



BMJ Open Healthy food prescription incentive programme for adults with type 2 diabetes who are experiencing food insecurity: protocol for a randomised controlled trial, modelling and implementation studies

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ABSTRACT

Introduction The high cost of many healthy foods poses a challenge to maintaining optimal blood glucose levels for adults with type 2 diabetes mellitus who are experiencing food insecurity, leading to diabetes complications and excess acute care usage and costs. Healthy food prescription programmes may reduce food insecurity and support patients to improve their diet quality, prevent diabetes complications and avoid acute care use. We will use a type 2 hybrid-effectiveness design to examine the reach, effectiveness, adoption, implementation and maintenance (RE-AIM) of a healthy food prescription incentive programme for adults experiencing food insecurity and persistent hyperglycaemia. A randomised controlled trial (RCT) will investigate programme effectiveness via impact on glycosylated haemoglobin (primary outcome), food insecurity, diet quality and other clinical and patient-reported outcomes. A modelling study will estimate longer-term programme effectiveness in reducing diabetes-related complications, resource use and costs. An implementation study will examine all RE-AIM domains to understand determinants of effective implementation and reasons behind programme successes and failures.

Methods and analysis 594 adults who are experiencing food insecurity and persistent hyperglycaemia will be randomised to a healthy food prescription incentive (n=297) or a healthy food prescription comparison group (n=297). Both groups will receive a healthy food prescription. The incentive group will additionally receive a weekly incentive (CAD\$10.50/household member) to purchase healthy foods in supermarkets for 6 months. Outcomes will be assessed at baseline and follow-up (6 months) in the RCT and analysed using mixed-effects regression. Longer-term outcomes will be modelled using the UK Prospective Diabetes Study outcomes simulation model-2. Implementation processes and outcomes will be continuously measured via quantitative and qualitative data.

Strengths and limitations of this study

- We will investigate the reach, effectiveness, adoption, implementation and maintenance of a healthy food prescription incentive programme for adults who are experiencing food insecurity and persistent hyperglycaemia.
- A randomised controlled trial and a modelling study will demonstrate the short- and longer-term impacts of the programme on glycosylated haemoglobin, other health-related outcomes, resource use and costs.
- An implementation study will support translation of findings into practice by examining determinants of effective implementation and reasons behind programme successes and failures.
- Patients' medication/insulin regimes may be intensified/de-intensified during the study and thus sensitivity analyses will be conducted to examine the potential impact of such changes on study findings.

Ethics and dissemination Ethical approval was obtained from the University of Calgary and the University of Alberta. Findings will be disseminated through reports, lay summaries, policy briefs, academic publications and conference presentations.

Trial registration number NCT04725630.

Protocol version Version 1.1; February 2022

BACKGROUND

Type 2 diabetes mellitus (T2DM) imposes a tremendous burden on healthcare systems

worldwide, as individuals with T2DM incur twice the healthcare costs as their age-matched and sex-matched counterparts.¹² The total economic costs of diabetes were US\$327 billion in 2017 in the USA, and CDN\$30 billion in Canada in 2019, making it among the most expensive chronic conditions in both nations.^{13 4} The human toll on individuals and their families is also substantial in terms of reduced quality of life associated with managing the disease.^{5 6} Many of these human and economic costs are avoidable, as adherence to a healthy diet within an overall diabetes management plan can yield clinically meaningful improvements in blood glucose levels, which can reduce diabetes complications over time.^{7–15} Average blood glucose levels are most often quantified using the glycosylated haemoglobin level (A1C), which represents the average blood sugar level over the previous 3 months.¹⁶ An absolute reduction of 0.5% in A1C is achievable through improving diet quality^{7 8} and is considered a clinically meaningful difference.¹⁷

The high and continually escalating costs of many healthy foods^{18 19} represents a formidable barrier to adhering to a healthy dietary pattern for individuals with T2DM, particularly for those who are experiencing food insecurity.^{20–24} Food insecurity refers to inadequate or insecure access to food due to financial constraints²⁵ and is a strong predictor of high-cost healthcare use.²⁶ Evidence indicates that individuals with T2DM who are experiencing food insecurity have lower diet quality than their food secure counterparts, leading to elevations in blood glucose levels,^{27–35} and high rates of diabetes complications and acute care use.^{29 32 36–39} 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.^{40–42} The coexistence of food insecurity and T2DM, therefore, has major implications for the sustainability of healthcare systems.

Although it is well known that food insecurity is a primary driver of acute care usage and costs, healthcare providers often lack effective strategies to address it. One approach to better address this problem is to assist patients who are experiencing food insecurity to purchase diabetes-appropriate foods through healthy food prescription programmes, which provide subsidies or incentives to improve access to healthy foods. Preliminary evidence from several studies suggests that these programmes may improve diet quality and self-reported health, while reducing food insecurity, A1C, hypertension and body mass index (BMI), including within Indigenous communities.^{43–59} Moreover, a recent meta-analysis of 13 studies found that healthy food prescription programmes may increase fruit and vegetable intake by 0.8 servings/day, reduce BMI by 0.6 kg/m² and reduce A1C by 0.8%, although the certainty of the evidence was rated as very low to moderate.⁶⁰ Qualitative data similarly suggest patients and care providers perceive financial, dietary and health benefits from these programmes, and support their ongoing delivery.^{43 50 61–63} Food prescription

programmes also appear to be cost-effective, with one recent modelling study indicating that a national healthy food prescription incentive programme in the USA could eliminate US\$100.2 billion in healthcare costs if implemented over the lifetime of beneficiaries.⁶⁴

Despite some promising initial findings, major knowledge gaps remain pertaining to the impact and optimal implementation of healthy food prescription programmes.⁶⁰ Most prior studies have been small and uncontrolled, and have examined a small number of self-reported outcomes using brief dietary^{44 45 48 63 65} and/or food insecurity screeners,^{47 50–53} and/or short descriptive surveys,^{44 61 63} rather than objective clinical outcomes. The majority of prior programmes have also subsidised the purchase of fruits and vegetables alone, without considering the relevance of entire dietary patterns to blood glucose levels and health outcomes.^{7 8 60} Moreover, there is virtually no understanding of the effectiveness and cost-effectiveness of these programmes over the longer-term, nor of optimal implementation strategies.⁶⁶

We will build on these initial findings through three concurrent studies, including a randomised controlled trial (RCT), a modelling study and an implementation study. We will use a type 2 hybrid effectiveness-implementation design, which entails dual testing of the effectiveness and implementation of an intervention.⁶⁷ Collective findings will be integrated to provide a comprehensive perspective of the reach, effectiveness, adoption, implementation and maintenance (RE-AIM)^{68 69} of a healthy food prescription incentive programme among adults who are experiencing food insecurity and persistent hyperglycaemia. First, the RCT will provide a basis for causal inference pertaining to programme effectiveness. It will entail an incentive to purchase a variety of healthy foods from all food groups, and will be powered to detect clinically meaningful changes in A1C, along with a comprehensive range of objective and self-reported health-related outcomes. A linked modelling study will provide a longer-term perspective of programme effectiveness in reducing diabetes-related complications, along with healthcare use and costs. Finally, a complementary implementation study will encompass quantitative and qualitative measures of all RE-AIM domains to support translation of research findings into practice and policy by helping to understand determinants of effective implementation and reasons behind programme successes and failures.

