

Food Rx + CHW: a Community Health Worker-led Medically Tailored Grocery Intervention to Address Food Insecurity and Type 2 Diabetes, a pilot randomized trial

Kristina M. Bridges*¹, Jennifer Woodward*¹, Megan Murray², Alyssa Leibengood², Leonidas Bantis³, Leny Montero¹, Donna Young⁴, Manuel Solano⁵, Vanessa Camacho⁴, Angela McCall⁴, Debra K. Sullivan⁶, K. Allen Greiner¹

¹ Department of Family Medicine and Community Health, University of Kansas Medical Center, Kansas

City, Kansas, USA

² School of Medicine, University of Kansas Medical Center, Kansas City, Kansas, USA

³ Department of Biostatistics, University of Kansas Medical Center, Kansas City, Kansas, USA

⁴ Community Health Council of Wyandotte County, Kansas City, Kansas, USA

⁵ Samuel U. Rodgers Health Center, Kansas City, Missouri, USA

⁶ Department of Dietetics and Nutrition, University of Kansas Medical Center, Kansas City, Kansas, USA

*Authors contributed equally to the work.

Corresponding author:

Kristina M. Bridges, PhD

3901 Rainbow Blvd, Kansas City, Kansas, 66205, USA

kbridges@kumc.edu

ABSTRACT

Background: Food insecurity increases an individual's risk of poor health outcomes from costly and preventable chronic diseases such as type 2 diabetes. Methods: In this pilot study, primary care patients with self-reported food insecurity and a diagnosis of type 2 diabetes received 12 weekly home deliveries of fresh produce and shelf-stable foods. About half of the participants were also supported by a community health worker (CHW) providing nutrition education, cooking instruction, and resource linkages (Food + CHW). Participants (n=31) self-checked hemoglobin A1c, blood pressure, and weight on devices at home at three time points: baseline, three months, and six months. Results: Participants (84% female, 32% Black, 66% White, 22% Hispanic, and 58 years old on average) had an average HbA1c of 8%. For the Food-only group (n=15), there was no significant change in hemoglobin A1c at either time point. For the Food + CHW group (n=16), the mean change in HbA1c was -0.85 (95% CI, [-0.048, -1.66], P value = 0.039) from baseline to 3 months and -1.65 (95% CI, [-2.84 - 0.472], P value = 0.012) from baseline to 6 months and a majority of participants (81%) had a reduction in hemoglobin A1c at six months. Diastolic blood pressure for the Food-only group increased by an average of 6.5 mmHg (p= 0.02) between baseline and 3 months but remained stable for the Food + CHW group. In both groups, systolic blood pressure and weight did not change significantly. Participants in the Food + CHW group reported significant increases in daily servings of fruit, nutrition label reading, eating meals cooked from scratch, and farmer's market shopping while the Food-only group did not. Conclusion: These findings suggest that CHWs support a patient's ability to reduce hemoglobin A1c through dietary behavior changes and sustain this reduction over time. This trial was retrospectively registered at ClinicalTrials.gov (NCT06476990) on June 20, 2024.

Keywords: Food insecurity, Community health worker, Food is medicine, Medically tailored groceries, Diabetes

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INTRODUCTION

Food insecurity—defined as limited or uncertain access to adequate food—remains a pervasive public health challenge in the United States, disproportionately affecting individuals with chronic conditions such as type 2 diabetes and increasing the risk for poor health outcomes.(1) Patients with the highest chronic disease burden often have the least access to healthy foods, creating a cycle that exacerbates poor health outcomes.(2) These disparities are rooted in historic structural inequities. Discriminatory housing policies such as redlining systematically denied Black and other minoritized communities access to mortgages and investment, concentrating poverty and limiting economic mobility. Over decades, these policies shaped neighborhood infrastructure, including the placement of grocery stores and transportation systems, resulting in persistent “food deserts” in formerly redlined areas.(3) Today, these communities continue to experience higher rates of both food insecurity and type 2 diabetes, illustrating the enduring impact of structural racism on health.(4-6)

The intersection of food insecurity and diabetes is particularly concerning because dietary quality is central to glycemic control and prevention of complications. Screening for food insecurity and other health-related social needs is crucial for providing comprehensive diabetes care. A previous study revealed that patients with a diagnosis of type 2 diabetes were 1.66 times more likely to self-report an SDOH need than patients without a diagnosis of type 2 diabetes and 1.57 times more likely to report food insecurity as a specific need.(7).

