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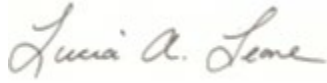
Statistical Analysis Plan (SAP)

Implementation of Innovative Food Prescription Programs in Older Adults

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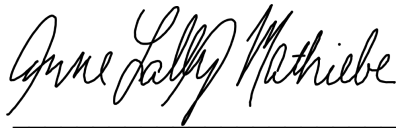
SIGNATURE PAGE

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Lucia Leone

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Anne Lally (Mathiebe)

ABBREVIATIONS

FI	Food Insecurity
F&V	Fruits and Vegetables
MM	Mobile Market
SAP	Statistical Analysis Plan
SNAP	Supplemental Nutrition Assistance Program

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1. Introduction

This study will help understand how novel attributes of food prescription programs including default delivery and customization can improve program utilization rates among older adults.

This statistical analysis plan (SAP) will describe the endpoints of the study and the analyses to evaluate our main outcomes.

2. Study design

2.1. Intervention Design

This was a three-arm randomized controlled trial with two intervention arms and a usual care. The intervention arms included home delivered produce prescriptions and home-delivered meal kits. The control participants received a voucher to receive an equivalent amount of produce as the intervention arms at a mobile market (approximately 12 servings/week per person) . Participants in all arms also received cooking utensils and equipment (e.g., pots, pans, knives). The intervention arms for this study used a default subscription model where participants can “set it and forget it” or choose to customize their food every week. Both intervention arms were designed using behavioral economic principles of default bias and used home delivery to reduce stigma and transportation barriers as well as improve participant choice.

Mobile Market Produce Prescription (Standard of Care Control)

Mobile market (MM) participants received a weekly voucher to purchase produce boxes (or equivalent amount of produce) from a mobile market at the medical center from which participants were recruited or from any of the 11 mobile market locations run by one of our community partners. Participants were asked to choose the market at which they would shop at the beginning of the study. They received all 12 of their weekly vouchers via mail and each one was only available for use on the designated week.

Delivered Produce Prescription

Produce prescription participants received weekly home deliveries of fresh F&V. Produce prescriptions were packed and delivered by a local business that aggregates food from local farms and delivers to homes. Produce box contents changed weekly based on seasonal availability, but the amount of food given weekly remained constant throughout the study. At enrollment, participants were signed up to receive a weekly box based on their household size (small box for 1-3 or large box for 4-6 people) and participants had the ability to fully customize their produce selections each week through the online ordering platform or by calling a study coordinator. They could also skip their delivery, however, if they did nothing, they received a default box.

Delivered Meal Kit

Meal kit participants received all the ingredients each week to make three recipes. Food in the meal kits was portioned when possible, however participants also received a stock-up box of common ingredients (e.g., olive oil, vinegar, spices) at the beginning of the study to limit the need for portioning of frequently used items. Meal kits were designed to have either two or four servings each (depending on household size) and participants had the option to choose three meal kits each week from a menu of 5 or 6 options. Weekly options were repeated every 4 weeks and at the beginning of each 4-week period participants could choose their meal kit choices for the following 4 weeks either by phone or e-mail. Those who did not choose their meals received three default options with accommodation for vegetarian diets. All meal kits were created with attention to balancing macronutrients and including low glycemic index foods in order to make them diabetic friendly. The meal kits were designed by a nutritionist with feedback from the CAB and our food partners. In order to have an equivalent amount of produce to the two produce prescription arms, participants also received a selection of fruit each week which was not part of the meals themselves. Participants in this arm also had the option to skip their delivery either online or by phone.

Participant Communications and Education

In both intervention arms, participants received weekly printed information sheets with food and nutrition education inside of their boxes. In addition, all arms received the meal kit recipes; they were sent weekly (with the corresponding ingredients) in the meal kit arm and at the beginning of the study in the other arms. Participants in the intervention arms who provided an e-mail or phone number received alerts when their orders could be customized as well as delivery reminders. Mobile market participants were sent text reminders to visit the market prior to their chosen market day.

