

Healthy Food Rx Results – 12 Months



Prepared by:
Maggie Wilkin, Betty Sun, Koi Mitchell and Lizania Romero
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For more information, contact
Maggie Wilkin, Principal Investigator
margaret.wilkin@wellness.phi.org

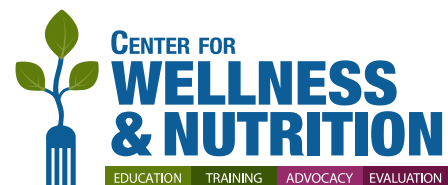


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STUDY KEY FINDINGS

Over a 12-month period of participating in the Healthy Food Rx program, patients with diabetes reported **statistically significant improvements** in:

Hemoglobin A1C

- Decreased significantly by 0.35% overall and by 0.80% among those outside of target range at baseline

Food insecurity

- Decreased significantly by 10% in the survey sample

Diet quality

- Daily fruit and vegetable consumption increased significantly (0.28 and 0.14 times per day)

Diabetes self-management tasks

- Overall number of tasks respondents reported doing regularly increased from around 3 to over 4, on average
- Percentage doing the following specific tasks also increased significantly:
 - Doing more physical activity
 - Following my diabetes meal plan
 - Going to diabetes education and/or nutrition education classes
 - Talking with mentors & friends about diabetes management and healthy living



BACKGROUND

The Healthy Food Rx program is part of Abbott and the Abbott Fund's Future Well Communities initiative – a multi-year program that aims to advance health access and equity by removing the barriers that prevent people with diabetes from living healthy lives in Stockton, California, through community-clinical partnerships. The Public Health Institute – Center for Wellness and Nutrition (PHI CWN) is funded by the Abbott Fund to design, implement, and evaluate the Healthy Food Rx program. The Healthy Food Rx project's goal is to increase the implementation of successful strategies that increase access to fresh, seasonal fruits and vegetables and other healthy foods in low-income communities disproportionately affected by diabetes with a healthy food prescription (Rx) program.

In San Joaquin County, California, there is a 13.9% prevalence of diabetes and chronic diseases are the primary cause of poor health outcomes and death (San Joaquin, 2022). Additionally, an estimated 48% of residents in San Joaquin County are at risk for developing diabetes (Babey, 2016). Stockton, California, has the eight most unhealthy census tracts in the county with the highest levels of poverty. Residents have limited access to healthy foods and are at higher risk of developing chronic diseases, such as obesity, heart disease, diabetes, and asthma. Obesity rates and diabetes prevalence were 20 times higher in San Joaquin County as compared to the state of California, with higher rates seen in communities of color compared to their white counterparts. San Joaquin County residents that participated in focus groups linked food insecurity to the high levels of obesity and diabetes seen in their neighborhoods (San Joaquin, 2022).

The Healthy Food Rx project provided healthy food boxes through community partnerships, enabling home delivery and complementary nutrition education opportunities, every other week for up to 12 months. The primary goal of this evaluation was to assess the relationship between participation in the Healthy Food Rx program and participants' dietary behaviors, hemoglobin A1C, food insecurity and self-reported diabetes self-management behavior. The participants were surveyed at enrollment, after 6 months (Phase 1) and 12 months (Phase 2) in the program.

The following evaluation questions were examined in this project:

- Have participants' A1C levels improved significantly during their participation in the program?
- Has diet quality improved (self-reported consumption of fruits, vegetables, and water) after participation in the program?
- Do participants report less food insecurity after participating in the program?
- What are the diabetes self-management behaviors reported by participants before and after participating in the program?

METHODOLOGY

Participants and Procedures

Community Medical Centers, a Federally Qualified Health Center, identified Healthy Food Rx program participants in their clinic database. People were eligible to participate in the Healthy Food Rx program if they were over the age of 18, diagnosed with diabetes (type 1 or type 2), currently under the care of their Community Medical Centers physician, resided in Stockton, California, and had current hemoglobin A1C (A1C) bloodwork labs on file, a measure of glycemic control over the previous two to three months. Patients were enrolled into the program by a health educator via telephone (due to COVID-19 precautions, visits were virtual) and invited all program participants to participate in the program evaluation using approved informed consent procedures. Choosing not to participate in the program evaluation did not preclude them from participating in the Healthy Food Rx program.

Healthy Food Rx participants received a home-delivered food box every other week throughout the program which included ingredients for a culturally tailored, family-sized healthy meal as well as pantry staples such as beans, rice, additional produce, and nuts. The box also contained a recipe card and a link to an online video of the recipe. Food boxes were designed by nutrition educators, ingredients were purchased by a local distributor, packaged by a regional food bank, and delivered to participants via a partnership with DoorDash. This delivery model ensured that almost 100% of participants received all food boxes.

