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RESEARCH ARTICLE

Health Center–Based Community-Supported Agriculture: An RCT

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Introduction: Socioeconomically vulnerable individuals often face poor access to nutritious food and bear a disproportionate burden of diet-related chronic illness. This study tested whether a subsidized community-supported agriculture intervention could improve diet quality.

Study design: An RCT was conducted from May 2017 to December 2018 (data analyzed in 2019).

Setting/Participants: Adults with a BMI >25 kg/m^2 seen at a community health center in central Massachusetts, or who lived in the surrounding county, were eligible.

Intervention: Individuals were randomized to receive either subsidized community-supported agriculture membership (which provided a weekly farm produce pickup from June to November) or healthy eating information (control group). For equity, the control group received financial incentives similar to the intervention group.

Main outcome measures: The primary outcome was the Healthy Eating Index 2010 total score (range, 0–100; higher indicates better diet quality; minimum clinically meaningful difference, 3). Healthy Eating Index was assessed using 3 24-hour recalls per participant collected each growing season. Intention-to-treat analyses compared Healthy Eating Index scores between the intervention and control group, accounting for repeated measures with generalized estimating equations.

Results: There were 128 participants enrolled and 122 participants for analysis. The participants' mean age was 50.3 (SD=13.6) years; 82% were women; and 88% were white, non-Hispanic, with a similar distribution of baseline characteristics comparing the intervention and control groups. Baseline Healthy Eating Index total score was 53.9 (SD=15.3) in the control group and 55.1 (SD=15.2) in the intervention group (p=0.68). The intervention increased the mean Healthy Eating Index total score relative to the control group (4.3 points higher, 95% CI=0.5, 8.1, p=0.03). Food insecurity was lower in the intervention group (RR=0.68, 95% CI=0.48, 0.96).

Conclusions: A community-supported agriculture intervention resulted in clinically meaningful improvements in diet quality. Subsidized community-supported agriculture may be an important intervention for vulnerable individuals.

Trial registration: This study is registered at www.clinicaltrials.gov NCT03231592.

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INTRODUCTION

Poor diet quality is a leading cause of excess morbidity and mortality—responsible for more deaths than any other risk factor and more than 10% of all disability-adjusted life years in the U.S.[1] Improving diet quality is a public health priority and a key goal of chronic disease prevention efforts.[2] Further, the U.S. population exhibits notable disparities in diet quality such that groups with lower SES tend to have worse diet quality and bear a disproportionate burden of diet-related disease.[1,3,4] Despite overall progress in improving diet quality in recent decades, socioeconomic disparities in diet quality have increased,[3] and disparities are particularly wide for fruit and vegetable consumption.[5]

Diet quality is lower among individuals with lower SES, as indicated by lower income and less educational attainment, for several reasons.[6] Food insecurity, uncertain access to nutritious food owing to cost,[7] incentivizes the consumption of processed, calorie-dense foods laden with sodium and added sugars, which are cheaper on a per-calorie basis than fruits and nonstarchy vegetables.[8] Further, individuals with lower SES may have access to fewer local healthy food retailers and face transportation barriers to obtaining food.[6]

Nevertheless, there have been successful interventions to improve diet quality in those with lower SES. Examples of this include education interventions[9−13] and, notably, the Healthy Incentives Pilot,[14,15] a randomized study that examined the effect of providing a 30% subsidy for purchases made at farmer's markets with Supplemental Nutrition Assistance Program (SNAP) benefits. However, these interventions have not seen widespread implementation, which has led to searches for alternative interventions to improve diet quality for individuals with lower SES. A promising approach is community-supported agriculture (CSA).[16−19] A common small farm vegetable and fruit distribution model, CSAs ask that before the beginning of a growing season, individuals or households purchase a share of the produce of a local farm.[19] This farm will then provide, generally weekly, an allotment of seasonal produce for the subscribers. Benefits of the CSA approach include the variety of seasonally available produce, connection with a local business, and a membership-based model, which may facilitate engagement.[16,17,20] These features may lead to improved diet quality. A prior feasibility study in federally qualified health center patients found that CSA participation was associated with an increase in the variety of vegetables eaten.[21] Because individuals with lower SES, however, may be unable to purchase a CSA share unaided, this study sought to determine whether a CSA share could improve diet quality in individuals at high risk of diet-related illness, as defined by having a BMI >25 kg/m^2. The hypothesis tested herein was that a subsidized CSA share would improve diet quality.

