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Addressing Food Insecurity and Chronic Disease in Community Health Centers: Protocol of a quasi-experimental evaluation of Recipe4Health

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Abstract

Introduction

Chronic diseases are highly prevalent in communities served by community health centers in the US. Food insecurity frequently co-occurs in the same communities and hinders effective prevention and management. Community health centers are increasingly implementing programs to address the dual challenge of chronic disease and food insecurity, yet they have been infrequently evaluated.

Methods and analysis

A quasi-experimental study was designed to evaluate the effectiveness of Recipe4Health, a program to decrease chronic disease and food insecurity in community health centers. Recipe4Health includes two components: 1) A 'Food Farmacy' that includes 16 weekly deliveries of produce; and 2) A 'Behavioral Pharmacy' which is a group medical visit. We will use surveys to collect food security status, patient-reported health behaviors (e.g., fruit and vegetable intake, physical activity), and health outcomes (e.g., depressive symptoms). We will also use electronic health record (EHR) data on laboratory values, prescriptions, and health care utilization. We will compare pre/post changes among participants who receive the Food Farmacy alone and those who receive the Food Farmacy and Behavioral Pharmacy. We will also use propensity score matching to compare Recipe4Health participants to a control group of patients in clinics where Recipe4Health has not been implemented for EHR-derived outcomes. This will provide critical evidence on the effectiveness of primary care-based strategies to address food insecurity and chronic disease.

Ethics and dissemination

This study was approved by the Stanford University Institutional Review Board (reference protocol ID 57239). Appropriate study result dissemination will be determined in partnership with the Community Advisory Board.

Strengths and limitations of this study

- Recipe4Health is a comprehensive approach to addressing food insecurity and diet-sensitive chronic conditions in community health centers that serve diverse patient populations
- The quasi-experimental design will provide rigorous evidence of effectiveness of Recipe4Health on food insecurity, health behaviors, health outcomes, and healthcare utilization.
- The key limitation is that we are not able to assess all outcomes among the propensity-score matched control group.

Introduction

The dual challenge of chronic disease and food insecurity disproportionately impacts racial/ethnic minority communities and those characterized by lower socioeconomic status. For example, 12% of Black adults and 11% of Latinx adults have diabetes, which is 1.7 and 1.6 times higher than the prevalence of diabetes among non-Hispanic white adults respectively.[1] Similarly, neighborhoods characterized by lower socioeconomic status have a significantly higher prevalence of diabetes compared to more affluent neighborhoods.[2,3] Food insecurity – the lack of consistent access to sufficient quantities of healthy food for an active and healthy life – is disproportionately prevalent in the same communities impacted by chronic disease.[4] Chronic disease and food insecurity are interrelated; food insecurity contributes to the development of chronic diseases and can hinder effective prevention and management efforts.[5,6] 'Food as Medicine' approaches and specifically produce prescriptions are increasingly employed to address this dual challenge; however, there is a paucity of evidence to guide practice and inform policy.[7-10]

'Food as Medicine' approaches emphasize the important role that food and nutrition play in health and healthcare.[10] Produce prescriptions are one 'Food as Medicine' strategy that have shown promise for decreasing food insecurity, increasing fruit and vegetable intake, and improving diet-sensitive chronic conditions.[11-17] Produce prescriptions are defined as medical treatments prescribed by healthcare professionals for patients with food insecurity and/or diet-sensitive chronic conditions aimed at increasing fruit and vegetable consumption. For example, community health center patients (n=128; 88% non-Hispanic white) randomized to receive a subsidized community supported agriculture box ($300 toward the cost of 24 weekly boxes of produce) experienced significantly greater improvement in diet quality (using the Healthy Eating Index) than patients who were randomized to receive a financial incentive equal to the cost of the subsidy. Although there were improvements in patient-reported outcomes (e.g., quality of life, depressive symptoms) and other health indicators (e.g., body mass index, blood pressure, glucose, lipid levels) among those randomized to receive the box compared to those who received the financial incentive, the differences were not statistically significant.[13]

There is little evidence regarding the impact of produce prescription programs in combination with other strategies aimed at behavior change. One study of a program that combined produce prescriptions with group medical visits, or shared medical appointments, showed that patients (n=48; 27% Latino, 23% Black) increased their daily fruit and vegetable consumption from 5.2 to 6.4 servings at four months ($p<0.01$). Among those with pre-existing hypertension, there was a decrease in systolic blood pressure from 146.1 mmHg at baseline to 129.9 mmHg at four months ($p<0.01$) and among those with depression, a decrease in depressive symptoms from 14.5 at baseline to 7.7 at four months ($p<0.01$).[11] Group medical visits bring multiple patients together for health education and peer support and also offer the opportunity for one-on-one time with primary care providers. Benefits of the group medical visit have included improved clinical outcomes, patient satisfaction with healthcare, and clinician wellbeing.[18,19]

To build on this growing evidence, rigorous research on the impact of the combination of produce prescriptions and group medical visits on patient-reported outcomes as well as health and healthcare outcomes is needed. This study will use a quasi-experimental design with a propensity score matched control group to examine the effectiveness of Recipe4Health, which includes a produce prescription program and a group medical visit. This study will significantly add to the existing literature on the effect of produce prescription programs on nutrition, health, and healthcare utilization outcomes.

Methods and analysis

This study will take place in five community health centers in Alameda County, California. The participating community health centers serve a primarily low-income population that is predominantly Latinx and Black and either underinsured or with public insurance.

Intervention description

Recipe4Health is the result of a multi-sectoral collaboration between Alameda County; Community Health Center Network, a consortium of community health centers; Open Source Wellness, a non-profit organization; and Dig Deep Farms, a local farm. Recipe4Health began in Fall 2019 as one of nine produce prescription programs funded by the U.S. Department of Agricultural Gus Schumacher Nutrition Incentive Program (USDA GusNIP). Recipe4Health includes two components: 1) Food Farmacy: 16 weekly deliveries of organic produce; and 2) Behavioral Pharmacy™: weekly group medical visits for four months. Adult patients (age 18 and older) can be referred to the Food Farmacy with or without the Behavioral Pharmacy based on discussions with the patient.

All clinic staff receive a minimum of two hours of training on screening for food insecurity and workflows for implementing Recipe4Health. Medical Assistants screen for food insecurity using the 2-item Hunger Vital Sign.[20] Staff that prescribe Recipe4Health to patients, including primary care providers, behavioral health providers, nurses, diabetes educators, and registered dieticians, receive an additional eight hours of clinical nutrition training to use 'Food as Medicine' to prevent and manage diet-sensitive chronic conditions. Staff prescribe Recipe4Health to patients with food insecurity and/or chronic health conditions (e.g., obesity, prediabetes, type 2 diabetes, hypertension, depression, anxiety). Food insecurity and these diet-sensitive chronic conditions were selected because of the potential for improvement in health status as a result of increased vegetable consumption and/or from group medical visits.

Food Farmacy: The Food Farmacy is provided by Dig Deep Farms, a social-enterprise program of the Alameda County Deputies Sheriffs Activities League that grows and distributes healthy food in Alameda County. Dig Deep Farms uses regenerative agriculture practices and creates jobs for justice-involved individuals. Dig Deep Farms provides 16 weekly doorstep deliveries of regenerative organic produce that equates to approximately 16 servings per week. Deliveries commonly include produce such as collards, rainbow chard, kale, beets, green onions, zucchini, and lemons.

Behavioral Pharmacy: Open Source Wellness implements a four-month group medical visit series on Zoom for up to 24 patients that is led by a team of trained health coaches with participation by a primary care provider. The Behavioral Pharmacy targets four behaviors: physical activity, healthy eating, social connection, and stress reduction through a consistent structure (Table 1). To maintain continuity and provide support and accountability, coaches engage their groups via text messages in between weekly groups. A primary care provider engages with the group and provides 1:1 care in a breakout room. The individual meetings allow for frequent medication reviews and refills, reassessment and treatment planning, interdisciplinary team referrals, and reinforcement of individual behavior goals.

Table 1. Recipe4Health Behavioral Pharmacy implemented by Open Source Wellness			
Weekly components	Session time	Behavioral targets	Description and examples
Group physical activity	20-30 mins	Physical activity, Social connection	• Playful, socially-engaging physical activity accessible to various physical ability/mobility levels
Mindfulness meditation	5-10 mins	Stress reduction	• Different mindfulness techniques are introduced: ⇒ Breath-focused ⇒ Gratitude ⇒ Progressive muscle relaxation • Walking meditations
Interactive lesson on varied health topic	10-20 mins	Rotates among all four targets: Healthy eating, physical activity, stress reduction, social connection	• Topics can include: ⇒ Turning exercise into play ⇒ Self-care ⇒ Eating healthy on a budget ⇒ Boundary setting • Behavior change (e.g., SMART goals)
Nutrition lesson incorporating Food Farmacy produce of the week	5-10 mins	Healthy eating	• The nutrition lesson covers topics such as: ⇒ Increasing vegetable consumption ⇒ Decreasing sugar intake • Making dietary changes in ways that are culturally relevant and paced appropriately to patients' levels of motivation and health conditions
Group health coaching	45-60 mins	Includes all four targets: Healthy eating, physical activity, stress reduction, social connection	• Participants write their personal behavior goal for that week (e.g., drink one glass of water instead of one can of soda per day, walk 30 minutes 4 times this week, reach out to a friend). • The small-group health coaching expands on the lesson using motivational interviewing and social support to help participants to adopt and maintain new healthy behaviors.

Study design

The quasi-experimental design will include three approaches that leverage the available survey and EHR data and provide the most rigorous design given existing permissions for data access:

1. Within-group pre-post analysis of patient-reported and EHR-derived outcomes for patients in the: 1) Food Farmacy; and 2) Food Farmacy plus Behavioral Pharmacy.
2. Comparison of pre-post outcomes between patients in the: 1) Food Farmacy; and 2) Food Farmacy plus Behavioral Pharmacy.
3. Comparison of EHR outcomes between patients in the: 1) Food Farmacy only; 2) Food Farmacy plus Behavioral Pharmacy; 3) Propensity score-matched patients who did not participate (control).

The within-group comparison of patient-reported outcomes and EHR-derived data will provide preliminary evidence of effectiveness of Recipe4Health among patients who are referred only to the Food Farmacy compared to those who are also participating in the Behavioral Pharmacy. The comparison of EHR-derived outcomes among Recipe4Health participants compared to non-participants will provide additional evidence of effectiveness relative to patients who are similar but who have not been offered Recipe4Health. We have also identified *a priori* effect modifiers including age, race/ethnicity, clinic site, and relevant medical conditions such as obesity, hypertension, diabetes, and depression. In addition to these comparisons, we will examine how engagement in the Behavioral Pharmacy, measured by session attendance, impacts patient-reported and EHR-derived outcomes. This will provide information on effectiveness among those who engage in the intervention as designed versus those who attend fewer sessions.

Participants

The study will focus on adult patients (18 and over) excluding pregnant women. Pregnant women and children can be enrolled in the Food Farmacy and their participation will be evaluated in a separate study as outcomes will need to be defined that reflect their respective

unique developmental stage. There are three groups of patients that will be included in the analysis:

1. Patients enrolled in the Food Farmacy with and without the Behavioral Pharmacy who have completed baseline and follow-up surveys.
2. Patients enrolled in the Food Farmacy with and without the Behavioral Pharmacy who have available EHR data for baseline and 6-or 12-month follow-up.
3. Patients who are not enrolled in the Food Farmacy or Behavioral Pharmacy who are identified using propensity score matching from clinic sites that are not participating in Recipe4Health.

We will use propensity score matching to identify a control group of patients who are as similar as possible to participating patients except they have not been offered Recipe4Health. This use of matching is an example of matching as nonparametric preprocessing as argued for in Ho et al 2007.[21] This matching design has two-levels: (i) at the facility-level, using expert knowledge and feedback from the providers and community members who receive care at the facilities, we will create pair-matches of facilities with exactly one facility that provides the intervention (d=1) and one facility that does not (d=0) within each pair; (ii) within facility-pairs, we will perform an individual-level propensity score matching. While the facility-level pairs reduce the number of candidate patient-level matches (and therefore likely increases the potential for covariate imbalance), the variation of treatment patterns and care from facility to facility is large enough that getting buy-in from community members and providers is believed to be substantially improved by designing the analysis around facility-level contrasts.

