2024 Proposed Idea

(Applicant must complete this two-page form as it is. Agency identifying information must be removed or the application will not be reviewed. Please read the attached documents before completing this form: 1.) HRSA HIV-Related Glossary of Service Categories to understand federal restrictions regarding each service category, 2.) Criteria for Reviewing New Ideas, and 3.) Criteria & Principles to Guide Decision Making.)

THIS BOX TO BE COMPLETED BY RWPC SUPPORT STAFF ONLY

#1 Control Number Date Received 04/10/24

Proposal will be reviewed by the: Quality Improvement Committee on: 05/14/24 (date)
Priority & Allocation Committee on: 05/23/24 or 06/18, 19 or 20/24 (date)

THIS PAGE IS FOR THE QUALITY IMPROVEMENT COMMITTEE
(See Glossary of HIV-Related Service Categories & Criteria for Reviewing New Ideas)

1. SERVICE CATEGORY: **FOOD BANK/HOME DELIVERED MEALS**
(The service category must be one of the Ryan White Part A or B service categories as described in the HRSA Glossary of HIV-Related Service Categories.)

This will provide 700 clients with 6 months of 10 meals/weekly units of service.

2. ADDRESS THE FOLLOWING:

A. DESCRIPTION OF SERVICE:

Medically tailored meals are delivered to individuals living with severe and chronic illnesses who are unable to prepare their own meals. Menus are tailored to the medical needs of the recipients by a Registered Dietitian-Nutritionist (RDN). Meal recipients are referred to the meal program by a medical provider or their healthcare plan. The provider indicates the type of menu supporting health for people with HIV and a week's worth of lunches and dinners, are frozen or chilled, then delivers weekly to the recipients' homes. Meal plans are tailored by RDN and prepared by our chef-lead culinary department. Recipients receive regular nutrition education information and access to an RDN for consultation. In addition, will screen all clients for food insecurity and connect them with food and state-funded social and health services such as SNAP, Medicaid, as needed. Our organization has identified partnerships that could refer members that are already receiving care as PLWH.

B. TARGET POPULATION (Race or ethnic group and/or geographic area):

People living with HIV (PLWH), living in Harris County and minoritized and marginalized communities such as African American, Hispanic, male and female.

C. SERVICES TO BE PROVIDED (including goals and objectives):

Meal recipients are referred to the meal program by a medical provider or their healthcare plan. The provider indicates the type of menu supporting health for people with HIV and a week's worth of lunches and dinners, are frozen or chilled, then delivers weekly to the recipients' homes. Meal plans are tailored by a RDN and prepared by our chef-lead culinary department. Recipients receive regular nutrition education information and access to an RDN for consultation. In addition, will screen all clients for food insecurity and connect them with food and state-funded social and health services such as SNAP, Medicaid, as needed.

Goals/objectives:

1. Fewer hospitalization admissions
2. Reduction in health care costs
3. Fewer skilled nursing facility admissions
4. Reduction in emergency department visits
5. Reduction in inpatient admissions

D. ANTICIPATED HEALTH OUTCOMES (Related to Knowledge, Attitudes, Practices, Health Data, Quality of Life, and Cost Effectiveness):

1. Better adherence to medication and address HIV associated nutritional deficiencies or dietary needs.
2. Improve lab results for PLWH with chronic and co-occurring conditions such as hypertension, cholesterol, or diabetes.
3. Improve quality of life.
4. Increase nutrition literacy, knowledge, and perception of nutritious food.

3. ATTACH DOCUMENTATION IN ORDER TO JUSTIFY THE NEED FOR THIS NEW IDEA. AND, DEMONSTRATE THE NEED IN AT LEAST ONE OF THE FOLLOWING PLANNING COUNCIL DOCUMENTS:

__X_ **Current Needs Assessment (Year: 2020)** **Page(s): 24-25 Paragraph: 1-7**
___ Current HIV Comprehensive Plan (Year:_____) Page(s): ___Paragraph: ___
___ Health Outcome Results: Date: _____ Page(s): ___Paragraph: ___
___ Other Ryan White Planning Document:
Name & Date of Document: _____ Page(s): ___Paragraph: ___

RECOMMENDATION OF QUALITY IMPROVEMENT COMMITTEE:
___ Recommended ___ Not Recommended ___ Sent to How To Best Meet Need

REASON FOR RECOMMENDATION:

THIS PORTION IS FOR THE PRIORITY AND ALLOCATIONS COMMITTEE
(See Criteria and Principles to Guide Decision Making)

THIS BOX TO BE COMPLETED BY RWPC SUPPORT STAFF ONLY AND INCLUDE A BRIEF HISTORY OF RELATED SERVICE CATEGORY, IF AVAILABLE.

CURRENTLY APPROVED RELATED SERVICE CATEGORY ALLOCATION/UTILIZATION:
Allocation: $_____0_____
Expenditure: $_____0_____ Year-to-Date

Utilization: _N/A_Unduplicated Clients Served Year-to-Date _0_ Units of Service Provided Year-to-Date

AMOUNT OF FUNDING REQUESTED:
$3,360,000 This will provide funding for the following purposes which will further the objectives in this service category: (describe how): **Funding will cover food and delivery cost. Funding will also include administrative, technology, and packaging cost associated with ongoing meal support for 700 clients.**

PLEASE STATE HOW THIS IDEA WILL MEET THE PRIORITY AND ALLOCATIONS CRITERIA AND PRINCIPLES TO GUIDE DECISION MAKING. SITE SPECIFIC STEPS AND ITEMS WITHIN THE STEPS:

RECOMMENDATION OF PRIORITY AND ALLOCATIONS COMMITTEE:

___ Recommended for Funding in the Amount of: $_____
___ Not Recommended for Funding
___ Other:

REASON FOR RECOMMENDATION:

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Comprehensive and Medically Appropriate Food Support Is Associated with Improved HIV and Diabetes Health

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Abstract Food insecurity is associated with negative chronic health outcomes, yet few studies have examined how providing medically appropriate food assistance to food-insecure individuals may improve health outcomes in resource-rich settings. We evaluated a community-based food support intervention in the San Francisco Bay Area for people living with HIV and/or type 2 diabetes mellitus (T2DM) to determine the feasibility, acceptability, and potential impact of the intervention on nutritional, mental health, disease management, healthcare utilization, and physical health outcomes. The 6-month intervention provided meals and snacks designed to comprise 100% of daily energy requirements and meet nutritional guidelines for a healthy diet. We assessed paired outcomes at baseline and 6 months using validated measures. Paired *t* tests and McNemar exact tests were used with continuous and dichotomous outcomes, respectively, to compare pre-post changes. Fifty-two participants (out of 72 initiators) had both baseline and follow-up assessments, including 23 with HIV, 24 with T2DM, and 7 with both HIV and T2DM. Median food pick-up adherence was 93%. Comparing baseline to follow-up, very low food security decreased from 59.6% to 11.5% ($p<0.0001$). Frequency of consumption of fats ($p=0.003$) decreased, while frequency increased for fruits and vegetables ($p=0.011$). Among people with diabetes, frequency of sugar consumption decreased ($p=0.006$). We also observed decreased depressive symptoms ($p=0.028$) and binge drinking ($p=0.008$). At follow-up, fewer participants sacrificed food for healthcare ($p=0.007$) or prescriptions ($p=0.046$), or sacrificed healthcare for food ($p=0.029$).

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Among people with HIV, 95% adherence to antiretroviral therapy increased from 47 to 70% ($p = 0.046$). Among people with T2DM, diabetes distress ($p < 0.001$), and perceived diabetes self-management ($p = 0.007$) improved. Comprehensive, medically appropriate food support is feasible and may improve multiple health outcomes for food-insecure individuals living with chronic health conditions. Future studies should formally test the impact of medically appropriate food support interventions for food-insecure populations through rigorous, randomized controlled designs.

Keywords Food · Nutrition · HIV · Diabetes · Community-based · Food security · Food support · Food assistance · Intervention · Medically tailored

Abbreviations

ARV	Antiretroviral
ED	Emergency department
GED	General Educational Development
HbA1c	Glycated hemoglobin
HFSSM	Household Food Security Survey Module
PDSMS	Perceived Diabetes Self-Management Scale
POH	Project Open Hand
SNAP	Supplemental Nutrition Assistance Program
SSDI	Social Security Disability Income
SRO	Single room occupancy
SSI	Supplemental Security Income
T2DM	Type 2 diabetes mellitus
UCSF	University of California, San Francisco

Introduction

Food insecurity is a barrier to health and well-being [1, 2]. Thirteen percent of US households, or 42 million people, are food-insecure [3], with low-income households and households headed by racial/ethnic minorities disproportionately affected [3]. Food insecurity increases the risk of acquisition of and poor outcomes associated with both infectious and non-communicable diseases [4, 5]. In HIV, food insecurity is associated with increased risk of HIV acquisition [6] and transmission [7,8], poor medication adherence [9, 10], worse immunologic [10, 11] and virologic outcomes [10, 12, 13], morbidity [14], and mortality [15]. In diabetes, food insecurity is associated with increased risk of type 2 diabetes mellitus (T2DM) [4], poorer diabetes self-management [16, 17], poorer glycemic (i.e., blood sugar) control [4], and increased hypoglycemic events [18]. Our previously published conceptual framework posits that food insecurity negatively impacts health through nutritional (e.g., weight, diet quality), mental health (e.g., depression, stress), and behavioral pathways (e.g., medication adherence and disease self-management) [19, 20]. Intervention research is needed to understand not only whether medically appropriate food assistance may improve health but also to test whether food insecurity may be causally related to negative health outcomes.

There is a critical need for effective programs to improve the health of food-insecure populations with chronic illness or risk factors for chronic illness [19, 20]. Sixty percent of food-insecure US households have participated in at least one federal food and nutrition assistance program, the largest being the Supplemental Nutrition Assistance Program (SNAP, called Cal-Fresh in California) [21]. SNAP benefits may be insufficient for people with chronic illness to access healthy foods, which tend to cost more than less healthy foods [22–24]. In addition, many food-insecure individuals are excluded from participation in the federal food safety-net: in 2012, almost 30% of food-insecure households in the US had incomes above the eligibility thresholds for federal nutrition assistance [25]; SNAP also excludes undocumented immigrants. In California, the state with the second largest number of HIV diagnoses [26], individuals who receive Supplemental Security Income (SSI), a common source of disability income, are excluded from participating in SNAP [27].