METHODS

Overview

Ethics, privacy and confidentiality

This research has been approved by the University of Calgary Conjoint Health Research Ethics Board (REB20-0543) and the University of Alberta Health Research Ethics Board Biomedical Panel (Pro00107116). Any protocol deviations will be

approved in advance by the board and updated in the clinical trials registry. All participants will provide informed consent prior to data collection (online supplemental additional file 1). Participant data will be anonymised and stored on a password-protected University server. Only the principal investigators and research coordinators will have access to identifiable participant information and the final trial datasets.

Setting

This research will take place in Alberta, Canada between May 2021 and December 2023. Participants will primarily be recruited through primary care and diabetes specialty clinics located in urban and rural communities, including clinics with an explicit focus on serving people who identify as Indigenous.

Study oversight

Scientific steering committee

A scientific steering committee will oversee all aspects of the research, receive and review reports from the study's advisory boards and subcommittees, and will have final decision-making authority. It will be comprised of the study's five co-principal investigators (DO, ES, RB, LLL and DJTC).

Advisory board

A multistakeholder advisory board will provide high-level oversight for the research and will advise the scientific steering committee on study conduct. Members will include policy-makers, academic experts, representatives from Alberta Health Services (the provincial health authority), an Indigenous public health expert and a patient.

Indigenous advisory board

An Indigenous advisory board will ensure that research activities within Indigenous clinics proceed in a culturally sensitive, relevant, responsive, equitable and reciprocal manner that is guided by Indigenous Ownership, Control, Access and Possession of data principles (OCAP)⁷⁰ and complies with Government of Canada guidance for Indigenous Research.^{71 72} The board will include Indigenous elders and patients, along with academic experts, policy-makers, managers and front-line practitioners from the public health and healthcare sectors who are themselves Indigenous, or who work closely with Indigenous peoples.

Primary care clinic subcommittee

The primary care clinic (PCC) subcommittee will include PCC managers, staff and patients. As participant recruitment and implementation of the intervention unfolds, PCC managers and staff will collect feedback from their respective clinics and will share it with the larger group as a learning tool and to inform ongoing adaptations.

Implementation support team

The implementation support team will consist of research coordinators and assistants who will execute the daily tasks required to administer, plan, support, monitor and evaluate the healthy food prescription incentive programme.

Patient and public involvement

This research has been informed by substantial prior^{73–77} and ongoing engagement with patients experiencing financial barriers to chronic disease care. Patient partners (who are not study participants) will help to pilot test infrastructural supports (eg, healthy food prescription pamphlet, usability of the list of eligible foods), care pathways and implementation processes, and will be members of the advisory boards and PCC subcommittee. Patients who are study participants will provide continuous programme feedback via a dedicated study help-line/email, and by completing implementation fidelity checklists. At the conclusion of the study, participants will be invited to describe their programme experiences via a postintervention questionnaire and during in-depth, semistructured interviews.

Lands and food hold deep cultural, symbolic and spiritual significance for Indigenous peoples.⁷⁸ Staff and patients from Indigenous PCCs will codesign clinical care pathways and other procedures that are context-specific and culturally appropriate for Indigenous patients, and that respect and promote Indigenous worldviews, particularly those surrounding food procurement and consumption. We will ensure that representatives from Indigenous clinics are involved at all stages of the research, including study design, pilot testing infrastructural supports, interpreting results and formulating conclusions, and that their agreement is obtained prior to communicating any research findings that pertain to them. As previously described, the Indigenous advisory board will also oversee all aspects of the research.

Evaluation framework and theory of change

RE-AIM^{68 69} will provide a structured means of integrating data from the RCT, modelling and implementation studies to understand the RE-AIM of the healthy food prescription incentive programme.

Our theory of change (figure 1) draws on Barnard *et al's*⁷⁹ conceptual model linking material needs insecurities with diabetes outcomes, and posits that reduced food insecurity and improved diet quality will be key mediators of improved blood glucose levels (quantified via A1C), which will help to reduce diabetes complications, and healthcare resource use and costs. Each construct will be examined to affirm or disprove the proposed pathway.

Randomised controlled trial

The RCT protocol adheres to the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) and Template for Intervention Description and Replication (TIDieR) reporting guidelines (table 1; online supplemental additional file 2–4).

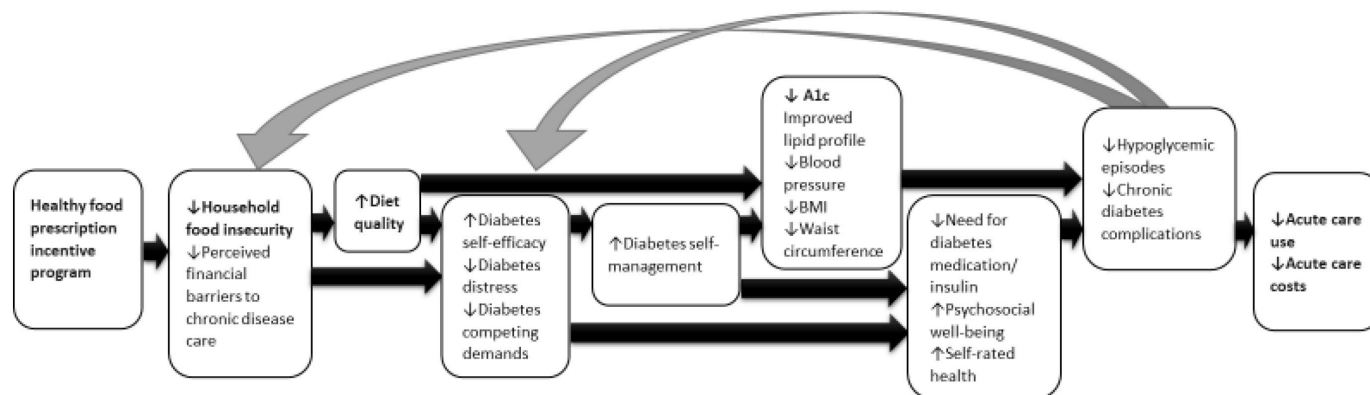


Figure 1 Healthy food prescription programme logic model. A1C an indicator of average blood glucose levels over the previous 3 months. A1C, glycosylated haemoglobin.