METHODS

This study was conducted in Franklin County, Massachusetts. Franklin County is a rural area in Massachusetts with lower levels of median household income and college education rates than the state overall[22] and higher levels of food insecurity.[23]

Study Population

Participants were recruited primarily from those receiving care at the Community Health Center of Franklin County (a federally qualified community health center), but those who lived in the surrounding area of Franklin County, Massachusetts were also eligible. Participants had to be adults (aged >18 years) with a BMI >25 kg/m^2, determined by review of clinical records or by participant self-report, in the 1 year before study eligibility assessment. This BMI criterion was selected as those with a BMI >25 kg/m^2 are at increased risk for diet-related morbidity and mortality.[24] Exclusion criteria included those who were pregnant or planning to become pregnant during the study period and self-report of life-threatening food allergies to foods grown by the CSA. All study participants provided written informed consent, and the study was approved by the IntegReview IRB (protocol FMPP2016-Just Roots). Participants were recruited in several ways. Within the federally qualified health center, primary care providers discussed the study with potentially eligible participants and referred interested individuals to the study. Posters and flyers were also put up within the health center. In the Greenfield community, posters were put up in frequented places and Just Roots, the CSA organization, provided information about the study at local events. Facebook posts also advertised the study. All recruitment materials were IRB-approved before use. Recruitment was conducted by study staff who were affiliated with either the health center or Just Roots.

Measures

An RCT (NCT03231592) was conducted from May 2017 to December 2018. Data were analyzed in 2019. Participants in the trial were randomized using variable-size block randomization, in a 1:1 ratio, with a computer-generated randomization sequence.[25] Group assignment was concealed using a sealed envelope, and the randomization sequence was not shared with those enrolling participants. One investigator (SAB) developed the sequence, whereas research assistants enrolled participants and revealed allocation assignment. Randomization assigned individuals to either the intervention group, which received a financial subsidy they then used to purchase a CSA membership, or a control group that received healthy eating information (the "Choose MyPlate" brochure[26]) and financial incentives for research visit attendance that equaled the value of the financial subsidy provided to the intervention group. This "cash-benchmarking"[27] design effectively tested the marginal benefit of the CSA membership itself, rather than the financial value of that membership, and ensured that both intervention and control groups received something of benefit for study participation.

After providing informed consent, participants completed the first research visit, which occurred before the start of the 2017 growing season. They were then randomized before the start of the growing season.

Following randomization, participants completed 4 additional research visits (Appendix Figure 1, available online): 1 at the end of the 2017 growing season, 1 during the winter of 2018, 1 at the beginning of the 2018 growing season, and 1 at the end of the 2018 growing season. Each of the 5 research visits included completing a standard questionnaire; a 24-hour dietary recall using the Automated Self-Administered 24-Hour Dietary Assessment Tool system; and having height, weight, and blood pressure measured. During the first (baseline) research visit, all assessments were made before randomization. A table of assessments made at each visit is presented as Appendix Table 1, available online. Anthropometric assessments used the same calibrated instruments for all participants and followed a standardized procedure. After the research visit, participants had blood drawn for nonfasting laboratory assessment at the hospital-based laboratory associated with the health center. In addition to the research visits, participants also completed telephone-based 24-hour dietary recalls using the Automated Self-Administered 24-Hour Dietary Assessment Tool system.[28] Three dietary recalls occurred during each growing season and 3 occurred during the nongrowing season, in addition to completion of a baseline 24-hour recall during the initial study visit. To the greatest extent possible, recalls were done without advance notice, to provide an accurate reflection of what participants were eating when they did not know their eating would be observed. These diet recalls were used to calculate Healthy Eating Index (HEI) 2010 scores as an index of diet quality.[29] To avoid limitations because of low health literacy, all materials were read aloud to participants, including the diet recalls, which were read from the computer screen.

