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Providing medically tailored groceries and food resource coaching through the charitable food system to patients of a safety-net clinic: a randomized controlled trial protocol

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Title: Providing medically tailored groceries and food resource coaching through the charitable food system to patients of a safety-net clinic: a randomized controlled trial protocol

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Strengths and limitations:

A strength of this study includes the use of a randomized controlled trial (RCT) design with participants randomized to one of three groups – usual food pantry services (control), medically tailored groceries (MTG) (intervention 1), and MTG coupled with food resource coaching (intervention 2) to isolate the impact of each layer of support. A long-term partnership with a non-profit community food assistance organization, Crossroads Community Services (hereafter Crossroads), enables the study's program implementation and serves as another core strength. Food is medicine (FIM) programs typically require purchasing intervention food resources, such as medically tailored food obtained from a retailer. In contrast, implementing FIM programming by leveraging existing food assistance organizations' inventory may be more sustainable in the long-term, as participants can continue receiving services at study end. Lastly, recruitment through a local safety-net clinic in the Southern sector of Dallas reaches African American or Black and Hispanic or Latino(a) community members with lower-income, groups that are most impacted by food insecurity and diet-sensitive health disparities[1-4] and may therefore most benefit from participating in FIM interventions.

The limitations include the inability to fully mask study groups to which participants have been assigned. While study arms will be masked for outcomes assessors, the team members implementing services and participants cannot be masked due to the nature of the interventions - participants know if they receive coaching or not. The current lack of information on novel intervention effects on outcomes of interest (e.g., food selections from the pantry, dietary quality) serves as an additional challenge. We estimate that with a sample size of 210 people (70 per group), the study is powered to detect a small interactive group by time effect (f=0.11) on measures taken at baseline and follow-up. However, the effect size produced by these interventions is currently unknown, and the possibility of high participant dropout could render the study underpowered to detect small effects.

Introduction:

Over 10% of households in the United States and over 17% of households with children experienced food insecurity in 2022,[5] and food insecurity increases the risk of adverse health outcomes.[6,7] Simultaneously, there is a rise in chronic, diet-sensitive diseases that dominate healthcare spending in the United States (e.g., type-2 diabetes, high cholesterol, obesity, and cardiovascular disease).[8,9] The emerging FIM movement[10] seeks to use nourishing food in combination with other medical treatments to advance the prevention, management, and treatment of diet-sensitive disease. For food insecure communities, FIM strategies may have the potential to increase food security and improve related health conditions.[11,12]

FIM strategies range from population level healthy food programs that provide education (e.g., USDA's MyPlate) and food access (e.g., Supplemental Nutrition Assistance Program (SNAP) or Women Infants and Children (WIC)), to more intensive provision of medically tailored foods through prepared meals, nutrition expert-guided selection of groceries, and produce provision alongside educational interventions.[12-14] The integration of these programs varies widely and addressing health-related food needs for populations that experience food insecurity introduces additional complexity.[15-18] There is growing evidence that health system partnerships with community organizations that have food assistance expertise, such as food banks and pantries, offer a pathway for long-term sustainability of FIM and the agility to pivot strategy based on local needs and preferences.[19-21]

Our study will be implemented in partnership with Crossroads, which operates a high-capacity, client-choice pantry and is the largest non-profit food redistributor in the North Texas region. In alignment with the types of services provided by pantries, we will implement a MTG FIM strategy within the pantry context. MTG's will be identified from Crossroads' inventory, which is selected from the bulk inventory secured by the North Texas Food Bank. We also have a small amount of funding to purchase supplemental grocery items when MTG items are not available from the food bank. We will report on the proportion of total MTG food that is secured

through the normal pantry distribution systems compared to the food that is purchased from retailers.

At Crossroads, households are allocated points based on the dietary requirements of household members. Points act as a form of currency such that the amount of food each household gets at each monthly visit is enough for 21 meals for each household member up to a maximum of 500-points (five household members).[22] This 500-point maximum was put into place to ensure equity in the availability of product for all shoppers seeking services, as the need for food access continues to grow and challenges were presented with supply when large households received larger quantities of food (e.g., 1200 points). While the use of a point system such as the one used at Crossroads is not necessary for implementation of MTG, the MTG approach we investigate is meant to be implemented within the context of a client-choice pantry that scales allotments with household size. Scaling food allocations by household size is the standard model employed by high-capacity, evidence-based pantries in the US.[23]

MTG consists of minimally prepared foods that might be offered in a pantry setting but are carefully selected to support health goals. In some cases, MTG may require a shift in typical pantry inventories so a full mix of healthy foods can be offered. The MTG food must be prepared by the patient or caregiver at home, ideally promoting self-efficacy in health-promoting food preparation. Also called medically tailored food packages or boxes, these groceries combine ingredients across food categories to optimize a nutritionally complete dietary pattern.

While some evidence exists to support the theory and process for medically tailoring groceries,[24-28] evidence is generally lacking regarding how MTG can be provided at the household level and the proper 'dosing' in the context of food insecure households.[10] In our intervention, the quantity of MTG provided is scaled with the size of the patient's household. Food insecurity is a household-level condition and food pantries "treat" food insecurity at the

household-level. Thus, it seems plausible that FIM strategies that intend to address both diet quality and food security should also adopt a household-level framing.

Another strategy we are testing as a complement to MTG is food resource coaching. Since 2020, Crossroads, Ascend Dallas (a local non-profit leader in financial coaching), and co-author TL have been developing F3: From Food to Finances, a novel food resource coaching program that provides Crossroads shoppers with training in securing resources to promote food, nutrition, and economic security. To our knowledge, the food resource coaching intervention is novel, and no peer-reviewed publications have explored the impact of food resource coaching in a no-cost food pantry or clinical setting. However, other researchers have explored using financial resource coaching in a clinic setting,[29,30] which served as a model for the development of food resource coaching. Therefore, we hypothesize that patients receiving MTG and coaching in our study will have the greatest improvements in patient engagement, adherence, and dietary quality over the study period.

Our study objectives include execution of a between-group, repeated measures RCT to identify feasibility and early-stage effectiveness of recruiting patients with lower income and at least one diet-related chronic disease (N=210) from Parkland Health, a large safety-net health center. Participants are randomly assigned to one of three groups: 1) usual pantry services which includes food for up to 21 meals for up to five people in the household, 2) pantry services with MTG, and 3) pantry services with MTG and monthly one-on-one food resource coaching sessions.

In addition, we aim to describe our collaborative process for defining MTG from a pantry meeting the needs of a local community experiencing food insecurity and co-located with the safety-net health center. First, we evaluated common evidence-based dietary patterns to identify a pattern with broad applicability to multiple chronic diseases and feasible application within an MTG intervention aligned with low-cost food assistance programs. Next, we sought to apply the dietary pattern in a pantry setting where inventories are limited and fluctuating, and

people have diverse cultural and personal food preferences. Finally, we aimed to pragmatically design and develop an MTG program rooted in pantry inventory data. This manuscript describes both the study protocol and aspects of our protocol for implementing medically tailoring groceries and food resource coaching in a food pantry.

Methods and analysis

We use SPIRIT reporting guidelines, which are uploaded as a supplement.[31]

Recruitment

Recruitment takes place via multiple routes. Providers and other healthcare staff at the Parkland C.V. Roman Health Center, a community safety-net primary care clinic, make referrals to the study via recruitment fliers posted in patient exam rooms and discussion about the study with patients. Second, the study staff send approved emails to potentially eligible patients. These emails inform patients of the study occurring at their clinic and provide contact information to learn more. The main recruitment method employed is in-person tabling at clinic entry. The recruitment team sit at a table in the lobby Monday, Wednesday, and Friday and introduce the study to patients, screening anyone interested. The team shares fliers with a QR code, linking patients to the eligibility screener where they can submit their information on their personal device. The team also has tablets that patients can use to complete the eligibility screener if preferred. Alternatively, if an interested patient has limited time and is unable to complete while onsite, they can take a recruitment flier and fill out the screener at their convenience.

Eligibility criteria

A participant must be: a patient at the C.V Roman Health Center, over the age of 18, have reliable transportation, be eligible for TEFAP (earn less than 185% of the federal poverty threshold, self-report), diagnosed with at least one of three diet-related chronic disease categories (dyslipidemia, hypertension, or diabetes, verified in EHR), have no illnesses, allergies, or sensitivities that severely limit what they can eat (e.g., put them at risk from

consuming food from the pantry), live in one of the 18 ZIP codes served by Crossroads that surround the local safety net clinic, be able to give informed consent, and willing to fully participate.

Randomization

Two randomization tables with equal group allocation using Excel are created by a team member that is not involved with participant recruitment, consent, or data collection. The randomization tables are uploaded into RedCap, one for "development" (e.g., survey testing) and one for "production" when data collection begins. The team members executing randomization in RedCap are unaware of which group each participant will be randomized to until they execute the instrument to assign a group.

Study setting

Once patients are recruited, consented, and complete the baseline questionnaire, they are randomized into one of the three study groups and scheduled for their first pantry appointment. This pantry is co-located within a connected one million square foot commercial retail complex, on the other side of the building from the Parkland clinic. The pantry is within a renovated storefront near the complex entrance and is approved by the City of Dallas Department of Health for storing and distributing food to community members.

Usual pantry services (control group)

All participants that use Crossroads pantry receive food for up to 21 meals for up to five people in the household. We have estimated that a family of four receives approximately $250 USD worth of groceries from Crossroads each month. Appointments at Crossroads are monthly. When participants arrive at Crossroads, they complete a process called "intake, survey, and order". At intake, Crossroads staff collect household demographics to confirm pantry eligibility, which is set by The Emergency Food Assistance Program (TEFAP) guidelines[32] and to allocate household points for pantry shopping. At the beginning of the shopper's appointment their next

appointment is scheduled, as authors TL and SP have found that appointments encourage pantry attendance.[33]

After intake is completed, shoppers are asked to answer a brief survey module. There are 4 different survey modules that rotate, to maximize the amount of information obtained to improve pantry services while minimizing shopper survey burden. The order process is completed using Salesforce®. The Salesforce® interface displays the picture and description of each item currently available in the pantry and the number of points the item costs. Crossroads pantry allocates points based on an algorithm that follows 2015-2020 dietary guidelines for recommended intake based on the age, sex, and activity level of each person in the household. Participants can select any food items until they use all their allocated points. With the exception that there are some inventory restrictions in place depending on the amount of inventory available for an item in each week (e.g., up to three pounds of onions, up to two pounds of almonds) as availability may fluctuate. After shoppers make their grocery selections on the computer, their grocery list is printed and they select items off the shelves, which is set-up like a small grocery store. The process of making food selections prior to shopping reduces congestion in the small grocery area, allowing Crossroads to serve more shoppers. After selecting all items on their list, shoppers check out with pantry staff or volunteers, have their groceries bagged, and exit the pantry.

Recipes are always available to Crossroads shoppers at the main market and are available to the control group in this study as well. Recipes are in a labeled box on top of the desk that is visible to the shopper and if a shopper asks for recipes, they are provided, but they are not explicitly introduced by a team member.

Medically tailored groceries (intervention one)

A community-academic partnership team including a culinary medicine (CM)-trained registered dietitian (MS), a CM-trained physician (JA), a public health nutrition and behavioral scientist (KHH), a health economist (TL), and pantry leadership (AF, BS), collaborated to

identify an evidence-based dietary pattern and apply that pattern to groceries provided within the charitable food system. Rooted in an existing evidence-based dietary pattern and scoring system for individual consumption and household grocery purchases,[28,34,35] our team developed a simple, pragmatic model to medically tailor groceries from the pantry using the Dietary Approaches to Stop Hypertension (DASH) dietary pattern recommendations. The DASH dietary pattern emphasizes fruits, vegetables, whole grains, legumes, nuts, and low-fat dairy while limiting added sugars, sodium, and red and processed meats. DASH was selected given extensive evidence for the dietary pattern's efficacy improving a variety of preventable chronic diseases, including those which are a focus of this study.[34,36,37] Notably, this overall model for medically tailoring pantry groceries also aligns with the American Heart Association's recent scientific statement on popular dietary pattern alignment with health recommendations, the 2020-2025 Dietary Guidelines for Americans,[38] and the EAT Lancet Commission's report[39] on optimizing nourishing dietary patterns and supporting planetary health and sustainability.

The team applied the food category principles of the DASH diet to score foods available in the pantry's inventory over the prior year on a scale of one-five based on alignment with the DASH diet and a) high nutrient density; b) balanced energy intake; c) chronic disease prevention and management; d) affordability, and e) sustainability. In the five-point scoring system, a five represents the highest recommendation for nutrient density and contribution to a dietary pattern associated with disease prevention and health promotion.[40] Rather than defining a precise number of servings per category or specific windows of sodium, added sugar, or other nutrients, the team developed a universally applicable strategy described in detail in the following paragraph to encourage the dietary pattern that will optimize nutrition. Specific tailoring to precise intake of certain nutrients requires ongoing engagement with a registered dietitian nutritionist, which is beyond the scope of most charitable food organizations. Our proposed approach balances practical implementation constraints and supports most people seeking to

prevent or treat diet-sensitive conditions including cardiometabolic diseases, many cancers, and obesity. Furthermore, as food insecurity is a household-level condition, the provision of foods that align with nutritious categories in an overall pattern supports the reality of household distribution of food.