Although many national and community resources exist to help increase access to healthy food, such as the Supplemental Nutrition Assistance Program (SNAP) and nutrition incentive programs that double SNAP dollars for locally grown

produce, (8) these programs are underutilized due to barriers such as a lack of awareness or misinformation, burdensome administrative requirements, and a lack of transportation to utilize services. (9, 10) Community health workers (CHWs) have emerged as a powerful solution to directly address these barriers, particularly in underserved settings.(11)

CHWs are natural helpers and trusted members of their communities. They receive training in cultural competency and humility, trauma-informed care, motivational interviewing, community resource connections, and health education and coaching.(12) CHWs support clients in identifying goals and interventions to reduce health-related social needs and improve health.(12) Several studies have outlined the positive return on investment in CHW programs, including decreasing healthcare utilization and cost, increasing access to care, and improving diabetes outcomes.(13-15) Studies have shown that increased access to healthy foods; healthy eating education; enrollment in federal, state, and local benefits; and food Rx programs can improve health outcomes and reduce healthcare costs for patients with diabetes.(16-19) We hypothesize that these food Rx programs delivered with CHW support will result in sustainable health benefits.

In this pilot study, primary care patients with type 2 diabetes and self-reported food insecurity were enrolled at an academic medical center situated in a county with a history of redlining and disinvestment and a food insecurity rate of 16.1%, higher than the national rate of 13.7%,(20)to investigate the effectiveness of a CHW-delivered healthy food prescription, food provision, and capacity-building intervention.. This innovative intervention provided patients with CHW visits, home delivery of fresh produce, shelf-stable food, nutrition and cooking education, and tailored benefit enrollment and community resource linkage and compared this to

provision of food alone. This approach was intended to bridge the food insecurity gap for patients while ensuring that they are linked to the appropriate resources to continue to access fresh, healthy food.

METHODS

Study design and participants

Food Rx + CHW was a 3-month CHW-led medically tailored grocery intervention at one academic medical center in a county with a history of redlining (21) and disinvestment(22) in the Midwest United States. Study design: Two arm, unblinded RCT with demographic control. Eligible participants were patients from the medical center, aged 18 years or older, English or Spanish speaking, with a diagnosis of type 2 diabetes and a most recent HbA1c > 7 , and who had previously answered “yes” to the food insecurity needs question (“In the last 12 months, did you ever eat less than you should because there wasn’t enough money for food?”) on an SDOH screener during a patient care visit.(23) Patients were excluded if the last known address was outside the delivery zone (the Kansas City Metro area) or if they resided in a facility that provided all meals. All primary care patients at the academic medical center are screened annually for SDOH needs via a modified version of the Health Leads screening tool. Prior to contact and recruitment, eligible patients were randomly assigned to receive 12 weekly food deliveries and support from a CHW (Food + CHW group) or food delivery only (Food-only group). We used an Excel-based adaptive randomization tool to ensure an equal distribution of participants by age, race, and gender between the two groups. Research staff and CHWs called eligible patients via telephone to inform them about the study and invite them to participate. If patients were interested, research staff or CHWs sent a

link to a consent form and reviewed it with the patient before obtaining written consent via an electronic signature. The deidentified electronic health records of individuals from primary care clinics who met the study inclusion and exclusion criteria but were not included in the study (declined, unable to contact) were analyzed as controls for demographic comparisons and healthcare utilization outcomes (control group).

The implementation of this pilot study occurred during the COVID-19 pandemic, and all participant interactions were required by the research institution to be contactless and/or virtual. This study adheres to the CONSORT guidelines for reporting clinical trials. This study was approved by the Institutional Review Board of the University of Kansas Medical Center as Study 00144654. Informed consent was obtained from all the participants and/or their legal guardians. This trial was retrospectively registered at ClinicalTrials.gov (NCT06476990) on June 20, 2024.

Intervention

All participants received 12 weekly contactless deliveries of food. CHWs conducted three virtual study visits with participants to administer surveys and/or collect biomarker measurements at weeks 1, 12, and 24. No changes in the frequency of visits with the patient's provider were recommended. Virtual visit 1 involved the completion of study forms, assessment of household size for most meals, cultural preferences, food allergies, baseline cooking and eating habits, and assessment of knowledge and usage of local and/or federal food support programs as well as instructing patients how to use home kits and devices (provided by the study) to measure and report their HbA1c, weight and blood pressure. At week 12, participants repeated home measurement of their HbA1c, weight and blood

pressure; completed post-intervention surveys on diet, knowledge and usage of food access programs and resources; and completed an anonymous feedback questionnaire on the strengths and opportunities for improvement in the program. At week 24, participants measured and self-reported their final HbA1c, weight, and blood pressure results.

