Primary Care and Food Bank Collaboration to Address Food Insecurity: A Pilot Randomized Trial

Robert L Ferrer[1] , Luz-Myriam Neira[2], Gualberto L De Leon Garcia[2], Kristin Cuellar[2] and Jasmine Rodriguez[1]

[1]Department of Family and Community Medicine, UT Health San Antonio, San Antonio, TX, USA.
[2]San Antonio Food Bank, San Antonio, TX, USA.

ABSTRACT: Food insecurity is common in the United States and linked to poor control of conditions influenced by diet. We conducted a pilot randomized trial to test whether a novel partnership between a primary care practice and a municipal food bank would improve control of type 2 diabetes among patients with food insecurity. Participants received food bank produce delivered twice monthly to the practice site, brief teaching from a food bank dietitian, and home-based education from a community health worker. After 6 months, glycosylated hemoglobin decreased (absolute change) by 3.1% in the intervention group vs 1.7% in the control group ($P = .012$). Scores on Starting the Conversation–Diet, a brief dietary measure, improved in the intervention group by 2.47 on a 14-point scale ($P < .001$). Body mass indexes (BMIs) were unchanged. In this early-stage study, onsite collaboration between primary care and a regional food bank generated clinically meaningful reductions in HbA_{1c} and improvements in diet.

KEYWORDS: Food insecurity, primary health care, diabetes mellitus, type 2, vulnerable populations

Introduction

Food insecurity, defined as "limited or uncertain availability of nutritionally adequate and safe foods,"[1] is a risk factor for poor diet[2] because people living in poverty often have fewer feasible food choices. Healthier foods can cost more per calorie than unhealthy foods.[3,4] And quality food markets are less available in poor neighborhoods or people may lack transportation to reach them.[5] Other features of poverty, such as risk aversion, are also relevant. People may be uncertain that investment of time and money in shopping and cooking will improve their health or worry that unfamiliar foods served to their family will go to waste.[6] Food insecurity is associated with diabetes mellitus,[7] with pervasive effects on diabetes control, including food purchases favoring cheaper, high refined-carbohydrate foods, fewer fruits and vegetables, decreased self-efficacy in managing diabetes, increased risk of poor glycemic control or hypoglycemia, trading off spending for food and medication, and poor mental health.[8–10]

These complex, interacting connections between poverty and disease self-management require responsive intervention models. Recent National Academy of Medicine reports[11,12] aim to re-conceptualize the approach to health behavior change, envisioning multi-sectoral interventions aligning health care and social services to address health behaviors' multiple determinants. As the adverse health effects of food insecurity have become clear, health care organizations are seeking community partners that can help address their patients' needs for an adequate supply of nutritious foods.[12] Food banks, whose mission is to reduce food insecurity, are present in many communities[13] and thus positioned to partner with health care organizations to promote healthy eating.

Historically, food banks prioritized food quantity—alleviating hunger—over quality, but the steady rise in obesity and its associated chronic conditions, including type 2 diabetes, has motivated the food aid sector to consider how it might also promote health while addressing hunger. For example, many food banks are now developing supply chains for fresh produce or growing their own.[14] Others are contributing to chronic disease management, for example, by offering education in diabetes self-management.[9]

Given primary care's central role in managing diet-related chronic illness, our study objective was to test whether a novel collaboration between a primary care practice and a municipal food bank could improve food security while also achieving better control of type-2 diabetes mellitus.

Methods

We recruited participants from a diabetes registry at a primary care practice caring for an underserved inner-city population (53% of patients receive care under Medicaid or a county assistance program) in San Antonio, Texas. Eligible patients included adults with a glycosylated hemoglobin (HbA_{1c}) value >9% and positive response to at least 1 of 2 questions on a screen[15] for food insecurity: "We worried whether our food would run out before we got money to buy more" and "The food we bought just didn't last and we didn't have money to get more." Responses of "often true" or "sometimes true" were classified as positive screens.

The study was powered for the primary outcome, change in HbA_{1c} level. At alpha = .05 (2-sided) and beta = .20, 29 participants in each group were required to detect an absolute mean difference of 1.5% from baseline HbA_{1c}.

Randomization occurred in blocks of 4. To maintain allocation concealment, group assignment used sequentially numbered, opaque, sealed envelopes.

