**Form A**

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COVER PAGE

Official title: Identifying Food Pantry Client and Staff Preferences for Nutritious no Prep Ready-to-eat Meals Versus Ingredient Bundles as an Effort to Increase Food Security, Improve Nutrition, and Promote Well-being

NCT number: NCT05593510

Document date: August 30th, 2022

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If an item does not apply to your research project, indicate that the question is "**not applicable**" – do not leave sections blank

**Click once on the highlighted entry in each box to provide your response.** Click the item number/letter or word, if hyperlinked, for detailed instructions for that question. If your response requires inserting a table, picture, etc, you may need to first delete the box that surrounds the answer and then insert your table or other special document.

**1. Purpose and objectives.** *List the purpose and objectives:*

The specific aims of this pilot study are: **Aim 1**) *To identify whether no prep ready to eat meals (intervention) or ingredient bundles (control) have higher client acceptability, liking, satisfaction, and perceived diet quality ratings.* **Hypothesis**: No prep ready to eat meals will have higher client acceptability, liking, satisfaction, and perceived diet quality scores than ingredient bundles. **Rationale**: Previous research has shown that acceptance, liking, satisfaction, and perceived diet quality are important determinants of the foods people are willing to eat and the ultimate success of diet-related interventions[12]. Aim 1 will establish which strategy is most acceptable and desirable for food pantry clients to inform the development of a future randomized-controlled trial that will aim to test which strategy is most effective at improving objective dietary quality and reducing health-related risk factors. **Aim 2**) *To identify whether no prep ready to eat meals (intervention) or ingredient bundles (control) have higher feasibility ratings with food pantry staff.* **Hypothesis:** No prep ready to eat meals will have higher feasibility ratings than ingredient bundles among pantry staff. **Rationale**: It's unclear how much staff time and pantry resources are needed to put together an ingredient bundle from a recipe or store no prep ready to eat meals in appropriate refrigeration units. This pilot study will determine the resources needed to carry out each program and determine which is preferable and feasible for the pantry staff that would be asked to carry out either model given that staff buy-in is a key component to intervention success[13].

**2. Background.**

- Describe past experimental and/or clinical findings leading to the formulation of your study.
- For research involving investigational drugs, describe the previously conducted animal and human studies.
- For research that involves FDA approved drugs or devices, describe the FDA approved uses of this drug/device in relation to your protocol.
- Attach a copy of the approved labeling as a product package insert or from the Physician's Desk Reference.

You may reference sponsor's full protocol or grant application (section number and/or title) or if none, ensure background includes references.

Please respond to all components of this item, or clearly indicate which components are not applicable.

**a. Background**

Reviews conducted in 2019 and 2022 have highlighted the urgent need for disease prevention strategies within the charitable food system, given the lack of evidence-based interventions. The most commonly reported interventions provide nutrition education, referrals to a social worker or health care provider, and/or behavioral economic approaches that "nudge" clients to select healthier options in client choice pantries[22,23]. Some of these strategies have been effective at increasing food security and improving client selection of healthier food items at one point in time, however, it is a small literature base, few studies have been designed for long-term sustainability in partnership with pantry clients and staff, and most haven't measured changes in food intake.

One promising nutrition intervention is ingredient bundling, which pairs fruits, vegetables, whole grains, and lean proteins with a recipe that instructs participants on how to cook the meal. Ingredient bundles have been shown to increase ones perceived value of goods[24] and are hypothesized to reduce some of the search and planning time associated with making healthier food choices[25]. Bundles were reported as a preferred nudging strategy by pantry clients in a formative research study[5] and were found to increase selection of kale and whole grains when compared to recipe tasting and "treatment as usual" control groups in a between-subjects experiment in Connecticut[9]. However, in a study of Supplemental Nutrition Assistance Program (SNAP) shoppers, meal bundles were ineffective at improving grocery purchases[25] and no additional studies promoting ingredient bundles have been conducted in food pantries to determine if the Stein et al. findings are replicable.