Study design and objectives

A 6-month, parallel-group RCT will examine the effectiveness of a healthy food prescription incentive programme, compared with a healthy food prescription alone, in improving the following outcomes among 594 adults who are experiencing food insecurity and persistent hyperglycaemia (ie, A1C 7%–12%):

1. Primary outcome: Average blood glucose levels measured by A1C.
2. Secondary outcomes:
 - a. Blood glucose levels: Proportion of patients with elevated A1C (ie, $\geq 8.5\%$); blood glucose measured by fructosamine.
 - b. Dietary intake: Diet quality; skin carotenoids.
 - c. Intermediate clinical outcomes: Blood lipids; blood pressure; BMI; waist circumference; need for antihyperglycaemic medication/insulin.
 - d. Patient-reported outcomes: Psychosocial well-being; self-rated health; diabetes self-efficacy; diabetes self-management; diabetes distress; diabetes competing demands; perceived financial barriers to chronic disease care; hypoglycaemic episodes; household food insecurity.
3. Exploratory outcomes: Subjective social status; perceived income adequacy; work productivity and activity impairment; medication and physical activity adherence.

Primary care clinics

PCCs will be recruited, including urban, rural and Indigenous clinics. To be eligible, clinics must serve lower-income patients, agree to allow their physicians, registered dietitians and/or nurses to dispense healthy food prescriptions, appoint a staff member to liaise with the implementation support team, and be willing to receive training. The final list of study sites, currently projected at 30 clinics, will be available in the clinicaltrials.gov registry.

Participants

Healthcare providers will use information from electronic medical records to identify patients with T2DM and

persistent hyperglycaemia (ie, A1C 7%–12%), including patients living in rural and urban areas, and those who identify as Indigenous. Potentially eligible patients will be invited to complete a brief screening questionnaire to identify risk of food insecurity based on the Hunger Vital Sign,^{80–82} and perceived income adequacy.^{83–85} Eligible patients will be adults (18–85 years) with T2DM (or diabetes of unknown aetiology) and persistent hyperglycaemia (ie, A1C 7%–12%) who are experiencing food insecurity and/or perceive that it is difficult/very difficult to make ends meet, do not reside in a facility that provides meals (eg, shelter, long-term care, prison), and can communicate in English or have someone to translate. Patients will be excluded if they have an A1C < 7% or > 12% (given the recommendation for antihyperglycaemic treatment escalation for those with A1C > 12%), have signs/symptoms of metabolic decompensation, have an eating disorder, have experienced diabetic ketoacidosis or a hyperglycaemic hyperosmolar emergency in the past year, or if they experienced a severe hypoglycaemic event in the past 3 months. Patients will also be excluded if they are pregnant or trying to conceive, breast feeding, participating in other clinical trials, if someone in their household is currently or has previously participated, if they are unwilling/unable to shop in study-affiliated supermarkets for the next 6 months, if they plan to leave Canada for more than 2 weeks in the next 6 months, or if they will not be able to complete data collection at 6 months.

Eligible patients will be asked to provide consent to their healthcare provider to be contacted by the research team. A research assistant will contact patients to confirm all eligibility criteria have been met, obtain informed consent and provide instructions for collection of baseline data. Participants may elect to report baseline patient-reported data immediately over the telephone, or independently via the study's online data collection platforms. Any patients identified as at risk of food insecurity at screening, but who do not respond affirmatively to any of the items on the full 18-item Household Food Security Survey Module or who do not indicate that it is difficult/very difficult to make ends meet during baseline

Table 1 SPIRIT flow diagram

	Study period					
	Enrolment	Allocation	Postallocation	Close-out	Follow-up	
	-T ₁	0	T ₁ Baseline	T ₂ +6 mos	T ₃ +12 mos	T ₄ +10 years
Time point						
Enrolment						
Eligibility screen	X					
Informed consent	X					
Randomisation		X				
Allocation		X				
Interventions						
Healthy food prescription incentive group			↔			
Healthy food prescription comparison group			↔			
Assessments						
Sociodemographic and health-related characteristics			X	X		
Primary outcome: haemoglobin A1C			X	X		
Patient-reported outcomes: psychosocial well-being, self-rated health, diabetes self-efficacy, diabetes self-management, diabetes distress, diabetes competing demands, perceived financial barriers to chronic disease care, hypoglycaemic episodes, work productivity and activity impairment, household food insecurity, subjective social status, perceived income adequacy, medication and physical activity adherence			X	X		
Biochemical measures: fructosamine, skin carotenoids, blood lipids, serum creatinine, albumin-to-creatinine ratio, haemoglobin			X	X		
Physical measures: weight, height, waist circumference, blood pressure, heart rate			X	X		
Urinalysis: albuminuria			X	X		
Diet quality			Twice	Twice		
Administrative health data: Medication/insulin type and dose, comorbidities, diabetes complications, haemoglobin A1C			X	X		
Patient, care provider and clinic characteristics, reasons for non-participation and drop-out			↔			

Continued

Table 1 Continued

Time point	Study period			
	Enrolment	Allocation	Postallocation	Follow-up
	-T ₁	0	T ₁ Baseline	T ₂ +6 mos T ₃ +12 mos T ₄ +10 years
Healthy food prescriptions prescribed			X	
Healthy food incentives offered, earned and redeemed				
Questionnaires			X	
Qualitative interviews, observations, meeting notes, notes on emails/calls to help-line				
Implementation fidelity				

A1C, glycosylated haemoglobin; SPIRIT, Standard Protocol Items: Recommendations for Interventional Trials.

data collection will be excluded. Participants will have biochemical and physical measurements performed at a community laboratory or at their PCC. Participants with an A1C outside the 7%–12% range will be excluded at that point. All participants will subsequently receive a healthy food prescription pamphlet from a healthcare provider (ie, physician, nurse, registered dietitian) and a brief, high-level overview of its contents using standardised teaching guidelines, either virtually or in-person during a clinic visit.