It was necessary to determine a clinically meaningful difference in HEI total score to power the study. For this study, a 3-point difference in HEI total score was taken to indicate a clinically meaningful difference. Although there is uncertainty in the field regarding what a clinically meaningful difference is, 4 lines of evidence led to the selection of this level (discussed in detail in Appendix Text 1, available online).[3,15,30−35] Estimates were that 100 participants, 50 in each group, would be necessary to give 80% power to detect a difference of this magnitude or larger, assuming an SD of 12, and using a repeated measures regression analysis for hypothesis testing. To account for attrition, planned enrollment was 120 participants. Initially, the plan was to enroll all participants before the 2017 growing season. Ultimately, 101 participants enrolled before the 2017 growing season. To protect against attrition, an additional 21 participants were recruited before the beginning of the 2018 growing season. This created 2 cohorts—Cohort A, those who were enrolled for both the 2017 and 2018 growing seasons, and Cohort B, those who were enrolled for the 2018 growing season only. Randomization was blocked within the cohorts, and other than the duration of participation, study procedures were identical across the cohorts. Participants were not masked to study assignment, but outcome assessment (e.g., conducting 24-hour recalls) was masked. Full follow-up was defined as completing all study visits through fall 2018.

Intervention

The intervention consisted of the purchase of a CSA membership at Just Roots, a nonprofit community organization that operates Greenfield Community Farm. The intervention group participants were given $300 per growing season for study participation, and were required to purchase a CSA share. Individuals could select either a "full" or a "small" share at their preference. The full cost of a full share was $690, and the full cost of a small share was $480. Separately from the study, the Just Roots CSA also offers discounted share prices for SNAP recipients (study participants who were also SNAP recipients were eligible for these). Membership entitled the participant to a weekly share of the farm's produce from June to November during the growing season, lasting 24 weeks in total. In a given week, there were 15−20 types of produce available, from which a participant would select 9 (for a large share) or 6 (for a small share) items. Example foods included carrots, scallions, cucumbers, squash, tomatoes, leeks, kale, collard greens, Swiss chard, celery, salad greens, beets, sweet peppers, eggplant, hot peppers, tomatillos, melons, and bok choy. The produce was picked up by the participant at the farm or in downtown Greenfield. Each week, the farm also provided 2 recipes. One of the recipes was demonstrated and sampled at each of the distributions. Along with the recipes, basic information about the featured foods was provided. For the control group, an equivalent cash amount ($300 per growing season) was provided, allocated across the scheduled research visits. Individuals in the control group could not purchase a Just Roots CSA share, although there were no other restrictions on how participants spent this money. Control group participants were also given a Choose MyPlate healthy eating guide (www.choosemyplate.gov/).

As noted, the primary outcome was the total HEI 2010 score. HEI 2010 ranges from 0 to 100 and measures adherence to U.S. Department of Agriculture dietary recommendations across 12 subscores (Appendix Table 2, available online).[29] Higher HEI values always indicate better adherence. The subscores comprise 8 adequacy scores, for which greater consumption is desirable and thus leads to a higher score, and 4 moderation scores, for which lower consumption is desirable and thus leads to a higher score. In addition to examining changes in total HEI score, changes in HEI subscores were examined.

In addition to diet quality, 2 other major categories of outcomes were examined in secondary or exploratory analyses. The first was participant-reported outcomes, and the second was anthropometric and laboratory measurements. For participant-reported outcomes, assessments were food security (using the U.S. Department of Agriculture 6-item food security survey module, with 2 or more affirmative responses coded as food insecure),[36] the Patient-Reported Outcomes Measurement Information System Global Health 10-item raw score (a generic measure of global health, summing physical and mental health items),[37] the raw score from 4-item Patient-Reported Outcomes Measurement Information System assessments of depressive and anxiety symptoms,[38] cost-related medication underuse (using 4 items derived from the Medical Expenditure Panel Survey regarding not filling a prescription owing to cost, delaying filling a prescription because of cost, skipping doses to save money, or taking less of a prescribed medication owing to cost, and, as in prior studies, coded such that any affirmative response indicated cost-related medication underuse),[39] and trade-offs between food and medication purchases.[40] Anthropometric measurements were height and weight (used to calculate BMI) and systolic and diastolic blood pressure. Laboratory assessments were serum lipids, serum glucose, and HbA1c.