Community-based food support programs, including food banks, food pantries, soup kitchens, and meal delivery organizations, fill important gaps in the federal and state food safety-nets, particularly in urban settings [25]. Some longstanding organizations—primarily serving chronically ill populations in large urban areas—have promoted that "food is medicine," i.e., providing medically appropriate food to chronically ill populations, can improve health and reduce healthcare costs [28]. Yet few studies—none for HIV and few for diabetes [29] —have prospectively tested the role of community-based food assistance programs in improving the health of chronically ill individuals [30]. Little is known about whether, and through what mechanisms, nutritionally comprehensive, medically appropriate food assistance (i.e., designed to meet medical recommendations for specific health populations) can improve health outcomes for low-income, chronically ill populations.

To address these gaps, we conducted a study to evaluate the feasibility, acceptability, and potential impact [31] of *Food = Medicine*, a novel, medically appropriate 6-month food assistance intervention. We hypothesized that the intervention would improve nutrition, mental health, and health behaviors [19, 20].

Methods

Study Design

We assessed changes in nutritional and health outcomes among chronically ill individuals before and after the 6-month *Food = Medicine* intervention. Our study included people with HIV and/or T2DM because our previously published conceptual framework suggested similar mechanisms may govern the relationship between food insecurity and health in these groups [20].

Population and Recruitment

The study was conducted in partnership with Project Open Hand (POH), a San Francisco Bay Area-based non-profit organization that provides food assistance to individuals living with life-threatening and chronic illnesses, and to seniors. POH provides free meals and groceries to over 8000 clients either with HIV, other critical illnesses, or who are seniors. POH began serving people with T2DM around the same time as *Food = Medicine* was implemented, having served people with HIV for over 20 years.

POH eligibility criteria for the *Food = Medicine* intervention were: being (or in the process of becoming) a current POH client, certified by a physician as living with HIV and/or T2DM, English- or Spanish-speaking, age 18 or older, and low-income under ~300% federal poverty line. For clients who had accessed regular services for at least 6 months, POH selected clients with service adherence >75% to maximize intervention fidelity. Clients requiring home-delivered meals or a special diet such as a renal, full vegetarian, or vegan diet were excluded from the intervention to simplify procedures, although plans are underway to expand to these groups in the future. Clients meeting the inclusion criteria were identified from a master list of POH clients, and recruited into the intervention until capacity was reached. After POH had recruited participants, but before the start of the intervention, the UCSF study team invited all participants to take part in the evaluation of *Food = Medicine*. All *Food = Medicine* clients were eligible to participate in the evaluation, but participation in the evaluation was not mandatory to receive the intervention.

Food = Medicine Intervention Description

The *Food = Medicine* intervention was developed in consultation with POH nutritionists and the study investigators, and implemented by POH from April 2014 to June 2015. The intervention provided meals and snacks fulfilling 100% of daily caloric requirements, tailored to meet nutritional guidelines for a healthy diet. Average energy requirements used to design daily meals were 1800–2000 kcal for people living with HIV and

Table 1 Examples of Food = Medicine intervention meals and snacks

	Examples
Breakfast	Bagel, 2 tbsp. low fat cream cheese, and 1 piece of fresh fruit 1 cup instant oatmeal, 1 cup 1% low fat milk, ½ banana, and 1 hard cooked egg 1 slice whole wheat bread, 2 tbsp. peanut butter, 1 orange, and 1 cup 1% low fat milk 1 cup plain yogurt, 2 tbsp. sliced almonds, and 1.5 cups frozen berries
Lunch	Mushroom-zucchini quiche Oven roasted cod w/ yogurt sauce Cajun style pork with red beans and rice Herb baked salmon w/ mushroom sauce w/ whole wheat penne
Dinner (meat)	Pork loin chop w/ marinara sauce, wild rice and peas Chicken thigh w/ mushroom sauce, polenta, peas, and carrots Peruvian beef stew w/ tomato, pepper, onion, and quinoa Chicken and sausage gumbo w/ brown rice and corn
Dinner (vegetarian)	Black bean and corn chili Roasted tofu caponata and brown rice Stuffed bell peppers with tomato Provencal Veggie burger w/ tomato glaze and egg noodles
Snacks	8 pieces of baby carrots, ¼ cup hummus, and 1 piece of fresh fruit ½ cup Tuscan bean salad and 1 piece of fresh fruit 1 apple, 2 tbsp. peanut butter, and 1 piece of fresh fruit ½ cup low fat 1% cottage cheese, 3 pieces Melba toast crackers, and 1 piece of fresh fruit

1800 kcal for people with T2DM. This threshold evolved to account for varied energy requirements experienced by individuals of different size and metabolic needs. Meal plans varied each week but were the same across HIV and T2DM groups (see examples in Table 1). Meal plans were based on the Mediterranean diet featuring fresh fruits and vegetables, lean proteins, healthy fats (e.g., olive oil), and whole grains, and were low in refined sugars and saturated fats. The carbohydrate and saturated fat levels were set based on current recommendations from the American Diabetes Association and American Heart Association, respectively. All food was fresh, with limited pre-packaged food offered as snacks or grocery items (e.g., yogurt, sliced bread). Participants (or a surrogate) picked up their food twice per week at designated times from POH facilities.

Data Collection

Trained, master's level research staff independent of POH conducted in-person survey interviews and anthropometric assessments, and coordinated blood draws (for participants with diabetes only). Survey topics broadly covered food security and nutrition, mental health and psychosocial outcomes, substance use, healthcare behaviors, and health status. Height and weight were measured. Phlebotomy was performed by certified phlebotomists using universal precautions. Participants were reimbursed $20 cash after each interview (including anthropometry) and $10 for completing the blood draw.

Measures

Nutritional Measures We measured food security using the USDA Household Food Security Survey Module (HFSSM) [3, 32], which categorizes individuals as having high, marginal, low, or very low food security over the previous 6 months (Cronbach's alpha 0.906). Diet quality was assessed using the 18-item Multifactor Screener [33], tailored to be relevant to low-income populations with HIV and/or diabetes. The screener assesses frequency of consumption of different types of foods in the previous 30 days; values were then converted to "times per day" participants consumed vegetables and fruits, protein, grains, starches, and dairy. We assessed height using a wall-mounted Seca stadiometer and weight using a Health O Meter scale (402KL). Body mass index (BMI) was then calculated as kg/m^2.

Mental Health and Substance Use Measures We assessed depressive symptoms using the Patient Health Questionnaire (PHQ-9) [34], with higher scores indicating higher depressive symptoms (probable depression ≥10). We assessed hazardous drinking using the Alcohol Use Disorders Identification Test (AUDIT-C) [35] (score >4 for men and >3 for women), and measured binge drinking as having five or more drinks at one occasion in the past 30 days. We also assessed current smoking (currently smoked every day, some days, or not at all) and illicit drug use (used crack/cocaine, methamphetamines, and/or heroin over the past 90 days (yes/no), and how many days in the past 90 days used *any* of these drugs).

Healthcare Behaviors Competing demands were captured by asking how often the participant had to go without food because they needed the money for healthcare, or vice versa. We assessed acute-care utilization in the previous 90 days as the number of emergency department (ED) visits and hospitalizations as the number of overnight stays in a hospital bed.

HIV-Specific Measures We assessed internalized HIV stigma using the negative self-image subscale of the HIV Stigma Scale [36, 37]; higher scores indicated higher levels of stigma (Cronbach's alpha 0.875). Self-reported antiretroviral therapy (ART) adherence in the previous 7 days was assessed using the visual analog scale (VAS). Non-adherence was defined as <95% adherence [38, 39].

Diabetes-Specific Measures We assessed diabetes-specific distress using the Diabetes Distress Scale (DDS) [40], with higher scores indicating higher levels of distress (Cronbach's alpha 0.902). Diabetes self-efficacy was assessed using the Perceived Diabetes Self-Management Scale (PDSMS) [41]; higher scores indicated higher self-efficacy (Cronbach's alpha 0.893). Fasting blood sugar and HbA1c were assessed via blood draw and analyzed by Quest Diagnostics using spectrophotometry and immunoturbidimetry, respectively. Higher levels of fasting glucose and HbA1c indicate worse current and longer-term glycemic control, respectively.

Demographics and Socioeconomic Status We collected information on age, gender [42], race/ethnicity, non-US nativity, educational attainment, partnership status,

location of receiving POH services, employment status, annual household income, savings, and receipt of government benefits.

Process Measures We assessed program adherence (percentage of pick-ups attended by the participant or surrogate) using POH administrative records. Self-reported process outcomes included (1) reasons for missing pick-ups, (2) quantity of intervention food eaten, (3) prevalence and frequency of throwing away intervention food, (4) prevalence and frequency of sharing intervention food, and persons with whom food was shared, and (5) frequency and sources of non-intervention food eaten.

Analysis

We computed means and standard deviations for continuous variables, and proportions for categorical variables, separately for study completers and non-completers. We tested differences in baseline characteristics between these two groups using two sample *t* tests and χ^2 tests.

To compare pre-post changes in outcomes, we used paired *t* tests and McNemar exact tests with continuous and dichotomous outcomes, respectively. We compared pre-post outcomes for the study group as a whole, as well as by HIV and T2DM status. We considered a pre-post difference to be statistically significant at $\alpha = 0.05$ for a one-tailed test. Stata 14 (Stata Corp., College Station, TX, USA) was used.

Ethics Statement

The Human Research Protection Program (HRPP) of the University of California, San Francisco (UCSF) approved the study. Participation in the study was voluntary and had no impact on the receipt of services from POH or participation in the intervention. Informed written consent was obtained from all participants.