In addition to food, participants in the Food + CHW group also received 7 weekly virtual sessions with a CHW (four 90-minute ZOOM counseling sessions and three 30- to 60-minute check-in phone calls) during the first seven weeks of the intervention. CHWs were bilingual English and Spanish. CHW sessions included diabetes-appropriate cooking and nutrition education and personalized benefit enrollment and linkage to existing food access resources (for example, SNAP, Double up Food Bucks, and Kansas Senior Farmers Market Vouchers). To prepare for providing cooking and nutrition education, CHWs completed structured training designed and led by a registered dietitian and nutrition educators affiliated with a local community food bank. The training curriculum was adapted from publicly available USDA MyPlate resources and covered core nutrition education topics, including label reading, stocking a healthy pantry, recipe interpretation and substitutions, maximizing vegetable intake, and reducing consumption of sugar-sweetened beverages. The curriculum also incorporated diabetes-specific nutrition guidance, with emphasis on healthy eating strategies for glycemic control and portion balance, including use of the Diabetes Plate method from the American Diabetes Association.⁽²⁴⁾ After completing training, CHWs delivered these educational components to participants during scheduled intervention sessions.

Each weekly food box contained approximately \$8 worth of shelf-stable food items purchased from a local food bank (beans, canned vegetables and no-sugar-

added fruit, shelf-stable dairy products, canned tuna, and whole grains) and \$25 of fresh produce (5-7 items, including leafy greens, peppers, potatoes, broccoli, carrots, zucchini, cauliflower, celery, cabbage, asparagus, apples, or strawberries). When seasonably available, fresh vegetables and fruits were sourced from local farmers via a local food hub. When local produce was not available, CHWs sourced produce from grocery stores.

Outcome Measurements

The primary outcome was decrease in hemoglobin A1c. Secondary outcomes were blood pressure, weight, diet, cooking skills, and utilization of food access resources.

Biomarkers

All patients were provided with hemoglobin A1c self-test kits (A1CNow Self-Check manufactured by pts Diagnostics), blood pressure cuffs (Arm-type fully automated digital blood pressure monitor with a regular or large cuff, model BSP-11, Omega Medical Instruments), and electronic scales (INNOVA Imports Living). CHWs guided participants to self-collect and report HbA1c, weight, and blood pressure measurements at three time points: week 1 (baseline), week 12 (immediately after food delivery and CHW intervention ended), and week 24 (3 months post intervention).

Diet and cooking

CHWs assessed participants' diet quality via a combination of a 2-item fruit and vegetable serving screener (25) and three questions designed by the nutrition services team at our food bank partner to assess nutrition education. The fruit and

vegetable screener asked participants how many servings of fruit and vegetables they usually eat each day. The participants were asked to select zero or a range of servings ranging from 1--2, 3--4, 5--6, or 7--9. The responses were converted to the midpoint for each range (e.g., 1--2 servings = 1.5). The remaining three diet questions were "On average, how often do you fill half your plate with fruits and/or vegetables?" "On average, how often do you drink sugary beverages (soft drinks, energy drinks, sweetened tea, juice, sweetened coffee drinks)?" and "When obtaining food, how often do you read a label for nutrition information?" Participants were asked to select never, 1 day/week, 2-3 days/week, 4-6 days/week, every day. If a range was reported, the midpoint was calculated.

The CHWs assessed cooking skills with two questions on a 0--4 scale: "How often do you eat meals cooked from scratch in your home (more than reheating prepared foods)? (never, rarely, few times a month, few times a week, daily)" and "How would you rate your comfort level in cooking healthy meals? (not at all comfortable, somewhat, not sure, very, extremely)." Additionally, participants were asked to rate how good they are on a list of cooking skills (Table 4), where 1 is poor and 7 is excellent. (26)

Knowledge and utilization of food access resources

The participants were asked to select from a list designed by the study team and CHWs of possible barriers limiting and strategies to improve fruit and vegetable access (Table 2). The participants were asked to indicate how frequently they obtained their food from a list of options (Table 3) on a scale of 0= I never get food there; 1= Less than once a week; 2= 1--2 times a week; 3= 3--4 times a week; 4= 5--6 times a week; 5= At least once a day. The mean frequency scores were

calculated. The participants were also asked if they were aware of and/or used a list of food access resources (Table 3) on a scale of 0=I've never heard of this; 1=I don't use it, but I've heard of it; 2=I use this. The mean awareness and utilization scores were calculated.