Statistical Analysis

Analyses followed the intention-to-treat principle, which categorized participants by their randomization assignments regardless of adherence to the intervention or incomplete follow-up, and included them in all analyses. Descriptive statistics were conducted. Trial reporting guidelines advising against hypothesis testing comparing groups on baseline characteristics were followed.[41,42] Primary analyses examined diet quality and compared the HEI scores of those in the intervention and control groups during the growing season (i.e., when the intervention was occurring). Owing to the randomized design, these were adjusted only for study cohort. A standard longitudinal data analysis strategy was used, wherein the measurement occasion is the unit of analysis, and the analysis accounted for repeated assessments within individuals using generalized estimating equations with robust CIs. A 2-sided p-value <0.05 was taken to indicate statistical significance. To check that the results were not influenced by chance imbalances between groups, additional analyses were conducted that adjusted for the baseline measurement of the outcome (sometimes called the ANCOVA approach), date of measurement assessment (to account for seasonality), and demographics (age, gender, and race/ethnicity). Additional analyses further adjusted for education and income, in addition to baseline HEI score, date, and demographics. Moreover, to examine the overall effect of the intervention on diet quality throughout the year, analyses were conducted that included 24-hour recalls both during the growing season (when the intervention was occurring) and during the nongrowing season. Finally, to account for intervention nonadherence (not picking up the produce every week) or censoring before the final study visit owing to loss to follow-up, analyses were conducted that estimated the "per-protocol" effect.[43] This effect can be thought of as the difference in diet quality between the intervention and control group that would have been observed if all participants had adequate adherence (defined as picking up produce at least 70% of weeks of the growing season) and no participants had been lost to follow-up. To calculate the per-protocol effect, a targeted maximum likelihood estimation approach was used.[44,45] This approach models the relationship between treatment, all baseline covariates, censoring (either owing to nonadherence or loss to follow-up), and outcomes using an ensemble of machine learning algorithms,[46] and then uses these models to estimate the per-protocol effect, with an efficient influence curve−based CI for statistical inference.[44]

For the secondary and exploratory analyses, all followed the same structure, and used data obtained during the intervention period. Either log Poisson (for dichotomous outcomes)[47] or linear (for continuous outcomes) regression was used, with generalized estimating equations to account for repeated measures, and adjusted for the baseline value of outcome and cohort. All analyses were conducted in SAS, version 9.4 and R, version 3.4.2.

RESULTS

There were 128 individuals initially enrolled in the trial and 6 withdrew before the start of intervention, leaving 122 participants (Figure 1) for analysis. The mean age of study participants was 50.2 (SD=13.8) years, and 81% of participants were women (Table 1). The median income was 146% of the federal poverty guideline (25th percentile, 92%; 75th percentile, 245%). At baseline, 39% of participants reported receiving SNAP benefits. Overall, follow-up was good with 100 (82%) completing full follow-up. Loss to follow-up was nondifferential across groups (14 lost to follow-up in the intervention group compared with 8 in the control group; p=0.10) (Appendix Table 4, available online). Among individuals who received the intervention, adherence was also good, with the median percentage of weekly CSA shares an individual picked up being 79% (25th percentile, 49%; 75th percentile, 92%).

As expected by randomization, baseline characteristics were well balanced across the intervention and control groups (Table 1). In addition, characteristics were similar among those who enrolled at the start of the study, Cohort A, compared with those enrolled in second year, Cohort B (Appendix Table 2, available online). No participants reported adverse events related to study participation.

In the primary analysis, using data from the growing season (i.e., when the intervention was occurring), the intervention led to significant improvement in the total HEI score (60.2 in the intervention group vs 55.9 in the control group; difference, 4.3; 95% CI=0.5, 8.1, p=0.03) (Table 2). Sensitivity analyses that adjusted, in case of chance imbalance, for date of dietary recall, baseline total HEI score, and demographics, found similar benefit for the intervention (difference: 3.7, 95% CI=0.3, 7.0, p=0.03). Analyses that included both in-season and out-of-season assessments also found a similar benefit (difference: 4.1, 95% CI=0.3, 7.9, p=0.03). Further