We designed the MTG carts to include only food scoring in the higher point categories (4 or 5 points). Table 1 includes our proposed MTG scoring categories, which were developed by evaluating available pantry inventory against the DASH dietary pattern recommendations. To implement the MTG grocery carts, we use the pantry's client-choice model whereby shoppers select food from the pantry within a given number of points that are allocated to them based on household size. Shoppers in the MTG group are shown a grocery cart with at least 50% of their point allocation prepopulated with MTG items in their cart. Shoppers can remove MTG items and add additional items if they choose. MTG categories and products provided are the same for all participants. The quantity of MTG products populated is the same for household sizes of one or two people, quantity is doubled for household sizes of three or more people. Table 2 includes a sample MTG cart based on a household size of two people. Figure 1 shows a visual depiction of how the MTG are implemented in Crossroads Salesforce® inventory system with part of a prepopulated MTG cart. This approach combines expertise in applying nutrition as part of a medical treatment or prevention plan, linking prescribed groceries to a culinary lens of utility and complementary food pairings, and a pragmatic understanding of food preferences of our target communities based on data collected from pantry shoppers.[41,42]

Table 1. Medically tailored groceries (MTG) scoring categories

Score	Food Categories/Examples	Notes
5	Vegetables and Fruits	Fresh or frozen (no sauce)
	Legumes (e.g., lentils, beans, peas)	Dried, canned, or frozen
	Whole Grains (e.g., oats, brown rice, quinoa)	Minimally processed

	Nuts and seeds (e.g., walnuts, pecans, almonds, pepitas)	Unsalted/unflavored, raw
	Seafood (e.g., cod, salmon, shrimp)	Fresh or frozen
4	Seafood (e.g., tuna, salmon)	Canned
	Whole grain pastas, breads	Minimal added sugar, sodium
	Canned vegetables and fruits	Minimal added sugar, sodium
	Minimally processed lean poultry (chicken, turkey)	Fresh, frozen, or canned
	Eggs	
3	Minimally processed lean animal protein (90% lean beef, lamb, venison, pork tenderloin)	Fresh or frozen
	Reduced fat dairy (e.g., yogurt, cheese, milk)	No added sugars
	Salted or flavored nuts	Added sodium, sugar
2	Minimally processed animal protein, *not lean* (e.g., beef, pork)	High saturated fat content
	100% fruit juices	High natural sugar content
	Lower sugar breakfast cereals (e.g., shredded wheat)	Added sugar content
	Mixed meals that do not feature vegetables or legumes	Added sodium
	Full fat dairy (including cream, cheese)	High saturated fat content
	Bread, pasta, crackers, rice (non-whole grain)	Added sodium
1	Desserts (candies, cookies, cakes, ice cream, etc.)	High added sugar
	Sugar-sweetened beverages (including many juices)	High added sugar
	Sweetened breakfast cereals	High added sugar
	Ultra-processed snack foods (e.g., chips, snack bars)	High added sodium, sugar
	Ultra-processed breakfast meats (e.g., sausage, bacon)	High added sodium, sat fat
	Ultra-processed cheese	High added sodium, sat fat

Table 2. Sample medically tailored grocery (MTG) cart for household size of 2

MTG Category	Sample MTG Products*	MTG Points

Three whole grains (e.g., brown rice, quinoa, couscous, whole wheat pasta, corn tortilla, oatmeal)	1 Brown rice	4
Three whole grains (e.g., brown rice, quinoa, couscous, whole wheat pasta, corn tortilla, oatmeal)	1 Oatmeal	3
Three whole grains (e.g., brown rice, quinoa, couscous, whole wheat pasta, corn tortilla, oatmeal)	1 Oatmeal	3
Three beans or legumes (canned or bagged)	1 Can Pinto Beans	4
Three beans or legumes (canned or bagged)	1 Can Lentils	8
Three beans or legumes (canned or bagged)	1 Can Red kidney beans	4
Four canned or frozen vegetable (e.g., no salt added green bean, corn, peas, mixed veg, collard greens, diced tomatoes)	1 Can corn	3
Four canned or frozen vegetable (e.g., no salt added green bean, corn, peas, mixed veg, collard greens, diced tomatoes)	1 Can mixed vegetables	3
Four canned or frozen vegetables (e.g., no salt added green bean, corn, peas, mixed veg, collard greens, diced tomatoes)	1 Can peas	4
Four canned or frozen vegetables (e.g., no salt added green bean, corn, peas, mixed veg, collard greens, diced tomatoes)	1 Frozen broccoli	3
Four canned or frozen fruits (e.g., no sugar added pears, peaches, applesauce, pineapple, mixed)	1 Can pear	4
Four canned or frozen fruits (e.g., no sugar added pears, peaches, applesauce, pineapple, mixed)	1 Can peaches	4
Four canned or frozen fruits (e.g., no sugar added pears, peaches, applesauce, pineapple, mixed)	1 Can peaches	4
Four canned or frozen fruits (e.g., no sugar added pears, peaches, applesauce, pineapple, mixed)	1 Can mixed fruit	4
Two fresh vegetables	1 one lb. bag of carrots	4
Two fresh vegetables	1 one lb. bag of onions	4
Two fresh fruits	1 one lb. bag of apples	8
Two fresh fruits	1 Cantaloupe	8
Nuts or seeds	1 two lb. bag of almonds	8
Canned lean proteins (e.g., chicken, fish, salmon)	1 Can salmon (3-5 servings)	4
Canned lean proteins (e.g., chicken, fish, salmon)	1 5 lb. bag frozen chicken thighs	15
Eggs or eggbeaters	1 Eggbeaters (8-9 servings)	4
	Total points MTG	110
	Total points allocated	210
	Percentage MTG	52%

Participants in the MTG group have recipes handed to them directly rather than having to ask for recipes. The team running appointments is trained not to discuss recipes at length as to not contaminate this group with coaching.

Medically tailored groceries + food resource coaching (intervention two)

Participants in this group receive the same MTG intervention described in the section above and food resource coaching. Food resource coaching is led by trained Crossroads and UTSW staff. Coaches are trained in coaching methodology by experts at Ascend Dallas (40 hours of in-person training), a premier financial coaching organization supporting community members since 1908. Ascend training is then coupled with training intended to translate coaching methodology to the context of nutrition and resource coaching for households experiencing food insecurity (80 hours of in-person training). Once trained, coaches have a period of intense mentorship whereby they conduct coaching appointments in close consultation with established resource coaches for their first one-two weeks of coaching. The mentorship continues after coaches are fully trained and working independently to ensure ongoing support and identification of ways in which the coaching experience can be more impactful for shoppers.

In this study, the coaching intervention takes place over four monthly sessions. In each session, shoppers meet with the resource coach in-person as part of their visit to the community market prior to making food selections. Shoppers self-direct the focus of their coaching based on their self-selected goals, which means sessions may focus more heavily on achieving nutritional goals or financial goals depending on the person. Examples of coaching content all participants receive include training in meal planning, developing a monthly food budget, and how to access additional food and social resources (e.g., SNAP enrollment, discount retailers).

After coaching is completed, shoppers proceed to order groceries through the Salesforce® inventory application with their coach. The coach explicitly identifies the MTG, explains how the items align with healthy dietary recommendations for people with chronic diseases, and shares twelve recipes each month that incorporate MTG items. At the end of the

four-month MTG + coaching intervention, shoppers are invited to continue to more in-depth financial coaching or resource coaching programs that are available at the flagship Crossroads location, a seven-minute drive from where the FIM intervention is located.

Criteria for Discontinuing

This study is minimal risk, therefore, there are no safety-related stoppage criteria. Participants in all groups are informed in the consent form that they can choose not to answer any question that makes them uncomfortable and can discontinue participation any time.

Strategies to Improve Retention and Adherence

To improve retention and adherence, participants are provided with physical appointment cards and sent text messages with their pantry appointment date and time immediately after making the appointment and the day prior. Participants receive $15 USD in the form of a gift card after completing the baseline questionnaire and another after completing the month four pantry appointment. Subject matter experts that reviewed the study on behalf of the funder recommended a bonus payment to encourage adherence and data collection, therefore, participants receive a $15 bonus payment if they complete all appointments and study activities (e.g. questionnaires).

For participants that no show pantry appointments, daily attempts are made to reschedule the appointment within the week of the missed appointment. Weekly attempts are made to reschedule the participant throughout the four-month intervention period thereafter. If participants completely miss a month, the next time they return they receive those months services. For example, if a participant misses month two, and returns to the pantry in month three, they only have month three and four services left and would take the follow-up questionnaire at the end of month four as planned. There are no limits to the number of times a participant can reschedule their appointment, however, they can only reschedule during the four-month intervention period + 10 days.

Participants are contacted through their indicated preferred method of contact first (text, call, email). However, if they continue to be unreachable using their preferred method of contact and they have provided another method, after two weeks of attempt to contact, the team will attempt to use another method.

Timeline

The participant timeline of enrollment, interventions, and assessments is included in **Table 3**.

Table 3. Participant timeline of enrollment, interventions, and assessments

	STUDY PERIOD						
	Enrollment	Allocation	Post-allocation				Close-out
TIMEPOINT	$-t_1$	0	t_1	t_2	t_3	t_4	t_x
	ENROLLMENT:						
Eligibility screen	X						
Informed consent	X						
Allocation		X					
	INTERVENTIONS						
Usual pantry services			←	—	—	→	
MTG*			←	—	—	→	
MTG* + food resource coaching			←	—	—	→	
	ASSESSMENTS						
Demographics, address, diagnosis	X						
Intervention feasibility, adherence, satisfaction, fidelity			←	—	—	—	→
Nutrition security, food security, perceived diet quality, diet quality, cooking and food provisioning self-efficacy and food agency, general	X						X

self-efficacy, loneliness, adaptive capacity, wellbeing							

*MTG=Medically tailored groceries, t=Month

Measures

All quantitative measures collected as part of this study are described and cited in **Table 4**.

Table 4. Study Measures

Item or measure	Description	Measure Citation
Participant characteristics		
Demographic characteristics	Self-report survey age (continuous), gender (categorical: female, male, other), ethnicity (categorical: Hispanic or Latino(a), not Hispanic or Latino(a)), race (categorical: African American or Black, Asian, Native American, American Indian, or Alaskan Native, Pacific Islander, Samoan, or Hawaiian, Multiethnic or mixed or more than one race or ethnicity, White), education (continuous, years), employment (categorical: full-time, part-time, unemployed looking for work, unemployed not looking for work, receiving disability payments, retired, home maker, student, temporarily laid off), financial assistance (categorical includes all federal assistance programs), income (categorical: less than $10,000 through more than $100,000 USD), health insurance (categorical: Insurance through a current or former employer or union, insurance purchased directly from an insurance company, government medical insurance, TRICARE, VA, Indian Health Service, Other), household makeup (count: number and age of each person living in the household).	N/A
Address	Self-report survey street address, city, state, and ZIP code	N/A
Diagnosis	Participants are asked to self-report if they have one of three chronic disease types (e.g., high blood pressure, diabetes, dyslipidemias) in the eligibility screener. If a chronic disease is reported, the	N/A

	diagnosis is confirmed in the Epic electronic health record.	
Primary outcomes – Intervention feasibility, adherence, and satisfaction		
Intervention feasibility – recruitment and retention	Feasibility includes the number of people screened, eligible, enrolled, and completed which is tracked through RedCap and excel spreadsheets by the study team. Recruitment is calculated as the number of people enrolled divided by the number of people screened. Retention is calculated as the number of people that completed the study divided by the number of people that enrolled.	Jacques RM, Ahmed R, Harper J, et al. Recruitment, consent and retention of participants in randomised controlled trials: a review of trials published in the National Institute for Health Research (NIHR) Journals Library (1997-2020). BMJ Open. 2022;12(2):e059230. Published 2022 Feb 14. doi:10.1136/bmjopen-2021-059230
Intervention adherence – appointments completed	Adherence includes the number of participants that attend each appointment as set, the number of appointments rescheduled, and the percentage of monthly appointments completed. Data is recorded in and extracted from the pantry's Salesforce® system.	New measure
Intervention adherence – selection of MTG	The proportion of points allocated to MTG items in the prepopulated cart and the proportion of points allocated to MTG items in the final cart after shoppers have made their desired adjustments. Data is recorded in and extracted from the pantry's Salesforce® system.	New measure
Intervention fidelity – recipes	Use of the study recipes – "Did you use the recipes provided from the market?" Categorical: Yes, no, didn't notice any recipes response options. Asked of all groups in a self-report survey at follow-up.	Adapted from: Hollis-Hansen K, Tan S, Bargnesi S, et al. Feasibility and implementation of a grocery shopping intervention for adults diagnosed with or at-risk for type 2 diabetes. Public Health Nutr. 2023;26(10):2118-2129. doi:10.1017/S1368980023001453
Intervention satisfaction – General	General intervention satisfaction is measured by asking "How likely is it that you would recommend this program to a friend of colleague?" from a scale of one (very unlikely) to 10 (extremely likely). Asked of all groups in a self-report survey at follow-up.	New measure
Intervention satisfaction – Pantry services	Five-item food satisfaction survey (e.g., "The food has been helpful" "The food provided was food my household likes to eat") with a four-point Likert scale (Strongly agree to strongly disagree). Asked of all groups in a self-report survey at follow-up.	Adapted from Dunmire M. Level of Satisfaction Among Food Pantry Clients, Staff/Volunteers, and Directors and its Association with Client Choice in Food Pantry Layouts South Dakota State University; 2019.
Intervention satisfaction – food resource coaching	Coaching satisfaction is measured among those randomized to receive it using five-items (e.g., "the sessions with the coach were helpful" "the information provided by the coach was easy to understand") and a	New measure

