



BMJ Open Impact of a farmers' market nutrition coupon programme on diet quality and psychosocial well-being among low-income adults: protocol for a randomised controlled trial and a longitudinal qualitative investigation

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ABSTRACT

Introduction Low-income populations have poorer diet quality and lower psychosocial well-being than their higher-income counterparts. These inequities increase the burden of chronic disease in low-income populations. Farmers' market subsidies may improve diet quality and psychosocial well-being among low-income populations. In Canada, the British Columbia (BC) Farmers' Market Nutrition Coupon Programme (FMNCP) aims to improve dietary patterns and health among low-income participants by providing coupons to purchase healthy foods from farmers' markets. This study will assess the impact of the BC FMNCP on the diet quality and psychosocial well-being of low-income adults and explore mechanisms of programme impacts.

Methods and analysis In a parallel group randomised controlled trial, low-income adults will be randomised to an FMNCP intervention (n=132) or a no-intervention control group (n=132). The FMNCP group will receive 16 coupon sheets valued at CAD\$21/sheet over 10–15 weeks to purchase fruits, vegetables, dairy, meat/poultry/fish, eggs, nuts and herbs at farmers' markets and will be invited to participate in nutrition skill-building activities. Overall diet quality (primary outcome), diet quality subscores, mental well-being, sense of community, food insecurity and malnutrition risk (secondary outcomes) will be assessed at baseline, immediately post-intervention and 16 weeks post-intervention. Dietary intake will be assessed using the Automated Self-Administered 24-hour Dietary Recall. Diet quality will be calculated using the Healthy Eating Index-2015. Repeated measures mixed-effect regression will assess differences in outcomes between groups from baseline to 16 weeks post-intervention. Furthermore, 25–30 participants will partake in semi-structured interviews during and 5 weeks after programme completion to explore participants' experiences with and perceived outcomes from the programme.

Strengths and limitations of this study

- This randomised controlled trial will assess the causal impact of a farmers' market healthy food subsidy on the diet quality and psychosocial well-being of low-income adults and will provide evidence of the sustainability of programme impacts.
- This study will use valid measurement tools to assess outcomes, thus increasing accuracy of effect estimates.
- A longitudinal qualitative evaluation will explore participants' experiences of accessing nutritious foods, perceived outcomes and how they were achieved, to inform programme improvements.
- The data are self-reported and, therefore, subject to self-reported measurement bias, and as the study is longitudinal, there is also a risk of lost to follow-up.

Ethics and dissemination Ethical approval was obtained from the University of Calgary Conjoint Health Research Ethics Board, Rutgers University Ethics and Compliance, and University of Waterloo Office of Research Ethics. Findings will be disseminated through policy briefs, conference presentations and peer-reviewed publications.
Trial registration number NCT03952338.

BACKGROUND

Income is among the strongest determinants of diet quality^{1,2} and overall health.¹ A clear socioeconomic gradient exists whereby individuals with lower incomes experience higher rates of nutrition-related chronic diseases^{3–5} relative to those with higher incomes. Low household income is also a key determinant of household food insecurity,^{6–11} which is

associated with lower diet quality^{12–15} and inadequate nutrient intake.^{16 17} Evidence suggests that low-income populations tend to consume diets lower in fruits and vegetables and higher in refined white grains, high-fat meats, fried foods and added fats.^{18 19} These inequities in diet quality may partly explain the greater vulnerability of low-income and food insecure populations to poor health outcomes^{18 20–22} and undernutrition.^{16 17}

The many factors underpinning differential dietary patterns among low-income groups can be conceptualised through the socioecological model.^{23 24} The socioecological model depicts the complex and reciprocal interactions among multiple levels of influence, including individual, social, community, and policy level factors that shape dietary patterns and health outcomes.^{23–26} At the individual level, factors such as psychological state^{19 27} and nutrition-related knowledge²⁷ have been shown to influence dietary patterns.^{26 28–31} For instance, high self-efficacy for consuming fruits and vegetables is associated with greater fruit and vegetable intake.^{32 33} The social level encompasses social and cultural contexts that influence dietary patterns.^{27 34} Low-income populations generally have low social support^{33 35} and social capital,^{36–38} which are, in turn, associated with poorer dietary intake and health outcomes.^{33 39} The community level includes the physical environments in which people live and work.^{24 31} Studies from the United States (USA)^{24 40–43} and Canada⁴⁴ have shown that disadvantaged neighbourhoods generally have more fast food outlets, which are associated with greater purchasing and consumption of unhealthy foods.⁴¹ The policy level encompasses policies that influence the distribution of dietary patterns and health outcomes across a population.^{1 45} Interventions at the policy level provide significant potential for sustainable, cost-effective and equitable health impacts.^{46 47} Fiscal policies that influence food prices and affordability (eg, taxation, subsidies) are particularly important for supporting healthy dietary patterns among low-income groups,⁴⁸ because the economic resources of low-income populations are often insufficient to purchase healthy foods consistent with dietary recommendations.^{18 49 50} Given the multi-level contexts in which dietary patterns are situated, interventions at any single level (eg, individual level interventions) are unlikely to substantially improve diet quality and health outcomes among low-income populations.^{24 51} Policies and interventions that address determinants of poor dietary patterns and ill health at all levels^{52–54} are required to effectively reduce nutrition and health inequities.^{55 56} Notably, farmers' market healthy food subsidy programmes are growing in interest as multilevel interventions that aim to improve access to and intake of nutritious foods among low-income populations.^{57–60} As government funded food subsidy programmes, farmers' market subsidy programmes clearly operate at the policy level.