Results

Sample Characteristics

We completed baseline assessments on all 72 participants who initiated the Food = Medicine intervention. Of these, 56 (77.8%) completed the intervention, and 52 (72.2%) completed both the intervention and follow-up study assessments (Fig. 1). Compared to study completers, non-completers were significantly more likely to be based in Alameda County compared to San Francisco County, be of younger age, have lower educational attainment, and lower average income (Table 2).

Among study completers, 23 individuals were living with HIV alone, 22 were living with T2DM alone, and 7 had a dual HIV/T2DM diagnosis (Table 2). Most participants identified as men (65.1%) and were between 50 and 64 years of age (71.2%). Less than one third of participants identified as white or Caucasian (28.9%). The majority had attained a high school degree/GED or higher (86.5%). Only 17.3% were employed; the majority were receiving either SSI and/or SSDI (65.4%), and 21.6% were receiving SNAP/CalFresh (i.e., "food stamps"). On average, the median time participants were POH clients before starting the intervention was 212 months, or about 17 years [interquartile range (IQR) 42.6, 560], but differed by condition. By condition, median months as a POH client were 435 [IQR 213, 569] (HIV) and 1.08 [IQR 0, 60.4] (T2DM).

Compared to participants living with HIV, those with T2DM were more likely to be older, female, African American, employed, and receiving SNAP benefits, and less likely to have a high school education and to be receiving SSI or SSDI (table not shown).

Changes during the Food = Medicine Intervention

Over the course of the study, we observed a significant decrease in the severity of food insecurity experienced by participants (Fig. 2). Very low food security affected 59.6% of participants at baseline and only 11.5% at follow-up. Likewise, high food security was infrequent at baseline (9.62%) and experienced by the majority at follow-up (53.9%). Differences in food insecurity over time were statistically significant at $p < 0.0001$. The HIV and T2DM groups experienced similar changes in food insecurity.

Diet quality changed across several domains over the course of the study in the overall sample (Table 3). The frequency of consuming fatty foods decreased from 3.19 times per day to 2.21 times ($p = 0.003$), while the frequency of consuming fruits and vegetables increased from 1.85 to 2.34 times per day ($p = 0.011$). We observed a trend in decreased frequency of consumption of sugary foods ($p = 0.07$); however, this was only

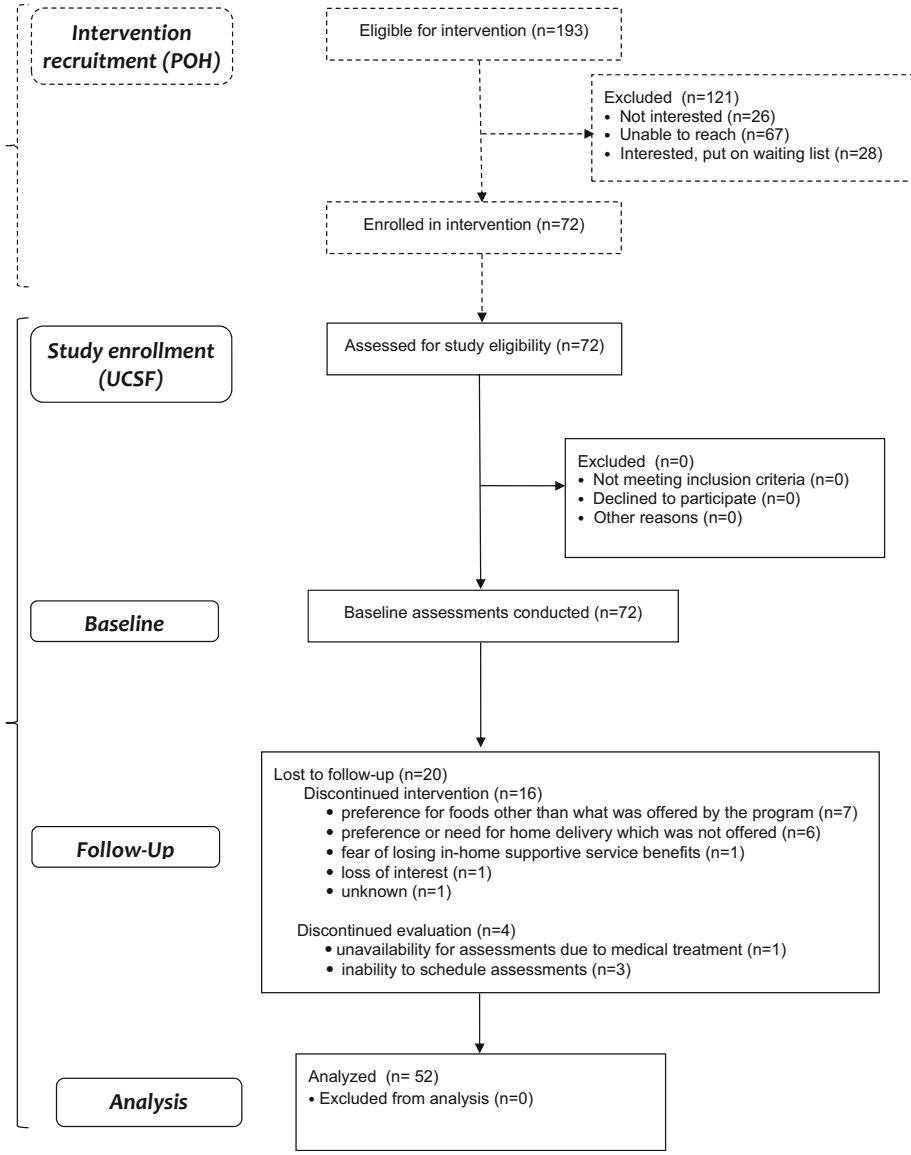

Fig. 1 Participant flow diagram

statistically significant in the T2DM group among whom consumption of sugary foods or drinks decreased from 0.994 to 0.650 times per day ($p = 0.006$) (diabetes-specific results not shown in table). In addition, average BMI decreased from 31.2 at baseline to 30.1 at follow-up ($p = 0.08$) in the overall group. Among participants with T2DM, BMI decreased from 36.1 at baseline to 34.8 at follow-up ($p = 0.035$); among participants with HIV, BMI did not change meaningfully from the baseline of 25.3 (disease-specific results not shown in table). While only one person in the overall sample was underweight at baseline, this individual was no longer underweight at follow-up.

Mental health and substance use also changed over the course of the study for the overall sample (Table 3). Compared to baseline, participants at follow-up had significantly fewer depressive symptoms (7.58 to 5.84; $p = 0.028$). Furthermore, participants reporting binge drinking decreased from 26.0 to 13.5% ($p = 0.008$). In addition, we observed decreases related to substance use that were not statistically significant, including decreased prevalence of hazardous drinking (17.3 to 13.5%, $p = 0.31$) and current smoking (44.2 to 38.5%, $p = 0.19$).

We investigated trends in competing needs and acute-care utilization between baseline and follow-up

Table 2 Characteristics of study participants at baseline by study completion status

Characteristic	Completers ($n = 52$)	Non-completers ($n = 20$)	p value
HIV and T2DM diagnosis[a], %			
Has HIV (no T2DM)	44.2	55.0	0.15
Has T2DM (no HIV)	42.3	25.0	0.38
Has both HIV and T2DM	13.5	20.0	0.45
POH service location, %			
Client in San Francisco County	76.9	45.0	*0.004*
Client in Alameda County (i.e., Oakland)	23.1	55.0	
Length of time POH client (months), median (IQR)	212 (42.6, 560)	153 (0.917, 475)	0.734
Age, median (IQR)	57.2 (50.9, 60.7)	52.9 (49.3, 56.6)	*0.016*
Gender, %			
Male	65.1	75.0	0.46
Female	26.9	15.0	
TransFemale/Transwoman	1.92	0	
Other	5.77	10.0	
Race/ethnicity[b], %			
Native American	9.62	5.00	0.40
Asian/Pacific Islander	1.92	5.00	
Black/African American	28.9	45.0	
Hispanic/Latino	21.2	30.0	
White/Caucasian	28.9	10.0	
Other /Mixed	9.62	5.00	
Born outside the US, %	21.2	30.0	0.51
Education, %			
Less than high school/GED	13.5	25.0	*0.014*
High school/GED	17.3	40.0	
More than high school/GED	69.2	35.0	
Housing, %			
Apartment or house	76.0	65.0	0.11
SRO or nightly hotel	20.0	25.0	
Staying with friends or relatives	2.00	10.0	
Other	2.00	0	
Partnered (married, or committed relationship), %	15.4	25.0	0.25
Employed, %	17.3	10.0	0.37
Annual income, median (IQR)	$13,588 ($10,764, $20,000)	$10,500 ($9800, $11,556)	*0.021*
Less than $500 in savings, %	73.1	95.0	0.09
Receives SSI and/or SSDI, %	65.4	70.0	0.89
Receives SNAP/Cal-Fresh (i.e., food stamps), %	21.6	35.0	0.1

T2DM type 2 diabetes mellitus, *POH* project open hand, *GED* general educational development, *SRO* single room occupancy, *SSI* supplemental security income, *SSDI* social security disability income, *SNAP* supplemental nutritional assistance program. P-values presented in *italics* are $p<0.05$.

[a] Sample sizes by condition were $n = 30$ (HIV) and $n = 29$ (T2DM), including HIV/T2DM dually diagnosed individuals

[b] Race/ethnicity categories are not mutually exclusive

for the overall sample (Table 3). Over the previous 6 months, fewer participants reported giving up healthcare for food (decreased from 34.6 to 19.2%, $p = 0.029$), or giving up food to spend money on

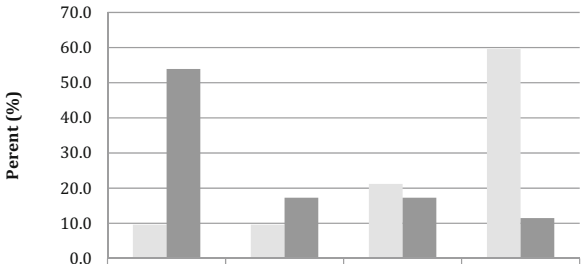

Fig. 2 Severity of food insecurity at baseline and follow-up ($n = 52$). Values are percents. Differences in food security categorization at baseline and follow-up statistically significant at $p < 0.0001$ (McNemar exact test)

healthcare (decreased from 38.5 to 19.2%, $p = 0.007$) or spend money on prescriptions (decreased from 28.9 to 15.4%, $p = 0.046$). Although not statistically significant, there were decreased tendencies of having at least one hospitalization in the previous 3 months (15.7 to 5.77%, $p = 0.11$) and reporting at least one ED visit (26.9 to 17.3%, $p = 0.15$). In the DM group, hospitalizations fell from 25.0 to 6.90% ($p = 0.09$) and ED visits from 31.0 to 13.8% ($p = 0.09$). In the HIV group, hospitalizations fell from 10.0 to 3.33% ($p = 0.31$), while the number of ED visits did not change (disease-specific results not shown in Table 3).