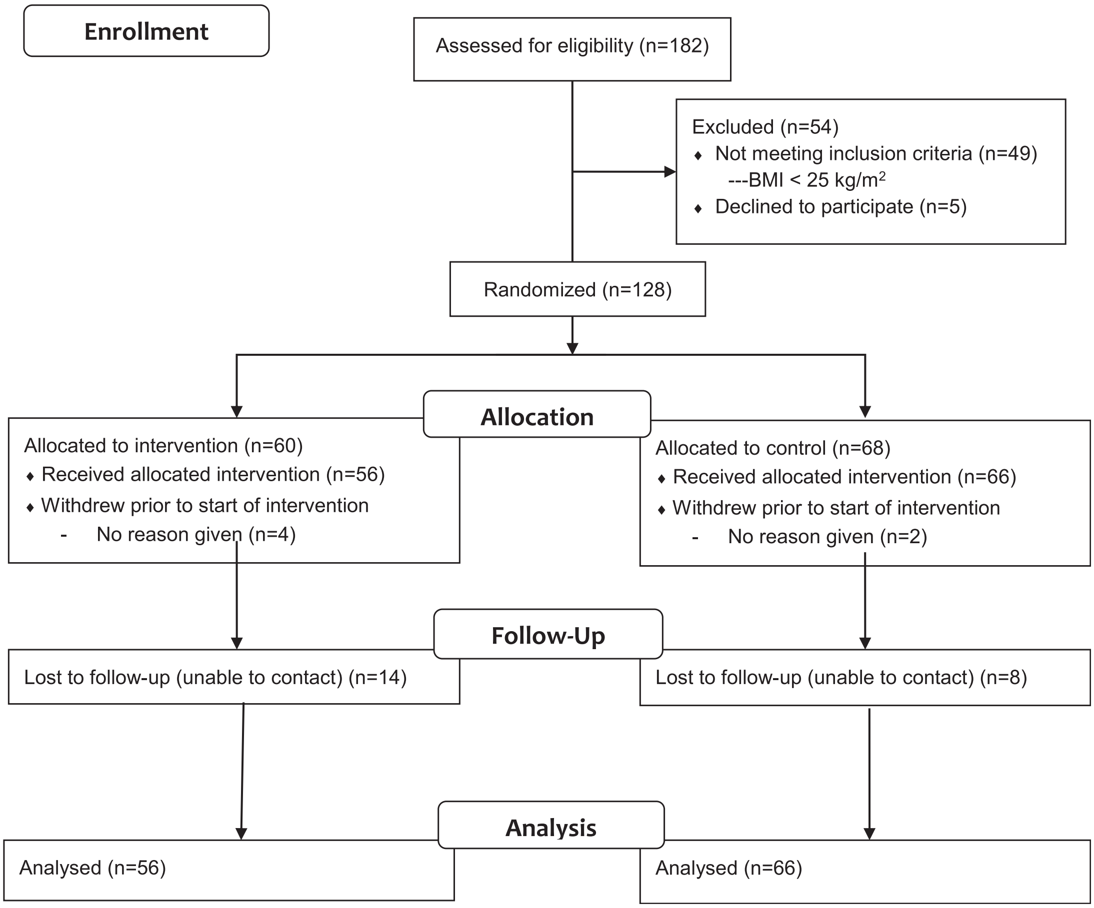

Figure 1. CONSORT diagram.

adjustment for income and education also found similar results (difference: 4.8, 95% CI=1.3, 8.4, p=0.007). Per-protocol analyses, which estimate what the intervention effect would have been had everyone adhered to their assigned treatment and completed full follow-up, were also in favor of the intervention (difference: 4.8, 95% CI=2.3, 7.2, p=0.0001). Interaction testing revealed that there was no difference in effect on total HEI score when comparing Cohort A and Cohort B participants (p=0.77). Analyses of subscores revealed significant improvements in categories clearly associated with the food provided (total vegetables, total fruit, and whole fruit) and lower consumption of empty calories, such as sugar-sweetened beverages.

Baseline food insecurity prevalence was 42% in the control group and 31% in the intervention group. During the intervention, prevalence fell to 32% in the control group and 11% in the intervention group. The difference between groups, adjusting for baseline food security, was in favor of the intervention (RR=0.68, 95% CI=0.48, 0.96). With regard to other secondary participant-reported outcomes, point estimates for other participant-reported outcomes were generally in favor of the intervention, but had wide CIs and were not significantly different (Table 3).