At the community level, farmers' markets have the potential to alleviate barriers associated with accessing

healthy foods,^{43 61 62} as they offer fresh, local produce^{43 63 64} and can be set up in communities that otherwise have limited access to healthy foods.⁶⁵ Although some studies suggest that the high perceived and objective cost of produce at farmers' markets is a barrier for low-income populations,^{58 66 67} others have found that low-income shoppers in the USA perceived farmers' market prices to be reasonable/fair,⁵⁸ and that farmers' market subsidy programmes reduce food insecurity among programme participants.^{60 68} Moreover, objective price comparisons in USA and Canadian markets showed that prices were lower or comparable to those at other food retailers.^{43 69 70} Farmers' market food subsidies also support local farmers and promote sustainable local food systems⁷¹ by increasing awareness of farmers' markets within communities⁷² and increasing the customer base, thereby generating increased sales.⁷¹

Farmers' market food subsidy programmes can also influence social level determinants of dietary intake.^{32 73} Farmers' markets act as social spaces, increasing social interactions between community members and farmers,^{63 74} thereby fostering a sense of community and increasing psychosocial well-being of programme participants.⁷⁵ These social aspects of farmers' markets are particularly important for low-income groups, as social exclusion and isolation are associated with food insecurity and low-income status.^{76 77} Finally, at the individual level, farmers' market healthy food subsidy programmes have been shown to improve participant fruit and vegetable intake,^{65 68 78–81} and farmers' market programmes that offer nutrition skill-building activities may enhance participant food- and nutrition-related knowledge and skills^{32 82} and attitudes towards the importance of fruit and vegetable consumption.⁸²

Farmers' market food subsidy programmes may, therefore, represent a promising multilevel approach to improving the diet quality and psychosocial well-being⁸³ of low-income populations; however, several knowledge gaps remain.⁶⁵ First, given the short-term nature of the intervention, it is unclear whether any positive programme outcomes will be sustained over time. However, one study demonstrated that provision of a farmers' market fruit and vegetable subsidy of US\$10/week for 6 months resulted in an increase in fruit and vegetable intake of 1.4 servings/1000 kcal, which was sustained 6 months following programme completion.⁷⁹ Second, although prior studies have examined the impact of farmers' market subsidies on fruit and vegetable intake,^{65 68 78–81} psychosocial well-being⁷⁵ and food insecurity,^{60 68} potential positive impacts of farmers' market subsidies on other relevant outcomes such as subjective social status, sense of community, mental well-being and malnutrition risk have not been examined. Subjective social status and sense of community are closely associated with social participation and support.^{84–86} In addition, poor mental well-being (eg, depression, stress) in low-income populations is often linked to financial strain^{87 88} and social

isolation and exclusion.⁷⁷ Therefore, we hypothesise that the combined financial support from subsidies and the social aspects of shopping at farmers' markets and participating in skill-building activities may improve participants' mental well-being, subjective social status and sense of community. Moreover, farmers' market subsidies may influence malnutrition risk by providing additional funds to purchase nutritious foods.

In addition, most previous studies have been cross-sectional^{61 78 89–93} or used a pre/post design,^{57 60 94} and/or lacked a control group,^{60 61 95} each of which does not allow for causal inference.⁶⁵ Most have also been conducted over short time frames. Randomised controlled trials (RCTs) conducted over longer time frames can provide stronger evidence of the dietary and health impacts of farmers' market food subsidy programmes and their sustainability over time.⁶⁵ Furthermore, most studies have only assessed changes in fruit and vegetable consumption and have measured dietary intake using brief fruit and vegetable screeners⁶⁵ rather than more comprehensive and valid assessment tools such as food frequency questionnaires and 24-hour dietary recalls.^{65 72} Assessment of overall dietary intake is important, as when one aspect of diet changes, such as fruit and vegetable intake, concurrent changes occur in other aspects of dietary intake.⁹⁶ Moreover, studies suggest that use of farmers' market food subsidies may differ according to age and sex^{81 97–99}; however, evidence is limited on how the impacts of such programmes vary across these groups. Finally, the majority of studies have been conducted in the USA, and evidence from other nations is sparse.⁴³

Efforts to more fully understand the impacts of farmers' market food subsidies can be enhanced by qualitative data pertaining to participants' in-depth experiences of accessing nutritious foods, and their perceptions of programme outcomes. Previous qualitative studies have shown positive perceived outcomes from farmers' market food subsidy programmes, including perceived greater exposure to and intake of fruits and vegetables; increased resources to purchase healthy foods^{100 101}; and improved quality of life and mental well-being.⁷⁵ However, despite the documented benefits of farmers' market subsidy programmes, the unique barriers that low-income populations may face in accessing such programmes remain important considerations, including limited market hours and feelings of stigma that may be associated with using subsidies.^{59 100–103} Most previous qualitative studies have also been conducted at a single point in time,^{73 75 100 101} limiting understanding of how participants' experiences might change once subsidy programmes end and whether outcomes are maintained over time.