Sample size calculation

Based on local administrative data, we expect a mean baseline A1C of 8.5% (SD=1.4%) in our population.⁸⁶ Assuming 5% type I error, 30% attrition⁸⁷ and potential design effects based on sampling in different clinics (25% inflation), 594 participants are required for 90% power to detect a difference in A1C of 0.5%, which is often considered a minimally important clinical difference.¹⁷

Randomisation and blinding

Following baseline data collection and delivery of the healthy food prescription pamphlet, participants will be randomised to a healthy food prescription incentive (n=297) or a healthy food prescription comparison group (n=297) with a 1:1 allocation ratio using a computer-generated, concealed, blocked randomisation sequence created by an independent statistician. Blocking variables will include gender, clinic type/location (urban, rural, Indigenous) and baseline A1C (7%–8.5%, 8.6%–12%). Allocation concealment will be ensured via secure storage of the randomisation sequence separately from the participant database, which will only be accessible by the statistician. To ensure researcher blinding, allocation assignment will be operationalised via REDCap (Research Electronic Data Capture) following completion of baseline data collection. Intervention assignment will be communicated by research assistants via a telephone call. Participants cannot be blinded to treatment allocation, however details of the healthy food incentive, including its monetary value and the types of foods that are eligible, will not be divulged to participants in the comparison group. Care providers, individuals who collect biochemical and physical measurements and data analysts will be blinded to group allocation.

INTERVENTION

Development of the healthy food prescription incentive programme was informed by the social prescribing literature, Research to Equip Primary Healthcare for Equity principles of equity-oriented healthcare,⁸⁸ initiatives elsewhere (eg, Wholesome Wave⁸⁹), and stakeholder consultation. The comparison group will receive a one-time healthy food prescription pamphlet. The incentive group will receive a one-time healthy food prescription pamphlet and a weekly incentive valued at CDN\$10.50/household member (ie, CDN\$1.50/household member

per day) to purchase healthy foods in study-affiliated supermarkets. Thus, the study is designed to test the impact of a healthy food incentive, which is an intervention that targets economic rather than knowledge-related barriers to healthy eating. Aside from labelling the nutritional advice delivered as a ‘prescription’ (which may have some independent impact on participants’ behaviour), the healthy food prescription closely mimics current care (ie, nutrition counselling) and is unlikely to substantially change dietary intake in the context of significant economic constraints.^{90–95} The value of the incentive exceeds the benefit provided by many similar US programmes^{56 89} in order to more closely bridge the gap in food spending between food secure and insecure households in Canada.⁹⁶ The value of the incentive that each household will receive will be calculated based on the number of household members at baseline and will remain consistent throughout the intervention regardless of changes in household size. A household member is defined as a partner or a dependent child or adult who resides at the same location at least 50% of the time. The intervention will be delivered over 6 months to allow sufficient time for dietary changes to be reflected in approximately two AIC cycles.⁹⁷

The healthy food prescription pamphlet was designed by registered dietitians and modelled after a previous food prescription programme to be a visually appealing, low literacy resource⁹⁸ (online supplemental additional file 5). The cover page contains the following preprinted prescription ‘I prescribe a healthy eating pattern of minimally processed foods that have little to no added fat, sugar or salt,’ with space for the care provider to add their signature, date and patient information. The inner pages outline an evidence-based healthy dietary pattern, with key messages to consume a variety of whole, minimally processed foods from all food groups with little to no added fat, sugar or salt, to spread carbohydrate foods over the day, to satisfy thirst with water, and to avoid sugary drinks, refined grains, sweets, confectionary and desserts.^{7 99} A diabetes-appropriate recipe is provided along with links to connect patients with sources of free/lower-cost food, additional recipes, nutrition information, other helpful community services and sources of emergency food assistance. Feedback from PCC staff, patients and the advisory boards was incorporated into the final version of the pamphlet.

The healthy food incentive consists of a weekly incentive valued at CDN\$10.50/household member to purchase healthy foods in study-affiliated supermarkets. The list of incentive-eligible foods includes whole, minimally processed foods with little to no added fat, sugar or salt from all food groups^{7 99} (table 2). Once a household reaches their spending threshold they will receive an immediate payback in loyalty card points of the same value (ie, a redeemable value of CDN\$10.50/household member). For instance, if a two-person household spends CDN\$21 over a 1-week period on incentive-eligible foods (in a single shop or across multiple shops), they will

Table 2 Foods that qualify for the healthy food incentive

Food group	Eligible items
Vegetables and fruits	Fresh vegetables and fruit
	Frozen vegetables and fruit
	Canned vegetables
Meat, poultry and fish	Fresh meat, poultry and fish
	Canned fish
Meat alternatives	Dried or canned lentils, chickpeas or beans
	Whole eggs
	Whole almonds
Dairy products	White cow’s milk
	Unsweetened fortified soy beverage
	Plain yoghurt
	Hard cheddar cheese
Whole grain foods	Whole grain pasta
	Brown rice
	Large flake rolled oats
	100% whole wheat bread
	Bran flakes cereal

receive a loyalty card points payback with a redeemable value of CDN\$21. The value of the points incentive is capped at CDN\$10.50/household member, meaning that households that exceed this spending threshold will not receive additional points, while those that do not meet this threshold will not receive any points that week. The offers will be renewed weekly. While progress towards the minimum spend for triggering the points payback will be reset weekly, loyalty card points never expire and will carry over between weeks if left unspent. Loyalty card points can be redeemed in CDN\$10 increments to purchase anything in store, with no restrictions. Importantly, while there is no requirement to do so, participants may use loyalty card points as payment for purchases that will earn them even more points in return (ie, by using their points to purchase incentive-eligible foods).

At baseline, participants’ loyalty cards will be preloaded with the dollar amount of points that matches their household size so that they can earn their first points payback by purchasing incentive-eligible foods without paying out-of-pocket. Participants will then be encouraged to repeat this pattern of redeeming loyalty card points weekly to earn more loyalty card points for shopping the following week. Participants who run out of loyalty card points to meet their offer’s spending threshold can request a second allocation of loyalty card points for resuming the cycle of redeeming points to earn more points without spending out-of-pocket.

A booklet was created with pictures of incentive-eligible foods to assist participants to locate them. The process of collecting and redeeming loyalty card points using the

booklet was pilot tested with two participants, with good results. Research assistants will review the booklet and rules pertaining to how loyalty card points may be earned and redeemed with participants prior to the intervention. They will also assist participants to download the supermarket's app where they can review details of the healthy food incentive, monitor their loyalty card points balance, and their progress towards meeting their weekly spending threshold. Participants without mobile phones can also login to their loyalty card account via computer or consult the bottom of their store receipt to view the number of loyalty card points they have accumulated. Research assistants will email/text participants at the beginning of the intervention to identify and resolve any difficulties they may have had in collecting and/or redeeming loyalty card points. Participants will also have continuous access to a study email and telephone help-line where they can ask study-related questions and inquire about their loyalty card points balance or spending progress.

DATA COLLECTION

To support retention, all participants (regardless of treatment allocation) will receive CDN\$100 following completion of data collection at baseline (0 months) and again at follow-up (6 months).

