Impact of a farmers' market healthy food subsidy on the diet quality of adults with low incomes in British Columbia, Canada: a pragmatic randomized controlled trial

Michelle L. Aktary¹, Sharlette Dunn², Tolulope Sajobi², Heather O'Hara³, Peter Leblanc³, Gavin R. McCormack^{1,2,4,5}, Stephanie Caron-Roy¹, Kylie Ball⁶, Yun Yun Lee¹, Sara Nejatinamini², Raylene A. Reimer¹, Bo Pan⁷, Leia M. Minaker⁸, Kim D. Raine⁹, Jenny Godley^{2,10}, Shauna Downs¹¹, Candace I. J. Nykiforuk⁹, Dana Lee Olstad^{1,2*}

¹Faculty of Kinesiology, University of Calgary, 2500 University Drive NW, Calgary, AB T2N 1N4, Canada; ²Department of Community Health Sciences, Cumming School of Medicine, University of Calgary, 3280 Hospital Drive NW, Calgary, AB T2N 4N1, Canada; ³British Columbia Association of Farmers' Markets, 203-2642 Main Street, Vancouver, BC V5T 3E6, Canada; ⁴School of Architecture, Planning and Landscape, University of Calgary, 2500 University Drive NW, Calgary, AB T2N 1N4, Canada; ⁵Faculty of Sport Sciences, Waseda University, 2 Chome-579-15 Mikajima, Tokorozawa, Saitama 359-1192, Japan; ⁶Deakin University, Institute for Physical Activity and Nutrition (IPAN), School of Exercise and Nutrition Sciences, Geelong 3216, Australia; ⁷EPICORE Centre, University of Alberta, Suite 362, Heritage Medical Research Centre, University of Alberta Edmonton, AB T6G 2S2, Canada; ⁸School of Planning, University of Waterloo, 200 University Avenue West, Waterloo, ON N2L 3G1, Canada; ⁹School of Public Health, University of Alberta, 3-300 Edmonton Clinic Health Academy, 11405-87 Avenue, Edmonton, AB T6G 1C9, Canada; ¹⁰Department of Sociology, University of Calgary, 2500 University Drive NW, Calgary, AB T2N 1N4, Canada; ¹¹School of Public Health, Rutgers University, 683 Hoes Lane W, Piscataway, NJ 08854, USA.

Conflict of interest: HO is the Executive Director of the British Columbia Association of Farmers' Markets. PL is the Program Manager for the British Columbia Farmers' Market Nutrition Coupon Program. All other authors (MLA, SD, TS, GRM, SCR, KB, YYL, SN, RAR, BP, LMM, KDR, JG, SD, CIJN, DLO) report no conflicts of interest.

*Corresponding author: Dr. Dana Lee Olstad Department of Community Health Sciences, Cumming School of Medicine, University of Calgary, 3280 Hospital Drive NW, Calgary, AB T2N 4N1, Canada (403) 210-8673 dana.olstad@ucalgary.ca

Funding: This work was funded by the Canadian Institutes of Health Research (reference number 155916). MA received scholarship support from the Maple Leaf Centre for Action on Food Security and the Alberta Graduate Excellence Scholarship. Partial funding for statistical support was provided by the Alberta Strategy for Patient Oriented Research (SPOR) SUPPORT Unit and The Epidemiology Coordinating and Research (EPICORE) Centre.

Short running head: Impact of a farmers' market healthy food subsidy

Clinical trials registration number NCT03952338 https://clinicaltrials.gov/ct2/home

Data described in the manuscript, code book, and analytic code will be made available upon email request to the corresponding author.

Abbreviations: ASA24-Canada-2018: Automated Self-Administered 24-Hour Dietary Assessment Tool Canada; BMI: body mass index; BC: British Columbia; CI: confidence interval; CONSORT: Consolidated Standards of Reporting Trials; FMNCP: Farmers' Market Nutrition Coupon Program; HEI-2015: Healthy Eating Index 2015; RCT: randomized controlled trial; REDCap: Research Electronic Data Capture; TEE: total energy expenditure; TEI: total energy intake; US: United States 1 Abstract

Background: Adults with low incomes have lower diet quality than their higher income
counterparts. In Canada, the British Columbia Farmers' Market Nutrition Coupon Program
(FMNCP) provides coupons to low-income households to purchase healthy foods in farmers'
markets.

6

7 **Objective:** To examine the impact of the FMNCP on the diet quality of adults with low incomes.
8

9 **Design:** In a pragmatic randomized controlled trial conducted in 2019, adults with low incomes 10 $(\geq 18 \text{ years})$ were randomized to an FMNCP intervention (n=143) or a no-intervention control 11 group (n=142). The FMNCP group received 16 coupon sheets valued at \$21/sheet over 10–15 12 weeks to purchase healthy foods from farmers' markets. Participants completed a questionnaire 13 and two 24-hour dietary recalls at baseline (0 weeks), immediately post-intervention (10-15)14 weeks), and 16 weeks post-intervention (26–31 weeks). Diet quality was calculated using the 15 Healthy Eating Index-2015 (HEI-2015). Linear mixed-effects regression assessed differences in 16 HEI-2015 total (primary outcome) and component scores (secondary outcomes) between the 17 FMNCP and control groups at post-intervention and 16 weeks post-intervention. Subgroup 18 analyses examined program impacts by sex and age group (18-59 years, ≥ 60 years). 19

Results: There were no significant differences in HEI-2015 total scores between the FMNCP
and control groups at post-intervention (-0.07; 95% confidence interval (CI) -4.07, 3.93) or 16
weeks post-intervention (1.22; 95% CI -3.00, 5.44) overall or among subgroups. There were no
significant between-group differences in HEI-2015 component scores at post-intervention,

24	although there were significant differences in component scores for dairy and fatty acids at 16
25	weeks post-intervention.
26	
27	Conclusion: The FMNCP did not significantly improve diet quality among adults with low
28	incomes over the study period. Further research is needed to explore whether higher subsidy
29	amounts or a longer intervention period is needed to meaningfully improve diet quality among
30	adults with low incomes.
31	
32	Key words: Randomized controlled trial, diet quality, Healthy Eating Index, low-income, adults,
33	farmers' market, healthy food subsidy, 24-hour dietary recall
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47 Introduction

In high-income countries such as Canada (1) and the United States (US) (2), populations with low incomes have poorer diet quality than their higher income counterparts. These dietary inequities have persisted and even widened in some cases over the past several decades (1, 2). Dietary inequities increase the burden of nutrition-related chronic diseases among populations with low incomes and thus are a key contributor to health inequities (3).