The program included 2 phases; Phase 1 included the first 6 months of the program. Soon after the end of the first 6 months, eligible participants were invited to continue for Phase 2, another 6 months for a total of 12 months in the program. To be eligible for Phase 2, participants must have had updated A1C labs on file that were measured within 90 days before or after their final Phase 1 food box. Evaluation participants were asked to complete a 10-minute baseline survey during enrollment and at the end of Phases 1 (6 months) and 2 (12 months), including questions on dietary intake, diabetes management behaviors, and food security. Surveys were conducted over the telephone by trained clinic staff in both English and Spanish and responses were recorded in the UniteUs platform, an online, secure data platform that is Health Insurance Portability and Accountability Act of 1996 (HIPAA) compliant. Participants received \$10 gift cards for completion of the 6-month and 12-month surveys. Data collection dates for the surveys are shown in Table 1.

Table 1. Data Collection Dates for Each Survey

Survey	Data Collection Dates
Baseline	April 2021 – July 2021
6-month (Phase 1)	October 2021 – March 2022
12-month (Phase 2)	August 2022 – January 2023

In addition to survey data collection, lab-verified A1C values were collected from medical records. Table 2 displays the participation numbers by Phase and type of data.

Table 2. Participation Numbers by Phase and Type of Data

Enrolled in Healthy Food Rx Program <i>n</i> = 451	Survey Data	A1C Data	Both Survey and A1C Data Available
Baseline	374	-	-
6-month (Phase 1)	319 (85% retention)	119	89
12-month (Phase 2)	204 (64% retention)	92 (77% retention)	67 (75% retention)

Measures

Glycated hemoglobin A1C. A1C is a measure of glycemic control over approximately the past three months (American Diabetes Association, 2019; Penttilä, 2016). According to standards of medical care for diabetes by the American Diabetes Association, lowering A1C with a goal of less than 7.0% has been associated with a reduction in the risk of multiple complications including microvascular and neuropathic complications, as well as myocardial infarction and cardiovascular death (American Diabetes Association, 2003). At 6 months, A1C data were available for 119 Healthy Food Rx participants and at 12 months, A1C data were available for 92 participants who provided Health Insurance Portability and Accountability Act of 1996 (HIPAA) consent for medical records access and had two A1C measures corresponding to the timing of the surveys. A1C data were provided to PHI CWN by Community Medical Center staff including a unique ID that could be matched to survey data. A1C measures were considered valid for baseline if they were measured from 6 months before to 2 months after the participant received their first food box. At 6 months, measures were valid from 3 months before to 2 months after the last box and at 12 months, values were considered valid if they occurred within 100 days of the last box. The window was extended for the final box to maximize the amount of data included in analysis. A1C values of 7.0% or greater at baseline were classified as outside of the target range and those less than 7.0% were considered within the target range (Penttilä, 2016).

Food insecurity. To measure food insecurity for this evaluation, two items from the Economic Research Service's U.S. Household Food Security Survey Module (Economic Research Service, 2012) were administered. Participants were classified as food insecure if they answered sometimes or often true to either of the following: "We worried whether our food would run out before we got money to buy more," or "The food that we bought just didn't last, and we didn't have money to get more." This method was developed by Hager et al and recommended by the American Academy of Pediatrics as a practical measure to screen for household food security (Gitterman, 2015; Hager, 2010). This method is also recommended by Feeding America to screen for household food insecurity across the U.S. (Feeding America, n.d).



Healthy diet. Diet quality is a crucial factor in the management of diabetes. Poor diet quality is associated with poorer glycemic control among adults with diabetes (Shaheen, 2021). Survey data measured the consumption frequency of fruits and vegetables per day on a 6-level Likert scale using questions from The Expanded Food and Nutrition Education Program adult education survey where one equaled "I rarely eat fruits/vegetables" and six equaled "more than four times per day" (Barale, 2020). A similar scale measured water consumption, however, one equaled "I never drink water" and six equaled "five times per day." The original values were re-coded to represent daily consumption frequency and treated as a continuous variable to assess mean daily intake frequency.

Other measures. Participants also reported if they regularly conducted diabetes self-management tasks, including checking blood sugar, taking medications as prescribed, following a healthy diet, accessing a social support system, and participating in physical activity in the survey. Demographic information including age, gender, race, ethnicity, and primary language was also collected via medical records and the survey.