	four-point Likert scale (Strongly agree to strongly disagree). Asked of group receiving food resource coaching only in a self-report survey at follow-up.	
Exploratory outcomes		
Nutrition security	Nutrition security is a validated measure of a household's perceived ability to acquire nutritious foods. The outcome is the mean of the four items scored from 0 (if the participant selects "Always") to 4 (if the participant selects "Never"). Asked of all groups in self-report survey at baseline and follow-up.	Calloway EE, Carpenter LR, Gargano T, Sharp JL, Yaroch AL. (2022). Development of new measures to assess household nutrition security, and choice in dietary characteristics. Appetite. https://doi.org/10.1016/j.appet.2022.106288
Food Security	Food security is sufficient access to food to meet a households' nutritional needs. The measure is scored using the USDA six-item, short form food security survey module where affirmative responses are summed, and responses can be analyzed categorically (0-1 = high or marginal food security, 2-4 = low food security, 5-6 = very low food security) or as a count depending on the distribution of the data. Asked of all groups in self-report survey at baseline and follow-up.	Blumberg SJ, Bialostosky K, Hamilton WL, Briefel RR. The effectiveness of a short form of the Household Food Security Scale. Am J Public Health. 1999;89(8):1231-1234. doi:10.2105/ajph.89.8.1231
Perceived diet quality	Perceived dietary quality is measured using a single validated item "In general, how healthy is your overall diet?" with excellent, very good, good, fair, and poor response options. Asked of all groups in self-report survey at baseline and follow-up.	Sullivan VK, Johnston EA, Firestone MJ, Yi SS, Beasley JM. Self-Rated Diet Quality and Cardiometabolic Health Among U.S. Adults, 2011-2018. Am J Prev Med. 2021;61(4):563-575. doi:10.1016/j.amepre.2021.04.033
Diet quality	The Mini-Eating Assessment Tool (Mini-EAT) is a rapid dietary screener that measures consumption of fruits and vegetables, whole grains, refined grains, fish and seafood, legumes, nuts, and seeds, low-fat dairy, high-fat dairy, and sweets. Asked of all groups in self-report survey at baseline and follow-up.	Lara-Breitinger KM, Medina Inojosa JR, Li Z, Kunzova S, Lerman A, Kopecky SL, Lopez-Jimenez F. Validation of a Brief Dietary Questionnaire for Use in Clinical Practice: Mini-EAT (Eating Assessment Tool). J Am Heart Assoc. 2023 Jan 3;12(1):e025064. doi: 10.1161/JAHA.121.025064. Epub 2022 Dec 30. PMID: 36583423; PMCID: PMC9973598.

Cooking and food provisioning self-efficacy and food agency.	Cooking and food provisioning action scale (CAFPAS) measures an individual's cooking and food provisioning specific self-efficacy and food agency. Asked of all groups in self-report survey at baseline and follow-up.	Karlsson, S. et al. (2023) An evaluation and shortening of the Cooking and Food Provisioning Action Scale (CAFPAS) using item response theory', Food Quality and Preference, 108, p. 104880. Available at: https://doi.org/10.1016/j.foodqual.2023.104880.
General self-efficacy	Assesses how much people believe they can achieve their goals, despite difficulties. Asked of all groups in self-report survey at baseline and follow-up.	Chen, G., Gully, S. M., & Eden, D. (2001). Validation of a new general self-efficacy scale. Organizational research methods, 4(1), 62-83.
Adaptive capacity	A measure of household resiliency that captures a household's ability to react and adapt to a financial shock. Asked of all groups in self-report survey at baseline and follow-up.	Calloway EE, Carpenter LR, Gargano T, Sharp JL, Yaroch AL. (2022). Development of three new multidimensional measures to assess household food insecurity resilience in the United States. Frontiers in Public Health. https://doi.org/10.3389/fpubh.2022.1048501
UCLA Loneliness Scale	Loneliness is perceived isolation from others and is measured using the UCLA loneliness scale. Each of the 11 items begins with a question stem, "How much of the time do you feel…" and uses a three-point Likert scale ranging from 1 (often) to 3 (hardly ever or never) to measure loneliness. Asked of all groups in self-report survey at baseline and follow-up.	11-item UCLA Loneliness scale from Lee J, Cagle JG. Validating the 11-Item Revised University of California Los Angeles Scale to Assess Loneliness Among Older Adults: An Evaluation of Factor Structure and Other Measurement Properties. Am J Geriatr Psychiatry. 2017;25(11):1173-1183. doi:10.1016/j.jagp.2017.06.004
EuroQol: EQ-5D-5L	The EQ-5D-3L is a measure of wellbeing and includes items on mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. Asked of all groups in self-report survey at baseline and follow-up.	Feng YS, Kohlmann T, Janssen MF, Buchholz I. Psychometric properties of the EQ-5D-5L: a systematic review of the literature. Qual Life Res. 2021;30(3):647-673. doi:10.1007/s11136-020-02688-y

Analytic plan

We will first use analysis of variance (ANOVA) to assess whether participants differ by group on potential covariates: age, household size, children in the household, race and ethnicity, income, obesity, self-rated health, chronic disease diagnoses, self-efficacy, and number of appointments attended.

Intervention feasibility, adherence, and satisfaction will be compared across intervention arms using ANOVA to compare group means on continuous variables. Participants enrolled and coaching sessions attended will be quantified by study month and calendar month to examine temporal trends. We will also examine change in rates of participation across different subpopulations characterized by patient and household characteristics (e.g., household size, morbidity).

Nutrition security, food security, and diet quality changes between baseline and follow-up will be compared across study arms using multiple regression models that include study participant characteristics and indicators for study arm. Impact of study arm on average monthly points spent on MTG and nutritional quality of the market order will be estimated using multiple regression models. Models will include patient characteristics and indicators for the study arm. We will also estimate a longitudinal model that includes all four observations characterizing the MTG composition and nutritional quality of each participant's market order in each study month. This model will include a trend variable indicating study month and the interaction between trend and study arm indicators, which will provide evidence for whether duration in each intervention arm impacted changes in the market order composition.

Qualitative Component

A subset of participants (N=60) are randomly selected to participate in pre- and post-intervention qualitative interviews using a randomization website that allows participants to see their randomization in real time (https://pickerwheel.com/tools/yes-or-no-wheel/) until 60 people complete pre-intervention interviews. A semi-structured qualitative interview guide and codebook was developed by CP and KHH, and critically reviewed by JA, TL, SP, and MB. Interviews are conducted by CP in English and Spanish over the phone and last about 30-minutes. Interviews are conducted prior to the intervention and within 30 days of completing all study appointments. The qualitative interviews are focused on identifying key program components most impactful to support nutrition behavior change in populations with lower

income and optimal design of the linkage between the health system and community resources. Deductive thematic analysis of Qualitative data will be conducted using the study codebook.

Patient and Public Involvement

The public are included in the design of the study in that Crossroads staff assist with protocol planning and implementation. Additionally, extensive preliminary data were collected from community members to understand nutrition intervention and cuisine preferences. We also plan to share results with patients using an infographic or other brief clear once study analyses are completed.

Ethics and dissemination

Research Ethics Approval

This study was approved by the UT Southwestern Medical Center Institutional Review Board (STU-2023-1166) and the Parkland Health Office of Research Administration. The study is preregistered on ClinicalTrials.gov (NCT06242808) as of February 2nd, 2024.

Protocol Amendments

Protocol amendments will be documented via American Heart Association reporting requirements as well as on ClinicalTrials.gov.

Consent

Participants read the consent form to themselves or have the consent form read to them by a study team member depending on their preference. Participants consent electronically via RedCap on their personal device or a study tablet after the study team determines eligibility and prior to completing the baseline questionnaire or randomization. Participants can also elect to receive a physical or electronic copy of the signed consent form for their records.

Confidentiality

Study staff across sites (e.g., in the clinic, pantry, qualitative co-investigator) use first and last names when scheduling participant appointments, which participants are informed of and agree to in the consent form. However, those names are not connected to the participant's

data. All participant data (e.g., questionnaire responses, health information, interview transcripts) are associated with a study code number. Identifying information and clinical information is only available to those team members who are research ethics and HIPAA credentialed as well as IRB and PI approved to have access. No identifying information is reported in any academic or medical journals or meetings.

Access to data

For data collected by the study team, de-identified data will be hosted in the Texas Data Repository, an open-source platform for publishing and managing datasets created by Texas higher education institutions using Harvard's Dataverse software. The data will be made available at the time of publication and shared with anyone that creates a free account and makes a reasonable request for data. Currently, data deposited into the Texas Data Repository is available in perpetuity.

Ancillary and post-trial care

Participants can continue to receive pantry services and food resource coaching from Crossroads at the end of the study if they remain eligible for charitable food assistance.

Dissemination policy

Findings will be disseminated through academic publications and conferences, ClinicalTrials.gov, UTSW (UT Southwestern) Communications, PI KHH's website (nicheresearch.org), and University and MPIs' social media. The team does not intend to use any professional writers.

Authors Contributions:

JA, TL, and KHH, conceptualized the study and secured funding to carry out the study. MEB and SP contributed to study protocol design and edited the funding proposal. JA, MS, and KHH developed the MTG point allocation and scoring system. AF and BS contributed to protocol development and implementation. MS and CH developed study recipes. CH aligned recipes to

the MTG scoring system and the market's available inventory each month. CP developed the qualitative interview guide. JA, WW, TL, and KHH led manuscript preparation. All authors critically reviewed the manuscript and provided valuable feedback and edits.

Funding statement: This study was funded by an American Heart Association (AHA) Food is Medicine Grant (24FIM1262347) awarded to authors JA, TL, and KHH. The funder had subject matter experts peer review all grantees and provide recommendations for study improvement. This peer review led to our team adding intervention group 1 (MTG only) and a $15 bonus payment for participants that complete all study activities, to encourage completing follow-up data collection. The funder had no influence on the decision to submit this manuscript or the reporting of this study.

Competing interests statement: Unrelated to this work, KHH is a Program Advisor (paid consultant) on The Special Supplemental Nutrition Program for Women, Infants, and Children Community Innovation and Outreach program (WIC CIAO) on behalf of the Center for Nutrition and Health Impact. Unrelated to this work, JA serves on the Advisory Board and is a Committee Chair for The American College of Culinary Medicine focused on the development of educational strategy and tools in graduate medical education.