While there are clear advantages of ingredient bundling, there are some disadvantages. There is staff time associated with identifying recipes and bundling ingredients from the available food donations or procurements and there is the added time and food preparation burden for clients. Furthermore, previous research has highlighted that people experiencing food insecurity may not have as much kitchen space or equipment as people who are food secure[10]. Among a sample of 211 Crossroads clients specifically, 55% did not have a mixing bowl, 54% reported not owning a casserole dish, and 23% did not

have cutting knives or a blender[26], these are kitchen tools frequently recommended for healthier meal preparation strategies and required to prepare many recipes, such as stir fries, smoothies, and casseroles.

No prep ready-to-eat meals alleviate the time and food preparation constraints faced by people experiencing food insecurity and provide the opportunity to encourage more nutritious food consumption in a potentially preferable package. While market research and consumer scientists have identified no prep ready-to-eat meals as a burgeoning food retail avenue[26], these meals have **not** been empirically tested as a strategy for improving food security, dietary quality, and health outcomes among clients in a food pantry setting. Given the novelty of this idea, formative research is needed to confirm the intervention is desirable to food pantry clients and feasible for food pantry personnel to carry out.

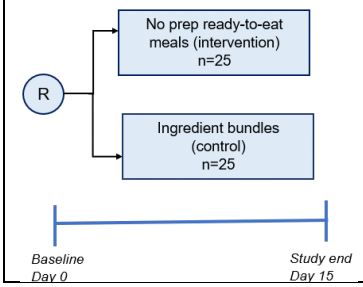
**b. Current practice**

Currently, food pantry clients at Crossroads receive food in one of three ways:

1) Emergency box filled with food provisions filled by pantry staff – the number of pounds received is dependent on the household size and age of household members, the pantry client does not get to choose the food they receive
2) With an appointment, clients walkthrough the pantry and select food off shelves and from inside refrigeration units based on a point system – points are distributed based on household size and age of household members and the pantry inventory, the pantry client chooses the food they receive
3) With an appointment, clients select food using a web-based application that displays live inventory. Clients select food using the application based on the same in-house point system, the pantry client chooses the food they receive

**3. Study Design.**
Describe the study design (e.g., single/double blind, parallel, crossover, etc.) Consider inserting a scheme to visually present the study design.

Figure 3. Proposed study design




To test the first hypothesis, I will use a randomized repeated measures between-subjects design with half of the participants randomized to receive 14-days of no prep ready-to-eat meals (intervention, n=35) and half of the participants randomized to receive 14-days of ingredient bundles (control, n=35) (**Figure 3**).

To test the second hypothesis, I will use a mixed-methods approach with food pantry staff (N=10), including questionnaires with fixed and open-ended items on feasibility and satisfaction of each distribution strategy followed by 30-minute semi-structured 1-1 interviews conducted by UT Southwestern study staff.

**4. Research Plan / Description of the Research Methods:**

**4.a.** Provide a **comprehensive narrative** describing the **research methods**.

1) Provide the **order in which tests/procedures will be performed**,
2) Provide the **setting** for these events and a description of the **methods used to protect privacy** during the study.
3) Provide the **plan for data analysis** (include as applicable the **sample size calculation)**

Please respond to all components of this item, or clearly indicate which components are not applicable.

**C.1.5 Intervention Methods**

After completing consent forms, participants will be randomized to receive no prep ready-to-eat meals or ingredient bundles using random number generation. Participants will be unaware of their assignment until they are asked to select study meals, in which case it will be obvious because of the food items available to select. Participants will complete questionnaires and then select meals – they can select up to 2-meals, or the bundles needed to make 2-meals, for 14-days for themselves and 2 additional members of their household. Participants will elect to receive one week of meals after selection and come back to pick-up the second week of meals or they will take home all study meals at one time (participants choice). Participants will return at the end of the 2-week study period to complete the follow-up questionnaires and receive payment. A study timeline of intervention components and data collection is provided in **Table 1** to aid visualization of the study plan and timeline for **food pantry clients**.