In British Columbia (BC), Canada, the average monthly cost to purchase a healthy diet for a family of four is CAN\$1019,¹⁰⁴ nearly one-half the income from low-wage employment.¹⁰⁵ The BC Farmers' Market Nutrition Coupon Programme (FMNCP) is a healthy eating initiative that offers a healthy food subsidy, along with supportive nutrition skill-building activities, for low-income

populations.¹⁰⁶ It is the only government-funded programme of this type in Canada. Between 2007 and 2017, participants received CAN\$15/week. This amount was determined based on a USA farmers' market coupon programme that provided on average US\$10–US\$30 for participants¹⁰⁷ and based on the availability of funds. The amount increased to CAN\$21/week in 2017 to account for increased food costs. In 2018, the FMNCP served over 11 000 individuals, including 532 pregnant women, 1084 seniors and 4965 children.¹⁰⁸ The programme facilitates access to nutritious foods for low-income families, pregnant women and older adults by providing participants with coupons valued at CAN\$21/week to purchase fruits, vegetables, dairy, meat/poultry/fish, eggs, nuts and cut herbs from participating BC farmers' markets.¹⁰⁶ Farmers' markets that participate in the FMNCP operate 1–2 days per week, with hours that vary by location. While coupons may only be redeemed from June to November, most communities offer indoor markets that are open year-round.^{106 109} The goal of the FMNCP is to provide financial support for low-income households to purchase and consume healthier foods, thereby improving diet quality^{51 110} and overall health.^{111 112} The programme also aims to minimise further marginalisation of low-income individuals by encouraging their participation in farmers' markets, which are important social spaces that may foster social and mental well-being.^{58 113 114} Currently, the FMNCP operates in 57 BC communities and reaches over 3900 households¹⁰⁶; however, the need remains substantial, with over 15 communities on waiting lists to participate. It is unclear if the FMNCP is achieving its aims, as the programme's outcomes have not been rigorously investigated.

This study was co-designed with the BC Association of Farmers' Markets and the FMNCP in order to achieve the following objectives:

1. Conduct an RCT to examine the impact of the BC FMNCP on the following outcomes immediately post-intervention and at 16 weeks post-intervention among low-income adults:
 - a. Mean overall diet quality (primary outcome).
 - b. Mean diet quality subscores, mental well-being scores, sense of community, odds of experiencing household food insecurity and odds of malnutrition risk (secondary outcomes).
 - c. Mean subjective social status (exploratory outcome).
2. Conduct a longitudinal qualitative evaluation to:
 - a. Describe participants' experiences of accessing nutritious foods, including facilitators and barriers, during and after the programme.
 - b. Explore perceived short-term outcomes from the programme, how these outcomes are achieved and whether they are sustained after the programme ends.

METHODS

Randomised controlled trial

Study design

This parallel group RCT will collect data at three time points: baseline (time 1; 0 weeks, June 2019), immediately following the FMNCP (time 2; 10–15 weeks, October 2019) and 16 weeks after the FMNCP ends (time 3; 26–31 weeks, February 2020).

Programme overview

The FMNCP functions through a collaborative partnership between the BC Association of Farmers' Markets, the BC Ministry of Health, farmers' markets and community partners (ie, local non-profit organisations). The BC Association of Farmers' Markets supports, develops and promotes farmers' markets across BC¹⁰⁶ and oversees the operations of the FMNCP. The FMNCP is supported by the province of BC and the Provincial Health Services Authority. Community partners distribute coupons to programme participants from their organisation locations (eg, pregnancy outreach and community services agencies) on a weekly or biweekly basis and offer nutrition skill-building activities such as cooking classes or community gardens to promote nutrition- and food-related knowledge and skills.¹⁰⁶

Recruitment

The FMNCP Director will identify approximately 15 BC communities for the study (from the existing FMNCP and from programme waiting lists) with the aim of achieving similar rural/urban coverage as the existing FMNCP. Within each community, the FMNCP director will recruit community partners by contacting those who are members of the BC Association of Farmers' Markets and offer nutrition skill-building activities for low-income groups. Community partners within study communities will be responsible for identifying and enrolling eligible low-income adults into the study from among their existing clients and will share study details via phone, email or in-person, using posters and other recruitment aids as needed. Community partners will assess eligibility using a screening questionnaire and will obtain voluntary, informed consent from eligible participants (see online supplementary file 1).

Patient and public involvement

All aspects of this study were co-designed with managers from the FMNCP who are directly involved in delivering the programme. Although programme participants did not directly participate in study design, evidence pertaining to the life circumstances and challenges that low-income populations may encounter was considered. Community partners will support study participants in completing study surveys, and a study helpline will allow community partners and participants to contact researchers for support. We will report key study findings to community partners and study participants, among

other stakeholders via facilitated deliberative dialogue and lay summaries.

Eligibility criteria

Individuals will be eligible to participate if they meet the following criteria:

- ▶ Adults (≥18 years).
- ▶ Low-income as determined by community-specific thresholds (~CAN\$18 000/year annual household income before taxes).
- ▶ No expected change in household income prior to study completion.
- ▶ ≤8 people living in the home (including the participant).
- ▶ No expected change in household composition prior to study completion.
- ▶ Primary food shopper for the household.
- ▶ Does not self-report dementia or Alzheimer's disease.
- ▶ Able to speak, read and write in English (or have someone who can assist them).
- ▶ No plans to move from principal residence prior to study completion.
- ▶ Has not previously participated in the BC FMNCP.