The individual-level propensity score model will be built using a logistic model that estimates the probability of a specific patient receiving care at either a facility that offered the program (d=1) or a facility that did not offer the program (d=0). The propensity score matching will seek to balance relevant sociodemographic (e.g., age, race/ethnicity, sex), clinical characteristics (e.g., ICD-9/ICD-10 diagnosis codes, and classes of medications that a participant had filled in the last year) that would lead to referral to either intervention programs, and health outcomes (e.g., HbA1c, LDL cholesterol) (Table 2). The propensity score uses the past 18 months of data. A sketch of the model used to fit the individual-level propensity scores is:

Pr(facility type = 1) = logit(age + race + ethnicity + sex + ICD-9/ICD-10 codes + …)

where each facility-pair has its own propensity score model fit, each model is thus built to account for within-pair, between facility covariate imbalances.

Due to computational limits given the size of the data sets (e.g., some facilities have 20,000 patients), we will use a stratified optimal matching design[22] to identify approximately up to four control patients for each intervention participant from clinic sites that are as similar as possible to participating clinic sites. We anticipate using covariates such as patient's sex as stratification in these matches (a.k.a. "exact matching" within sex category) in order to improve runtime of the matching algorithm).

Table 2. Variables included in propensity score model	
Race/ethnicity	Categorical (Black, Asian, American Indian/Alaska Native, Hispanic, Unknown)
Date of referral*	Continuous
Sex	Categorical (Male/Female)
Language	Categorical (English, Spanish)
Age	Continuous (years)
Insurance type	Categorical (Medicare, Medicaid, other)
Referred to Cal Fresh	Categorical (yes/no)
Height	Continuous
Weight	Continuous (pounds)
Blood pressure Diastolic	Continuous
Blood pressure Systolic	Continuous
BMI	Continuous
Taken medication for:	
Psychological diagnosis	Categorical (yes/no)
Emotional state	Categorical (yes/no)
Cardiovascular disease	Categorical (yes/no)
High cholesterol	Categorical (yes/no)
Musculoskeletal pain	Categorical (yes/no)
Diabetes	Categorical (yes/no)
HbA1c lab test	Continuous
Blood glucose Test	Continuous
Total Cholesterol	Continuous
HDL Cholesterol	Continuous
LDL Cholesterol	Continuous
Triglycerides	Continuous
Number of medical visits	Continuous
* The referral date for control patients is the most recent visit date in the 18 months prior to the launch of Recipe4Health	

Measures

In collaboration with all partners, outcomes and measures which would plausibly improve as a result of increased produce consumption and/or participation in the Behavioral Pharmacy were chosen (Table 3). The primary outcome for the intervention will be daily fruit/vegetable intake, using the score from the 10-item Dietary Screener Questionnaire (DSQ-10).[23] The DSQ asks participants about their consumption in the past month. Diet optimization is a cornerstone for effective chronic disease management, generally preceding improvement in health outcomes, and consumption of fresh fruits and vegetables is the aspect of dietary intake most directly influenced by this intervention.[24-26] Other measures will include health behaviors (e.g., physical activity[27]), mental health (e.g., loneliness[28], depressive symptoms[29], anxiety symptoms[30]), quality of life (CDC 4-item Health-related Quality of Life[31]), food security status[20], biometrics (body mass index, blood pressure), laboratory data (e.g., HbA1c, blood glucose, lipid levels), relevant indices calculated from laboratory data (e.g. HOMA-IR as an estimator of insulin resistance), medication use, and healthcare utilization (e.g., emergency department visits, hospitalizations).

Survey measures: We will collect data at baseline and four months (immediately post intervention). A trained bicultural/bilingual research assistant will administer surveys in English or Spanish over the phone (via REDCap) to collect the outcomes in Table 2 from participants who are participating in the Food Farmacy only. Staff from Open Source Wellness will collect survey data from participants in the Behavioral Pharmacy prior to the first meeting and monthly including after the final meeting at four months. The monthly surveys for the Behavioral Pharmacy are to guide treatment. Surveys will not be collected from control participants.

EHR measures: Participating community health centers in Recipe4Health use the OCHIN EHR.[32] Community Health Center Network, a consortium of community health centers based in

Alameda County, curates and maintains the source for EHR data for all participating clinics. Laboratory and biometric measures will be abstracted for participating and non-participating (control) patients at baseline and up to 12 months follow-up as indicated in Table 2. Because this study relies on data collected as part of routine clinical care, we established an allowable window around each time point. For baseline, the allowable window will be four months prior to referral and one month after, and for the six and 12 month time points, the allowable window will be three months before and after. Prescribed medications and healthcare utilization (e.g., Emergency Department visits, hospitalizations, no shows) will be summarized for the 12 month window before and after the referral date.

Potential modifiers: We will extract information on potential modifiers from the EHR at baseline including demographic characteristics (e.g., age, race/ethnicity, clinic site) and relevant conditions from EHR such as obesity, hypertension, diabetes, prediabetes, depression.

Table 3. Outcomes, potential effect modifiers and intervention engagement measures

Outcomes	Measures or source	Baseline	Follow-up	Food Farmacy	Food Farmacy + Behavior Pharmacy	Control
Primary outcome (survey)		After referral; before first delivery/ visit*	4 months	X	X	
Fruit and vegetable consumption	Dietary Screener Questionnaire (DSQ) 10[26]					
Secondary outcomes (survey)						
Physical activity	Exercise vital sign[30]					
Health-related quality of life	Healthy Days Core Module (CDC HRQOL– 4) [34]					
Social isolation	UCLA loneliness 3-item[31]					
Food insecurity	Household food insecurity Short Form (6-item)[23]					
Depressive symptoms	Nine-item Patient Health Questionnaire (PHQ-9) [32]					
Anxiety symptoms	Generalized Anxiety Disorder 7-Item (GAD-7) [33]					
Secondary outcomes (EHR)		4 months prior to referral and 1 month after	6 months and 12 months with allowable window of 3 months prior and 3 month after each time point			
HbA1c	EHR Lab			X	X	X
Microalbumin, urine	EHR Lab			X	X	X
Fasting glucose	EHR Lab					
Fasting insulin	EHR Lab					
HOMA-IR (calculated)	EHR Lab					
Total cholesterol	EHR Lab			X	X	X
HDL cholesterol	EHR Lab			X	X	X
LDL cholesterol	EHR Lab			X	X	X
Triglycerides	EHR Lab			X	X	X
non-HDL cholesterol (calculated)	EHR Lab			X	X	X
BMI (calculated)	EHR Vital Signs			X	X	X
Weight	EHR Vital Signs			X	X	X
Systolic blood pressure	EHR Vital Signs			X	X	X
Diastolic blood pressure	EHR Vital Signs			X	X	X
Food insecurity	EHR Vital Signs Hunger Vital Sign [REF 8]			X	X	X

Depressive symptoms	Nine-item Patient Health Questionnaire (PHQ-9) in EHR [REF 5]			X	X	X
	Two-item Patient Health Questionnaire (PHQ-2) in EHR [REF 5]			X	X	X
Anxiety Disorder	Generalized Anxiety Disorder 7-Item (GAD-7) Scale in EHR [REF 6]			X	X	X
Prescribed medications	EHR prescription	12 months prior to referral	12 months prior to referral	X	X	X
Emergency Department visits	EHR emergency visits	12 months prior to referral	12 months after referral	X	X	X
Hospitalization (acute and ICU)	EHR inpatient visits			X	X	X
Potential modifiers:						
Demographics	Age, race/ethnicity, clinic site		NA	X	X	X
Health status at baseline	Relevant conditions from EHR such as obesity, hypertension, diabetes, prediabetes, depression		NA	X	X	X
Intervention engagement:						
Number of food bags delivered	DDF redemption records (?)	Ongoing		X	X	
Session attendance	OSW attendance records (in-clinic or online)	Ongoing			X	

Abbreviation: BMI indicates body mass index; EHR, electronic health record; HDL, High Density Lipoprotein; LDL, low-density lipoproteins; ICU, Intensive Care Unit.
* If patient cannot be reached before the first delivery, research staff attempt to contact until the third delivery.

Sample size and power

We chose these effect sizes based on our preliminary data and other available literature.[34] The sample size needed to detect a significant effect for the primary dietary outcome based on Dietary Screener Questionnaire (DSQ-10).[23] Conservatively, with a sample of 140 in Food Farmacy and Behavioral Pharmacy and 1:1 ratio of matched controls we will have 80% power to detect an effect size of 0.4 or greater between Food Farmacy in conjunction with Behavioral Pharmacy and control at α=0.025 (2-sided).[33] With a sample of 250 in Food Farmacy only and 1:1 ratio of matched controls we will have 80% power to detect an effect size of 0.3 or greater between Food Farmacy only and control at α=0.025 (2-sided).[33] This assumes at least 85% retention at four months. Actual power may be greater as we anticipate a greater number of patients in R4H and because there will be a greater number (up to four) of control patients. Additionally, power may be greater due to increased efficiency associated with the use of a mixed model with baseline and covariate adjustments.

Data management

Data sources will include surveys, EHR, group visit attendance, and produce redemption. Data from different sources is linked with a common identifier (medical record number) and the de-identified for analysis with use of an assigned unique study ID. Stanford established a data use agreement with Community Health Center Network (EHR data), Dig Deep Farms (food redemption data), and Open Source Wellness (Behavioral Pharmacy data) to enable accessing and linking data from the different sources. All data will be stored on a secure server at Stanford University. Only the study biostatistician will have access to data with identifiers.

Data analysis

We will examine within group changes in patient-reported outcomes for those in the Food Farmacy alone, those in the Food Farmacy with the Behavioral Pharmacy, and difference between within group changes of these two intervention groups using the following model:

$$Yt = \beta 0 + \beta 1 Y0 + \beta 2\, X\, T + \varepsilon. \qquad (1)$$

let Yt be the change of participants' post-intervention values of the outcome variable at month T (1, 2, 3 or 4) from baseline to arm X (i.e., X=1 for Food Farmacy + Behavioral Pharmacy and X=0 for Food Farmacy only). We will adjust for the baseline value of the outcome (Y0) due to its association with the outcome. ε is the random error accounting for repeated measures within each participant. All the continuous survey outcomes will be analogous, but with different outcome variables. The survey categorical outcomes (e.g., general health status: excellent/very good/good vs. fair/poor and food insecurity status: secure/marginal secure vs. low/very low secure) will be tested using a similar generalized linear mixed model, but with binomial distribution for the outcome Yt.

Additionally, we will compare within group changes for the Food Farmacy along and the Food Farmacy plus Behavioral Pharmacy with the propensity score-matched control group. We will expand model (1) to add the three study groups and the random effect of matching pairs as follows:

$$Yt = \beta 0 + \beta 1 X1 + \beta 2\, X2 + \beta 3 Y0 + (\beta 4 + \beta 5 X1 + \beta 6 X2)\, T + c + v + \varepsilon. \qquad (2)$$

let Yt be the change of participants' post-intervention values of the outcome variable at time T (6 or 12 months) from baseline to arm X1 or X2 (i.e., X1=1 for Food Farmacy + Behavioral Pharmacy and X2=1 for Food Farmacy only, otherwise X1=0 and X2=0 for control). Baseline values on the outcome variable (Y0) will be included. Given the propensity score matching, c

and v are the random effects due to matching clinics and pairs, and ε is the random error accounting for repeated measures within each participant.

For the medication prescription and healthcare utilization (ED visits and hospitalization), we will use generalized linear mixed models[35-37] assuming a Poisson distribution for count outcomes (e.g., number of ED visits and hospitalizations for each patient in 12 months post baseline) and a binomial distribution for binary outcomes (e.g., medication dose reduction in 12 months post baseline). The model will be the simplified version of model (2) without T and covariance structure for random error ε.

We will also conduct exploratory subgroup analyses (e.g. among patients with diabetes) to evaluate potential effect modifiers for the EHR outcomes by expanding model (2) to include appropriate modifier-by-group interaction terms. In this context, testing whether the β coefficients of the interaction terms are equal to zero is equivalent to testing the null hypothesis that the variable of interest does not independently modify the intervention effect.

Patient and public involvement

Our partnership recognizes the importance of involving patients and other key stakeholders in our research and seeks to advance the science of community engagement through our work. Prior to launching the study, partners came together to discuss goals, objectives, roles, responsibilities, decision making, and dissemination strategies in a facilitated process that culminated in a written partnership agreement. The process of generating written agreements are a cornerstone of effective partnerships development and key for maintenance of the partnership and conflict resolution. We also developed a Community Advisory Board (CAB) made up of key stakeholders, patients, health coaches, primary care providers, food system representatives, policy experts, and healthcare payors. CAB members will play key roles in informing the implementation of the study as well as dissemination of findings. We will ensure the CAB is integrated in all phases of the research through participatory decision making, capacity building, and co-learning during each CAB meeting.