2.2. Participant Recruitment and Enrollment

Participant Identification

We worked with two primary care clinics of a local hospital system to identify and recruit eligible participants. Eligible participants were patients aged 65 and older who screened positive for FI through an existing two question screener that all patients receive at their annual visit. This screener asks patients if “in the last 12 months, did you ever, eat less than you felt you should because there wasn’t enough money for food” and “do you have access to fresh fruits and vegetables within two miles of your residence.” Patients who answered in the affirmative for the first or negative to the second question were eligible for the study. The population health team extracted an initial list of potential participants from the medical records of patients who visited the included clinics in the past year. All potentially eligible participants received an information sheet about the study and a letter from the primary care clinic encouraging them to participate. The letter stated they had two weeks to opt out of being contacted by a research team member from the University at Buffalo for potential recruitment. Then, the contact information for those who did not opt-out was provided to the research team. In addition to the initial list, some participants were recruited after viewing a flyer at their healthcare provider's office and contacting the research team directly or being referred by their physician to the study.

Randomization and Recruitment Process

Randomization for the study was designed following blocked randomization with randomly selected block sizes method to increase the probability of even distribution of our finite pool of potential participants across interventions. The research team called potential participants who did not opt out of being contacted. The potential participant was recruited to the specific intervention arm slot that was currently being filled without describing the two additional intervention arms of the study. If they were interested, we further assessed eligibility (see eligibility criteria below under 5. Population to be Analyzed) and enrolled them in the study.

Enrollment

After recruitment, participants were verbally consented and scheduled to complete a baseline survey over the phone. After the baseline survey was completed, they received a packet in the mail detailing study activities including timeline, consent form, and intervention arm-specific information such as participating mobile market locations, meal kit selections, and account information to login and customize their produce box using an online platform. Finally, they completed a phone call with a research coordinator to orient them to the study arm to which they were randomized and troubleshoot any issues they may have redeeming their prescriptions. During this call, participants were assessed to determine which cooking supplies they would need from a list of 23 common kitchen tools (e.g., measuring spoons, chef's knife, tongs, skillet, baking sheets, etc.) to be able to use the food provided. Once enrolled, participants started the intervention to which they were assigned and received 12 deliveries over 15 weeks with three break weeks for public holidays including Thanksgiving, Christmas, and New Year's Day.

2.3. Data Collection

Baseline Survey

The baseline survey was administered over the phone survey and included demographic measures. Gender was self-reported using an open-ended survey question, with the interviewer then assigning the response to a predefined category (man, woman, non-binary/third gender, prefer to self-describe, prefer not to answer). Racial and ethnic identification were also self-reported using the convention established by the 2020 United States Census. Additional demographics included age, household income, marital status, education, employment status, government assistance participation in the past 12 months (e.g., SNAP, Medicaid, etc.) and total mouths to feed within the household (children and adults).

Weekly Process Surveys

Each week, intervention participants received a text or email survey (based on their preference) on the evening of their food delivery day (Wednesday or Thursday). The surveys asked participants to confirm prescription redemption (receipt of delivery) and collect data on usage of study-provided food and recipes during the previous week. The weekly survey also asked participants about any barriers they were facing to prescription redemption, food usage, or study participation. If a participant did not respond to the survey, login to the ordering website, or call

the study team by Sunday evening, they received a call on Monday to complete the survey and troubleshooting any issues. Participants who expressed challenges in their survey responses to redeeming their prescription were also contacted to troubleshoot issues. If intervention participants did not have any contact with the study team for 2 weeks (i.e., no response to surveys or e-mails, no online login, or no phone calls), their deliveries were discontinued until they reinitiated contact. Usual care control arm participants also received weekly surveys asking if they redeemed their prescription at the mobile market and how much food they used. In the case of a spouse being recruited, only one survey was sent per household and was completed by the primary shopper.