Randomisation

Following baseline data collection, eligible participants will be randomised to the FMNCP group (n=132) or a no-intervention control group (n=132), with a 1:1 allocation ratio. An independent researcher from the Clinical Research Unit at the University of Calgary will generate a blocked randomisation sequence that stratifies participants into blocks according to sex (male, female), geographical location (rural, urban), pregnancy (yes, no) and breastfeeding (yes, no). Blocked randomisation will help to ensure balanced representation of participants in study arms.¹¹⁵ Research Electronic Data Capture (REDCap), a secure, web-based data collection and management application¹¹⁶ hosted at the University of Calgary, will be used to randomise participants into the FMNCP and control groups on the basis of this randomisation sequence. The study coordinator will subsequently communicate participant group assignments to community partners and participants. Allocation concealment will be ensured via secure storage of the randomisation sequence separately from the participant database, which will only be accessible by the study coordinator and the Clinical Research Unit. Researchers will remain blinded to respondent condition throughout the study. Although participants cannot be blinded to group allocation, they will be blinded to the specific study objectives to reduce expectancy bias, whereby communication of expected study outcomes influences participants' behaviour.^{117–120}

Intervention

In the existing FMNCP, community partners distribute one to two sheets of coupons per week (each sheet contains CAN\$21 in coupons) to programme participants for a total of 16 sheets. Coupons can be used over

16–20 weeks to purchase fruits, vegetables, dairy, meat/poultry/fish, eggs, nuts and cut herbs at participating BC farmers' markets. However, to allow sufficient time to recruit participants for this study, community partners will distribute 16 coupon sheets to the FMNCP group over 10–15 weeks (households with 5–8 individuals will receive 32 coupon sheets). To ensure participants receive all 16 coupon sheets, community partners will provide two coupon sheets per household during weeks 1–6 of the intervention. Participants may redeem coupons at farmers' markets at a frequency of their choice (eg, redeem coupons weekly or redeem several weeks' worth of coupons simultaneously). Participants in the FMNCP group will be invited to participate in nutrition skill-building activities (eg, cooking classes) offered by community partners throughout the intervention period, although participation is not required (this is consistent with the existing FMNCP). The types and frequency of nutrition skill-building activities offered vary across community partners. For the duration of the study, the control group will not receive coupons nor be eligible to participate in nutrition skill-building activities but will be eligible to participate in the FMNCP the following farmers' market season. As participants in the control group already receive other supports from community partners, they will continue to meet with their community partner as they normally would throughout the intervention period.

Data collection

Data will be collected from the FMNCP and control groups at three time points: time 1: baseline (0 weeks), time 2: immediately post-intervention (10–15 weeks)

and time 3: 16 weeks post-intervention (26–31 weeks). At each time point, participants will complete a questionnaire assessing sociodemographic characteristics, health-related variables and secondary and exploratory outcomes, followed by a 24-hour dietary recall to assess diet quality (table 1). The questionnaire and dietary recall will be integrated within a web-based platform developed and pilot tested by the researchers.¹²¹ A second dietary recall will be completed 2–5 days later to better estimate usual intake and account for within-individual variation in diet quality. All participants will receive cash incentives valued at CAN\$20 at time 1 and CAN\$40 at each time 2 and 3. Participants will also receive small gifts prior to data collection at time 2 and 3, which will serve as a reminder for the upcoming data collection.

At baseline, researchers will provide participants with a username and password to access the web-based platform. Participants will be encouraged, but not required, to complete baseline data collection at a community partner location immediately after providing informed consent. Community partners will record whether data collection was completed at a community partner location or elsewhere (eg, home). Immediately post-intervention and at 16 weeks post-intervention, participants will receive an email requesting that they complete data collection (ie, questionnaire and dietary recall) at a location of their choice.

Questionnaire

The questionnaire will be administered via REDCap at all three time points and will collect data on sociodemographic characteristics, health-related variables, sense of community, mental well-being, household food insecurity,

Table 1 Randomised controlled trial outcomes and measurement tools

Outcome	Method	Measurement tool
Primary outcome		
Overall diet quality	Two 24-hour dietary recalls at time 1, 2 and 3*†‡	<ul style="list-style-type: none"> ▶ Automated Self-Administered 24-hour Dietary Recall ▶ Healthy Eating Index-2015
Secondary outcomes		
Diet quality subscores	Two 24-hour dietary recalls at time 1, 2 and 3*†‡	<ul style="list-style-type: none"> ▶ Automated Self-Administered 24-hour Dietary Recall ▶ Healthy Eating Index-2015
Sense of community	Questionnaire at time 1, 2 and 3*†‡	▶ Brief Sense of Community Scale
Mental well-being	Questionnaire at time 1, 2 and 3*†‡	▶ Warwick-Edinburgh Mental Well-being Scale
Household food insecurity	Questionnaire at time 1, 2 and 3*†‡	▶ Household Food Security Survey Module
Malnutrition risk	Questionnaire at time 1, 2 and 3*†‡	▶ Malnutrition Universal Screening Tool
Exploratory outcome		
Subjective social status	Questionnaire at time 1, 2 and 3*†‡	▶ MacArthur Scale of Subjective Social Status community ladder

*Time 1: baseline (0 weeks).

†Time 2: immediately post-intervention (10–15 weeks).

‡Time 3: 16 weeks post-intervention (26–31 weeks).



malnutrition risk, and subjective social status. Questions related to the FMNCP intervention (eg, coupon receipt) will be included in the questionnaire at time 2 only.

Sociodemographic characteristics and health-related variables

Sociodemographic characteristics and health-related variables that will be assessed include date of birth, sex, race/ethnicity, years lived in Canada, marital status, household size, number of children living in the home, perceived physical health, pregnancy/breastfeeding, smoking status, height, weight, educational level, employment status, annual household income, main source of income and community of residence.