Healthcare utilization

After the study was concluded, a chart review was completed to gather data on healthcare utilization, including emergency department visits, inpatient admissions, and primary care appointments. Utilization was compared pre- and post-intervention for the Food-only group, Food + CHW group, and control group. Utilization data were compared for the 12-month period prior to the intervention start date and the 12-month period after the intervention start date. For controls, the pre/postdate was the date at which the individual was invited to participate.

Program acceptability

Participants completed program satisfaction surveys upon completion. The participants were asked to rate how much they liked the overall program, the food boxes, and working with the CHW using a 0-100 sliding scale. The participants were also asked to describe what they liked and did not like and what they would change about the program.

Statistical analysis

Table 1 provides a description of the study and control populations. For all continuous variables of interest, we report descriptive statistics that include the mean, standard deviation, and standard error of the mean. For longitudinal

measurements of HbA1c, systolic blood pressure, and diastolic blood pressure, we compared levels at baseline vs 3 months and baseline vs 6 months for the Food-only and Food + CHW arms via paired t tests. When this comparison indicated a statistically significant difference, we followed up with the nonparametric paired-Wilcoxon test to avoid the assumption of any distributional form. In all the cases, a significant difference assessed by the paired t test was also confirmed as significant by the paired-Wilcoxon test. The confidence intervals (95% CIs) for the differences between baseline and 3 months are provided in Table 5 for both the Food + CHW group and the Food-only group. The corresponding p values that assess whether these differences are significant are also given in the same table. The analysis of healthcare utilization for the three groups, control, food-only and food + CHW, was performed analogously. Comparisons among these three groups in terms of pre- and post-emergency department visits, inpatient admissions, and primary care appointments were conducted via paired t tests, with nonparametric paired Wilcoxon tests used to confirm significance.

RESULTS

Between May 2021 and December 2021, we enrolled 47 participants in the Food Rx + CHW intervention. Two hundred eight patients met the inclusion criteria (78 family medicine patients and 130 other primary care patients in the research registry), 81 patients were reached and informed of the study, and 47 agreed to participate (58% enrollment rate). The participants were 84% female, 32% Black, 58 years old on average, with an average HbA1c of 8%. These demographics are similar to the county in which the medical center is situated (21% Black, 37% Hispanic, and 43% White). The increase in the proportion of Black patients

compared to the surrounding county is consistent with Black residents in the county having the highest rate of food insecurity, 25% (compared to 16% overall, 13% for White residents, and 18% for Hispanic residents). Sixteen participants dropped out of the study before completion Food-only (n=8) and Food + CHW (n=8). Our data indicate that there are no statistically significant differences between the Food-only and Food + CHW groups at baseline. More specifically, the Mann–Whitney U test for the variables HbA1c, Systolic, Diastolic, BMI, and Age presented p values of 0.342, 0.158, 0.589, 0.274, and 0.875, respectively, at baseline between the two groups.

Table 1 Participant characteristics

Characteristic	Enrolled n=47	Completed Study n=31	Food + CHW n=16	Food-only n=15	Control n=41
Age (m)	57.8	58	57.9	58.1	52.6
Gender n (%)					
Female	40 (85.1)	26 (84)	14 (87.5)	12 (80)	25 (60.9)
Male	7 (14.9)	5 (16)	2 (12.5)	3 (20)	16 (39.1)
Race n (%)					
Black/African American	16 (34.0)	10 (32)	6 (37.5)	4 (26.7)	19 (46.3)
White	29 (61.7)	20 (66)	9 (56.3)	11 (73.3)	20 (48.8)
American Indian, Alaska Native	0	0	0	0	2 (4.9)
Asian	0	0	0	0	0
Native Hawaiian or other Pacific Islander	0	0	0	0	0
Multiple races	2 (4.3)	1 (2)	1 (6.3)	0	0
Ethnicity n (%)					
Hispanic or Latino	11 (23.4)	9 (29)	3 (18.8)	6 (40)	5 (12.2)
Education n (%)					
Some HS	-	2 (6.5)	1 (6.3)	1 (6.7)	-
HS Grad/GED	-	14 (45.2)	7 (43.8)	7 (46.7)	-
Some college or tech	-	13 (41.9)	8 (50.0)	5 (33.3)	-

College graduate	-	8 (25.8)	3 (18.8)	5 (33.3)	-
HbA1c, M (SD)	-		8.37 (2.15)	7.71 (1.82)	-
Systolic BP	-		138.2 (13.1)	130.8 (15.2)	-
Diastolic BP	-		78.5 (9.8)	76.6 (10.4)	-
BMI, M (SD)			35.34 (5.34)	32.82 9 (6.99)	

Abbreviations: HbA1c, glycated hemoglobin; BP, blood pressure; HS, high school; M, mean; SD, standard deviation

During the baseline survey, participants answered yes or no to a list of barriers to accessing fruits and vegetables and to a list of potential strategies to improve their access to and consumption of fruits and vegetables. The top barriers reported were 'prices are too expensive' and 'they go bad before I eat them.' The most popular strategies that participants indicated would help them eat more fruits and vegetables were 'coupons/price discounts' and a 'nearby farmers' market.'