53

54 Farmers' markets offer a unique opportunity to support healthy dietary patterns by increasing 55 access to fresh, local produce (4) and enhancing nutrition- and food-related knowledge through 56 interactions with vendors (5-7). Within this context, farmers' market fruit and vegetable subsidy 57 programs are growing in interest as policy interventions to improve fruit and vegetable intake 58 among populations with low incomes (5, 8, 9). Evidence from US studies suggests that farmers' 59 market fruit and vegetable subsidies are associated with increased fruit and vegetable 60 consumption among adults with low incomes (5, 10-13). However, while these studies suggest 61 that farmers' market fruit and vegetable subsidies may improve fruit and vegetable intake, they 62 used study designs that cannot show causality. Furthermore, previous studies examined 63 associations between farmers' market fruit and vegetable subsidies and fruit and vegetable intake 64 alone, rather than overall diet quality, which can better capture the multidimensionality of dietary 65 intake (14). All but one study used brief fruit and vegetable screeners rather than dietary 66 assessment instruments that capture more detailed dietary intakes with less bias, such as 24-hour 67 dietary recalls (15). Most previous studies also failed to examine the sustainability of program 68 impacts. Examining whether potential changes in diet quality are maintained after healthy food 69 subsidies end can shed light on possible underlying mechanisms of action. For instance, if any

70 improvements in diet quality are not sustained after the subsidies end, then the underlying 71 mechanisms may be primarily economic. However, if any improvements in diet quality are 72 sustained, this may indicate that subsidies also acted as cognitive nudges or led to shifts in food 73 preferences. Alternatively, or in addition, such a finding may indicate that the program enhanced 74 participants' food and nutrition knowledge, such as through nutrition skill-building or via 75 interactions with food vendors. To our knowledge, no published randomized controlled trials 76 (RCT) have examined the impacts of farmers' market healthy food subsidies on diet quality 77 among adults with low incomes.

78

79 The British Columbia (BC) Farmers' Market Nutrition Coupon Program (FMNCP) is the largest 80 and longest running government-funded farmers' market food subsidy program in Canada (16-81 18). While program participants have reported consuming more fruits and vegetables and fewer 82 highly processed foods since participating in the FMNCP (19), program impacts have not yet 83 been rigorously examined. Accordingly, we undertook a pragmatic RCT to examine the impacts 84 of the FMNCP on the diet quality (primary outcome), diet quality component scores, sense of 85 community, mental well-being, household food insecurity, malnutrition risk (secondary 86 outcomes), and subjective social status (exploratory outcome) of adults with low incomes 87 immediately following the FMNCP (post-intervention) and 16-weeks post-intervention. This 88 paper reports findings pertaining to overall diet quality and diet quality component scores. 89

90 Methods

91 Program overview

92 The FMNCP was established in 2007 and is delivered as a collaborative partnership among the 93 BC Association of Farmers' Markets, the BC Ministry of Health, the Provincial Health Services 94 Authority, local farmers' markets, and community partners. The program is primarily funded by 95 the BC Ministry of Health, with additional financial support provided by local community 96 organizations (20). The aim of the FMNCP is to increase access to healthy local foods for low-97 income families and older adults in order to improve their diet quality and overall health (17). 98 While the FMNCP has continued to expand each year, reaching 15,862 individuals across 78 BC 99 communities in 2019, many low-income households remain on waiting lists to access the 100 program. This pragmatic RCT was conducted alongside the existing FMNCP to examine 101 program impacts as it is normally delivered. The program was scaled up to accommodate an 102 additional 285 individuals from program wait lists for this study. Participants from the existing 103 FMNCP were not enrolled as it would have been unethical to randomize existing participants to 104 a control group that received no coupons.

105

106 Study design

107 This was a parallel-group pragmatic RCT in which participants were randomized 1:1 to the 108 FMNCP intervention group or a no-intervention control group. This study was conducted in 109 accordance with the Tri-Council Policy Statement and the Declaration of Helsinki. Ethical 110 approval was obtained from the Conjoint Health Research Ethics Board at the University of 111 Calgary (REB18-0508; Calgary, Alberta, Canada), University Ethics and Compliance at Rutgers 112 University (FWA00003913; Newark, New Jersey, US), and the Office of Research Ethics at the 113 University of Waterloo (ORE #40724; Waterloo, Ontario, Canada). This study is described in 114 accordance with the Consolidated Standards of Reporting Trials (CONSORT) statement (21).

Full study details have been published elsewhere (22). Deviations from the pre-registered study
protocol are detailed in the online supplementary materials (Supplementary methods).

117

118 Participants, recruitment, and eligibility

119 From May to August 2019, community partners (non-profit organizations, such as pregnancy 120 outreach and community services agencies) recruited study participants from among their 121 existing clients on the FMNCP wait list and through social media and flyer advertisements. 122 Adults with low incomes aged 18 years or older were eligible to participate if they: 1) had not 123 previously participated in the FMNCP; 2) met community-specific FMNCP annual household 124 income eligibility cut-offs (in many communities this was < CDN \$18,000/year; however, these 125 thresholds were higher in communities with higher costs of living); 3) had ≤ 8 people living in 126 the home, including the participant (to limit dilution of program impacts due to larger households 127 sharing foods purchased with the coupons); 4) were the primary food shopper for the household; 128 5) did not self-report dementia or Alzheimer's disease; 6) were able to speak, read, and write in 129 English (or had someone to assist them); and 7) did not expect to move or to have any changes in 130 their household income or composition prior to study completion. Eligible participants 131 completed a screening questionnaire at a community partner site and provided voluntary 132 informed consent to participate in the study prior to completing baseline data collection.

133

134 Sample size calculation

The sample size calculation used a minimally important difference in HEI-2015 scores based on an RCT that examined the impact of a fruit and vegetable subsidy on the diet quality of adults with low incomes (23). This study found that HEI-2010 scores were 4.7 points higher among those in the intervention group compared to those in the control group at post-intervention (23).
Assuming a type I error of 5%, potential design effects of 10%, and an attrition rate of 30% by
16-weeks post-intervention, a target sample size of 264 participants was calculated to detect a
5.0-point difference in HEI-2015 scores with 80% power. This difference is equivalent to, for
example, an additional 1.1 cup equivalents of vegetables per 1,000 kcal/day (24).

