Official Title of the Study: Nourish: A Pilot Study and Co-Design

NCT Number: NCT06398197

Date of the Document: June 27, 2024

ONLY use this template for non-exempt studies involving human interaction (e.g., Survey, Interviews, Focus Groups, Educational Research Activities)
DO NOT USE if there are any Biomedical or Clinical Components

INSTRUCTIONS:

- *Carefully complete the protocol.*
- *DO NOT open or edit in google docs.*
- *DO NOT upload PDFs of protocol or consent forms. Use PDFs sparingly.*
- *Depending on the nature of what you are doing, some sections may not be applicable to your research. If so, please mark as N/A.*
- *When you write a protocol, keep an electronic copy. You will need to modify this copy when making changes.*
- *Consider using a different color font for your answers.*

PROTOCOL TITLE:
Include the full protocol title.
Nourish Pilot & CoDesign Study

PRINCIPAL INVESTIGATOR:
Name: Melissa Prescott PhD, RDN, FAND

Indicate the origin of this protocol (who conceived of and leads the development of the protocol regardless of funding):
☒ Investigator initiated *(Investigator(s) developed protocol, regardless of funding)*
☐ Industry *(Pharmaceutical, Device, etc.) (Industry developed protocol)*
☐ Federal *(NIH, DOD, etc.)*
☐ Cooperative Group *(SWOG, GOG, etc.)*
☐ Other - Please specify: Click here to enter text.

Has this study been disapproved by or withdrawn from any other IRB?
☐ Yes ☒ No
If so, please explain: Click here to enter text.

Does this study involve cancer research or cancer-related issues?
☐ Yes ☒ No
If yes, indicate the PRMC number: Click here to enter text.

Is this a student led study?
☐ Yes ☒ No
If yes, is the student: ☐ Undergrad ☐ Graduate Student ☐Other Click here to enter text.
If yes, is the project: ☐ Capstone ☐ Master's thesis ☐ PhD dissertation

☐Other Click here to enter text.

Is this work part of a larger collaborative research project where more than one institution is participating in the research? (*In collaborative projects, data/specimens/results are often shared between researchers at the participating institutions, and they will publish together.)*

☒ **No** ☐ **Yes**

If yes, please explain.

Click here to enter text.

1.0 Funding

If this study is grant funded, is the money coming directly to CWRU from the study sponsor?

☐ Yes ☒ No ☐ N/A, not grant funded

2.0 Objectives

Directions: Describe the purpose, specific aims or objectives. Be sure to also include the hypothesis being tested. The purpose of this study is to pilot a culinary nutrition and food literacy intervention entitled Nourish and its corresponding evaluation components to evaluate their feasibility and engage participants in the re-design of the intervention following completion of the Nourish pilot. Specifically, we aim to:

1. Determine whether the Nourish intervention is delivered as intented in terms of time use and objectives delivered.
2. Determine the feasibility of the recruitment, retention, evaluation, and participant engagement methods.
3. Assess participant perspectives on the Nourish intervention so they can be leveraged to re-design the intervention to ensure they are culturally and socially relevant.

3.0 Background

Directions: Describe the relevant prior experience and gaps in current knowledge describing how this study will add to existing knowledge. Include any relevant preliminary data. Currently, 12.8% of Americans experience food insecurity (1), and food insecurity is associated with elevated perceived stress (2-3). Food literacy is proficiency in food related skills and knowledge, including food preparation and cooking skills, basic nutrition knowledge, and the ability to prevent food waste. Recent research conducted in Australia suggests that food literacy interventions are associated with improved food security (4). Traditionally food literacy interventions take a recipe-based approach to culinary nutrition and lack information about key components of food literacy, such as food storage and food waste reduction techniques. However, recent research by the PI contends that recipes may be difficult for food insecure individuals to implement at home, given the challenge of procuring ingredients (5), suggesting the need for a new approach. In addition, food insecure households face additional environmental challenges, such as owning fewer cooking utensils, compared to food secure households (6). Based on the Social Cognitive Theory, the Nourish intervention addresses these

limitations by incorporating food waste reduction, food storage knowledge, and improv cooking skills (cooking with what you have on hand) into food literacy and culinary nutrition education, as well as providing key cooking utensils. Eventually, our team plans to test the impact of the Nourish intervention on food literacy, perceived stress, diet quality and food security to determine if food literacy interventions can positively impact perceived stress, diet, and food security. The present pilot study will test the feasibility and acceptability of the Nourish intervention and corresponding evaluation, as well as provide participant feedback on the intervention.

Please add relevant references at the end of the protocol, not at the end of this section.

4.0 Inclusion and Exclusion Criteria

Directions: Describe how individuals will be screened for eligibility.

Individuals will be verbally screened for eligibility to determine they are 18 years of age or older and determine that they are able to attend in-person, Nourish classes.

Using the tables below, describe the inclusion and exclusion criteria that will define who will be included and excluded in your final study sample.

	Inclusion
1.	Age range: Adults aged 18 and over
2.	Ability to attend classes (in person)
3.	
4.	

	Exclusion
1.	Non-English speaking
2.	
3.	
4.	

5.0 Number of Research Participants

What is the target enrollment number of research participants? *Make sure to include a specific upper limit. NOTE:* If this is a multi-site study, also include the total number of research participants across all sites.

E.g., "We will enroll 25 subjects at CWRU and plan to enroll 150 subjects study wide."