Ethics and dissemination

Approval for this study was granted by the Stanford University Institutional Review Board (reference protocol ID 57239). Informed consent will be obtained from the Behavioral Pharmacy participants by Open Source Wellness for the surveys. Stanford research staff will obtain informed consent for surveyed participants enrolled in the Food Farmacy only. A waiver of consent was obtained to utilize EHR data for evaluation. In addition to dissemination in the scientific literature, we will provide periodic updates on study progress to the Alameda County Board of Supervisors and to other key stakeholders in Alameda County. Dissemination to the clinics will include a dashboard to provide real-time information on screening and referral rates for food insecurity, as well as update presentations. Dissemination avenues for patient participants, as well as other community members, will include periodic summaries and updates in the Dig Deep Farms newsletter.

Discussion

The overall goal of the Recipe4Health evaluation is to generate evidence that can be implemented in community health centers to effectively address food insecurity and diet-sensitive chronic disease. This work is especially focused on improving nutrition and chronic diseases within under-resourced communities and communities of color. Recipe4Health is an innovative approach to addressing food insecurity and diet-sensitive chronic disease in primary care. Within this model, providers and their patients can decide on participating in the produce prescription program alone or in combination with the group medical visit. The focus on local

produce and support from the group medical visit may complement existing approaches that address food insecurity in healthcare, such as screening and referral to governmental and community-based programs for food assistance. Additionally, Recipe4Health uses a “food as medicine” approach for treating chronic conditions.

Advantages of Recipe4Health include a focus on foods that support prevention and management of chronic disease, integration of a behavioral intervention that supports adoption and maintenance of optimal health behaviors for patients that need additional support, reducing stigma associated with accessing help for food by offering food in the healthcare setting. The proposed evaluation of Recipe4Health will provide critical evidence that other community health centers can use for developing, implementing, and evaluating similar programs aimed at addressing food insecurity and chronic disease in similar settings.

This study is designed to provide evidence that will inform policies relevant to addressing food insecurity and diet-sensitive chronic disease in healthcare settings. There is an increased focus on addressing social determinants of health in healthcare settings due to their influence on health outcomes. As such, national, state, and local policies are increasingly supporting addressing social determinants of health as part of a comprehensive approach to healthcare. Nationally, some states are obtaining waivers that allow Medicaid funding to be used to address social needs like food insecurity that historically have not been viewed as relevant medical concerns. Additionally, states like California are considering pilot projects similar to Recipe4Health that would include a produce prescription and behavioral support for patients covered by Medicare (Medi-Cal in California). At the local level, community health centers are increasingly implementing programs similar to Recipe4Health. The Recipe4Health evaluation incorporates stakeholder engagement into the design, implementation, and dissemination to maximize the potential that findings will have direct policy implications. Inclusion of stakeholders on the evaluation team and the CAB allows for identification of policy relevant outcomes, comparisons, and subgroup analyses. Additionally, stakeholders can facilitate dissemination of findings beyond the scientific literature to ensure that decision makers can incorporate findings into policies and programs.

The quasi-experimental study has important limitations. Randomization to Recipe4Health is not feasible in this real-world implementation of a produce prescription program. Without randomization to these three groups (Food Farmacy only, Food Farmacy plus Behavioral Pharmacy, and control), it is difficult to determine whether observed changes in patient-reported and EHR-derived outcomes are due to Recipe4Health or other differences between these groups. Additionally, although randomized controlled trials offer the most rigorous evidence of effectiveness, the generalizability of findings can be compromised by differences among patients who are willing and able to participate compared to those who do not. Thus, a quasi-experimental design using propensity-score matching offers preliminary evidence of effectiveness in a real-world setting that is reflective of the target population. Second, it would be ideal to collect patient-reported outcomes from the propensity score-matched control group. Existing permissions for data access only permitted obtaining EHR data from the propensity score-matched control. Finally, because the design relies on available data and does not assure collection of health outcome metrics (e.g. laboratory data) at baseline and follow-up, information on some EHR outcomes may be sparse. This may be a particular issue because of an increased reliance on remote telehealth over in-person visits as a result of the COVID pandemic.

Despite these limitations, the Recipe4Health evaluation will provide critical evidence on the effectiveness of the program on patient-reported outcomes such as food insecurity, health behaviors, and psychosocial well-being, as well as EHR-derived outcomes, and healthcare utilization. With the support of the Community Advisory Board, we will ensure that results are directly and rapidly communicated to decision makers to support implementation and dissemination of programs that address food insecurity in community health centers.

Author contributions:
LGR, SC, LX, BOEA, WC, MB, and JT conceptualized and designed the study; LGR, LX, BOEA, WC, MB, and JT drafted the manuscript; SC, EN, EM, ATL, and EM critically revised the manuscript for important intellectual content; and LGR and SC obtained funding.

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None

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Addressing Food Insecurity and Chronic Conditions in Community Health Centers: Protocol of a quasi-experimental evaluation of Recipe4Health

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Title: Addressing Food Insecurity and Chronic Conditions in Community Health Centers: Protocol of a quasi-experimental evaluation of Recipe4Health

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Abstract

Introduction

Chronic conditions, such as diabetes, obesity, heart disease, and depression, are highly prevalent and frequently co-occur with food insecurity in communities served by community health centers in the US. Community health centers are increasingly implementing 'Food as Medicine' programs to address the dual challenge of chronic conditions and food insecurity, yet they have been infrequently evaluated.

Methods and analysis

The goal of this quasi-experimental study was to evaluate the effectiveness of Recipe4Health, a 'Food as Medicine' program. Recipe4Health includes two components: 1) A 'Food Farmacy' that includes 16 weekly deliveries of produce; and 2) A 'Behavioral Pharmacy' which is a group medical visit. We will use mixed models to compare pre/post changes among participants who receive the Food Farmacy alone (n=250) and those who receive the Food Farmacy and Behavioral Pharmacy (n=140). The primary outcome, fruit and vegetable consumption, and secondary outcomes (e.g., food security status, physical activity, depressive symptoms) will be collected via survey. We will also use electronic health record (EHR) data on laboratory values, prescriptions, and health care utilization. Propensity score matching will be used to compare Recipe4Health participants to a control group of patients in clinics where Recipe4Health has not been implemented for EHR-derived outcomes. Data from surveys, EHR, group visit attendance, and produce delivery is linked with a common identifier (medical record number) and then de-identified for analysis with use of an assigned unique study ID. This study will provide critical evidence on the effectiveness of primary care-based strategies to address food insecurity and chronic conditions.

Ethics and dissemination

This study was approved by the Stanford University Institutional Review Board (reference protocol ID 57239). Appropriate study result dissemination will be determined in partnership with the Community Advisory Board.

Strengths and limitations of this study

- Recipe4Health is a multi-component approach that is aimed at addressing food insecurity and nutrition-sensitive chronic conditions in community health centers that serve diverse patient populations
- The quasi-experimental design will provide evidence of effectiveness of Recipe4Health on food insecurity, health behaviors, health outcomes, and healthcare utilization.
- The key limitation is that we are not able to assess all outcomes among the propensity-score matched control group.

Introduction

The dual challenge of chronic conditions, such as diabetes, obesity, heart disease, and depression, and food insecurity disproportionately impacts racial/ethnic minority communities and those characterized by lower socioeconomic status. For example, 12% of Black adults and 11% of Latinx adults have diabetes, which is 1.7 and 1.6 times higher than the prevalence of diabetes among non-Hispanic white adults respectively.[1] Similarly, neighborhoods characterized by lower socioeconomic status have a significantly higher prevalence of diabetes compared to more affluent neighborhoods.[2,3] Food insecurity – the lack of consistent access to sufficient quantities of healthy food for an active and healthy life – is disproportionately prevalent in the same communities impacted by chronic conditions.[4] Chronic conditions and food insecurity are interrelated; food insecurity contributes to the development of chronic conditions and can hinder effective prevention and management efforts.[5,6] The Supplemental Nutrition Assistance Program (SNAP, or "food stamps") has existed in the US since 1933 to address hunger and food insecurity,[7] but while mitigating hunger can influence the dietary patterns among under-resourced populations, SNAP was not created with the purpose of mitigating chronic conditions, per se. [8] 'Food as Medicine' approaches and specifically produce prescriptions, which are aimed at patients, are increasingly employed to address this dual challenge; however, there is a paucity of evidence to guide practice and inform policy.[9-12]

'Food as Medicine' approaches emphasize the important role that food and nutrition play in health and healthcare.[12] Produce prescriptions are one 'Food as Medicine' strategy that have shown promise for decreasing food insecurity, increasing fruit and vegetable intake, and improving nutrition-sensitive chronic conditions.[13-19] Produce prescriptions are defined as medical treatments prescribed by healthcare professionals for patients with food insecurity and/or nutrition-sensitive chronic conditions aimed at increasing fruit and vegetable consumption. For example, community health center patients randomized to receive a subsidized community supported agriculture box ($300 toward the cost of 24 weekly boxes of produce) experienced significantly greater improvement in diet quality (using the Healthy Eating Index) than patients who were randomized to receive a financial incentive equal to the cost of the subsidy. Although there were improvements in patient-reported outcomes (e.g., quality of life, depressive symptoms) and other health indicators (e.g., body mass index, blood pressure, glucose, lipid levels) among those randomized to receive the box compared to those who received the financial incentive, the differences were not statistically significant.[15]

There is little evidence regarding the impact of produce prescription programs in combination with other strategies aimed at behavior change. One study of a program that combined produce prescriptions with group medical visits, or shared medical appointments, showed that patients significantly increased their daily fruit and vegetable consumption from 5.2 to 6.4 servings at four months. Among those with pre-existing hypertension, there was a significant decrease in systolic blood pressure from 146.1 mmHg at baseline to 129.9 mmHg at four months and among those with depression, a significant decrease in depressive symptoms from 14.5 at baseline to 7.7 at four months.[13] Group medical visits bring multiple patients together for health education and peer support and also offer the opportunity for one-on-one time with primary care providers. Benefits of the group medical visit have included improved clinical outcomes, patient satisfaction with healthcare, and clinician wellbeing.[20,21]

To build on this growing evidence, research on the impact of the combination of produce prescriptions and group medical visits on patient-reported outcomes as well as health and healthcare outcomes is needed. This study will use a quasi-experimental design with a propensity score matched control group to examine the effectiveness of Recipe4Health, which

includes a produce prescription program and a group medical visit, for improving health behaviors, health outcomes, and healthcare utilization. This study will significantly add to the existing literature on the effect of produce prescription programs on nutrition, health, and healthcare utilization outcomes.

Methods and analysis

The objective of this study is to examine the effectiveness of Recipe4Health for improving health behaviors, health outcomes, and healthcare utilization among patients in five community health centers in Alameda County, California. The participating community health centers serve a primarily low-income population that is predominantly Latinx and Black and either underinsured or with public insurance. The data will be collected and analyzed from August 2021 to December 2024.

Intervention description

Recipe4Health is the result of a multi-sectoral collaboration between Alameda County; Community Health Center Network, a consortium of community health centers; Open Source Wellness, a non-profit organization; and Dig Deep Farms, a local farm. Recipe4Health began in Fall 2019 as one of nine produce prescription programs funded by the U.S. Department of Agricultural Gus Schumacher Nutrition Incentive Program (USDA GusNIP). Recipe4Health includes two components: 1) Food Farmacy: 16 weekly deliveries of organic produce; and 2) Behavioral Pharmacy: weekly group medical visits for four months. Adult patients (age 18 and older) can be referred to the Food Farmacy with or without the Behavioral Pharmacy based on discussions with the patient.

All clinic staff receive a minimum of two hours of training on screening for food insecurity and workflows for implementing Recipe4Health. Medical Assistants screen for food insecurity using the 2-item Hunger Vital Sign: 1) Within the past 12 months we worried whether our food would run out before we got money to buy more; 2) Within the past 12 months the food we bought just didn't last and we didn't have money to get more.[22] Staff that prescribe Recipe4Health to patients, including primary care providers, behavioral health providers, nurses, diabetes educators, and registered dieticians, receive an additional eight hours of clinical nutrition training to use 'Food as Medicine' to prevent and manage nutrition-sensitive chronic conditions. Staff prescribe Recipe4Health to patients with food insecurity and/or chronic health conditions (e.g., obesity, prediabetes, type 2 diabetes, hypertension, depression, anxiety). Food insecurity and these nutrition-sensitive chronic conditions were selected because of the potential for improvement in health status as a result of increased vegetable consumption and/or from group medical visits. Prescribing staff and patients collaboratively decide between Food Farmacy only or Food Farmacy with the Behavioral Pharmacy.