143

144 *Randomization*

145 An independent statistician generated a concealed blocked randomization sequence, using sex 146 (male, female), geographic location (rural, urban), pregnancy, and breastfeeding as blocking 147 variables. Following baseline data collection, the study research coordinator (SD) randomized 148 participants using REDCap (Research Electronic Data Capture), a secure, web-based data 149 collection and management application (25). SD communicated group allocation to participants 150 and community partners via email. Participants could not be blinded to their group assignment 151 but were blinded to the study's specific objectives. Researchers who collected and analyzed the 152 data remained blinded to participant group allocation.

153

154 Intervention

Sixteen community partners from communities across BC (5 rural and 11 urban) provided coupons to study participants. Participants in the FMNCP group received coupons to purchase fresh fruits and vegetables, dairy, meat, poultry, fish, eggs, nuts, and cut herbs at BC farmers' markets and were invited to attend nutrition skill-building activities, such as cooking classes. The frequency and types of nutrition skill-building activities vary by community partner and thus, consistent with the existing FMNCP, participation in the nutrition skill-building activities was 161 not required. Community partners normally provide households with one coupon sheet valued at 162 \$21/sheet (7 coupons in \$3 denominations) each week for 16 weeks (totalling \$336); however, to 163 allow for a longer recruitment period, participants received the intervention over 10-15 weeks 164 rather than 16 weeks. Participants received double the number of coupons during some weeks to 165 ensure they received the full 16 weeks' worth of coupons. Coupons were distributed from June to 166 October 2019 and were redeemable at any point during the farmers' market season until 167 November 2019. For the duration of the study, those in the control group did not receive coupons 168 and were not eligible to participate in the nutrition skill-building activities. Participants in the 169 control group were invited to participate in the FMNCP during the subsequent 2020 farmers' 170 market season (19).

171

172 Data collection

173 The FMNCP and control groups completed data collection at baseline (time 1; 0 weeks May-174 August 2019), post-intervention (time 2; 10–15 weeks, two weeks before farmers' market 175 closures, October-November 2019), and 16 weeks post-intervention (time 3; 26-31 weeks, 176 February-March 2020). At each time point, participants completed an online questionnaire and 177 an online 24-hour dietary recall at a community partner site or a location of their choice (e.g., at 178 home). Participants received an email invitation to complete a second dietary recall 2–5 days 179 later (15). Community partners were trained to assist participants in completing data collection. 180 Participants also had the option to complete data collection over the telephone with a researcher. 181 To encourage survey completion, participants received cash incentives valued at CDN \$20 at 182 time 1 and CDN \$40 at each of time 2 and 3.

183

184 Sociodemographic characteristics and health-related information

185 The questionnaire was administered via REDCap and collected data on baseline 186 sociodemographic characteristics including age, sex, height, race/ethnicity, years lived in 187 Canada, and community of residence. At each time point, participants also reported their marital 188 status, household size, number of children living in the home, perceived physical health, 189 pregnancy, breastfeeding, smoking status, weight, highest educational level, employment status, 190 total annual household income before taxes, and main source of income. Information on 191 secondary and exploratory outcomes (sense of community, mental well-being, household food 192 insecurity, malnutrition risk, and subjective social status) was also collected (22) and will be 193 reported in future publications. At post-intervention only, participants reported whether they 194 received coupons and attended nutrition skill-building activities, and the frequency and amount 195 of their own money spent and the types of foods purchased at farmers' markets.

196

197 *Dietary intake*

198 Participants reported all foods and beverages consumed from midnight to midnight the previous

day using the validated (26, 27) Automated Self-Administered 24-hour Dietary Assessment Tool

200 for Canada (ASA24-Canada-2018) (28). The ASA24-Canada-2018 is an online, self-

201 administered 24-hour dietary recall developed by the US National Cancer Institute, modified to

202 reflect the Canadian food supply (29). The ASA24 collects dietary recalls using an adapted

203 version of the Automated Multiple Pass Method (27), which has been shown to reduce

204 underreporting and memory-associated issues with dietary reporting (30).

205

Studies have suggested that the ASA24 is suitable for multiethnic (31) and low-income (32) populations; however, a previous study conducted with FMNCP participants identified several challenges associated with independently using the ASA24 (33). Thus, researchers were made available via email or a toll-free study helpline to assist participants in completing data collection. Interrater reliability in conducting dietary recalls over the phone and entering data into the ASA24-Canada-2018 at each time point among researchers remained high, with an intraclass correlation of 0.98.

213

214 Researchers made up to four attempts to contact participants who failed to initiate data collection 215 or who had incomplete responses or potentially implausible dietary intakes. Previously 216 established cut-offs were used to identify participants to contact to further investigate the 217 plausibility of dietary intake data (i.e., <500 kcal/d or >3,500 kcal/d for females and <800 kcal/d 218 or >4,000 kcal/d for males (34)). Researchers manually entered missing data for those who were 219 successfully contacted. For instance, at baseline, post-intervention, and 16 weeks post-220 intervention, researchers assisted 21.8% (n=62), 17.2% (n=47), and 22.4% (n=57) of 221 participants, respectively, who had not initiated or who had potentially implausible dietary 222 recalls. At each time point, we were unable to contact 3.5% (n=10), 3.7% (n=10), and 4.7%223 (n=12) of participants whose dietary recalls were potentially implausible; however, given the 224 day-to-day variability in dietary intakes (35), all reported dietary intakes were retained unless 225 confirmed incomplete by the participant.

226

227 *Coupon distribution and redemption*

Community partners recorded the number of coupons distributed to each participant, allowing researchers to track overall coupon distribution and redemption. However, the corresponding bar code to track participant-specific coupon distribution and redemption was not consistently recorded. Farmers' market vendors tracked which foods were purchased with coupons (e.g., fruits and vegetables) by using check boxes on the back of each coupon. Thus, we had data pertaining to overall, but not participant-specific, coupon distribution and redemption.

235 Data analysis

236 *Diet quality*

237 Diet quality was calculated using the validated (36) Healthy Eating Index-2015 (HEI-2015) 238 using dietary intake data obtained from the ASA24-Canada-2018. HEI-2015 scores reflect 239 adherence to the 2015-2020 Dietary Guidelines for Americans (24), which coincide closely with 240 recommendations in Canada. The HEI-2015 has shown predictive validity (36), and HEI scores 241 have been associated with indicators of socioeconomic position (37) and chronic disease (38). 242 The National Cancer Institute's simple scoring algorithm was used to calculate HEI-2015 total 243 and component scores (24). Unlike other HEI-2015 scoring methods, the simple scoring 244 algorithm provides HEI-2015 scores at the individual level and can therefore accommodate 245 covariates in regression models (24). HEI-2015 scores were calculated using SAS macros 246 provided by the National Cancer Institute by summing component scores for adequacy (total 247 fruits, whole fruits, total vegetables, greens and beans, whole grains, dairy, total protein foods, 248 seafood and plant proteins, fatty acids) and moderation (refined grains, sodium, added sugars, 249 saturated fats) components. For adequacy components, a higher score indicates higher intake, 250 whereas, for moderation components, a higher score indicates a lower intake (24). HEI-2015

total scores can range from 0-100, with a higher score indicating a higher diet quality (24). At
each time point, HEI-2015 scores were averaged when two recalls were available (n=211 to
249), otherwise a single recall was used (n=14 to 43).