Follow-up Survey

The week after the 12-week intervention ended, participants were contacted by phone to complete a follow-up survey including dietary/health outcome measures and the utilization questions (i.e., weekly survey questions) about the previous week's delivery. Thus, the final week of utilization data was collected over the phone in lieu of another weekly survey. Additional questions asked participants about program satisfaction and perceptions of F&V purchasing/eating: "how likely is it that you would recommend the Golden Harvest Food Produce Prescription program to a friend or family member? Please answer on a scale of 0-10 with 0 meaning not recommend at all and 10 means you would very highly recommend it"; "Has the food prescription program changed the amount of fruits and vegetables that your family buys/eats?" Possible answer choices include we are eating/buying more, about the same or less.

2.4. Sample size calculation

Power for this study is based on our primary outcome of food prescription redemption. In order to detect a difference in usage of 45% using a chi-square ($w=0.426$ at $p=0.05$ and 80% power) between either intervention arm and the usual care arm, we will need 54 participants (18 per arm). This assumes a redemption rate of 30% for usual care and 75% for delivery. These redemption numbers are conservative compared to published usage rates for usual care (under 18%) and delivery (89%).

3. Aims and objectives

Our specific aims for this study include:

- Compare food prescription program utilization using a 3-arm randomized controlled trial
- Optimize program implementation using a mixed method approach including process surveys and interviews with providers, participants, and food delivery partners.
- Explore intervention impact on fruit and vegetable intake, nutrition security, and self-efficacy for preparing healthy meals

4. Outcomes

This section will present outcomes investigated in the study to answer the above study aims and objectives.

4.1 Primary Outcome

Program Redemption

Redemption will be measured as the weekly usage of the interventions. Participants will receive an automatic notification after each delivery (or weekly for the usual care arm) and will be asked to confirm that they received their delivery/redeemed their prescription. If they do not initially confirm, they will receive two reminder notifications. Redemption will be measured as the percentage of all 12 deliveries/mobile market visits that are confirmed via post on the usage survey. Self-report redemption data will also be compared to point-of-sale and delivery software records.

4.2 Secondary Outcomes

Program Usage

Usage will be measured in the self-reported weekly text surveys that will ask participants approximately what percentage of the fruits and vegetables that they receive was used by someone in their household: all (coded as 100%), most (coded as 75%), about half (coded as 50%), some (coded as 25%) and none (coded as 0%). Answers from all completed surveys over 12 weeks will be averaged to get a percent usage for each participant.

Program Interest by Consenting to Being Contacted/Voiced Interest to Recruiter

Program interest is defined as the percentage of the total eligible individuals that were referred to the program who were 1.) reachable for recruitment and 2.) did not decline participation via either opt-out letter or when contacted by researchers (those who declined prior to being provided detail on their assigned intervention).

Program Enrollment

Program enrollment will be measured as the percentage of patients eligible and referred that decide to enroll. Patients who choose not to enroll will be asked to provide more information on why they do not want to enroll.

4.3 Other/Exploratory Outcomes

Fruit and Vegetable Consumption will be assessed using the 2021 Behavioral Risk Factor Surveillance System FV module. This screener reviews several food type categories including fruit juice, fruit, beans, dark green- and orange-colored vegetables and other vegetables.

Nutrition Security will be measured using a combination of the USDA Food Security Survey Module, which assesses accessibility and affordability, with the new suite of nutrition security measures that complement the USDA instrument to help capture the remaining pillars of nutrition security (availability, utilization, and stability). Availability will be assessed with the Perceived Limited Availability Measure. Three items assess perceived limited availability at food stores. The types of food include "quality fruits and vegetables," "food we liked," and "foods that were good for our health and well-being". Accessibility and Affordability will be assessed using the 10-item USDA Adult Food Security Survey Module adapted to examine the past semester's intake. USDA's scoring system adds affirmative responses: 0, high food security; 1-2, marginal food security; 3-5, low food security; and 6-10, very low food security. Utilization will be

measured as described above. Stability will be assessed with the Food Insecurity Stability measure. It evaluates the temporal state of an individual's chronic, seasonal, intra-monthly, and intermittent food insecurity.