Questionnaires

Electronic questionnaires will encompass sociodemographic and health-related items, dietary intake in the previous 24 hours, and a variety of patient-reported outcomes. The final questionnaires will be reviewed by the advisory boards and scientific steering committee to establish face and content validity, and will be pretested with patients.

Sociodemographic and health-related variables will be recorded in REDCap using existing items from the Canadian Community Health Survey where available,¹⁰⁰ including date of birth, sex at birth, gender identity, race/ethnicity, years lived in Canada, household size and composition, number of household members with T2DM, educational attainment, employment status, marital status, annual household income, main income source, access to extended health benefits, participation in income support programmes, smoking status, housing status, medication/insulin type and dose, duration of diabetes and physical activity level.¹⁰¹

Patient-reported outcomes will be assessed using the following validated scales: WHO Well-Being Scale,¹⁰² Stanford Diabetes Self-Efficacy Scale,^{103 104} Diabetes Self-Management Questionnaire,^{105 106} Problem Areas in Diabetes Scale-5 to assess diabetes distress,¹⁰⁷ EQ-5D-5L to assess self-rated health,¹⁰⁸ hypoglycaemic episodes,³⁰ Work Productivity and Activity Impairment Questionnaire,¹⁰⁹ Health Canada's Household Food Security Survey Module to assess experiences of marginal, moderate and severe household food insecurity in the past 6 months¹¹⁰⁻¹¹² and medication adherence.¹¹³ We

will also assess diabetes competing demands¹¹⁴ and perceived financial barriers to chronic disease care, the latter of which has undergone testing via focus groups and cognitive interviews.¹¹⁵ Subjective social status will be assessed using the MacArthur Scale of Subjective Social Status national and community ladders.^{116 117} Participants will report perceived income adequacy by answering the question: 'Thinking about your total monthly income, how difficult or easy is it for you to make ends meet?'.⁸³⁻⁸⁵

Quality of dietary intake will be assessed using the online Automated Self-Administered 24-hour Dietary Recall for Canada (ASA24-Canada-2018) whereby all participants will report all foods and beverages consumed from midnight to midnight the previous day, including location of consumption and dietary supplements.¹¹⁸⁻¹²⁰ The ASA24 has demonstrated good correspondence with standardised interviewer administered dietary recalls and with true intakes.^{119 121} Participants will receive an unannounced email/text 2-4 days later prompting them to complete a second dietary recall to provide a more precise estimate of usual intake.¹²² Dietary intake data will be used to calculate subscores and an overall Healthy Eating Index-2015 score from 0 to 100 for each participant, which provides a valid assessment of overall diet quality consistent with recommendations in the healthy food prescription pamphlet.^{123 124}

To reduce missing data, REDCap will be configured to require a response prior to proceeding to the next question, although 'don't know' and 'refuse to answer' will be response options. Research assistants will also review all completed questionnaires and will telephone participants within 24 hours to request responses to any unanswered questions.

Clinical measurements

Biochemical measurements will include quantification of blood glucose levels via A1C (standardised to the Diabetes Complications and Control Trial)¹²⁵⁻¹²⁸ and fructosamine, as A1C can be unreliable for some patients and fructosamine is more sensitive to acute changes.¹²⁹ Blood lipids (total, HDL and LDL cholesterol, triglycerides, apolipoprotein B), serum creatinine (to calculate estimated glomerular filtration rate), albumin-to-creatinine ratio and haemoglobin concentration will also be quantified. Participants will provide a urine sample to detect albuminuria. All samples will be analysed by Alberta Precision Laboratories and DynaLIFE Medical Labs.

Physical measurements will adhere to standardised measurement protocols and will be performed a minimum of two times by trained researchers/clinicians, including weight and height to calculate BMI, waist circumference, systolic and diastolic blood pressure (using oscillometric devices approved by Hypertension Canada) and heart rate. Skin carotenoids will be assessed using Pharmanex Biophotonic Scanners as biomarkers of fruit and vegetable intake.¹³⁰

Administrative health data

A1C levels and information on comorbidities and diabetes complications will be obtained from Alberta Health Services' Analytics, Data Integration, Measurement and Reporting database. The secondary outcome of need for antihyperglycaemic medication/insulin will be quantified by monitoring changes in medication/insulin use (ie, initiation or discontinuation), type (ie, Metformin, Sulfonylureas, Repaglinide, DPP-4 inhibitors, GLP1 receptor agonists, SGLT2-inhibitors, Acarbose, Thiazolidinediones, Statins or other lipid-lowering agents, Renin-angiotensin aldosterone antagonists and other anti-hypertensive agents) and dosage recorded in the Pharmaceutical Information Network Database.¹³¹ We will also collect administrative data on health events and healthcare use on an ongoing basis postintervention to support understanding of longer-term outcomes.

Implementation fidelity

Implementation fidelity will be continuously assessed using a combination of quantitative and qualitative measures as part of the implementation study (described below).

Data monitoring and adverse events

We have not established stopping guidelines or a data monitoring committee as the intervention is low risk. In addition, physicians will be free to adjust patients' medication regimens to achieve improved glycaemia as per usual care. Given that serious adverse events are unlikely, adverse events will not be monitored and no provisions have been made for compensation. Interim analyses will not be conducted. At the conclusion of the study, participants will continue to be followed by their care providers.

Data analysis

Mixed-effects linear and multinomial logistic/ordinal regression will assess group differences in outcomes at follow-up, adjusted for baseline values of each outcome, blocking variables and covariates (specific to each outcome), with subgroup analyses by gender, severity of food insecurity, rural residence, Indigenous status, baseline A1C (7%–8.5%, 8.6%–12%) and insulin use. Participant-specific and PCC-specific variations will be modelled using random effects. A dose–response analysis will examine whether outcomes depend on the value of healthy food incentives earned and/or redeemed. Missing data will be handled using full information maximum likelihood under a missing at random assumption. Analyses will be intention-to-treat using all available data.

For the primary outcome of A1C, covariates will include the following: age, gender, race/ethnicity, educational attainment, years lived in Canada, number of children living in the home, marital status, change in number of household members since baseline, access to extended health benefits, participation in other income support programmes, diabetes duration and physical activity level.

Sensitivity analyses

Sensitivity analyses will examine outcomes among patients whose antihyperglycaemic medication/insulin regimen was unchanged during the 3 months prior to the study, throughout the study period, and when patients taking insulin are excluded. We will also examine the impact of excluding patients who were started on lipid-lowering or anti-hypertensive therapy from models assessing impact on blood lipids and blood pressure, respectively. Additional sensitivity analyses will consider the impact on findings when food insecurity is modelled as a continuous, rather than as a categorical outcome,¹³² when diet quality is assessed via the new Healthy Eating Food Index-2019,¹³³ and when an indicator of energy intake misreporting (ie, the ratio of reported energy intake to estimated energy expenditure) is included in models assessing impact on diet quality.

