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Effect of an Intensive Food-as-Medicine Program on Health and Health Care Use
A Randomized Clinical Trial

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IMPORTANCE Food-as-medicine programs are becoming increasingly common, and rigorous evidence is needed regarding their effects on health.

OBJECTIVE To test whether an intensive food-as-medicine program for patients with diabetes and food insecurity improves glycemic control and affects health care use.

DESIGN, SETTING, AND PARTICIPANTS This stratified randomized clinical trial using a wait list design was conducted from April 19, 2019, to September 16, 2022, with patients followed up for 1 year. Patients were randomly assigned to either participate in the program immediately (treatment group) or 6 months later (control group). The trial took place at 2 sites, 1 rural and 1 urban, of a large, integrated health system in the mid-Atlantic region of the US. Eligibility required a diagnosis of type 2 diabetes, a hemoglobin A_{1c} (HbA_{1c}) level of 8% or higher, food insecurity, and residence within the service area of the participating clinics.

INTERVENTION The comprehensive program provided healthy groceries for 10 meals per week for an entire household, plus dietitian consultations, nurse evaluations, health coaching, and diabetes education. The program duration was typically 1 year.

MAIN OUTCOMES AND MEASURES The primary outcome was HbA_{1c} level at 6 months. Secondary outcomes included other biometric measures, health care use, and self-reported diet and healthy behaviors, at both 6 months and 12 months.

RESULTS Of 3712 patients assessed for eligibility, 3168 were contacted, 1064 were deemed eligible, 500 consented to participate and were randomized, and 465 (mean [SD] age, 54.6 [11.8] years; 255 [54.8%] female) completed the study. Of those patients, 349 (mean [SD] age, 55.4 [11.2] years; 187 [53.6%] female) had laboratory test results at 6 months after enrollment. Both the treatment (n = 170) and control (n = 179) groups experienced a substantial decline in HbA_{1c} levels at 6 months, resulting in a nonsignificant, between-group adjusted mean difference in HbA_{1c} levels of −0.10 (95% CI, −0.46 to 0.25; P = .57). Access to the program increased preventive health care, including more mean (SD) dietitian visits (2.7 [1.8] vs 0.6 [1.3] visits in the treatment and control groups, respectively), patients with active prescription drug orders for metformin (134 [58.26] vs 119 [50.64]) and glucagon-like peptide 1 medications (114 [49.56] vs 83 [35.32]), and participants reporting an improved diet from 1 year earlier (153 of 164 [93.3%] vs 132 of 171 [77.2%]).

CONCLUSIONS AND RELEVANCE In this randomized clinical trial, an intensive food-as-medicine program increased engagement with preventive health care but did not improve glycemic control compared with usual care among adult participants. Programs targeted to individuals with elevated biomarkers require a control group to demonstrate effectiveness to account for improvements that occur without the intervention. Additional research is needed to design food-as-medicine programs that improve health.

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Visual Abstract

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Supplemental content

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An increase in diet-related chronic diseases has led to widespread interest in addressing food insecurity and related social determinants of health to improve patient health and reduce health care costs.[1-6] Food-as-medicine programs, which include produce prescription programs and medically tailored meals, are growing in popularity among payers and health care systems.[7-10]

The program we study is an influential, clinic-based, food-as-medicine program.[11,12] It was designed for patients with type 2 diabetes and hemoglobin A_{1c} (HbA_{1c}) levels of 8.0% or higher (to convert percentage of total hemoglobin to proportion of total hemoglobin, multiply by 0.01) who were food insecure. The program is intensive, providing patients with enough healthy ingredients for 10 meals each week for the entire household. The program is comprehensive, including consultations with dietitians, nurses, and coaching from community health workers.

Observational studies of food-as-medicine interventions have found improvements in food security and diet but mixed evidence regarding impacts on health and health care use.[8,13-18] An observational evaluation of the program we study noted improvements in HbA_{1c} levels of 1 to 2 points,[19] and a small, uncontrolled pilot study found that the program was associated with substantially reduced health care claims.[19]

Reviews of the literature call for randomized clinical trials (RCTs) to more rigorously estimate the effects of food-as-medicine programs.[20-23] Among a handful of published randomized evaluations, results are mixed. A randomized crossover study[24] found that delivering medically tailored meals to patients with diabetes improved diet and food security, and a randomized pilot study[25] of a clinic-based, medically tailored meal program with home visits found improvements in HbA_{1c} levels. However, trials of 1 food bank-based intervention and 2 medically tailored meal programs found no detectable change in health or hospitalization.[26-28] Compared with most of the food-as-medicine programs that have been evaluated, the current program stands out for its intensity in terms of program duration (averaging 1 year), the amount of healthy food provided, its modality as a clinic-based program, and the intention to increase engagement with preventive health care.

Key Points

Question Among patients with diabetes who are food insecure, does an intensive food-as-medicine program that provides healthy groceries plus dietitian consultations, education, and health coaching improve glycemic control compared with usual care?

Findings In this randomized clinical trial of 465 adults who were provided access to a food-as-medicine program, hemoglobin A_{1c} levels did not improve among those who had access to the program compared with a control group; however, their engagement with preventive health care increased as designed.

Meaning Because this intensive food-as-medicine program did not improve glycemic control, these results suggest that further efforts are needed to understand how programs that address food insecurity can improve health.