Finally, we examined HIV- and T2DM-specific health outcomes (Table 4). Among participants with HIV, ARV medication adherence of 95% or greater increased from 46.7% of participants at baseline to 70.0% of participants at follow-up ($p = 0.046$). In addition, there was a decrease in internalized HIV stigma scores 12.2 to 11.5 ($p = 0.21$) which was not statistically significant.

Among participants with T2DM, diabetes distress scores decreased from 2.64 to 2.02 ($p < 0.001$) and perceived diabetes self-management scores increased from 24.8 to 27.3 ($p = 0.007$). Finally, mean HbA1c was 9.23% at baseline and 8.75% at follow-up ($p = 0.41$), but this difference was not statistically significant. We also saw a higher prevalence of optimal glycemic control (defined as HbA1c <7%) [10.3 to 19.2%; $p = 0.08$].

Process Outcomes

The median adherence to food pick-ups was 93% based on administrative records (IQR 83, 100) (Table 5). The most common reasons participants reported for missing a pick-up were being too sick or injured to pick up food (38.5%), arrived too late (28.8%), having a healthcare appointment (25.0%), having a surrogate that did not follow through on the pick-up (21.2%), and having a logistical (not financial) transportation problem (19.2%). While almost 78.9% of participants reported eating all or most of the intervention food in a usual week, 90.4% reported throwing away intervention food at some point, 84.6% reported ever sharing intervention food with others, and 57.8% reported sharing intervention food at least once per week. Among participants who shared intervention food, they most commonly shared with friends (56.8%), neighbors (52.3%), and a spouse or partner (25.0%). Finally, almost 78.9% reported eating non-intervention foods at least once per week; only 3.9% reported never eating non-intervention food. Among those who consumed non-intervention foods, the most commonly consumed non-intervention foods were sweet snacks or desserts (76.9%), fast food (75.0%), vegetables (75.0%), and fruits (71.2%).

Discussion

Provision of comprehensive, medically appropriate food assistance was feasible for both HIV and diabetes. Our results show that providing this assistance may improve outcomes for both conditions in food-insecure populations. Further rigorous testing of the intervention is needed to provide evidence as to whether policies to promote medically appropriate food assistance in chronically ill, economically distressed populations are merited.

The *Food = Medicine* intervention is part of a broader, nationwide "Food is Medicine" coalition [43] to mobilize food and nutrition safety-net programs and policies to mitigate the negative health, quality of life, and economic impacts of chronic illness. Nutrition-focused HIV service organizations are central in this coalition, supported by dedicated federal healthcare funding for nutritional wrap-around services via the Ryan White Care Act. The coalition includes organizations serving individuals with many life-threatening and/or chronic illnesses, particularly conditions for which access to a healthy diet is paramount, such as diabetes and heart disease. Rigorous evaluation of medically tailored meal services that may have concrete health impacts across diverse conditions is needed, especially given expanding opportunities to provide or

Table 3 Diet, mental health, and health behavior outcomes at baseline and follow-up ($n = 52$)

	Baseline	Follow-up	p value[a]
Diet quality (times consumed per day), mean (SD)			
Fats	3.19 (2.17)	2.21 (1.5)	*0.003*
Proteins	4.49 (2.38)	4.89 (1.78)	0.1
Dairy	1.63 (1.18)	2.02 (1.13)	*0.009*
Grains and starches	2.21 (1.36)	3.02 (6.11)	0.17
Fruits and vegetables	1.85 (1.54)	2.34 (1.34)	*0.011*
Sugars	1.95 (2.81)	1.30 (1.69)	0.07
Body mass index	31.2 (8.53)	30.6 (8.39)	0.08
Mental health and substance use			
Depressive symptoms (range 0–27), mean (SD)	7.58 (6.92)	5.84 (5.79)	*0.028*
Current smoking, %	44.2	38.5	0.19
Hazardous drinking, %	17.3	13.5	0.31
Binge drinking (≥5 drinks at same occasion in the past 30 days), %	26.9	13.5	*0.008*
Illicit drug use (in the last 3 months), %	17.3	23.1	0.19
Days of illicit drug use (in the last 3 months), mean (SD)	4.96 (16.7)	3.50 (11.8)	0.24
Competing demands			
In previous 6 months, participant gave up…			
Healthcare to spend time or money getting food, %	34.6	19.2	*0.029*
Food to spend money on healthcare (incl. transportation), %	38.5	19.2	*0.007*
Food to spend money on prescriptions, %	28.9	15.4	*0.046*
Acute-care utilization			
Emergency department visits (≥1 in last 3 months), %	26.9	17.3	0.15
Hospitalizations (≥1 in past 3 months), %	15.7	5.77	0.11

Values are means and standard deviations or percentages. *T2DM* type 2 diabetes mellitus

[a] Data reported are p values based on paired data, i.e., data for individuals present at both baseline and follow-up. Paired t tests (for continuous variables) or McNemar test (for dichotomous variables) were used to compare outcomes across study assessments. This table does not include baseline data for 20 individuals who did not have follow-up data. Pvalues presented in *italics* are $p<0.05$.

reimburse nutrition services (including food) via Medicaid, Medicare, and private insurance under the Affordable Care Act [28].

Over 6 months, we observed significant improvements in food security and in outcomes related to all three mechanisms through which we posited food insecurity may impact HIV and diabetes health (nutritional, mental health, and behavioral). We observed dramatic improvements in depression, diabetes distress, diabetes self-management, trading-off between food and healthcare, and HIV medication adherence. Despite insufficient power to detect improvements in HbA1c or acute-care utilization, our results suggested possible improvements in glycemic control and reduced hospitalizations and ED visits among participants with T2DM.

While a growing literature has documented the mostly positive impacts of food assistance on medication adherence and other outcomes for people with HIV in low-income countries [44, 45], the USA and other high-income countries lack parallel studies. Among people with diabetes, a recent prospective study in the USA suggests that medically appropriate "food boxes" tailored for a diabetic diet, provided together with diabetes self-management and linkage to care, may improve glycemic control and other markers of diabetes health, including fruit and vegetable intake, self-management, and medication adherence [29]. The study observed improvements in diabetes distress and HbA1c of similar magnitude as our study. Two observational studies showed that medically appropriate food support may be associated with fewer missed appointments [46] as well as decreased

Table 4 HIV- and T2DM-specific study outcomes at baseline and follow-up

	Overall		
	Baseline	Follow-up	*p* value[a]
HIV-specific outcomes ($n = 30$)			
Internalized HIV stigma (range 7–28]), mean (SD)	12.2 (4.28)	11.5 (4.10)	0.21
ART adherence ≥95%, %	46.7	70.0	*0.046*
T2DM-specific outcomes ($n = 29$)			
Diabetes distress (range 1–6), mean (SD)	2.64 (0.905)	2.02 (0.777)	*<0.001*
Perceived diabetes self-management score (range 8–40), mean (SD)	24.8 (6.35)	27.3 (6.73)	*0.007*
HbA1c %, mean (SD)	9.23 (2.61)	8.75 (1.95)	0.41
HbA1c <7% (optimal control), %	10.3	19.2	0.08
Fasting glucose, mean (SD)	164 (86.1)	151 (80.5)	0.48

Values are means and standard deviations or percentages. *ART* antiretroviral, *HbA1c* glycated hemoglobin, *HIV* human immunodeficiency virus

[a] Data reported are *p* values based on paired data, i.e., data for individuals present at both baseline and follow-up. Paired *t* tests (for continuous variables) or McNemar test (for dichotomous variables) were used to compare outcomes across study assessments. This table does not include baseline data for 15 individuals with HIV and 9 individuals with T2DM who did not have follow-up data.P-values presented in italics are p<0.05.

acute-care utilization and healthcare costs [47]. Our study is one of the first to prospectively evaluate comprehensive, medically appropriate food assistance for people with chronic illness in high-income countries.

The focus on medically appropriate food assistance embodied by *Food = Medicine* and other similar interventions is especially salient given the need to address concurrent food insecurity and obesity in chronically ill populations. HIV-specific food assistance in resource-poor settings is generally tailored for underweight populations, although treated populations with HIV increasingly have higher BMIs [48, 49]. We previously showed that providing energy-dense forms of food assistance to overweight or obese, food-insecure individuals with treated HIV infection leads to weight gain [50], increasing the risk for chronic comorbidities. In contrast, our study suggests that providing three meals a day plus snacks that meet 100% of daily energy requirements while meeting guidelines for a heart-healthy, diabetes diet (for all participants) may result in weight loss or no change in weight among individuals with T2DM.

Society incurs high costs from uncontrolled chronic disease such as T2DM [51], particularly among low-income, food-insecure, and/or underinsured populations who are more likely to delay care, use the emergency room, and require hospital inpatient services [52]. Identifying less resource-intensive ways to help individuals manage their illnesses in the context of competing subsistence needs is therefore critical for the optimal use of public funds. A retrospective study conducted by the Metropolitan Area Neighborhood Nutrition Alliance (MANNA) compared chronically ill clients receiving three meals a day for 6 months with a similar group of Medicaid patients. They found that monthly healthcare costs were 28% lower and average inpatient costs were 30% lower among MANNA clients receiving the meal intervention compared to Medicaid patients not receiving meals [47]. In our study, food and packaging costs for the *Food = Medicine* intervention were $6.58 a day per participant ($1184 for 6 month intervention) in contrast to $2774, the cost per inpatient day in a California hospital [53]. While these preliminary studies are promising, formal, rigorously designed cost-effectiveness studies are needed to assess the economic value of medically appropriate food assistance for chronically ill populations.