**Table 1. Study plan and timeline for food pantry clients.**

| Baseline appointment (Day 0) | Intervention (Day 1 - Day 14) | Follow-up appointment (Day 15) |
|---|---|---|
| 1. Informed consent<br>2. Randomization<br>3. Questionnaires (demographics, current pantry use, acceptability, satisfaction, liking, diet quality)<br>4. Selection of preferred no prep ready-to-eat meals OR ingredient bundles from the available study foods depending on study assignment<br>5. Follow-up appointment scheduled | 1. Participants and family members consume no prep ready-to-eat meals or ingredient bundles at-home for 14-days<br>2. Depending on the client's preference, reminder phone calls, texts, and/or emails are sent leading up to their follow-up appointment | 1. Questionnaires (demographics, current pantry use, acceptability, satisfaction, liking, diet quality)<br>2. Participant thank you and payment |

**C.1.5.1 No prep ready-to-eat meals**

Roots Food Group provides nutrient-dense dietician developed no prep ready-to-eat meals to many of the 14 million people on Medi-Cal in California through Aetna and HealthNet. The community-based 501c3 arm of Roots Food Group, Roots Food Foundation, provides the same meals and other resources to people living with blindness at no cost. Roots Food Foundation has agreed to donate and supply meals for this study.

Pantry clients will select study meals for up to 14-days' worth of meals for themselves and 2-members of their household using Crossroads online food selection platform (this platform is already built and is how clients currently select pantry foods). Roots Food Group produces over 70 meals. We have elected to study 14-days of meals to offer clients variety and determine which flavors are most desirable to clients. After ordering, meals will be retrieved from a refrigeration unit, boxed by pantry staff, and brought to the participant to take home. An example dinner is "Teriyaki Chicken with Roasted Potatoes and Broccoli", and an example breakfast is "Omelet with Peppers and Zucchini". Meals can be stored in a refrigerator or freezer and eaten immediately or after reheating depending on the meal and consumer preference. 94% and 86% of Crossroads clients reported owning a refrigerator and microwave respectively when previously surveyed[27] and microwaves are available in many community centers and gas stations for public use. This makes no prep ready-to-eat meals a potential solution to many of the challenges faced by Crossroads pantry clients and people experiencing food insecurity.

**C.1.5.2 Ingredient bundles**

Ingredient bundles will group individual meal ingredients (e.g., chicken, teriyaki, broccoli, potatoes) in a bag or box and pair those healthy food items with a recipe that instructs the client on how to make a healthier meal. Similar to the no prep ready-to-eat meal initiative, clients will select ingredient bundles for themselves and 2-members of their household using Crossroads online food selection platform. The no prep ready-to-eat meals chosen by the PI will be selected based on the ability to closely replicate the meal as an ingredient bundle using food pantry inventory. "Teriyaki Chicken with Roasted Potatoes and Broccoli" is an example of a Roots Food Group meal that will be available for clients to select as most of the required ingredients are purchased by or donated to Crossroads and typically available to clients. For this study, the study team will purchase groceries for this group. This is to ensure availability of study foods and to procure specific ingredients, such as spices and sauces (e.g., teriyaki), cooking oils, and fresh fruits and vegetables. Having costs associated with ingredient bundles also makes the expense burden associated with each strategy more equal, which helps confirm the feasibility and sustainability of either intervention going forward.

