A healthy food prescription incentive program for adults with type 2 diabetes who are experiencing food insecurity: A pragmatic randomized controlled trial.

Statistical Analysis Plan

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Abbreviations

Abbreviation/Acronym	Definition
A1C	Glycosylated haemoglobin level
Apo B	Apolipoprotein B
ASA24-2018-Canada	Automated Self-Administered 24-Hour Dietary Assessment Tool for Canada
BMI	Body Mass Index
FoodRx	Healthy food prescription incentive program
HDL	High-Density Lipoprotein
HEFI-2019	Healthy Eating Food Index-2019
HEI-2015	Healthy Eating Index – 2015
LDL	Low-Density Lipoprotein
PIA	Perceived Income Adequacy
PROM	Patient-Reported Outcome Measures
QALY	Quality-Adjusted Life-Years
RCT	Randomised Controlled Trial
T2DM	Type 2 Diabetes Mellitus
UPF	Ultra-Processed Foods

1. Introduction[1]

Type 2 diabetes (T2DM) places a tremendous burden on healthcare systems worldwide, as individuals with T2DM incur twice the healthcare costs as their age- and sex-matched counterparts.[1, 2] The total economic costs of diabetes were CDN$30 billion in Canada in 2019, making it among the most costly chronic conditions.[3-5] The human toll on individuals and their families is also substantial in terms of diminished quality of life associated with managing T2DM.[6, 7] Many of these human and economic costs can be mitigated by adhering to a healthy diet within an overall diabetes management plan. A healthy diet can yield clinically meaningful improvements in blood glucose levels, which can reduce diabetes complications over time.[8-11]

The high and continually escalating costs of many healthy foods[12, 13] represents a formidable barrier to following a healthy dietary pattern for individuals with T2DM, particularly for those who are experiencing food insecurity.[14-17] Food insecurity, described as inadequate or insecure access to food due to financial constraints[18], is a strong predictor of high-cost healthcare use.[19] Evidence indicates individuals with T2DM who are experiencing food insecurity have lower diet quality than their food secure counterparts, leading to elevations in blood glucose levels,[20, 21] and high rates of diabetes complications and acute care use.[22] Indigenous groups (constitutionally recognised as First Nations, Inuit and Métis) are a population of particular concern, given their disproportionately high rates of both T2DM and food insecurity.[23] The coexistence of food insecurity and T2DM, therefore, has major implications for healthcare costs. Although the adverse impacts of food insecurity on diet quality and blood glucose levels are well documented, effective strategies to address these challenges remain limited.

2. Rationale and Objectives

Healthy food prescription programs are innovative approaches to address these adverse impacts by assisting individuals who are experiencing food insecurity to purchase diabetes appropriate foods. These programs provide financial benefits or incentives to improve access to healthy foods for populations with food insecurity and chronic conditions. Current evidence suggests these programs may improve diet quality, blood glucose levels, and other health-related outcomes, while reducing food insecurity, including within Indigenous communities.[24-26] We conducted a randomized controlled trial (RCT) to investigate the effectiveness of a 12-month healthy food prescription incentive program (FoodRx program) on glycosylated hemoglobin levels (A1C; which represent average blood sugar levels over the previous 3 months.[27]) and additional secondary and exploratory outcomes among adults with T2DM who were experiencing food insecurity.

2.1 Hypotheses

Primary Objective: To investigate the effectiveness of the FoodRx healthy food prescription incentive program in reducing A1C.

> H_0 (null hypothesis): the healthy food prescription incentive program ***does not*** reduce A1C by a clinically meaningful difference of at least 0.5% between the intervention and comparison groups at 12-months.
>
> H_1 (alternative hypothesis): the healthy food prescription incentive program ***does*** reduce A1C by a clinically meaningful difference of at least 0.5% between the intervention and comparison groups at 12-months.

Secondary and Exploratory Objectives: To investigate the effectiveness of the FoodRx healthy food prescription incentive program in reducing food insecurity, and improving clinical health markers, dietary intake, and patient-reported outcome measures (PROMs).

[1] A comprehensive study protocol has been published (doi:10.1136/bmjopen-2021-050006).

3. Methods

3.1 Study Design

The FoodRx study was a parallel-group pragmatic RCT. Participants were assigned to a healthy food prescription incentive intervention group or a healthy food prescription-only comparison group. This study was conducted in accordance with the Tri-Council Policy Statement and the Declaration of Helsinki. Ethical approval was obtained from the Conjoint Health Research Ethics Board at the University of Calgary (REB20-0543; Calgary, Alberta, Canada), and the Research Ethics Office at the University of Alberta (Pro00107116; Edmonton, Alberta, Canada). This study is described in accordance with the TIDieR Checklist[28] and the CONSORT statement[29-31]. The study was preregistered in the clinicaltrials.gov database (NCT04725630) and the full study protocol has been published elsewhere[32].

3.2 Intervention and Frameworks

The FoodRx program consisted of 2 core elements. The first element was a one-time healthy food prescription designed to resemble current diabetes nutrition education by outlining a diabetes-appropriate dietary pattern. It was a low literacy resource with minimal text and colourful images. The information included a prescription for a healthy eating pattern, diabetes-relevant dietary tips (e.g., drink water when thirsty), a diabetes-appropriate recipe, community resource links, and emergency food assistance information tailored to each participant's community. Clinical research nurses from the FoodRx project team and the University of Alberta's Quality Management in Clinical Research Unit explained the healthy food prescription to all participants at baseline (0 months). As the prescription mimicked current standard of care, it was expected to have minimal influence on the dietary patterns of participants within the context of acute financial barriers.[33-38]

The second element was a weekly healthy food incentive of CDN$10.50 per household member for 12 months. Participants earned the weekly incentive by purchasing whole, minimally processed foods with little to no added fat, sugar, or salt from all food groups in study-affiliated supermarkets, which were part of a large chain with multiple banners and locations.[8, 39] Incentive-eligible foods included dairy products; whole grain bread, pasta, and cereal; fresh, frozen, and canned vegetables; fresh and frozen fruit; fresh, plain meats, fish, and poultry; canned fish and meat alternatives (eggs, canned and dried beans, plain almonds). Researchers calculated incentive amounts based on total household size as reported at baseline (0 months), which was communicated to participants after randomization. Once participants reached their spending threshold as defined by their household size, they immediately received loyalty card points equal to their eligible spending (e.g., a two-person household spending CDN$21 received CDN$21 in points). The incentive was capped at CDN$10.50 per person per week, and points were only given to households that met or exceeded their threshold each week. Although progress towards meeting the minimum spend was reset weekly, earned points carried over between weeks, did not expire, and could be redeemed for anything in-store in CDN$10 increments. However, participants were encouraged to use these points to continue the earn-reward cycle by purchasing incentive-eligible foods. At baseline, participants' loyalty cards were preloaded with points equivalent to one week's incentive amount to allow initial participation without paying out-of-pocket. The incentive redemption mechanism was pilot tested[40] and is fully described elsewhere.[32]

3.3 Data Collection Schedule and Data Sources

Participants in both groups completed data collection at baseline (0-months), mid- (6-months), and post-intervention (12-months with data collection beginning 2 weeks prior to participants' program end date). Participants completed a self-administered online questionnaire in REDCap[41], 2 online 24-hour dietary recalls using the Automated Self-Administered 24-Hour Dietary Assessment Tool for Canada (ASA24-2018-Canada)[42], and biochemical and physical measurements (e.g., blood samples, height, weight, skin carotenoids) as per the schedule in Figure 1.

Baseline (0 months)	•All outcomes •Blocking variables •Sociodemographic and health-related characteristics
Mid-Intervention (6-months)	•Blood glucose levels (A1C, fructosamine) •Food Insecurity •Dietary Recalls
Post-Intervention (12-months)	•All outcomes •Sociodemographic and health-related characteristics except for those not expected to change (e.g., race/ethnicity)

Figure 1: Data Collection Schedule

3.4 Randomization and Blinding

Prior to randomization, participants completed baseline data collection and received the healthy food prescription. Researchers randomized participants to either the FoodRx (n=299) or comparison (n=297) group with a 1:1 allocation ratio using a computer-generated, concealed, blocked randomization sequence in REDCap (Research Electronic Data Capture)[41] created by an independent statistician. Blocking variables included gender identity (woman, man), recruitment location (urban setting, rural setting, Indigenous primary care clinic), and baseline A1C (6.5-8.5%, 8.6-12%). The intervention group received both a healthy food prescription and a healthy food incentive. The comparison group received a healthy food prescription alone.

Due to the nature of the intervention, participants were not blinded to their allocation; however, they were blinded to study objectives. Participants in the comparison group were also blinded to the details of the healthy food incentive, including its monetary value and eligible foods. Care providers and researchers who collected and analyzed the data were blinded to treatment allocation with the exception of a research assistant who assisted participants in the intervention group throughout the trial.

4. Trial Population

4.1 Recruitment, Eligibility Criteria, and Screening

From May 2021 to December 2023, research assistants recruited participants through primary care clinics and community organizations (e.g., food banks) in urban and rural locations throughout the province of Alberta, Canada.