For exploratory anthropometric and biomarker outcomes, point estimates were favorable with regard to weight, blood pressure, and HbA1c, but differences were not statistically significant with the exception of diastolic blood pressure (Appendix Table 3, available online). No clinically meaningful or statistically significant differences were observed with regard to lipid profiles.

DISCUSSION

This RCT found that a subsidized CSA intervention significantly improved diet quality, compared with a cash-benchmark control condition. Further, it reduced food insecurity. Examination of the diet quality subscores showed that the areas of improvement were consistent with types of foods provided by

Table 1. Baseline Characteristics of Participants

Characteristics	Overall (*n*=122) *n* (%) or mean (SD)	Intervention group (*n*=56) *n* (%) or mean (SD)	Control group (*n*=66) *n* (%) or mean (SD)
Cohort B[a]	21 (17.2)	11 (19.6)	10 (15.2)
Age, years	50.16 (13.77)	49.07 (15.07)	51.09 (12.61)
Female	99 (81.1)	48 (85.7)	51 (77.3)
Race/ethnicity			
White, non-Hispanic	110 (90.2)	50 (89.3)	60 (90.9)
Black, non-Hispanic	3 (2.5)	1 (1.8)	2 (3.0)
Hispanic	2 (1.6)	2 (3.6)	0 (0.0)
Asian/multi-/Other	7 (5.7)	3 (5.4)	4 (6.1)
Education			
Less than HS diploma	7 (7.1)	2 (4.5)	5 (9.1)
HS diploma	19 (19.2)	9 (20.5)	10 (18.2)
Greater than HS diploma	73 (73.7)	33 (75.0)	40 (72.7)
Ratio of income to federal poverty guideline (median [IQR])	1.46 [0.92, 2.45]	1.48 [0.86, 2.48]	1.32 [1.03, 2.26]
Born in U.S.	96 (97.0)	43 (97.7)	53 (96.4)
Receiving SNAP benefits	47 (39.2)	20 (36.4)	27 (41.5)
Food insecure	44 (36.7)	17 (30.9)	27 (41.5)
Cost-related medication underuse	23 (19.2)	8 (14.5)	15 (23.1)
Put off buying medications to afford food	18 (15.0)	8 (14.5)	10 (15.4)
PROMIS-10 global raw score	32.19 (6.51)	32.22 (6.36)	32.17 (6.68)
PROMIS 4-item depression raw score	7.76 (3.33)	7.62 (3.03)	7.88 (3.60)
PROMIS 4-item anxiety raw score	7.51 (3.00)	7.33 (2.97)	7.66 (3.04)
HEI total score	54.93 (15.29)	56.07 (15.12)	53.96 (15.48)
HEI 1 score	3.29 (1.73)	3.36 (1.61)	3.22 (1.84)
HEI 2 score	2.04 (2.32)	1.85 (2.29)	2.20 (2.36)
HEI 3 score	2.54 (2.13)	2.98 (2.12)	2.17 (2.08)
HEI 4 score	2.82 (2.29)	3.27 (2.23)	2.44 (2.28)
HEI 5 score	2.98 (3.84)	2.77 (3.87)	3.16 (3.83)
HEI 6 score	5.53 (3.51)	5.12 (3.74)	5.89 (3.30)
HEI 7 score	4.01 (1.52)	4.17 (1.32)	3.88 (1.67)
HEI 8 score	2.60 (2.31)	2.62 (2.39)	2.60 (2.26)
HEI 9 score	4.76 (3.53)	4.59 (3.60)	4.91 (3.50)
HEI 10 score	4.61 (3.62)	4.94 (3.68)	4.34 (3.57)
HEI 11 score	6.68 (3.59)	7.04 (3.07)	6.39 (3.98)
HEI 12 score	13.05 (6.15)	13.38 (5.80)	12.77 (6.47)
Weight, kg	92.02 (20.86)	89.42 (16.29)	94.22 (23.97)
BMI, kg/m^2	33.91 (7.91)	33.21 (8.02)	34.50 (7.83)
Systolic blood pressure, mm Hg	127.79 (19.82)	131.55 (21.53)	124.67 (17.87)
Diastolic blood pressure, mm Hg	77.99 (12.48)	80.85 (13.28)	75.62 (11.35)
Serum glucose, mg/dL	110.92 (46.82)	114.79 (44.99)	107.96 (48.37)
HbA1c, %	5.72 (1.22)	5.78 (1.18)	5.68 (1.25)
High-density lipoprotein cholesterol, mg/dL	56.76 (16.48)	54.93 (13.82)	58.11 (18.20)
Low-density lipoprotein cholesterol, mg/dL	109.70 (41.84)	108.39 (39.44)	110.65 (43.86)
Total cholesterol, mg/dL	197.07 (44.36)	195.93 (41.75)	197.91 (46.53)
Triglycerides, mg/dL	168.82 (154.38)	190.92 (218.36)	152.55 (78.94)