Data Analysis

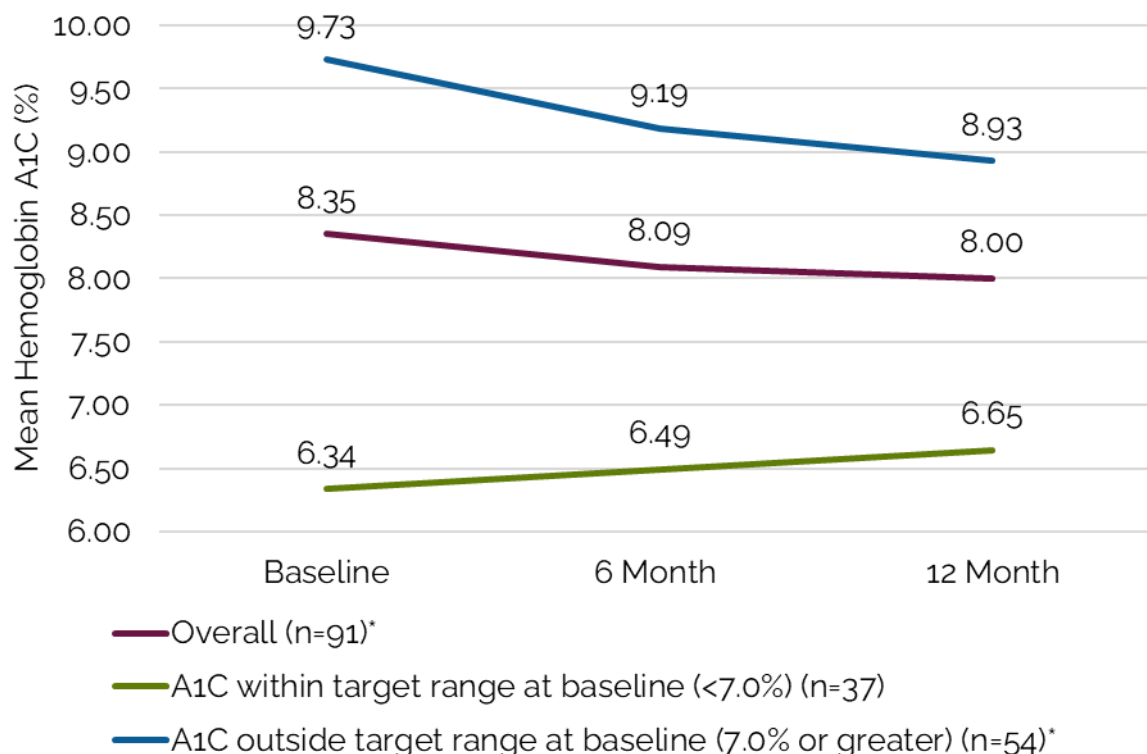
All data were examined for completeness and values out of range were removed from the analysis. Descriptive statistics (frequencies and means) were calculated for all demographic and outcome variables at both time points. Paired t-tests (continuous variables) and McNemar's test (categorical variables) were conducted to examine changes over time in outcome variables of interest. Changes in A1C and consumption variables (fruit, vegetables, and water) were calculated by subtracting the baseline value from the follow-up value and modeled with demographic characteristics (gender, ethnicity, age) to identify differences in the change over time by group. Additional longitudinal mixed models were conducted to determine if the linear changes over time in the mean outcomes of interest were differential by demographic groups. For the majority of the analyses, the sample that had data for all three time points was used (for A1C: $n = 92$, for survey data: $n = 204$). Data analyses were conducted using R Software, IBM SPSS Statistics V28, and SAS Software for Windows V9.4. An alpha of less than 0.05 was considered statistically significant for all analyses.

RESULTS

Glycated hemoglobin A1C (A1C)

As shown in Figure 1, average A1C across the whole sample decreased by 0.35% from baseline to 12 months, a statistically significant decrease (significant change, $p = 0.048$). Among those outside of target range at baseline (A1C = 7.0% or greater, $n = 54$), A1C decreased by 0.80% from 9.73% to 8.93% ($p = 0.003$) after 12 months in the program. In models comparing A1C change by demographic groups, there were no differences in change over time by age, gender or ethnicity.

Figure 1. Mean A1C For Healthy Food Rx Participants by Baseline A1C Group



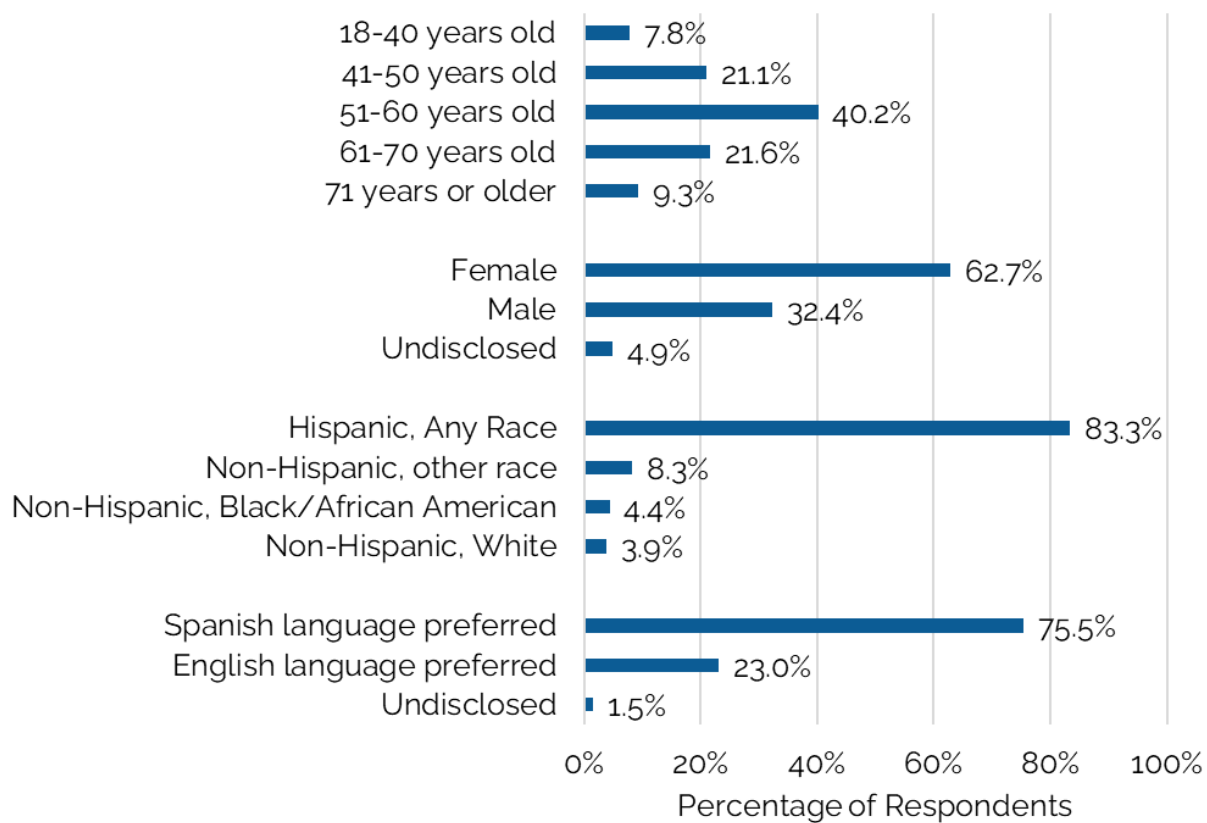
Note: Only those who consented to share medical information are included in the analysis.