Mental well-being

Mental well-being will be assessed using the valid 14-item Warwick-Edinburgh Mental Well-Being Scale.¹²² Scale items are positively phrased and assess various aspects of mental well-being such as positive affect (eg, optimism), psychological functioning (eg, self-confidence) and satisfaction with interpersonal relationships.^{123–125} The scale has been validated in a variety of age, sex and socioeconomic status groups¹²⁵ and cultural contexts,¹²² has captured change within short-term interventions,^{126–129} and has demonstrated high test–retest reliability with an intra-class correlation of 0.83.¹²⁵ Responses are scored on a 5-point Likert scale from 1 (none of the time) to 5 (all of the time) and are summed to provide a single score ranging from 14 to 70.^{122 124} A higher score indicates higher perceived mental well-being.¹²²

Household food insecurity

Household food insecurity will be assessed using Health Canada's validated 18-item Household Food Security Survey Module (HFSSM), which includes a 10-item adult scale and an 8-item child scale for households with children under 18 years of age.¹³⁰ The HFSSM typically assesses experiences of household food insecurity over the past year¹¹; however, similar to how the HFSSM has been modified in previous studies,^{76 131–133} it will be modified to assess experiences of household food insecurity in the past month. The HFSSM assesses experiences of marginal (one affirmative response), moderate (adult subscale 2–5 affirmative responses/child subscale 2–4 affirmative responses) and severe (adult subscale ≥ 6 affirmative responses/child subscale ≥ 5 affirmative responses) food insecurity.¹³⁰ The HFSSM has been validated in a variety of population groups and languages,^{134 135} has captured changes in food security status during short-term interventions¹³² and has good test–retest reliability with a Pearson correlation coefficient of $r=0.75$.¹³⁶

Sense of community

Sense of community will be assessed using the validated 8-item Brief Sense of Community Scale.¹³⁷ Scale components are designed to assess each sense of community dimension according to the McMillan-Chavis (1986) model^{138 139} for sense of community, which includes four elements: membership, influence, integration and

fulfilment of needs, and a shared emotional connection.^{138 139} Each item is scored using a Likert Scale of 1 (strongly disagree) to 5 (strongly agree).¹³⁷ Total sense of community scores can range from 8 to 40 with a higher score indicating greater needs fulfilment, group membership, influence and emotional connection within the community.

Malnutrition risk

Malnutrition risk will be calculated using the validated Malnutrition Universal Screening Tool (MUST).^{140 141} The MUST assesses malnutrition risk using body mass index (BMI) (scored as 0: BMI >20 , 1: BMI 18.5–20, 2: BMI <18.5), unplanned weight loss in the past 3–6 months (scored as 0: $<5\%$ of body weight, 1: 5%–10% of body weight, 2: $>10\%$ of body weight) and acute disease effect score (acute illness with no or likely no nutritional intake for >5 days).¹⁴¹ Unplanned weight loss will be modified to the past 3 months to accommodate the study timeline. In addition, acute disease effect is unlikely to occur in community settings¹⁴¹ and will, therefore, be excluded.^{142 143} Overall malnutrition risk will be calculated by adding together subscores for BMI and unplanned weight loss, with 0 indicating low risk, 1 indicating medium risk, and ≥ 2 indicating high risk of malnutrition.¹⁴² The MUST is an appropriate tool to assess malnutrition in community-dwelling^{143 144} adults aged ≥ 18 years,^{144–146} as it was designed to screen for malnutrition in all patient groups and care settings.¹⁴⁴ The MUST has been used to assess change in short-term interventions¹⁴⁷ and has demonstrated high test–retest reliability with a Cohen's kappa coefficient of $\kappa=0.94$.¹⁴⁵

Subjective social status

Subjective social status will be assessed using the validated MacArthur Scale of Subjective Social Status community ladder,^{86 148} which consists of a single-item Visual Analogue Scale whereby respondents place themselves on a ladder rung according to their perceived social standing relative to others in their community.^{148 149} Response values can range from 1 to 10, with a higher score indicating higher perceived social status.¹⁴⁸ The subjective social status community ladder has been used to capture changes from short-term interventions.¹⁵⁰

FMNCP intervention data

At time 2 only, participants in both the intervention and control groups will report whether they received FMNCP coupons and attended nutrition skill-building activities (to assess contamination of the control group), how often and how much of their own money was spent at farmers' markets during the intervention period and the types of foods purchased.

Dietary intake

Participants will complete two unannounced dietary recalls at each time point. Twenty-four hour dietary recalls are a recommended dietary assessment method to evaluate the effect of an intervention on diet quality, as

they have less systematic error than other self-reported dietary assessment tools.^{151 152} Administration of unannounced dietary recalls minimises reactivity bias, where participants adjust their dietary intake in anticipation of having to report it.¹⁵³

Participants will record all foods and beverages consumed (excluding supplements) from midnight to midnight the previous day using Health Canada's validated Automated Self-Administered 24-hour Dietary Recall (ASA24-Canada-2018),^{152 154–156} an automated online dietary assessment tool.^{155 156} The ASA24 collects information regarding dietary intake in a series of four steps: (1) foods consumed at each meal/snack, (2) queries regarding omitted meals/snacks, (3) details (eg, cooking methods, portions) and (4) review of commonly forgotten items.^{152 157} The ASA24 concludes with a question querying whether reported intake was less than usual, usual or more than usual.¹⁵⁷ The ASA24 has been used with older, multiethnic and disadvantaged adults^{118–120 152 158} and was preferred by a majority of participants compared with interviewer-administered recalls¹¹⁸; however, in a recent study among BC FMNCP participants, we identified several usability issues with the ASA24.¹²¹ For example, participants reported difficulties in searching for specific foods and making changes to entered meals.¹²¹ We will aim to address these challenges by including a pictorial user guide in survey invitation emails, and by training community partners to assist participants in-person with the ASA24-Canada-2018. Further, participants and community partners will have access to a toll-free study helpline available 10 hours/day, 6 days/week during data collection. Helpline operators will provide assistance via telephone or email, and include three registered dietitians and the study coordinator, all of whom completed a half-day training session. Inter-rater reliability in entering meals into the ASA24-Canada-2018 among the helpline operators was high, with an intraclass correlation of 0.98.