Methods

Study Design

The food-as-medicine program was evaluated using an RCT with a wait list design, stratified by location and level of HbA_{1c} (≥9.5% or <9.5%). An RCT was conducted because a change in outcomes over time for the treatment group alone could reflect regression to the mean, a particular concern when program eligibility is determined using elevated results of health measurements.[23,29-31] The trial received institutional review board approval from the health system, and the trial protocol and planned analyses (Supplement 1) were publicly prespecified on April 10, 2019. Health system staff implemented the recruitment protocols and administered the intervention but were blinded to results prior to trial completion. Informed consent was oral. This study followed the Consolidated Standards of Reporting Trials (CONSORT) reporting guideline.

Intervention

Eligibility and Program Details

There were 4 eligibility criteria for the program: (1) diagnosis of type 2 diabetes and an HbA_{1c} level of 8.0% or higher; (2) self-reported food insecurity (determined by a 2-question survey); (3) residence within the program's service area; and (4) affiliation with the health system. Program participants were invited to visit a clinic weekly to receive healthy groceries curated by a dietitian, and they were able to receive preventive care and education as part of the visits. Participants could choose among a variety of fruits, vegetables, and entrees each week. The food was sufficient for 2 meals per day, 5 days per week, for the participant and all members of their household and came with recipes and cooking instructions. Participants met with a dietitian to set and track goals and were encouraged to complete diabetes self-management training.

Nurses provided preventive care, such as foot examinations, and community health care workers supported engagement through telephone calls and consultations at the clinic. Participants' biometric measurements and medication use were tracked. The program has no predetermined end date, but typical engagement lasted approximately 1 year. The average annual cost per participant is $2000 (eAppendix 1 and eTable 1 in Supplement 2). The control group received usual care, a letter describing the locations of local food banks (eAppendix 2 and eFigures 1 and 2 in Supplement 2), and the ability to join the program in approximately 6 months. Given that joining a wait list can impact behavior, we measure changes in health and healthy behaviors as part of the evaluation.

Recruitment and Randomization

The trial took place in 2 communities in the mid-Atlantic region of the US: 1 in a borough with a population of roughly 10 000 and the other in a city with a population of roughly 80 000. Recruitment took place on a rolling basis over a 2-year period (April 19, 2019, to June 16, 2021) and the trial continued until September 16, 2022. Potentially eligible patients were identified through the health system's electronic health record (EHR), as well as referrals to the program from area physicians. Health system staff contacted patients to describe the study; consenting patients were randomized to start the program immediately (treatment group) or in 6 months (control

group), stratified by location and HbA_{1c} level category. The wait list design was advocated on grounds of equity and ethics.[32] The 6-month wait was chosen based on research suggesting measurable improvements to HbA_{1c} levels within the first 6 months of participation (eAppendix 3 in Supplement 2). Race categories included American Indian or Alaska Native, Asian, Black or African American, Native Hawaiian or Other Pacific Islander, White, and unknown. Ethnicity categories included Hispanic and non-Hispanic. In the analyses, we included indicators for Hispanic and non-Hispanic Black. Race and ethnicity were determined by self-report as recorded in the health system's EHR. We considered race and ethnicity to examine the heterogeneity of effects for each group.

COVID-19 Pandemic Modifications

The program continued through the COVID-19 pandemic without interruption but with modifications. Weekly food pickup was changed to every other week in March 2020. Dietitian and care team consultations, as well as classes, were moved to telemedicine, later returning to in-person communication (eAppendix 1 in Supplement 2). Inpatient use remained stable, while emergency department (ED) use declined beginning in March 2020, and outpatient visits dropped sharply in spring 2020 before rebounding (eAppendix 2 and eFigures 3-5 in Supplement 2). Due to balanced recruitment and a randomized design, exposure to the pandemic was similar across the treatment and control groups. We examined the robustness of results across different time periods.

Data

The health system's EHR provided demographic information, laboratory test results, weight, blood pressure, and health care use. Prescription drug orders were recorded, and whether they were dispensed at major pharmacy chains was observed using Surescripts.[33] For patients enrolled in the health system's insurance plan, paid claims were available.

The biometric outcome measures included venous blood samples, collected at the health system's laboratories, and surveys were requested 3 times: at program entry, at 6 months, and at 12 months (eMethods in Supplement 2). Each of the 3 times, patients were compensated ($50) for completing both tasks (blood sample and survey). Visits to the clinic were tracked.

Outcomes

The primary outcome was the participants' HbA_{1c} level, which measures average blood glucose level over the prior 3 months (as opposed to daily glucose monitoring),[34] at 6 months from enrollment into the trial, when the treatment group had access to the program for 6 months and the control group was just gaining access to the program. We also examined the HbA_{1c} level at 12 months, when the treatment group had access to the program for 12 months and the control group had access for 6 months. Specifically, for each patient, the 6-month laboratory test result was that observed closest to 180 days, within a window of 150 days to 300 days after entry into the study; for 12-month outcomes, we considered the laboratory test result closest to 360 days, within a window of 330 days to 480 days after study entry. We reported results for different time windows as well.

Secondary outcomes included other biometric measures; health care use as determined from the EHR and paid claims; and survey responses regarding diet, preventive care, diabetes knowledge, barriers to healthy eating, health attitudes, diabetes self-efficacy, and overall health and well-being. These outcomes were examined 6 months and 12 months after patients entered the trial.

