ANCILLARY REVIEWS

DO NOT DELETE. Submit the completed checklist below with your protocol.

Which ancillary reviews do I need and when do I need them? Refer to HRP-309 for more information about these ancillary reviews.			
Select yes or no	**Does your study…**	*If yes…*	**Impact on IRB Review**
☐ **Yes** **X No**	Include Gillette resources, staff or locations	*Gillette Scientific review and Gillette Research Administration approval is required. Contact:* *research@gillettechildrens.com*	**Required prior to IRB submission**
☐ **Yes** **X No**	Involve Epic, or Fairview patients, staff, locations, or resources?	*The Fairview ancillary review will be assigned to your study by IRB staff* *Contact:* ancillaryreview@Fairview.org	**Approval must be received prior to IRB committee/ designated review.** **Consider seeking approval prior to IRB submission.**
☐ **Yes** **X No**	Include evaluation of drugs, devices, biologics, tobacco, or dietary supplements or data subject to FDA inspection?	*STOP – Complete the Medical Template Protocol (HRP-590)* *The regulatory ancillary review will be assigned to your study by IRB staff* *Contact: medreg@umn.edu* *See https://policy.umn.edu/research/indide*	
☐ **Yes** **X No**	Require Scientific Review? Not sure? See guidance in the Investigator Manual (HRP-103).	*ONLY REQUIRED BIOMEDICAL RESEARCH REVIEWED BY FULL COMMITTEE*	
☐ **Yes** **X No**	Relate to cancer patients, cancer treatments, cancer screening/prevention, or tobacco?	*Complete the CPRC application process.* *Contact: ccprc@umn.edu*	
☐ **Yes** **X No**	Include the use of radiation? (x-ray imaging, radiopharmaceuticals, external beam or brachytherapy)	*Complete the AURPC Human Use Application and follow instructions on*	**Approval from these committees must be**

		the form for submission to the AURPC committee. *Contact: barmstro@umn.edu*	**received prior to IRB approval;** **These groups each have their own application process.**
☐ **Yes** **X No**	Use the Center for Magnetic Resonance Research (CMRR) as a study location?	*Complete the CMRR pre-IRB ancillary review* *Contact: ande2445@umn.edu*	
☐ **Yes** **X No**	Include the use of recombinant or synthetic nucleic acids, toxins, or infectious agents?	*STOP – Complete the Medical Template Protocol (HRP-590)*	
☐ **Yes** **X No**	Include the use of human fetal tissue, human embryos, or embryonic stem cells?	*STOP – Complete the Medical Template Protocol (HRP-590)*	
☐ **Yes** **X No**	Include PHI or are you requesting a HIPAA waiver?	*If yes, HIPCO will conduct a review of this protocol.* *Contact: privacy@umn.edu*	
☐ **Yes** **X No**	Use data from the Information Exchange (IE)?	*The Information Exchange ancillary review will be assigned to your study by IRB staff* *Contact: ics@umn.edu*	**Approval must be received prior to IRB approval.** **These groups do not have a separate application process but additional information from the study team may be required.**
☐ **Yes** **X No**	Use the Biorepository and Laboratory Services to collect tissue for research?	*STOP – Complete the Medical Template Protocol (HRP-590)* *The BLS ancillary review will be assigned to your study by IRB staff.* *Contact: Jenny Pham Pham0435@umn.edu*	
☐ **Yes** **X No**	Have a PI or study team member with a conflict of interest?	*The CoI ancillary review will be assigned to your study by IRB staff* *Contact: becca002@umn.edu*	
☐ **Yes** **X No**	Need to be registered on clinicaltrials.gov?	*If you select "No" in ETHOS, the clinicaltrials.gov ancillary review will be assigned to your study by IRB staff* *Contact: kmmccorm@umn.edu*	

☐ **Yes** x **No**	Require registration in OnCore?	*If you select "No" or "I Don't Know" in ETHOS, the OnCore ancillary review will be assigned to your study by IRB staff* *Contact: oncore@umn.edu*	**Does not affect IRB approval.**