As with any pre-post study without a comparison group, observed improvements in our study may be due to external factors or represent preexisting trends, rather than represent a change due to the intervention. Nevertheless, we believe it is plausible that improvements are attributable at least in part to the intervention. The external environment for low-income individuals in the San Francisco Bay Area during the time of our study was one of economic crisis characterized by an

Table 5 Process outcomes at follow-up

Intervention food pick-up adherence and access	
Pick-up adherence (% of food pick-ups attended)[a], median (IQR)	93 (83, 100)
When missed a pick-up, the reason was[b]:	
I was injured, or too sick to pick up food, %	38.5
I was running late and arrived after pick-up had ended, %	28.8
I had a healthcare appointment, %	25.0
My surrogate did not follow through in picking up food, %	21.2
I had a transportation problem (e.g., bus didn't come), %	19.2
Intervention food utilization	
Ate "all" or "most" intervention food in a usual week, %	78.9
Ever threw away food, %	90.4
% of food thrown away in an average week, median (IQR)	10 (5, 18)
Ever shared food with others, %	84.6
Shared food at least once per week, %	57.8
Among those sharing intervention food, the food was shared with[c], %:	
Friend	56.8
Neighbor	52.3
Spouse or partner	25.0
Household member other than partner, including roommate	15.9
Family member that lives outside of your household	13.6
Non-intervention food eaten during the study	
Ate non-intervention foods at least once per week, %	78.9
Types of non- intervention food eaten during the study, %:	
Sweet snacks or desserts	76.9
Fast food, including hotdogs, pizza, etc.	75.0
Vegetables	75.0
Fruits	71.2
Sodas	65.4
Salty snacks	57.7
Foods from my culture	48.1

Values are medians and interquartile ranges or percents

[a] Based on administrative records

[b] Top five reasons for missing a pick-up. Less common reasons included: I had enough food already (15%), coming twice a week was hard for me (13%), I was too busy to pick up food (12%), and I forgot (8%), among others

[c] Five most common types of people participants reported sharing intervention food with. Other less common answers included homeless individuals in their neighborhood (8%), a sexual partner other than a spouse (8%), and dependent children (4%)

overwhelmingly high cost of living and severe housing shortage, compromising access to basic needs [54]. Thus, it is unlikely that the external environment was fully responsible for the observed improvements in health and well-being during the study. In addition, plausibility is enhanced by our observation of improvements related to each of the mechanisms (nutritional, mental health, and behavioral) linking food security to health posited by our conceptual framework. To obtain more conclusive data, however, it is critical to formally test the impact of comprehensive, medically appropriate food assistance using a rigorous, randomized controlled design.

In addition to the pre-post design, our study has additional limitations. Most HIV participants in our study were long-standing clients of POH while most T2DM participants were new clients. Thus, the transition from no services directly to a comprehensive nutrition intervention for participants with T2DM is likely to explain the greater improvements in several outcomes in this group. In addition, POH selected intervention participants with relatively high adherence to POH regular services to maximize likely exposure to the intervention. This selection process applied primarily to clients with HIV who had a longer history at POH to assess adherence. This group may have had greater housing stability, lower life chaos, less mental illness, and less drug addiction than less adherent clients. This may have either biased our results toward the null if excluded individuals had greater need for the intervention or away from the null because intervention adherence was high. Social desirability could have affected participants' responses. Due to the small size of our study, we were underpowered to detect changes in a number of study outcomes, including diabetes control (HbA1c and fasting glucose), and hospitalizations. Furthermore, we did not collect laboratory measures of CD4 cell count or HIV viral load, and therefore could not directly assess the change in HIV clinical outcomes. Finally, our use of a brief diet quality instrument did not allow us to collect detailed information on diet composition or measure precise dietary intakes.

Our study provides initial support to the proposition that "Food is Medicine" may be an effective, low-cost strategy to improve health in vulnerable populations. By preventing worsened illness and acute illness episodes, medically appropriate food support may reduce societal healthcare costs [47] as well as prevent further impoverishment of critically ill individuals. The ultimate goal is to move toward greater health equity by disrupting the

cycle of food insecurity and poor health created by the syndemics of poverty and chronic illness.

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Compliance with Ethical Standards

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Conflict of Interest K Palar, T Napoles, LL Hufstedler, H Seligman, FM Hecht, EA Frongillo, and SD Weiser report no conflicts of interest. M Ryle and K Madsen are current POH employees; S Pitchford was a POH employee at the time of the study.

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JAMA Internal Medicine | Original Investigation

Association Between Receipt of a Medically Tailored Meal Program and Health Care Use

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Invited Commentary page 793

Supplemental content

IMPORTANCE Whether interventions to improve food access can reduce health care use is unknown.

OBJECTIVE To determine whether participation in a medically tailored meal intervention is associated with fewer subsequent hospitalizations.

DESIGN, SETTING, AND PARTICIPANTS A retrospective cohort study was conducted using near/far matching instrumental variable analysis. Data from the 2011-2015 Massachusetts All-Payer Claims database and Community Servings, a not-for-profit organization delivering medically tailored meals (MTMs), were linked. The study was conducted from December 15, 2016, to January 16, 2019. Recipients of MTMs who had at least 360 days of preintervention claims data were matched to nonrecipients on the basis of demographic, clinical, and neighborhood characteristics.

INTERVENTIONS Weekly delivery of 10 ready-to-consume meals tailored to the specific medical needs of the individual under the supervision of a registered dietitian nutritionist.

MAIN OUTCOMES AND MEASURES Inpatient admissions were the primary outcome. Secondary outcomes were admission to a skilled nursing facility and health care costs (from medical and pharmaceutical claims).

RESULTS There were 807 eligible MTM recipients. After matching, there were 499 MTM recipients, matched to 521 nonrecipients for a total of 1020 study participants (mean [SD] age, 52.7 [14.5] years; 568 [55.7%] female). Prior to matching and compared with nonrecipients in the same area, health care use, health care cost, and comorbidity were all significantly higher in recipients. For example, preintervention mean (SD) inpatient admissions were 1.6 (6.5) in MTM recipients vs 0.2 (0.8) in nonrecipients ($P < .001$), and mean health care costs were $80 617 ($312 337) vs $16 138 ($68 738) ($P < .001$). Recipients compared with nonrecipients were also significantly more likely to have HIV (21.9% vs 0.7%, $P < .001$), cancer (37.9% vs 11.3%, $P < .001$), and diabetes (33.7% vs 7.0%, $P < .001$). In instrumental variable analyses, MTM receipt was associated with significantly fewer inpatient admissions (incidence rate ratio [IRR], 0.51; 95% CI, 0.22-0.80; risk difference, −519; 95% CI, −360 to −678 per 1000 person-years). Similarly, MTM receipt was associated with fewer skilled nursing facility admissions (IRR, 0.28; 95% CI, 0.01-0.60; risk difference, −913; 95% CI, −689 to −1457 per 1000 person-years). The models estimated that, had everyone in the matched cohort received treatment owing to the instrument (and including the cost of program participation), mean monthly costs would have been $3838 vs $4591 if no one had received treatment owing to the instrument (difference, −$753; 95% CI, −$1225 to −$280).

CONCLUSIONS AND RELEVANCE Participation in a medically tailored meals program appears to be associated with fewer hospital and skilled nursing admissions and less overall medical spending.

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Following an appropriate diet is a cornerstone of maintaining health and managing illness. However, dietary adherence is difficult for those with complex medical conditions. These difficulties are compounded for socioeconomically vulnerable individuals. This population often faces food insecurity, that is, lack of or uncertainty about access to nutritious food owing to cost,[1] and other barriers to dietary adherence that include physical disability that impedes food shopping, areas with low retail food access (food deserts), and lack of time to prepare appropriate meals. Although the association between these factors and poor health is clear,[2-7] how best to intervene is not apparent.

One emerging strategy to address both food insecurity and these additional barriers in medically complex individuals is medically tailored meal (MTM) delivery. The MTM program involves the home delivery of meals prepared under the supervision of registered dietitian nutritionists to meet the specific nutritional needs of the individual. By helping to improve nutrition, MTMs may improve health and thus lower health care use and cost. Alternatively, it is conceivable that MTM delivery provides limited measurable value given the challenging circumstances of potential recipients. These issues often include poverty and attendant health-related social needs, such as lack of adequate housing and transportation,[8,9] which MTM delivery may not address. In a prior study of individuals dually eligible for Medicare and Medicaid, a research group found that MTM delivery participation was associated with lower health care use.[9] However, because of the restricted study sample, questions about generalizability remained unanswered, along with questions about the sensitivity of the results to possible unmeasured confounding.

In this study, we sought to understand the association between MTM delivery participation and subsequent health care use and cost in a broader population—the state of Massachusetts as reflected in the Massachusetts All-Payer Claims Database (MA-APCD). We further sought to minimize the potential limitation of unmeasured confounding by using an instrumental variable strategy combined with careful matching. Based on prior work,[9] we hypothesized that MTM delivery participation would be associated with lower use of particularly expensive health care, such as inpatient admissions, and thus also be associated with lower health care expenditures.

Key Points

Question Is participating in a medically tailored meal delivery program for medically and socially complex adults associated with fewer inpatient admissions?

Findings In this cohort study of 1020 adults that used a combined instrumental variable analysis and matching approach, participation in a medically tailored meal delivery program was associated with approximately half the number of inpatient admissions.

Meaning For medically and socially complex adults, participating in a medically tailored meal delivery program may reduce inpatient admissions, although cautious interpretation is warranted because intervention receipt was not randomized.