Diet-Related Psychosocial Constructs

Self-efficacy to purchase, prepare and eat fresh FV will be measured with a 10-point Likert scale using a selection of items adapted from a study of shoppers where self-efficacy was shown to be correlated with nutrition behaviors.

Barriers to eating FV will be measured using a 4-point Likert scale (strongly agree to strongly disagree) previously tested in lower-income adults which reflects common benefits/barriers found in the literature.

Health Status

Health status and disease risk will be measured using one subscale of the RAND 36-Item Short Form Health Survey (SF-36): 1.) General health: 1 item with a 5-point Likert scale where 1 is excellent and 5 is poor; this is combined with the EQ-5D-5L survey, which consists of 2 pages: the EQ-5D descriptive system and the EQ visual analogue scale (EQ VAS). The descriptive system comprises five dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Each dimension has 5 levels: no problems, slight problems, moderate problems, severe problems and extreme problems. The EQ VAS records the patient's self-rated health on a vertical visual analogue scale where the endpoints are labelled 'The best health you can imagine' and 'The worst health you can imagine'.

5. Population to be Analyzed

We worked with two primary care clinics of a local hospital system in Buffalo, NY to identify and recruit eligible participants. Eligible participants were patients aged 65 and older who screened positive for food insecurity (FI) through an existing two question screener that all patients receive at their annual visit. This screener asks patients if "in the last 12 months, did you ever, eat less than you felt you should because there wasn't enough money for food" and "do you have access to fresh fruits and vegetables within two miles of your residence." Patients who answered in the affirmative for the first or negative to the second question were eligible for the study. Additional eligibility criteria included: English speaking, age 65 or older, ability to store food and prepare meals at home, being the primary grocery shopper for their household, having no severe food allergies, and receiving care through our clinical partner. If the individual was not the primary grocery shopper, their spouse or caregiver was considered for participation, provided they met the other eligibility requirements.

6. Analyses

Program utilization and satisfaction outcomes were analyzed using Analysis of Variance (ANOVA) and were followed with orthogonal contrasts comparing three combinations of group comparisons (Meal Kit/Produce Prescription, Meal Kit/Mobile Market, Produce

Prescription/Mobile Market). Enrollment and behavioral outcomes were compared using frequency tables and chi-square analyses. All analyses were conducted using SAS 9.4.

Additional details of the analyses for primary outcomes can be found below:

Question Set	Answer options	Variable Creation	Analysis Plan <i>For all main outcomes we need to control for relevant demographic variables</i>
Primary Outcomes from Baseline/Follow-up Survey			
Demographics	various	Will combine categories with small numbers of respondents BMI: created from height and weight AHA required: <ul style="list-style-type: none"> • Age (Specific age at enrollment) • Gender (Man / Non-Binary/Third Gender / Woman / Prefer to Self-Describe / Prefer Not to Answer) • Sex • Race (American Indian or Alaska Native / Asian / Black or African American / Native Hawaiian / Other Pacific Islander) / White / Some other 	1. Descriptive 2. Will test for differences between Ix and Control groups and include any variables that differ as co-variables in outcome analyses

		<p>race / Prefer not to answer)- <i>create a new variable with multi-racial for people who select more than one</i></p> <ul style="list-style-type: none"> • Ethnicity (Are you of Hispanic, Latino/a, or Spanish Origin? Yes / No / Prefer not to answer) • Insurance Type • Household Size • Plus food security 	
Fruit and Vegetable Consumption	Frequency (per day, week or month)		Aim 2 Exploratory Outcome-change by group at follow-up Correlation between F&V intake and usage
Nutrition Security			Aim 2 Exploratory Outcome-change by group at follow-up
USDA Adult Food Security Module (10 questions)	Responses of “yes,” “often,” “sometimes,” “almost every month,” and “some months but not every month” are coded as affirmative.	<p>The sum of affirmative responses to a specified set of items is referred to as the household’s raw score on the scale comprising those items.</p> <p>Raw score zero— High food security among adults Raw score 1-2— Marginal food</p>	Aim 2 Exploratory Outcome - change by group at follow-up