The intervention lasted 6 months and included the following components:

a. Biweekly allotment of fresh produce and other healthy vegetables delivered by a "Mobile Mercado" truck from the San Antonio Food Bank to the clinical site. Study participants received a schedule of delivery dates. The allotment contained approximately 10 pounds of fresh produce, which varied seasonally. Produce types included onions, green beans, eggplant, beets, okra, zucchini, cucumbers, squash, leafy greens, red and sweet potatoes, citrus, fruits, and berries; herbs were included once a month. Each allotment also included 10 pounds of canned food, including beans, vegetables, and fish or chicken.

b. Teaching by a registered dietician from the Food Bank. With each food delivery, the dietitian engaged patients in brief education based on current nutritional guidelines for people with diabetes mellitus.[16] Practical modules included reading food labels, counting carbohydrates, healthy food shopping on a fixed income, maintaining a home pantry, managing meals outside the home, creating menus, and healthy drinks. Education was designed to be culturally appropriate and responsive to low-income consumers' needs. For example, menu lists included healthy items approved for purchase on food assistance benefits. The Food Bank also screened patients to assess eligibility for other assistance programs.

c. Up to 3 home visits by a *promotor* affiliated with the practice. These community health workers[17] used a rubric, the "six-piece puzzle" of food, physical activity, medicines, self-care, numbers (HbA_{1c}, blood pressure, cholesterol), and trust (in health care team and personal relationships), to frame self-management goals. The promotor and patient together determined the number of visits.

Primary outcome was change in HbA_{1c}, an indicator strongly associated with diabetes outcomes such as ischemic vascular disease, retinopathy, nephropathy, and costs.[18,19] Secondary outcomes included body mass index (BMI) and "Starting the Conversation–Diet," a 7-item rapid dietary assessment for intake of (1) fruits/vegetables, (2) fast food, (3) chicken/fish/beans, (4) snack chips/crackers, (5) soda, (6) sweets, and (7) butter.[20] Respondents indicated times per week consumed on a 3-point scale: 1 or less, 2 to 3 times, or 4 or more times. We coded responses so that healthier behaviors receive higher scores, with a possible range from 7 to 21. We planned to assess all endpoints 6 months after enrollment.

Analyses are intention-to-treat. To visually compare the overall outcome distributions among intervention and control subjects, we created separate kernel density plots for each

Table 1. Baseline characteristics.

	INTERVENTION	CONTROL
Age, y	54.8	54.6
Women	66%	59%
Income below US$1500/month	100%	93%
Hispanic ethnicity	93%	97%
Spanish as primary language	48%	41%
County insurance coverage	66%	66%
Entry BMI, kg/m²	34.8	33.9
Entry glycosylated hemoglobin	10.9%	11.0%
Entry STC-Diet[a]	12.3	12.0

Abbreviations: BMI, body mass index; STC-Diet, Starting the Conversation–Diet.
[a]STC-Diet includes 7 items, each scored 1 to 3; coded so higher score indicates better diet.

outcome at enrollment and end-of-study within each group. Between-group differences for each outcome were evaluated with repeated-measures mixed-effect models (using the STATA xtmixed command),[21] which are robust to missing data because they allow subjects with differing numbers of repeated measures to remain in the analysis.[22]

The study was approved by the institutional review board (IRB) at the University of Texas Health Science Center at San Antonio. All participants provided written informed consent.

Results

We randomized 29 participants to each study arm. Sample demographics and baseline measures are summarized in Table 1. Mean age was 54 (range = 34-72), with 22 men and 36 women. All but 3 subjects were Hispanic. Half the participants had less than a ninth-grade education and 96% reported a monthly personal income below US$1500. Two thirds received care under a county health insurance plan. The intervention and control groups were generally balanced, although the intervention group had a higher proportion of women, those with Spanish as their primary language, and income less than US$1500/month. At enrollment, the mean BMI was 32.0 kg/m² and mean HbA_{1c} was 11.0%. End of study data were available for 19 participants in the intervention group and 24 in the control group.

The study CONSORT diagram appears in Figure 1.

The mean interval between baseline and final HbA_{1c} measurements was 221 days in the intervention arm and 207 days in the control arm. Intervention-group participants received an average of 7.8 food allotments, with a range of 4 to 11. They were visited at home by a community health worker (CHW) an average of 2.6 times with a range of 0 to 3.