Methods

Study Design

This study used an incident-user matched cohort design in which individuals who did and did not receive MTMs were matched on the basis of preintervention period demographic, health care use, and area-level (eg, neighborhood poverty) data. Our analytic strategy used a type of instrumental variable analysis termed near/far matching, which combines matching with traditional instrumental variable analysis to filter a larger cohort down to its most informative pairs—those who are as similar as possible on demographic and clinical factors but differ in the amount of encouragement to participate in the intervention that they received.[10-14] The instrumental variable that metaphorically encouraged participation was the distance an individual lived from Community Servings, a not-for-profit food and nutrition organization that delivers MTMs to individuals with serious medical illness.

Study Setting and Participants

We linked data at the individual level from the 2011-2015 MA-APCD and the service delivery records of Community Servings. To preserve participant privacy, the Massachusetts Center for Health Information and Analysis, which oversees the MA-APCD, conducted a deterministic link, using name, date of birth, sex, and address to determine MTM receipt. Then, a deidentified analytic data set was created. Community Servings was the only MTM delivery program operating in Massachusetts during the study period.

Institutional review board approval was obtained from the Massachusetts Department of Public Health, the Human Subjects Research Committee at Partners Health Care, and the Office of Human Research Ethics at the University of North Carolina at Chapel Hill, with waiver of informed consent.

To be eligible for the study, individuals had to be 18 years or older, have a home address within 100 km of Community Servings (approximately the delivery radius for the program), and be captured in the MA-APCD at least 360 days before the index date. The index date was the date of enrollment in the MTM delivery program for intervention recipients and a randomly assigned date for nonrecipients. The study was conducted from December 15, 2016, to January 16, 2019.

MTM Program

Each week, the MTM program delivered 10 meals tailored to a recipient's specific medical needs. A registered dietitian nutritionist could choose up to 3 among 17 dietary tracks (eg, appropriate for diabetes and end-stage renal disease). No outreach was made to recruit participants as part of the intervention. Instead, individuals were referred for MTM delivery by a clinician (eg, a primary care physician or social worker) on the basis of both nutritional and social risk. This procedure means that a clinician certified that the individual both had a clinical condition that required medically tailored meals and faced substantial social barriers, such as poverty or food

insecurity, to following an appropriate diet, and that the individual was at substantial risk of clinical deterioration. The clinician and potential recipient then completed an enrollment packet (eAppendix in the Supplement), which was sent to intervention program staff for review. Any person living in the delivery area could apply, so applications came from numerous clinics and health care systems. Key considerations for enrollment were clinical need and the inability of the individual to meet their nutritional needs and follow a medically appropriate diet in the absence of program participation (eg, owing to an income level that prevented purchase of health foods, or mobility limitations secondary to clinical conditions that prevented cooking for oneself). Meals were provided at no cost to the recipients.

Community Servings received funding to support the MTM program from philanthropy supplemented by the Ryan White Act funds for persons living with HIV. Meal receipt continued until the individual chose to withdraw or no longer needed MTMs (eg, owing to an improvement in social circumstances). Meals are delivered in person, but there is not a home-visiting or meal-sharing component to the intervention, unlike some other nutritional assistance programs, such as Meals on Wheels.

Outcomes

In our conceptual framework,[15] receipt of MTMs was most likely to affect health over the short term by providing necessary nutrition (concurrently reducing the consumption of medically inadvisable foods) and by freeing resources that could be used for medications or other expenses that may have associations with improved health, such as rent or transportation. For example, a previous study of this intervention demonstrated a large increase in diet quality when individuals were receiving the meals.[16] We hypothesized that these benefits would help to prevent acute exacerbations of chronic conditions and allow for more consistent adherence to outpatient management plans. Therefore, the primary outcome of this study was inpatient admissions, which we hypothesized would be reduced with receipt of the intervention. Secondary outcomes were admission to a skilled nursing facility (because these largely reflect post-acute care after an inpatient admission, lower inpatient admissions should also lead to lower skilled nursing facility admissions), and total health care costs (the sum of combined medical and pharmaceutical claims), expressed on a per-person per-month basis.

Our original protocol included a separate examination of emergency department visit rates, but the deidentified analytic data set limited our ability to identify unique emergency department visits, so we could not conduct these analyses. We used the consumer price index to inflation-adjust all spending to 2017.[17] To account for intervention costs, we added $350 per month for each MTM recipient, which is the approximate per-person cost of program operation (including dietary tailoring, food, and delivery). For all outcomes, we winsorized the upper percentiles to reduce the influence of outliers.[18] We conducted sensitivity analyses without winsorization.

Covariates

We examined data on a number of covariates that could confound the association between MTM receipt and health care use (eMethods, eTable 1, eFigure 1 in the Supplement). All covariate data came from the preindex period. These covariates included age (years), sex, and insurance type (commercial, Medicare, Medicaid, or other, including uninsured), which were consistently available from the MA-APCD. Furthermore, data on race/ethnicity (categorized as non-Hispanic white, non-Hispanic black, Hispanic, Asian, other, or multiracial), and disability status were provided for some records and used when available; otherwise, we created a category indicating that data were not provided. For comorbidities, we used the Gagne index.[19] In addition, we created indicators for specific comorbidities that frequently prompt MTM receipt (HIV infection, cancer, end-stage renal disease, diabetes, and congestive heart failure).[19] For patterns of health care use, we created counts of inpatient admissions, skilled nursing facility admissions, home health visits, and total medical and pharmaceutical costs. To account for the possibility that a triggering event may have led to MTM receipt, we developed an indicator of inpatient admission within 6 months of the index date. To account for area-level socioeconomic status, we used data from the American Community Survey[20] to calculate the percentage of individuals living in poverty within the zip code tabulation area of the study participant. Finally, to summarize the large number of *International Classification of Diseases, Ninth Revision* diagnosis codes and medications associated with medical, procedural, and pharmaceutical claims, we used the high-dimensional propensity score approach of Schneeweiss et al[21] and used the high-dimensional propensity score as an additional matching variable.

Statistical Analysis

Our major concern was to address the potential for confounding introduced by nonrandom assignment to the intervention. To do this we used near/far matching[12,14] and constructed to a matched cohort that was as similar as possible on relevant sociodemographic and clinical characteristics, but differed in whether an individual was encouraged or discouraged to receive the intervention based on an instrumental variable. In this study, the instrumental variable was the geographic distance between Community Servings' single location and the centroid of an individual's zip code tabulation area (owing to privacy concerns, data on smaller geographic areas were not available). Those living closer are subtly encouraged to enroll. Further details of this instrumental variable approach, and instrument testing, are provided in the eMethods, eTable 2, and eTable 3 in the Supplement.

For matching, after preprocessing we conducted an optimal nonparametric match using Mahalanobis distance and a simulated annealing optimization algorithm.[14] This technique enabled us to achieve the best balance on the potential confounders while maximizing the difference in distance from Community Servings. We used standardized mean difference (SMD) as a metric of balance.

Once the matched cohort was identified, we conducted analyses using the 2-stage residual inclusion approach to in-

strumental variable analyses.[22] We fit a first-stage logistic model that predicts receipt of MTM using distance and the above-mentioned covariates. Next, the residuals, defined as the difference between the observed and predicted values from the first-stage model, were calculated. Third, the second-stage model was fit by regressing the outcome on receipt of the intervention, along with the residuals from the first-stage model and the other covariates. For event outcomes (inpatient and skilled nursing facility admissions), we fit Poisson regression models. For the spending outcome, we fit log-link γ regression models, selecting γ regression after conducting modified Park tests.[23] All models were adjusted for covariates to account for residual imbalance after matching and for the index date to account for secular trends. Our analyses followed the intention-to-treat approach whereby individuals who enrolled in the intervention continued to be analyzed as part of the intervention even if they stopped participating.

To express the results of these models on the absolute (risk difference) and relative (risk ratio) scale, we used recycled predictions,[24] which standardizes the estimates over the observed distribution of covariates. To obtain 95% CIs, we used a nonparametric bootstrap of the entire process (both the first- and second-stage models), with 1000 replications.[22] We also conducted sensitivity analyses using the E-value approach. This approach quantifies the strength of association that an unmeasured confounder would need to have with both the treatment and outcome in order to render the observed treatment-outcome association null.[25,26]

For descriptive analyses, the *P* value was determined using unpaired *t* tests for continuous variables or χ^2 tests for categorical variables. A 2-tailed *P* value <.05 was taken to indicate statistical significance. All statistical analyses were conducted in SAS, version 9.4 (SAS Institute Inc), and R, version 3.4.2 (R Foundation for Statistical Computing).

Results

Participants

There were 1706 MTM program recipients in the MA-APCD, of whom 991 were incident recipients (58.1%). Among incident recipients, 807 individuals (81.4%) had the requisite 360 days of preindex follow-up to permit matching. Before matching, intervention recipients and nonrecipients differed substantially even when restricted to the age- and sex-matched subset residing in the same areas (**Table 1**). For example, mean (SD) preindex costs were $80 617 ($312 337) in MTM recipients vs $16 138 ($68 738) in nonrecipients (*P* < .001), mean (SD) inpatient admissions were 1.6 (6.5) vs 0.2 (0.8) in nonrecipients (*P* < .001), and mean comorbidity index was 5.2 (4.2) vs 0.9 (2.1) in nonrecipients (*P* < .001) (possible range from −1 to 26, with higher numbers indicating greater burden of comorbidity). Recipients were also significantly more likely to have cancer (306 [37.9%] vs 5860 [11.3%], *P* < .001) and diabetes (272 [33.7%] vs 3609 [7.0%], *P* < .001), compared with nonrecipients.

Following matching, there were 509 encouraged individuals (those living closer to Community Servings, regardless of whether they received the intervention) and 511 discouraged individuals. The matched cohort was more balanced, with SMD less than 0.2 for all covariates (**Table 2**). Postindex follow-up was similar for both groups, with a mean (SD) of 21.4 (12.8) months in recipients vs 22.1 (12.5) months in nonrecipients (*P* = .41). Among recipients, the mean (SD) duration of receipt was 12.4 (10.6) months and the median duration was 9.0 (interquartile range, 6.0-18.0) months.