The purpose of the helpline is twofold: (1) to serve as a support platform for community partners to ask questions and update researchers and (2) to assist participants in completing data collection. If needed, helpline operators will verbally read all questions to participants and enter their responses online on their behalf. To maintain blinding, operators will remind participants not to disclose their group assignment during the call. Supporting participants during data collection will help to minimise missing and inaccurate data and participant attrition. To further minimise attrition, if data collection is not completed within 48 hours of the initial prompt, researchers will make up to four attempts to contact participants by email and/or phone. Community partners will also remind participants to complete data collection.

Data collected by community partners and farmers' market vendors

Community partners will maintain records of the number of coupons distributed to each participant (by recording

the unique bar code number on each coupon) and the frequency and types of nutrition skill-building activities attended. Farmers' market vendors will track coupon redemption and foods purchased with coupons (eg, fruits, vegetables, dairy) by using check boxes on the back of each coupon. Farmers' market managers will collect redeemed coupons from vendors and submit them to the FMNCP. They will complete tracking sheets noting the number of coupons redeemed and foods purchased with coupons.

Data analysis

Healthy Eating Index-2015

Diet quality scores and subscores will be calculated using the validated Healthy Eating Index-2015 (HEI-2015),^{159–163} a tool used to assess conformance with the 2015–2020 Dietary Guidelines for Americans.¹⁶² HEI-2015 subscores will be examined to gain insight into the specific dietary components that change in response to the intervention.¹⁶⁴ HEI scores are associated with indicators of socioeconomic position¹⁶⁵ and chronic disease.^{22 161 166–169} Although Canadian adaptations of the HEI have been developed, they have either not been validated, are not density based or reflect dietary recommendations that are no longer current.^{13 170} Given that dietary recommendations in Canada and the USA are similar,^{171–173} the HEI-2015 remains an appropriate tool to assess diet quality of Canadians.

The HEI-2015 encompasses thirteen dietary components to assess overall diet quality,¹⁶² including nine 'adequacy' components (recommended foods/nutrients, including total fruits, whole fruits, total vegetables, greens and beans, whole grains, dairy, total protein foods, seafood and plant proteins, fatty acids) and four 'moderation' components (foods/nutrients recommended to limit, including refined grains, sodium, added sugars, saturated fats). Component scores are density based and, therefore, independent of energy intake.^{162 164} Diet quality (total HEI-2015 scores and subscores) will be calculated using the simple HEI scoring algorithm.¹⁶² This method provides scores at the individual level and can, therefore, accommodate the multilevel nature of our data and include covariates.¹⁶² HEI-2015 scores will be calculated using three nutrient databases linked to the ASA24-Canada-2018:¹⁷⁴ the Canadian Nutrient File and the US Department of Agriculture's (USDA) Food and Nutrient Database for Dietary Surveys to convert dietary intakes to energy and nutrient intakes and the USDA Food Patterns Equivalents Database to convert dietary intakes to dietary constituents (eg, fruits) and measurement units consistent with HEI-2015 scoring standards (eg, cup-equivalents of fruit).^{163 164 175 176} Ratios for each of the dietary constituents (eg, quantity of fruit per 1000 kcal) will be calculated for each participant and scored using HEI-2015 scoring standards. The total score for each participant will be derived by adding the scores for intake of 'adequacy' and 'moderation' components with

possible scores ranging from 0 to 100. A higher score indicates a higher quality diet.¹⁶²

Statistical analyses

Descriptive analyses will be conducted to examine participant characteristics by group at each time point. Characteristics of study completers (ie, provided data at time 3) and non-completers will also be compared.

Analyses will be intention-to-treat, in which participants will be analysed within the groups to which they were randomised regardless of adherence (eg, failure to redeem coupons) or drop-out. The analyses will include all participants who provided data at baseline. Repeated measures mixed-effect regression will assess differences in mean HEI-2015 scores, HEI-2015 subscores, mental well-being, sense of community and subjective social status between the FMNCP and control groups immediately post-intervention and 16 weeks post-intervention. Multinomial logistic regression will be used to assess differences in the odds of experiencing household food insecurity and malnutrition risk for the FMNCP group compared with the control group immediately post-intervention and 16 weeks post-intervention. Statistical models will include intervention group (FMNCP vs control), time from baseline, intervention-by-time interaction, blocking variables (ie, sex, rural/urban, pregnancy, breastfeeding), baseline values of the outcome, data collection mode (online, phone), household size and place of data collection (community partner, other) as fixed-effects covariates. Participant-specific (ie, repeated measures) and rural/urban variations in outcomes will be modelled using random effects. Models will also include covariates specific to each outcome to increase the precision of estimates.⁹⁶ For the primary outcome of overall diet quality, models will include children living in the home (yes, no), sex, age, BMI, marital status, race/ethnicity, perceived health, smoking, day of dietary recall completion and dietary recall number (ie, dietary recall 1 or 2). Adjusted group differences (ie, FMNCP vs control) in outcomes will be estimated using 95% CIs and corresponding p values.

Subgroup analyses will examine whether the impact of the intervention on primary and secondary outcomes differs according to age group or sex. Dose-response analyses will examine whether the impact of the FMNCP on overall diet quality depends on the number of coupons redeemed and the number of nutrition skill-building activities attended. Interactions will be retained in statistical models if $p < 0.10$. Analyses will be conducted in Stata (V.15.1, StataCorp), with $p < 0.05$ indicating statistically significant differences between groups.