		security among adults Raw score 3-5— Low food security among adults Raw score 6-10— Very low food security among adults	
Cooking at home (1)*	Every day, 5-6 days per week, 3-4 days per week, 1-2 days per week, Never -- I do not prepare any main meals at home	Create a continuous variable Everyday=1 1-2= 1.5 3-4= 3.5 5-6= 5.5 Never= 0	Aim 2 Exploratory Outcome For baseline, we will just look at descriptive – i.e. days per week cooking at home For follow-up we will look at change in average days per week cooking by arm
Self- Efficacy Cooking & Eating F&V (7)*	10- point scale (1 to 10)	continuous variable Combine to create a score ranging from 7 to 70	Aim 2 Exploratory Outcome Compare change in self-efficacy by intervention arm
Health Status	Excellent Very good Good Fair poor		descriptive
Past year doctor visits	Continuous numerical		descriptive
Past year hospital visit	Continuous numerical		descriptive
Primary Outcomes from Weekly Usage Survey and Recruitment			
Enrollment		Look at the percent of people who were offered a given intervention that accepted it	Aim 2 Main Outcome Need to compare by arm
Redemption	Yes/No	This question is asked every week for 12 weeks on the weekly survey. These answers will be combined to determine a percent of deliveries that were confirmed for each person. If the data is missing, we	Aim 2 Main Outcome Need to compare by arm

		mark them as a no. Sensitivity analyses can be used to look at actual deliveries and voucher redemptions vs. reported deliveries and voucher redemptions.	
Usage- About how much of the fruits and vegetables in the box were used by someone in your household?	Answers coded as follows: a. all (100%) b. most (75%) c. about half (50%) d. some (25%) e. none (0%) f. I did not receive a box last week (missing or 0)	Combine e. and f. ??? This question is asked every week for 11 weeks on the weekly survey and then a 12 th time on the follow-up survey. These answers will be combined.	Aim 2 Outcome- compare by arm
What was the main reason you didn't use all the food?	a. there were items my family did not like b. it was more than we could eat c. we did not know how to prepare it d. we had enough food from other sources and didn't need it e. we didn't have time to prepare it f. there was a problem with the food appearance or quality g. other (please specify)	Not at the individual level- just looking at the total for all the times the questions were asked- denominator is the number of times the question was answered	Descriptive by arm
What happened to the food you didn't use	a. I gave it away b. I threw it out or composted it c. I plan to use it in the future d. other (please specify):	Same as above	Descriptive by arm
Customization	Yes/no		Only asked to intervention arms Explore as a moderator for usage?

Reason for no customization	<p>3.b. If no, what was the main reason you didn't customize your fruit and vegetable box?</p> <p>a. I forgot to do it before the cut-off time</p> <p>b. I didn't have access to the internet</p> <p>c. I had trouble using the website</p> <p>d. I didn't want to</p> <p>e. other (please specify)</p>		Descriptive
Recipe Usage	Yes/no	Look at percentage of time they said yes across all answered questions- missing is excluded (not tied to redemption)	Compare by arm
What was the main reason you didn't try the recipes?	<p>b. I didn't receive any recipes</p> <p>c. I didn't have the other ingredients needed to make them</p> <p>d. I didn't have the kitchen tools needed to make the recipes</p> <p>e. The recipe was complicated or hard to follow</p> <p>f. I didn't have the time or energy</p> <p>g. other (please specify)</p>		Descriptive by arm
How many different recipes did you make this week	<p>a. 1</p> <p>b. 2</p> <p>c. 3</p> <p>d. 4 or more recipes</p>	<p>Create continuous variable by coding 4 or more as 4.</p> <p>if they said no above for using the recipes then this is a 0.</p> <p>This question is asked every week</p>	Aim 1 Exploratory outcome

		for 11 weeks on the weekly survey and then a 12 th time on the follow-up survey. These answers will be combined-	
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