**C.1.6 Measures**

**C.1.6.1 Pantry Client Measures**

At the baseline appointment participants will complete informed consent and a questionnaire that includes demographics, typical food pantry utilization, satisfaction, acceptability, liking, and perceived diet quality. Satisfaction items will be adapted from previously validated food pantry client satisfaction surveys (e.g., "How satisfied are you with the amount/variety/frequency of food that you and others in your household receive at this food pantry?")[28]. Possible responses range from very satisfied and somewhat satisfied to somewhat dissatisfied and very dissatisfied. Liking of study foods will be measured by showing the name and picture of the meal or ingredient bundle and asking participants to respond to a hedonic 9-point bipolar scale with four measures of liking and four measures of dislike and a neutral "neither like nor dislike" item[29]. Acceptability will be measured by showing the name and picture of the meal and asking the client whether they and/or members of their household ate the meal within the past 2-weeks and whether they would select the meal again if given the opportunity in the future[30]. Perceived dietary quality will be measured using a single validated item that asks participants to rate their overall diet quality as "excellent," "very good," "good," "fair," or "poor"[31]. At the follow-up appointment, participants will complete the same liking and acceptability ratings, and a similar satisfaction questionnaire and perceived diet quality item, except wording will be slightly modified to "How satisfied were you with the amount of food that you and others in your household received at the food pantry **in the past 2-weeks**?" "How would you rate your dietary quality **over the past 2-weeks**?"). These measures will allow us to determine between-group

differences at baseline as well as within- and between-group changes in acceptability, satisfaction, liking, and diet-quality after consuming meals over time. These measures will also identify client's preferred meal flavors and frequency as well as the quantity desired in a future intervention.

**C.1.6.2. Pantry Staff Measures**
Food pantry staff will answer feasibility items for each of the intervention groups, such as desire to implement each food distribution strategy in the future, perceived appropriateness of the intervention given their organizational goals, perceived sustainability, and financial/staff resources needed to carry out the intervention longer term[32]. Staff participants will also respond to qualitative open-ended response items such as "Describe any challenges experienced with distributing ingredient bundles" "Describe any challenges experienced with distributing no prep ready-to-eat meals". Responses to the questionnaire will be followed with 30-minute semi-structured 1-1 interviews with study personnel, which give pantry staff the opportunity to directly voice any challenges or preferences that come up when implementing either approach. The pantry personnel perspective will allow us to design a feasible and sustainable longer-term intervention.

**C.1.7. Analytic Plan**
**C.1.7.1. Analytic Plan for Pantry Client Data**
Descriptive statistics (e.g., means, percentages, chi-squared tests of independence) will be used to describe participant characteristics and baseline differences. The independent variable of interest will be randomized group assignment (e.g., no prep ready to-eat-meals vs. ingredient bundles). Spearman's correlation and/or repeated measures Analysis of Variance (ANOVA) will be used to describe the association between group assignment and client's perceived diet quality at follow-up. If normally distributed, repeated-measures ANOVA is acceptable and will be used. If non-normal, Spearman's correlation will be used. For the other three outcomes of interest (satisfaction, acceptability, and liking) sum scores will be calculated, and model assumptions will be tested (e.g. residual distributions) before proceeding with repeated-measures Analysis of Variance (ANOVA) to test for group effects on study outcomes of interest and group-by-time interactions.

**C.1.7.2 Analytic Plan for Pantry Staff Data**
Descriptive statistics (e.g., means, percentages) will be used to describe quantitative items on staff feasibility and satisfaction. Qualitative thematic analysis of open-ended questionnaires and interviews will be synthesized into key findings and suggestions for future intervention development.

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**4.b. List of the study intervention(s) being tested or evaluated under this protocol**

☐ **N/A -** this study does not test or evaluate an intervention. Skip to item 4.d.