Table 2. Barriers and strategies to improve fruit and vegetable access

	Frequency (n=39)	Percentage
Barriers to access		
Prices are too expensive	21	53.8
Stores are too hard to get to	4	10.3
They go bad before I eat them	4	10.3
Fruits and vegetables are of poor quality where I shop	3	7.7
Fruits and vegetables that I want are unavailable where I shop	2	5.1
Not enough time to shop for fruits and vegetables	1	2.6
Not enough time to prepare fruits and vegetables	1	2.6
No kitchen equipment to prepare/store fruits and vegetables	1	2.6
I don't like fruits and vegetables	0	0
Not enough fruits and vegetables to feed everyone in my home	0	0
My family won't eat them	0	0
Strategies to increase access		
Coupons/price discounts	35	89.7
Nearby farmers' market	29	74.4

Better variety and quality where you shop	28	71.8
New/improved supermarket nearby	26	66.7
Learning how to prepare them so they taste better	19	48.7
More fruits and vegetables in restaurants	18	46.2
Free/low-cost veggie box from health clinic	17	43.6
More stores accepting SNAP/WIC vouchers	14	35.9
Getting adult family members to eat them	14	35.9
Food buying co-op (discounted group purchasing)	13	33.3
Getting kids to eat them	8	20.5

At baseline, participants reported obtaining food most frequently from grocery stores, followed by fast food and “sit-down” restaurants. After the intervention, participants in the Food + CHW group reported obtaining food from farmers’ markets significantly more than at baseline (Table 3).

Table 3. Food Access Resources

	Food-only N=15 frequency score M (SD)	P value difference baseline to 3mo	Food + CHW N=16 frequency score M (SD)	P value difference baseline to 3mo
How often do you get food from: (frequency score 0-4)				
Grocery store		0.332		0.248
Baseline	2.27 (1.03)		1.56 (0.63)	
3 mo	2.07 (0.79)		1.81 (0.83)	
Dollar store		0.763		0.066
Baseline	0.733 (0.70)		0.94 (1.06)	
3 mo	0.867 (0.83)		0.50 (0.52)	
Corner Store		0.655		0.157
Baseline	0.33 (0.72)		0.25 (0.58)	
3 mo	0.40 (0.63)		0.38 (0.62)	
Farmers’ market		0.132		0.013 *
Baseline	0.40 (0.63)		0.31 (0.60)	
3 mo	0.73 (0.59)		0.88 (0.81)	
Food pantry		1.000		0.317
Baseline	0.60 (0.63)		0.56 (0.63)	
3 mo	0.60 (0.51)		0.80 (0.94)	
Church		0.705		0.317
Baseline	0.27 (0.46)		0.31 (0.48)	
3 mo	0.33 (0.49)		0.20 (0.56)	
Community Organization		0.084		0.705
Baseline	0.07 (0.26)		0.19 (0.40)	
3mo	0.47 (0.74)		0.13 (0.50)	

Fast Food		0.596		0.435
Baseline	1.33 (1.11)		1.63 (1.36)	
3 mo	1.40 (1.06)		1.38 (1.26)	
Sit-down restaurant		1.000		0.726
Baseline	1.07 (0.92)		1.00 (1.030)	
3 mo	1.07 (0.59)		0.81 (0.66)	
Health clinic or hospital		1.000		0.157
Baseline	0.27 (0.59)		0.133 (0.35)	
3 mo	0.27 (0.59)		0 (0)	
Friend or family		0.480		0.141
Baseline	0.53 (0.74)		0.75 (0.77)	
3 mo	0.67 (0.82)		0.40 (0.63)	
Gas station		0.655		0.564
Baseline	0.47 (0.74)		0.20 (0.41)	
3 mo	0.40 (0.63)		0.27 (0.59)	
Workplace cafeteria		0.197		0.157
Baseline	0.13 (0.35)		0.13 (0.34)	
3 mo	0.60 (1.40)		0 (0)	
Home/community garden		0.083		0.083
Baseline	0 (0)		0.27 (0.59)	
3 mo	0.20 (0.41)		0.07 (0.26)	
Do you use the following resource:				
SNAP		0.025*		1.00
Baseline	1.53 (0.52)		1.13 (0.34)	
3 mo	1.20 (0.56)		1.13 (0.34)	
WIC		1.00		1.00
Baseline	0.93 (0.26)		0.94 (0.25)	
3 mo	0.93 (0.26)		0.94 (0.25)	
Double up Food Bucks		0.655		0.317
Baseline	0.60 (0.63)		0.44 (0.51)	
3 mo	0.67 (0.62)		0.56 (0.51)	
KS Farmers Market Nutrition Incentive		0.009*		0.021*
Baseline	0.00 (0.00)		0.25 (0.45)	
3 mo	0.73 (0.80)		0.75 (0.58)	
Healthy Corner Store		0.180		0.059
Baseline	0.20 (0.41)		0.19 (0.40)	
3 mo	0.40 (0.63)		0.50 (0.52)	
Combined utilization score		0.129		0.014*
Baseline	7.33 (2.59)		6.81 (1.68)	
3 mo	8.33 (3.50)		8.5 (2.22)	