Statistical Analysis

We used an intent-to-treat approach for the analyses. For our primary outcome, HbA_{1c} levels, and other laboratory test results and use measures, we used longitudinal data and estimated mixed-effects models. We reported both unadjusted differences and adjusted differences using models that included baseline measures. The longitudinal mixed-effects model provided statistical power to detect a 0.5-percentage point decline in the HbA_{1c} level and a 25% decline in hospital use (80% power). The threshold of statistical significance was 2-sided $P < .05$. For program engagement and survey outcomes at 6 months and 12 months after trial entry, we estimated linear regression models with prespecified covariates for strata, 5-year age bins, sex, race, and ethnicity. Further details regarding estimation are provided in eAppendix 4 and eTable 2 in Supplement 2.

For laboratory test results, baseline represented the preenrollment laboratory test result closest to the date of consent with a control for the number of days between the test and study consent. For the HbA_{1c} level, we had a baseline measure for all patients, as it was used to determine eligibility; for other laboratory test results, if a patient did not have a result in the prior 12 months, we used multiple imputation. For use outcomes, the baseline measure was the number of episodes in the year prior to consent (for EHR outcomes) or paid claims in the year prior to consent (for claims outcomes).

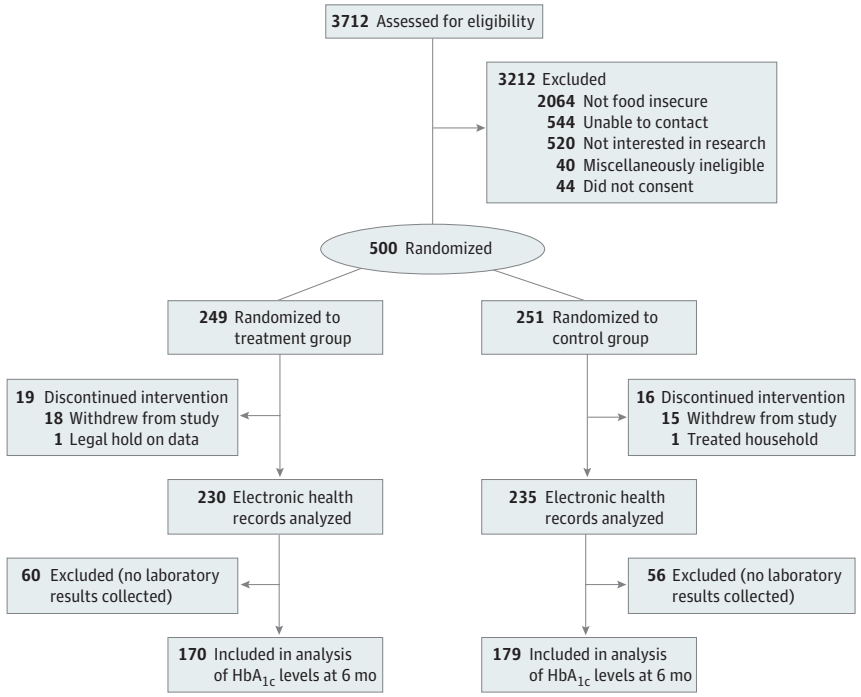
Point estimates with 95% CIs using heteroskedasticity-robust SEs are reported. For categories of survey outcomes, we report results for individual measures as well as an index with a mean (SD) of 0 (1) among the control group. We used inverse covariance weighting across the individual measures to calculate each index to avoid adding weight to highly correlated measures.[35] Statistical analyses were performed using Stata, version 16.0 (StataCorp LLC).

Results

Characteristics of the Study Population

The **Figure** shows that 3712 patients were assessed for eligibility. Among these, 3168 patients were contacted, 1064 eligible patients were asked to join the study, and 500 consented to participate and were recruited between April 2019 and June 2021. The patients who withdrew (n = 33) were similar to those who remained (eTable 3 in Supplement 2), and the withdrawal rate was similar across treatment and control (eTable 4 in Supplement 2); 465 patients (mean [SD] age, 54.6 [11.8] years; 255 [54.8%] female) completed the study. Of those patients, 349 (mean [SD] age, 55.4 [11.2] years) had laboratory test results at 6 months after enrollment; 187 (53.6%) were female and 162 (46.4) male; 31 (8.9%) were Hispanic; 26 (7.4%) were non-

Figure. CONSORT Diagram



All patients allocated to the treatment group were advised by the food-as-medicine program at the beginning of their study participation, with varying levels of engagement. All patients allocated to the control group were contacted approximately 6 months later to begin the program, also with varying levels of engagement. Treated household refers to 1 patient who was discovered after randomization to be living with another patient and had been already receiving food. HbA_{1c} indicates hemoglobin A_{1c}.

Hispanic Black; 287 (82.2%) were non-Hispanic White; and 5 (1.4%) were non-Hispanic with another or unknown race. The study population had a mean (SD) baseline HbA_{1c} level of 10.29% (2.02%) (**Table 1**). The rate of laboratory test completion at 6 months was 75% and was balanced across treatment and control (eTable 4 in Supplement 2). Patients in the laboratory measures, survey, and claims subsamples had similar characteristics compared with the overall sample (Table 1 and eTables 5-8 and eFigure 6 in Supplement 2).