We will also consider the impact on findings when models are adjusted for changes in medication/insulin type and dosage that occurred between baseline and follow-up. We propose to use a novel scoring system that attempts to match the changes made with the expected clinical impact on A1C.¹³⁴ The following changes will be assigned one point (expected change in A1C of ~0.5%): less than full dose of Metformin (<2000 mg/day), 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 or insulin adjustment by <20% of total daily dose. Two points (expected change in A1C of ~1%) will be assigned for: full dose of Metformin, Sulfonylureas or Repaglinide; any dose of GLP1 receptor agonists or Thiazolidinedione; initiation of bolus insulin or insulin adjustment of >20% of total daily dose. Points will be attributed cumulatively for all medication/insulin changes. 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.

Markov chain Monte Carlo multiple imputation, inverse probability weighting and available case analysis will be used to investigate the impact of different assumptions about missing data on estimated programme impacts.^{135–137} Pattern mixture methods models¹³⁸ will be used to explore the robustness of study findings to the assumption that data were missing not at random.¹³⁹

Modelling study

Study design and objectives

A modelling study will estimate longer-term effectiveness of the healthy food prescription incentive programme on diabetes-related complications, resource use and costs.

Data collection

The individual-level data required as inputs for the model will be captured in the baseline and follow-up assessment phase of the RCT, as previously described. Model inputs required to estimate programme impact on longer-term resource use and costs will be obtained



from Alberta Health Services' Analytics, Data Integration, Measurement and Reporting database, including emergency department, inpatient, specialist, general practice and urgent care costs. The costs of the intervention will include administrative costs associated with implementing the programme and the costs of incentives at a household level. The time to administer the programme will be based on the non-research hours of the study personnel and unit costs will be obtained from the Alberta Wage and Salary Survey.¹⁴⁰

Data analysis

The potential longer-term health and economic impacts of the healthy food prescription incentive programme will be modelled using the validated UK Prospective Diabetes Study outcomes simulation model-2.¹⁴¹ Health-related model outputs will include differences between the incentive and comparison groups in cardiovascular events, amputation, blindness, renal failure, diabetic foot ulcers, and mortality over 1 year, 5 years and lifetime scenarios. Model outputs related to the economic impacts of the intervention will include the incremental difference in costs and quality-adjusted life-years¹⁴² between the incentive and comparison groups, the incremental cost-effectiveness ratio and the net benefit. A budget impact analysis will explore the difference in costs (eg, prescriptions, physician visits, hospitalisations) considering the RE-AIM domains, and return on investment from the public payer perspective over 1 year, 5 years and lifetime scenarios.

Implementation study

Study design and objectives

A mixed-methods implementation study will evaluate the RE-AIM^{68 69} of the healthy food prescription incentive programme in order to understand determinants of effective implementation and reasons behind programme successes and failures (table 3). The Consolidated Framework for Implementation Research (CFIR) consolidates determinants of effective implementation into five domains (intervention characteristics, inner setting, outer setting, characteristics of individuals, implementation process), and will accordingly structure our investigation of determinants of effective implementation, including barriers and facilitators, within RE-AIM's implementation domain.¹⁴³

Implementation process

The implementation process will unfold according to the four phases and action-oriented steps in the Quality Implementation Framework (QIF).^{144 145}

QIF phase 1: Initial considerations regarding the host setting

1. Stakeholder buy-in: Partnership agreements will be finalised with all stakeholders.
2. Implementation support team: An implementation support team will be formed to administer, plan, support, monitor and evaluate implementation of the intervention.
3. Training: Study personnel will be trained in principles of equity-oriented care^{88 146 147} and study procedures.

Table 3 Logic model for the implementation of a healthy food prescription incentive programme

Goal: to support adults who are experiencing food insecurity and persistent hyperglycaemia to manage their diabetes with a healthy diet.

Situation: In Alberta, more than 54 000 adults are experiencing food insecurity and type 2 diabetes, including 13 600 Indigenous individuals who bear a disproportionately high burden¹⁷¹⁻¹⁷⁴ This group of Albertans incurs CDN\$842 million/year in healthcare costs, with a small subset of 9600 individuals with persistent hyperglycaemia incurring nearly one-quarter of these costs.^{20 24 170 171 175} Nevertheless, although it is well known that food insecurity is a primary driver of acute care usage and costs, primary care providers often lack effective strategies to address it.

Inputs	Activities	Outputs	Short-term outcomes	Longer-term outcomes	Impact
<ul style="list-style-type: none"> ▶ Patient-oriented research, with patients as partners ▶ A type 2 hybrid effectiveness-implementation study design ▶ Scientific committee, advisory boards and PCC subcommittee ▶ PCC support and infrastructure ▶ Organisational champions ▶ Funding and in-kind support from Alberta Innovates, Alberta Blue Cross, Alberta Health Services and Nu-Skin ▶ Implementation support team ▶ Technical support 	<ul style="list-style-type: none"> ▶ Development of partnership agreements ▶ Readiness, capacity, barriers/facilitators and implementation assessments ▶ Cocustomisation of care pathways and implementation strategies ▶ Education and training, including booster training ▶ Ongoing monitoring and evaluation ▶ Regular communication, including continuous implementation feedback 	<ul style="list-style-type: none"> ▶ Healthy food prescriptions prescribed ▶ Healthy food incentives offered, earned and redeemed ▶ Patient, care provider and PCC participation ▶ Staff training ▶ Patient and provider experiences and perceived outcomes ▶ Determinants of effective implementation ▶ Reasons for programme successes/failures ▶ Cost-effectiveness analysis 	<ul style="list-style-type: none"> ▶ Successful integration of care pathways within PCC workflows ▶ Increased awareness of effective strategies to reduce food insecurity ▶ Increased empowerment for patients and care providers ▶ Increased care provider motivation to sustain care pathways ▶ Improved diet quality ▶ Reduced food insecurity ▶ Improved diabetes management 	<ul style="list-style-type: none"> ▶ Improved quality of care ▶ Improved patient satisfaction ▶ Improved glycaemia ▶ Reduced chronic diabetes complications ▶ Commitments from Alberta Health Services, PCCs, Alberta Blue Cross and supermarkets to collaborate for longer-term sustainability 	<ul style="list-style-type: none"> ▶ Decreased acute care usage ▶ Decreased acute care costs

PCC, primary care clinic.