Adults aged 18-85 years with T2DM were eligible to participate if they: 1) had persistent hyperglycemia, defined as an A1C between 6.5-12% at baseline (0 months); blood glucose levels below 6.5% are considered clinically acceptable and those above 12% require urgent anti-hyperglycemic treatment with insulin, 2) experienced household food insecurity in the past 6 months, indicated by answering affirmatively to at least one question on Health Canada's Household Food Security Survey Module (HFSSM)[43], 3) spoke English or had someone to assist them during the study, and 4) were willing to travel to Calgary or Edmonton to complete data collection if they were not referred by a primary care clinician

Exclusion criteria included significant diabetes complications (i.e., intensive insulin therapy, current metabolic decompensation, diabetic ketoacidosis and/or hyperglycemic hyperosmolar emergency within the past year, recurrent severe hypoglycemia within the past 3 months, hypoglycemic unawareness), and conditions that may have influenced typical dietary patterns (i.e., pregnancy, breastfeeding, diagnosed eating disorder). Participants were excluded if they resided in a facility that provided meals (e.g., retirement home), were participating in other clinical trials that might interfere with the FoodRx program, did not have ongoing and reasonable access to

study-affiliated supermarkets, planned to leave Canada for more than 2 weeks at a time during the intervention, and/or had other household members that participated in the study.

Researchers assessed eligibility at baseline (0 months) using a screening questionnaire and participants indicated their informed consent to participate prior to beginning baseline data collection.

4.2 Sample Size

The sample size calculation was based on A1C, the primary outcome for the RCT. A mean baseline A1C of 8.5% (SD=1.4%) was expected in our population based on local administrative data.[44] For 90% power to detect a minimally important clinical difference in A1C of 0.5%[45], 594 participants were required assuming 5% type 1 error, 30% attrition[46], and potential design effects based on sampling in different primary care clinics and communities (25% inflation).

4.3 Stopping Guidance and Interim Analysis

The FoodRx program was deemed a low risk to cause adverse events; thus, no stopping guidance was required, and no interim analyses were planned or conducted. Participants continued their regular care with their primary care physician and/or other care providers during the trial, including adjustments to medication regimes to improve glycemia at the providers discretion. At the conclusion of the study, participants continued to be followed by their care providers.

4.4 Analysis Timing and Data Cleaning

Analyses will commence in fall 2025, beginning with the primary outcome. Analyses for secondary and exploratory outcomes will commence in late fall of 2025. We will maintain an audit file documenting data cleaning and preparation processes.

4.5 Baseline Characteristics

At baseline, we collected data on blocking variables (i.e., gender identity, recruitment location, A1C), and sociodemographic and health-related characteristics including date of birth, sex at birth, race/ethnicity and Indigenous identity, Canadian citizenship*[2], years lived in Canada, postal code*, home ownership, marital status, household size and composition, household changes*, relocation during the FoodRx program*, educational attainment, education location*, annual household income, main income source, participation in income support programs, access to extended health benefits, employment status, smoking status, duration of diabetes, and number of household members with T2DM with space to identify the member (e.g., daughter).

5. Outcomes

This section is comprised of outcome descriptions including definitions, variable types, measurement, scoring, and cut points as applicable for each outcome. Non-RCT outcomes included in Section 7 are also described herein. All statistical models are described in Section 7.

5.1 Primary Outcome

T2DM is a chronic metabolic disorder characterized by high blood glucose levels resulting from insulin resistance and/or impaired insulin secretion by the pancreas.[47] Monitoring blood glucose is essential to effective T2DM management. In this study, glycemic control was primarily quantified using A1C, which reflects average blood glucose levels over the previous 3 months.[48] An absolute reduction of 0.5% in A1C is achievable through improving diet quality[8, 9] and is considered a clinically meaningful difference.[45] The 12-month FoodRx program provided adequate time to see dietary changes in 4 A1C cycles.

[2] *Indicates this characteristic was added after protocol registration.

The priority source for A1C will be blood samples, which participants provided at an Alberta Precision Laboratory or DynaLIFE Medical Lab of their choice. Blood sample collection and testing were standardized to the Diabetes Complications and Control Trial.[49-52] When A1C results are not available from blood samples participants' provided specifically for the RCT, we will extract A1C results from medical records and/or the Alberta Health Services' Analytics Data Integration, Measurement, and Reporting database. For extracted A1C, we will use results that were collected 3 months before or after the time point of interest (e.g., 3 months before or after the participant's post-intervention lab collection date). We will analyze 12-month A1C as a continuous outcome.

5.2 Secondary Outcomes

5.2.1 Blood Glucose Levels

Glycemic control will also be assessed by 1) examining A1C levels as a continuous outcome at 6- and 18-months* to assess effectiveness of the intervention at midpoint and 6 months after cessation, 2) calculating the proportion of participants with elevated A1C as a binary outcome (A1C≥8.5%,), and 3) examining fructosamine levels at 6- and 12-months as a continuous outcome as A1C can be unreliable for some participants[53-55] and fructosamine is more sensitive to acute changes.[56]

5.2.2 Clinical Health Markers

Biochemical/Physical Measurements The following biochemical and physical measurements for blood lipids, blood pressure, BMI, and waist circumference were collected for each participant. All measurements adhered to standardized measurement protocols and were performed a minimum of two times by trained researchers/clinicians.

1. Blood lipids include total cholesterol, high-density lipoprotein (HDL) cholesterol, low-density lipoprotein (LDL) cholesterol, triglycerides, and apolipoprotein B (Apo B). Dyslipidemia, defined as atypical blood lipid levels, is a common comorbidity in T2DM and can increase the risk of cardiovascular disease and other diabetes related complications. Blood lipids were measured by means of blood samples. Lipids will be analyzed as continuous outcomes.
2. Blood pressure is measured via systolic and diastolic blood pressure values. Hypertension, defined as persistent elevated blood pressure, is a common comorbidity in T2DM, and can increase the risk of numerous diabetes related complications. Systolic and diastolic blood pressure were measured with Automatic Professional Blood Pressure monitors from BIOS Medical from the approved Hypertension Canada list. Systolic and diastolic blood pressure will be analyzed as continuous outcomes.
3. BMI is an indicator of adiposity.[57] Excess body fat is associated with poor glycemic control, increased insulin resistance, and increased cardiometabolic risk. BMI will be calculated using height as measured with a stadiometer, and body weight as measured with a digital scale with no shoes and light clothing. BMI will be analyzed as a continuous outcome.
4. Waist circumference is a clinical measure of abdominal adiposity, which is strongly associated with insulin resistance, and increased risk of cardiovascular disease.[58] Waist circumference was measured with non-elastic Seca 201 measuring tapes at the mid-point between the lowest border of the rib cage and the iliac crest.[59] Waist circumference will be analyzed as a continuous outcome.

Need for Antihyperglycemic Medication/Insulin Diet quality has significant impacts on glycemic control in the management of T2DM, including the need for antihyperglycemic medications and insulin use. Evidence indicates as diet quality improves, the need for medications/insulin can be de-intensified or discontinued altogether.[60] Data to assess this outcome will be extracted from the Pharmaceutical Information Network (PIN) database.[61] Need for antihyperglycemic medication/insulin will be quantified by monitoring changes in medication/insulin 1) usage, defined as initiation or discontinuation, and 2) type including Metformin, Sulfonylureas, Repaglinide, DPP-4 inhibitors, GLP1 receptor agonists, SGLT2-inhibitors, Acarbose, Thiazolidinediones. Need for antihyperglycemic medication/insulin will be analyzed as an ordinal outcome.

We will use a novel scoring system that assigns points for each change based on its anticipated impact on A1C. Points will be attributed cumulatively for all qualifying changes during the program.

For an expected change in A1C of ~0.5%, 1 point will be assigned to the following changes.

- less than full dose of Metformin (<2000 mg/day) or Sulfonylureas (Gliclazide<60 mg/day, Glyburide <10 mg/day) or Repaglinide (<5 mg/day)
- any dose of DPP-4 inhibitor, SGLT2-inhibitor or Acarbose
- initiation of basal insulin

For an expected change in A1C of ~1%, 2 points will be assigned to the following changes.

- full dose of Metformin, Sulfonylureas or Repaglinide
- any dose of GLP1 receptor agonists or Thiazolidinedione
- initiation of bolus insulin

Addition of medication/insulin will be scored positively and reductions scored negatively to arrive at a final cumulative medication/insulin adjustment score for each participant. Deintensification will be considered a positive, and intensification will be considered a negative.

5.2.3 Dietary Patterns

Healthful dietary patterns are essential for the management of T2DM, and are the mechanism through which A1C improves or declines.[62] We used both subjective and objective measurements to provide a comprehensive assessment of the quality of participants' dietary patterns.

Dietary Intake We collected self-reported (i.e., subjective) dietary intake data to assess the quality of dietary patterns using the ASA24-2018-Canada online system, which is a modified version of the ASA24 based on the Canadian food supply, portion sizes, and nutrition composition.[63] Participants reported all foods, beverages, and supplements consumed from midnight-to-midnight the previous day as well as if their reported intake was more than usual, usual, or less than usual. The system also recorded the date and time for each recall. Participants completed 2 x 24-hour dietary recalls for a total of 6 recalls to better capture the intake of episodically consumed foods and daily variability, thereby, providing more accurate estimates of usual dietary intake. Prompts to enter a second recall were sent 2-5 days after the first recall, with the specific interval determined at random. Participants entered dietary recalls on any day of the week including weekends (Friday-Sunday). This data will be used to determine recall day and season of measurement, which is defined as spring (March-May), summer (June-August), autumn (September-November), and winter (December-February).