254

255 Statistical analyses

256 Descriptive statistics summarized participant characteristics and HEI-2015 scores by intervention257 group at each time point.

258

259 Linear mixed effects models were used to analyze differences in HEI-2015 total and component 260 scores for the FMNCP and control groups at post-intervention and 16 weeks post-intervention. 261 Models included group, time, and a group by time interaction as fixed effects. Random effects 262 accounted for repeated measures within participants, and a random slope for time using an 263 unstructured covariance matrix allowed each participants' intake to vary across time. Model 264 assumptions, such as normality and linearity of residuals, were met. Mixed models computed 265 maximum likelihood estimates for missing data, under a missing at random assumption. Data 266 were analyzed using an intention-to-treat approach in which participants were analyzed within 267 the groups to which they were randomized regardless of dropout or adherence to their assigned 268 intervention group.

269

To increase the precision of effect estimates (39), models were adjusted for blocking variables
(sex, geographic location, pregnancy, and breastfeeding), age, highest educational level,
race/ethnicity, marital status, body mass index (BMI), smoking status, perceived physical health,
number of household members, children living in the home, and the day on which the dietary

recalls were completed (i.e., both weekend (Friday to Sunday), both weekday, or one weekendand one weekday).

277	Previous studies have suggested that the use of and response to farmers' market fruit and
278	vegetable subsidies may vary according to individual level factors such as age (40) and sex (41).
279	Thus, two a priori subgroup analyses were conducted to examine between-group differences in
280	HEI-2015 total scores by sex and age group at post-intervention and 16 weeks post-intervention.
281	Age was categorized as adults (18-59 years) and older adults (≥ 60 years) to align with age
282	groups used in the existing FMNCP.
283	
284	Missing data
285	Baseline variables with missing values ranged from 0.4% (perceived physical health) to 10.9%
286	(race/ethnicity). A total of 22 (7.72%) and 41 (14.4%) HEI-2015 scores were missing at post-
287	intervention and 16 weeks post-intervention, respectively. Missing HEI-2015 scores and
288	participant dropout were included as indicator variables in separate logistic regression models (0
289	= missing/dropout, 1 = observed/remained in study). Predictors of missing outcome measures
290	and participant dropout were examined separately, as some participants who remained in the
291	study had missing outcomes. Models included covariates used in the primary analysis and other
292	potential predictors of missingness including total annual household income, main source of
293	income, and years lived in Canada.
294	

295 Statistical analyses were conducted in Stata (version 15.1, StataCorp), R (version 4.1.0, R

296 Foundation for Statistical Computing, Vienna), and SAS (version 9.4.40 Cary, NC: SAS

Institute). Statistical significance was set at a p-value of <0.05.

298

299 Sensitivity analyses

We conducted multiple sensitivity analyses. First, missing HEI-2015 scores were imputed using multiple imputation with chained equations under a missing at random assumption. Fifteen imputations were performed (42). Imputation models included HEI-2015 total scores and all baseline covariates from the linear mixed model. Predictive mean matching was used for continuous variables and logistic and multinomial logistic regressions were used for binary and categorical variables, respectively.

306

307 Second, the ratio of reported total energy intake (TEI) to predicted total energy expenditure 308 (TEE) was included in the models as a continuous variable to adjust for dietary intake 309 misreporting (43-45). TEE was calculated using validated equations developed by the Institute of 310 Medicine, accounting for participants' age, sex, height, weight, and physical activity level (46). 311 We assumed a low physical activity level of 1.5 (45). These equations were developed to predict 312 TEE of non-pregnant or breastfeeding adults with BMIs 18.5 or higher; therefore, we excluded 313 pregnant and breastfeeding females and participants classified as underweight (BMI<18.5) 314 (n=42) from these sensitivity analyses (45, 46). Participants whose reported energy intake was 315 beyond ± 1 SD from their TEI:TEE were classified as under- or over-reporters of dietary intake 316 (43). Note while researchers used simple thresholds (i.e., <500 kcal/d or >3,500 kcal/d for 317 females and <800 kcal/d or >4,000 kcal/d for males (34)) to identify participants with potentially

implausible intakes for follow-up during data collection, TEI:TEE was used for this sensitivity
analysis as it is a recommended method to estimate and adjust for dietary intake misreporting
(43-45).

321

322 Using self-reported data from the questionnaire, we conducted per-protocol and as-treated 323 analyses to examine the extent to which contamination of the intervention groups may have 324 affected study outcomes. The per-protocol analysis included participants who adhered to their 325 group allocation (i.e., participants in the FMNCP group who reported receiving coupons (n=139) 326 and participants in the control group who reported not receiving coupons (n=116)). In an 327 additional per-protocol analysis, we considered both coupon receipt and nutrition skill-building 328 attendance. This analysis included participants in the FMNCP group who reported receiving 329 coupons (n=139) and participants in the control group who reported not receiving coupons nor 330 attending nutrition skill-building activities (n=97). This per-protocol analysis did not exclude 331 participants in the FMNCP group who did not attend nutrition skill-building activities, as 332 attendance is not a requirement in the existing FMNCP. In the as-treated analysis, participants 333 were analyzed according to the intervention actually received. That is, participants who received 334 coupons were analyzed as part of the FMNCP group (n=165) and participants who did not 335 receive coupons were analyzed as part of the control group (n=120). Participation in nutrition 336 skill-building was not considered because our aim was to assess the FMNCP as delivered, and in 337 the existing FMNCP, nutrition skill-building activities are not a requirement of program 338 participation.

339

Finally, a small number of participants completed one (n=20) or both (n=8) dietary recalls two weeks or more after farmers' market closures and thus program impacts may have been missed for some. Therefore, a sensitivity analysis was conducted whereby participants who completed dietary recalls two weeks or more after farmers' market closures were excluded.