4. **Assess needs, fit, capacity, readiness and adaptations:** Implementation strategies will be tailored by clinic using a theory-informed modified conjoint analysis¹⁴⁸ in which PCC staff will complete a questionnaire to identify potential implementation barriers and facilitators within the five domains of CFIR. Researchers will use the CFIR-Expert Recommendations for Implementing Change compilation matching tool to identify strategies to mitigate the barriers and leverage the facilitators identified by each clinic.^{143 148–152}
5. **Preimplementation planning and adaptations:** The implementation support team will develop a preimplementation plan and timeline and will execute it, including codveloping infrastructural supports, training modules and care pathways with PCC staff and patients. The Indigenous advisory board will progress relationship building with Indigenous PCCs and will work with them to adapt infrastructural supports and care pathways as required.
6. **Capacity building and supportive organisational climate:** PCC staff will be trained in principles of equity-oriented care^{88 146 147} and study procedures. Training sessions and codesign processes will enhance buy-in and readiness to change. One staff designate per organisation will liaise with the implementation support team weekly and will serve as an organisational champion.
7. **Study planning:** The implementation support team will develop study protocols and procure materials for all three studies.
 - QIF phase 2: Creating a structure for implementation
 1. **Implementation planning and adaptations:** The implementation support team will use findings from the modified conjoint analysis to develop a detailed implementation plan and timeline, cocustomise it with PCCs, and assign specific roles and responsibilities. Incentive-related procedures will be finalised with our supermarket partner.
 - QIF phase 3: Implementation and ongoing implementation structure
 1. **Programme implementation and data collection:** The healthy food prescription incentive programme will be implemented and data collection for the RCT and modelling study will proceed (figure 2).
 2. **Technical support and communication:** The implementation support team will provide ongoing support to PCC staff, including via weekly meetings with staff designates. Booster training sessions will be held when new/modified processes are introduced and for new staff.
 3. **Implementation study and feedback mechanisms:** The implementation support team will collect data continuously for the implementation study. Ongoing monitoring and provision of feedback to PCCs will support continuous quality improvement.

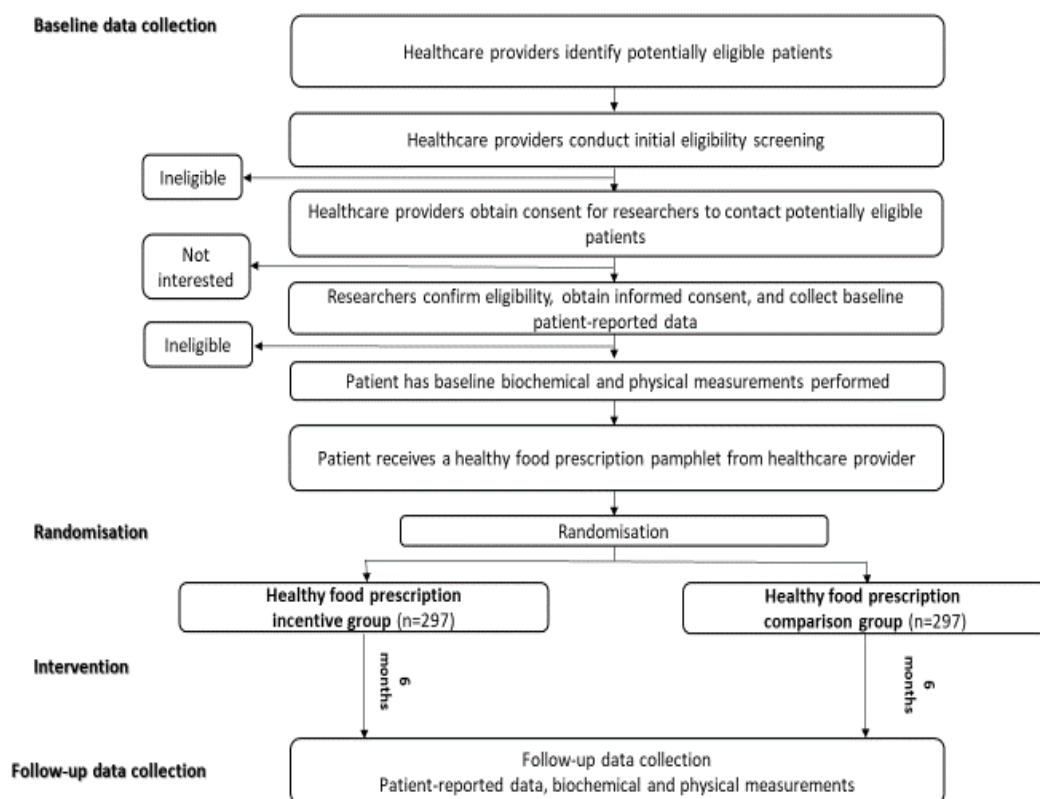


Figure 2 Healthy food prescription programme care pathway.

QIF phase 4: Improving future applications

1. Data analysis: The research team will analyse and integrate data from all three studies.
2. Knowledge translation and learning from experience: The research team and advisory boards will jointly interpret and disseminate findings. Outcomes from a deliberative dialogue^{153 154} knowledge translation event will inform sustainability planning.

Data collection

Implementation processes and outcomes related to all five RE-AIM domains, and determinants of effective implementation within CFIR domains, will be repeatedly measured via quantitative and qualitative data collected by trained research assistants. Participants will receive CDN\$30 for participating in interviews.

Quantitative data

Quantitative data will be collected via the following: (1) Administrative records of patients, care providers and PCCs that did and did not participate (reach and adoption); care providers trained, healthy food prescriptions prescribed, and healthy food incentives offered, earned and redeemed, including redemption location (implementation); (2) Implementation fidelity checklists (implementation) and (3) Quantitative questionnaire items completed by PCC staff and patients to report perceived programme outcomes (effectiveness); perceived programme experiences, facilitators, barriers, mechanisms of impact, quality of infrastructural supports and determinants of effective implementation (implementation); and longer-term programme feasibility, acceptability and willingness to participate in or deliver it, success in integrating the programme within existing workflows and how aspects of the programme were sustained over time (maintenance).

Qualitative data

Qualitative data will be collected via the following: (1) Reported reasons why patients, care providers and PCCs decline to participate in or drop out from the study (adoption and maintenance); (2) Qualitative questionnaire items completed by PCC staff and patients to provide suggestions for programme improvement (maintenance); (3) Notes from patient emails/calls to the study help-line (all domains); (4) Notes from meetings with PCC and supermarket staff liaisons (all domains); (5) Semistructured interviews with patients and members of the Indigenous advisory board (all domains) and (6) Qualitative observations of Indigenous advisory board meetings (all domains).

Implementation fidelity

From the measures summarised above, objective measures of implementation fidelity will include administrative records of healthy food prescriptions prescribed, and of healthy food incentives offered, earned and redeemed. Perceived measures of implementation fidelity will be

reported by patients via quantitative checklists and semi-structured interviews.