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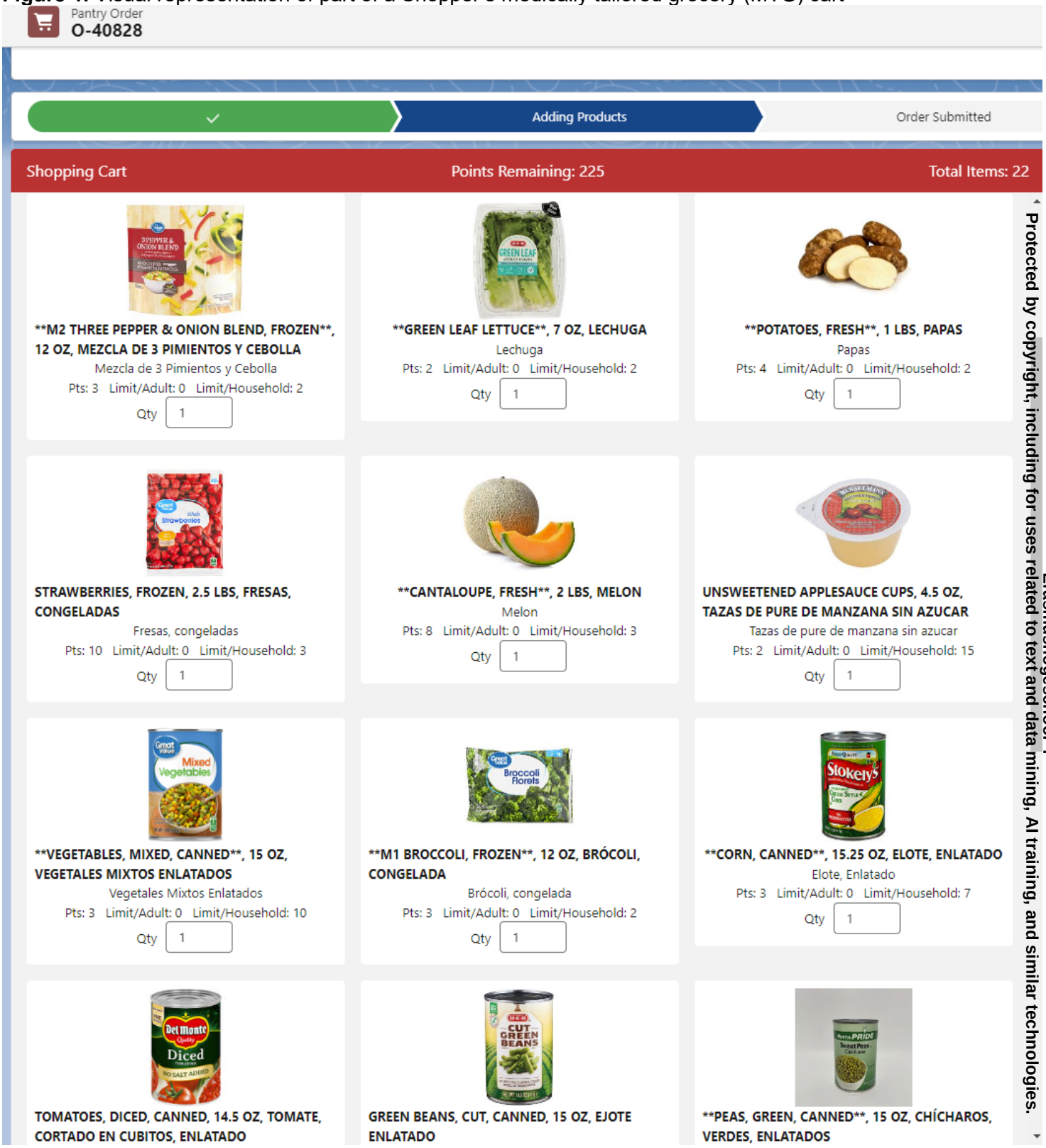
Figure 1. Visual representation of part of a Shopper's medically tailored grocery (MTG) cart



Information Sheet about participation in a research study titled: Medically tailored groceries and food resource coaching for patients of a safety-net clinic

To be conducted at

Parkland Health - Parkland C.V. Roman Health Center
3560 W. Camp Wisdom Rd, Suite 100 Dallas, TX 75237

Who is conducting the study? Dr. Kelseanna Hollis-Hansen, PhD, MPH, Dr. Jaclyn Albin, MD, and Dr. Tammy Leonard, PhD researchers at UT Southwestern Medical Center and Parkland Health are conducting the study.

What is the purpose of the research? To determine feasibility and to learn how people that use the Parkland C. V. Roman Health Center feel about receiving services from a free community food market.

Who is participating in the research? 1) Adults 18 years of age or older; 2) Income less than 185% of the federal poverty threshold (self-report); 3) diagnosis of a diet-related chronic disease (i.e., Diabetes, Dyslipidemia, Hypertension) verified by electronic health record; 4) residence in one of the 18 ZIP codes served by Crossroads Community Services that surround the RedBird clinic (75203, 75208, 75211, 75212, 75216, 75217, 75224, 75232, 75233, 75236, 75237, 75241, 75249, 75052, 75104, 75115, 75116, 75137); 5) able to give informed consent; 6) willing to participate; 7) not moving or planning to move from the area within the next 6-months.

Do you have to be in this study? You do not have to participate if you don't want to, and you may stop the study at any time. If you decide to stop taking part in this research study, it will not affect your relationship with Parkland, Crossroads, or UT Southwestern. Whether you participate or not will have no effect on your legal rights or the quality of your health care now or in the future.

This study will take place over a period of four and a half months, but data will only be collected on two days (at your first and fifth appointment). The maximum active time commitment is 6 hours. 1-hour and 30-minutes at the baseline appointment, 30-minutes to 1-hour at the second, third, and fourth appointment, and 1-hour and 30-minutes at the fifth appointment.

What are the research procedures? If you're interested, you will complete a screening survey to determine eligibility. If you are eligible and decide to participate, you will be randomly assigned by chance like drawing numbers out of a hat into one of three groups. You have a 33% chance of being assigned to any group and you cannot switch groups.

At the initial appointment, participants will consent, enroll in REDCap, and be randomized. The study team will explain the group you were randomly assigned to and schedule your appointment with Crossroads market for within the next two weeks, depending on your schedule.

Once you're assigned to one of the three groups, you will complete a questionnaire about yourself (age, gender, race/ethnicity, etc.), your diet, and nutrition-related behaviors. Questionnaires will be delivered using REDCap. You will also complete a follow-up questionnaire at the fifth appointment. Questionnaires are estimated to take 20-30 minutes.

Participants in all three groups will then complete 4 monthly in-person visits to Crossroads pop-up market, a free community food market, which is located onsite at RedBird Mall. Participants in one group will complete food resource coaching at the Crossroads market and be advised to select medically tailored groceries from the inventory. Participants in the other group will also be shown the medically tailored groceries but will not receive food resource coaching. Participants in the third group will independently make their food selections from the market with assistance from a volunteer or Crossroads staff member.

After you have completed your appointment and selected your food, you will be scheduled for a follow-up appointment in one month.

IRB Approved Date: 4/12/2024

Information Sheet about participation in a research study titled: Medically tailored groceries and food resource coaching for patients of a safety-net clinic

Additionally, 60 participants will be randomly selected to complete one-on-one telephone interviews with a study team member. This will take place after the initial and fifth appointment, after completing the questionnaires. Questions will cover techniques to best screen and link patients to supportive services and community resources. These interviews are estimated to take 30-45 minutes. Additional payments will be provided for these interviews.

What are the risks and benefits? Potential risks are minimal and may include slight discomfort with answering personal questions and loss of confidentiality. You will be assigned a special code instead of using your name to help reduce the confidentiality risk. This study is voluntary, and you do not have to answer questions that make you feel uncomfortable, and you do not have to participate to continue receiving services at Parkland. As a part of this study, you will receive free nutritious food from Crossroads market, which we anticipate will benefit participants. We hope the information learned from this study will also benefit other people in the future.

Costs and Compensation. There are no costs associated with this study. You will receive pantry services and groceries at no cost to you. You will receive a set of cooking utensils after completing the consent process, and you will receive $15 after completing the baseline questionnaire and attending your first appointment at Crossroads RedBird. When you complete the follow-up questionnaire at the fifth appointment, you will receive another $15.

If you complete all study activities, you will be given an additional $15 bonus payment at the end of the study. This includes completing the two questionnaires, plus attending all pantry appointments and coaching appointments (if applicable). This makes the total study payment up to $45.

The 60 randomly selected participants that complete telephone interviews will receive an additional payment of $25 per interview, making their total study payment up to $95.

Confidentiality. Information we learn about you in this study will be handled in a confidential manner. If we publish the results of the study in a scientific journal or book, we will not identify you.

Any data collected as part of this study may be used for future research studies without your consent. Any information that identifies you will be removed before it is used for future research studies.

Research policies require that private information about you be protected and this is especially true for your health information. However, the law sometimes allows or requires others to see your information. The information given below describes how your privacy and the confidentiality of your research records will be protected in this study. Medical information collected during this study and the results of any test or procedure that may affect your medical care may be included in your medical record. The information included in your medical record will be available to health care providers and authorized persons including your insurance company.

What is Protected Health Information (PHI)? Protected Health Information is information about a person's health that includes information that would make it possible to figure out whose it is. According to the law, you have the right to decide who can see your protected health information. If you choose to take part in this study, you will be giving your permission to the investigators and the research study staff (individuals carrying out the study) to see and use your health information for this research study. In carrying out this research, the health information we will see and use about you will include: *diagnosis of diabetes, dyslipidemia, and/or hypertension; height, weight, and body mass index*.

IRB Approved Date: 4/12/2024

Information Sheet about participation in a research study titled: Medically tailored groceries and food resource coaching for patients of a safety-net clinic

We will get this information by using EPIC to access your health record.

How will your PHI be shared?

Because this is a research study, we will be unable to keep your PHI completely confidential. We may share your health information with people and groups involved in overseeing this research study including:

- The Sponsor, American Heart Association, Inc. funding the study. The sponsor includes any people, entities, groups or companies working for or with the sponsor or owned by the sponsor. The sponsor will receive written reports about your participation in the research. The sponsor may look at your health information to assure the quality of the information used in the research.
- The members of the local research team.
- The Institutional Review Board, Human Research Protection Program Office and the Compliance Office of the University of Texas Southwestern Medical Center, and other groups that oversee how research studies are carried out.
- The Research offices at the University of Texas Southwestern Medical Center and Parkland Health and Hospital System
- Representatives of domestic and foreign governmental and regulatory agencies may be granted direct access to your health information for oversight, compliance activities, and determination of approval for new medicines, devices, or procedures.

If you decide to participate in this study, you will be giving your permission for the groups named above, to collect, use and share your health information. If you choose not to let these groups collect, use and share your health information as explained above, you will not be able to participate in the research study.

Parts of your PHI may be photocopied and sent to a central location or it may be transmitted electronically, such as by e-mail or fax. The groups receiving your health information may not be obligated to keep it private. They may pass information on to other groups or individuals not named here.

How will your PHI be protected?

In an effort to protect your privacy, the study staff will use code numbers instead of your name, to identify your health information. Initials and numbers will be used on any photocopies of your study records, and other study materials containing health information that are sent outside of the University of Texas Southwestern Medical Center or Parkland for review or testing. If the results of this study are reported in medical journals or at meetings, you will not be identified.

Do you have to allow the use of your health information?

You do not have to allow (authorize) the researchers and other groups to see and share your health information. If you choose not to let the researchers and other groups use your health information, there will be no penalties, but you will not be allowed to participate in the study.

After you enroll in this study, you may ask the researchers to stop using your health information at any time. However, you need to say this in writing and send your letter to:

Dr. Kelseanna Hollis-Hansen
UT Southwestern Medical Center
O'Donnell School of Public Health
5323 Harry Hines Blvd.
Dallas, TX 75390

If you tell the researchers to stop using your health information, your participation in the study will end and the study staff will stop collecting new health information from you and about you for this study. However, the

IRB Approved Date: 4/12/2024

Information Sheet about participation in a research study titled: Medically tailored groceries and food resource coaching for patients of a safety-net clinic

study staff will continue to use the health information collected up to the time they receive your letter asking them to stop.

Can you ask to see the PHI that is collected about you for this study?

The federal rules say that you can see the health information that we collect about you and use in this study. Contact the study staff if you have a need to review your PHI collected for this study.

Because of the type of research, you can only access your PHI when the study is done. At that time, you have the right to see and copy the medical information we collect about you during the study, for as long as that information is kept by the study staff and other groups involved.

How long will your PHI be used?

You agree to let us use and disclose your health information for purposes of the study until the end of the study. This permission to use your personal health information expires when the research ends and all required study monitoring is over.

Contact Information for questions or comments:

The University of Texas Southwestern Medical Center Human Research Protection Program (HRPP) oversees research on human subjects. HRPP and Institutional Review Board (IRB) representatives will answer any questions about your rights as a research subject, and take any concerns, comments or complaints you may wish to offer. You can contact the HRPP by calling the office at 214-648-3060.

Before you agree to participate, make sure you have read (or been read) the information provided above; your questions have been answered to your satisfaction; and you have freely decided to participate in this research.

This form is yours to keep.

BMJ Open

Providing medically tailored groceries and food resource coaching through the charitable food system to patients of a safety-net clinic in Dallas, Texas: a randomized controlled trial protocol

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Primary Subject Heading:	Public health
Secondary Subject Heading:	Nutrition and metabolism
Keywords:	Food Insecurity, Cardiovascular Disease, Social Support, Randomized Controlled Trial

Title: Providing medically tailored groceries and food resource coaching through the charitable food system to patients of a safety-net clinic in Dallas, Texas: a randomized controlled trial protocol

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Keywords: Food security, food assistance, cardiovascular diseases, metabolic diseases, randomized controlled trial

Word count: 4,581

Abstract:
Introduction: Linking patients living with chronic, diet-related diseases and food insecurity to charitable food assistance, medically tailored groceries, and food resource coaching may empower patients to better manage their health in a way that is economically sustainable. This protocol paper describes the implementation of a study evaluating medically tailored groceries and food resource coaching in a food pantry setting.
Methods and analysis: A randomized controlled trial whereby patients of a safety-net health center will be screened for The Emergency Food Assistance Program (TEFAP) and study eligibility. Eligible patients will be randomized to receive four months of usual pantry services (control), medically tailored groceries (intervention 1), or medically tailored groceries and food resource coaching (intervention 2) from a co-located food pantry. Measures collected monthly include adherence, fidelity, and food selections from the pantry. Measures collected at baseline and follow-up include food and nutrition security, diet quality, household resiliency, loneliness, and overall wellbeing. Qualitative interviews (N=60) will be conducted pre- and post-intervention. Analyses will include multiple regression models to analyze changes from baseline to follow-up as well as changes between groups over time. Deductive thematic analysis of qualitative data will be conducted.
Ethics and dissemination: This study was approved by the UT Southwestern Medical Center Institutional Review Board (STU-2023-1166) and the Parkland Health Office of Research Administration. This is protocol version two, modification approved on June 3rd, 2024. Findings will be disseminated through academic conferences, journals, and to the public.
Registration information: The study is preregistered on ClinicalTrials.gov (NCT06242808) as of February 2nd, 2024.