M, mean; SD, standard deviation.

At baseline and 3 months, the participants reported their diet and cooking behaviors and skills. The Food + CHW group reported a significant increase in the number of daily servings of fruit. Additionally, the Food + CHW group reported more

frequent use of nutrition labels and cooking meals from scratch as well as greater comfort in cooking healthy meals and improved ability to prepare meals in advance (Table 4).

Table 4. Diet quality and cooking skills

	Food-only N=15 M (SD)	P value difference baseline to 3mo	Food + CHW N=16 M (SD)	P value difference baseline to 3mo
Diet assessment				
Servings of fruit per day		0.403		0.014 *
Baseline	1.83 (1.12)		1.56 (0.88)	
3 mo	1.93 (1.01)		2.50 (1.22)	
Servings of vegetables per day		0.309		0.076
Baseline	1.83 (1.34)		1.81 (1.09)	
3 mo	1.67 (0.81)		2.38 (0.99)	
Half of plate vegetables and fruit (days/week)		0.309		0.208
Baseline	4.73 (2.37)		4.03 (2.85)	
3 mo	4.40 (2.32)		4.75 (2.42)	
Drink sugary beverages (days/week)		0.349		0.198
Baseline	3.37 (2.70)		4.16 (3.06)	
3 mo	3.67 (2.98)		3.53 (2.83)	
Read nutrition labels (frequency score 0-4)		0.121		0.046 *
Baseline	2.53 (1.25)		2.44 (1.36)	
3 mo	3.00 (1.07)		3.06 (1.24)	
Cooking assessment				
Cook "from scratch" (frequency score 0-4)		0.957		0.009 *
Baseline	2.33 (0.82)		1.81 (1.17)	
3 mo	2.40 (0.63)		2.50 (0.73)	
Comfort level cooking (comfort score 0-4)		0.319		0.054
Baseline	2.47 (1.13)		2.06 (1.29)	
3 mo	2.80 (1.26)		2.69 (1.14)	
Cooking skills (rated 1-7)				
Select produce		0.527		1.000
Baseline	5.20 (1.26)		5.06 (1.53)	
3 mo	5.40 (0.91)		5.06 (1.44)	
Peel and chop vegetables		0.521		0.305
Baseline	4.73 (1.58)		5.13 (1.59)	
3 mo	4.93 (1.28)		4.88 (1.45)	
Prepare vegetable		0.085		0.096
Baseline	4.67 (1.59)		5.25 (1.53)	
3mo	5.33 (0.72)		4.94 (1.44)	

Prepare meat		0.729		1.000
Baseline	5.33 (0.72)		5.44 (0.81)	
3 mo	5.47 (0.74)		5.44 (0.51)	
Prepare fish		0.388		0.498
Baseline	3.73 (1.87)		3.06 (2.54)	
3 mo	4.07 (1.87)		3.31 (2.57)	
Follow recipes		0.199		0.168
Baseline	3.87 (1.73)		4.50 (1.86)	
3 mo	3.20 (2.01)		3.75 (2.29)	
Prepare meals in advance		0.288		0.036 *
Baseline	2.47 (2.17)		1.56 (1.71)	
3 mo	2.07 (1.71)		2.56 (2.31)	
Plan means in advance		0.178		0.348
Baseline	2.33 (1.99)		1.81 (2.07)	
3 mo	3.20 (1.86)		2.44 (2.03)	
Roast food in oven		0.021 *		0.931
Baseline	4.13 (1.64)		5.00 (1.13)	
3 mo	4.73 (1.39)		4.94 (1.00)	
Read storage information		0.519		0.558
Baseline	4.80 (1.52)		4.44 (2.03)	
3 mo	4.47 (1.41)		4.25 (2.14)	
Balance meals based on nutrition		0.971		0.546
Baseline	4.13 (1.60)		3.69 (1.92)	
3 mo	4.33 (1.40)		3.88 (1.23)	
Bake cakes and bread		0.117		0.469
Baseline	4.00 (1.65)		4.00 (1.97)	
3 mo	4.60 (1.50)		4.38 (1.71)	
Cook soup, chili, or stew		0.914		0.792
Baseline	5.13 (1.13)		5.44 (0.73)	
3 mo	5.07 (0.96)		5.50 (0.63)	