**Change from baseline to 12 months is statistically significant based on a paired t-test, $p < 0.05$.*

Description of the survey sample

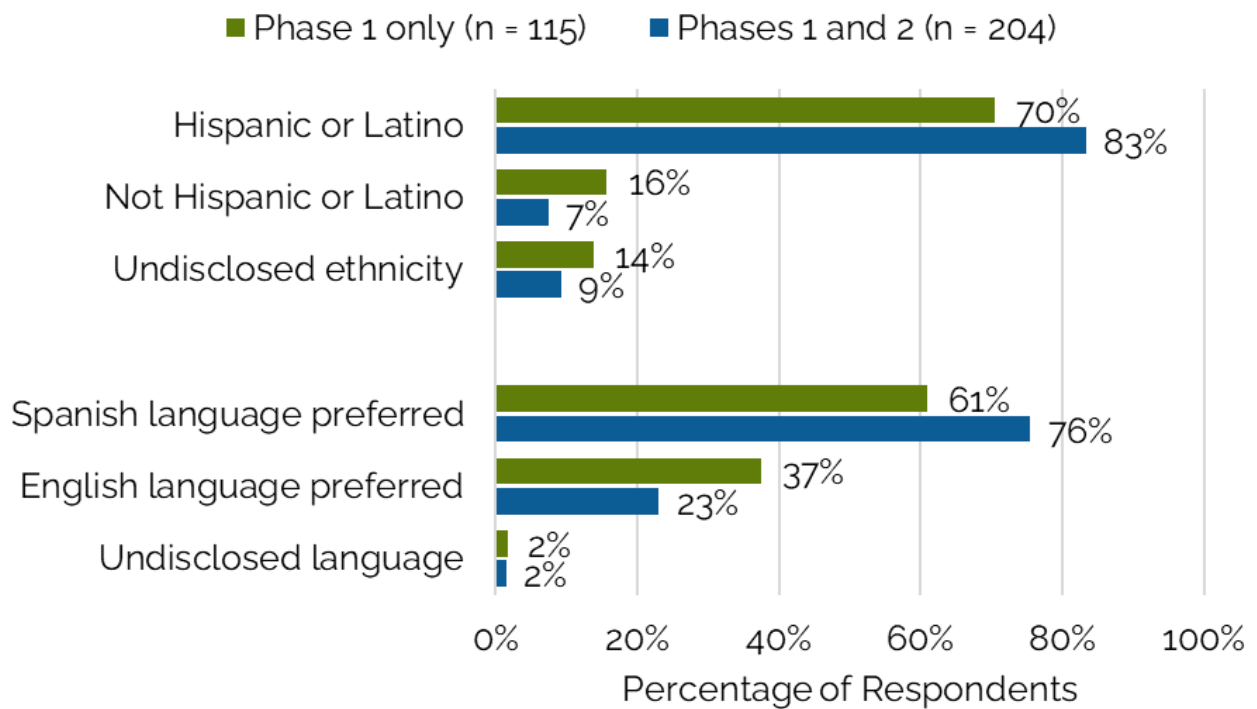
There were 374 Healthy Food Rx participants who completed a pre-survey. Of those, 85% ($n = 319$) also completed a 6-month survey and 55% ($n = 204$) completed surveys at all three timepoints (baseline, 6-month, and 12-month). As shown in Figure 2, among Healthy Food Rx participants who completed both phases of the evaluation (12-months), 71% were over the age of 50 and almost two thirds (63%) identified as female. The majority of participants reported Hispanic/Latino ethnicity (83%) and preferred Spanish as their language (75%).

Figure 2. Description of the Sample That Completed Both Phases 1 and 2 ($n = 204$).



To examine differences in program retention, comparisons between those only completing Phase 1 and those who completed both phases were conducted. There were no differences by age and gender, however, as shown in Figure 3, those completing both phases were significantly more likely to be of Hispanic or Latino ethnicity than non-Hispanic or Latino (83% versus 70%, $p = 0.02$) and have Spanish as their preferred language (76% versus 61%, $p = 0.02$).