Figure 2 depicts the intervention and control groups' distributions of change in HbA_{1c}, BMI, and STC-Diet over followup. HbA_{1c} decreased in both groups, but the drop was 1.4%
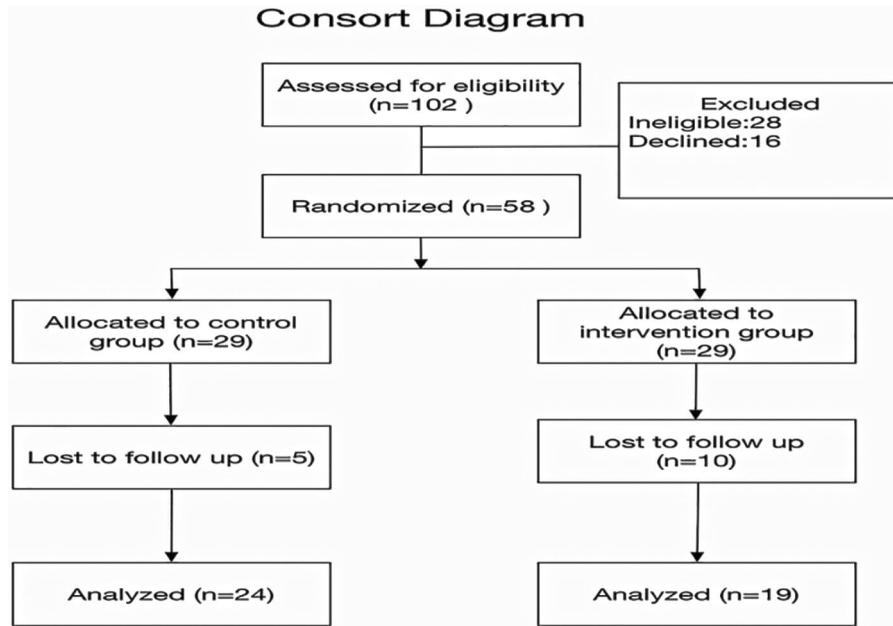
Consort Diagram

Figure 1. Study CONSORT diagram

Outcome distributions for intervention and control groups

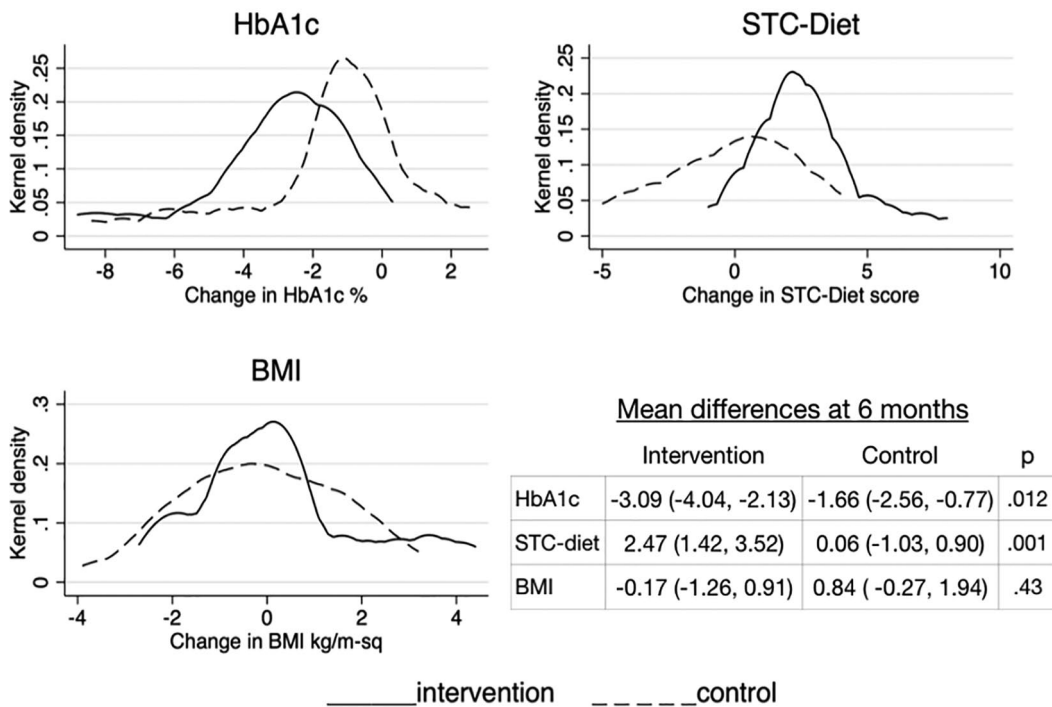|	Intervention	Control	p
HbA1c	-3.09 (-4.04, -2.13)	-1.66 (-2.56, -0.77)	.012
STC-diet	2.47 (1.42, 3.52)	0.06 (-1.03, 0.90)	.001
BMI	-0.17 (-1.26, 0.91)	0.84 (-0.27, 1.94)	.43