[a]Cohort B participants were inadvertently not asked about income, education, or nativity during their baseline examination.
HEI, Healthy Eating Index; HS, high school; PROMIS, Patient Reported Outcome Measurement Information System; SNAP, Supplemental Nutrition Assistance Program.

the intervention, which supports the causal role of the intervention in improving diet quality. Several robustness checks and sensitivity analyses further support the impact of the intervention, and long-term epidemiologic studies support the clinical meaningfulness of the observed effect size.[3,34]

Table 2. HEI Results Comparing Intervention to Control Participants During the Intervention Period

Variable	Intervention	Control	*p* for difference[a]
HEI total[b] (0–100)	60.2	55.9	**0.03**
Adequacy scores (higher score indicates greater consumption)			
HEI 1: total vegetables (0–5)	4.2	3.7	**0.008**
HEI 2: greens and beans (0–5)	2.7	2.3	0.16
HEI 3: total fruit (0–5)	3.2	2.2	**<0.0001**
HEI 4: whole fruit (0–5)	3.1	2.4	**0.007**
HEI 5: wholegrain (0–10)	2.9	3.0	0.99
HEI 6: total dairy (0–10)	5.1	5.6	0.23
HEI 7: total protein (0–5)	4.2	4.2	0.95
HEI 8: seafood and plant protein (0–5)	3.0	2.6	0.19
Moderation scores (higher score indicates lower consumption)			
HEI 9: fatty acids (0–10)	5.4	5.0	0.27
HEI 10: sodium (0–10)	3.5	3.9	0.23
HEI 11: refined grain (0–10)	7.7	7.6	0.61
HEI 12: “empty” calories (0–20)	15.1	13.4	**0.01**

Note: Boldface indicates statistical significance (p<0.05).
[a]*p*-value for difference represents test of difference in mean score comparing intervention group during intervention period to control group during intervention period.
[b]Score range in parentheses. Higher score always represents “better” consumption (e.g., a higher “empty” calories score represents lower consumption of “empty” calories).
HEI, Healthy Eating Index.

This study extends current knowledge regarding nutritional intervention in participants with lower SES. At baseline, participants in this study had total HEI scores that were below average for Americans overall (mean HEI-2010 score was 59 in 2010, and the mean score for the updated HEI-2015 score using more recent data was also 59).[48] However, the CSA intervention was effective in raising the score to above the national average. The intervention effect seen in this study was similar to that seen in the Healthy Incentives Pilot,[14] though in a different patient population. Prior qualitative and feasibility studies of cost-offset CSAs have found them to be feasible interventions, and that participants value the opportunity to increase their fruit and vegetable consumption.[20,21,49] A randomized trial of cost-offset CSA for obesity prevention for children is ongoing, with results expected soon.[18] A recent randomized trial of food pantry clients with diabetes found that a healthy food box could increase fruit and vegetable consumption.[50] This study extends these findings by examining a relatively unselected group of health center patients, many of whom were not SNAP eligible, and provides an alternative method of intervention to improve diet quality. Testing interventions in individuals with incomes in the range observed in the sample is important as these individuals may have incomes too high to qualify for many government programs, but too low to escape the deleterious effects of lower SES on health. Further, this study supports the substitution hypothesis, whereby a key mechanism for worse diet quality in individuals with lower SES is that foods classified within the HEI 2010 empty calories subscore are cheaper than foods like fruits and vegetables.[6] Once fruits and vegetables were made more easily available, their consumption went up and consumption of empty calories decreased.