Program Engagement

Table 2 presents measures of program engagement. At 6 months, patients randomized to the treatment group had much greater engagement with the program, as intended. The mean (SD) number of visits to the program clinic was 13.00 (6.43) for the treatment group and 0.72 (1.20) for the control group. All visits included food pickup and the potential to meet with a dietitian, nurse, and/or community health worker. At 12 months, the gap was similar; the treatment group's mean (SD) attendance was 23.40 (12.20) clinic visits over the year compared with 10.64 (6.90) visits for the control group. Differences in preventive care (Table 2 and eFigures 7-9 in Supplement 2) after 6 months showed that those assigned to the treatment group compared with the control group had more mean (SD) encounters with a dietitian (2.7 [1.8] vs 0.6 [1.3] visits) and more mean (SD) diabetes self-management trainings (2.2 [1.4] vs 0.4 [0.7] classes).

Results on self-reported engagement and achievement of program objectives showed that at 6 months, the treatment group compared with the control group reported a mean (SD) increase in vegetable consumption (6.3 [20.7] vs 4.0 [2.9] times eating dark green vegetables in previous week) and number of patients who never ate fast food (71 of 164 [43.3%] vs 62 of 171 [36.3%]) and a reduction in consumption of sweetened beverages (mean [SD], 2.8 [3.4] vs 3.4 [4.5] times in previous week), although these differences were not statistically significant (Table 2). Most (153 of 164 [93.3%]) in the treatment group reported that their diet had improved from 1 year before; the control group also tended to report an improved diet (132 of 171 [77.2%]), although substantially less so than the treatment group. At 6 months, among 335 patients, the treatment group scored 0.38 SDs higher (95% CI, 0.18-0.58) than the control group in the diet improvement index score, and the treatment group was also 0.36 SDs higher (95% CI, 0.16-0.57) on the index of engagement and preventive care, primarily due to a greater likelihood of meeting with a dietitian, participating in a diabetes class, and receiving a foot examination within the past year (eTable 9 in Supplement 2). In both the treatment and control groups, there were individuals who reported eating more than 50 vegetables in 1 week. While the adjusted mean difference changed somewhat depending on how we incorporated these measures, the adjusted mean difference in the diet improvement index was similar regardless of those methods. Among 330 patients who completed a set of questions testing their knowledge of diabetes, the proportion of questions answered correctly was higher for the treatment group by 0.04 (adjusted mean difference, 95% CI 0.01-0.08). In contrast, between the treatment group and control group, there was no detectable change in indices for healthy attitudes (n = 334; adjusted mean difference, 0.13 [95% CI, -0.07 to 0.34]), diabetes self-efficacy (n = 335; -0.03 [95% CI, -0.25 to 0.20]), or exercise and smoking (n = 335; 0.05

Table 1. Characteristics of Patients at Baseline[a]

Characteristic	Full sample, No. (%) (N = 465)			Laboratory test sample at 6 mo, No. (%) (n = 349)		
	Overall	Control group (n = 235)	Treatment group (n = 230)	Overall	Control group (n = 179)	Treatment group (n = 170)
HbA_{1c} level (primary outcome), mean (SD), %[b]	10.29 (2.02)	10.29 (2.00)	10.30 (2.05)	10.21 (2.03)	10.13 (1.99)	10.29 (2.08)
Age, mean (SD), y	54.6 (11.8)	54.4 (12.4)	54.8 (11.3)	55.4 (11.2)	55.0 (11.7)	55.8 (10.7)
Sex						
Female	255 (54.8)	125 (53.2)	130 (56.5)	187 (53.6)	91 (50.8)	96 (56.5)
Male	210 (45.2)	110 (46.8)	100 (43.5)	162 (46.4)	88 (49.2)	74 (43.5)
Race and ethnicity						
Hispanic	39 (8.4)	23 (9.8)	16 (7.0)	31 (8.9)	16 (8.9)	15 (8.8)
Non-Hispanic Black	41 (8.8)	18 (7.7)	23 (10.0)	26 (7.4)	15 (8.4)	11 (6.5)
Non-Hispanic White	378 (81.3)	189 (80.4)	189 (92.2)	287 (82.2)	145 (81.0)	142 (83.5)
Non-Hispanic or other	7 (1.5)	5 (2.1)	2 (0.9)	5 (1.4)	3 (1.7)	2 (1.2)
Location						
Rural	131 (28.2)	67 (28.5)	64 (27.8)	105 (30.1)	54 (30.2)	51 (30.0)
Urban	334 (71.8)	168 (71.5)	166 (72.2)	244 (69.9)	125 (69.8)	119 (70.0)
Prior-year health care use						
Any inpatient admission	107 (23.0)	48 (20.4)	59 (25.7)	85 (24.4)	40 (22.3)	45 (26.5)
Any ED visit	191 (41.1)	94 (40.0)	97 (42.2)	148 (42.4)	81 (45.3)	67 (39.4)
Prescriptions						
Any diabetes medication	405 (87.1)	206 (87.7)	199 (86.5)	304 (87.1)	157 (87.7)	147 (86.5)
Metformin	231 (49.7)	116 (49.4)	115 (50.0)	176 (50.4)	90 (50.3)	86 (50.6)
Insulin	231 (49.7)	117 (49.8)	114 (49.6)	176 (50.4)	87 (48.6)	89 (52.4)
GLP-1	150 (32.3)	73 (31.1)	77 (33.5)	107 (30.7)	53 (29.6)	54 (31.8)
Other glucose-lowering medications	124 (26.7)	59 (25.1)	65 (28.3)	94 (26.9)	46 (25.7)	48 (28.2)
Time between tests, mean (SD), d[c]	NA	NA	NA	302 (111)	299 (108)	306 (114)

Abbreviations: ED, emergency department; GLP-1, glucagon-like peptide 1; HbA_{1c}, hemoglobin A_{1c}; NA, not applicable.