Figure 3. Demographic differences between Phase 1 only completers versus Phase 1 and 2 completers.

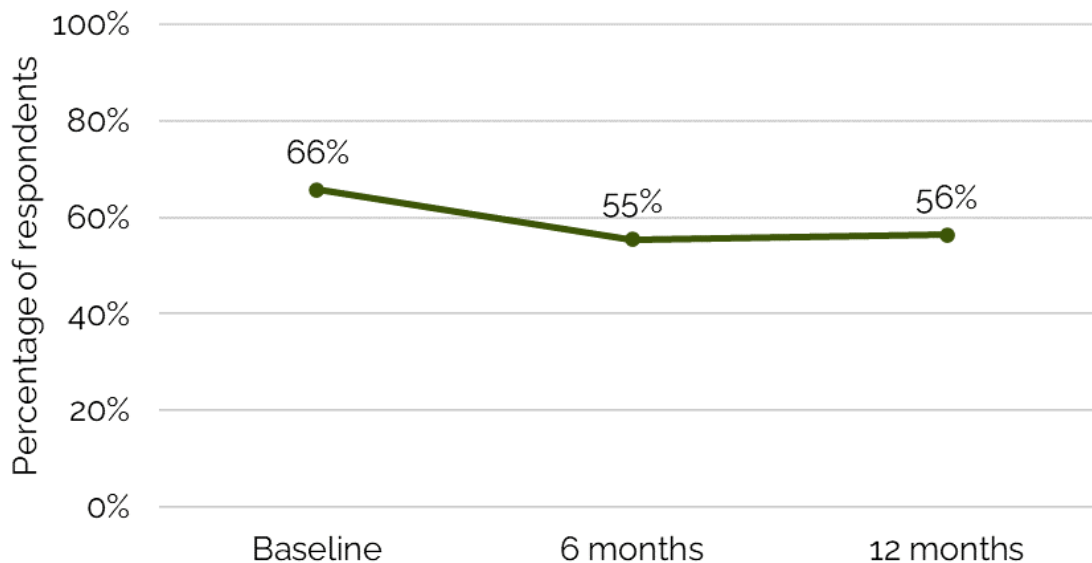


Note: Hispanic or Latino ethnicity and those with preferred language as Spanish were statistically more likely to complete both phases of the evaluation than their counterparts ($p = 0.02$) based on chi-squared test of homogeneity.

Food Security

The U.S. Department of Agriculture (USDA) defines food insecurity as a lack of consistent access to enough food for an active, healthy life. Food insecurity is associated with important social determinants of health like lack of affordable housing, social isolation, economic/social disadvantage resulting from structural racism, chronic or acute health problems, high medical costs, and low wages. Shown in Figure 4, food insecurity decreased significantly in the sample after 6 months in Healthy Food Rx (decrease by 11%, $p = 0.005$) and the lower level was maintained after 12 months. There were not significant differences by demographic characteristics in change in food security status.

Figure 4. Percentage of Respondents with Food Insecurity by Time Point (n = 204).

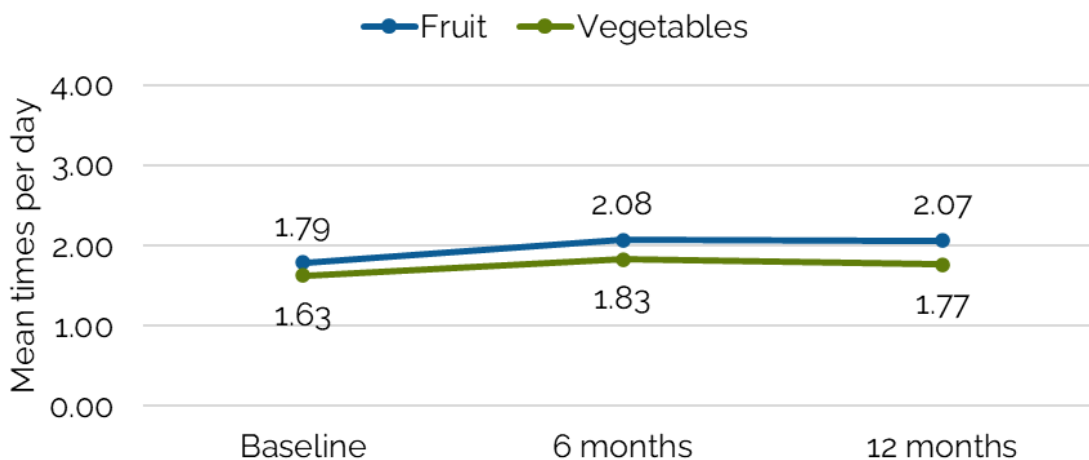


Note: Changes from baseline to 6 months and baseline to 12 months were significant based on a McNemar test for homogeneity in matched data ($p = 0.005$ and 0.018 , respectively)

Healthy Eating

Average fruit and vegetable consumption increased significantly after six months in the program and the higher level was mostly maintained after 12 months in the program (Figure 5). Fruit intake improved by 0.28 times per day, which equals almost 2 more times per week and vegetable intake improved by 0.14 times per day, or one more time per week after 12 months in Healthy Food Rx ($p = 0.001$ and 0.028 , respectively). In models comparing fruit, vegetable, and water consumption change by demographic groups, there were no differences in change over time by age, gender, ethnicity.