The target sample for Nourish is 40 participants. Twenty participants will receive the intervention immediately. An additional 20 participants will be in the delayed intervention control group. The upper limit is also 40 due to space constraints and small-group educational activities. This is not a multi-site study.

6.0 Special/Vulnerable Populations

Check which of the following special populations you may include:

- ☐ **Adults unable to consent**
- ☐ **Minors (infants, children, teenagers)**
  - ☐ Wards of the state (e.g. Foster Children)
- ☐ **Pregnant Women** (only if targeted)
- ☐ **Neonates**
- ☐ **Neonates of Uncertain Viability**
- ☐ **Employees**
- ☐ **Prisoners**
- ☐ **Illiterate Individuals**
- ☐ **Non-English Speaking**
- ☐ **Students**
- ☐ **Data on a subjects' specific tribal nations**
- ☒ **None**

1. If the research involves students or employees, describe how you will recruit so that:
   a) Employers or educators do not know if someone participated (until after grades have been assigned in the case of educators)
   b) Employers or educators do not *directly* recruit their own students or employees, and anything else to prevent feelings of coercion to those subordinate to their employer or educator.
   Not applicable.

2. If the research involves individuals that are included in a special/vulnerable population, describe the additional safeguards included to protect the rights and welfare of the individuals for each population indicated. Not applicable.

3. If excluding pregnant women, illiterate or non-English speaking individuals, provide a scientific rationale for the exclusion. Inconvenience or cost is not an acceptable rationale. Non-English speaking individuals will be excluded because we will be cooking in small groups during the intervention. While the risk of injury is no greater than that in everyday life activities, it is important that all participants be able to communicate with each other to maintain a safe cooking environment.

7.0 International information

☒ This is **not** an international study – *please leave rest of this section blank.*

☐ We will be conducting this research at the following international sites:
Click here to enter text.

☐ We are recruiting participants outside of the US from the following locations:
Click here to enter text.

☐ We are sending data outside of the US to the following locations:
Click here to enter text.

☐ We are receiving data from outside of the US from the following locations:
Click here to enter text.

8.0 Recruitment Methods

Note: Attach all applicable recruitment materials to the last section of the Smart form under "Recruitment Materials."

1. Which of the following methods will be used to recruit research participants? – *Select all that apply*
   - ☐ Email
   - ☐ Phone call
   - ☒ Letter
   - ☒ Advertisement (e.g., poster, flyer, etc.)
     - ☒ I attest that advertisements will only be placed **with permission**
   - ☐ Social media
     - Indicate the platform(s): *Click here to enter text.*
     - ☐ I attest that recruitment information will only be posted **with permission**
   - ☒ Other. *Please specify:* Snowball sampling

2. Describe when, where, how and by whom potential research participants will be recruited. Individuals involved in recruitment should be identified by role and not by name (e.g. study coordinator, co-investigator, research assistant).
   The study coordinator will recruit participants upon IRB approval. We will primarily use flyers distributed at local community organizations, churches, food pantries, health clinics, and nonprofits. Participation in the Nourish intervention will make individuals eligible for an additional optional opportunity to establish a co-designed Nourish curriculum and structure. All 40 participants will be eligible for the second opportunity, as long as they complete at least 7/8 classes of the intervention. These participants will be invited with a recruitment letter provided at the conclusion of class 7 and class 8 of the intervention. The recruitment letter will be provided by a research assistant.

3. Describe the feasibility of recruiting the required number of suitable research participants within the agreed recruitment period. For example, how many potential research participants do you have access to?
   As eligibility is broad enough to include a large portion of community members, we anticipate that it will be feasible to recruit 40 research participants. By recruiting at community organizations and locations near the setting of the intervention (teaching kitchen), it is more likely that these individuals will be able to attend in person classs at the kitchen, as well. We anticipate that this criteria will be the most challenging for individuals to meet, so will recruit near the physical meeting places used during the study.

9.0 Setting

Directions: Describe the sites and locations where your research team will conduct the research.

Baseline assessment meeting: Participants will meet the Nourish research team at a reserved room located at a branch of the Cleveland Public Library. Weekly Nourish classes: For the duration of 8 weeks, the Nourish culinary education intervention will take place at a community teaching kitchen located at Dave's Market Midtown (1929 E 61st St, Cleveland, OH 44103) or CornUcopia (7201 Kinsman Rd, Cleveland, OH 44104). Second-assessment meeting: Participants will meet the Nourish research team at a reserved room located at a branch of the Cleveland Public Library. Focus Group Series: Participants who complete at least 7 of the 8 Nourish classes will be invited to participate in 2, 90-minute semi-strucutred focus groups. These will take place online via Zoom.

10.0 Consent Process

Indicate whether you will be obtaining consent:

☒ Yes ☐ No

If yes, answer the following questions:

1. Describe *who* will consent the subjects and *where* the consent process will take place: The study coordinator and principal investigator will obtain informed consent. Informed consent will be obtained from registered participants prior to their participation in the first Nourish class session. The consent process will take place at a reserved room located at a branch of the Cleveland Public Library 2 weeks before the first Nourish class session. Participants who are eligible for the focus groups, will be consented during the post intervention assessment meeting in a reserved room located at a branch of the Cleveland Public Library.
   For the 2, 90 minutes semi-structured focus groups, we will attach a consent form to the recruitment letters provided to eligible participants (those completing at least 7 Nourish classes).