SI conversion factor: To convert percentage of total hemoglobin to proportion of total hemoglobin, multiply by 0.01.

[a] Data were derived from electronic health records.

[b] The baseline HbA_{1c} level was used to determine eligibility into the study and the program.

[c] Days between baseline and 6-month laboratory test results.

[95% CI, −0.18 to 0.28]). We did not observe differences in these outcomes at 12 months (eTable 10 in Supplement 2).

Biometric Outcomes

HbA_{1c} levels fell by a mean (SD) of 1.3 (2.3) percentage points for the control group (n = 179) and by 1.5 (2.2) percentage points for the treatment group (n = 170) after 6 months from study enrollment and then remained stable between 6 months and 12 months (eFigure 10 in Supplement 2). These findings resulted in an unadjusted between-group difference in the HbA_{1c} of −0.03 (95% CI, −0.42 to 0.35; P = .86) and an adjusted mean difference of −0.10 (95% CI, −0.46 to 0.25; P = .57), which were not statistically significant (**Table 3**). At 12 months, the adjusted mean difference was also not statistically significant (0.10 [95% CI, −0.30 to 0.50]; P = .60).

There was no detectable impact on other laboratory results, including cholesterol, triglycerides, and fasting glucose levels, at either 6 months or 12 months. The point estimates of treatment effects tended to be small—below 10% of the control group's SD—and inconsistent in sign. These results are robust to alternative model specifications and measurement periods (eTables 11-13 in Supplement 2).

In terms of weight, at 6 months, the adjusted mean difference of 1.95 kg (95% CI, 0.07-3.83; P = .04) suggests that the treatment group gained weight compared with the control group; there was no significant difference at 12 months. Blood pressure measurements were similar across treatment and control groups at both 6 months and 12 months, and differences were not significant.

Health Care Use and Self-Assessed Health

Assignment to the treatment group had no statistically significant impact on hospitalization or ED use, based on either the EHRs or paid claims, at 6 months or 12 months (**Table 4** and eFigures 11-13 in Supplement 2). Among 465 patients, the treatment increased the number of outpatient visits by 1.00 after 6 months (95% CI, 0.28-1.72; P = .007); however, at 12 months, the difference in outpatient visits was smaller and not statistically significant.

There was no detectable impact on total claims at either 6 months or 12 months. At 12 months, among 183 patients, a nonsignificant $1332 reduction in inpatient or ED claims (95% CI, -$3957 to $1294; P = .32) was offset by a nonsignificant $1348 increase in outpatient claims (95% CI, −$486 to $3181; P = .15).

Table 2. Program Engagement and Goal Attainment

Measure	Results at 6 mo, mean (SD), No. (%)			Results at 12 mo, mean (SD), No. (%)	
	Control group	Treatment group	Adjusted mean difference (95% CI)	Control group	Treatment group
Program-tracking measures (n = 349)					
Months with ≥1 site visit	0.36 (0.54)	4.91 (1.71)	NA	4.58 (2.50)	9.26 (3.78)
Site visits	0.72 (1.20)	13.00 (6.43)	NA	10.64 (6.90)	23.40 (12.20)
Measures of diabetes management services[a]					
Dietician visits	0.62 (1.26)	2.66 (1.75)	2.01 (1.74 to 2.29)	NA	NA
Diabetes self-management trainings	0.36 (0.72)	2.24 (1.44)	1.88 (1.67 to 2.09)	NA	NA
Endocrinology outpatient visits	0.48 (0.80)	0.59 (0.86)	0.05 (−0.08 to 0.18)	NA	NA
Weight loss and management outpatient visits	0.11 (0.52)	0.05 (0.35)	−0.06 (−0.12 to −0.003)	NA	NA
Measures of diet improvement[b]					
Times ate fruit in the past week (n = 333)	5.24 (3.40)	5.56 (3.34)	0.26 (−0.47 to 1.00)	NA	NA
Times ate dark green vegetables in the past week (n = 333)	4.01 (2.90)	6.29 (20.70)	2.00 (−0.68 to 4.66)	NA	NA
Times drank sweetened beverages in the past week (n = 329)	3.41 (4.50)	2.78 (3.45)	−0.61 (−1.50 to 0.28)	NA	NA
Reported never eating fast food, takeout, or at a restaurant (n = 335)	62 of 171 (36.3)	71 of 164 (43.3)	5.38 (−5.16 to 15.93)	NA	NA
Reported diet improved from 1 y ago (n = 335)	132 of 171 (77.2)	153 of 164 (93.3)	16.92 (9.22 to 24.61)	NA	NA
Diet improvement index score (n = 335)[c]	0 (1.00)	0.39 (0.79)	0.38 (0.18 to 0.58)	NA	NA
Measures of program engagement and attainment of program goals[b]					
Engagement and preventive care index score (n = 335)[c]	0 (1.00)	0.40 (0.83)	0.36 (0.16 to 0.57)	NA	NA
Diabetes knowledge score (n = 330)[d]	0.78 (0.15)	0.83 (0.15)	0.04 (0.01 to 0.08)	NA	NA
Healthy attitudes index score (n = 334)[c]	0 (1.00)	0.18 (0.88)	0.13 (−0.07 to 0.34)	NA	NA
Diabetes self-efficacy index score (n = 335)[c]	0 (1.00)	−0.08 (1.03)	−0.03 (−0.25 to 0.20)	NA	NA
Exercise and smoking improvement index score (n = 335)[c]	0 (1.00)	0.05 (1.07)	0.05 (−0.18 to 0.28)	NA	NA

Abbreviations: EHR, electronic health record; NA, not applicable.