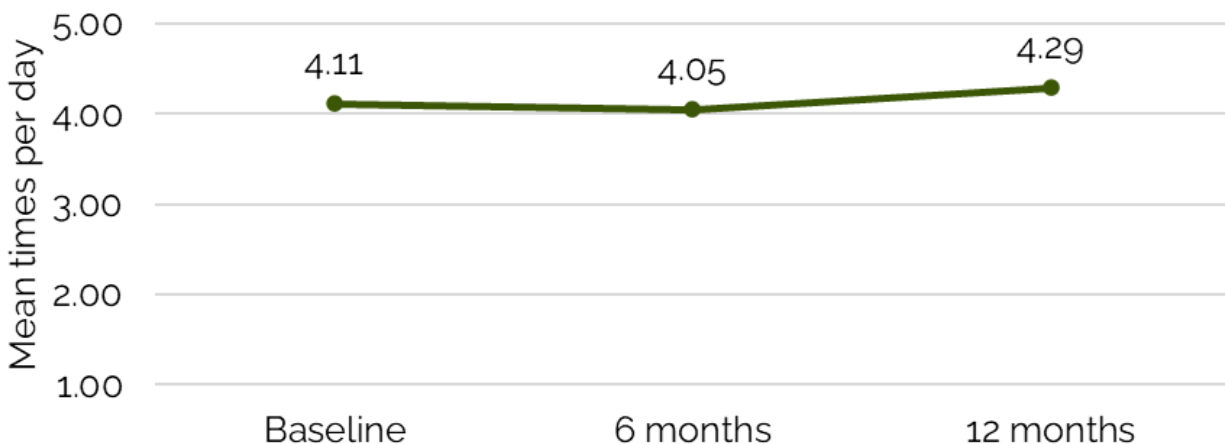
Figure 5. Mean fruit and vegetable consumption for Healthy Food Rx participants (n = 204).



Note: Changes from baseline to 6 months and baseline to 12 months were significant based on paired t -tests (6 mo: $p = 0.001$ and 0.007 , respectively, 12 mo: $p = 0.001$ and 0.028 , respectively).

Shown in Figure 6, water consumption was fairly consistent over time in the sample, there was a slight drop at the 6-month time point, but at all time points respondents reported drinking water more than four times per day, on average. The differences between baseline and 12 months and 6 months and 12 months were significant ($p = 0.016$ and 0.001 , respectively).

Figure 6. Mean water consumption for Healthy Food Rx participants with a pre- and 12 month-survey ($n = 204$), overall.