PROTOCOL COVER PAGE

Protocol Title	Evaluating Diet, Food Insecurity, and Food Purchasing Outcomes of a Full-Service Mobile Food Market with a Cluster Randomized Trial
Principal Investigator/Faculty Advisor	Name: Melissa Horning
	Department: School of Nursing
	Telephone Number: 612-624-1947 (office) 320-290-9043 (cell)
	Email Address: horn0199@umn.edu
Student Investigator	Name:
	Current Academic Status (Student, Fellow, Resident):
	Department:
	Telephone Number:
	Institutional Email Address:
Scientific Assessment	I believe Scientific Assessment is not required.
Version Number/Date:	Version: 7 Date of this protocol: 1/10/2023

REVISION HISTORY

Revision #	Version Date	Summary of Changes	Consent Change?
1	2/2/2022	In response to request for modifications, we have: 1) Revised to add the number of total contacts before someone is deemed lost to follow-up. 2) Added language to the consent form to specify for the additional interview (for the selected subsample) that their interviews will be audio recorded with a digital voice recorder and occur in person or by phone. 3) Selected the boxes indicating which type of storage will be used in section 18.7. 4) Formally added the IIA for Stephanie Wagner to the appropriate location on ETHOS (vs. just in the comment we submitted last week).	Yes.
2	6/29/2022	We have revised the following elements of the study: 1) We are shifting from two waves of six sites (12 total) for data collection/intervention to 3 waves of four sites each (12 total) for data collection/intervention as it works with the study timeline and is more feasible. 2) We revised the figure in section 5 to reflect the 3 waves. 3) We have revised one instance of inconsistency among proposed sample size (from 20 to 22) which aligns with our total proposed sample	

		(n=264) and power discussions. 4) We have revised site inclusion criteria. Specifically, some research criteria were removed specifically, as these are criteria for receiving the mobile market in general (not specific to the research). We have also delineated this differentiation between mobile market criteria vs. research criteria on the attached site screening script. 5) We have added a site screening script and site recruitment flyer.	
3	7/25/2022	1) We have added language about community meetings that will be conducted by the Mobile Market in partnership with the research staff/investigators present that will inform us better about our proposed processes. These meetings are aligned with community engaged research principles and will occur with current Mobile Market customers who are like our proposed participants but will not be research participants.	
4	9/23/2022	1. The Food Purchasing outcomes and data collection forms have been updated to reflect a change in study scope after funding. 2. Indicated that surveys will be completed via web-based REDCap survey on study iPad rather than paper-pen. 3. Added nutrition security scales to food security outcomes measures.	

		4. Streamlined and updated survey measures to reflect the best state of the science while also working to minimize participant burden. 5. Added information and protocol about the Mobile Market purchasing outcomes that will rely on data from the Market Members program. 6. Revised information about the Market Members' incentives to indicate that they are standard part of Mobile Market operations. 7. Updated process measure descriptions and added data collection protocols/instruments 8. Updated information about study cell phones and security procedures.	
	12/5/2022	1. "Additional" outcomes from the dietary recalls and the timeline for recall completion is updated and a new dietary recall protocol is attached that contains a concise description of the recalls without unnecessary operating procedures. 2. During the consent process, during the first data collection visit, we will provide a Participant Guide that succinctly summarizes the study activities (this guide is attached) 3. Additional recruitment materials have been developed and are now described and attached.	
	1/10/2023	1. Updated the process for site randomization, which will allow the study statistician to communicate with the mobile	Yes. Corrected typos, moved one text block and added link for

		market co-investigator so routes can be planned prior to the completion of baseline data collection. Sites, participants, research staff, PI, and UMN co-investigators will remain blinded to study site selection until after baseline data collection for each wave. 2. Updated inclusion criteria to include ASL speakers, who are specifically supported as residents at one of our community sites. Revised recall procedures to accommodate using an interpreter with these participants. 3. Updated website text to include URL. A screenshot is also now attached. 4. Clarified that we may use the Twilio feature in REDCap to automate text message reminders.	(future) ASL interpreted video of the document