[a] Data from participant EHRs. Adjusted differences used mixed-effects models with controls for baseline characteristics, and CIs were calculated using heteroskedasticity-robust, participant-clustered SEs. There were 2 observations for each participant, 1 at baseline and 1 at follow-up. The sample size was 930 (465 participants).

[b] Data from participant survey answers (eAppendix 4 in Supplement 2). Adjusted differences included prespecified controls for categories of age, race, ethnicity, sex, and strata indicators, and CIs were calculated using heteroskedasticity-robust SEs. Sample sizes for survey measure estimates varied slightly due to item nonresponses.

[c] Indexes in the control group were computed such that the mean (SD) index in the control group was 0 (1.00). Prespecified indexes were constructed to summarize questions related to each category and account for correlation across questions. Estimates for each question comprising components of the indexes are available in eAppendix 5 in Supplement 2.

[d] The proportion of answers to diabetes knowledge inventory items (see eTables 9 and 10 in Supplement 2) that were correct; scores range from 0 to 1, with higher scores indicating more knowledge.

These results are also robust to alternative model specifications and measurement periods (eTables 14 and 15 in Supplement 2).

Access to the program increased the probability of having an active prescription drug order for metformin (134 [58.26%] vs 119 [50.64%]) and glucagon-like peptide 1 medications (114 [49.56%] vs 83 [35.32%]). The adjusted mean difference for metformin was 7.18 percentage points (95% CI, 0.71-13.64 percentage points) and was 12.77 percentage points (95%

Table 3. Effects of Program on Biometric Outcomes[a]

Outcome[b]	Mean (SD)		Unadjusted mean difference (95% CI)[c]	Adjusted mean difference (95% CI)[c,d]
	Control group	Treatment group		
6 mo				
HbA_{1c} level, % (n = 698)	8.81 (1.98)	8.78 (1.64)	−0.03 (−0.42 to 0.35)	−0.10 (−0.46 to 0.25)
Cholesterol, mg/dL				
Low-density lipoprotein (n = 606)	85.20 (36.73)	93.55 (44.67)	8.35 (−0.83 to 17.53)	5.86 (−3.71 to 15.42)
High-density lipoprotein (n = 610)	41.83 (12.08)	41.28 (12.98)	−0.56 (−3.36 to 2.25)	−0.48 (−2.85 to 1.90)
Total (n = 604)	160.54 (48.39)	170.31 (55.50)	9.77 (−1.91 to 21.45)	4.94 (−7.56 to 17.44)
Triglycerides, mg/dL (n = 612)	201.01 (157.11)	223.57 (155.57)	22.56 (−12.35 to 57.47)	3.63 (−47.30 to 54.57)
Weight, kg (n = 800)	108.39 (29.85)	104.70 (27.06)	−8.14 (−20.57 to 4.30)	1.95 (0.07 to 3.83)
Systolic blood pressure, mm Hg (n = 756)	130.18 (20.30)	128.31 (19.07)	−1.87 (−5.85 to 2.11)	−0.38 (−4.16 to 3.40)
Diastolic blood pressure, mm Hg (n = 754)	74.76 (10.40)	74.20 (10.72)	−0.56 (−2.69 to 1.58)	−0.25 (−2.28 to 1.79)
12 mo				
HbA_{1c} level, % (n = 650)	8.60 (2.04)	8.74 (1.75)	0.14 (−0.27 to 0.56)	0.10 (−0.30 to 0.50)
Cholesterol, mg/dL				
Low-density lipoprotein (n = 534)	84.73 (36.62)	87.36 (36.74)	2.64 (−6.11 to 11.39)	3.75 (−6.20 to 13.71)
High-density lipoprotein (n = 546)	43.73 (17.08)	42.35 (12.74)	−1.39 (−4.96 to 2.18)	−0.33 (−4.06 to 3.40)
Total (n = 552)	165.38 (56.96)	164.83 (50.04)	−0.55 (−13.23 to 12.13)	−0.51 (−16.44 to 15.43)
Triglycerides, mg/dL (n = 536)	224.13 (268.94)	212.78 (153.42)	−11.35 (−63.90 to 41.19)	−25.63 (−83.77 to 32.50)
Weight, kg (n = 736)	107.77 (28.57)	103.38 (26.15)	−9.68 (−22.15 to 2.79)	1.88 (−0.14 to 3.89)
Systolic blood pressure, mm Hg (n = 702)	129.80 (18.45)	126.02 (17.24)	−3.77 (−7.52 to −0.03)	−2.49 (−6.04 to 1.05)
Diastolic blood pressure, mm Hg (n = 702)	73.98 (10.46)	74.48 (9.27)	0.50 (−1.57 to 2.57)	0.81 (−1.20 to 2.83)

Abbreviation: HbA_{1c}, hemoglobin A_{1c}.

SI conversion factors: To convert percentage of total hemoglobin to proportion of total hemoglobin, multiply by 0.01; low-density and high-density lipoproteins and total cholesterol to millimole per liter, multiply by 0.0259; triglycerides to millimoles per liter, multiply by 0.0113.

[a] Data were derived from electronic health records.