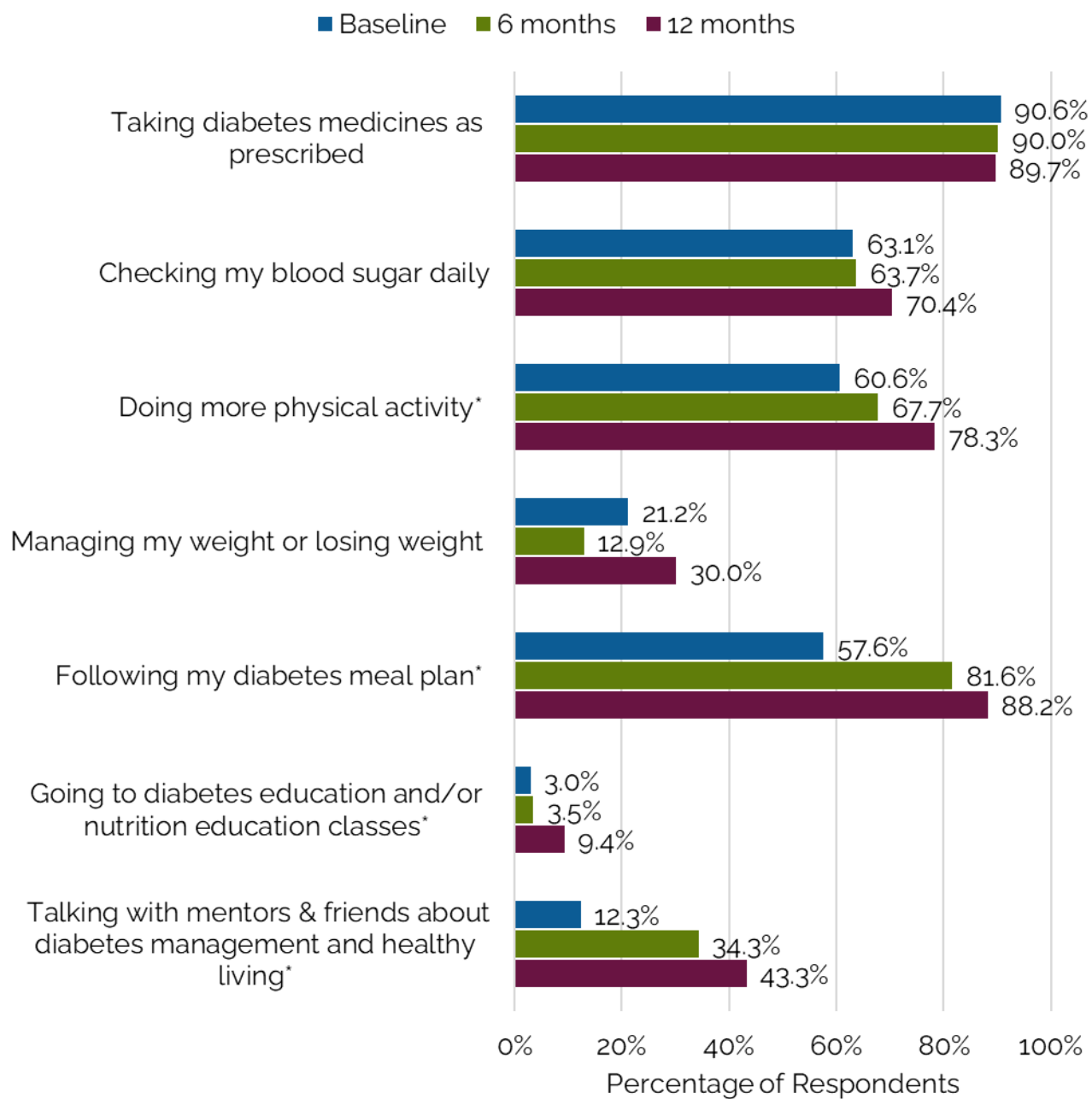


Note: The differences between baseline and 12 month and from 6 month to 12 month were significant ($p = 0.016$ and 0.001 , respectively) based on paired t -tests.

Diabetes Self-Management

Figure 7 shows diabetes self-management tasks reported on the survey. For most tasks, the percentage of those reporting each increased from baseline to 12 months. The majority of respondents were taking their diabetes medications as prescribed at all 3 time points. Most of the other tasks showed an increase in the percentage reporting them with significant increases in those doing more physical activity ($p < 0.001$), following their diabetes meal plan ($p < 0.001$), going to diabetes or nutrition education classes ($p = 0.011$) and talking with others about diabetes and healthy living ($p < 0.001$).

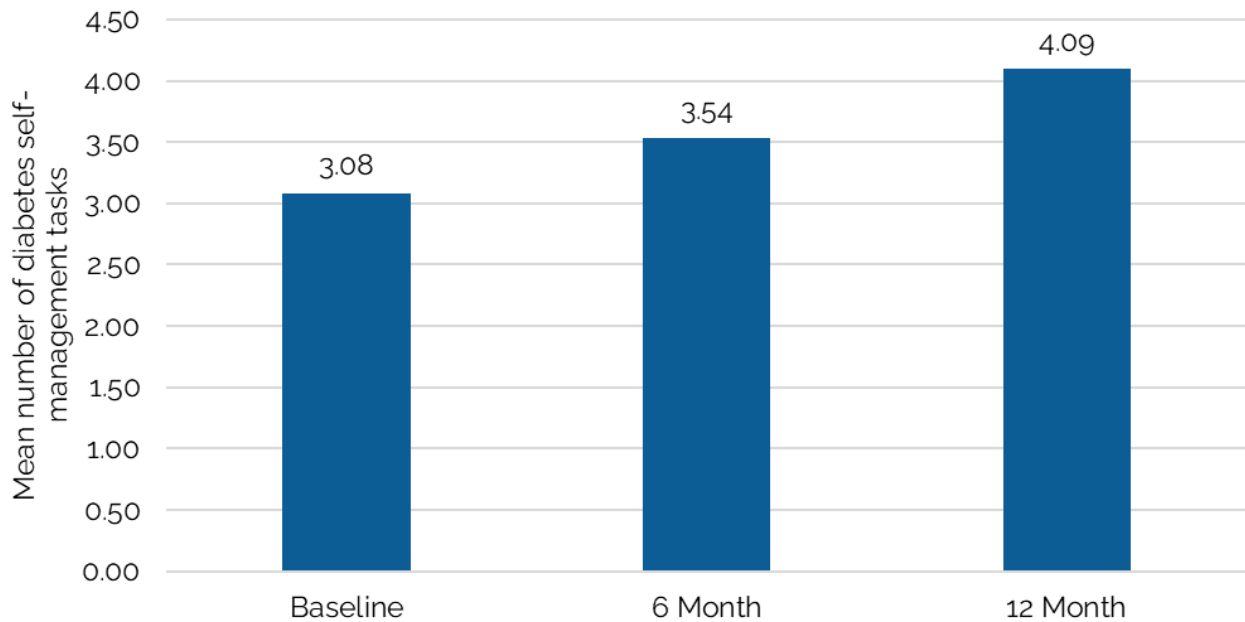
Figure 7. Diabetes Self-Management Tasks Respondents Reported Doing in the Previous 4 Weeks, (n = 204).



*Note: *Changes from baseline to 12 months were significant based on a McNemar test for homogeneity in matched data (p < 0.05).*

Most participants reported doing multiple activities to manage their diabetes. Figure 8 shows the average number of diabetes management tasks performed by respondents at each timepoint. At baseline, respondents were performing about 3 tasks on average which increased significantly to 3.54 ($p < 0.001$) after 6 months and to over 4 tasks after 12 months ($p < 0.001$).