_____intervention   _ _ _ _ _control

Figure 2. The figure presents 3 kernel density plots, separately displaying the distribution of pre- to post-intervention changes in intervention and control groups for each of the outcomes. The embedded table presents the mean differences (with 95% confidence interval) for the same comparisons. BMI indicates body mass index; STC-Diet, Starting the Conversation–Diet.

(absolute difference) greater in the intervention arm (*P*=.012; Cohen's *d*=−0.516). Scores on the STC-Diet scale improved by 2.47 points on a 21-point scale (95% confidence interval [CI]=1.42-3.52; Cohen's *d*=1.10) in the intervention group, while remaining unchanged in the control group. BMI decreased slightly in the intervention group, and increased slightly in the control group, but the differences were neither clinically nor statistically significant.

Discussion

This small randomized trial tested the benefits of closely linking a regional food bank and a primary care practice to address food insecurity and promote healthy diet among low-income patients with uncontrolled type 2 diabetes. Participants receiving regular produce allotments and brief teaching from a dietitian and CHW demonstrated clinically meaningful reductions in HbA_{1c} and improved scores on a brief diet quality measure. BMI did not change significantly.

The study's strengths include its randomized design and measurement of several relevant outcomes. Its major limitation is the small sample size and the number of dropouts, which was larger in the intervention group, likely because of the effort required to be present for food distributions. Also, with 3 intervention components, we are unable to isolate the effect of any one. Our rationale for bundling the interventions was to support patients in preparing and incorporating into their regular diet foods that they might not be accustomed to preparing, for example, mustard greens or zucchini.

The relatively large changes in HbA_{1c} during the study must be understood in the context of several downward forces on blood glucose levels inherent in the study design. First, we enrolled subjects with high HbA_{1c}, so a degree of regression to the mean is expected. Second, we recruited participants during primary care visits, thus identifying patients actively engaged in health care and potentially prepared to engage with other types of aid. Third, clinicians caring for patients with HbA_{1c} levels high enough to qualify for the study—well over recommended therapeutic target A_{1c} levels in diabetes[23]—would likely be choosing to intensify drug therapy for patients as part of their ongoing clinical management. Given these influences on HbA_{1c}, we believe the absolute HbA_{1c} difference between the treatment and control groups (1.4%) more accurately estimates the effect of the food bank partnership than the 3% reduction in the intervention group. Nonetheless, 1.4% is a clinically meaningful drop in A_{1c}, akin to adding a new drug to improve glycemic control.[24] Also, our inclusion of CHWs on the intervention team was designed to support patients in adopting new foods in their home environments. An additional feature of the project design that may have contributed to its effect was distributing food at the primary care site, alleviating the need for patients to travel to a new, perhaps unfamiliar location to receive food.

Reports on the strong association between food insecurity and poor control of chronic diseases linked to diet have motivated both clinical and food aid organizations to respond with new initiatives. Some clinical organizations have begun to screen and intervene for food insecurity. A review of these efforts[25] identified several commonly applied interventions including (1) referral to a list of resources such as federal benefit programs or food pantries (sometimes co-located); (2) assistance with federal benefits enrollment from case managers, social workers, or navigators; (3) immediate food provision from on-site gardens or stocks of food; and (4) produce vouchers that can be redeemed at food markets.