[b] Sampe sizes varied depending on the number of patients for whom laboratory results were obtained. There were 2 observations for each participants, 1 at baseline and 1 at follow-up; the n refers to the number of observations (twice the number of participants).

[c] Units of differences correspond to the laboratory units of measure in each category.

[d] Adjusted difference used mixed-effects models with controls for baseline characteristics. Multiple imputation for any missing baseline measure and test date was used; no imputations were made for the HbA_{1c} level outcome because baseline HbA_{1c} level measures were required for program enrollment (none are missing). All 95% CIs were calculated using heteroskedasticity-robust, participant-clustered SEs.

CI, 6.47-20.07 percentage points; P = .001) for glucagon-like peptide 1 (eTable 16 and eFigures 14 and 15 in Supplement 2). There was no detectable effect on self-assessed health or well-being (eTables 9 and 10 in Supplement 2).

Heterogeneity

Models estimated for prespecified subgroups and time periods indicated that the treatment group consistently had substantially higher engagement with the program but no detectable improvements in the HbA_{1c} level or inpatient or ED use (eTables 17-19 in Supplement 2). For example, because the program provided food for all members of the household, separate models were estimated for single-person and multiple-person households; similar results were found for both groups.

To examine whether modifications to the program due to the COVID-19 pandemic may have impacted the results, we examined patients whose 6-month HbA_{1c} levels were measured prior to March 2020. The size of this subsample provided 80% power to detect a 1-percentage point decline. No relative improvement in HbA_{1c} levels was observed in the treatment group, and the estimate was not significantly different from the main results (eTable 18 in Supplement 2). The program was also not found to affect the rate of COVID-19 diagnosis (eTable 20 in Supplement 2).

Discussion

In this randomized clinical trial that used a wait list design and was stratified by location and level of HbA_{1c}, access to an intensive food-as-medicine program improved self-reported diet, diabetes knowledge, and patient engagement with dietitians and nurses. Nevertheless, it did not result in an improvement in HbA_{1c} levels compared with usual care. The use of 95% CIs ruled out a treatment effect on HbA_{1c} levels of more than 0.5, which was smaller than prior observational studies of similar programs and the effect of diabetes medication or education.[36]

Notably, both the treatment and control groups experienced reductions in HbA_{1c} level of approximately 1.5 percentage points and then plateaued at 6 months, despite the control group gaining access to the program at that time. Eligibility for inclusion in the study required having an elevated level of HbA_{1c}, which may have improved over time with usual care and behavior change; regression to the mean has been observed in other interventions that determined eligibility based on adverse values of the primary outcome.[23,29-31] These reasons underscore the need for a control group when evaluating programs targeted to individuals with elevated biomarkers.

Table 4. Model Comparisons for Use Outcomes[a]

Outcome[b]	Control group (n = 235)	Treatment group (n = 230)	Adjusted mean difference (95% CI)[c]
6 mo			
Admissions frequency, No. (%)			
Inpatient or ED admission	84 (35.74)	70 (30.43)	−7.13 (−15.30 to 1.04)
Outpatient visit	207 (88.08)	215 (93.48)	5.23 (0 to 10.45)
Admissions by type, mean (SD), No.			
Inpatient or ED admissions	0.79 (1.68)	0.69 (1.36)	−0.04 (−0.27 to 0.20)
Outpatient visits	4.86 (4.63)	5.77 (4.88)	1.00 (0.28 to 1.72)
Claims values, mean (SD), $[d]			
Inpatient or ED	2162 (5285)	2175 (6176)	−4 (−1614 to 1607)
Outpatient	2023 (3493)	3314 (6553)	1376 (−45 to 2796)
Nursing facility	143 (1107)	60 (617)	−86 (−341 to 170)
Other	1040 (2245)	939 (1761)	−41 (−552 to 470)
Total	5368 (7993)	6489 (10 857)	1048 (−1568 to 3664)
Patients with active prescriptions, No. (%)			
Insulin	121 (51.49)	125 (54.35)	3.01 (−3.69 to 9.70)
Metformin	119 (50.64)	134 (58.26)	7.18 (0.71 to 13.64)
Sulfonylureas	41 (17.45)	27 (11.74)	−0.75 (−4.84 to 3.33)
GLP-1	83 (35.32)	114 (49.56)	12.77 (6.47 to 20.07)
Other glucose-lowering medications	67 (28.51)	78 (33.91)	3.24 (−3.17 to 9.66)
Any diabetes medication	218 (92.76)	215 (93.48)	2.73 (−0.89 to 6.36)
12 mo			
Any admissions frequency, No. (%)			
Inpatient or ED admission	110 (46.81)	96 (41.74)	−7.56 (−16.84 to 0.72)
Outpatient visit	224 (95.32)	221 (96.09)	0.47 (−3.14 to 4.08)
Admissions by type, mean (SD), No.			
Inpatient or ED admissions	1.50 (3.35)	1.22 (2.12)	−0.16 (−0.59 to 0.27)
Outpatient visits	10.07 (8.31)	10.10 (8.09)	0.20 (−1.01 to 1.41)
Claims values, mean (SD), $[d]			
Inpatient or ED	4545 (9951)	3285 (7850)	−1332 (−3957 to 1294)
Outpatient	4118 (5206)	5327 (7562)	1348 (−486 to 3181)
Nursing facility	375 (1731)	196 (1540)	−150 (−607 to 307)
Other	2044 (3438)	1722 (2841)	−211 (−1015 to 592)
Total	11 082 (14 797)	10 530 (14 125)	−424 (−4465 to 3617)
Patients with active prescriptions, No. (%)			
Insulin	121 (51.49)	125 (54.35)	2.99 (−4.47 to 10.44)
Metformin	110 (46.81)	129 (56.09)	8.87 (1.88 to 15.86)
Sulfonylureas	40 (17.02)	28 (12.17)	−0.84 (−5.85 to 4.16)
GLP-1	95 (40.42)	116 (50.43)	8.73 (0.86 to 1.66)
Other glucose-lowering medications	73 (31.06)	77 (33.48)	0.44 (−6.45 to 7.32)
Any diabetes medication	217 (92.34)	216 (93.91)	3.29 (−0.64 to 7.21)

