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Addressing food insecurity and chronic conditions in community health centres: 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 centres in the USA. Community health centres are increasingly implementing 'Food as Medicine' programmes 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' programme. Recipe4Health includes two components: (1) a 'Food Farmacy' that includes 16 weekly deliveries of produce and (2) a 'Behavioural 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 Behavioural Pharmacy (n=140). The primary outcome, fruit and vegetable consumption, and secondary outcomes (eg, 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 healthcare usage. 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 deidentified 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 centres that serve diverse patient populations.
⇒ The quasi-experimental design will provide evidence of effectiveness of Recipe4Health on food insecurity, health behaviours, health outcomes and healthcare usage.
⇒ 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 characterised 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, neighbourhoods characterised by lower socioeconomic status have a significantly higher prevalence of diabetes compared with more affluent neighbourhoods.[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 Programme (SNAP, or 'food stamps') has existed in the USA 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 emphasise 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 centre patients randomised to receive a subsidised 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 randomised to receive a financial incentive equal to the cost of the subsidy. Although there were improvements in patient-reported outcomes (eg, quality of life, depressive symptoms) and other health indicators (eg, body mass index, blood pressure, glucose, lipid levels) among those randomised to receive the box compared with those who received the financial incentive, the differences were not statistically significant.[15]

There is little evidence regarding the impact of produce prescription programmes in combination with other strategies aimed at behaviour change. One study of a programme 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 4 months. Among those with pre-existing hypertension, there was a significant decrease in systolic blood pressure from 146.1 mm Hg at baseline to 129.9 mm Hg at 4 months and among those with depression, a significant decrease in depressive symptoms from 14.5 at baseline to 7.7 at 4 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 well-being.[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 programme and a group medical visit, for improving health behaviours, health outcomes and healthcare usage. This study will significantly add to the existing literature on the effect of produce prescription programmes on nutrition, health and healthcare usage outcomes.

METHODS AND ANALYSIS

The objective of this study is to examine the effectiveness of Recipe4Health for improving health behaviours, health outcomes and healthcare usage among patients in five community health centres in Alameda County, California. The participating community health centres 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 analysed 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 centres; Open Source Wellness, a non-profit organisation and Dig Deep Farms, a local farm. Recipe4Health began in Fall 2019 as one of nine produce prescription programmes funded by the US Department of Agricultural Gus Schumacher Nutrition Incentive Programme. Recipe4Health includes two components: (1) Food Farmacy: 16 weekly deliveries of organic produce and (2) Behavioural Pharmacy: weekly group medical visits for 4 months. Adult patients (age 18 and older) can be referred to the Food Farmacy with or without the Behavioural Pharmacy based on discussions with the patient.

All clinic staff receive a minimum of 2 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 did not last and we did not have money to get more.[22] Staff that prescribe Recipe4Health to patients, including primary care providers, behavioural health providers, nurses, diabetes educators and registered dieticians, receive an additional 8 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 (eg, obesity, pre-diabetes, 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 Behavioural Pharmacy.

Food Farmacy: The Food Farmacy is provided by Dig Deep Farms, a social-enterprise programme 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

Table 1 Recipe4Health Behavioural Pharmacy implemented by Open Source Wellness

Weekly components	Session time	Behavioural targets	Description and examples
Group physical activity	20–30 min	Physical activity, social connection	► Playful, socially engaging physical activity accessible to various physical ability/mobility levels
Mindfulness meditation	5–10 min	Stress reduction	► Different mindfulness techniques are introduced: – Breath-focused – Gratitude – Progressive muscle relaxation ► Walking meditations
Interactive lesson on varied health topics	10–20 min	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 ► Behaviour change (eg, SMART goals)
Nutrition lesson incorporating Food Farmacy produce of the week	5–10 min	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 min	Includes all four targets: healthy eating, physical activity, stress reduction, social connection	► Participants write their personal behaviour goal for that week (eg, drink one glass of water instead of one can of soda per day, walk 30 min four 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 behaviours

such as collards, rainbow chard, kale, beets, green onions, zucchini and lemons.

Behavioural Pharmacy: Open Source Wellness implements a 4-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 Behavioural Pharmacy targets four behaviours: 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 behaviour goals.

Study design

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

- Within-group pre/post analysis of patient-reported and EHR-derived outcomes for patients in the: (1) Food Farmacy and (2) Food Farmacy plus Behavioural Pharmacy.
- Comparison of pre/post outcomes between patients in the: (1) Food Farmacy and (2) Food Farmacy plus Behavioural Pharmacy.
- Comparison of EHR outcomes between patients in the: (1) Food Farmacy only; (2) Food Farmacy plus Behavioural 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 with those who are also participating in the Behavioural Pharmacy. The comparison of EHR-derived outcomes among Recipe4Health participants compared with 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 Behavioural 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 vrsus those who attend fewer sessions.

Participants

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

- Patients enrolled in the Food Farmacy with and without the Behavioural Pharmacy who have completed baseline and follow-up surveys.
- Patients enrolled in the Food Farmacy with and without the Behavioural Pharmacy who have available EHR data for baseline and 6-month or 12-month follow-up.
- Patients who are not enrolled in the Food Farmacy or Behavioural 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 Behavioural 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 Behavioural 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 Recipe-4Health. This use of matching is an example of matching as non-parametric preprocessing as argued by Ho *et al*.[24] This matching design has two-levels: (1) 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; (2) 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 programme (d=1) or a facility that did not offer the programme (d=0). The propensity score matching will seek to balance relevant sociodemographic (eg, age, race/ethnicity, sex), clinical characteristics (eg, 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 programmes, and health outcomes (eg, HbA1c, low-density lipoprotein cholesterol) (table 2). The propensity score uses the past 18 months of data.