2. The time that will be devoted to the consent discussion: A minimum of 20 minutes will be devoted to the consent discussion for each participant. The explanation of the research and participation explanation will summarize the objectives of the research; overview of the Nourish curriculum; potential risks of participation; expectations of participation, including participation in weekly nutrition/cooking classes, weekly surveys, and outside-of-class discussions. For the focus group consenting process, we will begin the focus group with an overview of the consent form that has been previously provided to them and provide an opportunity for questions. This is expected to take about 5 minutes.

3. Any waiting period available between informing the prospective subject and obtaining the consent: If requested, a participant will be granted a waiting period after providing an explanation of the research and participation. It is anticipated that the Nourish team will receive consent from participants while in person after the consent discussion and before completing baseline assessments.

4. Steps that will be taken to ensure the research participants' understanding: During the consent conversation, the research team will periodically ask potential research participants if they understand the information being shared with them, and whether or not they have any questions.

5. Any process to ensure ongoing consent: Ongoing consent will be implied by the completetion of weekly class evaluation surveys.

6. Steps that will be taken to minimize the possibility of coercion or undue influence to the subjects: Potential participants will be given ample time to review all consent documents. The research team will answer all questions, and offer a waiting period between informing the potential participant and obtaining consent if requested.

For Adult Participants

Indicate if you will be asking for a waiver or alteration of consent process or documentation (consent will not be obtained, or written consent will not be documented)

☒ Yes ☐ No

If yes, explain how the research involves no more than minimal risk. Note: We are only asking for a waiver of signed consent for the focus groups. The focus groups will be conducted online and will not ask personal questions. It will only consist of feedback questions about the Nourish classes and evaluation procedures.

Indicate which part of the consent process you are requesting to be waived or altered and the questions following your choice(s):

☒ I will obtain consent, but not participant's signature. (Waiver of documentation)

1. Give the rationale for the request of a waiver of signed consent. We seek a waiver of signed consnent for the focus groups because they will be completed online, and it would be a participant burden to collect signatures from participants.

2. Please describe how you will be documenting that a participant has consented. If a participant choses to participate in the focus group, this will be implied consent.

3. Indicate if the subjects will be provided with written information about the study, and provide justification if you will not be providing a written explanation of the research. We will provide a printed copy of the consent form with the recruitment letter.

☐ I will obtain consent, but request a waiver of some of the elements of consent (e.g. use of deception). (Alteration)

☐ I will not obtain any consent; I am requesting a full waiver of consent.

Only answer if you are requesting an <u>alteration of consent</u>, or a <u>full waiver</u> of consent, please answer the following:

1. Give the rationale for the request of a waiver or alteration of the consent process. Click here to enter text.

2. Explain why the waiver or alteration of consent will not adversely affect the rights and welfare of the participants. Click here to enter text.

3. Explain why the research could not practicably be carried out without the waiver or alteration of consent. Click here to enter text.

4. Indicate if the subjects will be provided with additional information about the study after participation. Click here to enter text.

**Be sure to upload a consent script or information sheet with your study protocol*

Additional Considerations for Consent Process with Adults

<u>Non English Speakers</u> *(Please select one)*

☒ I am **<u>not</u>** enrolling non-English speaking individuals in this research study. The following is justification for why non-English speaking individuals cannot be enrolled: Non-English speaking individuals will be excluded because we will be cooking in small groups during the intervention. While the risk of injury is no greater than that in everyday life activities, it is important that all participants be able to communicate with each other to maintain a safe cooking environment.

☐ I will be targeting non-English speaking adults

1. Describe the process to ensure that the oral and written information provided to those research participants will be in that language during initial consent as well as throughout the study. Click here to enter text.

2. List the language(s) other than English that will be targeted: Click here to enter text.

☐ I am **<u>not</u>** targeting non-English speaking individuals. If a non-English speaking individual is eligible for the study, we will use the following procedures to enroll:

1. Describe the process to ensure that the oral and written information provided to those research participants will be in that language during initial consent as well as throughout the study. Click here to enter text.

Adults Unable to Consent

☒ I am **not** enrolling adults unable to consent in this research study – *please leave the rest of this section blank.*

☐ There is an anticipated direct benefit to the subject. Explain: *Click here to enter text.*

☐ There is NOT an anticipated direct benefit to the subject. Explain: Click here to enter text.

1. Describe the process to determine whether an individual is capable of consent. Click here to enter text.

2. List the individuals from whom permission will be obtained in order of priority (e.g. durable power of attorney for health care, court appointed guardian for health care decisions, spouse, and adult child). Click here to enter text.

3. For research conducted outside of the state, provide information that describes which individuals are authorized under applicable law to consent on behalf of a prospective subject to their participation in the procedure(s) involved in the research. Click here to enter text.
   ☐ N/A

4. Describe the process for assent of the research participants. Indicate:
   - Which subjects that are unable to consent will be required to give assent? If not all, explain why. *Click here to enter text.*

   - Describe whether assent of the research participants will be documented and the process to document assent. Click here to enter text.

   ☐ The subject will be informed about the research to the extent compatible with the subject's understanding.
   ☐ Subjects will be closely monitored.
   ☐ The subject will be withdrawn if they appear unduly distressed.