We will use this data to assess the alignment of participants' dietary intake with national nutrition guidance by using the appropriate scoring algorithms to calculate Healthy Eating Food Index 2019 (HEFI-2019)[64, 65] and Healthy Eating Index-2015 (HEI-2015)[66-69] scores. The HEFI-2019 is a 10-component index that aligns with the content and objectives of Canada's Food Guide 2019 (CFG-2019). Total HEFI-2019 scores are the sum of individual component scores, and range from 0-80 with higher scores indicating greater adherence to CFG-2019 guidelines.[64] The HEI-2015 is a 13 component index that sums component scores for adequacy (foods that align with nutritional guidelines) and moderation (foods with suggested limited intake), and a total score, which ranges form 0-100, with higher scores indicating higher adherence to the 2015-2020 Dietary Guidelines for Americans. For each index, scores will be calculated as the mean of two recalls when available; if only one recall is available, a single score will be used. HEFI-2019 and HEI-2015 scores will be analyzed as continuous outcomes.

*Ultra-Processed Foods** We will use dietary intake data collected with the ASA24-2018-Canada to calculate the proportion of energy consumed from ultra-processed foods (UPF), which are manufactured foods and beverages that contain few to no whole foods. All foods and beverages reported in dietary recalls will be classified using the NOVA classification system, which includes definitions and examples.[70] This system classifies foods and beverages into 4 groups, including unprocessed or minimally processed, processed culinary ingredients,

processed, or ultra-processed. The numerator for each group will be the average energy intake from UPF from both recalls and the denominator for all groups will be the total average daily energy intake from both recalls at each timepoint. UPF will be analyzed as a continuous outcome.

Skin Carotenoids Notwithstanding their demonstrated validity[71], dietary recalls are subjective self-reports and are prone to reporting errors and bias.[72] To address these issues, we collected skin carotenoid data to provide objective approximations of vegetable and fruit consumption, which are key components of healthy dietary patterns.[73] Carotenoids are phytonutrients only present in food and are abundant in vegetables and fruit. Once consumed, they are stored in both blood and skin. Skin carotenoids are valid and reliable measures of fruit and vegetable intake,[74] and are positively correlated with plasma carotenoids.[75] We measured carotenoids dermally using Pharmanex Biophotonic Scanners (NuSkin Enterprises, Provo, UT, USA), which are non-invasive measurements taken through participants' palms. Researchers collected 3 scans for each participant. Each scan provides a score ranging from 10,000 to 80,000, with 10,000 indicating a diet low in carotenoids and 80,000 indicating a diet very high in carotenoids.[76] Researchers collected 3 scans for each participant. Scores for each participant will be calculated by averaging these 3 measurements. Skin carotenoids will be analyzed as a continuous outcome.

*Supplements** Participants also reported dietary supplement intake in each recall. Evidence suggests consuming supplements containing carotenoids may substantially increase plasma and skin carotenoid levels.[77, 78] We will create a binary indicator variable to capture supplement intake. Intake is defined as consumption of supplements containing beta-carotene, lycopene, lutein, zeaxanthin, alpha-carotene, or gamma-carotene both individually and in combination. No intake is defined as consumption of supplements that do not include the aforementioned carotenoids or supplement consumption was not reported in the dietary recalls. Supplement intake will be included as a covariate to account for potential influence on observed skin carotenoid levels, thereby allowing estimates to better reflect consumed foods.

5.2.4 Patient Reported Outcomes

Household Food Insecurity

Household food insecurity, defined as inadequate or insecure access to food due to financial constraints,[79] was assessed using Health Canada's validated 18-item Household Food Security Survey Module (HFSSM).[80] We slightly modified the module to fit the study's data collection schedule. Response options were preserved in their original format, with the sole modification being a change in the reference period from 12 months to 6 months. Participants rated the frequency in which they 1) worried about running out of food for themselves and/or household members including children, 2) cut the size of their meals or skipped meals, and/or 3) went entire days without eating because there was not enough money for food. Response values range from 1 (never true) to 3 (often true) for primary questions, and 1 (only 1 or 2 weeks) to 3 (almost every week) for sub questions. Adults with children <18 years of age living in the home completed all 18 module questions. Adults with no children living in the home completed the 10 questions for adults only. Scoring is determined by the total number of affirmative responses, which are subsequently classified as food secure, marginally food insecure, moderately food insecure, or severely food insecure as described in Table 1.

We will assess the presence of household food insecurity as a binary variable by comparing those who were experiencing food insecurity (≥ 1 affirmative responses) to those who were food secure (0 affirmative responses). We will also assess the severity of household food insecurity as an ordinal variable by comparing those who experienced marginal, moderate, or sever food insecurity to those who were food secure.

Status	Interpretation	10 item adult food security scale	8 item child food security scale
Food secure	No report of income-related problems of food access.	No items affirmed	No items affirmed
Marginally food insecure	Some indication of worry or an income-related barrier to adequate, secure food access	Affirmed no more than 1 item on either scale	
Moderately food insecure	Compromise in quality and/or quantity of food consumed by adults and/or children due to a lack of money for food.	2 to 5 affirmative responses	2 to 4 affirmative responses
Severely food insecure	Disrupted eating patterns and reduced food intake among adults and/or children	6 or more affirmative responses	5 or more affirmative responses

Note: In cases where a household meets the condition of two different classifications (that is, different status on the child and adult scales), the household is given the more severe classification).

Table 1: Reproduced from PROOF[43] with permission and in accordance with licensing requirements.[81]

Diabetes Self-Efficacy

Diabetes self-efficacy was assessed using the validated 8-item Stanford Diabetes Self-Efficacy Scale, which measures self-reported confidence in completing activities related to diabetes management.[82, 83] The questions query current feelings of confidence in completing activities for managing diabetes, including regular meals, choosing appropriate foods, regular exercise, and activities to promote glycemic control. Response values range from 1 (not at all confident) to 10 (totally confident). The total score is the mean of the responses to all questions with higher scores indicating more self-efficacy and lower scores indicating less self-efficacy. Diabetes self-efficacy will be analyzed as a continuous outcome.

Diabetes Self-Management

Diabetes self-management was assessed using the validated 16-item Diabetes Self-Management Questionnaire, which measures self-care behaviour.[84, 85] The questions assess self-care behaviours associated with glycemic control for both type 1 and type 2 diabetes over the previous 8 weeks, including monitoring blood sugar levels, regular appointment attendance, adherence to medication regimen, and physical activity. Response values range from 0 (does not apply to me) to 3 (applies to me very much). Subscales include Glucose Management (items 1, 4, 6, 10, 12), Dietary Control (items 2, 5, 9, 13), Physical Activity (items 8, 11, 15), and Health-Care Use (items 3, 7, 14). Item 16 provides an overall rating of diabetes self-care. Scores will be calculated as sums of all item scores and then transformed to a scale with a range of 0 (lowest rating of self-care) to 10 (highest rating of self-care). A score of ≤6 indicates lower self-care. Diabetes Self-Management will be analyzed as a continuous outcome.

Diabetes Distress

Diabetes distress was assessed using the validated 5-item Problem Areas in Diabetes Scale (PAID5), which measures emotional distress related to diabetes.[86] The questions provide a rapid screening of current emotional distress due to diabetes, including fear, depression, worry, capacity, and coping. Response values range from 0 (not a problem) to 4 (serious problem). Possible scores range from 0-20 with higher scores suggesting greater diabetes-related emotional distress and lower scores indicating lower diabetes-related emotional distress. The total score will be calculated by summing responses for all questions. A total score of ≥8 indicates possible distress. Diabetes distress will be analyzed as a continuous outcome.

Diabetes Competing Demands

Diabetes competing demands was assessed using a 4-item scale purposively developed by Lorig et al (1996)[87], which measures frequency of delaying the purchase of necessities. The questions queried how often participants must make decisions between purchasing necessities for either daily life or diabetes management (e.g., food, medication, supplies) over the previous 6 months. Response values range from 1 (never) to 4 (always). A trade-off is considered to have occurred if a participant answers "often" or "sometimes" to either question. Diabetes competing demands will be analyzed as a binary outcome.

Perceived Financial Barriers to Chronic Disease Care

Perceived financial barriers to chronic disease care was assessed using 2 items from the Barriers to Care for People with Chronic Health Conditions survey.[88] The questions assessed the frequency of encountering difficulties purchasing necessities and supplies over the previous 6 months. Response values range from 1 (always) to 5 (never). Sub questions query specific services, equipment, or medication. Financial barriers are present if a participant answers always, often, or sometimes to either question. Perceived financial barriers to chronic disease care will be analyzed as a binary outcome (yes, no).

Hypoglycemic Episode Frequency

Frequency of hypoglycemic episodes (i.e., low blood sugar reaction so severe the participant required glucagon, physician support, or emergency assistance) in the previous 6 months was assessed using the validated single-item Hypoglycemic Episode tool.[89] Response values include 0 times, 1-3 times, 4-6 times, 7-11 times, and ≥12 times. Hypoglycemic episode frequency will be analyzed as an ordinal outcome.