Food Farmacy: The Food Farmacy is provided by Dig Deep Farms, a social-enterprise program of the Alameda County Deputies Sheriffs Activities League that grows and distributes healthy food in Alameda County. Dig Deep Farms uses regenerative agriculture practices and creates jobs for justice-involved individuals. Dig Deep Farms provides 16 weekly doorstep deliveries of regenerative organic produce that equates to approximately 16 servings per week. Deliveries commonly include produce such as collards, rainbow chard, kale, beets, green onions, zucchini, and lemons.

Behavioral Pharmacy: Open Source Wellness implements a four-month group medical visit series on Zoom for up to 24 patients that is led by a team of trained health coaches with

participation by a primary care provider. The Behavioral Pharmacy targets four behaviors: physical activity, healthy eating, social connection, and stress reduction through a consistent structure (Table 1). To maintain continuity and provide support and accountability, coaches engage their groups via text messages in between weekly groups. A primary care provider engages with the group and provides 1:1 care in a breakout room. The individual meetings allow for frequent medication reviews and refills, reassessment and treatment planning, interdisciplinary team referrals, and reinforcement of individual behavior goals.

Table 1. Recipe4Health Behavioral Pharmacy implemented by Open Source Wellness

Weekly components	Session time	Behavioral targets	Description and examples
Group physical activity	20-30 mins	Physical activity, Social connection	• Playful, socially-engaging physical activity accessible to various physical ability/mobility levels
Mindfulness meditation	5-10 mins	Stress reduction	• Different mindfulness techniques are introduced: ⇒ Breath-focused ⇒ Gratitude ⇒ Progressive muscle relaxation • Walking meditations
Interactive lesson on varied health topics	10-20 mins	Rotates among all four targets: Healthy eating, physical activity, stress reduction, social connection	• Topics can include: ⇒ Turning exercise into play ⇒ Self-care ⇒ Eating healthy on a budget ⇒ Boundary setting • Behavior change (e.g., SMART goals)
Nutrition lesson incorporating Food Farmacy produce of the week	5-10 mins	Healthy eating	• The nutrition lesson covers topics such as: ⇒ Increasing vegetable consumption ⇒ Decreasing sugar intake • Making dietary changes in ways that are culturally relevant and paced appropriately to patients' levels of motivation and health conditions
Group health coaching	45-60 mins	Includes all four targets: Healthy eating, physical activity, stress reduction, social connection	• Participants write their personal behavior goal for that week (e.g., drink one glass of water instead of one can of soda per day, walk 30 minutes 4 times this week, reach out to a friend). • The small-group health coaching expands on the lesson using motivational interviewing and social support to help participants to adopt and maintain new healthy behaviors.

Study design

This study uses a quasi-experimental design, which is common when randomization is not practical, ethical, or allowable.[23] The quasi-experimental design will include three approaches that leverage the available survey and EHR data and provide the highest quality evidence possible given existing permissions for data access:

1. Within-group pre-post analysis of patient-reported and EHR-derived outcomes for patients in the: 1) Food Farmacy; and 2) Food Farmacy plus Behavioral Pharmacy.
2. Comparison of pre-post outcomes between patients in the: 1) Food Farmacy; and 2) Food Farmacy plus Behavioral Pharmacy.
3. Comparison of EHR outcomes between patients in the: 1) Food Farmacy only; 2) Food Farmacy plus Behavioral Pharmacy; 3) Propensity score-matched patients who did not participate (control).

The within-group comparison of patient-reported outcomes and EHR-derived data will provide preliminary evidence of effectiveness of Recipe4Health among patients who are referred only to the Food Farmacy compared to those who are also participating in the Behavioral Pharmacy. The comparison of EHR-derived outcomes among Recipe4Health participants compared to non-participants will provide additional evidence of effectiveness relative to patients who are similar but who have not been offered Recipe4Health. We have also identified *a priori* effect modifiers including age, race/ethnicity, clinic site, and relevant medical conditions such as

obesity, hypertension, diabetes, and depression. In addition to these comparisons, we will examine how engagement in the Behavioral Pharmacy, measured by session attendance, impacts patient-reported and EHR-derived outcomes. This will provide information on effectiveness among those who engage in the intervention as designed versus those who attend fewer sessions.

Participants

The inclusion criteria are adult patients (18 and over) in one of the five participating community health centers in one of the following three categories:

1. Patients enrolled in the Food Farmacy with and without the Behavioral Pharmacy who have completed baseline and follow-up surveys.
2. Patients enrolled in the Food Farmacy with and without the Behavioral Pharmacy who have available EHR data for baseline and 6-or 12-month follow-up.
3. Patients who are not enrolled in the Food Farmacy or Behavioral Pharmacy who are identified using propensity score matching from clinic sites that are not participating in Recipe4Health.

We plan to recruit 250 in the Food Farmacy only and 140 in the Food Farmacy with Behavioral Pharmacy. We will exclude pregnant women. Pregnant women and children can be enrolled in the Food Farmacy and their participation will be evaluated in a separate study as outcomes will need to be defined that reflect their respective unique developmental stage. All patients enrolled in the Food Farmacy with and without the Behavioral Pharmacy will be invited to participate in the surveys via phone call from a research assistant. We will use all available EHR data in the allowable windows for enrolled patients.

We will identify up to four control patients for each participant. We will use propensity score matching to identify a control group of patients who are as similar as possible to participating patients except they did not originally receive care at a facility that offered Recipe4Health. This use of matching is an example of matching as nonparametric preprocessing as argued for in Ho et al 2007.[24] This matching design has two-levels: (i) at the facility-level, using expert knowledge and feedback from the providers and community members who receive care at the facilities, we will create pair-matches of facilities with exactly one facility that provides the intervention (d=1) and one facility that does not (d=0) within each pair; (ii) within facility-pairs, we will perform an individual-level propensity score matching. While the facility-level pairs reduce the number of candidate patient-level matches (and therefore likely increases the potential for covariate imbalance), the variation of treatment patterns and care from facility to facility is large enough that getting buy-in from community members and providers is believed to be substantially improved by designing the analysis around facility-level contrasts.

The individual-level propensity score model will be built using a logistic model that estimates the probability of a specific patient receiving care at either a facility that offered the program (d=1) or a facility that did not offer the program (d=0). The propensity score matching will seek to balance relevant sociodemographic (e.g., age, race/ethnicity, sex), clinical characteristics (e.g., ICD-9/ICD-10 diagnosis codes, and classes of medications that a participant had filled in the last year) that would lead to referral to either intervention programs, and health outcomes (e.g., HbA1c, LDL cholesterol) (Table 2). The propensity score uses the past 18 months of data.

Due to computational limits given the size of the data sets (e.g., some facilities have 20,000 patients), we will use a stratified optimal matching design[25] to identify approximately up to four control patients for each intervention participant from clinic sites that are as similar as possible to participating clinic sites. We anticipate using covariates such as patient's sex as stratification

in these matches (a.k.a. “exact matching” within sex category) in order to improve runtime of the matching algorithm).

Table 2. Variables included in propensity score model	
Race/ethnicity	Categorical (Black, Asian, American Indian/Alaska Native, Hispanic, Unknown)
Date of referral*	Continuous
Sex	Categorical (Male/Female)
Language	Categorical (English, Spanish)
Age	Continuous (years)
Insurance type	Categorical (Medicare, Medicaid, other)
Referred to Cal Fresh	Categorical (yes/no)
Height	Continuous
Weight	Continuous (pounds)
Blood pressure Diastolic	Continuous
Blood pressure Systolic	Continuous
BMI	Continuous
Taken medication for:	
Psychological diagnosis	Categorical (yes/no)
Emotional state	Categorical (yes/no)
Cardiovascular disease	Categorical (yes/no)
High cholesterol	Categorical (yes/no)
Musculoskeletal pain	Categorical (yes/no)
Diabetes	Categorical (yes/no)
HbA1c lab test	Continuous
Blood glucose Test	Continuous
Total Cholesterol	Continuous
HDL Cholesterol	Continuous
LDL Cholesterol	Continuous
Triglycerides	Continuous
Number of medical visits	Continuous
* The referral date for control patients is the most recent visit date in the 18 months prior to the launch of Recipe4Health	

Measures

In collaboration with all partners, outcomes and measures which would plausibly improve as a result of increased produce consumption and/or participation in the Behavioral Pharmacy were chosen (Table 3). The primary outcome for the intervention will be daily fruit/vegetable intake, using the score from the 10-item Dietary Screener Questionnaire (DSQ-10).[26] The DSQ-10 asks participants about their consumption in the past month. Diet optimization is a cornerstone for effective chronic disease management, generally preceding improvement in health outcomes, and consumption of fresh fruits and vegetables is the aspect of dietary intake most directly influenced by this intervention.[27-29] Other measures will include health behaviors (e.g., physical activity[30]), mental health (e.g., loneliness[31], depressive symptoms[32], anxiety symptoms[33]), quality of life (CDC 4-item Health-related Quality of Life[34]), food security status[22], biometrics (body mass index, blood pressure), laboratory data (e.g., HbA1c, blood glucose, lipid levels), relevant indices calculated from laboratory data (e.g. HOMA-IR as an estimator of insulin resistance), medication use, and healthcare utilization (e.g., emergency department visits, hospitalizations).

Survey measures: We will collect data at baseline and four months (immediately post intervention). A trained bicultural/bilingual research assistant will administer surveys in English or Spanish over the phone (via REDCap) to collect the outcomes in Table 2 from participants who are participating in the Food Farmacy only. Staff from Open Source Wellness will collect survey data from participants in the Behavioral Pharmacy prior to the first meeting and monthly

including after the final meeting at four months. The monthly surveys for the Behavioral Pharmacy are to guide treatment. Surveys will not be collected from control participants.

EHR measures: Participating community health centers in Recipe4Health use the OCHIN EHR.[35] Community Health Center Network, a consortium of community health centers based in Alameda County, curates and maintains the source for EHR data for all participating clinics. Laboratory and biometric measures will be abstracted for participating and non-participating (control) patients at baseline and up to 12 months follow-up as indicated in Table 2. Because this study relies on data collected as part of routine clinical care, we established an allowable window around each time point. For baseline, the allowable window will be four months prior to referral and one month after, and for the six and 12 month time points, the allowable window will be three months before and after. Prescribed medications and healthcare utilization (e.g., Emergency Department visits, hospitalizations, no shows) will be summarized for the 12 month window before and after the referral date.

Potential modifiers: We will extract information on potential modifiers from the EHR at baseline including demographic characteristics (e.g., age, race/ethnicity, clinic site) and relevant conditions from EHR such as obesity, hypertension, diabetes, prediabetes, depression.