Research Participants Who Are Not Yet Adults (infants, children, teenagers)

☒ I am not enrolling participants who are not yet adults in this research study. – *please leave the rest of this section blank*

1. Will parental permission be obtained from:
   ☐ One parent even if the other parent is alive, known, competent, reasonably available, and shares legal responsibility for the care and custody of the child

☐ Both parents unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child

☐ Requesting a waiver of parental permission

If you are getting parental/guardian permission:

a. Indicate how you will be documenting the permission:

☐ Signed consent form

☐ Requesting a waiver of documentation of parental permission

b. Describe whether permission will be obtained from individuals other than parents, and if so, who will be allowed to provide permission. Describe the process used to determine these individuals' authority to consent to each child's participation in research. Click here to enter text.

If a waiver of parental permission is being requested:

a. Describe how the study is designed for a subject population for which parental/guardian permission is not a reasonable requirement to protect the subjects, if applicable. Click here to enter text.

b. Describe how the research could not practicably be carried out without the waiver of parental permission. Click here to enter text.

c. Indicate if the subjects will be provided with additional information about the study after participation. Click here to enter text.

2. Will assent be obtained from:

☐ all of the children

☐ some of the children

☐ none of the children

If assent will be obtained from some children, indicate which children will be required to assent. Click here to enter text.

If assent will be obtained from none of the children, indicate the rationale. Click here to enter text.

When assent of children is obtained, describe how it will be documented. Click here to enter text.

3. For children who are pregnant, describe how assent and permission are obtained. Click here to enter text.

☐ N/A

11.0 Sharing of Results with Research Participants

Individual test or research results will be shared with research participants (this is not referring to sharing through standard academic channels, e.g., publishing, presentation, etc.):

☐ Yes ☒ No

If yes, describe how the results will be shared. *Click here to enter text.*

Individual test results will be shared with others (e.g., lab results given to a primary care physician):

☐ Yes ☒ No

If yes, describe with whom and how the results will be shared. Click here to enter text.

12.0 Study Design/Procedures

Directions:

1) Describe the overall study design (e.g.: single visit, single-blind, double-blind, non-randomized, randomized, blood draw, investigational drug, device etc.).
2) Provide a description of all study-related research procedures being performed, including the length of time involved.
3) Include procedures being performed to monitor research participants for safety or minimize risks.
4) Describe the source records including medical or educational records, which will be used to collect data about subjects.
5) Include a description of any device being used to collect data (e.g., eye tracker, step counter). If the device itself is being studied, include additional information in Section 29.

1. The study follows a randomized controlled trial with a delayed intervention control design. The immediate cooking class group will receive their intervention in week 3 of the study, and the delayed cooking class group will receive their intervention in week 13 of the study.

2. Baseline assessment meeting: Regardless of randomized group, all participants will attend this meeting in week 1. Participants will come to a branch of the Cleveland Public Library to sign their consent form and complete the survey portion of their baseline assessment, consisting of Percieved Stress Scale, USDA Food Security Screener, and the Food Literacy, Environment, and Waste (FLEW) assessment which will be conducted via Qualtrics on tablets provided by the researchers. Two aspects of the baseline evaluation will be conducted after the baseline meeting: a) a series of two 24-hour dietary recalls (via phone calls) lasting approximately 30 minutes each and b) participants will be asked to weigh and log their food waste for one week. During the baseline assessment meeting, participants will be asked to share their phone number and participants will be given a kitchen food scale and waste log. They will be asked to return the log on the first day of class. Additionally, participants will be told what they can expect to happen at each Nourish class and will be coached on how to sign up for GroupMe to receive out-of-class information about Nourish. The duration of the baseline assessment meeting will be

approximately 60 minutes, and will occur two weeks before the immediate cooking classes grou's 8-week Nourish class sessions begin.

Weekly Nourish classes: Each Nourish class will last 90 minutes, and will run for 8 consecutive weeks, with one class per week. The immediate cooking class group will receive the Nouirsh clasess in weeks 3-10, and the delayed intervention group will commence the Nourish intervention in weeks 13-20 (after the second intervention assessment period is complete).

Nourish will be held in the teaching kitchen at Dave's Market or CornUcopia. Each class will involve brief instructional video clips, hands-on cooking and tasting experiences. Participants will work individually and as part of small groups during instructional sessions. At the end of each class, participants will receive a grocery bundle and a kitchen gadget that serves both as an incentive and implementation support to promote improved cooking frequency and confidence. Participants will be asked to post photos of what they made with their groceries to the GroupMe, and we will encourage them to engage with fellow classmates on the GroupMe to encourage social support of cooking. Participants will earn raffle tickets for each time they post to the GroupMe and attend a class. A raffle drawing for a pressure cooker will be done at the second-assessment meeting (week 12) for the immediate cooking class group and at the last Nourish class for the delayed group (week 20).

The delayed intervention group will commence the Nourish intervention after the post-intervention assessment period is complete (in weeks 13-20).

A research assistant will attend each class to observe time use and lesson objectives covered.

Second assessment meeting: Participants will come to a branch of the Cleveland Public Library to complete their post assessment, consisting of PSS, USDA Food Security Screener, and the FLEW, as well as their return food waste log. Additionally, participants will be encouraged to enroll in an optional focus group series to provide feedback on Nourish. The duration of the second-assessment meeting will be approximately 35 minutes, and will occur in Week 12.

Focus Group Series: All participants who complete at least 7 of 8 classes of the Nourish intervention will be invited to participate in a series of 2, 90-minute semi-structured, online focus groups to provide additional input on how to improve the lessons. The focus groups timing will depend upon the randomization group. The immediate cooking class group will complete focus groups in weeks 13 and 17; the delayed cooking class group will complete them in weeks 21 and 25. The research team aims to recruit 4-6 participants for each focus group. These sessions will be facilated by a trained facilitator and additional trained staff will take notes. No participant names will be recorded within the focus group discussion notes. Focus group sessions will be audio-recorded; files will be stored in CWRU Box.