Psychosocial Well-Being

Psychosocial well-being was assessed using the validated 5-item WHO Well-Being Index.[90, 91] The questions measure subjective well-being over the previous 2 weeks by querying positive mood, calm feelings, vigour, feeling well rested, and interest in daily life. Response values range from 0 (at no time) to 5 (all the time). Raw scores will be calculated by totaling answers from all questions, with a range from 0 (worst possible quality of life) to 25 (best imaginable quality of life). A percentage score will be calculated by multiplying the raw score by 4, with a range from 0% (worst possible well-being) to 100% (best possible well-being). A score of ≤ 50 suggests poor psychosocial well-being. Psychosocial well-being will be analyzed as a continuous outcome.

Quality-Adjusted Life-Years

Self-rated health was assessed using the validated European Quality of Life Five Dimension Five Level Scale (EQ-5D-5L).[92, 93] The questions measure current self-rated heath across 5 dimensions including mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. Response values range from 1 (no problems) to 5 (extreme problems), with one response selected for each domain. Health states can be reported descriptively as a 5-digit code, reflecting the level selected in each domain, or converted into a single index value using country-specific population-based preference weights.[94-96] The index values represent 1.0 (full health) to 0.0 (death), with scores less than 0 representing states worse than death. Higher index values represent better health. We will use the Canadian Eq-5D-5L value set, specifically the model 4 scoring algorithm (combines both time trade-off and discrete choice experiment data), to calculate index values. These health-related quality-of-life scores will be used to estimate a quality-adjusted life-year (QALY) using an area under the curve approach.[97] The QALY will be analyzed as a continuous outcome.

5.3 Exploratory Outcomes

5.3.1 Perceived Income Adequacy

Perceived income adequacy was assessed using the validated single-item Perceived Income Adequacy tool, which measures current difficulty making ends meet.[98-100] Response options are given on a Likert Scale ranging from very difficult to very easy. Endorsements of *neither easy nor difficult*, *easy*, or *very easy* indicate income is

perceived as adequate, and *very difficult*, and *difficult* indicate income is perceived as inadequate. Perceived income adequacy will be analyzed as a binary outcome.

5.3.2 Subjective Social Status

Subjective social status refers to an individuals' perceived position within the social hierarchy relative to others in their community and/or nation[101], and has been shown to adversely impact health outcomes beyond objective measures of socioeconomic status (e.g., income).[102] This outcome was assessed using the validated MacArthur Scale of Subjective Social Status national and community ladders.[103] Using a picture of a ladder, respondents used a visual analog scale to place themselves on a ladder rung according to their current perceived social standing relative to others in their nation and in their community. Both ladder scales use a discrete scale ranging from 1 (bottom rung indicates lowest status) to 10 (top rung indicates highest status), with a higher score indicating higher perceived social status in relation to others within ones' nation and community. Subjective social status will be analyzed as a continuous outcome.

5.3.3 Work Productivity and Activity Impairment

Work productivity and impairment was assessed using the validated 6-item Work Productivity and Impairment tool. The questions measure impairments in paid work and regular activities due to health issues in the past 7 days.[104, 105] The tool yields 4 percentage scores including absenteeism (work time missed), presenteeism (impairment at work/reduced on-the-job effectiveness), work productivity loss (overall work impairment), and activity Impairment (impairment in non-work activities). Higher scores indicate greater productivity loss and/or activity impairment. Work productivity and activity impairment will be analyzed as a continuous outcome.

5.3.4 Medication Adherence

Adherence to prescribed medications was assessed using the validated single-item Medication Adherence measure, which is a visual scale measuring how often participants took their prescribed medication in the past 7 days.[106] Response values range from 0-100% with anchors at 0% (none at all) – 50% (half of prescribed doses) – 100% (all doses of prescribed medications). Higher percentage values indicate greater medication adherence. Medication adherence will be analyzed as a continuous outcome.

5.3.5 Physical Activity Level

Physical activity level was assessed using a validated single-item physical activity tool, which measures how many days during the past 7 days participants took part in 30 minutes or more of moderate to vigorous exercise.[107] Response values range from 0 (0 days) to 7 (7 days) with higher numbers indicating higher physical activity levels. Physical activity level will be analyzed as a discrete outcome.

5.4 Non-RCT Outcomes

The following outcomes are included in the planned manuscripts, although data were not collected as part of the RCT. Results for other FoodRx studies will be reported in manuscripts described elsewhere.

5.4.1 Incentive Usage

Incentive usage will be assessed as a count of the number of weeks participants earned the incentive and/or redeemed the incentive. The total possible weeks for both earning and redeeming the incentive is 52 weeks.

5.4.2 Healthcare Costs

Annual total healthcare costs for each participant will be calculated using provincial administrative databases, with costs representing the sum of hospital costs, emergency department and day surgery costs, physician service costs, and publicly funded pharmacy costs. Hospital costs will be estimated using the Discharge Abstract Database (DAD) through resource intensity weights multiplied by cost per weighted case. Emergency department and day surgery costs will be derived from the National Ambulatory Care Reporting System (NACRS). Physician service costs will be calculated from Practitioner Claims data, and community pharmacy costs

will be obtained from the Pharmaceutical Information Network. All analyses will be conducted from the public healthcare payer perspective and reported in 2025 Canadian dollars, with costs analyzed as a continuous variable that accounts for the potential presence of large numbers of zero values and the non-negative nature of cost data.

6. Statistical Principles

6.1 Regression Model Assumptions

We will assess whether the assumptions for each regression model are met, and will take appropriate corrective steps if violations are identified. In analyses where the proportional-odds assumption is violated, we will use generalized proportional odds models to preserve the ordinal nature of the outcome(s) in question and allow covariate effects to vary across thresholds as necessary. In analyses with severe violations, we will use multinomial logistic regression models.

6.2 Hypothesis Testing

For hypothesis testing, confidence intervals are set at 95% and statistical significance is set at $p < 0.05$. Confidence intervals and absolute p-values will be reported in all manuscripts, regardless of statistical significance. Adjusted and unadjusted estimates will be reported.[108] When interpreting results, emphasis will be placed on effect sizes, confidence intervals, and clinical relevance rather than statistical significance alone.

6.3 Analysis Population

Analyses will be intention-to-treat using all available data for parameter estimation of primary, secondary, and exploratory outcomes.

6.4 Missing Data

Missing data due to withdrawal or loss-to-follow-up is expected despite mitigation strategies that were in place to reduce missingness. We will examine missing data during cleaning to 1) document potential reasons for missingness, 2) examine the plausibility of a missing at random assumption, and 3) identify auxiliary covariates that may be predictive of outcomes to inform our assumptions and handling of missing data.[109]

Missing data will be handled using full information maximum likelihood under a missing at random assumption, provided this assumption appears plausible after examining the data.[109, 110] Preliminary auxiliary variables, which will be assessed for each outcome, are detailed in Section 7.

To investigate the impact of different assumptions regarding missing data on estimated program impacts, we will use Markov chain Monte Carlo multiple imputation regardless of the percentage of missingness, inverse probability weighting, and available case analysis.[111-113] We will also use pattern mixture methods models[114] to explore the robustness of study findings to the assumption that data are not missing at random.[109, 115]

6.5 Multiple Comparisons

We have used current guidelines for multiplicity to assess the risk of increased Type I error rates in this study.[116, 117] As such, we will not adjust for multiple comparisons given the RCT 1) is exploratory, 2) includes 2 distinct treatment arms, 3) has a single pre-specified primary outcome that is the basis for statistical inference, 4) positions secondary and exploratory outcomes as supportive to the primary outcome and as hypothesis-generating, 5) did not include interim analyses, 6) will account for repeated measures using mixed-effect models with group by time and time-treatment interactions (testing for contrasts at each timepoint)[117], 7) includes pre-specified exploratory sub-group analyses, and 8) includes exploratory sensitivity analyses to assess treatment consistency across groups. In addition, multiplicity adjustments increase the chance of type 2 errors, and assume all null hypotheses are true (i.e., all positive results are false positives). Lastly, these adjustments assume all outcomes are independent, which is not the case for the FoodRx RCT as many outcomes are related (e.g., blood lipids, systolic and diastolic blood pressure). All results will be interpreted with caution considering p-values,

confidence intervals, and effect sizes. Findings for secondary results, and secondary and exploratory outcomes will be presented as exploratory.[118]

6.6 Statistical Software

Statistical analyses will be conducted in Stata[119], and R[120] using versions specified in the final manuscripts.

7. Analyses

To describe the analyses, we have grouped all outcomes according to the manuscript in which they will be reported. Mixed-effects linear, logistic, and/or non-linear regression models will be used to assess group differences in outcomes at baseline and post-intervention.

The incentive program was paused after 11 weeks due to problems with delivery of the incentive. The incentive program resumed 12 weeks later when the issues were rectified. This restart impacted 31 participants who had completed baseline data collection, been randomized, and begun the program. Those who chose to remain in the program completed baseline data collection a second time, resulting in duplicate baseline measures. The following analyses will include the second set of baseline data unless otherwise specified (i.e., sensitivity analysis).

7.1 Descriptive Analyses

Descriptive statistics will be presented for baseline characteristics described in Section 4.5. Statistical testing for differences in baseline characteristics between groups will not be conducted as differences in these characteristics are due to chance.[29, 31] Descriptive statistics will be presented by intervention group using means and standard deviations for continuous variables, and frequencies and percentages for categorical variables. See Appendix A for a table containing all study outcomes and variables.