Table 3. Outcomes, potential effect modifiers and intervention engagement measures

Outcomes	Measures or source	Baseline	Follow-up	Food Farmacy	Food Farmacy + Behavior Pharmacy	Control
Primary outcome (survey)		After referral; before first delivery/ visit*	4 months	X	X	
Fruit and vegetable consumption	Dietary Screener Questionnaire (DSQ) 10[26]					
Secondary outcomes (survey)						
Physical activity	Exercise vital sign[30]					
Health-related quality of life	Healthy Days Core Module (CDC HRQOL– 4) [34]					
Social isolation	UCLA loneliness 3-item[31]					
Food insecurity	Household food insecurity Short Form (6-item)[22]					
Depressive symptoms	Nine-item Patient Health Questionnaire (PHQ-9) [32]					
Anxiety symptoms	Generalized Anxiety Disorder 7-Item (GAD-7) [33]					
Secondary outcomes (EHR)		4 months prior to referral and 1 month after	6 months and 12 months with allowable window of 3 months prior and 3 month after each time point			
HbA1c	EHR Lab			X	X	X
Microalbumin, urine	EHR Lab			X	X	X
Fasting glucose	EHR Lab					
Fasting insulin	EHR Lab					
HOMA-IR (calculated)	EHR Lab					
Total cholesterol	EHR Lab			X	X	X
HDL cholesterol	EHR Lab			X	X	X
LDL cholesterol	EHR Lab			X	X	X
Triglycerides	EHR Lab			X	X	X
non-HDL cholesterol (calculated)	EHR Lab			X	X	X
BMI (calculated)	EHR Vital Signs			X	X	X
Weight	EHR Vital Signs			X	X	X
Systolic blood pressure	EHR Vital Signs			X	X	X
Diastolic blood pressure	EHR Vital Signs			X	X	X
Food insecurity	EHR Vital Signs Hunger Vital Sign [REF 8]			X	X	X

Depressive symptoms	Nine-item Patient Health Questionnaire (PHQ-9) in EHR [REF 5]			X	X	X
	Two-item Patient Health Questionnaire (PHQ-2) in EHR [REF 5]			X	X	X
Anxiety Disorder	Generalized Anxiety Disorder 7-Item (GAD-7) Scale in EHR [REF 6]			X	X	X
Prescribed medications	EHR prescription	12 months prior to referral	12 months prior to referral	X	X	X
Emergency Department visits	EHR emergency visits	12 months prior to referral	12 months after referral	X	X	X
Hospitalization (acute and ICU)	EHR inpatient visits			X	X	X
Potential modifiers:						
Demographics	Age, race/ethnicity, clinic site		NA	X	X	X
Health status at baseline	Relevant conditions from EHR such as obesity, hypertension, diabetes, prediabetes, depression		NA	X	X	X
Intervention engagement:						
Number of food bags delivered	DDF redemption records (?)	Ongoing		X	X	
Session attendance	OSW attendance records (in-clinic or online)	Ongoing			X	

Abbreviation: BMI indicates body mass index; EHR, electronic health record; HDL, High Density Lipoprotein; LDL, low-density lipoproteins; ICU, Intensive Care Unit.
* If patient cannot be reached before the first delivery, research staff attempt to contact until the third delivery.

Sample size and power

Primary analysis: survey outcomes
We chose these effect sizes based on our preliminary data and other available literature.[36] The sample size needed to detect a significant effect for the primary dietary outcome based on the DSQ-10.[26] Conservatively, with a sample of 140 in Food Farmacy and Behavioral Pharmacy and 1:1 ratio of matched controls we will have 80% power to detect an effect size of 0.4 or greater between Food Farmacy in conjunction with Behavioral Pharmacy and control at α=0.025 (2-sided).[37] With a sample of 250 in Food Farmacy only and 1:1 ratio of matched controls we will have 80% power to detect an effect size of 0.3 or greater between Food Farmacy only and control at α=0.025 (2-sided).[37] This assumes at least 85% retention at four months. Actual power may be greater as we anticipate a greater number of patients in R4H and because there will be a greater number (up to four) of control patients. Additionally, power may be greater due to increased efficiency associated with the use of a mixed model with baseline and covariate adjustments.

Exploratory analyses: EHR outcomes
While this study is powered for the primary outcomes collected in the surveys, access to EHR data affords exploratory analyses of additional outcomes. We categorize these as exploratory analyses and provide guidance here on our anticipated precision. Based on prior enrollment experience, the anticipated number of members in the treatment facilities, and a large control reserve, we anticipate we will be able to achieve at least 2000 matched pairs (that is, 2000 participants who participated in the intervention matched to 2000 who did not). Using a simple difference in means estimator, the square root law suggests standard errors will be approximately 0.022*σ, where σ is the between-unit variance of the outcome of interest. If the matchings are as-if randomly paired then σ is the same as the variation of the outcome itself. If the matching imposes high correlations between the pairs within the set then σ is substantially reduced. Wald-type intervals estimated from a naïve matched pairs t-test would thus be of approximate width 0.088*σ. Equivalently, if this were under a standard testing framework (alpha = 0.05, power = 0.80, two-side rejection, and the other usual assumptions) then there is sufficient information for detecting an effect size of 0.10.

Data management
Data sources will include surveys, EHR, group visit attendance, and produce redemption. Data from different sources is linked with a common identifier (medical record number) and the de-identified for analysis with use of an assigned unique study ID. Stanford established a data use agreement with Community Health Center Network (EHR data), Dig Deep Farms (food redemption data), and Open Source Wellness (Behavioral Pharmacy data) to enable accessing and linking data from the different sources. All data will be stored on a secure server at Stanford University. The data will be reviewed weekly in team meetings to identify and address quality issues. Only the study biostatistician will have access to data with identifiers.

Data analysis
We will examine within group changes in patient-reported outcomes for those in the Food Farmacy alone, those in the Food Farmacy with the Behavioral Pharmacy, and difference between within group changes of these two intervention groups using the following model:

$$Yt = \beta 0 + \beta 1 Y0 + \beta 2 \, X \, T + \beta \, 3^{*} C + \varepsilon. \qquad (1)$$

let Yt be the change of participants' post-intervention values of the outcome variable at month T (1, 2, 3 or 4) from baseline to arm X (i.e., X=1 for Food Farmacy + Behavioral Pharmacy and X=0 for Food Farmacy only). We will adjust for the baseline value of the outcome (Y0) due to its association with the outcome. C is the categorical variable used to account for clinic-level clustering of individuals. ε is the random error accounting for repeated measures within each participant. All the continuous survey outcomes will be analogous, but with different outcome variables. The survey categorical outcomes (e.g., general health status: excellent/very good/good vs. fair/poor and food insecurity status: secure/marginal secure vs. low/very low secure) will be tested using a similar generalized linear mixed model, but with binomial distribution for the outcome Yt.

Additionally, we will compare within group changes for the Food Farmacy along and the Food Farmacy plus Behavioral Pharmacy with the propensity score-matched control group. We will expand model (1) to add the three study groups and the random effect of matching pairs as follows:

$$Yt = \beta0 + \beta1X1 + \beta2\ X2 + \beta3Y0 + (\beta4 + \beta5X1 + \beta6X2)\ T + c + v + \varepsilon. \quad (2)$$

let Yt be the change of participants' post-intervention values of the outcome variable at time T (6 or 12 months) from baseline to arm X1 or X2 (i.e., X1=1 for Food Farmacy + Behavioral Pharmacy and X2=1 for Food Farmacy only, otherwise X1=0 and X2=0 for control). Baseline values on the outcome variable (Y0) will be included. Given the propensity score matching, c and v are the random effects due to matching clinics and pairs, and ε is the random error accounting for repeated measures within each participant.

For the medication prescription and healthcare utilization (ED visits and hospitalization), we will use generalized linear mixed models[38-40] assuming a Poisson distribution for count outcomes (e.g., number of ED visits and hospitalizations for each patient in 12 months post baseline) and a binomial distribution for binary outcomes (e.g., medication dose reduction in 12 months post baseline). The model will be the simplified version of model (2) without T and covariance structure for random error ε.

We will use all available data for each outcome for each analysis. We will handle missing data through maximum likelihood estimation via mixed modeling.[41]

We will also conduct exploratory subgroup analyses (e.g. among patients with diabetes) to evaluate potential effect modifiers for the EHR outcomes by expanding model (2) to include appropriate modifier-by-group interaction terms. In this context, testing whether the β coefficients of the interaction terms are equal to zero is equivalent to testing the null hypothesis that the variable of interest does not independently modify the intervention effect.

Patient and public involvement

Our partnership recognizes the importance of involving patients and other key stakeholders in our research and seeks to advance the science of community engagement through our work. Prior to launching the study, partners came together to discuss goals, objectives, roles, responsibilities, decision making, and dissemination strategies in a facilitated process that culminated in a written partnership agreement. The process of generating written agreements are a cornerstone of effective partnerships development and key for maintenance of the partnership and conflict resolution. We regularly solicit patient feedback to improve the intervention. This is done through the interactions between health coaching staff in the Behavior Pharmacy and patients, and the surveys with patients who participate in the Food Pharmacy-only arm of the intervention. Feedback from patients are discussed during regular partnership

meetings and guide ongoing operations. The partnership also receives feedback from clinic staff around the referral process and dissemination opportunities. Lastly, we developed a Community Advisory Board (CAB) made up of key stakeholders, patients, health coaches, primary care providers, food system representatives, policy experts, and healthcare payors. CAB members will play key roles in informing the implementation of the study as well as dissemination of findings.

Ethics and dissemination

Approval for this study was granted by the Stanford University Institutional Review Board (reference protocol ID 57239). Informed consent will be obtained from the Behavioral Pharmacy participants by Open Source Wellness for the surveys. Stanford research staff will obtain informed consent for surveyed participants enrolled in the Food Farmacy only. A waiver of consent was obtained to utilize EHR data for evaluation. In addition to dissemination in the scientific literature, we will provide periodic updates on study progress to the Alameda County Board of Supervisors and to other key stakeholders in Alameda County. Dissemination to the clinics will include a dashboard to provide real-time information on screening and referral rates for food insecurity, as well as update presentations. Dissemination avenues for patient participants, as well as other community members, will include periodic summaries and updates in the Dig Deep Farms newsletter.

Discussion

This study is designed to provide evidence that will inform policies relevant to addressing food insecurity and nutrition-sensitive chronic conditions in healthcare settings. There is an increased focus on addressing social determinants of health in healthcare settings due to their influence on health outcomes. As such, national, state, and local policies are increasingly supporting addressing social determinants of health as part of a comprehensive approach to healthcare. Nationally, some states are obtaining waivers that allow Medicaid funding to be used to address social needs like food insecurity that historically have not been viewed as relevant medical concerns. Additionally, states like California are considering pilot projects similar to Recipe4Health that would include a produce prescription and behavioral support for patients covered by Medicaid (Medi-Cal in California). At the local level, community health centers are increasingly implementing programs similar to Recipe4Health. The Recipe4Health evaluation incorporates stakeholder engagement into the design, implementation, and dissemination to maximize the potential that findings will have direct policy implications. Inclusion of stakeholders on the evaluation team and clinic partners and the CAB allows for identification of policy relevant outcomes, comparisons, and subgroup analyses. Additionally, stakeholders can facilitate dissemination of findings beyond the scientific literature to ensure that decision makers can incorporate findings into policies and programs.

The quasi-experimental study has important limitations. While randomization to these three groups (Food Farmacy only, Food Farmacy plus Behavioral Pharmacy, and control) would give the most rigorous demonstration of causal inference, in this real-world implementation of a produce prescription program, randomization is not feasible. Thus, a quasi-experimental design was chosen, using propensity-score matching to compare observed changes in EHR-derived outcomes in R4H participants compared to control patients in the same target population, minimizing group differences. In this kind of quasi-experimental design, the conclusions may still suffer from bias arising from imbalances in pre-intervention covariate distributions; a formal sensitivity analysis (e.g., gamma sensitivity) can be used to bound the amount of bias necessary to qualitatively change the study's "naïve" interpretation. [42] A second limitation is that while it would be ideal to collect patient-reported outcomes from the propensity score-matched

control group, our existing permissions for data access only permitted obtaining EHR data from the propensity score-matched control patients. Finally, because the design relies on available data and does not assure collection of health outcome metrics (e.g. laboratory data) at baseline and follow-up, information on some EHR outcomes may be sparse. This may be a particular issue because of an increased reliance on remote telehealth over in-person visits as a result of the COVID-19 pandemic.

Despite these limitations, the Recipe4Health evaluation will provide important preliminary evidence on the effectiveness of the program on patient-reported outcomes such as food insecurity, health behaviors, and psychosocial well-being, as well as EHR-derived outcomes, and healthcare utilization. With the support of the CAB, we will ensure that results are directly and rapidly communicated to decision makers to inform ongoing and developing programs that address food insecurity in community health centers.

Author contributions:
LGR, SC, LX, BOEA, WC, MB, and JT conceptualized and designed the study; LGR, LX, BOEA, WC, MB, and JT drafted the manuscript; SC, EN, EM, ATL, and EM critically revised the manuscript for important intellectual content; and LGR and SC obtained funding.