Due to computational limits given the size of the data sets (eg, 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.
BMI, body mass index; HDL, high-density lipoprotein; LDL, low-density lipoprotein.

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 Behavioural 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 optimisation 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 behaviours (eg, physical activity[30]), mental health (eg, 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 (eg, HbA1c, blood glucose, lipid levels), relevant indices calculated from laboratory data (eg, HOMA-IR as an estimator of insulin resistance), medication use and healthcare usage (eg, emergency department (ED) visits, hospitalisations).

Survey measures

We will collect data at baseline and 4 months (immediately postintervention). 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 Behavioural Pharmacy prior to the first meeting and monthly including after the final meeting at 4 months. The monthly surveys for the Behavioural Pharmacy are to guide treatment. Surveys will not be collected from control participants.

EHR measures

Participating community health centres in Recipe-4Health use the OCHIN EHR.[35] Community Health Center Network, a consortium of community health centres 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-month 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 4 months prior to referral and 1 month after, and for the 6-month and 12-month time points, the allowable window will be 3 months before and after. Prescribed medications and healthcare usage (eg, ED visits, hospitalisations, no shows) will be summarised 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 (eg, age, race/ethnicity, clinic site) and relevant conditions from EHR such as obesity, hypertension, diabetes, pre-diabetes, depression.

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 Behavioural 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 Behavioural Pharmacy and control at α=0.025 (two-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 (two-sided).[37] This assumes at least 85% retention at 4 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 categorise these as exploratory analyses and provide guidance here on our anticipated precision. Based on prior enrolment 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 (ie, 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 $0.022*\sigma$, 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 $0.088*\sigma$. 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

Table 3 Outcomes, potential effect modifiers and intervention engagement measures

Outcomes	Measures or source	Baseline	Follow-up	Food Farmacy	Food Farmacy+Behaviour 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	Generalised 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[8]			X	X	X
Depressive symptoms	Nine-item Patient Health Questionnaire (PHQ-9) in EHR[5]			X	X	X
	Two-item Patient Health Questionnaire (PHQ-2) in EHR[5]			X	X	X
Anxiety disorder	Generalised Anxiety Disorder 7-Item (GAD-7) scale in EHR[6]			X	X	X
Prescribed medications	EHR prescription	12 months prior to referral	12 months prior to referral	X	X	X

Continued

Table 3 Continued

Outcomes	Measures or source	Baseline	Follow-up	Food Farmacy	Food Farmacy+Behaviour Pharmacy	Control
Emergency department visits	EHR emergency visits	12 months prior to referral	12 months after referral	X	X	X
Hospitalisation (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, pre-diabetes, 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	

*If patient cannot be reached before the first delivery, research staff attempt to contact until the third delivery.
BMI, body mass index; EHR, electronic health record; HDL, high-density lipoprotein; ICU, intensive care unit; LDL, low-density lipoprotein.

record number) and the deidentified 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 (Behavioural 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 Behavioural Pharmacy, and difference between within group changes of these two intervention groups using the following model:

$$Yt = \beta 0 + \beta 1Y0 + \beta 2XT + \beta 3 \times C + \varepsilon \quad (1)$$

Let Yt be the change of participants' postintervention values of the outcome variable at month T (1, 2, 3 or 4) from baseline to arm X (ie, X=1 for Food Farmacy+Behavioural 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 (eg, 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 generalised 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 Behavioural 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:

$$Yt = \beta 0 + \beta 1X1 + \beta 2X2 + \beta 3Y0 + (\beta 4 + \beta 5X1 + \beta 6X2)T + c + \nu + \varepsilon \quad (2)$$

Let Yt be the change of participants' postintervention values of the outcome variable at time T (6 or 12 months) from baseline to arm X1 or X2 (ie, X1=1 for Food Farmacy+Behavioural 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 ν 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 usage (ED visits and hospitalisation), we will use generalised linear mixed models[38–40] assuming a Poisson distribution for count outcomes (eg, number of ED visits and hospitalisations for each patient in 12 months postbaseline) and a binomial distribution for binary outcomes (eg, medication dose reduction in 12 months postbaseline). 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 modelling.[41]

We will also conduct exploratory subgroup analyses (eg, 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 recognises 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 Behaviour 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. Finally, 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 Behavioural 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 use 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 behavioural support for patients covered by Medicaid (Medi-Cal in California). At the local level, community health centres are increasingly implementing programmes similar to Recipe4Health. The Recipe4Health evaluation incorporates stakeholder engagement into the design, implementation and dissemination to maximise 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 programmes.

The quasi-experimental study has important limitations. Randomisation to these three groups (Food Farmacy only, Food Farmacy plus Behavioural Pharmacy, and control) would give the most rigorous demonstration of causal inference. However, randomisation was not feasible for the community partners involved in this real-world implementation of a produce prescription programme. Thus, a quasi-experimental design was chosen, using propensity-score matching to compare observed changes in EHR-derived outcomes in R4H participants compared with control patients in the same target population, minimising group differences. In this kind of quasi-experimental design, the conclusions may still suffer from bias arising from imbalances in preintervention covariate distributions; a formal sensitivity analysis (eg, 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 (eg, 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 programme on patient-reported outcomes such as food insecurity, health behaviours and psychosocial well-being, as well as EHR-derived outcomes, and healthcare usage. With the support of the CAB, we will ensure that results are directly and rapidly communicated to decision makers to inform ongoing and developing programmes that address food insecurity in community health centres.

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