3. There is no more risk than everyday activities. Potential risks wil be discussed with eligible individuals during the consent process. Participant risk will be minimized by protecting privacy during weekly class assessments and focus group discussions.

4. Subject data will be collected through the following tools collected before and after the 8-week Nourish curriculum: 2-dietary recalls, Perceived Stress Scale, USDA Food Security Screener, FLEW Assessment, and food waste log, as well as weekly post-class surveys completed online after each of the 8 classes.

5. No devices will be used.

Use Shift+Return to add line breaks.

13.0 Study Timeline (optional)

14.0 ClinicalTrials.gov Information

Directions: If this study has been registered on ClinicalTrials.gov, provide the ClinicalTrials.gov identifier and the investigator/sponsor responsible for registering. If this study has not been registered on ClinicalTrials.gov, provide the rationale as to why and if/when it will be. If it does not meet the requirement for being registered on ClinicalTrials.gov, please state that.

This study does not meet the requirement for being registered on clincaltrials.gov

15.0 List of Data to be Collected

1. *Indicate what identifiers you will collect*
   - ☒ Name
   - ☐ Address *(e.g., Zip code, other geographical designation, etc.)*
   - ☐ Dates related to an individual *(e.g., Date of admission, birth, surgery, etc.)*
   - ☒ Telephone number
   - ☐ Fax number
   - ☒ Email address
   - ☐ Social security number
   - ☐ Medical record number
   - ☐ Health plan beneficiary number
   - ☐ Account number

- ☐ Certificate/license number
- ☐ Any vehicle or other device serial
- ☐ Device identifiers or serial numbers
- ☐ Web URL
- ☐ Internet protocol (IP) address
- ☐ Finger or voice prints *(includes audio recordings)**
- ☐ Photographic images *(includes video recordings or CTs or MRIs of heads)**
- ☐ Other: Any characteristic that would uniquely identify the individual
  If other, please explain: Click here to enter text.
- ☐ None

*-Please note, audio or video recordings on smart phones is not allowed. Devices must be encrypted.

2. List all other data to be collected for the research study. Attach all data collection tools on the Local Site Documents page of the SpartaIRB smart form (Other Attachments).
   1. 8 post-class surveys per participant
   2. 2 Perceived Stress Scale per participant
   3. 2 USDA Food Security Screeners per participant
   4. 2 FLEW assessments per participant and food waste tracking logs
   5. 4 24-hour dietary recalls per participant
   7. Data from 2 semi-structured focus groups

16.0 Online Data Collection

☐ We will not collect data through an online platform.

1. List the online platform to be used. The preferred platforms are REDCap and Qualtrics, as these provide good data security and have options for collecting data without individually identifiable information.
   The weekly post-class surveys, baseline and post intervention assessments will all utilize the platform Qualtrics. The two focus groups will be conducted via CWRU Zoom. Participants can join either via mobile phone or computer. REDCap will be used to schedule participant dietary recall interview in order to keep phone numbers secure.

2. If your intent is to collect the data without identifiers linked to an individual (including IP addresses), describe how you will ensure that no identifiable information will be associated with the data.
   - ☒ Qualtrics: enable Anonymize Responses setting (removes IP addresses and location data)
   - ☐ REDCap: use of the Public Survey Link
   - ☐ REDCap: use of a Participant List without a Participant Identifier field
     (Note: this does maintain a connection between the data and the individual, but it is only accessible to REDCap support personnel and not the researchers. Data collected in this manner should not be referred to as anonymous, but rather as data that is deidentified to the researchers).

☒ Other: REDCap will be used internally to record participant phone numbers and dietary recall information

17.0 Data Analysis Plan

Directions: Describe the data analysis plan, including any statistical procedures. If applicable, provide a power analysis, and study/safety endpoints. Descriptive statistics of Likert scale weekly class survey questions and thematic analyses of weekly survey open-ended questions and focus groups will be used to assess participant perspectives of the pilot study. Classroom observation notes will be used to determine whether the Nourish and intervention is delivered as intended. Feasibility of recruitment and retention will be based on the number of participants recruited and retained through to completion of post-intervention assessments. In addition, we will analyze the pilot data collected. A series of one-way analysis of covariance will be conducted to determine statistically significant differences at post-intervention between the intervention and delayed intervention control groups on each outcome variable, controlling for the pre-treatment assessment scores on the variable analyzed. Outcome variables consist of total volume of food waste, FLEW assessment scores, food security, perceived stress, and diet quality as assessed by the Dietary Inflammatory Index.

18.0 Confidentiality of Data

1. To maintain the confidentiality of the data:

   ☒ I will use a unique study identifier to code individuals' identifiable data and will store the master list separate from the study data.

   ☐ I will use a unique study identifier to code individuals' data, but it will never be linked to a master list.

   ☐ Other- please explain: Click here to enter text.

   Provide a plan to maintain or destroy identifiers once analysis of identifiable information is complete. Identifiers will be securely stored in box and maintained throughout the elayed control intervention. One year after analysis of identifiable information is complete, identifiers will be deleted.

   ☒ I attest that any recordings (audio or video) saved to a portable device will be deleted by formatting the device's storage memory.

How are you storing your electronic data?