Health Care Use

In the matched cohort, there were 1242 inpatient admissions and 1213 skilled nursing admissions over 1822.1 person-years of follow-up. In instrumental variable analysis combined with matching and intervention, receipt was associated with significantly fewer inpatient admissions (incidence rate ratio [IRR], 0.51; 95% CI, 0.22-0.80). In absolute terms, this translates to fewer estimated admissions per 1000 person-years (−519; 95% CI, −360 to −678) had everyone in the matched cohort been encouraged into treatment by the instrument compared with no one being encouraged into treatment. Similarly, intervention receipt was associated with fewer skilled nursing facility admissions (IRR, 0.28; 95% CI, 0.01-0.60; absolute reduction, −913; 95% CI, −689 to −1457 per 1000 person-years). Most skilled nursing admissions (880 [72.5%] of 1213) came from individuals with an inpatient admission.

Sensitivity analyses using nonwinsorized outcomes were similarly in favor of intervention participation, without any qualitative differences compared with the main analyses (eTable 4 in the Supplement). Sensitivity analyses also revealed that it would require strong unobserved confounding to render the treatment-outcome association null (eFigure 2 and eTable 5 in the Supplement).

Health Care Costs

In instrumental variable analysis combined with matching, participation in the intervention was associated with lower health care costs. The models estimated that, had everyone in the matched cohort been encouraged into treatment (and including the cost of program participation), mean monthly costs would have been $3838 vs $4591 if no one had been encouraged into treatment (relative risk of mean per person per month expenditures difference, 0.84; 95% CI, 0.67-0.998; risk difference, −$753; 95% CI, −$1225 to −$280). This difference represents approximately 16% lower health care costs. Sensitivity analyses using nonwinsorized outcomes were more strongly in favor of intervention participation (eTable 4 in the Supplement). The point estimate for the reduction in medical costs related to inpatient and skilled nursing facility visits was $712 (95% CI, $1930 lower to $505 higher) per month, which is consistent with lower use of these services as the main source of the estimated reduction in total expenditures.

Discussion

In this study using MA-APCD data, we found that participation in an MTM delivery program was associated with fewer inpatient admissions, and with fewer skilled nursing facility

Table 1. Demographic and Clinical Characteristics of the Unmatched Sample

Characteristic	Overall (N = 52 533)	Community Servings Participation Status			
		Did Not Participate (n = 51 726)	Participated (n = 807)	*P* Value[a]	SMD
Distance from Community Servings, mean (SD), km[b]	24.0 (14.1)	24.1 (13.9)	16.7 (19.4)	<.001	0.44
Age, mean (SD), y	52.3 (14.5)	52.3 (14.5)	51.1 (14.8)	.02	0.08
Female, No. (%)	32 230 (61.4)	31 800 (61.5)	430 (53.3)	<.001	0.17
Race/ethnicity, No. (%)					0.80
Non-Hispanic white	5280 (10.1)	5103 (9.9)	177 (21.9)	<.001	
Non-Hispanic black	1110 (2.1)	982 (1.9)	128 (15.9)		
Hispanic	498 (0.9)	453 (0.9)	45 (5.6)		
Multiracial or other	173 (0.3)	158 (0.3)	15 (1.9)		
Information not provided	45 472 (86.6)	45 030 (87.1)	442 (54.8)		
Insurance, No. (%)					0.89
Other	13 994 (26.6)	13 893 (26.9)	101 (12.5)	<.001	
Private	18 940 (36.1)	18 842 (36.4)	98 (12.1)		
Medicare	8142 (15.5)	7980 (15.4)	162 (20.1)		
Medicaid	11 457 (21.8)	11 011 (21.3)	446 (55.3)		
Disability status indicator, No. (%)	1791 (3.4)	1656 (3.2)	135 (16.7)	<.001	0.67
Experienced triggering event, No. (%)[c]	2943 (5.6)	2637 (5.1)	306 (38.0)	<.001	0.87
No. of visits in past 12 mo, mean (SD)					
Inpatient	0.2 (1.1)	0.2 (0.8)	1.6 (6.5)	<.001	0.31
Skilled nursing facility	0.3 (3.6)	0.3 (3.6)	0.5 (3.0)	.12	0.06
Home health	1.6 (19.4)	1.4 (18.0)	16.7 (61.0)	<.001	0.34
Total health care costs in past 12 mo, mean (SD), $	17 129 (78 816)	16 138 (68 738)	80 617 (312 337)	<.001	0.29
Comorbidity index, mean (SD)[d]	1.0 (2.2)	0.9 (2.1)	5.2 (4.2)	<.001	1.28
HIV-positive, No. (%)	541 (1.0)	364 (0.7)	177 (21.9)	<.001	0.71
History, No. (%)					
Cancer	6166 (11.7)	5860 (11.3)	306 (37.9)	<.001	0.65
End-stage renal disease	3547 (6.8)	3244 (6.3)	303 (37.5)	<.001	0.82
Diabetes	3881 (7.4)	3609 (7.0)	272 (33.7)	<.001	0.70
Congestive heart failure	3706 (7.1)	3426 (6.6)	280 (34.7)	<.001	0.74
% Living in poverty in zip code tabulation area, mean (SD)	10.2 (7.7)	10.0 (7.5)	19.9 (8.8)	<.001	1.21

Abbreviation: SMD, standardized mean difference.

[a] *P* value determined using *t* tests for continuous variables or χ^2 test for categorical variables.

[b] Community Servings, a not-for-profit organization delivering medically tailored meals.

[c] An inpatient visit in the 6 months immediately before the index date.

[d] Range, −1 to 26, with higher numbers indicating greater burden of comorbidity.

admissions. Individuals who received MTMs were substantially more ill than the overall population: 37.9% had cancer diagnoses and 33.7% had diabetes. It is unlikely that similar results would be seen were the intervention applied to a healthier population, as the risk of admission or high health care costs, even in the absence of intervention, would be substantially lower. Furthermore, intervention recipients were those with clinical, nutritional, and social risk factors that interacted to produce a high short-term risk of clinical deterioration if they did not receive nutritional intervention. Although these risk factors are a common combination, we caution against overgeneralizing the results of this study to other contexts. For example, programs to reduce hospital readmissions or reduce health care costs among individuals with high past-year costs often include those with heterogeneous reasons for use of health care services. Because health care use in many of these cases may not be driven by the combination of clinical, nutritional, and social risk factors that MTM programs address, we would not expect to see the results observed in this study when applied to a more heterogeneous population. When considering how best to improve health care use, we think it is necessary to understand the drivers of that use and develop specific interventions to address those specific drivers.

This study is consistent with prior literature and expands our knowledge regarding the associations between MTM and health care use. A previous study found associations with reduced use and cost that were similar in magnitude, but that study was restricted to Medicare-Medicaid dual eligibles.[9] The present study adds information on a broader segment of the population and, to the extent that the instrumental variable assumptions are met, adds robustness against unmeasured confounding. Other studies of meal delivery programs have found associations with reduced nursing home admissions,[27] reduced 30-day readmission rates,[28] and improved heart failure symptoms.[29] Furthermore, studies of the Supplemental Nutrition Assistance Program have shown associations with lower health care use and cost, supporting the idea of food insecurity as a modifiable risk factor for adverse health care use.[10,30,31] Following the success of an earlier pilot program,[32]

Table 2. Demographic and Clinical Characteristics of the Matched Sample

Characteristic	Overall (N = 1020)	Encouragement Status[a]			
		Discouraged (n = 511)	Encouraged (n = 509)	*P* Value[b]	SMD
Participated in Community Servings, No. (%)[c]	499 (48.9)	227 (44.4)	272 (53.4)	.01	0.18
Distance from Community Servings, mean (SD), km	17.2 (16.5)	23.7 (18.0)	10.7 (11.7)	<.001	0.86
Age, mean (SD), y	52.7 (14.5)	52.6 (15.0)	52.8 (14.0)	.82	0.01
Female, No. (%)	568 (55.7)	285 (55.8)	283 (55.6)	.90	0.02
Race/ethnicity, No. (%)				.42	0.12
Non-Hispanic white	243 (23.8)	121 (23.7)	122 (24.0)		
Non-Hispanic black	138 (13.5)	77 (15.1)	61 (12.0)		
Hispanic	46 (4.5)	23 (4.5)	23 (4.5)		
Multiracial or other	17 (1.7)	11 (2.2)	6 (1.2)		
Information not provided	576 (56.5)	279 (54.6)	297 (58.3)		
Insurance, No. (%)				.37	0.11
Other	119 (11.7)	54 (10.6)	65 (12.8)		
Private	114 (11.2)	51 (10.0)	63 (12.4)		
Medicare	213 (20.9)	108 (21.1)	105 (20.6)		
Medicaid	574 (56.3)	298 (58.3)	276 (54.2)		
Disability status indicator, No. (%)	180 (17.6)	93 (18.2)	87 (17.1)	.53	0.07
Experienced triggering event, No. (%)[d]	272 (26.7)	135 (26.4)	137 (26.9)	.91	0.01
No. of visits in past 12 mo, mean (SD)					
Inpatient	1.0 (1.9)	1.0 (2.0)	0.91 (1.7)	.43	0.05
Skilled nursing facility	0.5 (3.7)	0.3 (1.5)	0.7 (5.1)	.11	0.10
Home health	15.4 (64.3)	17.0 (66.3)	13.8 (62.2)	.42	0.05
Total health care costs in past 12 mo, mean (SD), $	54 470 (73 081)	54 280 (75 590)	54 661 (70 546)	.93	0.01
Comorbidity index, mean (SD)[e]	4.23 (4.1)	4.17 (4.3)	4.29 (4.0)	.64	0.02
HIV-positive, No. (%)	165 (16.2)	88 (17.2)	77 (15.1)	.41	0.06
History, No. (%)					
Cancer	382 (37.5)	183 (35.8)	199 (39.1)	.31	0.07
End-stage renal disease	286 (28.0)	139 (27.2)	147 (28.9)	.60	0.04
Diabetes	278 (27.3)	132 (25.8)	146 (28.7)	.34	0.06
Congestive heart failure	293 (28.7)	143 (28.0)	150 (29.5)	.65	0.03
% Living in poverty in zip code tabulation area, mean (SD)	19.0 (9.7)	19.2 (10.2)	18.7 (9.3)	.37	0.06

Abbreviation: SMD, standardized mean difference.