344

345 **Results**

346 A total of 285 adults completed baseline data collection and were randomized to the FMNCP 347 intervention (n=143) or the no-intervention control group (n=142). At post-intervention, 272 348 participants remained in the study (95.4%), while 254 participants remained at 16 weeks post-349 intervention (89.1%; Figure 1). Dropout rates were similar between intervention groups. 350 Participants were more likely to drop out from the study if they were widowed, had lived more 351 years in Canada, or smoked occasionally. Participants were less likely to drop out if their main 352 source of income was from social assistance or 'other' sources (e.g., refugee sponsorship). HEI-353 2015 scores were more likely to be missing among those who were widowed and had lived more 354 years in Canada, and less likely to be missing among those who relied on social assistance as 355 their main source of income) (Supplementary results: Supplementary Table 4).

356

357 *Participant characteristics*

358 Participant characteristics at baseline are described in **Table 1**. Similar to participants in the

existing FMNCP (47), most were female (90.5%), under 60 years of age (79.7%; mean age 43

- 360 years), and had children < 19 years living in the household (65.9%). The majority of participants
- 361 self-identified as White (37.7%) or South and West Asian (35.0%). Thirty-nine percent of
- 362 participants reported a total annual household income of < 20,000/year, 39.8% reported a high

363 school education or less, 56.1% were married or common-law, 86.7% were non-smokers, and 364 68.0% reported their health as 'good' or better. The mean baseline HEI-2015 total score was 60.2 365 out of a possible 100, similar to that of a nationally representative sample of adult females with 366 low incomes living in Canada (mean HEI-2015 score 59.1) (1). 367 368 Coupon distribution and redemption 369 Community partners distributed 85.0% of coupons to participants over the study period (13,580 370 coupons distributed out of 15,820 allocated coupons), with lower distribution rates primarily 371 attributable to participants not picking up the coupons. The coupon redemption rate at farmers'

372 markets was 99.1% (13,463 coupons were redeemed out of 13,580 coupons distributed).

373

Four participants (2.8%) in the FMNCP group reported that they did not receive any coupons,

while 26 participants (18.3%) in the control group reported receiving coupons. Given that the bar

376 code numbers for the coupons distributed to participants were not consistently recorded, we were

unable to verify how many coupons these 26 participants received.

378

379 Food purchasing

380 Based on data provided by farmers' market vendors, participants primarily used coupons to

purchase vegetables (39.0%), fruit (17.6%), meat and fish (11.1%), eggs (10.1%), with fewer

coupons redeemed to purchase dairy (3.7%), cut herbs (0.5%), and nuts (0.02%).

383

Farmers' market food purchasing data obtained from the questionnaire showed that 62.1% of

385 participants in the FMNCP group reported purchasing food from farmers' markets at least once

386 per week (using FMNCP coupons or their own money) (**Supplementary results**:

387	Supplementary Tables 1 to 3). Nearly half of the participants in the FMNCP group (48.8%)
388	reported spending some of their own money (excluding coupons) at a farmers' market once per
389	month or more during the season. Among those who reported spending their own money, 47.7%
390	spent over \$10 during their most recent farmers' market visit. Participants in the FMNCP group
391	reported primarily using their own money to purchase vegetables (33.3%), 'other' food items
392	(e.g., breads, baked goods) (22.6%), meat (15.5%), and fruit (14.3%). Few participants used their
393	own money to purchase dairy (4.9%), eggs (4.9%), cut herbs (1.2%), and nuts (0.0%).
394	
395	Among participants in the control group, 17.0% reported purchasing foods at a farmers' market
396	at least once per week, with 73.6% reporting spending over \$10 during their most recent farmers'
397	market visit. Participants in the control group reported purchasing primarily vegetables (58.5%),
398	fruits (17.0%), and other food items (11.3%). Few participants used their own money to purchase
399	dairy (5.7%), meat (5.7%), eggs (1.9%), and nuts (0.0%).

400

401 *Nutrition skill-building activities*

402 Only 35.7% (n=45) of participants in the FMNCP group reported attending nutrition skill-

403 building activities. Moreover, while those in the control group were meant to be excluded, 24.4%

404 (n=29) reported attending nutrition skill-building activities during the study period.

405

406 *Diet quality*

407 There were no significant differences in adjusted HEI-2015 total scores between the FMNCP and

408 control groups at post-intervention (-0.07; 95% confidence interval (CI) -4.07, 3.93)) or 16

409	weeks post-intervention (1.22; 95% CI -3.00, 5.44) (Table 2). Unadjusted and adjusted estimates
410	of all variables included in the models are available in the supplementary results
411	(Supplementary Table 5). Subgroup analyses did not reveal any significant between-group
412	differences in HEI-2015 scores by sex or age group (Supplementary results: Supplementary
413	Table 6). There was a trend towards higher HEI-2015 scores among the FMNCP and control
414	groups at post-intervention in unadjusted models; however, this trend was attenuated in fully
415	adjusted models (Supplementary results: Supplementary Table 5).
416	
417	There were no significant differences in HEI-2015 component scores at post-intervention;
418	however, there was a trend for intake of refined grains (-1.15; 95% CI -2.34, 0.04; p=0.06) and
419	whole fruit (0.60; 95% CI -0.06, 1.26, p=0.07) to be higher in the FMNCP group compared to
420	the control group at post-intervention (Table 2). Note that although the signs are the opposite of
421	one another they both signify higher intake in the FMNCP group because refined grains are a

422 moderation component (and therefore reverse scored), while whole fruits are an adequacy

423 component. In addition, dairy intake was significantly higher (1.47; 95% CI 0.31, 2.62) and fatty

424 acid intake was significantly lower (-1.30; 95% CI -2.57, -0.04) among those in the FMNCP

425 group at 16 weeks post-intervention. Both components are adequacy components.

426

427 Sensitivity analyses

428 Approximately 60% of participants misreported their dietary intake at each time point when
429 examined using TEI:TEE, with no differences between groups. Effect estimates after adjusting
430 for dietary intake misreporting remained non-significant, with slightly wider confidence intervals
431 (Supplementary results: Supplementary Table 7). Similarly, the effect estimates from the

432 imputed models and the per-protocol and as-treated analyses remained non-significant. Estimates
433 from analyses that excluded participants who completed one (n=20) or both (n=8) dietary recalls

434 two or more weeks following market closures also remained non-significant.

435

436 Discussion

To our knowledge, this is the first published RCT to examine the impact of a farmers' market
healthy food subsidy on the diet quality of adults with low incomes. There were no significant
differences in HEI-2015 total scores between groups at post-intervention or 16 weeks postintervention. Similarly, subgroup analyses did not reveal significant between-group differences
in HEI-2015 scores by sex or age group. There were no significant between-group differences in
HEI-2015 component scores post-intervention, although there were significant differences in
component scores for dairy and fatty acids at 16 weeks post-intervention.