* Denotes significance

For the Food + CHW group, there was a statistically significant reduction in the average value of HbA1c by 0.85 points from baseline to 3 months ($p=0.039$) and by 1.65 points from baseline to 6 months ($p=0.012$) (Table 5). Eighty-one percent of participants in the Food +CHW group (13/16) experienced a reduction in HbA1c over the course of the intervention. There was no significant change in HbA1c in the Food-only group at either time point. Diastolic blood pressure increased on average by 6.5 mmHg ($p= 0.02$) between baseline and 3 months for the Food-only group and remained stable for the Food +CHW group. Systolic blood

pressure and body mass index (BMI) did not significantly change in either group (Table 5).

Table 5. Changes in metabolic risk factors from baseline within study groups

Variable	Change from baseline [95% CI]			
	Food-only (n=15)	P value	Food +CHW (n=16)	P value
HbA1c, %				
3 mo	-0.387 [0.324, -1.09]	0.263	-0.856 [-0.048, -1.66]	0.039 *
6 mo	0.083 [-0.663, 0.829]	0.786	-1.655 [-2.84, -0.472]	0.012 *
Systolic BP, mm Hg				
3 mo	5.78 [17.20, -5.62]	0.293	-1.20 [13.58, -15.98]	0.828
6 mo	9.00 [-13.26, 31.26]	0.325	1.87 [17.83, 21.58]	0.828
Diastolic BP, mm Hg				
3 mo	6.50 [11.81, 1.19]	0.020 *	0 [-10.61, 10.61]	1.00
6 mo	12.40 [-2.25, 27.05]	0.079	3.38 [17.27, -10.52]	0.584
BMI kg/m ²				
3 mo	-1.18 [-4.358, 6.732]	0.646	-0.62 [-0.277, 1.519]	0.161
6 mo	-0.54 [-6.269, 7.351]	0.861	-0.16 [-4.698, 5.020]	0.943

Abbreviations: CI, confidence interval; CHW, community health worker; HbA1c, glycated hemoglobin; BP, blood pressure. * Denotes significance

There was no significant difference in primary care physician (PCP), inpatient hospitalization (IP), or emergency department (ED) visits pre/post for either Food-only or Food+ CHW group. In the control group, the number of PCP visits decreased significantly, and the number of IP admissions decreased significantly. We did not observe a significant decrease in PCP visits or IP hospitalizations in patients who were participating in this study (data not shown).

Overall satisfaction with the program was 95% for both groups. The participants reported 89% satisfaction with the fresh food boxes and 76%

satisfaction with the shelf-stable food box, with no difference in satisfaction between the Food-only and Food + CHW groups. The participants requested more variety in the shelf-stable box.

DISCUSSION

This pilot study of a CHW-led medically tailored grocery intervention for primary care patients with food insecurity and type 2 diabetes provides evidence that CHWs can enhance the effect of healthy food provision and may even help patients sustain a decrease in HbA1c. The primary outcome of this study was a change in HbA1c following the provision of 12 weekly deliveries of fresh produce and diabetes-appropriate pantry items. There was a statistically significant decrease in HbA1c from baseline to 3 months (-0.85) and from baseline to 6 months (-1.65) only for the Food + CHW group. The findings reported here are clinically significant, as research shows that a 1% decrease in HbA1c can decrease the risk of diabetes complications such as cardiovascular events and stroke.⁽²⁷⁾ We did not find substantial changes in blood pressure or weight among the Food + CHW group during the study period.