Figure 8. Average Number of Diabetes Self-Management Tasks Reported by Respondents, by Time Point ($n = 204$)



Note: The differences between all timepoints were significant ($p < 0.001$) based on paired t -tests.

LIMITATIONS

The purpose of this project was to evaluate a community-based intervention model to improve diabetes management and outcomes. Since this was not a randomized trial, there was not a comparison group, limiting the ability to attribute changes directly to the program. Convenience sampling was utilized, not allowing these results to be generalized to the larger population. Also, A1C values were obtained from a patient's health care record and not measured as part of the program. Those patients with available A1C data may be more likely to seek routine medical care and in turn, be more motivated to improve their health. It is important to note that significant improvements in healthy eating and food security were seen in the entire sample, regardless of whether they had a recent A1C measure. The sample largely consisted of Spanish-speaking Hispanic/Latino adults providing an opportunity to assess the impact of this type of program within this population, however, it limited the ability to compare across different racial and ethnic groups.

DISCUSSION

The results from this evaluation indicate that a program addressing social determinants of health by providing healthy meals, produce, and staple items delivered to participants' homes through community partnerships was associated with improved health outcomes in participants. The Healthy Food Rx program did not require attending health education classes to continue receiving boxes, or monthly engagement check-ins to renew the prescription, which led to almost all participants receiving all the food boxes throughout the 12-month program. Providing home-delivery of food boxes also eliminated a potential barrier for participation and addressed two important social determinants of health, food access and transportation. In a review of food is medicine studies, researchers found that the use of program benefits declined over time in most studies with only 9-18% of participants redeeming all benefits, partly due to transportation issues and access to retailers (Coleman-Jensen,2021). This low-touch, highly scalable intervention was able to reach the most people in an equitable manner with a food as medicine approach.

Reduction in A1C is critical for diabetes management and risk reduction and was a primary goal of this intervention. Reaching an A1C target of < 7% early in the course of the disease has been shown to reduce microvascular complications of type 1 and type 2 diabetes (Stratton, 2000). An improvement of 0.5% has been shown to be associated with improved health outcomes in people with diabetes and is widely considered a clinically significant change (Little, 2013). This evaluation showed a reduction of 0.35% in A1C among all respondents after 12 months in the program. However, among those outside of the target A1C range at baseline, there was a 0.54% reduction in A1C value at 6 months and a 0.80% reduction on average after receiving 12 months of healthy food boxes. While greater changes in A1C values have been shown in studies with a more intensive intervention such as required diabetes education and home visits (Ferrer, 2019; Feinberg, 2018) the results from this evaluation are similar or better than those in similar community-based interventions with little to no additional components (Bryce, 2017; Seligman, 2015). Additionally, this evaluation had a higher completion rate (64% versus 58% or lower) than similar studies, likely due to home-delivery and interviewer-administered surveys (Bhat, 2021).

Diet quality improved on average for all participants, with no significant differences in changes shown by demographic groups. The Diabetes Prevention Program Research Group has shown lifestyle changes such as diet and exercise to be more effective than medication to reduce the incidence of diabetes among those at risk for developing the disease (Knowler, 2002).

Program participants were very low-resource, with two-thirds considered food insecure at the beginning of the program compared to about 10% of U.S. households overall in 2021 (Coleman-Jensen, 2021). Despite this, a significant reduction in the percentage experiencing food security (from 66% to 55%) was shown, addressing an important social determinant of health within this population, increasing their likelihood of improved overall quality of life. At the end of the program, over half of participants still reported food insecurity, indicating that the amount of food provided by this program was not enough to reduce food insecurity at the household level for most participants. There is still a need in this community for greater food access, which could include referrals to benefits programs and food banks.

CONCLUSIONS AND NEXT STEPS

The results from this evaluation show that a low-touch, community-based program delivering healthy meals, produce, and staple food items twice per month with optional health education has the potential to improve health outcomes, food security, and healthy eating among populations most in need. Studies like this can inform policies supporting a variety of food is medicine models including healthy meal boxes, produce boxes, and medically-tailored meals addressing social determinants of health, increasing health equity, and improving disease self-management behaviors in low-resourced communities. These programs are a low-cost investment compared to other medical interventions and can be designed to meet the unique needs of the communities and populations being served, improve health outcomes, optimize medical spending, and increase client engagement. Creating a billing code series for healthy food prescription programs and issuing guidance across public and private healthcare services could increase the uptake of these types of programs as a reimbursable treatment option with the ability to customize programs to meet members' needs. Further, working across sectors at the community level maximizes local resources and expertise across the healthcare, public health, agricultural, and food sectors and leverages public and private funds to make these types of programs trusted and successful.

Currently, there are three more program evaluations are being conducted with variations on the Healthy Food Rx model studied in this report, one including a health coaching component in addition to meals, one including a comparison group and another allowing referrals from a broader range of community partners. These studies will allow for further exploration of the community collaborative model in improving health outcomes. Additionally, they will include a more diverse population to examine the impact of a healthy food prescription program on different populations.

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