7.2 Covariate Adjustments, Subgroup Analyses, and Sensitivity Analyses

Models will be adjusted for baseline values of each outcome, blocking variables, and covariates specific to each outcome, which are described in the manuscript sections.

Subgroup analyses will be conducted for one outcome in each paper. These analyses are described in each manuscript section.

We will conduct per protocol sensitivity analyses for each outcome wherein data for participants who did not adhere to their assigned group will be removed from the analysis. We will also conduct as-treated sensitivity analyses for each outcome wherein participants will be analyzed based on their incentive usage by 1) using pre-specified cut points based on percentage of incentives redeemed (25%, 50%, 75%), 2) basing usage on weeks used wherein participants who earned the incentive ≥ 27 weeks will be analyzed as part of the FoodRx group and participants who earned the incentive ≤ 26 weeks will be analyzed as part of the comparison group, and 3) basing usage on incentive level by comparing single households to the remaining levels (i.e., 2+ households and above). Additional sensitivity analyses are described in each manuscript section.

7.3 Role of Wahkohmakanah, Niiksokowaaks, All My Relations

This section describes the role of Wahkohmakanah (Cree), Niiksokowaaks (Blackfoot), All My Relations (English), the FoodRx Indigenous Advisory Board, herein referred to as AMR.

Subgroup analyses of Indigenous participants may be included in each manuscript, as determined by AMR members. AMR is embedded in the FoodRx research team and will be available to contextualize each analysis. In accordance with Indigenous Data Governance, specifically OCAP® principles[121], AMR and the FoodRx principal investigators will retain co-ownership and governance of the data and results specific to Indigenous participants in FoodRx. AMR will decide which results to report and how they will be presented in each manuscript. Once all

analyses are complete, AMR may choose to develop a summary discussion paper synthesizing all results for Indigenous participants.

7.4 Primary Manuscript

This paper will report results for 12-month A1C, our primary outcome, along with secondary and exploratory outcomes at 6-, 12-, and/or 18-months, including blood glucose levels, clinical health markers, and need for antihyperglycemic medication.

12-month A1C, Primary Outcome

We will assess the intention to treat effect of group assignment on mean A1C at 12-months as a continuous outcome using mixed-effects linear regression. The primary test will be the group x time interaction contrast at 12-months (i.e., post-intervention), which estimates between-group differences in mean A1C from baseline to 12 months. Models will be adjusted for baseline A1C to estimate treatment effect while holding baseline A1C constant, and additional blocking variables (gender, recruitment location). To improve the precision of effect estimates, models will also be adjusted for age, race/ethnicity, educational attainment, number of children living in the home, and diabetes duration. Additionally, all models will include a data source indicator variable (study measured vs administrative health data), group (FoodRx vs comparison), collection timing (number of days measurement was taken since baseline), and restart cohort indicator variable (did not restart vs did restart). We will include random intercepts for participants (participant study ID) to account for within-subject correlation due to repeated measures, and for primary care clinics (clinic study ID) to account for clustering of participants within clinics. Missing data for covariates will be addressed using full information maximum likelihood.

We will conduct subgroup analyses for 12-month A1C by baseline household food insecurity severity (marginal, moderate, severe), gender (man, woman, gender diverse), recruitment location (urban setting, rural setting, Indigenous primary care clinic), Indigenous identity, baseline A1C (≤8.5%, ≥8.6%), and baseline insulin use (no, yes).

We will conduct dose-response analyses to examine whether 12-month A1C differs based on the total value of incentives redeemed, a continuous variable, in the first 6 months for the mid-intervention analysis, and in the full 12-months for the post-intervention analysis.

In addition to per-protocol and as-treated analyses, we will conduct sensitivity analyses for 12-month A1C to examine 1) the impact of excluding A1C values obtained from administrative health data, 2) if findings differ when models include all participants regardless of A1C source, and a collection timing indicator variable (time since baseline, deviation from 12-month data collection timepoint), 3) the impact of using multiple imputation for missing data rather than full information maximum likelihood, 4) the impact of adjusting for changes in medication/insulin type and dosage between baseline and post-intervention follow-up, 5) the impact of including the first measure of baseline A1C collected before the trial was restarted, and 6) the impact of excluding participants who restarted the trial .

Blood Glucose Levels, Secondary Outcomes

6-month A1C We will assess group differences in 6-month A1C (i.e., mid-intervention) as a continuous outcome using mixed-effects linear regression. Models will be adjusted for baseline A1C, and additional blocking variables (gender, recruitment location). To improve the precision of effect estimates, models will also be adjusted for age, race/ethnicity, educational attainment, number of children living in the home, and diabetes duration. Models will also include group (FoodRx vs comparison), and baseline A1C data source (study measured vs administrative health data) indicator variables. We will include random intercepts for participants (participant study ID) to account for within-subject correlation due to repeated measures, and for primary care clinics (clinic study ID) to account for clustering of participants within clinics.

In addition to per-protocol and as-treated analyses, we will conduct sensitivity analyses for 6-month A1C to examine 1) the impact of excluding A1C values obtained from administrative health data, 2) if findings differ when models include all participants regardless of A1C source, and a collection timing indicator variable (time since baseline, deviation from 6-month data collection timepoint), 3) the impact of using multiple imputation for missing data rather than full information maximum likelihood, 4) the impact of adjusting for changes in medication/insulin type between baseline and mid-intervention follow-up, and 5) the impact of including the first measure of baseline A1C collected before the trial restart.

18-month A1C We will assess group differences in 18-month A1C (i.e., 6-months post-intervention) as a continuous outcome using mixed-effects linear regression. Models will be adjusted for baseline A1C, and additional blocking variables (gender, recruitment location). To improve the precision of effect estimates, models will also be adjusted for age, race/ethnicity, educational attainment, number of children living in the home, and diabetes duration. Models will also include group (FoodRx vs comparison), and baseline A1C data source (study measured vs administrative health data) indicator variables. We will include random intercepts for participants (participant study ID) to account for within-subject correlation due to repeated measures, and for primary care clinics (clinic study ID) to account for clustering of participants within clinics.

In addition to per-protocol and as-treated analyses, we will conduct sensitivity analyses for 18-month A1C to examine 1) the impact of excluding A1C values obtained from administrative health data, 2) if findings differ when models include all participants regardless of A1C source, and a collection timing indicator variable (time since baseline, deviation from 18-month data collection timepoint), 3) the impact of using multiple imputation for missing data rather than full information maximum likelihood, 4) the impact of adjusting for changes in medication/insulin type between baseline and 6-months post-intervention follow-up, and 5) the impact of including the first measure of baseline A1C collected before the trial restart.

Elevated A1C We will assess group differences in elevated A1C as a binary outcome using mixed-effects logistic regression (odds ratios). Models will be adjusted for baseline A1C, and additional blocking variables (gender, recruitment location). To improve the precision of effect estimates, models will also be adjusted for age, race/ethnicity, educational attainment, number of children living in the home, and diabetes duration. Models will also include group (FoodRx vs comparison), and baseline A1C data source (study measured vs administrative health data) indicator variables. We will include random intercepts for participants (participant study ID) and primary care clinics (clinic study ID). to account for clustering of participants within clinics.

In addition to per-protocol and as-treated analyses, we will conduct sensitivity analyses for elevated A1C to examine 1) the impact of excluding A1C values obtained from administrative health data, 2) if findings differ when models include all participants regardless of A1C source, and a collection timing indicator variable (time since baseline, deviation from 18-month data collection timepoint), 3) the impact of using multiple imputation for missing data rather than full information maximum likelihood, 4) the impact of adjusting for changes in medication/insulin type between baseline and 6-months post-intervention follow-up, and 5) the impact of including the first measure of baseline A1C collected before the trial restart.

Fructosamine We will assess group differences in fructosamine as a continuous outcome using mixed-effects linear regression at 6- and 12-months. Models will be adjusted for baseline fructosamine, and blocking variables (baseline A1C, gender, recruitment location). To improve the precision of effect estimates, models will also be adjusted for age, race/ethnicity, educational attainment, number of children living in the home, and diabetes duration. Additionally, all models will include baseline A1C data source (study measured vs administrative health data), and group (FoodRx vs comparison). We will include random intercepts for participants (participant study ID) to account for within-subject correlation due to repeated measures, and for primary care clinics (clinic study ID) to account for clustering of participants within clinics.

In addition to per-protocol and as-treated analyses, we will conduct sensitivity analyses for fructosamine to examine 1) the impact of excluding A1C values obtained from administrative health data, 2) if findings differ when models include all participants regardless of A1C source, and a collection timing indicator variable (time since baseline, deviation from 18-month data collection timepoint), 3) the impact of using multiple imputation for missing data rather than full information maximum likelihood, 4) the impact of adjusting for changes in medication/insulin type between baseline and 6-months post-intervention follow-up, and 5) the impact of including the first measure of baseline A1C collected before the trial restart.

Clinical Health Markers, Secondary Outcomes

Systolic Blood Pressure We will assess group differences in systolic blood pressure as a continuous outcome using mixed-effects linear regression. Models will be adjusted for baseline systolic blood pressure, and blocking variables (baseline A1C, gender, recruitment location). To improve the precision of effect estimates, models will also be adjusted for age, race/ethnicity, educational attainment, number of children living in the home, and diabetes duration. Additionally, all models will include baseline A1C data source (study measured vs administrative health data), and group (FoodRx vs comparison) indicator variables. We will include random intercepts for participants (participant study ID) to account for within-subject correlation due to repeated measures, and for primary care clinics (clinic study ID) to account for clustering of participants within clinics.

