mellitus (GDM) and other maternal and fetal complications. 1,2,3
- The primary treatment for GDM is nutritional therapy, which often begins late in pregnancy.<sup>3,4</sup>
- According to Diabetes Canada, there is a need for an effective and acceptable intervention that could improve glucose homeostasis and support pregnant individuals at risk for GDM.<sup>4</sup>

### Objective

To evaluate the effects of a nutritional intervention initiated early in pregnancy, based on the Canada's Food Guide (CFG), on glucose homeostasis in 150 pregnant individuals at risk for GDM, compared to usual care.

# Methods

Table 1. Study characteristics

# Participants

Intervention

**Outcomes** 

#### 150 pregnant individuals

• ≥ 18 years old

- ≤ 14 weeks of pregnancy
- ≥ 1 GDM risk factor according to Diabetes Canada<sup>4</sup>

A nutritional intervention initiated in the 1<sup>st</sup> trimester based on the health behavior change theory<sup>5</sup> and on the CFG including:

- 4 counseling sessions with a registered dietitian using motivational interviewing
- 4 phone follow-ups
- 10 video clips about healthy eating in pregnancy:
  - 1. The importance of healthy eating during pregnancy
  - 2. Should you eat differently during pregnancy?
  - 3. General recommendations for healthy eating
  - 4. Food precautions during pregnancy
  - 5. Habits to adopt when it comes to eating
  - 6. Why and how can we promote processed foods?
  - 7. The influence of the food environment
  - 8. Discomforts during pregnancy: what role does diet play?
  - 9. Nutrients for a healthy diet
  - 10. Understanding nutrition labelling
- a virtual community on Facebook with weekly publications on healthy eating during pregnancy relating to the 4 dimensions of social support<sup>6</sup>

### Control Usual prenatal care

- Change in **fasting plasma glucose** from V1 to V3
- Change in 2-h plasma glucose measurements following the ingestion of 75 g of glucose from the V1 to V3
  - Glycemic response (iAUC)
  - Hepatic and peripheral insulin resistance<sup>7,8</sup>
  - Beta-cell function<sup>9</sup>

Study desing
Single-center randomized controlled trial with 2 parallel arms and prospective follow-up

CFG, Canada's Food Guide; GDM, gestational diabetes mellitus; iAUC, incremental area under the curve; V1, V2, and V3, research visits at 1<sup>st</sup>, 2<sup>nd</sup>, and 3rd trimesters.

# Methods (continued)





Visit 1 (10-14 weeks): Data collection





Jutritional intervention
Usual prenatal care
Usual prenatal care

Control (n=75)

Follow-up 1 (16 weeks)

Session 1 (14 weeks)

Follow-up 2 (21 weeks)

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Session 3 (24 weeks)

Session 2 (18 weeks)

Follow-up 3 (27 weeks)

Follow-up 4 (33 weeks)

v-up 4 (33 weeks)

Visit 3 (34-36 weeks): Data collection

Session 4 (30 weeks)

Delivery

Visit 2 (24-26 weeks): Data collection

Post-partum (3 months): Data collection

### Table 2. Data collection

Variables	V1	V2	V3	PP
Sociodemographic status and medical history				
Weight and height				
Glucose, insulin, C-peptide, HbA1c*				
Dietary intakes (24h recalls), diet quality (HEFI-2019), dietary supplements use, eating behaviours (DEBQ), intuitive eating (IES-2)				
Physical activity (PPAQ/IPAQ)				
Perceived stress (PSS)				
Quality of life (SF-36), motivation (REBS)				
Social support				

\*Collected after a 12-h fast, as well as 15, 30, 60, and 90, 120 min after the ingestion of 75 g of glucose. DEBQ, Dutch Eating Behaviors Questionnaire; HbA1c, Glycated hemoglobin; HEFI-2019, Healthy Eating Food Index 2019; IES-2, Intuitive Eating Scale; IPAQ, International Physical Activity Questionnaire; PP, postpartum virtual data collection; PSS, Perceived Stress Scale; PPAQ, Pregnancy Physical Activity Questionnaire; REBS, Regulation of Eating Behavior Scale; SF-36, 36-Item Short Form Survey; V1, V2, and V3, research visits at 1st, 2nd, and 3rd trimesters.

### Anticipated results

- Recruitment of participants has been underway since April 2022.
- More than 50 % of the sample have been randomized.
- This project will determine if a nutritional intervention initiated early in pregnancy can improve glucose homeostasis of individuals at risk for GDM, compared to usual care, demonstrating the importance of nutritional management early in pregnancy.

# Publication



# References and funding

<sup>1</sup>Mijatovic-Vukas et al., Nutrients 2018; <sup>2</sup>Metzger et al., N Engl J Med 2008; <sup>3</sup>Johns et al., Trends Endocrinol Metab 2018; <sup>4</sup>Diabète Canada, Can J Diabetes 2018; <sup>5</sup>Hill et al., Midwifery 2013; <sup>6</sup>House, *Work stress and social support* 1981; <sup>7</sup>Matthews et al., Diabetologica. 1985; <sup>8</sup>Matsuda & DeFronzo, Diabetes Care 1999; <sup>9</sup>Singh & Saxena, World J Diabetes, 2010.

Please note that the references for the tools used for data collection, presented in Table 2, are available in the publication (open-acces), available by scanning the QR code on the left.