444

445 Although we are unaware of any published RCTs that have examined the impacts of farmers' 446 market healthy food subsidies on diet quality, prior RCTs have examined the impacts of healthy 447 food subsidies redeemable at multiple retailers, including farmers' markets, on the diet quality of 448 adults with low incomes (23, 49, 50). For instance, Olsho et al. (23) found that HEI-2010 scores 449 were 4.7 points higher among adults with low incomes receiving a 30% incentive for fruit and 450 vegetable purchases for 12 months compared to those in a no-intervention control group (23). 451 The study also found significant differences in several HEI-2010 component scores (e.g., total 452 fruit) (23). Conversely, Basu et al. (50) found that among adults with low incomes receiving 453 vouchers valued at \$20/month for 6 months, HEI-2015 scores significantly improved among 454 those receiving weekly unrestricted vouchers but not among those receiving fruit and vegetableonly vouchers (50). Finally, a meta-analysis of healthy food subsidy interventions in any setting
found a significant increase in fruit and vegetable purchases but not fruit and vegetable
consumption among populations with low incomes (51). However, the meta-analysis did not
examine impacts on diet quality.

459

460 Overall, the evidence suggests that healthy food subsidies may improve diet quality in some 461 circumstances but not in others. However, findings across studies cannot be directly compared 462 due to variations in study populations, subsidy type and amount, intervention location and 463 duration, and data collection methods. In order to determine whether and how healthy food 464 subsidies can be leveraged to improve diet quality in adults with low incomes, future studies 465 should consider 1) examining the role of underlying contextual factors (e.g., intervention 466 location), 2) conducting a dose-response analysis to examine whether program impacts depend 467 on the amount of subsidy received, and 3) using consistent data collection methods to better 468 support cross-study comparisons (52).

469

470 Several factors might account for our null findings. First, the value of FMNCP coupons may 471 have been inadequate to produce meaningful changes in diet quality. In 2017, the estimated cost 472 of food for a family of four in BC was \$1,019/month (53). According to this estimate, the 473 FMNCP subsidy of \$84/month contributed 8.2% to a household's monthly food cost, which may 474 have been insufficient to improve diet quality (54). Moreover, food prices in farmers' markets 475 are often higher than in more conventional food retailers such as supermarkets (55-57), which 476 may have limited how much food participants could purchase with the coupons. Second, 477 participants may have made their usual healthful food purchases at farmers' markets using

FMNCP coupons, rather than from their usual food retailers with their own funds. Foodpurchasing data from all food retailers may have provided further information on how

480 households adjusted their food budget upon receiving the FMNCP coupons.

481

482 Foods purchased with the coupons may have also been shared amongst all household members. 483 In particular, evidence suggests that adults attempt to shield children from experiences of 484 household food insecurity by compromising their dietary intake to prioritize children's 485 nutritional needs (58-60). Thus, future studies should examine the impacts of farmers' market 486 healthy food subsidies on the diet quality of all household members, particularly children. The 487 program length of 10-15 weeks may have also been too short for diet quality to substantially 488 change. Indeed, findings from our longitudinal qualitative investigation among FMNCP 489 participants suggest that a larger and longer-term subsidy may have better supplemented 490 participants' food budgets (6, 61). However, other studies have found positive impacts on diet 491 quality from food subsidy programs of similar duration (49).

492

493 Several other factors may have contributed to our findings. First, some participants may not have 494 received the full subsidy amount as not all allocated coupons were distributed, and some 495 participants reported sharing their coupons with a friend or others in the community (6). 496 However, this pragmatic RCT was designed to assess the effectiveness of the FMNCP in the real 497 world. For this reason, fidelity was imperfect, as might be expected under real-world conditions 498 of delivering a population-level intervention. Moreover, we ruled out other potential 499 explanations for our null findings, such as contamination, through multiple sensitivity analyses. 500 Second, several community partners did not offer nutrition skill-building activities. Nutrition

skill-building may have augmented the impact of the coupons, although the evidence remainsmixed in this respect (62, 63).

503

Reasons underlying the significant differences in HEI-2015 component scores for dairy and fatty acids at 16 weeks post-intervention are unclear. However, our food purchasing data indicate that few participants used the coupons or their own money to purchase dairy or nuts (a source of unsaturated fatty acids), suggesting that these findings may be spurious. Given the increased likelihood of type I errors due to multiple comparisons, these findings should be interpreted cautiously.

510

511 Limitations of this study should be considered. Dietary intake data were self-reported and may 512 be affected by misreporting (15). However, our sensitivity analysis showed similar outcomes 513 after adjusting for dietary intake misreporting. Data collection required computer and internet 514 access and literacy, which may have hindered some participants from accessing or accurately 515 completing the surveys (31). However, many participants completed data collection by telephone 516 or with a community partner, which may have mitigated data loss or inaccuracies. We collected 517 data from the primary food shopper in the household, precluding examination of program 518 impacts among other household members. We were unable to examine participant-specific 519 coupon distribution and redemption; however, as nearly all coupons were distributed and 520 redeemed, the lack of participant-specific data was relatively inconsequential. Finally, some 521 participants in the control group reported attending nutrition skill-building activities. However, it 522 is possible that they considered any skill-building activity (e.g., pregnancy classes) in their 523 response, rather than those specific to nutrition (e.g., cooking classes).

524

525 Despite these limitations, this study fills important knowledge gaps (51, 64). We undertook a 526 rigorously designed longitudinal RCT to examine the impact of the BC FMNCP on the diet 527 quality of adults with low incomes and found no significant differences in HEI-2015 scores. We 528 collected 24-hour dietary recalls using the validated ASA24-Canada-2018 (26, 32). Twenty-four-529 hour dietary recalls capture dietary intake data with less bias than other dietary assessment 530 instruments (15, 65). We examined overall diet quality, rather than fruit and vegetable intake 531 alone, using the validated HEI-2015 (35). Examining program impacts on diet quality at 16 532 weeks post-intervention allowed examination of longer-term program outcomes. Our retention 533 rate was high at 89.1%, as was the 99.1% coupon redemption rate. Finally, study participants 534 were recruited from the FMNCP waitlist and shared similar characteristics to those in the 535 existing FMNCP. Therefore, while findings may not represent all adults with low incomes, 536 findings may be generalizable to broader program participants.