In our study, CHWs talked with the Food + CHW group about where they obtained their food and provided education and guidance on accessing additional food resources and services. This group showed a significant increase in the use of farmers' markets post-intervention. Participants from both groups showed interest in farmers' markets at baseline. In the pre-survey, participants listed 'nearby farmers' market' as a preferred strategy to increase fruit and vegetable consumption second only to 'coupons or price discounts.' Both groups showed increased use of the Kansas Senior Farmers Market nutrition incentive program. Learning about the program through the pre-survey may have been enough

information for some in the Food-only group to access this service. Although none of the other food resource services significantly increased for the Food + CHW group, there was a significant increase in the aggregate score for all resources, indicating that the overall use of these services increased, likely due to CHW-mediated linkages and facilitation over the course of the intervention.

There was a significant decrease in the use of the SNAP program for participants in the Food-only group but not those in the Food + CHW group. Nationally, SNAP benefits increased during the pandemic, as more households reported difficulty obtaining food. According to the United States Department of Agriculture data for SNAP use, although overall SNAP dollars per household increased, the number of persons using SNAP declined in several states, including Kansas, between 2020 and 2021 and further declined between 2021 and 2022.(28)

In this study, participants in the Food + CHW group received diabetes-appropriate nutrition education, discussed ways to prepare provided food, and were encouraged to try new recipes. This group reported eating more fruits and vegetables after the intervention, although only the increase in fruits was statistically significant. We also observed significant increases in the frequency of reading nutrition labels and cooking meals from scratch and increased perceived skill in preparing meals in advance for this group. An increased frequency of nutrition label reading may have a significant effect on health. Previous studies have shown that nutritional label use is associated with improved diet (29, 30) and lower long-term diabetes risk.(31) Preparing meals in advance may aid in maintaining a healthy diet and avoiding convenient foods. There was a significant increase in the perceived skill of roasting food for the Food-only group, which was not observed in the Food + CHW group.

This study has several limitations. The sample size was small, 34% of enrolled participants did not complete the study, and the patients were from a single institution. In this pilot study, even though we comment on statistically significant differences in our measurements, we avoid building a regression model since our sample size in combination with the number of available covariates cannot ensure its validity. The Food-only group did not receive any kind of “attention control” intervention that provided these participants with anything on the scale of contact that the Food + CHW group received from CHWs. Analysis of diastolic blood pressure changes in the Food-only group could have been influenced by known wide variability in diastolic blood pressure measurements. Additionally, the control group for healthcare utilization rates consisted of individuals who were patients of the family medicine department and met initial inclusion criteria but could not be reached or declined to participate. They could have been categorically different because of these factors. Also, we do not have detailed data on diabetes medication use for participants.

Notably, this research study was funded and approved prior to the COVID-19 pandemic. Owing to the pandemic, all research projects were halted and then allowed to proceed with limited face-to-face contact. Because of this, the overall number of participants was smaller than initially projected, and the interventions were required to be contactless (telephone, video visits, contactless drop-offs). Although the trial was designed to be contactless, the 34% dropout rate may reflect pandemic-related challenges such as heightened stress, competing caregiving responsibilities, economic instability, and disruptions in routine healthcare access during COVID-19. Additionally, worldwide, nationally, and in our own health system, patient appointments were canceled and then eventually transitioned to digital

visits with limited in-person appointments. Nationally, rates of inpatient hospitalizations, emergency department visits, and clinic appointments changed drastically during the pandemic, which may have affected healthcare utilization results.

Conclusions

This small pilot study demonstrated the important supportive role that CHWs can play in the implementation of food is medicine interventions to address food insecurity and diet-related chronic diseases. Future research should evaluate a CHW-mediated food is medicine intervention in a fully powered trial. Healthcare payors may benefit from reimbursing for CHW-mediated food is medicine interventions to improve patients' health and the economic impact of diet and lifestyle-related chronic diseases.

List of abbreviations:

SDOH, social driver of health; SNAP, Supplemental Nutrition Assistance Program; CHW, community health worker; HbA1c, glycated hemoglobin; PCP, primary care physician; IP, inpatient hospitalization; ED, emergency department

Declarations

Ethics approval and consent to participate

This study was approved by the Institutional Review Board of the University of Kansas Medical Center as Study 00144654. Informed consent was obtained from all the participants and/or their legal guardians. This study adhered to the Declaration of Helsinki.

Consent for publication

Not applicable.

Availability of data and materials

Our informed consent form restricts the data usage solely to this current study, thus preventing its availability for use by other researchers.

Competing interests

The authors declare that they have no competing interests.

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Authors' contributions

KB, JW, DY, MS, DS, and KAG designed the study; KB, MM, AL, MS, VC, and AM collected the data; KB, JW, MM, LB, LM, and KAG analyzed and interpreted the data; KB, JW, KAG drafted and revised the manuscript. All authors read and approved the final manuscript.

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