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Competing interests:
None

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STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No.	Recommendation	Page No.	Relevant text from manuscript
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	1 and 2	Title: Addressing Food Insecurity and Chronic Conditions in Community Health Centers: Protocol of a quasi-experimental evaluation of Recipe4Health Abstract: The goal of this quasi-experimental study was to evaluate the effectiveness of Recipe4Health, a 'Food as Medicine' program.
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	NA	
Introduction				
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	3	"To build on this growing evidence, research on the impact of the combination of produce prescriptions and group medical visits on patient-reported outcomes as well as health and healthcare outcomes is needed."
Objectives	3	State specific objectives, including any prespecified hypotheses	4	The objective of this study is to examine the effectiveness of Recipe4Health for improving health behaviors, health outcomes, and healthcare utilization among patients in

				five community health centers in Alameda County, California.
Methods				
Study design	4	Present key elements of study design early in the paper	5	This study uses a quasi-experimental design that aims to evaluate an intervention but does not use randomization and are common when randomization is not practical, ethical, or allowable
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	4	… five community health centers in Alameda County, California. The participating community health centers serve a primarily low-income population that is predominantly Latinx and Black and either underinsured or with public insurance. The data will be collected and analyzed from August 2021 to December 2024.
Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls *Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants	6	The inclusion criteria are adult patients (18 and over) in one of the five participating community health centers in one of the following three categories:
		(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed	6	We will identify up to four control patients for each

		Case-control study—For matched studies, give matching criteria and the number of controls per case		participant. We will use propensity score matching to identify a control group of patients who are as similar as possible to participating patients except they have not been offered Recipe4Health.
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	7-10	Measures section and Table 3
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	9-10	Table 3
Bias	9	Describe any efforts to address potential sources of bias	5-11	The description of the propensity score matched control group addresses potential bias.
Study size	10	Explain how the study size was arrived at	11	Sample size and power section

Continued on next page

Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	NA	This level of detail is not included in the protocol manuscript and will be included in the primary outcome manuscript.
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	11, 12	
		(*b*) Describe any methods used to examine subgroups and interactions	12	
		(*c*) Explain how missing data were addressed	12	
		(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed *Case-control study*—If applicable, explain how matching of cases and controls was addressed *Cross-sectional study*—If applicable, describe analytical methods taking account of sampling strategy	NA	
		(*e*) Describe any sensitivity analyses	NA	
Results – Given that this is a protocol manuscript, the information on results is not relevant.				
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	NA	
		(b) Give reasons for non-participation at each stage	NA	
		(c) Consider use of a flow diagram	NA	
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	NA	
		(b) Indicate number of participants with missing data for each variable of interest	NA	
		(c) *Cohort study*—Summarise follow-up time (eg, average and total amount)	NA	
Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time	NA	
		Case-control study—Report numbers in each exposure category, or summary measures of exposure	NA	
		Cross-sectional study—Report numbers of outcome events or summary measures	NA	
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	NA	
		(*b*) Report category boundaries when continuous variables were categorized	NA	
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	NA	

Continued on next page

Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	NA
Discussion			
Key results	18	Summarise key results with reference to study objectives	NA
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	NA
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	NA
Generalisability	21	Discuss the generalisability (external validity) of the study results	NA
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	14

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

BMJ Open

Addressing Food Insecurity and Chronic Conditions in Community Health Centers: Protocol of a quasi-experimental evaluation of Recipe4Health

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Title: Addressing Food Insecurity and Chronic Conditions in Community Health Centers: Protocol of a quasi-experimental evaluation of Recipe4Health

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Abstract

Introduction

Chronic conditions, such as diabetes, obesity, heart disease, and depression, are highly prevalent and frequently co-occur with food insecurity in communities served by community health centers in the US. Community health centers are increasingly implementing 'Food as Medicine' programs to address the dual challenge of chronic conditions and food insecurity, yet they have been infrequently evaluated.

Methods and analysis

The goal of this quasi-experimental study was to evaluate the effectiveness of Recipe4Health, a 'Food as Medicine' program. Recipe4Health includes two components: 1) A 'Food Farmacy' that includes 16 weekly deliveries of produce; and 2) A 'Behavioral Pharmacy' which is a group medical visit. We will use mixed models to compare pre/post changes among participants who receive the Food Farmacy alone (n=250) and those who receive the Food Farmacy and Behavioral Pharmacy (n=140). The primary outcome, fruit and vegetable consumption, and secondary outcomes (e.g., food security status, physical activity, depressive symptoms) will be collected via survey. We will also use electronic health record (EHR) data on laboratory values, prescriptions, and health care utilization. Propensity score matching will be used to compare Recipe4Health participants to a control group of patients in clinics where Recipe4Health has not been implemented for EHR-derived outcomes. Data from surveys, EHR, group visit attendance, and produce delivery is linked with a common identifier (medical record number) and then de-identified for analysis with use of an assigned unique study ID. This study will provide important preliminary evidence on the effectiveness of primary care-based strategies to address food insecurity and chronic conditions.

Ethics and dissemination

This study was approved by the Stanford University Institutional Review Board (reference protocol ID 57239). Appropriate study result dissemination will be determined in partnership with the Community Advisory Board.

Strengths and limitations of this study

- Recipe4Health is a multi-component approach that is aimed at addressing food insecurity and nutrition-sensitive chronic conditions in community health centers that serve diverse patient populations
- The quasi-experimental design will provide evidence of effectiveness of Recipe4Health on food insecurity, health behaviors, health outcomes, and healthcare utilization.
- The key limitation is that we are not able to assess all outcomes among the propensity-score matched control group.

Introduction

The dual challenge of chronic conditions, such as diabetes, obesity, heart disease, and depression, and food insecurity disproportionately impacts racial/ethnic minority communities and those characterized by lower socioeconomic status. For example, 12% of Black adults and 11% of Latinx adults have diabetes, which is 1.7 and 1.6 times higher than the prevalence of diabetes among non-Hispanic white adults respectively.[1] Similarly, neighborhoods characterized by lower socioeconomic status have a significantly higher prevalence of diabetes compared to more affluent neighborhoods.[2 3] Food insecurity – the lack of consistent access to sufficient quantities of healthy food for an active and healthy life – is disproportionately prevalent in the same communities impacted by chronic conditions.[4] Chronic conditions and food insecurity are interrelated; food insecurity contributes to the development of chronic conditions and can hinder effective prevention and management efforts.[5 6] The Supplemental Nutrition Assistance Program (SNAP, or "food stamps") has existed in the US since 1933 to address hunger and food insecurity,[7] but while mitigating hunger can influence the dietary patterns among under-resourced populations, SNAP was not created with the purpose of mitigating chronic conditions, per se. [8] 'Food as Medicine' approaches and specifically produce prescriptions, which are aimed at patients, are increasingly employed to address this dual challenge; however, there is a paucity of evidence to guide practice and inform policy.[9-12]

'Food as Medicine' approaches emphasize the important role that food and nutrition play in health and healthcare.[12] Produce prescriptions are one 'Food as Medicine' strategy that have shown promise for decreasing food insecurity, increasing fruit and vegetable intake, and improving nutrition-sensitive chronic conditions.[13-19] Produce prescriptions are defined as medical treatments prescribed by healthcare professionals for patients with food insecurity and/or nutrition-sensitive chronic conditions aimed at increasing fruit and vegetable consumption. For example, community health center patients randomized to receive a subsidized community supported agriculture box ($300 toward the cost of 24 weekly boxes of produce) experienced significantly greater improvement in diet quality (using the Healthy Eating Index) than patients who were randomized to receive a financial incentive equal to the cost of the subsidy. Although there were improvements in patient-reported outcomes (e.g., quality of life, depressive symptoms) and other health indicators (e.g., body mass index, blood pressure, glucose, lipid levels) among those randomized to receive the box compared to those who received the financial incentive, the differences were not statistically significant.[15]

There is little evidence regarding the impact of produce prescription programs in combination with other strategies aimed at behavior change. One study of a program that combined produce prescriptions with group medical visits, or shared medical appointments, showed that patients significantly increased their daily fruit and vegetable consumption from 5.2 to 6.4 servings at four months. Among those with pre-existing hypertension, there was a significant decrease in systolic blood pressure from 146.1 mmHg at baseline to 129.9 mmHg at four months and among those with depression, a significant decrease in depressive symptoms from 14.5 at baseline to 7.7 at four months.[13] Group medical visits bring multiple patients together for health education and peer support and also offer the opportunity for one-on-one time with primary care providers. Benefits of the group medical visit have included improved clinical outcomes, patient satisfaction with healthcare, and clinician wellbeing.[20 21]

To build on this growing evidence, research on the impact of the combination of produce prescriptions and group medical visits on patient-reported outcomes as well as health and healthcare outcomes is needed. This study will use a quasi-experimental design with a propensity score matched control group to examine the effectiveness of Recipe4Health, which

includes a produce prescription program and a group medical visit, for improving health behaviors, health outcomes, and healthcare utilization. This study will significantly add to the existing literature on the effect of produce prescription programs on nutrition, health, and healthcare utilization outcomes.

Methods and analysis

The objective of this study is to examine the effectiveness of Recipe4Health for improving health behaviors, health outcomes, and healthcare utilization among patients in five community health centers in Alameda County, California. The participating community health centers serve a primarily low-income population that is predominantly Latinx and Black and either underinsured or with public insurance. The data will be collected and analyzed from August 2021 to December 2024.

Intervention description

Recipe4Health is the result of a multi-sectoral collaboration between Alameda County; Community Health Center Network, a consortium of community health centers; Open Source Wellness, a non-profit organization; and Dig Deep Farms, a local farm. Recipe4Health began in Fall 2019 as one of nine produce prescription programs funded by the U.S. Department of Agricultural Gus Schumacher Nutrition Incentive Program (USDA GusNIP). Recipe4Health includes two components: 1) Food Farmacy: 16 weekly deliveries of organic produce; and 2) Behavioral Pharmacy: weekly group medical visits for four months. Adult patients (age 18 and older) can be referred to the Food Farmacy with or without the Behavioral Pharmacy based on discussions with the patient.

All clinic staff receive a minimum of two hours of training on screening for food insecurity and workflows for implementing Recipe4Health. Medical Assistants screen for food insecurity using the 2-item Hunger Vital Sign: 1) Within the past 12 months we worried whether our food would run out before we got money to buy more; 2) Within the past 12 months the food we bought just didn't last and we didn't have money to get more.[22] Staff that prescribe Recipe4Health to patients, including primary care providers, behavioral health providers, nurses, diabetes educators, and registered dieticians, receive an additional eight hours of clinical nutrition training to use 'Food as Medicine' to prevent and manage nutrition-sensitive chronic conditions. Staff prescribe Recipe4Health to patients with food insecurity and/or chronic health conditions (e.g., obesity, prediabetes, type 2 diabetes, hypertension, depression, anxiety). Food insecurity and these nutrition-sensitive chronic conditions were selected because of the potential for improvement in health status as a result of increased vegetable consumption and/or from group medical visits. Prescribing staff and patients collaboratively decide between Food Farmacy only or Food Farmacy with the Behavioral Pharmacy.

Food Farmacy: The Food Farmacy is provided by Dig Deep Farms, a social-enterprise program of the Alameda County Deputies Sheriffs Activities League that grows and distributes healthy food in Alameda County. Dig Deep Farms uses regenerative agriculture practices and creates jobs for justice-involved individuals. Dig Deep Farms provides 16 weekly doorstep deliveries of regenerative organic produce that equates to approximately 16 servings per week. Deliveries commonly include produce such as collards, rainbow chard, kale, beets, green onions, zucchini, and lemons.

Behavioral Pharmacy: Open Source Wellness implements a four-month group medical visit series on Zoom for up to 24 patients that is led by a team of trained health coaches with

participation by a primary care provider. The Behavioral Pharmacy targets four behaviors: physical activity, healthy eating, social connection, and stress reduction through a consistent structure (Table 1). To maintain continuity and provide support and accountability, coaches engage their groups via text messages in between weekly groups. A primary care provider engages with the group and provides 1:1 care in a breakout room. The individual meetings allow for frequent medication reviews and refills, reassessment and treatment planning, interdisciplinary team referrals, and reinforcement of individual behavior goals.

Table 1. Recipe4Health Behavioral Pharmacy implemented by Open Source Wellness

Weekly components	Session time	Behavioral targets	Description and examples
Group physical activity	20-30 mins	Physical activity, Social connection	• Playful, socially-engaging physical activity accessible to various physical ability/mobility levels
Mindfulness meditation	5-10 mins	Stress reduction	• Different mindfulness techniques are introduced: ⇒ Breath-focused ⇒ Gratitude ⇒ Progressive muscle relaxation • Walking meditations
Interactive lesson on varied health topics	10-20 mins	Rotates among all four targets: Healthy eating, physical activity, stress reduction, social connection	• Topics can include: ⇒ Turning exercise into play ⇒ Self-care ⇒ Eating healthy on a budget ⇒ Boundary setting • Behavior change (e.g., SMART goals)
Nutrition lesson incorporating Food Farmacy produce of the week	5-10 mins	Healthy eating	• The nutrition lesson covers topics such as: ⇒ Increasing vegetable consumption ⇒ Decreasing sugar intake • Making dietary changes in ways that are culturally relevant and paced appropriately to patients' levels of motivation and health conditions
Group health coaching	45-60 mins	Includes all four targets: Healthy eating, physical activity, stress reduction, social connection	• Participants write their personal behavior goal for that week (e.g., drink one glass of water instead of one can of soda per day, walk 30 minutes 4 times this week, reach out to a friend). • The small-group health coaching expands on the lesson using motivational interviewing and social support to help participants to adopt and maintain new healthy behaviors.