Strengths and limitations:

- A strength of the study includes the use of a randomized controlled trial (RCT) design with participants randomized to one of three groups – usual food pantry services (control), medically tailored groceries (MTG) (intervention 1), and MTG coupled with food resource coaching (intervention 2) to isolate the impact of each layer of support.
- Implementing FIM programming by leveraging existing food assistance organizations' inventory may be more sustainable in the long term, as participants can continue receiving services at the end of the study.
- Lastly, recruitment through a local safety-net clinic in the Southern sector of Dallas, Texas reaches African American or Black and Hispanic or Latino(a) community members with lower-income, groups that are most impacted by food insecurity and diet-sensitive health disparities[1-4] and increases the generalizability and external validity of the findings.
- While study arms will be masked for outcomes assessors, the team members implementing services and participants cannot be masked due to the nature of the interventions - participants know if they receive coaching or not, therefore a limitation is the inability to fully mask study groups to which participants have been assigned.
- The study may be underpowered to detect small effects.

Introduction:

Over 10% of households in the United States and over 17% of households with children experienced food insecurity in 2022,[5] and food insecurity increases the risk of adverse health outcomes.[6,7] Simultaneously, there is a rise in chronic, diet-sensitive diseases that dominate healthcare spending in the United States (e.g., type-2 diabetes, high cholesterol, obesity, and cardiovascular disease).[8,9] The emerging FIM movement[10] seeks to use nourishing food in combination with other medical treatments to advance the prevention, management, and

treatment of diet-sensitive disease. For food insecure communities, FIM strategies may have the potential to increase food security and improve related health conditions.[11,12]

FIM strategies range from population level healthy food programs that provide education (e.g., USDA's MyPlate) and food access (e.g., Supplemental Nutrition Assistance Program (SNAP) or Women Infants and Children (WIC)), to more intensive provision of medically tailored foods through prepared meals, nutrition expert-guided selection of groceries, and produce provision alongside educational interventions.[12-14] The integration of these programs varies widely and addressing health-related food needs for populations that experience food insecurity introduces additional complexity.[15-18] There is growing evidence that health system partnerships with community organizations that have food assistance expertise, such as food banks and pantries, offer a pathway for long-term sustainability of FIM and the agility to pivot strategy based on local needs and preferences.[19-21]

Our study will be implemented in partnership with Crossroads, which operates a high-capacity client-choice pantry and is the largest non-profit food redistributor in the North Texas region. In alignment with the types of services provided by pantries, we will implement a MTG FIM strategy within the pantry context. MTG's will be identified from Crossroads' inventory, which is selected from the bulk inventory secured by the North Texas Food Bank. We also have a small amount of funding to purchase supplemental grocery items when MTG items are not available from the food bank. We will report on the proportion of total MTG food that is secured through the normal pantry distribution systems compared to the food that is purchased from retailers.

At Crossroads, households are allocated points based on the dietary requirements of household members. Points act as a form of currency such that the amount of food each household gets at each monthly visit is enough for 21 meals for each household member up to a maximum of 500-points (five household members).[22] This 500-point maximum was put into

place to ensure equity in the availability of product for all shoppers seeking services, as the need for food access continues to grow and challenges were presented with supply when large households received larger quantities of food (e.g., 1200 points). While the use of a point system such as the one used at Crossroads is not necessary for implementation of MTG, the MTG approach we investigate is meant to be implemented within the context of a client-choice pantry that scales allotments with household size. Scaling food allocations by household size is the standard model employed by high-capacity, evidence-based pantries in the US.[23]

MTG consists of minimally prepared foods that might be offered in a pantry setting but are carefully selected to support health goals. In some cases, MTG may require a shift in typical pantry inventories so a full mix of healthy foods can be offered. The MTG food must be prepared by the patient or caregiver at home, ideally promoting self-efficacy in health-promoting food preparation. Also called medically tailored food packages or boxes, these groceries combine ingredients across food categories to optimize a nutritionally complete dietary pattern.

While some evidence exists to support the theory and process for medically tailoring groceries,[24-28] evidence is generally lacking regarding how MTG can be provided at the household level and the proper 'dosing' in the context of food insecure households.[10] In our intervention, the quantity of MTG provided is scaled with the size of the patient's household. Food insecurity is a household-level condition and food pantries "treat" food insecurity at the household-level. Thus, it seems plausible that FIM strategies that intend to address both diet quality and food security should also adopt a household-level framing.

Another strategy we are testing as a complement to MTG is food resource coaching. Since 2020, Crossroads, Ascend Dallas (a local non-profit leader in financial coaching), and co-author TL have been developing F3: From Food to Finances, a novel food resource coaching program that provides Crossroads shoppers with training in securing resources to promote food, nutrition, and economic security. To our knowledge, the food resource coaching intervention is

novel, and no peer-reviewed publications have explored the impact of food resource coaching in a no-cost food pantry or clinical setting. However, other researchers have explored using financial resource coaching in a clinic setting,[29,30] which served as a model for the development of food resource coaching. Therefore, we hypothesize that patients receiving MTG and coaching in our study will have the greatest improvements in patient engagement, adherence, and dietary quality over the study period.

Our study objectives include execution of a between-group, repeated measures RCT to identify feasibility and early-stage effectiveness of recruiting patients with lower income and at least one diet-related chronic disease (N=210) from Parkland Health, a large safety-net health center. Participants are randomly assigned to one of three groups: 1) usual pantry services which includes food for up to 21 meals for up to five people in the household, 2) pantry services with MTG, and 3) pantry services with MTG and monthly one-on-one food resource coaching sessions. We also aim to collect pre- and post-intervention qualitative data from a subset of randomly selected participants (N=60) to solicit feedback on linkage to supportive services via the medical system and their experience with the program.

In addition, we aim to describe our collaborative process for defining MTG from a pantry meeting the needs of a local community experiencing food insecurity and co-located with the safety-net health center. First, we evaluated common evidence-based dietary patterns to identify a pattern with broad applicability to multiple chronic diseases and feasible application within an MTG intervention aligned with low-cost food assistance programs. Next, we sought to apply the dietary pattern in a pantry setting where inventories are limited and fluctuating, and people have diverse cultural and personal food preferences. Finally, we aimed to pragmatically design and develop an MTG program rooted in pantry inventory data. This manuscript describes both the study protocol and aspects of our protocol for implementing medically tailoring groceries and food resource coaching in a food pantry.

Methods and analysis

We use SPIRIT reporting guidelines, which are uploaded as a supplement.[31] The planned study start date was 4/1/2024 but was delayed to 5/31/2024 due to delays in construction at the satellite pantry. The planned data collection end date is 3/31/2025, the planned study end date is 6/30/25.

Sample Size

The current lack of information on novel intervention effects on outcomes of interest (e.g., food selections from the pantry, dietary quality) serves as a challenge to conducting a power analysis. We estimated that with a sample size of 210 people (70 per group), the study is powered to detect a small interactive group by time effect (f=0.11) on measures taken at baseline and follow-up. The sample size was selected based on what the study team, clinic, and community partners estimated might be feasible to recruit from the clinic and serve in the pantry within the 18-month grant timeline, and large enough to detect a small to medium size effect.

Recruitment

Recruitment takes place via multiple routes. Providers and other healthcare staff at the Parkland C.V. Roman Health Center, a community safety-net primary care clinic, make referrals to the study via recruitment fliers posted in patient exam rooms and discussion about the study with patients. Second, the study staff send approved emails to potentially eligible patients. These emails inform patients of the study occurring at their clinic and provide contact information to learn more. The main recruitment method employed is in-person tabling at clinic entry. The recruitment team sit at a table in the lobby Monday, Wednesday, and Friday and introduce the study to patients, screening anyone interested. The team shares fliers with a QR code, linking patients to the eligibility screener where they can submit their information on their personal device. The team also has tablets that patients can use to complete the eligibility screener if preferred. Alternatively, if an interested patient has limited time and is unable to complete while onsite, they can take a recruitment flier and fill out the screener at their convenience.

Eligibility criteria

A participant must be: a patient at the C.V Roman Health Center, over the age of 18, have reliable transportation, be eligible for TEFAP (earn less than 185% of the federal poverty threshold, self-report), diagnosed with at least one of three diet-related chronic disease categories (dyslipidemia, hypertension, or diabetes, verified in EHR), have no illnesses, allergies, or sensitivities that severely limit what they can eat (e.g., put them at risk from consuming food from the pantry), live in one of the 18 ZIP codes served by Crossroads that surround the local safety net clinic, be able to give informed consent, and willing to fully participate.

Randomization

Two randomization tables with equal group allocation using Excel are created by a team member that is not involved with participant recruitment, consent, or data collection. The randomization tables are uploaded into RedCap, one for “development” (e.g., survey testing) and one for “production” when data collection begins. The team members executing randomization in RedCap are unaware of which group each participant will be randomized to until they execute the instrument to assign a group.

Study setting

Once patients are recruited, consented, and complete the baseline questionnaire, they are randomized into one of the three study groups and scheduled for their first pantry appointment. This pantry is co-located within a connected one million square foot commercial retail complex, on the other side of the building from the Parkland clinic. The pantry is within a renovated storefront near the complex entrance and is approved by the City of Dallas Department of Health for storing and distributing food to community members.

Usual pantry services (control group)

All participants that use Crossroads pantry receive food for up to 21 meals for up to five people in the household. We have estimated that a family of four receives approximately $250

USD worth of groceries from Crossroads each month. Appointments at Crossroads are monthly. When participants arrive at Crossroads, they complete a process called “intake, survey, and order”. At intake, Crossroads staff collect household demographics to confirm pantry eligibility, which is set by The Emergency Food Assistance Program (TEFAP) guidelines[32] and to allocate household points for pantry shopping. At the beginning of the shopper’s appointment their next appointment is scheduled, as authors TL and SP have found that appointments encourage pantry attendance.[33]

After intake is completed, shoppers are asked to answer a brief survey module. There are 4 different survey modules that rotate, to maximize the amount of information obtained to improve pantry services while minimizing shopper survey burden. The order process is completed using Salesforce®. The Salesforce® interface displays the picture and description of each item currently available in the pantry and the number of points the item costs. Crossroads pantry allocates points based on an algorithm that follows 2015-2020 dietary guidelines for recommended intake based on the age, sex, and activity level of each person in the household. Participants can select any food items until they use all their allocated points. With the exception that there are some inventory restrictions in place depending on the amount of inventory available for an item in each week (e.g., up to three pounds of onions, up to two pounds of almonds) as availability may fluctuate. After shoppers make their grocery selections on the computer, their grocery list is printed and they select items off the shelves, which is set-up like a small grocery store. The process of making food selections prior to shopping reduces congestion in the small grocery area, allowing Crossroads to serve more shoppers. After selecting all items on their list, shoppers check out with pantry staff or volunteers, have their groceries bagged, and exit the pantry.

Recipes are always available to Crossroads shoppers at the main market and are available to the control group in this study as well. Recipes are in a labeled box on top of the

desk that is visible to the shopper and if a shopper asks for recipes, they are provided, but they are not explicitly introduced by a team member.

Medically tailored groceries (intervention one)

A community-academic partnership team including a culinary medicine (CM)-trained registered dietitian (MS), a CM-trained physician (JA), a public health nutrition and behavioral scientist (KHH), a health economist (TL), and pantry leadership (AF, BS), collaborated to identify an evidence-based dietary pattern and apply that pattern to groceries provided within the charitable food system. Rooted in an existing evidence-based dietary pattern and scoring system for individual consumption and household grocery purchases,[28,34,35] our team developed a simple, pragmatic model to medically tailor groceries from the pantry using the Dietary Approaches to Stop Hypertension (DASH) dietary pattern recommendations. The DASH dietary pattern emphasizes fruits, vegetables, whole grains, legumes, nuts, and low-fat dairy while limiting added sugars, sodium, and red and processed meats. DASH was selected given extensive evidence for the dietary pattern's efficacy improving a variety of preventable chronic diseases, including those which are a focus of this study.[34,36,37] Notably, this overall model for medically tailoring pantry groceries also aligns with the American Heart Association's recent scientific statement on popular dietary pattern alignment with health recommendations, the 2020-2025 Dietary Guidelines for Americans,[38] and the EAT Lancet Commission's report[39] on optimizing nourishing dietary patterns and supporting planetary health and sustainability.