☐ CWRU Redcap
☐ CWRU Secure Research Environment (SRE)
☒ CWRU Box
☐ OnCore
☐ CWRU Secure Network Drive, Which one?: Click here to enter text.
☐ Zoom Cloud
☐ Portable device (must be encrypted, not just password protected)

☐ Other - List storage method and provide justification: Click here to enter text.

Please note: if you're storing or entering your electronic data in any system other than an approved system listed above, please contact the CWRU IRB (cwru-irb@case.edu).

Excluding the above, are you using any cloud-based software or websites (i.e data has to go over the internet to be processed) to analyze data?
If so, please list below. E.g., transcription services, qualitative analysis services, etc. You may be asked to provide more information.

☒ Yes Please describe: Transcription service for online focus group sessions. Online focus group discussions, hosted by CWRU Zoom, will be audio recorded and recordings will be transcribed using NVivo Transcriptions. Audiorecordings will be deleted after transcription verification process is complete. Transcriptions will be uploaded into Nvivo 14. This software supports qualitative and mixed methods research that, relevant to Nourish, allows the research team to organize and analyze focus group discussion content via search, query, and visualization tools.

☐ No

2. ☒ I acknowledge that paper research data and documents will be stored in a double-locked secure environment in the following **location:** *Documents will be double-locked and stored within the principal investigators office suite at WG-48, Wood Building; 2109 Adelbert Road.*

   ☐ We will not have paper research documents.

3. Will data be shared with to institutions/persons outside of CWRU?

   ☐ Yes
   - With whom will data be shared? Click here to enter text.
   - List the exact data elements that will be shared: Click here to enter text.
   - Describe how data will be sent: Click here to enter text.

   ☒ No

   ☐ N/A

If sharing data, please complete a request to ensure the proper contracts/agreements are in place: https://case.edu/research/faculty-staff/technology-transfer/material-transfer-data-use-agreements

19.0 HIPAA Authorization

Does this study collect, access, use, or distribute any Protected Health Information (PHI)?
Protected Health Information (PHI) is (1) any individually identifiable health information transmitted or maintained in a medical record, paper or electronic, or (2) designated data set that was created, disclosed, or used in the course of providing a health care service such as diagnosis, payment or treatment.

☐ Yes ☒ No

If yes, indicate how HIPAA authorization will be obtained (check all that apply):

- ☐ HIPAA authorization is in the consent form
- ☐ I am receiving a Limited Data Set under a Data Use Agreement (DUA)
- ☐ Requesting a full or partial waiver of HIPAA for prescreening
  - ☐ I will complete the Request for Waiver of HIPAA Authorization form. *See SpartaIRB Library*
- ☐ Requesting a full or partial waiver of HIPAA
  - ☐ I will complete the Request for Waiver of HIPAA Authorization form. *See SpartaIRB Library*

20.0 FERPA Authorization

Does this study collect, access, use, or distribute any personally identifiable information from student records or personal education information from an education program (defined as: any program principally engaged in the provision of education, including, but not limited to, early childhood education, elementary and secondary education, postsecondary education, special education, job training, career and technical education, and adult education)? This includes, but is not limited to, classroom assignments and course evaluations.

☐ Yes ☒ No

If yes, how do you plan to get written authorization from the student (or parent if the student is a minor)?

☐ I will incorporate FERPA language* into the consent and obtain written and dated signature or authorized electronic signature using REDCap

☐ I will incorporate FERPA language* into a separate form and obtain written and dated signature or authorized electronic signature using REDCap

20.0 Risks to Research Participants

1. List the reasonably foreseeable risks such as breach of confidentiality, discomforts, hazards, or inconveniences to the research participants related to their participation in the research. Include a description of the probability, magnitude, duration, and reversibility of the risks. Include the physical psychological, social, legal, and economic risks. DO NOT REPLY WITH "NO RISKS" For example, loss of privacy, boredom, emotional distress, etc.

   Participation in the Nourish Pilot may result in participant inconveniences due to the requirement to travel to the meeting location for baseline/first and second assessments and for each in-person class. There is a low probability that the social aspect of the class setting may result in social risks, including embarrassment and frustration. The baseline/first and second assessments may cause some participant emotional distress due to topics of mindless eating and food waste. There is a low probability that participation in the codesign focus groups may result in discomforts and social risks, including

* FERPA language: 1. Specify the educational records that may be both accessed and used in the research. 2. State the purpose of the access and use of records. 3. Identify to whom the records disclosure may be made.

embarrassment, frustration, or anger. It is anticipated that these risks are reversible and will, thus, not extend beyond the duration of each step in the study design, including not extending beyond class time, athe duration of the assessments, and the duration of the focus groups. The magnitude of these risks is low due to minimal probability and severity.

2. If applicable, indicate which experimental procedures may have risks to the research participants that are currently unforeseeable. Click here to enter text.
   ☒ N/A
3. If applicable, describe the risks to others who are not research participants. Click here to enter text.
   ☒ N/A
4. Describe the availability of medical or psychological resources that research participants might need. Click here to enter text.
   ☒ N/A

21.0 Provisions to Protect the Privacy Interests of Research Participants

Directions: Indicate the measures that will be taken to protect research participants' privacy interests. Select all that apply:

☐ In person interactions will be conducted in a private space where conversations would not be overheard by others -- this could be at a specific location determined by the research team or at a location that the participant chooses.

☒ For online/remote data collection, participants will be advised to choose a location that would be private.

☐ Researchers will only contact participants if permission has been given to do so.