[a] Encouraged indicates individuals who lived closer to Community Servings; discouraged indicates individuals who lived farther away.

[b] *P* value from *t* tests for continuous variables or χ^2 test for categorical variables.

[c] Community Servings, a not-for-profit organization delivering medically tailored meals.

[d] An inpatient visit in the 6 months immediately prior to the index date.

[e] Range −1 to 26, with higher numbers indicating greater burden of comorbidity.

California recently announced a large-scale food-is-medicine demonstration project that will examine the health effects of medically tailored meals, and results are expected in 2020.

Our study has several implications for health policy. Medicaid programs in several states have piloted MTM delivery in various settings, and Medicare Advantage recently made changes that could allow coverage for some meal delivery programs.[33] For wide-scale implementation of MTM delivery to be successful, however, further research is needed. First, benefits of MTM participation should be established in large-scale randomized clinical trials. Second, because MTM delivery is a relatively expensive intervention, it will be necessary to target the intervention to those most likely to benefit. Individuals whose needs can be met with less-intensive activities (eg, navigation into the Supplemental Nutrition Assistance Program or community resources such as food pantries) may not require MTMs. Conversely, individuals with high health care expenditures that are not driven by nutrition are unlikely to benefit. A rigorous evidence base that elucidates when MTM programs are needed will be necessary for efficient use of health care resources. Ultimately, a range of options that vary in cost and level of service provided may be needed.

Limitations

The results of this study should be interpreted in light of several limitations. All instrumental variables rely on certain untestable assumptions. In this case, we assume that living closer to Community Servings does not affect health except via increasing the chance of program participation. Next, the association estimates of this study, which apply to a particular cohort of those at substantial clinical and nutritional risk, likely do not apply to the general population of high health care users, who may have other, potentially nonmodifiable, drivers for their health care use and costs. Furthermore, as in all instrumental variable analyses, the results are relevant for the marginal patient who might be encouraged to use the MTM program by the instrument (the local average treatment effect),

and should not be interpreted as the effect for all patients (the average treatment effect). The former is typically larger than the latter.

Next, although we know that individuals in the control group did not receive MTMs, we were unable to determine whether they received other nutrition interventions, such as Meals on Wheels or the Supplemental Nutrition Assistance Program. Furthermore, they may have received other enabling or supportive services that may not generate health care claims (eg, case management), which could bias the observed association to the null. In addition, because this study relied on claims data, measurement error regarding matching factors could have influenced the results, although we do not expect this association to be differential. Next, this study was able to examine only the association between intervention receipt as a whole and the study outcomes, rather than examining the individual components. Thus, even if there is a causal association between the intervention and the outcomes, we do not know what specific components (eg, the provision of food, the medically tailored preparation of the food, or any social connection provided by home delivery) of the intervention are responsible for the findings. In addition, we did not have data on individuals who were offered referral to the intervention but declined, which is another reason to be cautious when generalizing the results observed in this study and not to regard the results as an estimate of the average treatment effect (the effect that would be seen were the program applied to the entire eligible population). In addition, the study used data only from Massachusetts; thus, it is unclear whether the results would generalize to other states with different levels of insurance and services.

Conclusions

Receipt of MTMs appeared to be associated with meaningfully lower downstream medical events compared with nonreceipt. As the focus of health care in the United States turns to population health, the ability to intervene on health-related social needs will become increasingly important for improving both health and the value of health care. Medically tailored meal programs represent promising interventions and deserve further study as we seek to improve health for all Americans, particularly the most vulnerable.

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Invited Commentary

Food Is Medicine—The Promise and Challenges of Integrating Food and Nutrition Into Health Care

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Diet-related diseases produce crushing health and economic burdens. The estimated US costs of diabetes, cardiovascular diseases, obesity-related cancers, and other obesity-related conditions are approximately $1.72 trillion per year,[1] or 9.3% of the gross domestic product. This burden creates tremendous stress on government budgets, private businesses, and families. Marginalized groups often suffer most, with significant disparities in both diet and health leading to illness, suboptimal school and work performance, increased health costs, and lower productivity and wages.

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Although the important role of food in health is increasingly recognized, nutrition has not traditionally been well integrated into health care systems. One obstacle has been demonstrating the efficacy and cost implications of specific nutritional interventions. In this issue of *JAMA Internal Medicine*, Berkowitz and colleagues[2] evaluate one nutrition-focused intervention—free provision of medically tailored meals (MTMs) at home—and subsequent health care use. Using the Massachusetts All-Payer Claims database, the investigators matched individuals receiving MTMs with nonrecipients and assessed hospitalizations, skilled nursing facility admissions, and total health care expenditures. Outpatients were eligible for MTMs if they had a complex medical condition (eg, HIV, cancer, diabetes, end-stage renal disease, congestive heart failure) and were certified by a social worker or clinical health care professional as having substantial social barriers to healthy eating (eg, poverty, food insecurity).

Medically tailored meals were provided by a local not-for-profit organization, Community Servings, as 10 weekly ready-to-eat meals personalized by a registered dietician to each pa-

NEED AND ACCESSIBILITY FOR UNFUNDED SERVICES

The Ryan White HIV/AIDS Program allows funding of 13 core medical services and 15 support services, though only 17 of these services were funded in the Houston area at the time of survey. For this first time, the 2020 Houston Area HIV Needs Assessment collected data on the need for and accessibility to services that are allowable under Ryan White, but not currently funded in the Houston area. While these services are not funded under Ryan White, other funding sources in the community may offer them.

Overall Ranking of Unfunded Services, by Need

Participants of the 2020 Houston HIV Care Services Needs Assessment were asked to indicate which of allowable but currently unfunded services they needed in the past 12 months.

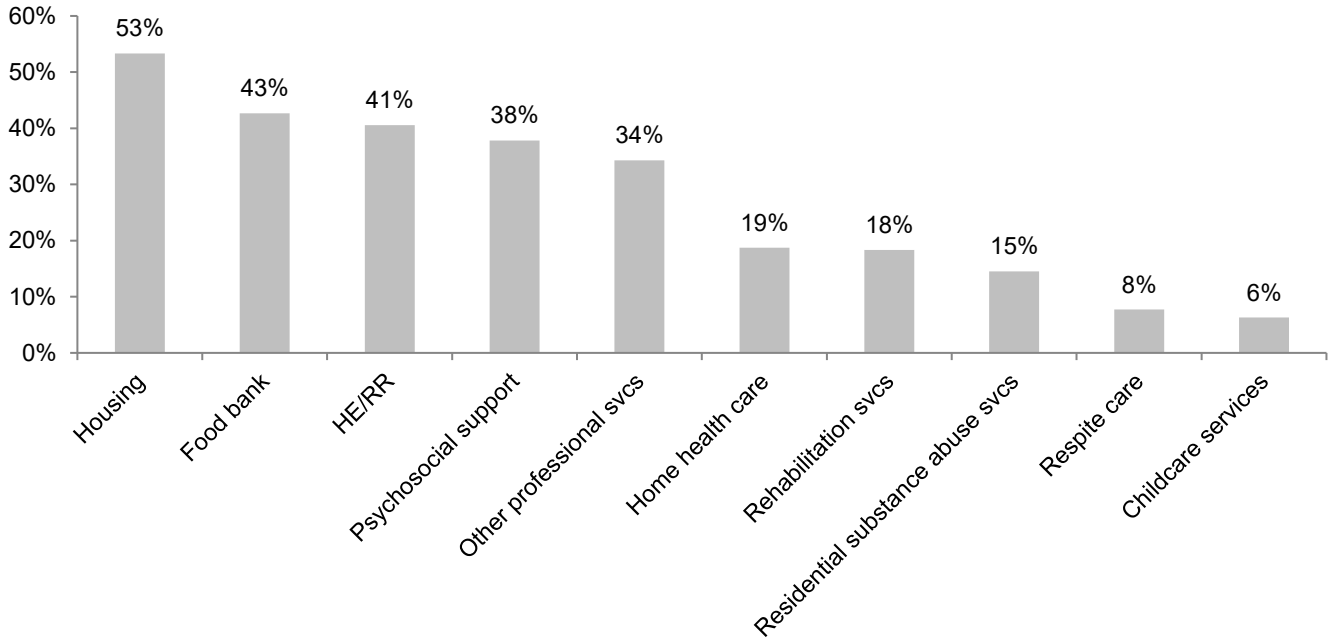
(**Graph 4**) At 53%, housing was the most needed unfunded service in the Houston Area, followed by food bank at 43%, health education/risk reduction at 41%, psychosocial support services at 38%, and other professional services at 34%. Of participants indicating a need for food bank, 69% reported needing services from a food bank, 6% reported needing home delivered meals, and 25% indicated need for both types of food bank service. Among participants indicating a need for psychosocial support services, 89% reported needing an in-person support group, 3% reported needing an online support group, and 8% indicated need for both types of psychosocial support.

Home health care had the highest need ranking of any unfunded core medical service, while housing received the highest need ranking of any unfunded support service.

GRAPH 4-Ranking of Unfunded HIV Services in the Houston Area, By Need, 2020

Definition: Percent of needs assessment participants stating they needed the unfunded service in the past 12 months, regardless of service accessibility.

Denominator: 569-572 participants, varying between service categories



Overall Ranking of Unfunded Services, by Accessibility

Participants were asked to indicate if each of the unfunded HIV services they needed in the past 12 months was easy or difficult for them to access.

(**Graph 5**) The most accessible unfunded service was health education/risk reduction at 93% ease of access, followed by rehabilitation services at 81%, psychosocial support services at 81%, residential substance abuse services at 78%, and respite care at 73%. The least accessible needed unfunded services was housing at 61%. Home health care had the highest accessibility ranking of any core medical service, while rehabilitation services received the highest accessibility ranking of any support service.

GRAPH 5-Ranking of Unfunded HIV Services in the Houston Area, By Accessibility, 2020

Definition: Of needs assessment participants stating they needed the unfunded service in the past 12 months, the percent stating it was easy to access the service.

Denominator: 569-572 participants, varying between service categories