| # | Study intervention(s) being tested or evaluated under the protocol<br><br>*Add or delete rows as needed* | Affiliate<br><br>Place a check next to institution(s) where the intervention will be performed | Local Standard Practice?<br>Indicate whether the intervention is considered acceptable practice locally for applicable institutions |
|---|---|---|---|
| 1 | Figure 1. Example no prep ready-to-eat meals<br>  <br><br>Image Citation: https://www.supermarketnews.com/deli/spartannash-debuts-private-label-ready-made-meals | ☐ UTSW | ☐ Yes |
| | | ☐ PHHS | ☐ Yes |
| | | ☐CMC | ☐ Yes |
| | | ☐THR | ☐ Yes |
| | | ☐TSRH | ☐ Yes |
| | | ☒ Other: Crossroads Community Services (Food pantry) | ☒ Yes |
| 2 | Figure 2. Example ingredient bundles or "meal kits"<br>  <br>Image Citation: https://www.everydayhealth.com/high-cholesterol/the-best-meal-kits-for-people-with-high-cholesterol/ | ☐ UTSW | ☐ Yes |
| | | ☐ PHHS | ☐ Yes |
| | | ☐CMC | ☐ Yes |
| | | ☐THR | ☐ Yes |
| | | ☐TSRH | ☐ Yes |
| | | ☒ Other: Crossroads Community Services (Food pantry) | ☒ Yes |

**4.c. Risk:Benefit Analysis of study interventions being tested or evaluated under this protocol**

For each study intervention identified in section 6b above, complete a risk:benefit analysis table.

*(Two tables are provided, copy & paste additional tables as needed or delete both tables if this study does not test an intervention)*

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**4.c.**
**Study Intervention #1**
No prep ready to eat meals

| **List each group exposed to this intervention on a separate line.** (e.g., experimental, control, Arm A, Arm B, etc) **Or** state All Groups/Subjects | For each group, list the **benefits** of this intervention. (Benefits can be directly from the intervention or from a monitoring procedure likely to contribute to the subject's wellbeing). If there are no benefits, state "none". |
|---|---|
| Experimental | Participants, many of whom are food insecure, receive extra free food as a part of this study |
| | |

**If you are requesting a Waiver of Informed Consent, complete the table below.**

If you have a consent form, **list the reasonably foreseeable risks in the consent form (and do not complete this section).**

List the risks according to the probability (likely, less likely or rare) and magnitude (serious or not serious).
(include: 1) expected adverse events; 2) rare and serious adverse events; 3) all other psychological, social, legal harms)
Do not delete frequency. Frequency must be estimated because it will assist you with determining which adverse events will require prompt reporting.

| | **Not serious** | **Serious** |
|---|---|---|
| **Likely** These risks are expected to occur in more than **20** out of **100** subjects. | • Not applicable | • Not applicable |
| | **Not serious** | **Serious** |
| **Less likely** These risks are expected to occur in **5-20** subjects or less out of **100** subjects. | • Potential discomfort from answering personal questions or trying new study foods | • Not applicable |
| | | **Serious** |
| **Rare** These risks are expected to occur in less than **5** subjects out of **100** | | • Not applicable |

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**4.c.**
**Study Intervention #2**
Ingredient bundles or "meal kits"

| **List each group exposed to this intervention on a separate line.** (e.g., experimental, control, Arm A, Arm B, etc) **Or** state All Groups/Subjects | For each group, list the **benefits** of this intervention. (Benefits can be directly from the intervention or from a monitoring procedure likely to contribute to the subject's well being). If there are no benefits, state "none". |
|---|---|
| Control | Participants, many of whom are food insecure, receive extra free food as a part of this study |
| | |

**If you are requesting a Waiver of Informed Consent, complete the table below.**

If you have a consent form, **list the reasonably foreseeable risks in the consent form (and do not complete this section).**

List the risks according to the probability (likely, less likely or rare) and magnitude (serious or not serious).
(include: 1) expected adverse events; 2) rare and serious adverse events; 3) all other psychological, social, legal harms)
Do not delete frequency. Frequency must be estimated because it will assist you with determining which adverse events will require prompt reporting.