Data analysis

Quantitative data

Quantitative findings pertaining to all five RE-AIM domains will be summarised using descriptive statistics and will inform areas for subsequent in-depth qualitative exploration. We will stratify our analyses by clinic type (urban, rural, Indigenous) to examine any meaningful differences between them.

Qualitative data

Qualitative data will be coded by two trained researchers using directed content analysis,¹⁵⁵ whereby development of an initial coding scheme for each set of interviews will be informed by RE-AIM, CFIR and other frameworks as appropriate. Concurrent data collection and analysis and regular meetings between researchers will permit iterative adjustments to the interview questions and coding schemes, and continuous evaluation of the adequacy of the samples.¹⁵⁶ Sampling will end when new concepts are no longer being identified in the data.

Data integration

Quantitative and qualitative data will be integrated during the analysis stage for the purposes of expansion (eg, qualitative data will help to elaborate and explain quantitative findings) and convergence (eg, to examine whether quantitative and qualitative fidelity ratings correspond).¹⁵⁷

Data integration and dissemination

Data from each of the three studies will be published separately, with an additional final publication that will integrate and synthesise their collective findings across all RE-AIM domains (table 4). These fully integrated data will be disseminated via technical reports, lay summaries, infographics, policy briefs, academic publications and oral/poster presentations.

DISCUSSION

Adults who are experiencing food insecurity cannot consume the healthy foods they require to manage their diabetes if they lack sufficient funds to purchase them. However, primary care providers often lack access to resources that could assist them to alleviate their patients' experiences of food insecurity. By addressing income-related causes of unhealthy dietary patterns and persistent hyperglycaemia, healthy food prescription programmes can equip clinicians with resources that assist their patients to maintain a healthier dietary pattern. Over the longer-term, maintenance of a healthier dietary pattern can improve health and reduce diabetes-related health-care expenditures.^{7-15 64}

We will investigate the RE-AIM of a healthy food prescription incentive programme for adults who are experiencing food insecurity and persistent hyperglycaemia. Through an RCT, modelling and implementation studies,

Table 4 Integration of findings from the randomised controlled trial, implementation study and modelling study to describe the reach, effectiveness, adoption, implementation and maintenance of a healthy food prescription incentive programme

Reach	Effectiveness	Adoption	Implementation	Maintenance
Randomised controlled trial				
	Impact on primary and secondary outcomes			
Implementation study				
Patient participation and representativeness	Perceived programme outcomes	PCC and care provider participation and representativeness	Perceived programme experiences, barriers, facilitators, determinants of effective implementation, quality of infrastructural supports, mechanisms of impact	Reasons why patients, care providers and PCCs drop-out
Reach of the intervention to other household members		Reasons why PCCs and care providers decline to participate	Care providers trained	Longer-term programme feasibility, acceptability, willingness to participate in or deliver it
Reasons why patients decline to participate			Healthy food prescriptions prescribed	Successful programme integration within workflows
			Healthy food incentives offered, earned and redeemed	How aspects of the programme are sustained over time
			Implementation fidelity	Suggestions for programme improvement
				Commitments from study partners to sustain the programme
Qualitative data from meetings, observations, semi-structured interviews, emails/calls to the help-line				
Modelling study				
	Impact on longer-term health outcomes, resource use and costs			

PCC, primary care clinic.

we will generate comprehensive, in-depth and robust data pertaining to the short- and longer-term impacts of the programme on glycaemia, other health-related outcomes, resource use and costs, while also providing valuable implementation data to support translation of research findings into practice and policy. Integration of findings from these three studies acknowledges the reality that although evidence of short-term effectiveness from RCTs is valuable, such data are on their own insufficient to promote widespread and high quality implementation. In this respect, the implementation study will be critical to unpack determinants of effective implementation and reasons underlying the programme's successes and failures. Notably, our findings will be immediately relevant to existing programmes such as Wholesome Wave, which has been providing fruit and vegetable prescriptions to US households since 2010,⁸⁹ and can inform more specific recommendations regarding strategies to address food insecurity in patients with diabetes.^{10 158} Moreover, opening up conversations around food insecurity may also provide a gateway to address other social determinants of health that constrain patients' health potential.

Potential risks and limitations

Our literature review^{43 61 73–75 98 159–165} and stakeholder engagement identified several potential study risks. First, a single implementation model may not be effective for all PCCs, which could adversely affect implementation fidelity. We will, therefore, use a modified conjoint analysis to select PCC-specific implementation strategies, cocustomise and pilot test care pathways with PCCs to ensure compatibility, and monitor implementation fidelity. We will also provide comprehensive training with booster sessions, continuous technical support, and will meet weekly with staff designates and promptly address any concerns. Ongoing engagement, the support of operational leaders within the healthcare system and over-recruitment of PCCs will help to mitigate against and accommodate drop-out, should it occur. Primary risks at the patient level include failure to earn incentives or drop-out. To mitigate against these risks, participants will receive training regarding how to earn and redeem loyalty card points, weekly reminders to do so, and will have access to a study help-line for support. Whereas subsidies such as the Supplemental Nutrition

Assistance Programme in the USA have been associated with stigma,¹⁶⁶ we expect that the incentive format of the current programme may reduce stigmatising experiences, thereby increasing participant engagement with the programme. Moreover, both groups will receive CDN\$100 at baseline and follow-up as compensation, which will also serve as a recruitment incentive.

Participants' antihyperglycaemic regimen may be intensified by their care provider during the observation period, which can exert a significant impact on A1C. The tendency to intensification and deintensification should be balanced between groups owing to randomisation, nevertheless, we will monitor medication/insulin type/dosage for use as adjustment variables in sensitivity analyses. In addition, need for antihyperglycaemic medication/insulin has been included as a secondary outcome, whereby deintensification will be considered a positive, and intensification a negative outcome.

Healthy food prescription programmes hold tremendous potential to improve health and reduce healthcare costs given that 20% of global morbidity and mortality is attributable to poor diet quality,¹⁶⁷ and that food insecurity is a strong predictor of high-cost healthcare use.^{26 168} In addition, the benefits of such programmes extend to all household members, including children, for whom positive health outcomes may accrue across the lifecourse. In an era of unsustainable increases in healthcare costs, the healthcare system ignores the socio-economic needs of patients at its peril.¹⁶³ Failure to effectively address food insecurity among adults with T2DM portends unsustainable escalations in healthcare usage and costs.^{29 32 36–38 168–170} We have proposed a comprehensive investigation of the RE-AIM of a healthy food prescription incentive programme. Ultimately, study findings will show whether a small upstream investment in a healthy food prescription incentive programme may avert substantially higher healthcare costs to treat diabetes complications after they emerge.

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