The team applied the food category principles of the DASH diet to score foods available in the pantry's inventory over the prior year on a scale of one-five based on alignment with the DASH diet and a) high nutrient density; b) balanced energy intake; c) chronic disease prevention and management; d) affordability, and e) sustainability. In the five-point scoring system, a five represents the highest recommendation for nutrient density and contribution to a dietary pattern associated with disease prevention and health promotion.[40] Rather than defining

a precise number of servings per category or specific windows of sodium, added sugar, or other nutrients, the team developed a universally applicable strategy described in detail in the following paragraph to encourage the dietary pattern that will optimize nutrition. Specific tailoring to precise intake of certain nutrients requires ongoing engagement with a registered dietitian nutritionist, which is beyond the scope of most charitable food organizations. Our proposed approach balances practical implementation constraints and supports most people seeking to prevent or treat diet-sensitive conditions including cardiometabolic diseases, many cancers, and obesity. Furthermore, as food insecurity is a household-level condition, the provision of foods that align with nutritious categories in an overall pattern supports the reality of household distribution of food.

We designed the MTG carts to include only food scoring in the higher point categories (4 or 5 points). Table 1 includes our proposed MTG scoring categories, which were developed by evaluating available pantry inventory against the DASH dietary pattern recommendations. To implement the MTG grocery carts, we use the pantry's client-choice model whereby shoppers select food from the pantry within a given number of points that are allocated to them based on household size. Shoppers in the MTG group are shown a grocery cart with at least 50% of their point allocation prepopulated with MTG items in their cart. Shoppers can remove MTG items and add additional items if they choose. MTG categories and products provided are the same for all participants. The quantity of MTG products populated is the same for household sizes of one or two people, quantity is doubled for household sizes of three or more people. Table 2 includes a sample MTG cart based on a household size of two people. Figure 1 shows a visual depiction of how the MTG are implemented in Crossroads Salesforce® inventory system with part of a prepopulated MTG cart. This approach combines expertise in applying nutrition as part of a medical treatment or prevention plan, linking prescribed groceries to a culinary lens of utility and complementary food pairings, and a pragmatic understanding of food preferences of our target communities based on data collected from pantry shoppers.[41,42]

Table 1. Medically tailored groceries (MTG) scoring categories

Score	Food Categories/Examples	Notes
5	Vegetables and Fruits	Fresh or frozen (no sauce)
	Legumes (e.g., lentils, beans, peas)	Dried, canned, or frozen
	Whole Grains (e.g., oats, brown rice, quinoa)	Minimally processed
	Nuts and seeds (e.g., walnuts, pecans, almonds, pepitas)	Unsalted/unflavored, raw
	Seafood (e.g., cod, salmon, shrimp)	Fresh or frozen
4	Seafood (e.g., tuna, salmon)	Canned
	Whole grain pastas, breads	Minimal added sugar, sodium
	Canned vegetables and fruits	Minimal added sugar, sodium
	Minimally processed lean poultry (chicken, turkey)	Fresh, frozen, or canned
	Eggs	
3	Minimally processed lean animal protein (90% lean beef, lamb, venison, pork tenderloin)	Fresh or frozen
	Reduced fat dairy (e.g., yogurt, cheese, milk)	No added sugars
	Salted or flavored nuts	Added sodium, sugar
2	Minimally processed animal protein, *not lean* (e.g., beef, pork)	High saturated fat content
	100% fruit juices	High natural sugar content
	Lower sugar breakfast cereals (e.g., shredded wheat)	Added sugar content
	Mixed meals that do not feature vegetables or legumes	Added sodium
	Full fat dairy (including cream, cheese)	High saturated fat content
	Bread, pasta, crackers, rice (non-whole grain)	Added sodium
1	Desserts (candies, cookies, cakes, ice cream, etc.)	High added sugar
	Sugar-sweetened beverages (including many juices)	High added sugar
	Sweetened breakfast cereals	High added sugar
	Ultra-processed snack foods (e.g., chips, snack bars)	High added sodium, sugar

Ultra-processed breakfast meats (e.g., sausage, bacon)	High added sodium, sat fat
Ultra-processed cheese	High added sodium, sat fat

Table 2. Sample medically tailored grocery (MTG) cart for household size of 2

MTG Category	Sample MTG Products*	MTG Points
Three whole grains (e.g., brown rice, quinoa, couscous, whole wheat pasta, corn tortilla, oatmeal)	1 Brown rice	4
Three whole grains (e.g., brown rice, quinoa, couscous, whole wheat pasta, corn tortilla, oatmeal)	1 Oatmeal	3
Three whole grains (e.g., brown rice, quinoa, couscous, whole wheat pasta, corn tortilla, oatmeal)	1 Oatmeal	3
Three beans or legumes (canned or bagged)	1 Can Pinto Beans	4
Three beans or legumes (canned or bagged)	1 Can Lentils	8
Three beans or legumes (canned or bagged)	1 Can Red kidney beans	4
Four canned or frozen vegetable (e.g., no salt added green bean, corn, peas, mixed veg, collard greens, diced tomatoes)	1 Can corn	3
Four canned or frozen vegetable (e.g., no salt added green bean, corn, peas, mixed veg, collard greens, diced tomatoes)	1 Can mixed vegetables	3
Four canned or frozen vegetables (e.g., no salt added green bean, corn, peas, mixed veg, collard greens, diced tomatoes)	1 Can peas	4
Four canned or frozen vegetables (e.g., no salt added green bean, corn, peas, mixed veg, collard greens, diced tomatoes)	1 Frozen broccoli	3
Four canned or frozen fruits (e.g., no sugar added pears, peaches, applesauce, pineapple, mixed)	1 Can pear	4
Four canned or frozen fruits (e.g., no sugar added pears, peaches, applesauce, pineapple, mixed)	1 Can peaches	4
Four canned or frozen fruits (e.g., no sugar added pears, peaches, applesauce, pineapple, mixed)	1 Can peaches	4
Four canned or frozen fruits (e.g., no sugar added pears, peaches, applesauce, pineapple, mixed)	1 Can mixed fruit	4
Two fresh vegetables	1 one lb. bag of carrots	4
Two fresh vegetables	1 one lb. bag of onions	4
Two fresh fruits	1 one lb. bag of apples	8
Two fresh fruits	1 Cantaloupe	8
Nuts or seeds	1 two lb. bag of almonds	8
Canned lean proteins (e.g., chicken, fish, salmon)	1 Can salmon (3-5 servings)	4
Canned lean proteins (e.g., chicken, fish, salmon)	1 5 lb. bag frozen chicken thighs	15
Eggs or eggbeaters	1 Eggbeaters (8-9 servings)	4

Total points MTG	110
Total points allocated	210
Percentage MTG	52%

Participants in the MTG group have recipes handed to them directly rather than having to ask for recipes. The team running appointments is trained not to discuss recipes at length as to not contaminate this group with coaching.

Medically tailored groceries + food resource coaching (intervention two)

Participants in this group receive the same MTG intervention described in the section above and food resource coaching. Food resource coaching is led by trained Crossroads and UTSW staff. Coaches are trained in coaching methodology by experts at Ascend Dallas (40 hours of in-person training), a premier financial coaching organization supporting community members since 1908. Ascend training is then coupled with training intended to translate coaching methodology to the context of nutrition and resource coaching for households experiencing food insecurity (80 hours of in-person training). Once trained, coaches have a period of intense mentorship whereby they conduct coaching appointments in close consultation with established resource coaches for their first one-two weeks of coaching. The mentorship continues after coaches are fully trained and working independently to ensure ongoing support and identification of ways in which the coaching experience can be more impactful for shoppers.

In this study, the coaching intervention takes place over four monthly sessions. In each session, shoppers meet with the resource coach in-person as part of their visit to the community market prior to making food selections. Shoppers self-direct the focus of their coaching based on their self-selected goals, which means sessions may focus more heavily on achieving nutritional goals or financial goals depending on the person. Examples of coaching content all participants receive include training in meal planning, developing a monthly food budget, and how to access additional food and social resources (e.g., SNAP enrollment, discount retailers).

After coaching is completed, shoppers proceed to order groceries through the Salesforce® inventory application with their coach. The coach explicitly identifies the MTG, explains how the items align with healthy dietary recommendations for people with chronic diseases, and shares twelve recipes each month that incorporate MTG items. At the end of the four-month MTG + coaching intervention, shoppers are invited to continue to more in-depth financial coaching or resource coaching programs that are available at the flagship Crossroads location, a seven-minute drive from where the FIM intervention is located.

Criteria for Discontinuing

This study is minimal risk, therefore, there are no safety-related stoppage criteria. Participants in all groups are informed in the consent form that they can choose not to answer any question that makes them uncomfortable and can discontinue participation any time.

Strategies to Improve Retention and Adherence

To improve retention and adherence, participants are provided with physical appointment cards and sent text messages with their pantry appointment date and time immediately after making the appointment and the day prior. Participants receive $15 USD in the form of a gift card after completing the baseline questionnaire and another after completing the month four pantry appointment. Subject matter experts that reviewed the study on behalf of the funder recommended a bonus payment to encourage adherence and data collection, therefore, participants receive a $15 bonus payment if they complete all appointments and study activities (e.g. questionnaires).

For participants that no show pantry appointments, daily attempts are made to reschedule the appointment within the week of the missed appointment. Weekly attempts are made to reschedule the participant throughout the four-month intervention period thereafter. If participants completely miss a month, the next time they return they receive those months services. For example, if a participant misses month two, and returns to the pantry in month three, they only have month three and four services left and would take the follow-up

questionnaire at the end of month four as planned. There are no limits to the number of times a participant can reschedule their appointment, however, they can only reschedule during the four-month intervention period + 10 days.

Participants are contacted through their indicated preferred method of contact first (text, call, email). However, if they continue to be unreachable using their preferred method of contact and they have provided another method, after two weeks of attempt to contact, the team will attempt to use another method.

Timeline

The participant timeline of enrollment, interventions, and assessments is included in **Table 3**.

Table 3. Participant timeline of enrollment, interventions, and assessments

	STUDY PERIOD						
	Enrollment	Allocation	Post-allocation				Close-out
TIMEPOINT	$-t_1$	0	t_1	t_2	t_3	t_4	t_x
	ENROLLMENT:						
Eligibility screen	X						
Informed consent	X						
Allocation		X					
	INTERVENTIONS						
Usual pantry services			←	—	—	→	
MTG*			←	—	—	→	
MTG* + food resource coaching			←	—	—	→	
	ASSESSMENTS						
Demographics, address, diagnosis	X						
Intervention feasibility, adherence, satisfaction, fidelity			←	—	—	—	→
Nutrition security, food security,	X						X

perceived diet quality, diet quality, cooking and food provisioning self-efficacy and food agency, general self-efficacy, loneliness, adaptive capacity, wellbeing							

*MTG=Medically tailored groceries, t=Month

Measures

Measures include demographic characteristics, address, diagnosis, intervention feasibility, adherence, and satisfaction, nutrition security, food security, perceived diet quality, diet quality, cooking and food provisioning self-efficacy and food agency, general self-efficacy, adaptive capacity, loneliness, and wellbeing. All quantitative measures collected as part of this study and measure citations are described in detail in the supplementary materials.

Analytic plan

We will first use analysis of variance (ANOVA) to assess whether participants differ by group on potential covariates: age, household size, children in the household, race and ethnicity, income, obesity, self-rated health, chronic disease diagnoses, self-efficacy, and number of appointments attended.

Intervention feasibility, adherence, and satisfaction will be compared across intervention arms using ANOVA to compare group means on continuous variables. Participants enrolled and coaching sessions attended will be quantified by study month and calendar month to examine temporal trends. We will also examine change in rates of participation across different subpopulations characterized by patient and household characteristics (e.g., household size, morbidity).

Nutrition security, food security, and diet quality changes between baseline and follow-up will be compared across study arms using multiple regression models that include study

participant characteristics and indicators for study arm. Impact of study arm on average monthly points spent on MTG and nutritional quality of the market order will be estimated using multiple regression models. Models will include patient characteristics and indicators for the study arm. We will also estimate a longitudinal model that includes all four observations characterizing the MTG composition and nutritional quality of each participant's market order in each study month. This model will include a trend variable indicating study month and the interaction between trend and study arm indicators, which will provide evidence for whether duration in each intervention arm impacted changes in the market order composition.

Qualitative Component

A subset of participants (N=60) are randomly selected to participate in pre- and post-intervention qualitative interviews using a randomization website that allows participants to see their randomization in real time (https://pickerwheel.com/tools/yes-or-no-wheel/) until 60 people complete pre-intervention interviews. A semi-structured qualitative interview guide and codebook was developed by CP and KHH, and critically reviewed by JA, TL, SP, and MB. Interviews are conducted by CP in English and Spanish over the phone and last about 30-minutes. Interviews are conducted prior to the intervention and within 30 days of completing all study appointments. The qualitative interviews are focused on identifying key program components most impactful to support nutrition behavior change in populations with lower income and optimal design of the linkage between the health system and community resources. Deductive thematic analysis of Qualitative data will be conducted using the study codebook.

Patient and Public Involvement

The public are included in the design of the study in that Crossroads staff assist with protocol planning and implementation. Additionally, extensive preliminary data were collected from community members to understand nutrition intervention and cuisine preferences. We also plan to share results with patients using an infographic or other brief clear once study analyses are completed.