| | **Not serious** | **Serious** |
|---|---|---|
| **Likely** These risks are expected to occur in more than **20** out of **100** subjects. | • Not applicable | • Not applicable |
| | **Not serious** | **Serious** |
| **Less likely** These risks are expected to occur in **5-20** subjects or less out of **100** subjects. | • Potential discomfort with answering personal questions or trying new study foods | • Not applicable |
| | | **Serious** |
| **Rare** These risks are expected to occur in less than **5** subjects out of **100** | | • Not applicable |

| | | | | |
|---|---|---|---|---|
| | **4.d**. List ALL other research procedures or components not listed in table 4.b.<br>***The combination of Tables 4b and 4d should account for all of the research procedures that will take place during this study.***<br><br>Consider grouping similar procedures under a single component (e.g., blood work, CT = safety assessments) | | | |
| | | | | |
| **#** | **Research component**<br>• **individual procedures**<br>*example:*<br>**Eligibility Assessments**<br>• History and physical<br>• Questionnaire<br>• Laboratory tests<br>*Add or delete rows as needed* | **Column A**<br>**Local Standard Practice** Indicate the number of times each procedure will be performed as stipulated in the research plan **that would be performed if the participant were not participating in the study.** | **Column B**<br>**Research Only**<br>Indicate the number of times each procedure will be performed solely for research purposes *(meaning that the participant would not undergo the same number of procedures or would not undergo the procedure(s) at the same frequency if they were not participating in the study)* | **Column D**<br>**Risks**<br>**If you are requesting a Waiver of Informed Consent, complete the table below.**<br><br>List the reasonably expected risks for each procedure or group of procedures under the following categories as appropriate:<br>• Serious and likely;<br>• Serious and less likely;<br>• Serious and rare;<br>• Not serious and likely;<br>• Not serious and less likely |
| **1** | **Eligibility Assessment** | | | |
| | 5-10-minute online or paper-based screener, participant decides their preference | Typically, there is no study eligibility assessment. However, clients are used to completing an eligibility assessment to use the pantry in general. | Once | Not serious and unlikely – discomfort or boredom from answering questions |
| **2** | **Questionnaires** | | | |
| | Demographics, current pantry use, acceptability of study foods, satisfaction with study foods, liking of study foods, diet quality, food frequency questionnaire | Clients typically answer 5-7 random research questions per visit which have been programmed into the pantry's web-based application by other researchers. Clients would typically **not** answer all the questions we are asking them to complete. | Twice (at baseline and follow-up – 2 weeks later) | Not serious and unlikely – discomfort or boredom from answering questions |
| **3** | **Selection of preferred no prep ready to eat meals OR ingredient bundles depending on group assignment** | | | |
| | Using the pantry's web-based application meals based on their group assignment. All meals will be added to the pantry inventory, but participants in each group will only see meals from their group assignment. | The client would be selecting food off shelves from the pantry (note: the client is still able to receive their typical monthly allowance from the pantry & this study provides additional food) | Clients will select food only one time, but they can decide to take it all at once or come back the following week to pick-up more of their order if it's too much food to take at once – they decide | Not serious and less likely – discomfort from trying new study foods, but since they are choosing what foods to take, this is less likely |
| **4** | **Participants eat study meals** | | | |
| | Participants eat the meals they selected | As frequently or infrequently as they like | Ideally once per day, but it's up to the client | Not serious and less likely – see 3D |

| 5 | Participants receive reminders | | | |
|---|---|---|---|---|
| | Participants receive reminder calls, texts, and/or emails to try the study foods and come back for to their follow-up appointment | Clients receive reminder texts, calls, and/or phone calls if they have a scheduled appointment with the pantry, it varies depending on the client | Three times | Not serious and less likely – client's will confirm it's okay to contact them and indicate to us which is their preferred method of contact (call, phone, email) |

**5. Safety Precautions.** *(Describe safeguards to address the serious risks listed above.)*

**a.** Describe the procedures for protecting against or minimizing any potential risks for each of the more than minimal risk research procedures listed above.

Not applicable, this study has no more than minimal risk

**b.** Where appropriate, discuss provisions for ensuring necessary medical or professional intervention in the event of adverse events, or unanticipated problems involving subjects.

Not applicable, this study has no more than minimal risk

**c.** Will the safeguards be different between/among groups?

☐ Yes ☑ No

Not applicable

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