☒ Other: In person interactions, in the form of class time, will be conducted within the teaching kitchen, which will only be accessible to enrolled participants of the Nourish Pilot Study. For the online focus groups, participants will be requested to choose a private location and keep discussions confidential.

22.0 Potential Benefit to Research Participants

☒ There is potential benefit to research participants.

Describe the potential benefits that individual research participants may experience from taking part in the research. Include the probability, magnitude, and duration of the potential benefits. *Do not list compensation.* During each of the 8 classes, Nourish participants will receive food during class and groceries and cooking supplies to take home that serve as implementation supports for continued meal preparation and cooking behaviors at home. We also expect that participants will also gain knowledge regarding improv cooking, food safety, and nutrition, and benefit from improved culinary nutrition skills and food literacy.

☐ There is **no** direct benefit to research participants.

If no direct benefit, state the potential benefit to society or others. *Do not list compensation.* Click here to enter text.

23.0 Withdrawal of Research Participants

Under what circumstance(s) would you withdraw a research participant from the research without their consent? (Check all that apply)

☐ Safety Reasons; please explain Click here to enter text.

☒ Not following study instructions

☐ Being suspected of being a bot or bad actor (online surveys only)

☒ Other; please explain If a participant's eligibility criteria changes, in that they are no longer able to attend in-person classes or in-person assessments.

☐ N/A; please explain Click here to enter text.

☐ None

Describe any procedures when a research participant withdraws or are withdrawn from the research, including partial withdrawal from procedures with continued data collection.

If a participant withdraws or is withdrawn from the study, their associated data and identifiers will be removed from the dataset and destroyed within 30 days of the participant providing notice to the research team. If a participant withdraws but has already submitted some class assessment surveys, these will remain as part of the dataset due to the anonymous nature. Pre-assessment data will not be retained.

☐ N/A

24.0 Alternatives to Participation

Directions: List other options to participation. If subjects will be compensated with extra course credit, the course instructor offering extra course credit must provide alternatives to earn extra course credit. The alternative assignment must require equal or less time and effort for the same amount of earned extra credit that you can earn through participation in research. If there are other available clinical treatments, what would be included if a subject continued on standard of care therapy. If there is a viable alternative you must list it in the consent.

Click here to enter text.

☒ The alternative is for research subjects not to participate.

25.0 Costs to Research Participants

☐ There are **no** costs to research participants or their insurance companies (there are no clinical visits or billable procedures.) – *please leave rest of this section blank*

1. Describe what costs research participants will be responsible for as a result of their participation in the research, including but not limited to: clinical services required by the protocol deemed billable to insurance, transportation to study visits, parking, costs of drugs,

cost of therapy, lost broken or stolen devices, etc. Participants will be responsible for covering any costs associated with transportation to assessment meetings and classes. All venues associated with the study will have free, accessible parking.

2. Explain who will be responsible for payment of provided services in the event of insurance denials. Not applicable.

3. List what procedures, drugs, devices, supplies will be paid by the study sponsor or covered by other funding. List the other funding source. Supplies necessary to participate in the classes will be covered by the study sponsor. This includes groceries and supplies required for cooking activities.

26.0 Research Participant Compensation

☐ There is no compensation or reimbursement for research participants – *please leave rest of this section blank*

☒ There is compensation for research participants.
Describe the schedule, payment method, and payment total of any incentives or compensation that research participants will receive for participation in the research (e.g., gift cards or cash with amount, t-shirts, devices, bags, swag, etc.) Participants will be compensated for the completion of the baseline/first and second assessments and compensated for each completed post-class survey. Participants will receive $125 (cash) for completing the survey, food waste tracking, and 24 hour diet recalls before the classes begin and an additional $125 (cash) for completing the survey, food waste tracking, and 24 hour diet recalls after the cooking classes end. Participants will be encouraged to eat the food prepared during classes and will receive a grocery bundle (~$15 value) and cooking gadget ($15 value) at the end of each class attended. Participants will receive $5 (cash) for completing a feedback survey on each lesson attended, for a maximum of $40 (cash) total for feedback surveys. Participants who complete at-home cooking challenges and post photos as proof to the class group chat, will be entered into a drawing to receive a pressure cooker. Each completed cooking challenge, as evidenced by submitted photo, will result in one submission for the drawing. For the focus group sessions, participants will receive a $25 electronic gift card for participating in each of the 2 focus groups.

☐ There will be reimbursement for research participants.
Describe the schedule, payment method, and payment total of any reimbursement that research participants will receive for participation in the research (e.g., gift cards or cash with amount, etc.) Click here to enter text.

27.0 Compensation for Research Related Injury

Describe who will pay for the costs of medical treatment and/or compensation in the event of a research related injury:

☐ Funding agency is providing some/all payment for injury

☒ Funding agency is providing no payment for injury

☐ N/A

28.0 Provisions to Monitor the Data to Ensure the Safety of Research Participants

1. Describe how often the data will be monitored for completeness, accuracy and adherence to the protocol. During the course of the 8-week Nourish curriculum, data will be monitored for completeness, accuracy, and protocol adherence daily as participants will be submitting post-class surveys during the time periods between consecutive classes, with special attention to the times immediately before and after classes when participants are likely to be submitting online surveys.

2. Indicate if there will be a Data and Safety Monitoring Board or Committee:
   ☒ There will **not** be a formal Data and Safety Monitoring Board/Committee.

   ☐ There will be a formal Data and Safety Monitoring Board/Committee.