In addition to per-protocol and as-treated analyses, we will conduct sensitivity analyses for systolic blood pressure to examine impact of excluding patients who were started on anti-hypertensive therapy.

Diastolic Blood Pressure We will assess group differences in diastolic blood pressure as a continuous outcome using mixed-effects linear regression. Models will be adjusted for baseline diastolic blood pressure, and blocking variables (baseline A1C, gender, recruitment location). To improve the precision of effect estimates, models will also be adjusted for age, race/ethnicity, educational attainment, number of children living in the home, and diabetes duration. Additionally, all models will include baseline A1C data source (study measured vs administrative health data), and group (FoodRx vs comparison) indicator variables. We will include random intercepts for participants (participant study ID) to account for within-subject correlation due to repeated measures, and for primary care clinics (clinic study ID) to account for clustering of participants within clinics.

In addition to per-protocol and as-treated analyses, we will conduct sensitivity analyses for diastolic blood pressure to examine impact of excluding patients who were started on anti-hypertensive therapy.

Lipids – Apolipoprotein B We will assess group differences in Apo B as a continuous outcome using mixed-effects linear regression. Models will be adjusted for baseline Apo B, and blocking variables (baseline A1C, gender, recruitment location). To improve the precision of effect estimates, models will also be adjusted for age, race/ethnicity, educational attainment, number of children living in the home, and diabetes duration. Additionally, all models will include baseline A1C data source (study measured vs administrative health data), and group (FoodRx vs comparison) indicator variables. We will include random intercepts for participants (participant study ID) to account for within-subject correlation due to repeated measures, and for primary care clinics (clinic study ID) to account for clustering of participants within clinics.

In addition to per-protocol and as-treated analyses, we will conduct sensitivity analyses for Apo B to examine the impact of excluding patients who were started on lipid-lowering therapy.

Lipids – Triglycerides We will assess group differences in triglycerides as a continuous outcome using mixed-effects linear regression. Models will be adjusted for baseline triglycerides, and blocking variables (baseline A1C, gender, recruitment location). To improve the precision of effect estimates, models will also be adjusted for age, race/ethnicity, educational attainment, number of children living in the home, and diabetes duration. Additionally, all models will include baseline A1C data source (study measured vs administrative health data), and group (FoodRx vs comparison) indicator variables. We will include random intercepts for participants

(participant study ID) to account for within-subject correlation due to repeated measures, and for primary care clinics (clinic study ID) to account for clustering of participants within clinics.

In addition to per-protocol and as-treated analyses, we will conduct sensitivity analyses for triglycerides to examine the impact of excluding patients who were started on lipid-lowering therapy.

Lipids – HDL We will assess group differences in HDL as a continuous outcome using mixed-effects linear regression. Models will be adjusted for baseline HDL, and blocking variables (baseline A1C, gender, recruitment location). To improve the precision of effect estimates, models will also be adjusted for age, race/ethnicity, educational attainment, number of children living in the home, and diabetes duration. Additionally, all models will include baseline A1C data source (study measured vs administrative health data), and group (FoodRx vs comparison) indicator variables. We will include random intercepts for participants (participant study ID) to account for within-subject correlation due to repeated measures, and for primary care clinics (clinic study ID) to account for clustering of participants within clinics.

In addition to per-protocol and as-treated analyses, we will conduct sensitivity analyses for HDL to examine the impact of excluding patients who were started on lipid-lowering therapy.

BMI We will assess group differences in BMI as a continuous outcome using mixed-effects linear regression. Models will be adjusted for baseline BMI, and blocking variables (baseline A1C, gender, recruitment location). To improve the precision of effect estimates, models will also be adjusted for age, race/ethnicity, educational attainment, number of children living in the home, and diabetes duration. Additionally, all models will include baseline A1C data source (study measured vs administrative health data), and group (FoodRx vs comparison) indicator variables. We will include random intercepts for participants (participant study ID) to account for within-subject correlation due to repeated measures, and for primary care clinics (clinic study ID) to account for clustering of participants within clinics.

In addition to per-protocol and as-treated analyses, we will conduct sensitivity analyses for BMI to examine the impact of BMI as an ordinal outcome (underweight/healthy weight, overweight, obese) using logistic regression models.

Waist Circumference We will assess group differences in waist circumference as a continuous outcome using mixed-effects linear regression. Models will be adjusted for baseline waist circumference, and blocking variables (baseline A1C, gender, recruitment location). To improve the precision of effect estimates, models will also be adjusted for age, race/ethnicity, educational attainment, number of children living in the home, and diabetes duration. Additionally, all models will include baseline A1C data source (study measured vs administrative health data), and group (FoodRx vs comparison) indicator variables. We will include random intercepts for participants (participant study ID) to account for within-subject correlation due to repeated measures, and for primary care clinics (clinic study ID) to account for clustering of participants within clinics.

In addition to per-protocol and as-treated analyses, we will conduct sensitivity analyses for waist circumference to examine the impact of waist circumference as a binary outcome for men (circumference ≥ 102 cm/40 inches), and women (circumference ≥ 88 cm/35 inches) using mixed-effects logistic regression models.

Need for Antihyperglycemic Medication/Insulin We will assess group differences in need for antihyperglycemic medication/insulin as an ordinal outcome using mixed-effects logistic regression. Models will be adjusted for baseline need for antihyperglycemic medication/insulin, and blocking variables (baseline A1C, gender, recruitment location). Additionally, all models will include baseline A1C data source (study measured vs administrative health data), and group (FoodRx vs comparison) indicator variables. To improve the precision of effect estimates, models will also be adjusted for age, race/ethnicity, educational attainment, number of children living in the home, and diabetes duration. We will include random intercepts for participants

(participant study ID) to account for within-subject correlation due to repeated measures, and for primary care clinics (clinic study ID) to account for clustering of participants within clinics.

In addition to per-protocol and as-treated analyses, we will conduct sensitivity analyses for need for antihyperglycemic medication/insulin to examine the impact of excluding patients whose medication/insulin therapy remained unchanged during the 3 months prior to their program start date, throughout the program, and when participants taking insulin are excluded.

Preliminary Auxiliary Variables

We will consider the following preliminary auxiliary variables based on theoretical relevance for the following outcomes.

Primary Outcome	
12-month A1C	Baseline A1C *or* fructosamine, systolic blood pressure, Apo B, BMI *or* waist circumference, duration of diabetes, insulin use, age, race/ethnicity, annual household income, educational attainment, number of children living in the home, diabetes duration;
Secondary Outcomes	
6-month A1C	Baseline A1C *or* fructosamine, systolic blood pressure, Apo B, BMI *or* waist circumference, duration of diabetes, insulin use, age, race/ethnicity, annual household income, educational attainment, number of children living in the home, diabetes duration;
18-month A1C	Baseline A1C *or* fructosamine, systolic blood pressure, Apo B, BMI *or* waist circumference, duration of diabetes, insulin use, age, race/ethnicity, annual household income, educational attainment, number of children living in the home, diabetes duration;
Elevated A1C	Baseline A1C *or* fructosamine, systolic blood pressure, Apo B, BMI *or* waist circumference, duration of diabetes, insulin use, age, race/ethnicity, annual household income, educational attainment, number of children living in the home, diabetes duration;
Fructosamine	Baseline A1C *or* fructosamine, systolic blood pressure, Apo B, BMI *or* waist circumference, duration of diabetes, insulin use, age, race/ethnicity, annual household income, educational attainment, number of children living in the home, diabetes duration;
Blood Pressure (systolic, diastolic)	Baseline A1C *or* fructosamine, BMI, employment status, age, race/ethnicity, annual household income, educational attainment, number of children living in the home, diabetes duration;
Lipids	Baseline A1C *or* fructosamine, BMI, employment status, age, race/ethnicity, annual household income, educational attainment, number of children living in the home, diabetes duration;
BMI	Baseline A1C, baseline waist circumference, blood lipids, employment status, physical activity level, age, race/ethnicity, annual household income, educational attainment, number of children living in the home, diabetes duration;
Waist Circumference	Baseline A1C, baseline BMI, blood lipids, employment status, physical activity level, age, race/ethnicity, annual household income, educational attainment, number of children living in the home, diabetes duration;
Need for medication/insulin	Fructosamine, baseline A1C, systolic blood pressure, blood lipids, insulin use, age, race/ethnicity, annual household income, educational attainment, number of children living in the home, diabetes duration;

7.5 Second Manuscript

This paper will report results for dietary patterns (secondary outcome), which includes dietary intake, UPF, and skin carotenoids at 6- and/or 12-months.

Dietary Intake

We will assess group differences in HEFI-2019 total and component scores as continuous outcomes using mixed-effects linear regression. Models will be adjusted for baseline HEFI-2019 total and component scores, and blocking variables (baseline A1C, gender, recruitment location). To improve the precision of effect estimates, models will also be adjusted for age, race/ethnicity, educational attainment, number of children living in the home, marital status, smoking status, dietary recall day (for 2 recalls: 2 weekend days, 2 weekdays, 1 weekend and 1 weekday; for 1 recall: 1 weekend, or 1 weekday), and usual intake (more than usual, usual, less than usual intake). Additionally, all models will include baseline A1C data source (study measured vs administrative health data), and group (FoodRx vs comparison) indicator variables. We will include random intercepts for participants (participant study ID) to account for within-subject correlation due to repeated measures, and for primary care clinics (clinic study ID) to account for clustering of participants within clinics. Missing data for covariates will be addressed using full information maximum likelihood.