Missing data

Missing data will be handled using full information maximum likelihood under a missing at random assumption. We will also attempt to minimise missing data by reviewing all data within 24 hours of receipt and by contacting participants to fill in missing or implausible

responses within 48 hours. Participants who drop out of the study will be asked to provide reasons for drop out to assess the plausibility of a missing at random assumption.

Sensitivity analyses

Markov chain Monte Carlo multiple imputation, inverse probability weighting and available case analysis will be used in a sensitivity analysis to investigate the impact of different assumptions about missing data on estimated programme impacts.^{59 177 178} Given the possibility of non-random attrition, pattern mixture methods models¹⁷⁹ will be used to explore the robustness of study findings to the assumption that data were missing not at random.¹⁸⁰

Sample size calculation

The sample size was calculated from an RCT that investigated the impact of a fruit and vegetable rebate on HEI-2010 scores in low-income participants in the USA,⁹⁶ and a cross-sectional study that assessed average diet quality scores in disadvantaged Canadians.⁴⁰ In the RCT, diet quality in the intervention group was 4.7 points higher (95% CI 2.4 to 7.1) at follow-up compared with controls.⁹⁶ This difference can be translated to, for example, an additional half serving of fruit per day, which is clinically meaningful and achievable.^{112 166} Assuming a type I error of 5%, an attrition rate of 30% by the 26–31 week follow-up, and potential design effects based on sampling within different communities (estimated at 1.1, or an inflation of 10%), 264 participants are required for 80% power to detect a 4.7-point difference in diet quality.

Longitudinal qualitative investigation

Methodology and theoretical framework

Methodology

A longitudinal qualitative study will be conducted concurrently with the RCT. Qualitative description will be used as a methodological approach¹⁸¹ to provide rich descriptions of participant experiences of accessing nutritious foods, perceived short-term outcomes from the programme and how outcomes were achieved. This methodology will allow for an in-depth exploration of BC FMNCP participants' experiences and perceptions related to the programme.

Theoretical framework

Data generation and analysis will be guided by Freedman *et al's*¹⁸² theoretical framework of nutritious food access. The framework was developed using data from interviews with low-income farmers' market shoppers.¹⁸² The model includes five interrelated domains: (1) economic (eg, household finances), (2) spatial-temporal (eg, transportation), (3) service delivery (eg, food quality), (4) social (eg, culture) and (5) personal factors (eg, nutrition knowledge). The theoretical framework highlights economic factors as key determinants of nutritious food access among low-income households and the importance of multilevel policies and interventions.¹⁸² Given that the FMNCP is a multilevel intervention, this framework will help guide data generation and analysis to

understand the role of each domain in shaping participants' programme experiences and perceived outcomes.

Sampling and recruitment

Three community partners from one urban and two rural communities that are part of the BC FMNCP will recruit participants. Individuals participating in the RCT will not be eligible to participate, as interviews could prompt additional behaviour change or differential reporting for the RCT. Within the selected communities, 25–30 adults from low-income households enrolled in the existing FMNCP will be purposefully selected to be representative of FMNCP participants. Eligibility criteria include adults with children and older adults who are receiving coupons for the first time, who are the primary food shopper for the household, can communicate in English, have eight or fewer people living in the home (including the participant), are not planning to move from their principal residence nor expecting any major changes to their annual household income prior to the second interview, and are willing to participate in two interviews. Participants will be offered a CAN\$25 and CAN\$35 cash incentive following the first and second interview, respectively.

Data generation

Data generation will occur at two time points: between weeks 8 and 12 of the FMNCP and 5–10 weeks after the programme ends. Semi-structured individual interviews will be conducted by two researchers with previous qualitative research experience. These researchers will develop an initial semi-structured interview guide, guided by the five domains of Freedman *et al's*¹⁸² theoretical framework. The initial interview guide will be designed to capture individual experiences of participating in the FMNCP and perceived outcomes of the programme, as well as how these outcomes were achieved. Follow-up interviews will also be semi-structured and will examine differences, similarities and changes in participant experiences with the programme and perceived outcomes following programme completion. Following an iterative approach, both interview guides will be pre-tested with two FMNCP participants and adjusted as needed throughout data generation.

In-person, 60 minute semi-structured interviews will be conducted with participants at both time points. Following each interview, demographic information will be collected such as sex, age, race/ethnicity, marital status, household composition, household income, education, employment status and household food insecurity. Interviews will be audio recorded and transcribed verbatim. Each researcher will interview the same individuals at each time point to enhance consistency and rapport. Descriptive field notes will be recorded during each interview to capture information on the setting and respondents' reactions to questions.

Data analysis

Data analysis will be iterative and conducted by researchers in two phases: a cross-sectional analysis at each time point and a longitudinal analysis. Coding will be managed and

organised using NVivo software (V.12.5, QSR International). In the cross-sectional analysis, data will be analysed separately at each time point. Researchers will use directed content analysis¹⁸³ to analyse the data, using the five domains of Freedman *et al's*¹⁸² framework to guide development of an initial coding scheme. The analysis will be semi-deductive based on the theoretical structure of the framework. Data that do not fit within the five domains will be coded inductively.¹⁸⁴ At each time point, researchers will independently analyse four interviews and subsequently meet to reach consensus about a coding scheme, aiming for a threshold of 80% as the criterion of acceptability.¹⁸² Constant comparison and memoing will ensure that interpretations and relationships between codes are consistent.¹⁸³ Researchers will then collate and categorise codes to generate themes.^{183 185} The second set of interviews will allow for further exploration of themes identified from the initial interviews, along with new themes that may be developed.