Study design

This study uses a quasi-experimental design, which is common when randomization is not practical, ethical, or allowable.[23] The quasi-experimental design will include three approaches that leverage the available survey and EHR data and provide the highest quality evidence possible given existing permissions for data access:

1. Within-group pre-post analysis of patient-reported and EHR-derived outcomes for patients in the: 1) Food Farmacy; and 2) Food Farmacy plus Behavioral Pharmacy.
2. Comparison of pre-post outcomes between patients in the: 1) Food Farmacy; and 2) Food Farmacy plus Behavioral Pharmacy.
3. Comparison of EHR outcomes between patients in the: 1) Food Farmacy only; 2) Food Farmacy plus Behavioral Pharmacy; 3) Propensity score-matched patients who did not participate (control).

The within-group comparison of patient-reported outcomes and EHR-derived data will provide preliminary evidence of effectiveness of Recipe4Health among patients who are referred only to the Food Farmacy compared to those who are also participating in the Behavioral Pharmacy. The comparison of EHR-derived outcomes among Recipe4Health participants compared to non-participants will provide additional evidence of effectiveness relative to patients who are similar but who have not been offered Recipe4Health. We have also identified *a priori* effect modifiers including age, race/ethnicity, clinic site, and relevant medical conditions such as

obesity, hypertension, diabetes, and depression. In addition to these comparisons, we will examine how engagement in the Behavioral Pharmacy, measured by session attendance, impacts patient-reported and EHR-derived outcomes. This will provide information on effectiveness among those who engage in the intervention as designed versus those who attend fewer sessions.

Participants

The inclusion criteria are adult patients (18 and over) in one of the five participating community health centers in one of the following three categories:

1. Patients enrolled in the Food Farmacy with and without the Behavioral Pharmacy who have completed baseline and follow-up surveys.
2. Patients enrolled in the Food Farmacy with and without the Behavioral Pharmacy who have available EHR data for baseline and 6-or 12-month follow-up.
3. Patients who are not enrolled in the Food Farmacy or Behavioral Pharmacy who are identified using propensity score matching from clinic sites that are not participating in Recipe4Health.

We plan to recruit 250 in the Food Farmacy only and 140 in the Food Farmacy with Behavioral Pharmacy. We will exclude pregnant women. Pregnant women and children can be enrolled in the Food Farmacy and their participation will be evaluated in a separate study as outcomes will need to be defined that reflect their respective unique developmental stage. All patients enrolled in the Food Farmacy with and without the Behavioral Pharmacy will be invited to participate in the surveys via phone call from a research assistant. We will use all available EHR data in the allowable windows for enrolled patients.

We will identify up to four control patients for each participant. We will use propensity score matching to identify a control group of patients who are as similar as possible to participating patients except they did not originally receive care at a facility that offered Recipe4Health. This use of matching is an example of matching as nonparametric preprocessing as argued for in Ho et al 2007.[24] This matching design has two-levels: (i) at the facility-level, using expert knowledge and feedback from the providers and community members who receive care at the facilities, we will create pair-matches of facilities with exactly one facility that provides the intervention (d=1) and one facility that does not (d=0) within each pair; (ii) within facility-pairs, we will perform an individual-level propensity score matching. While the facility-level pairs reduce the number of candidate patient-level matches (and therefore likely increases the potential for covariate imbalance), the variation of treatment patterns and care from facility to facility is large enough that getting buy-in from community members and providers is believed to be substantially improved by designing the analysis around facility-level contrasts.

The individual-level propensity score model will be built using a logistic model that estimates the probability of a specific patient receiving care at either a facility that offered the program (d=1) or a facility that did not offer the program (d=0). The propensity score matching will seek to balance relevant sociodemographic (e.g., age, race/ethnicity, sex), clinical characteristics (e.g., ICD-9/ICD-10 diagnosis codes, and classes of medications that a participant had filled in the last year) that would lead to referral to either intervention programs, and health outcomes (e.g., HbA1c, LDL cholesterol) (Table 2). The propensity score uses the past 18 months of data.

Due to computational limits given the size of the data sets (e.g., some facilities have 20,000 patients), we will use a stratified optimal matching design[25] to identify approximately up to four control patients for each intervention participant from clinic sites that are as similar as possible to participating clinic sites. We anticipate using covariates such as patient's sex as stratification

in these matches (a.k.a. “exact matching” within sex category) in order to improve runtime of the matching algorithm).

Table 2. Variables included in propensity score model	
Race/ethnicity	Categorical (Black, Asian, American Indian/Alaska Native, Hispanic, Unknown)
Date of referral*	Continuous
Sex	Categorical (Male/Female)
Language	Categorical (English, Spanish)
Age	Continuous (years)
Insurance type	Categorical (Medicare, Medicaid, other)
Referred to Cal Fresh	Categorical (yes/no)
Height	Continuous
Weight	Continuous (pounds)
Blood pressure Diastolic	Continuous
Blood pressure Systolic	Continuous
BMI	Continuous
Taken medication for:	
Psychological diagnosis	Categorical (yes/no)
Emotional state	Categorical (yes/no)
Cardiovascular disease	Categorical (yes/no)
High cholesterol	Categorical (yes/no)
Musculoskeletal pain	Categorical (yes/no)
Diabetes	Categorical (yes/no)
HbA1c lab test	Continuous
Blood glucose Test	Continuous
Total Cholesterol	Continuous
HDL Cholesterol	Continuous
LDL Cholesterol	Continuous
Triglycerides	Continuous
Number of medical visits	Continuous
* The referral date for control patients is the most recent visit date in the 18 months prior to the launch of Recipe4Health	

Measures

In collaboration with all partners, outcomes and measures which would plausibly improve as a result of increased produce consumption and/or participation in the Behavioral Pharmacy were chosen (Table 3). The primary outcome for the intervention will be daily fruit/vegetable intake, using the score from the 10-item Dietary Screener Questionnaire (DSQ-10).[26] The DSQ-10 asks participants about their consumption in the past month. Diet optimization is a cornerstone for effective chronic disease management, generally preceding improvement in health outcomes, and consumption of fresh fruits and vegetables is the aspect of dietary intake most directly influenced by this intervention.[27-29] Other measures will include health behaviors (e.g., physical activity[30]), mental health (e.g., loneliness[31], depressive symptoms[32], anxiety symptoms[33]), quality of life (CDC 4-item Health-related Quality of Life[34]), food security status[22], biometrics (body mass index, blood pressure), laboratory data (e.g., HbA1c, blood glucose, lipid levels), relevant indices calculated from laboratory data (e.g. HOMA-IR as an estimator of insulin resistance), medication use, and healthcare utilization (e.g., emergency department visits, hospitalizations).

Survey measures: We will collect data at baseline and four months (immediately post intervention). A trained bicultural/bilingual research assistant will administer surveys in English or Spanish over the phone (via REDCap) to collect the outcomes in Table 2 from participants who are participating in the Food Farmacy only. Staff from Open Source Wellness will collect survey data from participants in the Behavioral Pharmacy prior to the first meeting and monthly

including after the final meeting at four months. The monthly surveys for the Behavioral Pharmacy are to guide treatment. Surveys will not be collected from control participants.

EHR measures: Participating community health centers in Recipe4Health use the OCHIN EHR.[35] Community Health Center Network, a consortium of community health centers based in Alameda County, curates and maintains the source for EHR data for all participating clinics. Laboratory and biometric measures will be abstracted for participating and non-participating (control) patients at baseline and up to 12 months follow-up as indicated in Table 2. Because this study relies on data collected as part of routine clinical care, we established an allowable window around each time point. For baseline, the allowable window will be four months prior to referral and one month after, and for the six and 12 month time points, the allowable window will be three months before and after. Prescribed medications and healthcare utilization (e.g., Emergency Department visits, hospitalizations, no shows) will be summarized for the 12 month window before and after the referral date.

Potential modifiers: We will extract information on potential modifiers from the EHR at baseline including demographic characteristics (e.g., age, race/ethnicity, clinic site) and relevant conditions from EHR such as obesity, hypertension, diabetes, prediabetes, depression.

Table 3. Outcomes, potential effect modifiers and intervention engagement measures

Outcomes	Measures or source	Baseline	Follow-up	Food Farmacy	Food Farmacy + Behavior Pharmacy	Control
Primary outcome (survey)		After referral; before first delivery/ visit*	4 months	X	X	
Fruit and vegetable consumption	Dietary Screener Questionnaire (DSQ) 10[26]					
Secondary outcomes (survey)						
Physical activity	Exercise vital sign[30]					
Health-related quality of life	Healthy Days Core Module (CDC HRQOL– 4) [34]					
Social isolation	UCLA loneliness 3-item[31]					
Food insecurity	Household food insecurity Short Form (6-item)[22]					
Depressive symptoms	Nine-item Patient Health Questionnaire (PHQ-9) [32]					
Anxiety symptoms	Generalized Anxiety Disorder 7-Item (GAD-7) [33]					
Secondary outcomes (EHR)		4 months prior to referral and 1 month after	6 months and 12 months with allowable window of 3 months prior and 3 month after each time point			
HbA1c	EHR Lab			X	X	X
Microalbumin, urine	EHR Lab			X	X	X
Fasting glucose	EHR Lab					
Fasting insulin	EHR Lab					
HOMA-IR (calculated)	EHR Lab					
Total cholesterol	EHR Lab			X	X	X
HDL cholesterol	EHR Lab			X	X	X
LDL cholesterol	EHR Lab			X	X	X
Triglycerides	EHR Lab			X	X	X
non-HDL cholesterol (calculated)	EHR Lab			X	X	X
BMI (calculated)	EHR Vital Signs			X	X	X
Weight	EHR Vital Signs			X	X	X
Systolic blood pressure	EHR Vital Signs			X	X	X
Diastolic blood pressure	EHR Vital Signs			X	X	X
Food insecurity	EHR Vital Signs Hunger Vital Sign [REF 8]			X	X	X

Depressive symptoms	Nine-item Patient Health Questionnaire (PHQ-9) in EHR [REF 5]			X	X	X
	Two-item Patient Health Questionnaire (PHQ-2) in EHR [REF 5]			X	X	X
Anxiety Disorder	Generalized Anxiety Disorder 7-Item (GAD-7) Scale in EHR [REF 6]			X	X	X
Prescribed medications	EHR prescription	12 months prior to referral	12 months prior to referral	X	X	X
Emergency Department visits	EHR emergency visits	12 months prior to referral	12 months after referral	X	X	X
Hospitalization (acute and ICU)	EHR inpatient visits			X	X	X
Potential modifiers:						
Demographics	Age, race/ethnicity, clinic site		NA	X	X	X
Health status at baseline	Relevant conditions from EHR such as obesity, hypertension, diabetes, prediabetes, depression		NA	X	X	X
Intervention engagement:						
Number of food bags delivered	DDF redemption records (?)	Ongoing		X	X	
Session attendance	OSW attendance records (in-clinic or online)	Ongoing			X	

Abbreviation: BMI indicates body mass index; EHR, electronic health record; HDL, High Density Lipoprotein; LDL, low-density lipoproteins; ICU, Intensive Care Unit.
* If patient cannot be reached before the first delivery, research staff attempt to contact until the third delivery.

Sample size and power

Primary analysis: survey outcomes
We chose these effect sizes based on our preliminary data and other available literature.[36] The sample size needed to detect a significant effect for the primary dietary outcome based on the DSQ-10.[26] Conservatively, with a sample of 140 in Food Farmacy and Behavioral Pharmacy and 1:1 ratio of matched controls we will have 80% power to detect an effect size of 0.4 or greater between Food Farmacy in conjunction with Behavioral Pharmacy and control at α=0.025 (2-sided).[37] With a sample of 250 in Food Farmacy only and 1:1 ratio of matched controls we will have 80% power to detect an effect size of 0.3 or greater between Food Farmacy only and control at α=0.025 (2-sided).[37] This assumes at least 85% retention at four months. Actual power may be greater as we anticipate a greater number of patients in R4H and because there will be a greater number (up to four) of control patients. Additionally, power may be greater due to increased efficiency associated with the use of a mixed model with baseline and covariate adjustments.