We will conduct subgroup analyses for HEFI-2019 scores by baseline household food insecurity severity (marginal, moderate, severe), Indigenous identity (self-identified as First Nations, Inuk, Métis), gender (man, woman, gender diverse), recruitment location (urban setting, rural setting, Indigenous primary care clinic), baseline A1C (≤8.5%, ≥8.6%), and supplement intake.

In addition to per-protocol and as-treated analyses, we will conduct sensitivity analyses for HEFI-2019 scores to examine the impact on dietary patterns when they are assessed using the HEI-2015, and the impact of energy intake misreporting (i.e., reported total energy intake to predicted total energy expenditure) on the HEFI-2019 and HEI-2015 models. We will also calculate pairwise Pearson correlations between HEFI-2019 scores and skin carotenoids.[122]

Ultra-Processed Foods

We will assess group differences in proportion of energy consumed as UPF as a continuous outcome using mixed-effects linear regression. Models will be adjusted for baseline UPF, and blocking variables (baseline A1C, gender, recruitment location). To improve the precision of effect estimates, models will also be adjusted for age, race/ethnicity, educational attainment, number of children living in the home, marital status, and smoking status. Additionally, all models will include baseline A1C data source (study measured vs administrative health data), and group (FoodRx vs comparison) indicator variables. We will include random intercepts for participants (participant study ID) to account for within-subject correlation due to repeated measures, and for primary care clinics (clinic study ID) to account for clustering of participants within clinics. Missing data for covariates will be addressed using full information maximum likelihood.

In addition to per-protocol and as-treated analyses, we will conduct sensitivity analyses for UPF to examine the impact of energy intake misreporting (i.e., reported total energy intake to predicted total energy expenditure) in UPF models.

Skin Carotenoids

We will assess group differences in skin carotenoids as a continuous outcome using mixed-effects linear regression. Models will be adjusted for baseline skin carotenoid scores, and blocking variables (baseline A1C, gender, recruitment location). To improve the precision of effect estimates, models will also be adjusted for age, race/ethnicity, educational attainment, number of children living in the home, marital status, smoking status, supplement intake, and season of measurement (spring, summer, autumn, winter). Additionally, all models will include baseline A1C data source (study measured vs administrative health data), and group (FoodRx vs

comparison) indicator variables. We will include random intercepts for participants (participant study ID) to account for within-subject correlation due to repeated measures, and for primary care clinics (clinic study ID) to account for clustering of participants within clinics. Missing data for covariates will be addressed using full information maximum likelihood.

In addition to per-protocol and as-treated analyses, we will conduct sensitivity analyses for skin carotenoids to examine the impact on dietary patterns when they are assessed using the HEI-2015.

7.6 Third Manuscript

This paper will report results for household food insecurity presence and severity (secondary outcome), perceived income adequacy, and subjective social status (exploratory outcomes) at 6- and/or 12-months.

Household Food Insecurity

We will assess group differences in presence of household food insecurity as a binary outcome using mixed-effects logistic regression, and severity of household food insecurity as an ordinal outcome using mixed-effects logistic regression. Models will be adjusted for baseline severity of household food insecurity, and blocking variables (baseline A1C, gender, recruitment location). To improve the precision of effect estimates, models will also be adjusted for age, race/ethnicity, immigrant status, educational attainment, annual household income, home ownership, number of children living in the home, marital status, and diabetes duration. Additionally, all models will include baseline A1C data source (study measured vs administrative health data), and group (FoodRx vs comparison) indicator variables. We will include random intercepts for participants (participant study ID) to account for within-subject correlation due to repeated measures, and for primary care clinics (clinic study ID) to account for clustering of participants within clinics. Missing data for covariates will be addressed using full information maximum likelihood.

We will conduct subgroup analyses for household food insecurity by gender, recruitment location (urban setting, rural setting, Indigenous primary care clinic), Indigenous identity (self-identified as First Nations, Inuk, Métis), baseline A1C (6.5%-8.5%; 8.6%-12%).

We will conduct dose-response analyses to examine whether severity of household food insecurity differs based on the total value of incentives redeemed, a continuous variable, in the first 6 months for the mid-intervention analysis, and in the full 12-months for the post-intervention analysis.

In addition to per-protocol and as-treated analyses, we will conduct sensitivity analyses for household food insecurity to examine the impact on results when food insecurity is modelled as a continuous outcome using mixed-effects linear regression.[123]

Perceived Income Adequacy

We will assess group differences in perceived income adequacy as a binary outcome using mixed-effects logistic regression. Models will be adjusted for baseline perceived income adequacy, and blocking variables (baseline A1C, gender, recruitment location). To improve the precision of effect estimates, models will also be adjusted for age, race/ethnicity, immigrant status, educational attainment, annual household income, home ownership, number of children living in the home, marital status, and diabetes duration. Additionally, all models will include baseline A1C data source (study measured vs administrative health data), and group (FoodRx vs comparison) indicator variables. We will include random intercepts for participants (participant study ID) to account for within-subject correlation due to repeated measures, and for primary care clinics (clinic study ID) to account for clustering of participants within clinics. Missing data for covariates will be addressed using full information maximum likelihood.

We will conduct per-protocol and as-treated sensitivity analyses for perceived income adequacy as described in Section 7.2.

Subjective Social Status

We will assess group differences in subjective social status as a continuous outcome using mixed-effects linear regression. Models will be adjusted for baseline subjective social status, and blocking variables (baseline A1C, gender, recruitment location). To improve the precision of effect estimates, models will also be adjusted for age, race/ethnicity, immigrant status, educational attainment, annual household income, home ownership, number of children living in the home, marital status, and diabetes duration. Additionally, all models will include baseline A1C data source (study measured vs administrative health data), and group (FoodRx vs comparison) indicator variables. We will include random intercepts for participants (participant study ID) to account for within-subject correlation due to repeated measures, and for primary care clinics (clinic study ID) to account for clustering of participants within clinics. Missing data for covariates will be addressed using full information maximum likelihood.

We will conduct per-protocol and as-treated sensitivity analyses for subjective social status as described in Section 7.2.

7.7 Fourth Manuscript

This paper will report results for diabetes-specific PROMs (secondary outcomes) at 12 months, including diabetes self-efficacy, diabetes self-management, diabetes distress, diabetes competing demands, perceived financial barriers to chronic disease care, and hypoglycemic episodes.

Diabetes Self-Efficacy

We will assess group differences in diabetes self-efficacy as a continuous outcome using mixed-effects linear regression. Models will be adjusted for baseline diabetes self-efficacy, and blocking variables (baseline A1C, gender, recruitment location). To improve the precision of effect estimates, models will also be adjusted for age, race/ethnicity, educational attainment, annual household income, years lived in Canada, household composition, marital status, and diabetes duration. Additionally, all models will include baseline A1C data source (study measured vs administrative health data), and group (FoodRx vs comparison) indicator variables. We will include random intercepts for participants (participant study ID) to account for within-subject correlation due to repeated measures, and for primary care clinics (clinic study ID) to account for clustering of participants within clinics. Missing data for covariates will be addressed using full information maximum likelihood.

We will conduct subgroup analyses for diabetes self-efficacy by gender, severity of household food insecurity, recruitment location (urban setting, rural setting, Indigenous primary care clinic), Indigenous identity (self-identified as First Nations, Inuk, Métis), baseline A1C (6.5%-8.5%; 8.6%-12%), and insulin use (yes, any vs no, none).

In addition to per-protocol and as-treated analyses, we will conduct sensitivity analyses for diabetes self-efficacy as described in Section 7.2.

Diabetes Self-Management

We will assess group differences in diabetes self management as a continuous outcome using mixed-effects linear regression. Models will be adjusted for baseline diabetes self management, and blocking variables (baseline A1C, gender, recruitment location). To improve the precision of effect estimates, models will also be adjusted for age, race/ethnicity, educational attainment, annual household income, years lived in Canada, household composition, marital status, and diabetes duration. Additionally, all models will include baseline A1C data source (study measured vs administrative health data), and group (FoodRx vs comparison) indicator variables. We will include random intercepts for participants (participant study ID) to account for within-subject correlation due to repeated measures, and for primary care clinics (clinic study ID) to account for clustering of participants within clinics. Missing data for covariates will be addressed using full information maximum likelihood.

In addition to per-protocol and as-treated analyses, we will conduct sensitivity analyses for diabetes self management as described in Section 7.2.

Diabetes Distress

We will assess group differences in diabetes distress as a continuous outcome using mixed-effects linear regression. Models will be adjusted for baseline diabetes distress, and blocking variables (baseline A1C, gender, recruitment location). To improve the precision of effect estimates, models will also be adjusted for age, race/ethnicity, educational attainment, annual household income, years lived in Canada, household composition, marital status, and diabetes duration. Additionally, all models will include baseline A1C data source (study measured vs administrative health data), and group (FoodRx vs comparison) indicator variables. We will include random intercepts for participants (participant study ID) to account for within-subject correlation due to repeated measures, and for primary care clinics (clinic study ID) to account for clustering of participants within clinics. Missing data for covariates will be addressed using full information maximum likelihood.