Abbreviations: ED, emergency department; GLP-1, glucagon-like peptide 1.

[a] Data were derived from electronic health records and paid claims. Data consisted of the full analysis sample for electronic health records measures of use and patients with continuous enrollment in the insurance plan for at least 6 months following entry into the study for the claims outcomes.

[b] Sample sizes varied depending on whether the outcome was measured in the electronic health records or in insurance claims data. There were 2 observations for each participants, 1 at baseline and 1 at follow-up; the n refers to the number of observations (twice the number of participants). For EHR outcomes, the sample size was 930.

[c] Adjusted difference used mixed-effects models with controls for baseline characteristics. All 95% CIs were calculated using heteroskedasticity-robust, participant-clustered SEs. Adjusted differences are reported as estimates.

[d] Claims values were analyzed and reported only if the patient had continuous health plan coverage during the indicated period (402 observations at 6 months; 366 observations at 12 months).

A potential explanation is that the control group benefited from primary care that remained available to both groups. We did not observe an increase in outpatient care or prescription drug consumption in the control group after 6 months; however, the control group did report improved diet. The inability of the program to improve glycemic control was despite the treatment group's increased engagement in health care, a priority for patients with greater social disadvantage.[37]

Strengths and Limitations

This study's main strength is that it provides rigorous evidence of the impact of an intensive food-as-medicine program aimed at improving glycemic control. The study underscored the value of randomized trials of programs targeted to patients with elevated biomarkers because such individuals may experience improvements over time through usual care. The study also benefited from a wide range of outcomes, in-

cluding biometrics, health care use, and survey measures of behavioral change.

This study also has several limitations. First, it was conducted during the COVID-19 pandemic, and results may have differed in a nonpandemic period. Estimates were similar, although modestly powered, when estimated using only prepandemic data. Second, the study was conducted at 1 large-scale health system, for which usual care received by the control group may have been particularly effective; this may explain the improvements in HbA_{1c} levels exhibited by both the treatment and control groups. Results may have differed in other health care systems.

Furthermore, in a wait list design, control group members may take additional actions due to awareness of the program; however, we observed greater preventive health care and self-reported behavior change among the treatment group at 6 months. While self-reported outcomes may contain some degree of social-desirability bias,[38] we did not find improvements in all self-reported healthy behaviors, and more objective measures from data used were corroborative. Another limitation is that we did not have detailed recall measures of diet to verify the consumption of the food provided; instead, we examined summary measures of dietary improvements to minimize burden on patients. Finally, it may have taken longer than 6 months to 12 months for the intervention to change these outcomes.

Conclusions

In this randomized clinical trial, an intensive food-as-medicine program increased engagement with preventive health care but did not improve glycemic control compared with usual care among adult participants. Food-as-medicine programs differ in their design, and 1 explanation for the lack of health improvement in glycemic control is that providing healthy ingredients still may leave participants with the obstacle of preparing the meal. The primary alternative approach may be to deliver complete, medically tailored meals. Future research that tests how such program parameters are related to health improvements may inform the optimal design of food-as-medicine programs.

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Concept and design: Doyle, Alsan, Cawley.
Acquisition, analysis, or interpretation of data: All authors.
Drafting of the manuscript: Doyle, Alsan, Cawley.
Critical review of the manuscript for important intellectual content: All authors.
Statistical analysis: Doyle, Alsan, Skelley, Lu.
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Editor's Note

Food for Thought—Include Controls in Policy Evaluations

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Food insecurity and poor diet may play a role in worsening many chronic diseases including diabetes, hypertension, and congestive heart failure. Thus, providing medically tailored meals or food as medicine for patients could be an effective and safe intervention. The randomized clinical trial by Doyle et al[1] randomly assigned 230 patients with uncontrolled type 2 diabetes and food insecurity to receive healthy groceries for 10 meals per week for the entire household for 6 months and compared them with 235 patients who were placed on a wait list and received the food intervention after 6 months. The hemoglobin A_{1c} level improved in the group provided with food by approximately 1.5 percentage points after 6 months but improved by almost the same amount (1.3 percentage points) in the control group, resulting in a nonsignificant difference between the intervention and control groups.

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Some might consider it unethical not to provide healthy food to patients with uncontrolled type 2 diabetes and food insecurity. However, we believe a control group is crucial in this type of unblinded trial. If this trial had been uncontrolled, the intervention would have been found effective. We believe that the wait list design used in this trial was optimal. The design provided a randomized comparison group that did not get the food intervention at the same time as the intervention group but still provided 6 months of healthy food at the end of the waiting period.

Whenever possible, investigators should randomize interventions to avoid falsely concluding that pre- vs postintervention differences are due to the intervention.

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