Table of Contents

ABBREVIATIONS/DEFINITIONS

- NIH: National Institutes of Health
- SNAP: Supplemental Nutrition Assistance Program
- SSB: Sugar-Sweetened Beverages
- CBPR: Community Based Participatory Research
- USDA: United States Department of Agriculture
- RE-AIM: reach, effectiveness, adoption, implementation, maintenance
- HEI-2015: Healthy Eating Index-2015
- 2015-2020 DGA: 2015-2020 Dietary Guidelines for Americans
- NDSR: Nutrition Data System for Research
- WIC: Women, Infants and Children Special Supplemental Nutrition Assistance Program
- GED: General Educational Development
- REDCap: Research Electronic Data Capture
- ASL: American Sign Language

1.0 Objectives

1.1 Purpose:

The **overall objective** of the proposed study is to test the impact of an innovative full-service mobile market on diet quality, food insecurity, and food purchases and explore factors influencing adoption of mobile market shopping using a mixed methods approach.

Aim 1: Evaluate the impact of the full-service mobile market on dietary quality and food insecurity. Aim 1a: Diet quality, assessed via dietary recalls, will be measured at baseline and follow-up (6-months after market implementation) with the Healthy Eating Index-2015, an important predictor of chronic disease outcomes. Hypothesis 1a: We hypothesize relative to control site participants, intervention site participants will have improved diet quality at follow-up. Aim 1b: Food insecurity prevalence will be measured at baseline and follow-up with the 18-item U.S. Adult Food Security Survey Module. We will also use newly developed and validated measures to assess ***nutrition insecurity*** in the past 6 months, which helps us understand fuller contexts around choices people may make (e.g., compromise nutrition for a full stomach).[137] Hypothesis 1b: We hypothesize relative to control site participants, intervention site participants will have increased food and nutrition security at follow-up.

Aim 2: Evaluate the impact of the full-service mobile market on fruit and vegetable purchases. Forms documenting fruit and vegetable purchases will be collected from participants for 1 month at baseline and follow-up. Hypothesis 2: We hypothesize relative to control site participants, intervention site participants will purchase more servings of fruits and vegetables.

Aim 3: Explore factors that influence intervention participant adoption of mobile market shopping using a mixed methods approach. Aim 3a. Validated measures of personal, social, behavioral, and environmental factors (e.g., demographic characteristics, self-efficacy, social support, mobile market features) will be surveyed. Shopping adoption will be objectively measured during market implementation and at follow-up. Aim 3b. After follow-up, qualitative interviews will be conducted with a subset of high and low adopters. Research question guiding 3a & 3b: What factors influenced mobile market shopping adoption?

2.0 Background

2.1 Significance of Research Question/Purpose:

SIGNIFICANCE

Diet is a modifiable contributing factor for chronic health conditions that contribute to 4 of the 10 leading causes of death in the US,[1–3] underscoring the importance of the NIH's new strategic plan for nutrition research in 2020-2030.[4] This plan calls for research to leverage behavioral science and interventions to target multiple levels of the food environment to initiate and sustain healthy eating behaviors.[4] We will

advance the field by testing a sustainable food environment intervention to address nutrition-related disparities.

Individuals with low incomes and those who identify as being from racial/ethnic minority groups have disparately higher rates of poor diet quality, obesity, and related health conditions.[5–10] They also experience poorer food access and higher food insecurity,[11,12] which contribute to these disparities. Food insecurity (i.e., uncertain or insufficient access to enough food for an active, healthy life[13,14]) alone is linked to poorer diet quality,[15–17] obesity,[18,19] and diet/weight-related health conditions (e.g., hypertension, diabetes).[18,20–23] Food insecurity specifically adds an estimated 77 billion dollars to annual health care costs.[24] Further, food insecurity is associated with having multiple chronic conditions,[25,26] care for which comprises 66% of total U.S. health care expenditures.[27] In recent years, 18% of Americans have poor food access[28] and 11% experience food insecurity.[29,30] Moreover, food insecurity and poor food access are exacerbated by lack of or inadequate transportation to full-service grocery stores[31–33] and the unaffordability of healthy diets,[34,35] which may lead to more frequent purchase and intake of low-cost, energy-dense, low-nutrient foods.[36–38] Thus, it is critical to address affordable, healthy food access in high-need, under-resourced areas to reduce disparities and achieve equity in diet quality, food security, and in turn, obesity and diet/weight-related health conditions.