In the food aid sector, organizations have sought to procure—or grow—healthier foods for distribution,[14,26] and in some cases to directly deliver chronic disease management interventions. A recent trial, which bundled healthy food allotments with diabetes self-management education (DSME) delivered at 27 food pantries, improved food security and intake of fruits and vegetables but not glycemic control.[27] Although that intervention was designed to lower participant burden with co-located DSME and food provision, DSME participation was relatively low. In our study, participants received home-based education from CHWs, lowering participant burden while also allowing the health care team to better understand the food and social environment at home.

Another recent study[28] delivered medically tailored meals to the homes of people with diabetes and food insecurity, finding improvements in diet quality during the periods when participants received tailored meals. When compared with matched controls, people receiving medically tailored meals also experienced fewer emergency department visits and hospital admissions, and decreased medical spending.

Another potential intervention is a direct subsidy of healthy foods through public insurance. A microsimulation model evaluating a produce subsidy of 30 cents on the dollar, administered through an electronic benefits transfer system linked to Medicare and Medicaid, estimated that the subsidy would prevent almost 2 million cardiovascular events and generate US$39.7 billion in savings over 82 million participating beneficiaries.[29]

But a lesson from studies providing healthy food is that food alone may not be enough.[30] Many patients will require additional support to adopt new dietary patterns. To estimate the benefits and costs of different support strategies, future studies should compare the effects of providing produce with and without additional coaching from health educators, CHWs, or other staff affiliated with food banks or primary care practices.

Social determinants' profound impact calls for better integration between the health care, public health, and social service sectors.[31] In the health care sector, addressing food security will require practices to reliably identify patients with food insecurity and connect them with food assistance.[31] With a number of collaboration models deployed or in development, the task is now to understand which models work best in specific contexts of populations, organizational partners, resources, and delivery systems.[32]

This early report on diabetes outcomes from an on-site collaboration between a primary care practice and a food bank suggests that robust linkages between health care and social services[33] hold promise for increasing the likelihood that each organization achieves its mission—in this case to improve chronic disease control and to reduce hunger and food insecurity.

Author Contributions

RL Ferrer and LM Neira contributed to the conception of the research. All authors contributed to the design of the research. J Rodriguez contributed to the acquisition of data. RL Ferrer, LM Neira and J Rodriguez contributed to the analysis of data. All authors contributed to the interpretation of data. RL Ferrer drafted the manuscript. All authors critically revised the manuscript, agree to be accountable for the integrity and accuracy of the work, and approved the final manuscript.