Following initial data analysis at both time points, a longitudinal analysis will be conducted. For this analysis, one researcher will examine cross-sectional themes from both time points simultaneously, guided by Saldana's¹⁸⁶ descriptive and analytic/interpretive questions. Findings will be integrated into longitudinal themes that focus on participants' experiences, including facilitators and barriers of accessing nutritious foods during and after the FMNCP and perceived programme outcomes, including how they were achieved and whether and how outcomes were sustained.

Strategies to enhance rigour

Potential limitations and threats to the trustworthiness of study findings will be offset by applying strategies to enhance rigour including peer debriefing between researchers and the use of thick descriptions from participant interviews to remain true to participants' accounts. Researchers will also create an audit trail for a transparent description of study processes^{187 188} and provide rich details of the study context and thought process to allow readers to assess the transferability of study findings to other contexts.^{187 188}

ETHICS AND DISSEMINATION

Ethical approval was obtained from the Conjoint Health Research Ethics Board of the University of Calgary (REB18-0508) (Calgary, Alberta, Canada), University Ethics and Compliance from Rutgers University (FWA00003913) (Newark, New Jersey, USA), and the Office of Research Ethics from the University of Waterloo (ORE #40724) (Waterloo, Ontario, Canada). Ethics boards, researchers and FMNCP stakeholders will be informed of any study protocol modifications that impact the conduct of the study. Reporting will adhere to Template for Intervention Description and Replication (TIDieR) and Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) reporting standards. Study findings will be presented to stakeholders within government and communities across Canada to inform decision-making via a facilitated deliberative



dialogue, policy briefs and lay summaries. Researchers will disseminate results through peer-reviewed journal publications and conference presentations.

STUDY MANAGEMENT AND MONITORING

The principal investigator (DLO) will manage and oversee the study, review the study protocol and organise study meetings. All researchers are responsible for reviewing and agreeing on protocol modifications, as needed.

DATA MANAGEMENT

Participants will be issued a unique study identification number for all data collected. All personally identifying information will be kept separate from study data and stored securely on password-protected computers. Survey data will be stored on both the ASA24 and REDCap servers, which are secure and managed by their respective organisations. All data downloaded from these systems will be de-identified and only the researchers will have access to the data. A formal data monitoring committee will not be established as study-associated risks are minimal. No interim analyses or stopping guidelines have been established.

DISCUSSION

Inequities in diet-related chronic disease are an ongoing public health concern.^{189–191} Given that the determinants of dietary patterns are complex and multifactorial,^{18 40 46} it is crucial that public health initiatives address all socioecological levels to reduce dietary and health inequities in low-income populations.^{52 53 192} The BC FMNCP has the potential to improve diet quality, health and psychosocial well-being of low-income participants, as it is a multilevel programme that links the agricultural and health sectors and addresses determinants of health and dietary intake at all levels of the socioecological model, including individual (ie, skill-building activities), social (eg, interactions at farmers' markets), community (eg, improved access to healthy foods), and policy levels (eg, the programme offers government-funded food subsidies).

Previous studies that have assessed outcomes from farmers' market food subsidies are limited by weak study designs, short follow-up times, use of brief fruit and vegetables screeners, and primarily examined fruit and vegetable intake rather than overall diet quality.⁶⁵ This study will aim to overcome these and other limitations, and will specifically use an RCT design capable of supporting causal inference. A longitudinal qualitative evaluation will complement findings from the RCT by exploring participants' experiences of accessing nutritious foods during and after the programme and perceived programme outcomes and whether they are sustained over time. Together, findings from the RCT and qualitative longitudinal investigation will provide evidence to inform improvements to the FMNCP and similar programmes to ensure they achieve their aim of facilitating access to nutritious foods for low-income

households. Given that there are over 500 farmers markets across Canada and over 8000 across the USA,⁶³ these data offer significant potential to inform national and international scale-up.

Study limitations

Alongside its many important strengths, this study has methodological limitations. First, the data collected through the questionnaire and 24-hour dietary recall are self-reported and, therefore, subject to self-reported measurement bias,¹⁵¹ including reactivity and social desirability biases.^{151 153} This study will aim to minimise these biases by using self-administered online tools, which may reduce social desirability bias compared with interviewer administered surveys and recalls.¹⁵³ Although 24-hour dietary recalls will be unannounced at baseline, dietary recalls immediately post-intervention and 16 weeks post-intervention will be less so, as participants will receive emails inviting them to complete data collection and may take up to 48 hours to do so.

Second, lower socioeconomic position may be associated with lower computer literacy.^{193 194} Given that the surveys will be delivered via an online platform, participants may experience difficulty completing the surveys, which may result in implausible or missing responses. However, evidence suggests that most low-income individuals have access to and regularly use computers and the internet.^{158 195} Moreover, participants may complete data collection at a community partner location, where community partners can assist them, and researchers will be available for assistance via the study helpline.

As the study is longitudinal, there is also a risk of lost to follow-up. To maximise retention, community partners will maintain communication with participants between time points, and participants will receive incentives for completing data collection at each time point. In addition, in order to allow sufficient time to recruit participants for this study, participants will receive two coupon sheets for the initial 1–6 weeks and will have a shorter time frame in which to spend them, which is not fully consistent with how the programme operates but is necessary to allow sufficient time to recruit participants.

Finally, the use of a convenience sample may increase the risk of selection bias and may limit generalisability of study findings; however, participants with varying sociodemographic characteristics will be enrolled from communities across BC.

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Competing interests HO is the Executive Director of the British Columbia Association of Farmers' Markets. PL is the Programme Manager for the British Columbia Farmers' Market Nutrition Coupon Programme. DT is employed by Abbott Nutrition.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Not required.

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