In addition to per-protocol and as-treated analyses, we will conduct sensitivity analyses for diabetes distress to examine the impact on results when diabetes distress is modelled as an ordinal outcome using mixed-effects logistic regression.

Diabetes Competing Demands

We will assess group differences in diabetes competing demands as a binary outcome using mixed-effects logistic regression. Models will be adjusted for baseline diabetes competing demands, and blocking variables (baseline A1C, gender, recruitment location). To improve the precision of effect estimates, models will also be adjusted for age, race/ethnicity, educational attainment, annual household income, years lived in Canada, household composition, marital status, and diabetes duration. Additionally, all models will include baseline A1C data source (study measured vs administrative health data), and group (FoodRx vs comparison) indicator variables. We will include random intercepts for participants (participant study ID) to account for within-subject correlation due to repeated measures, and for primary care clinics (clinic study ID) to account for clustering of participants within clinics. Missing data for covariates will be addressed using full information maximum likelihood.

In addition to per-protocol and as-treated analyses, we will conduct sensitivity analyses for diabetes competing demands as described in Section 7.2.

Hypoglycemic Episode Frequency

We will assess group differences in hypoglycemic episode frequency as an ordinal outcome using mixed-effects logistic regression. Models will be adjusted for baseline hypoglycemic episode frequency, and blocking variables (baseline A1C, gender, recruitment location). To improve the precision of effect estimates, models will also be adjusted for age, race/ethnicity, educational attainment, annual household income, years lived in Canada, household composition, marital status, diabetes duration, and physical activity level. Additionally, all models will include baseline A1C data source (study measured vs administrative health data), and group (FoodRx vs comparison) indicator variables. We will include random intercepts for participants (participant study ID) to account for within-subject correlation due to repeated measures, and for primary care clinics (clinic study ID) to account for clustering of participants within clinics. Missing data for covariates will be addressed using full information maximum likelihood.

In addition to per-protocol and as-treated analyses, we will conduct sensitivity analyses for hypoglycemic episode frequency as described in Section 7.2.

7.8 Fifth Manuscript

This paper will report results for healthcare resource use, psychosocial well-being and self-rated health (secondary outcomes), and work productivity (exploratory outcome) at 12-months.

Healthcare Costs

We will assess group differences in healthcare costs using annual total healthcare costs as the outcome using a Generalized Linear Model with a Tweedie distribution and log link, which accounts for skewed distributions by modeling costs using a compound Poisson-Gamma distribution. This approach will effectively handle zero-inflated and highly variable expenditure data. Models will be adjusted for baseline healthcare resource use (i.e. previous years cost), and blocking variables (baseline A1C, gender, recruitment location). To improve the precision of effect estimates, models will also be adjusted for age, race/ethnicity, educational attainment, number of children living in the home, and diabetes duration.

Additionally, all models will include baseline A1C data source (study measured vs administrative health data), and group (FoodRx vs comparison) indicator variables. We will include random intercepts for participants (participant study ID) to account for within-subject correlation due to repeated measures, and for primary care clinics (clinic study ID) to account for clustering of participants within clinics. Missing data for covariates will be addressed using full information maximum likelihood.

We will conduct subgroup analyses for healthcare costs by gender, severity of household food insecurity, recruitment location (urban setting, rural setting, Indigenous primary care clinic), Indigenous identity (self-identified as First Nations, Inuk, Métis), baseline A1C (6.5%-8.5%; 8.6%-12%), and insulin use.

In addition to per-protocol and as-treated analyses, we will conduct sensitivity analyses for healthcare costs to examine the impact of pharmacy costs.

Self-Rated Health

We will assess group differences in EQ-5D-5L index values as a continuous outcome using mixed-effects linear regression. Models will be adjusted for baseline EQ-5D-5L index values, and blocking variables (baseline A1C, gender, recruitment location). To improve the precision of effect estimates, models will also be adjusted for age, race/ethnicity, educational attainment, number of children living in the home, and diabetes duration.

Additionally, all models will include baseline A1C data source (study measured vs administrative health data), and group (FoodRx vs comparison) indicator variables. We will include random intercepts for participants (participant study ID) to account for within-subject correlation due to repeated measures, and for primary care clinics (clinic study ID) to account for clustering of participants within clinics. Missing data for covariates will be addressed using full information maximum likelihood.

In addition to per-protocol and as-treated analyses, we will conduct sensitivity analyses for EQ-5D-5L index values to examine the impact of individual health dimensions on differences in overall utility.

Work Productivity and Activity Impairment

We will assess group differences in Work Productivity and Activity Impairment scores as a continuous outcome using mixed-effects binomial regression. Models will be adjusted for baseline Work Productivity and Impairment scores, and blocking variables (baseline A1C, gender, recruitment location). To improve the precision of effect estimates, models will also be adjusted for age, race/ethnicity, educational attainment, number of children living in the home, and diabetes duration.

Additionally, all models will include baseline A1C data source (study measured vs administrative health data), and group (FoodRx vs comparison) indicator variables. We will include random intercepts for participants (participant study ID) to account for within-subject correlation due to repeated measures, and for primary care clinics (clinic study ID) to account for clustering of participants within clinics. Missing data for covariates will be addressed using full information maximum likelihood.

In addition to per-protocol and as-treated analyses, we will conduct sensitivity analyses for Work Productivity and Impairment scores as described in Section 7.2.

Psychosocial Well-Being

We will assess group differences in WHO Well-Being Index scores as a continuous outcome using mixed-effects linear regression. Models will be adjusted for baseline WHO Well-Being Index scores, and blocking variables (baseline A1C, gender, recruitment location). To improve the precision of effect estimates, models will also be adjusted for age, race/ethnicity, educational attainment, number of children living in the home, and diabetes duration.

Additionally, all models will include baseline A1C data source (study measured vs administrative health data), and group (FoodRx vs comparison) indicator variables. We will include random intercepts for participants (participant study ID) to account for within-subject correlation due to repeated measures, and for primary care clinics (clinic study ID) to account for clustering of participants within clinics. Missing data for covariates will be addressed using full information maximum likelihood.

In addition to per-protocol and as-treated analyses, we will conduct sensitivity analyses for WHO Well-Being Index scores by 1) modeling scores as a binary outcome using validated cut points (≤50 for impaired well-being, ≤ 28 for likely depression), and 2) assessing clinically meaningful improvements, defined as a ≥ 10-point increase on the 0-100 scale[91, 124] using mixed-effects logistic regression.

7.9 Sixth Manuscript

This paper will assess for evidence of improvements in trade-offs that might result from reduced food insecurity through the FoodRx intervention. In this paper, we will report results for self-reported medication adherence, physical activity level, and perceived financial barriers to chronic disease care.

Medication Adherence

We will assess group differences in medication adherence as a continuous outcome using mixed-effects linear regression. Models will be adjusted for baseline medication adherence, and blocking variables (baseline A1C, gender, recruitment location). To improve the precision of effect estimates, models will also be adjusted for age, race/ethnicity, educational attainment, annual household income, marital status, number of children living in the home, and diabetes duration.

Additionally, all models will include baseline A1C data source (study measured vs administrative health data), and group (FoodRx vs comparison) indicator variables. We will include random intercepts for participants (participant study ID) to account for within-subject correlation due to repeated measures, and for primary care clinics (clinic study ID) to account for clustering of participants within clinics.

In addition to per-protocol and as-treated analyses, we will conduct sensitivity analyses for medication adherence as described in Section 7.2.

Physical Activity Level

We will assess group differences in physical activity level as a discrete outcome using mixed-effects Poisson regression. Models will be adjusted for baseline physical activity level, and blocking variables (baseline A1C, gender, recruitment location). To improve the precision of effect estimates, models will also be adjusted for age, race/ethnicity, educational attainment, annual household income, marital status, number of children living in the home, BMI, smoking status, and diabetes duration. Additionally, all models will include baseline A1C data source (study measured vs administrative health data), and group (FoodRx vs comparison) indicator variables. We will include random intercepts for participants (participant study ID) to account for within-subject correlation due to repeated measures, and for primary care clinics (clinic study ID) to account for clustering of participants within clinics. Missing data for covariates will be addressed using full information maximum likelihood.

In addition to per-protocol and as-treated analyses, we will conduct sensitivity analyses for physical activity level to examine the impact on results when physical activity level is modeled as an ordinal outcome using mixed-effects logistic regression.

Perceived Financial Barriers to Chronic Disease Care

We will assess group differences in perceived financial barriers to chronic disease care as a binary outcome using mixed-effects logistic regression. Models will be adjusted for baseline perceived financial barriers to chronic disease care, and blocking variables (baseline A1C, gender, recruitment location). To improve the precision of effect estimates, models will also be adjusted for age, race/ethnicity, educational attainment, annual household income, years lived in Canada, household composition, marital status, and diabetes duration. Additionally, all models will include baseline A1C data source (study measured vs administrative health data), and group (FoodRx vs comparison) indicator variables. We will include random intercepts for participants (participant study ID) to account for within-subject correlation due to repeated measures, and for primary care clinics (clinic study ID) to account for clustering of participants within clinics. Missing data for covariates will be addressed using full information maximum likelihood.

In addition to per-protocol and as-treated analyses, we will conduct sensitivity analyses for perceived financial barriers to chronic disease care as described in Section 7.2.

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