ORCID iD

Robert L Ferrer https://orcid.org/0000-0002-9377-9329

REFERENCES

1. United States Department of Agriculture Economic Research Service. https://www.ers.usda.gov/topics/food-nutrition-assistance/food-security-in-the-us/measurement.aspx.
2. Leung CW, Epel ES, Ritchie LD, Crawford PB, Laraia BA. Food insecurity is inversely associated with diet quality of lower-income adults. *J Acad Nutr Diet*. 2014;114:1943–19153.
3. Handbury J, Rahkovsky I, Schnell M. What drives nutritional disparities? Retail access and food purchases across the socioeconomic spectrum. NBER Working Paper No.21126. Cambridge, MA: National Bureau of Economic Research; April 2015.
4. Rao M, Afshin A, Singh G, Mozaffarian D. Do healthier foods and diet patterns cost more than less healthy options? A systematic review and meta-analysis. *BMJ Open*. 2013;3:e004277.
5. Berkowitz SA, Karter AJ, Corbie-Smith G, et al. Food insecurity, food "deserts," and glycemic control in patients with diabetes: a longitudinal analysis. *Diabetes Care*. 2018;41:1188–1195.
6. Ammerman AS, Hartman T, DeMarco MM. Behavioral economics and the supplemental nutrition assistance program. *Am J Prev Med*. 2017;52:S145–S150.
7. Seligman HK, Bindman AB, Vittinghoff E. Food insecurity is associated with diabetes mellitus: results from the National Health Examination and Nutrition Examination Survey (NHANES) 1999–2002. *J Gen Intern Med*. 2007;22:1018–1023.
8. Gucciardi E, Vahabi M, Norris N, Del Monte JP, Farnum C. The intersection between food insecurity and diabetes: a review. *Curr Nutr Rep*. 2014;3:324–332.
9. Seligman HK, Schillinger D. Hunger and socioeconomic disparities in chronic disease. *N Engl J Med*. 2010;363:6–9.
10. Ippolito MM, Lyles CR, Prendergast K, et al. Food insecurity and diabetes self-management among food pantry clients. *Public Health Nutr*. 2016;20:183–189.
11. Institute of Medicine. *Supporting a Movement for Health and Health Equity*. Washington, DC: The National Academies Press; 2014.
12. Institute of Medicine. *Creating Equal Opportunities for a Healthy Weight*. Washington, DC: The National Academies Press; 2013.
13. https://www.feedingamerica.org.
14. Wetherill MS, White KC, Rivera C, Seligman HK. Challenges and opportunities to increasing fruit and vegetable distribution through the US charitable feeding network: increasing food systems recovery of edible fresh produce to build healthy food access. *J Hunger Env Nutr*. 2018;26:1–20.
15. Gundersen C, Engelhard EE, Crumbaugh AS, Seligman HK. Brief assessment of food insecurity accurately identifies high-risk US adults. *Public Health Nutr*. 2017;20:1367–1371.
16. Evert AB, Boucher JL, Cypress M, et al. Nutrition therapy recommendations for the management of adults with diabetes. *Diabetes Care*. 2014;37:S120–S143.
17. Ferrer RL, Gonzalez Schlenker C, Lozano Romero R, et al. Advanced primary care in San Antonio: linking practice and community strategies to improve health. *J Am Board Fam Med*. 2013;26:288–298.
18. Wei M, Gaskill SP, Haffner SM, Stern MP. Effects of diabetes and level of glycemia on all-cause and cardiovascular mortality. *Diabetes Care*. 1998;21:1167–1172.
19. Wagner EH, Sandhu N, Newton KM, McCulloch DK, Ramsey SD, Grothaus LC. Effect of improved glycemic control on health care costs and utilization. *JAMA*. 2001;285:182–189.
20. Paxton AE, Strycker LA, Toobert DJ, Ammerman AS, Glasgow RE. Starting the conversation diet: performance of a brief dietary assessment and intervention tool for health professionals. *Am J Prev Med*. 2011;40:67–71.
21. StataCorp. *Stata Statistical Software: Release 14*. College Station, TX: StataCorp LP; 2015.
22. Zou B, Jin B, Koch GG, et al. On model selections for repeated measurement data in clinical studies. *Stat Med*. 2015;34:1621–1633.
23. American Diabetes Association. 6. Glycemic targets: standards of medical care in diabetes–2019. *Diabetes Care*. 2019;42:S61–S70.
24. Chaudhury CA, Duvoor C, Reddy Dendi VS. Clinical review of antidiabetic drugs: implications for type 2 diabetes management. *Front Endocrinol*. 2017;8:6.
25. Lundeen A, Siegel KR, Calhoun H, et al. Clinical-community partnerships to identify patients with food insecurity and address food needs. *Prev Chronic Dis*. 2017;14:E113.
26. Jarosz L. The city in the country: growing alternative food networks in metropolitan areas. *J Rural Studies*. 2008;24:231–244.
27. Seligman HK, Smith M, Rosenmoss S., et al. Comprehensive diabetes self-management support from food banks: a randomized controlled trial. *AJPH*. 2018;108:1227–1234.
28. Berkowitz SA, Terranova J, Hill C, et al. Meal delivery programs reduce the use of costly health care in dually eligible Medicare and Medicaid beneficiaries. *Health Aff*. 2018;37:535–542.
29. Lee Y, Mozaffarian D, Sy S, et al. Cost-effectiveness of financial incentives for improving diet and health through Medicare and Medicaid: a microsimulation study. *PLoS Med*. 2019;16:e1002761.
30. Kihlstrom L, Long A, Himmelgreen D. Barriers and facilitators to the consumption of fresh produce among food pantry clients. *J Hunger Env Nutr*. 2019;14:168–182.
31. Seligman HK, Berkowitz SA. Aligning programs and policies to support food security and public health goals in the United States. *Annu Rev Public Health*. 2019;40:319–337.
32. Pawson R, Tilley N. *Realistic Evaluation*. London, England: SAGE; 1998.
33. Park B, Coutinho AJ, Doohan N, et al. Revisiting primary care's critical role in achieving health equity: Pisacano Scholars' reflections from Starfield Summit II. *J Am Board Fam Med*. 2018;31:292–302.