537

538 Policy implications

539 Despite the potential for healthy food subsidy programs to supplement household food budgets, 540 these programs alone are unlikely to produce measurable and long-term improvements in diet 541 quality as they are generally short-term and provide small subsidies (6, 66). In addition, these 542 programs operate under the assumption that poor diet quality among populations with low 543 incomes is a food-related issue rather than a symptom of material deprivation (66). To 544 effectively improve diet quality among populations with low incomes, food subsidy programs 545 should be implemented in tandem with policies that address the structural processes driving the inequitable distribution of income and other social determinants of health, such as policies that
improve employment incomes and that increase access to education and affordable housing (67).

549 Conclusion

550 Despite growing interest in farmers' market healthy food subsidy programs as a means to 551 improve diet quality among populations with low incomes, this study demonstrated that the BC 552 FMNCP did not significantly improve the diet quality of adults with low incomes during the 553 study period. Further evidence is needed to elucidate whether higher subsidy amounts and 554 longer-term support may better support healthier dietary patterns among adults with low 555 incomes.

556

557 Acknowledgements: The research team would like to extend our sincere appreciation to the 558 managers and staff of the British Columbia Association of Farmers' Markets, the Farmers' 559 Market Nutrition Coupon Program, and the BC Ministry of Health for their partnership and 560 collaboration on this research study. We would additionally like to thank the community 561 partners, farmers' market vendors, and participants for their valuable contributions. We are also 562 grateful to our research assistants, Sayeeda Amber Sayed, Anjola Adeboye, Jennifer Fry, Jennis 563 Jiang, Justin Ancheta, Grant Tkachyk, Toyin Ogunyannwo, and Payge Dirk for their 564 contributions to the study, and to the Epidemiology Coordinating and Research (EPICORE) 565 Centre for their statistical support.

566

567 Contributors: MLA and DLO wrote the manuscript; PL delivered the intervention; MLA, SD,
568 SCR, and YYL collected the data; MLA, TS, and BP conducted the statistical analyses; all

569	authors (MLA,	SD, '	TS, HO,	PL,	GRM, SO	CR, KB,	YYL,	SN, RA	R, BP	, LMM,	KDR,	JG, S	SD,
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570 CIJN, DLO) contributed to study design, interpreted the data, and critically edited and approved

571	the final	manuscript.
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Figure 1. CONSORT flow diagram of Farmers' Market Nutrition Coupon Program study participants (n=285)

Characteristics	FMNCP (n = 143)	Control $(n = 142)$	Total $(n = 285)$
	n (%)	n (%)	n (%)
Age group			
18 to 59 years	112 (78.3)	115 (81.0)	227 (79.7)
60+ years	31 (21.7)	27 (19.0)	58 (20.4)
Sex			
Male	13 (9.1)	14 (9.9)	27 (9.5)
Female	130 (90.9)	128 (90.1)	258 (90.5)
Pregnant			
Yes	8 (5.6)	7 (4.9)	15 (5.3)
No	135 (94.4)	135 (95.1)	270 (94.7)
Breastfeeding			
Yes	12 (8.4)	12 (8.5)	24 (8.4)
No	131 (91.6)	130 (91.6)	261 (91.6)
Geography			
Urban	122 (85.3)	121 (85.2)	243 (85.3)
Rural	21 (14.7)	21 (14.8)	42 (14.7)
Race/ethnicity ¹			
White	47 (36.4)	50 (39.1)	97 (37.7)
Black	3 (2.3)	5 (3.9)	8 (3.1)
East or southeast Asian	14 (10.9)	11 (8.6)	25 (9.7)
South or west Asian	46 (35.9)	44 (34.4)	90 (35.0)
Indigenous	15 (11.6)	10 (7.8)	25 (9.7)
Other	4 (3.1)	8 (6.3)	12 (4.7)
Number of household members			
Single person	16 (11.4)	30 (21.1)	46 (16.3)
2 to 4 people	98 (69.5)	93 (65.5)	191 (67.5)
5 to 8 people	27 (19.2)	19 (13.4)	46 (16.6)
Children living in the home			
Yes	96 (67.6)	91 (64.1)	187 (65.9)
No	46 (32.4)	51 (35.9)	97 (34.2)
Annual household income			
Less than \$20,000	47 (37.9)	51 (41.1)	98 (39.5)
\$20,000 to \$39,999	41 (33.1)	15 (36.3)	86 (34.7)
\$40,000 to \$59,999	22 (17.7)	14 (11.3)	36 (14.5)
More than \$60,000	14 (11.3)	14 (11.3)	28 (11.3)
Educational attainment			
High School diploma or less	56 (40.3)	55 (39.3)	111 (39.8)
Some post-secondary or trade	44 (31.7)	40 (28.6)	84 (30.1)
Bachelor's degree	26 (18.7)	19 (13.6)	45 (16.1)
Graduate degree	12 (8.6)	25 (17.9)	37 (13.3)
Other	1 (0.7)	1 (0.7)	2 (0.7)
Marital status			
Married or common-law	74 (53.2)	83 (58.9)	157 (56.1)
Divorced	14 (10.1)	6 (4.3)	20 (7.1)
Separated	16 (11.5)	12 (8.5)	28 (10.0)
Single (never married)	25 (18.0)	32 (22.7)	57 (20.6)
Widowed	10 (7.2)	8 (5.7)	18 (6.4)
Self-reported physical health			
Poor	13 (9.2)	13 (9.2)	26 (9.2)
Fair	36 (25.4)	29 (20.4)	65 (22.9)

Table 1. Baseline characteristics of adults with low incomes (n=285) in the British Columbia Farmers' Market Nutrition Coupon Program study