Monitoring Harms

The study is minimal risk, and serious adverse events are not anticipated. Unintended effects or any unexpected adverse events that arise will be reported to the study sponsor and the Institutional Review Board (IRB) within five working days.

Ethics and dissemination

Research Ethics Approval

This study was approved by the UT Southwestern Medical Center Institutional Review Board (STU-2023-1166) and the Parkland Health Office of Research Administration. The study is preregistered on ClinicalTrials.gov (NCT06242808) as of February 2nd, 2024.

Protocol Amendments

Protocol amendments will be documented via American Heart Association reporting requirements as well as on ClinicalTrials.gov.

Informed Consent

Participants read the consent form to themselves or have the consent form read to them by a study team member depending on their preference. Participants consent electronically via RedCap on their personal device or a study tablet after the study team determines eligibility and prior to completing the baseline questionnaire or randomization. Participants can also elect to receive a physical or electronic copy of the signed consent form for their records. The consent form includes consent for both the quantitative and qualitative components of the study. In addition to completing the informed consent form, prior to conducting the qualitative interview, the interviewer sets expectations for the interview (e.g., length of time, types of questions asked and why questions are being asked, compensation for the interview), answers any questions the participants may have about the interview, and requests verbal consent to record the interview prior to beginning the interview or recording. The consent form can be found in the **Supplementary Materials**.

Confidentiality

Study staff across sites (e.g., in the clinic, pantry, qualitative co-investigator) use first and last names when scheduling participant appointments, which participants are informed of and agree to in the consent form. However, those names are not connected to the participant's data. All participant data (e.g., questionnaire responses, health information, interview transcripts) are associated with a study code number. Identifying information and clinical information is only available to those team members who are research ethics and HIPAA credentialed as well as IRB and PI approved to have access. No identifying information is reported in any academic or medical journals or meetings.

Access to data

For data collected by the study team, de-identified data will be hosted in the Texas Data Repository, an open-source platform for publishing and managing datasets created by Texas higher education institutions using Harvard's Dataverse software. The data will be made available at the time of publication and shared with anyone that creates a free account and makes a reasonable request for data. Currently, data deposited into the Texas Data Repository is available in perpetuity.

Ancillary and post-trial care

Participants can continue to receive pantry services and food resource coaching from Crossroads at the end of the study if they remain eligible for charitable food assistance.

Dissemination policy

Findings will be disseminated through academic publications and conferences, ClinicalTrials.gov, UTSW (UT Southwestern) Communications, PI KHH's website (nicheresearch.org), and University and MPIs' social media. The team does not intend to use any professional writers.

Authors Contributions:

JA, TL, and KHH, conceptualized the study and secured funding to carry out the study. MEB and SP contributed to study protocol design and edited the funding proposal. JA, MS, and KHH

developed the MTG point allocation and scoring system. AF and BS contributed to protocol development and implementation. MS and CH developed study recipes. CH aligned recipes to the MTG scoring system and the market's available inventory each month. CP developed the qualitative interview guide. JA, WW, TL, and KHH led manuscript preparation. All authors critically reviewed the manuscript and provided valuable feedback and edits. KHH is the guarantor.

Funding statement: This study was funded by an American Heart Association (AHA) Food is Medicine Grant (24FIM1262347) awarded to authors JA, TL, and KHH. The funder had subject matter experts peer review all grantees and provide recommendations for study improvement. This peer review led to our team adding intervention group 1 (MTG only) and a $15 bonus payment for participants that complete all study activities, to encourage completing follow-up data collection. The funder had no influence on the decision to submit this manuscript or the reporting of this study.

Competing interests statement: Unrelated to this work, KHH is a Program Advisor (paid consultant) on The Special Supplemental Nutrition Program for Women, Infants, and Children Community Innovation and Outreach program (WIC CIAO) on behalf of the Center for Nutrition and Health Impact. Unrelated to this work, JA serves on the Advisory Board and is a Committee Chair for The American College of Culinary Medicine focused on the development of educational strategy and tools in graduate medical education. All other authors have no competing interest to declare.

Acknowledgments: The authors would like to thank the entire team at Crossroads Community Services, especially Benaye Wadkins Chambers, Taylor Hall, and Adelle Trogdon who were instrumental in implementing this study. Thank you also to the team at Parkland Health and specifically the Parkland C.V. Roman Clinic, Ron Sessions and Dr. Berrie for their support of study recruitment.

Figure legend: This figure provides a visual representation of part of a Shopper's medically tailored grocery (MTG) cart including the type of MTG items, points allocated, and any item limits that might be in place to help the pantry manage inventory.

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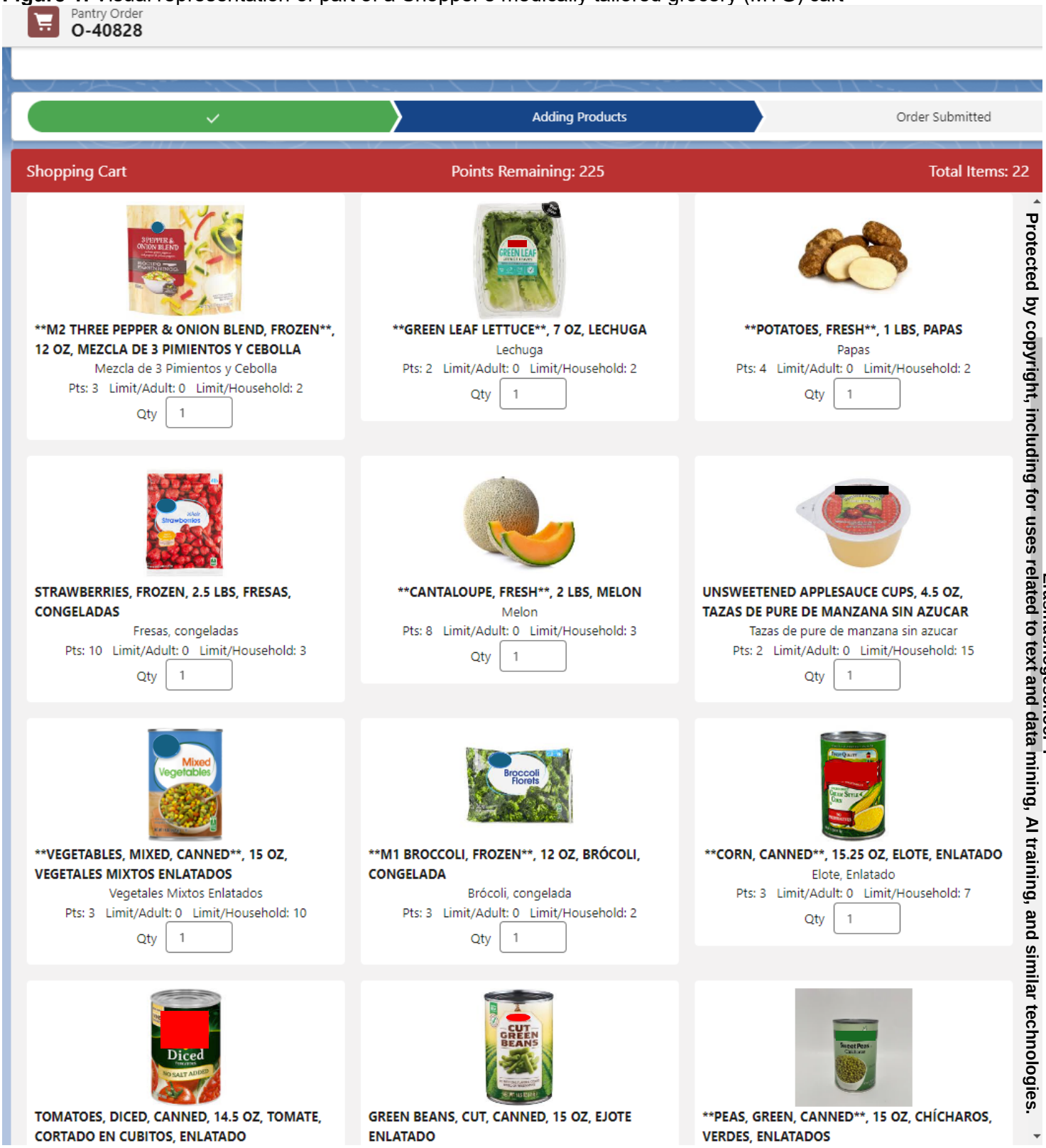
Figure 1. Visual representation of part of a Shopper's medically tailored grocery (MTG) cart



Supplementary Materials – Quantitative Study Measures

Item or measure	Description	Measure Citation
Participant characteristics		
Demographic characteristics	Self-report survey age (continuous), gender (categorical: female, male, other), ethnicity (categorical: Hispanic or Latino(a), not Hispanic or Latino(a)), race (categorical: African American or Black, Asian, Native American, American Indian, or Alaskan Native, Pacific Islander, Samoan, or Hawaiian, Multiethnic or mixed or more than one race or ethnicity, White), education (continuous, years), employment (categorical: full-time, part-time, unemployed looking for work, unemployed not looking for work, receiving disability payments, retired, home maker, student, temporarily laid off), financial assistance (categorical includes all federal assistance programs), income (categorical: less than $10,000 through more than $100,000 USD), health insurance (categorical: Insurance through a current or former employer or union, insurance purchased directly from an insurance company, government medical insurance, TRICARE, VA, Indian Health Service, Other), household makeup (count: number and age of each person living in the household).	N/A
Address	Self-report survey street address, city, state, and ZIP code	N/A
Diagnosis	Participants are asked to self-report if they have one of three chronic disease types (e.g., high blood pressure, diabetes, dyslipidemias) in the eligibility screener. If a chronic disease is reported, the diagnosis is confirmed in the Epic electronic health record.	N/A
Primary outcomes – Intervention feasibility, adherence, and satisfaction		

Intervention feasibility – recruitment and retention	Feasibility includes the number of people screened, eligible, enrolled, and completed which is tracked through RedCap and excel spreadsheets by the study team. Recruitment is calculated as the number of people enrolled divided by the number of people screened. Retention is calculated as the number of people that completed the study divided by the number of people that enrolled.	Jacques RM, Ahmed R, Harper J, et al. Recruitment, consent and retention of participants in randomised controlled trials: a review of trials published in the National Institute for Health Research (NIHR) Journals Library (1997-2020). BMJ Open. 2022;12(2):e059230. Published 2022 Feb 14. doi:10.1136/bmjopen-2021-059230
Intervention adherence – appointments completed	Adherence includes the number of participants that attend each appointment as set, the number of appointments rescheduled, and the percentage of monthly appointments completed. Data is recorded in and extracted from the pantry's Salesforce® system.	New measure
Intervention adherence – selection of MTG	The proportion of points allocated to MTG items in the prepopulated cart and the proportion of points allocated to MTG items in the final cart after shoppers have made their desired adjustments. Data is recorded in and extracted from the pantry's Salesforce® system.	New measure
Intervention fidelity – recipes	Use of the study recipes – "Did you use the recipes provided from the market?" Categorical: Yes, no, didn't notice any recipes response options. Asked of all groups in a self-report survey at follow-up.	Adapted from: Hollis-Hansen K, Tan S, Bargnesi S, et al. Feasibility and implementation of a grocery shopping intervention for adults diagnosed with or at-risk for type 2 diabetes. Public Health Nutr. 2023;26(10):2118-2129. doi:10.1017/S1368980023001453
Intervention satisfaction – General	General intervention satisfaction is measured by asking "How likely is it that you would recommend this program to a friend of colleague?" from a scale of one (very unlikely) to 10 (extremely likely). Asked of all groups in a self-report survey at follow-up.	New measure
Intervention satisfaction – Pantry services	Five-item food satisfaction survey (e.g., "The food has been helpful" "The	Adapted from Dunmire M. Level of Satisfaction Among Food Pantry

	food provided was food my household likes to eat") with a four-point Likert scale (Strongly agree to strongly disagree). Asked of all groups in a self-report survey at follow-up.	Clients, Staff/Volunteers, and Directors and its Association with Client Choice in Food Pantry Layouts South Dakota State University; 2019.
Intervention satisfaction – food resource coaching	Coaching satisfaction is measured among those randomized to receive it using five-items (e.g., "the sessions with the coach were helpful" "the information provided by the coach was easy to understand") and a four-point Likert scale (Strongly agree to strongly disagree). Asked of group receiving food resource coaching only in a self-report survey at follow-up.	New measure
Exploratory outcomes		
Nutrition security	Nutrition security is a validated measure of a household's perceived ability to acquire nutritious foods. The outcome is the mean of the four items scored from 0 (if the participant selects "Always") to 4 (if the participant selects "Never"). Asked of all groups in self-report survey at baseline and follow-up.	Calloway EE, Carpenter LR, Gargano T, Sharp JL, Yaroch AL. (2022). Development of new measures to assess household nutrition security, and choice in dietary characteristics. Appetite. https://doi.org/10.1016/j.appet.2022.106288
Food Security	Food security is sufficient access to food to meet a households' nutritional needs. The measure is scored using the USDA six-item, short form food security survey module where affirmative responses are summed, and responses can be analyzed categorically (0-1 = high or marginal food security, 2-4 = low food security, 5-6 = very low food security) or as a count depending on the distribution of the data. Asked of all groups in self-report survey at baseline and follow-up.	Blumberg SJ, Bialostosky K, Hamilton WL, Briefel RR. The effectiveness of a short form of the Household Food Security Scale. Am J Public Health. 1999;89(8):1231-1234. doi:10.2105/ajph.89.8.1231