   Provide information about the DSMB/C including the contact information of the committee member(s) (as applicable); whether it is independent from the study sponsor; how often it meets; the type of data that will be used; written reports, etc. Click here to enter text.

29.0 Additional Information

If you have any additional information regarding your study not covered in the template, please include it here. Click here to enter text.

30.0 Devices

Does the study include the use of a device that is integral to the study question?

☐ **Yes** – *Answer the questions below.*

☒ **No** – *Leave the rest of this section blank.*

☐ There is an active IDE (Investigational Device Exemption) for the proposed study.
Attach an official letter of support or proof of approval which identifies the IDE holder and IDE number to the SpartaIRB smartform.
List devices: Click here to enter text.

☐ The device has obtained a 501k clearance.
Attach 501k documentation to the SpartaIRB smartform.
List devices: Click here to enter text.

☐ The device meets the criteria for an IDE Exemption.
Download the IDE Exemption Form from the SpartaIRB library (HRP-580) and attach to the SpartaIRB smartform.
List devices: Click here to enter text.

☐ The device (and its use) is a non-significant risk device for the proposed study design. List devices here and provide the PI's rationale for the non-significant risk device determination. Click here to enter text.

If the research involves device(s), describe your plans to use, store, handle, administer and track those device(s) to ensure that they will be used only on research participants and be used only by authorized investigators. Click here to enter text.

31.0 Community-Based Participatory Research

☒ This is **not** a community-based participatory research project – please leave the rest of this section blank

☐ This is a community-based participatory research project
Describe the involvement of the community in the design and conduct of the research.
Click here to enter text.

Note: Community based research is research that is conducted as an equal partnership between academic investigators and members of a community. In Community Based Participatory Research (CBPR) projects, the community participates fully in all aspects of the research process.

32.0 MULTI-SITE RESEARCH (when CWRU is the IRB of Record)

Does this project have multiple sites?

☐ **Yes**

☒ **No** – please leave the rest of this section blank

Non-Local Site Information for Multi-Site Studies

*If this is a multi-site study where you are the **lead investigator,** list the following information for each relying site:*

1. Name of site: Click here to enter text.
2. PI of relying site: Click here to enter text.
3. Name of IRB contact: Click here to enter text.
4. Phone number of IRB contact: Click here to enter text.
5. Email address of IRB contact: Click here to enter text.

Non-Local Recruitment Methods for Multi-Site Studies

*If this is a multi-site study and research participants will be recruited by methods **not under the control of the local site** (e.g. call centers, national advertisements) describe those methods. Local recruitment methods are described above.*

1. *Describe when, where, and how potential research participants will be recruited.* Click here to enter text.

2. *Describe the methods that will be used to identify potential research participants.* Click here to enter text.

3. *Describe the materials that will be used to recruit research participants.* Click here to enter text.

Multi-Site Research Communication Plan (when you are the lead investigator)
*If this is a multi-site study where you are the **lead investigator**, describe the processes to ensure communication among sites including:*

☐ *All sites will have the most current version of the protocol, consent document, and HIPAA authorization*
☐ *All required approvals (initial, continuing review and modifications) have been obtained at each site (including approval by the site's IRB of record)*
☐ *All modifications have been communicated to sites, and approved (including approval of the site's IRB of record) before the modification is implemented*
☐ *All engaged participating sites will safeguard data, including secure transmission of data, as required by local information security policies*
☐ *All engaged participating sites will safeguard data, including secure transmission of data, as required by local information security policies*
☐ *All local site investigators conduct the study in accordance with applicable federal regulations and local laws*
☐ *All non-compliance with the study protocol or applicable requirements will be reported in accordance with local policy*

*If this is a multi-site study where you are the **lead investigator,** describe the method for communicating to engaged participant sites the following:*

1. *Problems:* Click here to enter text.
2. *Interim results:* Click here to enter text.
3. *The closure of the study:* Click here to enter text.

33.0 References

1. US Department of Agriculture, Economic Research Service. Food Security in the US. https://www.ers.usda.gov/topics/food-nutrition-assistance/food-security-in-the-u-s/key-statistics-graphics/
2. Graham, C. and Ciciurkaite, G., 2023. The Risk for Food Insecurity and Suicide Ideation among Young Adults in the United States: The Mediating Roles of Perceived Stress and Social Isolation. *Society and Mental Health*, *13*(1), pp.61-78.
3. Quintiliani, L.M., Whiteley, J.A., Zhu, J., Quinn, E.K., Murillo, J., Lara, R. and Kane, J., 2021. Examination of food insecurity, socio-demographic, psychosocial, and physical factors among residents in public housing. Ethnicity & Disease, 31(1), p.159.
4. West, E.G., Lindberg, R., Ball, K. and McNaughton, S.A., 2020. The role of a food literacy intervention in promoting food security and food literacy—OzHarvest's NEST Program. Nutrients, 12(8), p.2197.

5. Metcalfe, J.J., McCaffrey, J., Schumacher, M., Kownacki, C. and Prescott, M.P., 2022. Community-based nutrition education and hands-on cooking intervention increases farmers' market use and vegetable servings. Public Health Nutrition, 25(9), pp.2601-2613.
6. Oakley, A. R., C. J. Nikolaus, B. Ellison, and S. M. Nickols-Richardson. "Food insecurity and food preparation equipment in US households: exploratory results from a cross-sectional questionnaire." Journal of Human Nutrition and Dietetics 32, no. 2 (2019): 143-151.