Exploratory analyses: EHR outcomes
While this study is powered for the primary outcomes collected in the surveys, access to EHR data affords exploratory analyses of additional outcomes. We categorize these as exploratory analyses and provide guidance here on our anticipated precision. Based on prior enrollment experience, the anticipated number of members in the treatment facilities, and a large control reserve, we anticipate we will be able to achieve at least 2000 matched pairs (that is, 2000 participants who participated in the intervention matched to 2000 who did not). Using a simple difference in means estimator, the square root law suggests standard errors will be approximately 0.022*σ, where σ is the between-unit variance of the outcome of interest. If the matchings are as-if randomly paired then σ is the same as the variation of the outcome itself. If the matching imposes high correlations between the pairs within the set then σ is substantially reduced. Wald-type intervals estimated from a naïve matched pairs t-test would thus be of approximate width 0.088*σ. Equivalently, if this were under a standard testing framework (alpha = 0.05, power = 0.80, two-side rejection, and the other usual assumptions) then there is sufficient information for detecting an effect size of 0.10.

Data management
Data sources will include surveys, EHR, group visit attendance, and produce redemption. Data from different sources is linked with a common identifier (medical record number) and the de-identified for analysis with use of an assigned unique study ID. Stanford established a data use agreement with Community Health Center Network (EHR data), Dig Deep Farms (food redemption data), and Open Source Wellness (Behavioral Pharmacy data) to enable accessing and linking data from the different sources. All data will be stored on a secure server at Stanford University. The data will be reviewed weekly in team meetings to identify and address quality issues. Only the study biostatistician will have access to data with identifiers.

Data analysis
We will examine within group changes in patient-reported outcomes for those in the Food Farmacy alone, those in the Food Farmacy with the Behavioral Pharmacy, and difference between within group changes of these two intervention groups using the following model:

$$Yt = \beta 0 + \beta 1 Y0 + \beta 2 \, X \, T + \beta \, 3^{*} C + \varepsilon. \qquad (1)$$

let Yt be the change of participants' post-intervention values of the outcome variable at month T (1, 2, 3 or 4) from baseline to arm X (i.e., X=1 for Food Farmacy + Behavioral Pharmacy and X=0 for Food Farmacy only). We will adjust for the baseline value of the outcome (Y0) due to its association with the outcome. C is the categorical variable used to account for clinic-level clustering of individuals. ε is the random error accounting for repeated measures within each participant. All the continuous survey outcomes will be analogous, but with different outcome variables. The survey categorical outcomes (e.g., general health status: excellent/very good/good vs. fair/poor and food insecurity status: secure/marginal secure vs. low/very low secure) will be tested using a similar generalized linear mixed model, but with binomial distribution for the outcome Yt.

Additionally, we will compare within group changes for the Food Farmacy along and the Food Farmacy plus Behavioral Pharmacy with the propensity score-matched control group. We will expand model (1) to add the three study groups and the random effect of matching pairs as follows:

$$Yt = \beta0 + \beta1X1 + \beta2\ X2 + \beta3Y0 + (\beta4 + \beta5X1 + \beta6X2)\ T + c + v + \varepsilon. \quad (2)$$

let Yt be the change of participants' post-intervention values of the outcome variable at time T (6 or 12 months) from baseline to arm X1 or X2 (i.e., X1=1 for Food Farmacy + Behavioral Pharmacy and X2=1 for Food Farmacy only, otherwise X1=0 and X2=0 for control). Baseline values on the outcome variable (Y0) will be included. Given the propensity score matching, c and v are the random effects due to matching clinics and pairs, and ε is the random error accounting for repeated measures within each participant.

For the medication prescription and healthcare utilization (ED visits and hospitalization), we will use generalized linear mixed models[38-40] assuming a Poisson distribution for count outcomes (e.g., number of ED visits and hospitalizations for each patient in 12 months post baseline) and a binomial distribution for binary outcomes (e.g., medication dose reduction in 12 months post baseline). The model will be the simplified version of model (2) without T and covariance structure for random error ε.

We will use all available data for each outcome for each analysis. We will handle missing data through maximum likelihood estimation via mixed modeling.[41]

We will also conduct exploratory subgroup analyses (e.g. among patients with diabetes) to evaluate potential effect modifiers for the EHR outcomes by expanding model (2) to include appropriate modifier-by-group interaction terms. In this context, testing whether the β coefficients of the interaction terms are equal to zero is equivalent to testing the null hypothesis that the variable of interest does not independently modify the intervention effect.

Patient and public involvement

Our partnership recognizes the importance of involving patients and other key stakeholders in our research and seeks to advance the science of community engagement through our work. Prior to launching the study, partners came together to discuss goals, objectives, roles, responsibilities, decision making, and dissemination strategies in a facilitated process that culminated in a written partnership agreement. The process of generating written agreements are a cornerstone of effective partnerships development and key for maintenance of the partnership and conflict resolution. We regularly solicit patient feedback to improve the intervention. This is done through the interactions between health coaching staff in the Behavior Pharmacy and patients, and the surveys with patients who participate in the Food Pharmacy-only arm of the intervention. Feedback from patients are discussed during regular partnership

meetings and guide ongoing operations. The partnership also receives feedback from clinic staff around the referral process and dissemination opportunities. Lastly, we developed a Community Advisory Board (CAB) made up of key stakeholders, patients, health coaches, primary care providers, food system representatives, policy experts, and healthcare payors. CAB members will play key roles in informing the implementation of the study as well as dissemination of findings.

Ethics and dissemination

Approval for this study was granted by the Stanford University Institutional Review Board (reference protocol ID 57239). Informed consent will be obtained from the Behavioral Pharmacy participants by Open Source Wellness for the surveys. Stanford research staff will obtain informed consent for surveyed participants enrolled in the Food Farmacy only. A waiver of consent was obtained to utilize EHR data for evaluation. In addition to dissemination in the scientific literature, we will provide periodic updates on study progress to the Alameda County Board of Supervisors and to other key stakeholders in Alameda County. Dissemination to the clinics will include a dashboard to provide real-time information on screening and referral rates for food insecurity, as well as update presentations. Dissemination avenues for patient participants, as well as other community members, will include periodic summaries and updates in the Dig Deep Farms newsletter.

Discussion

This study is designed to provide evidence that will inform policies relevant to addressing food insecurity and nutrition-sensitive chronic conditions in healthcare settings. There is an increased focus on addressing social determinants of health in healthcare settings due to their influence on health outcomes. As such, national, state, and local policies are increasingly supporting addressing social determinants of health as part of a comprehensive approach to healthcare. Nationally, some states are obtaining waivers that allow Medicaid funding to be used to address social needs like food insecurity that historically have not been viewed as relevant medical concerns. Additionally, states like California are considering pilot projects similar to Recipe4Health that would include a produce prescription and behavioral support for patients covered by Medicaid (Medi-Cal in California). At the local level, community health centers are increasingly implementing programs similar to Recipe4Health. The Recipe4Health evaluation incorporates stakeholder engagement into the design, implementation, and dissemination to maximize the potential that findings will have direct policy implications. Inclusion of stakeholders on the evaluation team and clinic partners and the CAB allows for identification of policy relevant outcomes, comparisons, and subgroup analyses. Additionally, stakeholders can facilitate dissemination of findings beyond the scientific literature to ensure that decision makers can incorporate findings into policies and programs.

The quasi-experimental study has important limitations. Randomization to these three groups (Food Farmacy only, Food Farmacy plus Behavioral Pharmacy, and control) would give the most rigorous demonstration of causal inference. However, randomization was not feasible for the community partners involved in this real-world implementation of a produce prescription program. Thus, a quasi-experimental design was chosen, using propensity-score matching to compare observed changes in EHR-derived outcomes in R4H participants compared to control patients in the same target population, minimizing group differences. In this kind of quasi-experimental design, the conclusions may still suffer from bias arising from imbalances in pre-intervention covariate distributions; a formal sensitivity analysis (e.g., gamma sensitivity) can be used to bound the amount of bias necessary to qualitatively change the study's "naïve" interpretation. [42] A second limitation is that while it would be ideal to collect patient-reported

outcomes from the propensity score-matched control group, our existing permissions for data access only permitted obtaining EHR data from the propensity score-matched control patients. Finally, because the design relies on available data and does not assure collection of health outcome metrics (e.g. laboratory data) at baseline and follow-up, information on some EHR outcomes may be sparse. This may be a particular issue because of an increased reliance on remote telehealth over in-person visits as a result of the COVID-19 pandemic.

Despite these limitations, the Recipe4Health evaluation will provide important preliminary evidence on the effectiveness of the program on patient-reported outcomes such as food insecurity, health behaviors, and psychosocial well-being, as well as EHR-derived outcomes, and healthcare utilization. With the support of the CAB, we will ensure that results are directly and rapidly communicated to decision makers to inform ongoing and developing programs that address food insecurity in community health centers.

Author contributions:
LGR, SC, LX, BOEA, WC, MB, and JT conceptualized and designed the study; LGR, LX, BOEA, WC, MB, and JT drafted the manuscript; SC, EN, EM, ATL, and EM critically revised the manuscript for important intellectual content; and LGR and SC obtained funding.

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Competing interests:
None

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STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No.	Recommendation	Page No.	Relevant text from manuscript
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	1 and 2	Title: Addressing Food Insecurity and Chronic Conditions in Community Health Centers: Protocol of a quasi-experimental evaluation of Recipe4Health Abstract: The goal of this quasi-experimental study was to evaluate the effectiveness of Recipe4Health, a 'Food as Medicine' program.
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	NA	
Introduction				
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	3	"To build on this growing evidence, research on the impact of the combination of produce prescriptions and group medical visits on patient-reported outcomes as well as health and healthcare outcomes is needed."
Objectives	3	State specific objectives, including any prespecified hypotheses	4	The objective of this study is to examine the effectiveness of Recipe4Health for improving health behaviors, health outcomes, and healthcare utilization among patients in

				five community health centers in Alameda County, California.
Methods				
Study design	4	Present key elements of study design early in the paper	5	This study uses a quasi-experimental design that aims to evaluate an intervention but does not use randomization and are common when randomization is not practical, ethical, or allowable
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	4	… five community health centers in Alameda County, California. The participating community health centers serve a primarily low-income population that is predominantly Latinx and Black and either underinsured or with public insurance. The data will be collected and analyzed from August 2021 to December 2024.
Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls *Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants	6	The inclusion criteria are adult patients (18 and over) in one of the five participating community health centers in one of the following three categories:
		(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed	6	We will identify up to four control patients for each

		Case-control study—For matched studies, give matching criteria and the number of controls per case		participant. We will use propensity score matching to identify a control group of patients who are as similar as possible to participating patients except they have not been offered Recipe4Health.
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	7-10	Measures section and Table 3
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	9-10	Table 3
Bias	9	Describe any efforts to address potential sources of bias	5-11	The description of the propensity score matched control group addresses potential bias.
Study size	10	Explain how the study size was arrived at	11	Sample size and power section

Continued on next page

Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	NA	This level of detail is not included in the protocol manuscript and will be included in the primary outcome manuscript.
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	11, 12	
		(*b*) Describe any methods used to examine subgroups and interactions	12	
		(*c*) Explain how missing data were addressed	12	
		(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed *Case-control study*—If applicable, explain how matching of cases and controls was addressed *Cross-sectional study*—If applicable, describe analytical methods taking account of sampling strategy	NA	
		(*e*) Describe any sensitivity analyses	NA	
Results – Given that this is a protocol manuscript, the information on results is not relevant.				
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	NA	
		(b) Give reasons for non-participation at each stage	NA	
		(c) Consider use of a flow diagram	NA	
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	NA	
		(b) Indicate number of participants with missing data for each variable of interest	NA	
		(c) *Cohort study*—Summarise follow-up time (eg, average and total amount)	NA	
Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time	NA	
		Case-control study—Report numbers in each exposure category, or summary measures of exposure	NA	
		Cross-sectional study—Report numbers of outcome events or summary measures	NA	
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	NA	
		(*b*) Report category boundaries when continuous variables were categorized	NA	
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	NA	

Continued on next page

Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	NA
Discussion			
Key results	18	Summarise key results with reference to study objectives	NA
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	NA
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	NA
Generalisability	21	Discuss the generalisability (external validity) of the study results	NA
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	14

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.