An important consideration in interpreting the results of the study is the cash-benchmarking design that

Table 3. Participant-Reported Outcomes

Variable	Difference in means or RR[a] (95% CI)	*p*-value for difference
Food insecurity	0.68 (0.48, 0.96)	0.03
PROMIS-10 global raw score (range 14–48, higher is better)	0.19 (−0.72, 1.11)	0.68
PROMIS 4-item depression raw score (range: 4–20, lower is better)	−0.57 (−1.31, 0.18)	0.13
PROMIS 4-item anxiety raw score (range: 4–20, lower is better)	−0.53 (−1.21, 0.16)	0.13
Cost-related medication underuse	1.01 (0.66, 1.53)	0.97
Put off buying medications to afford food	0.73 (0.48, 1.11)	0.14

Note: [a]Control group is the reference category for all comparisons. Food insecurity, cost-related medication underuse, and putting off buying medications to afford food are presented as RR. PROMIS scores are presented as differences in means.
PROMIS, Patient Reported Outcome Measurement Information System.

compared the intervention with a control condition in which equivalent resources were provided to participants. This has the effect of homing in on findings where the intervention itself, as opposed to the financial value of the intervention, is most salient. For example, the study demonstrated added value in improving diet quality by providing healthy foods compared with unrestricted cash. But some participant-reported outcomes did not show differential change. For example, cost-related medication underuse, which by definition is related to financial constraints, showed no differential improvement. Understanding the situations in which intervention programs offer value added, above and beyond the monetary value of the resources provided, is important for focusing interventions on the areas where they can have the most impact. This will often involve a trade-off between the simplicity and low administrative overhead of cash or near-cash transfer programs and the additional benefit to be gained from more complex interventions such as the one tested in this study, which invariably involve more oversight and coordination than an unrestricted cash transfer. With increasing focus on addressing health-related social needs with programs that involve the healthcare system, and the attendant risk of medicalizing social issues, making this distinction will be increasingly important, and understanding implementation burdens and best practices for such interventions, from a healthcare system perspective, is an important area of future research.[51] Despite these strengths, cash-benchmark designs also have limitations. By offering an active comparator that is likely to have a stronger effect on the outcome than a usual care comparator, the cash-benchmark design may result in lower estimates of intervention effect than usual care designs.

The findings of this study suggest important directions for further work. First, it is important to replicate these findings in other settings and to understand how they may generalize to different areas of the country and groups with different demographic characteristics. Finding that the results are robust and have substantial long-term health impacts would have clear implications for health and public policy. A number of healthcare plans are experimenting with wellness benefits for beneficiaries, and subsidized CSA membership may fit into this approach.[52−55] Alternatively, local public health and business groups may support such a strategy, in pursuit of public health benefits and business development.[56,57]

Limitations

The findings of this study should be interpreted in light of its limitations. This was a single-site study with a predominately white non-Hispanic and female sample, so how the findings generalize to other settings is not known. Additionally, although study group assignment was masked for outcome assessors, this was not possible for the study participants themselves. Next, data on use and waste of the produce provided in the intervention were not collected. Next, attrition and lower-than-expected initial recruitment led to the addition of a second cohort of participants, who participated for only 1 growing season. However, there were no meaningful differences between the 2 cohorts, and interaction testing did not suggest effect modification by cohort. Finally, the study was not powered to detect differences in secondary and exploratory outcomes, so the observation of lack of differences in these areas is inconclusive. These limitations were balanced by several strengths. This was a randomized trial of a nutrition intervention with good follow-up, with most participants enrolled over 2 growing seasons. It used a pragmatic trial design without stringent eligibility criteria, and results were robust across a number of sensitivity analyses.

CONCLUSIONS

A CSA intervention, compared with a cash-benchmarked control condition, was effective in improving diet quality and reducing food insecurity among participants with a BMI >25 kg/m^2 largely drawn from a community health center. If future work replicates these findings, subsidized CSA may be an important intervention to improve the diet quality, and ultimately the health, of socioeconomically vulnerable adults.

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SUPPLEMENTAL MATERIAL

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