Good	65 (45.8)	69 (48.6)	134 (47.2)	
Very good	22 (15.5)	24 (16.9)	46 (16.2)	
Excellent	6 (4.2)	7 (4.9)	13 (4.6)	
Smoking				
Not at all	125 (87.4)	122 (85.9)	247 (86.7)	
Occasionally	5 (3.5)	9 (6.3)	14 (4.9)	
Daily	13 (9.1)	11 (7.8)	24 (8.4)	
Dietary intake misreporting				
(n=234)				
Plausible reporter	46 (40.7)	45 (37.2)	91 (38.9)	
Potential underreporter	64 (56.6)	73 (60.3)	137 (58.6)	
Potential overreporter	3 (2.7)	3 (2.5)	6 (2.6)	
	mean (SD)	mean (SD)	mean (SD)	
Age (years)	43.7 (16.0)	41.5 (16.2)	42.6 (16.1)	
BMI (kg/m^2)	27.5 (5.4)	26.2 (6.3)	26.8 (5.9)	
Years lived in Canada	25.0 (22.5)	24.1 (22.3)	24.5 (22.4)	
HEI-2015 Total and component sco	res			
Total score (0-100)	60.1 (14.3)	60.4 (14.7)	60.2 (14.5)	
Total vegetables (0-5)	3.9 (1.6)	4.0 (1.5)	3.9 (1.5)	
Greens and beans (0-5)	3.0 (2.3)	2.9 (2.3)	3.9 (2.3)	
Total fruits (0-5)	2.9 (2.1)	2.8 (2.1)	2.8 (2.1)	
Whole fruits (0-5)	2.9 (2.3)	3.1 (2.2)	3.0 (2.2)	
Whole grains (0-10)	4.4 (4.0)	4.6 (4.2)	4.5 (4.1)	
Dairy (0-10)	5.9 (3.5)	6.1 (3.4)	6.0 (3.4)	
Total protein foods (0-5)	4.2 (1.4)	4.2 (1.4)	4.2 (1.4)	
Seafood and plant proteins (0-5)	2.8 (2.2)	2.9 (2.2)	2.9 (2.2)	
Fatty acids (0-10)	5.7 (3.7)	5.5 (3.6)	5.6 (3.7)	
Sodium $(0-10)^2$	3.8 (3.4)	3.4 (3.5)	3.6 (3.4)	
Refined grains $(0-10)^2$	6.3 (3.7)	5.8 (3.6)	6.1 (3.7)	
Saturated fats $(0-10)^2$	6.1 (3.6)	6.7 (3.3)	6.4 (3.5)	
Added sugars $(0-10)^2$	8.4 (2.6)	8.4 (2.2)	8.4 (2.4)	

¹Response options included Arab, Black, Chinese, First Nations (Status & Non-Status), Japanese, Korean, Latin American, Metis, South Asian, Southeast Asian, West Asian, White, and Other. Race/ethnicity was recategorized to reduce the number of categories.

²Higher score indicates a lower intake.

FMNCP, Farmers' Market Nutrition Coupon Program; HEI-2015, Healthy Eating Index-2015

		Post-in	tervention			16 weeks post-intervention				
HEI-2015 total and	FMNCP	Control	0 (05% CI)		FMNCP	Control	0 (050) CI)			
(maximum scores	mean (SEM)	mean (SEM)	β (95% CI)	р	mean (SEM)	mean (SEM)	β (95% CI)	р		
(maximum score)	(SEM)	(SEWI)			(SEM)	(SEIVI)				
(100)	63.6 (1.3)	62.1 (1.3)	-0.07 (-4.07, 3.93)	0.97	62.0 (1.4)	59.2 (1.4)	1.22 (-3.00, 5.44)	0.57		
Adequacy components										
Total vegetables (5)	4.3 (0.1)	4.1 (0.1)	0.09 (-0.37, 0.55)	0.70	4.2 (0.1)	4.1 (0.1)	-0.05 (-0.61, 0.50)	0.85		
Greens and beans (5)	3.3 (0.2)	2.9 (0.2)	-0.07 (-0.84, 0.69)	0.85	3.4 (0.2)	3.0 (0.2)	-0.09 (-0.88, 0.70)	0.82		
Total fruits (5)	3.4 (0.2)	3.0 (0.2)	0.34 (-0.29, 0.98)	0.29	2.8 (0.2)	2.6 (0.2)	0.25 (-0.43, 0.93)	0.48		
Whole fruits (5)	3.6 (0.2)	3.1 (0.2)	0.60 (-0.06, 1.26)	0.07	3.3 (0.2)	2.8 (0.2)	0.71 (-0.04, 1.46)	0.06		
Whole grain (10)	4.9 (0.4)	4.3 (0.3)	-0.05 (-1.16, 1.05)	0.92	5.3 (0.4)	3.9 (0.4)	0.61 (-0.63, 1.84)	0.34		
Dairy (10)	5.7 (0.3)	6.0 (0.3)	-0.20 (-1.29, 0.89)	0.72	6.4 (0.3)	5.1 (0.3)	1.47 (0.31, 2.62)	0.01		
Total protein (5)	4.3 (0.1)	4.2 (0.1)	0.31 (-0.12, 0.74)	0.15	4.2 (0.2)	4.2 (0.2)	0.21 (-0.27, 0.69)	0.39		
Seafood and plant proteins (5)	3.2 (0.2)	3.0 (0.2)	-0.04 (-0.78, 0.71)	0.92	3.1 (0.2)	2.9 (0.2)	-0.10 (-0.90, 0.70)	0.81		
Fatty acids ² (10)	6.0 (0.4)	5.8 (0.4)	-0.27 (-1.47, 0.94)	0.67	5.2 (0.4)	6.0 (0.4)	-1.30 (-2.57, -0.04)	0.04		
Moderation components ³										
Sodium (10)	3.2 (0.3)	3.7 (0.3)	-0.30 (-1.45, 0.84)	0.61	2.9 (0.3)	3.8 (0.3)	-0.69 (-1.86, 0.48)	0.25		
Refined grains (10)	6.2 (0.3)	6.8 (0.3)	-1.15 (-2.34, 0.04)	0.06	6.3 (0.4)	5.7 (0.4)	0.08 (-1.25, 1.40)	0.91		
Saturated fats (10)	6.6 (0.3)	6.5 (0.3)	0.53 (-0.51, 1.57)	0.32	6.1 (0.3)	6.4 (0.3)	0.07 (-0.98, 1.13)	0.89		
Added sugars (10)	8.9 (0.2)	8.7 (0.2)	0.18 (-0.56, 0.92)	0.63	8.8 (0.23)	8.5 (0.2)	0.21 (-0.55, 0.97)	0.59		

Table 2. Differences in mean Healthy Eating Index-2015 total and component scores between the FMNCP and control groups at post-intervention and 16 weeks post-intervention $(n=285)^1$

¹Linear mixed effects models included group, time, and a group by time interaction as fixed effects. Random effects included repeated measures within participants, and a random slope for time using an unstructured covariance matrix. Models adjusted for baseline sex, pregnancy, breastfeeding, geographic location, age, highest educational level, race/ethnicity, marital status, body mass index, smoking status, perceived physical health, number of household members, children living in the home, and the day on which the dietary recalls were completed. ²Ratio of poly- and monounsaturated fatty acids to saturated fatty acids.

³Higher score indicates a lower intake.

Note: p-value for group by time interaction. Bold font indicates statistically significant differences (p<0.05).

FMNCP, Farmers' Market Nutrition Coupon Program; HEI-2015, Healthy Eating Index-2015