Perceived diet quality	Perceived dietary quality is measured using a single validated item “In general, how healthy is your overall diet?” with excellent, very good, good, fair, and poor response options. Asked of all groups in self-report survey at baseline and follow-up.	Sullivan VK, Johnston EA, Firestone MJ, Yi SS, Beasley JM. Self-Rated Diet Quality and Cardiometabolic Health Among U.S. Adults, 2011-2018. Am J Prev Med. 2021;61(4):563-575. doi:10.1016/j.amepre.2021.04.033
Diet quality	The Mini-Eating Assessment Tool (Mini-EAT) is a rapid dietary screener that measures consumption of fruits and vegetables, whole grains, refined grains, fish and seafood, legumes, nuts, and seeds, low-fat dairy, high-fat dairy, and sweets. Asked of all groups in self-report survey at baseline and follow-up.	Lara-Breitinger KM, Medina Inojosa JR, Li Z, Kunzova S, Lerman A, Kopecky SL, Lopez-Jimenez F. Validation of a Brief Dietary Questionnaire for Use in Clinical Practice: Mini-EAT (Eating Assessment Tool). J Am Heart Assoc. 2023 Jan 3;12(1):e025064. doi: 10.1161/JAHA.121.025064. Epub 2022 Dec 30. PMID: 36583423; PMCID: PMC9973598.
Cooking and food provisioning self-efficacy and food agency.	Cooking and food provisioning action scale (CAFPAS) measures an individual’s cooking and food provisioning specific self-efficacy and food agency. Asked of all groups in self-report survey at baseline and follow-up.	Karlsson, S. et al. (2023) An evaluation and shortening of the Cooking and Food Provisioning Action Scale (CAFPAS) using item response theory’, Food Quality and Preference, 108, p. 104880. Available at: https://doi.org/10.1016/j.foodqual.2023.104880.
General self-efficacy	Assesses how much people believe they can achieve their goals, despite difficulties. Asked of all groups in self-report survey at baseline and follow-up.	Chen, G., Gully, S. M., & Eden, D. (2001). Validation of a new general self-efficacy scale. Organizational research methods, 4(1), 62-83.
Adaptive capacity	A measure of household resiliency that captures a household’s ability to react and adapt to a financial shock. Asked of all groups in self-report survey at baseline and follow-up.	Calloway EE, Carpenter LR, Gargano T, Sharp JL, Yaroch AL. (2022). Development of three new multidimensional measures to assess household food insecurity resilience in the United States. Frontiers in Public Health. https://doi.org/10.3389/fpubh.2022.1048501

UCLA Loneliness Scale	Loneliness is perceived isolation from others and is measured using the UCLA loneliness scale. Each of the 11 items begins with a question stem, "How much of the time do you feel…" and uses a three-point Likert scale ranging from 1 (often) to 3 (hardly ever or never) to measure loneliness. Asked of all groups in self-report survey at baseline and follow-up.	11-item UCLA Loneliness scale from Lee J, Cagle JG. Validating the 11-Item Revised University of California Los Angeles Scale to Assess Loneliness Among Older Adults: An Evaluation of Factor Structure and Other Measurement Properties. Am J Geriatr Psychiatry. 2017;25(11):1173-1183. doi:10.1016/j.jagp.2017.06.004
EuroQol: EQ-5D-5L	The EQ-5D-3L is a measure of wellbeing and includes items on mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. Asked of all groups in self-report survey at baseline and follow-up.	Feng YS, Kohlmann T, Janssen MF, Buchholz I. Psychometric properties of the EQ-5D-5L: a systematic review of the literature. Qual Life Res. 2021;30(3):647-673. doi:10.1007/s11136-020-02688-y

Information Sheet about participation in a research study titled: Medically tailored groceries and food resource coaching for patients of a safety-net clinic

To be conducted at

Parkland Health - Parkland C.V. Roman Health Center
3560 W. Camp Wisdom Rd, Suite 100 Dallas, TX 75237

Who is conducting the study? Dr. Kelseanna Hollis-Hansen, PhD, MPH, Dr. Jaclyn Albin, MD, and Dr. Tammy Leonard, PhD researchers at UT Southwestern Medical Center and Parkland Health are conducting the study.

What is the purpose of the research? To determine feasibility and to learn how people that use the Parkland C. V. Roman Health Center feel about receiving services from a free community food market.

Who is participating in the research? 1) Adults 18 years of age or older; 2) Income less than 185% of the federal poverty threshold (self-report); 3) diagnosis of a diet-related chronic disease (i.e., Diabetes, Dyslipidemia, Hypertension) verified by electronic health record; 4) residence in one of the 18 ZIP codes served by Crossroads Community Services that surround the RedBird clinic (75203, 75208, 75211, 75212, 75216, 75217, 75224, 75232, 75233, 75236, 75237, 75241, 75249, 75052, 75104, 75115, 75116, 75137); 5) able to give informed consent; 6) willing to participate; 7) not moving or planning to move from the area within the next 6-months.

Do you have to be in this study? You do not have to participate if you don't want to, and you may stop the study at any time. If you decide to stop taking part in this research study, it will not affect your relationship with Parkland, Crossroads, or UT Southwestern. Whether you participate or not will have no effect on your legal rights or the quality of your health care now or in the future.

This study will take place over a period of four and a half months, but data will only be collected on two days (at your first and fifth appointment). The maximum active time commitment is 6 hours. 1-hour and 30-minutes at the baseline appointment, 30-minutes to 1-hour at the second, third, and fourth appointment, and 1-hour and 30-minutes at the fifth appointment.

What are the research procedures? If you're interested, you will complete a screening survey to determine eligibility. If you are eligible and decide to participate, you will be randomly assigned by chance like drawing numbers out of a hat into one of three groups. You have a 33% chance of being assigned to any group and you cannot switch groups.

At the initial appointment, participants will consent, enroll in REDCap, and be randomized. The study team will explain the group you were randomly assigned to and schedule your appointment with Crossroads market for within the next two weeks, depending on your schedule.

Once you're assigned to one of the three groups, you will complete a questionnaire about yourself (age, gender, race/ethnicity, etc.), your diet, and nutrition-related behaviors. Questionnaires will be delivered using REDCap. You will also complete a follow-up questionnaire at the fifth appointment. Questionnaires are estimated to take 20-30 minutes.

Participants in all three groups will then complete 4 monthly in-person visits to Crossroads pop-up market, a free community food market, which is located onsite at RedBird Mall. Participants in one group will complete food resource coaching at the Crossroads market and be advised to select medically tailored groceries from the inventory. Participants in the other group will also be shown the medically tailored groceries but will not receive food resource coaching. Participants in the third group will independently make their food selections from the market with assistance from a volunteer or Crossroads staff member.

After you have completed your appointment and selected your food, you will be scheduled for a follow-up appointment in one month.

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Additionally, 60 participants will be randomly selected to complete one-on-one telephone interviews with a study team member. This will take place after the initial and fifth appointment, after completing the questionnaires. Questions will cover techniques to best screen and link patients to supportive services and community resources. These interviews are estimated to take 30-45 minutes. Additional payments will be provided for these interviews.

What are the risks and benefits? Potential risks are minimal and may include slight discomfort with answering personal questions and loss of confidentiality. You will be assigned a special code instead of using your name to help reduce the confidentiality risk. This study is voluntary, and you do not have to answer questions that make you feel uncomfortable, and you do not have to participate to continue receiving services at Parkland. As a part of this study, you will receive free nutritious food from Crossroads market, which we anticipate will benefit participants. We hope the information learned from this study will also benefit other people in the future.

Costs and Compensation. There are no costs associated with this study. You will receive pantry services and groceries at no cost to you. You will receive a set of cooking utensils after completing the consent process, and you will receive $15 after completing the baseline questionnaire and attending your first appointment at Crossroads RedBird. When you complete the follow-up questionnaire at the fifth appointment, you will receive another $15.

If you complete all study activities, you will be given an additional $15 bonus payment at the end of the study. This includes completing the two questionnaires, plus attending all pantry appointments and coaching appointments (if applicable). This makes the total study payment up to $45.

The 60 randomly selected participants that complete telephone interviews will receive an additional payment of $25 per interview, making their total study payment up to $95.

Confidentiality. Information we learn about you in this study will be handled in a confidential manner. If we publish the results of the study in a scientific journal or book, we will not identify you.

Any data collected as part of this study may be used for future research studies without your consent. Any information that identifies you will be removed before it is used for future research studies.

Research policies require that private information about you be protected and this is especially true for your health information. However, the law sometimes allows or requires others to see your information. The information given below describes how your privacy and the confidentiality of your research records will be protected in this study. Medical information collected during this study and the results of any test or procedure that may affect your medical care may be included in your medical record. The information included in your medical record will be available to health care providers and authorized persons including your insurance company.

What is Protected Health Information (PHI)? Protected Health Information is information about a person's health that includes information that would make it possible to figure out whose it is. According to the law, you have the right to decide who can see your protected health information. If you choose to take part in this study, you will be giving your permission to the investigators and the research study staff (individuals carrying out the study) to see and use your health information for this research study. In carrying out this research, the health information we will see and use about you will include: *diagnosis of diabetes, dyslipidemia, and/or hypertension; height, weight, and body mass index*.

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We will get this information by using EPIC to access your health record.

How will your PHI be shared?

Because this is a research study, we will be unable to keep your PHI completely confidential. We may share your health information with people and groups involved in overseeing this research study including:

- The Sponsor, American Heart Association, Inc. funding the study. The sponsor includes any people, entities, groups or companies working for or with the sponsor or owned by the sponsor. The sponsor will receive written reports about your participation in the research. The sponsor may look at your health information to assure the quality of the information used in the research.
- The members of the local research team.
- The Institutional Review Board, Human Research Protection Program Office and the Compliance Office of the University of Texas Southwestern Medical Center, and other groups that oversee how research studies are carried out.
- The Research offices at the University of Texas Southwestern Medical Center and Parkland Health and Hospital System
- Representatives of domestic and foreign governmental and regulatory agencies may be granted direct access to your health information for oversight, compliance activities, and determination of approval for new medicines, devices, or procedures.

If you decide to participate in this study, you will be giving your permission for the groups named above, to collect, use and share your health information. If you choose not to let these groups collect, use and share your health information as explained above, you will not be able to participate in the research study.

Parts of your PHI may be photocopied and sent to a central location or it may be transmitted electronically, such as by e-mail or fax. The groups receiving your health information may not be obligated to keep it private. They may pass information on to other groups or individuals not named here.

How will your PHI be protected?

In an effort to protect your privacy, the study staff will use code numbers instead of your name, to identify your health information. Initials and numbers will be used on any photocopies of your study records, and other study materials containing health information that are sent outside of the University of Texas Southwestern Medical Center or Parkland for review or testing. If the results of this study are reported in medical journals or at meetings, you will not be identified.

Do you have to allow the use of your health information?

You do not have to allow (authorize) the researchers and other groups to see and share your health information. If you choose not to let the researchers and other groups use your health information, there will be no penalties, but you will not be allowed to participate in the study.

After you enroll in this study, you may ask the researchers to stop using your health information at any time. However, you need to say this in writing and send your letter to:

Dr. Kelseanna Hollis-Hansen
UT Southwestern Medical Center
O'Donnell School of Public Health
5323 Harry Hines Blvd.
Dallas, TX 75390

If you tell the researchers to stop using your health information, your participation in the study will end and the study staff will stop collecting new health information from you and about you for this study. However, the

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study staff will continue to use the health information collected up to the time they receive your letter asking them to stop.

Can you ask to see the PHI that is collected about you for this study?

The federal rules say that you can see the health information that we collect about you and use in this study. Contact the study staff if you have a need to review your PHI collected for this study.

Because of the type of research, you can only access your PHI when the study is done. At that time, you have the right to see and copy the medical information we collect about you during the study, for as long as that information is kept by the study staff and other groups involved.

How long will your PHI be used?

You agree to let us use and disclose your health information for purposes of the study until the end of the study. This permission to use your personal health information expires when the research ends and all required study monitoring is over.

Contact Information for questions or comments:

The University of Texas Southwestern Medical Center Human Research Protection Program (HRPP) oversees research on human subjects. HRPP and Institutional Review Board (IRB) representatives will answer any questions about your rights as a research subject, and take any concerns, comments or complaints you may wish to offer. You can contact the HRPP by calling the office at 214-648-3060.

Before you agree to participate, make sure you have read (or been read) the information provided above; your questions have been answered to your satisfaction; and you have freely decided to participate in this research.

This form is yours to keep.

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