There are significant limitations to current food purchasing interventions, and mobile markets provide a promising means of enhancing this work. To date, evaluations of the effectiveness of local food retail access interventions, such as introducing supermarkets in food deserts, have produced equivocal results.[39–47] Online food shopping is a newly available potential strategy for increasing food access for Supplemental Nutrition Assistance Program (SNAP) participants; however, initial research indicates *low use* of the online shopping option provided to SNAP participants as part of a randomized trial evaluating acceptance of SNAP/EBT online food shopping.[48] Online food shopping can also have cost-prohibitive fees not covered by SNAP benefits.[49] Mobile markets can address food insecurity and poor healthy food access in a way other food retail interventions cannot – mobile markets bring low-cost, high quality, healthy foods directly to the doorsteps of areas in greatest need, like high-rise low-income housing units, without competing inexpensive, energy-dense, low-nutrient foods, additional fees, or need for internet. The **scientific premise** is that mobile markets alter underserved communities by making healthy foods more accessible at affordable prices. By changing the food environment, mobile markets may reduce food insecurity, improve dietary intake, and increase the healthiness of food purchases, while also targeting personal, social, and behavioral factors that influence food selection and mobile market shopping adoption. Several small, produce-only mobile market research studies have demonstrated increases in fruit and vegetable access, purchase, and/or intake among customers.[50–54] Two cluster randomized trials have found produce-only mobile markets increased fruit and vegetable intake by as much as a half[55] to one

serving per day.[56] Such findings are promising, however, sustainability concerns[56,57] limit confidence in produce-only mobile markets. These data warrant testing the effectiveness of a full-service mobile market that sells foods from all food groups and staple food items as we have proposed. Full-service markets have potential to be a convenient "one-stop shop" for under-resourced Americans.

Full-service mobile markets are viable and sustainable. While some states like Minnesota are on the forefront of supporting mobile markets through funding legislation,[58] most mobile markets nationwide are grant funded and/or supported by philanthropic donations. As such, many produce-only mobile markets close due to financial non-viability or when external funding ends.[56,57] Full-service mobile markets also rely on a robust non-profit infrastructure and organizational partnerships to source foods at wholesale cost. However, aligned with recommendations from research, full-service mobile markets address viability and sustainability in two important ways.[52,55] First, full-service mobile markets' operational costs are supported by the sales of all food groups, thus, offsetting operational expenses more efficiently than through fruit and vegetable sales alone. Our formative work showed 50% of full-service mobile market sales were for fruits and vegetables and the other 50% were for protein, dairy, grain, and dry good purchases.[59] Second, selling only produce reduces reach and deters shopping because customers must go elsewhere to purchase other essential foods.[52,55] Therefore, the full-service mobile market can increase sales and reach by providing one-stop shopping, and thus has greater potential for sustainability.[52,55] Our study will evaluate the impact of an established and thriving non-profit full-service mobile market model on diet quality, food insecurity, and food purchases while also studying factors impacting market shopping adoption.

The full-service mobile market to be evaluated has high potential to improve diet, food security, and food purchase patterns. *The full-service Twin Cities Mobile Market was launched in 2014 in response to community need for affordable healthy food access.* It operates two city buses retrofitted into grocery stores, with food display shelving, refrigeration, freezers, and shopping carts. The market serves 24 community sites weekly[60] and is operated by a 501c3 non-profit organization. Operation costs are covered in part by revenue generated from food sales, with a subsidy provided by the market's non-profit infrastructure.

This mobile market reaches a critically high-need population. In 2019, we completed customer intercept surveys (N=302) and found 85% experienced food insecurity in the past year, as compared to 10-12% of the population locally or nationally.[61] Data also indicate customers had higher than average rates of diet/weight-related conditions: 30% of customers self-reported having a diabetes diagnosis compared to 12% of adults nationally,[10] and 45% self-reported hypertension compared with 34% nationally.[9] In a feasibility study with market customers and individuals recruited from the ever-growing waitlist of sites requesting market service, we measured height, weight, and blood pressure. Findings showed 58% customers had elevated blood pressure readings and 41% had

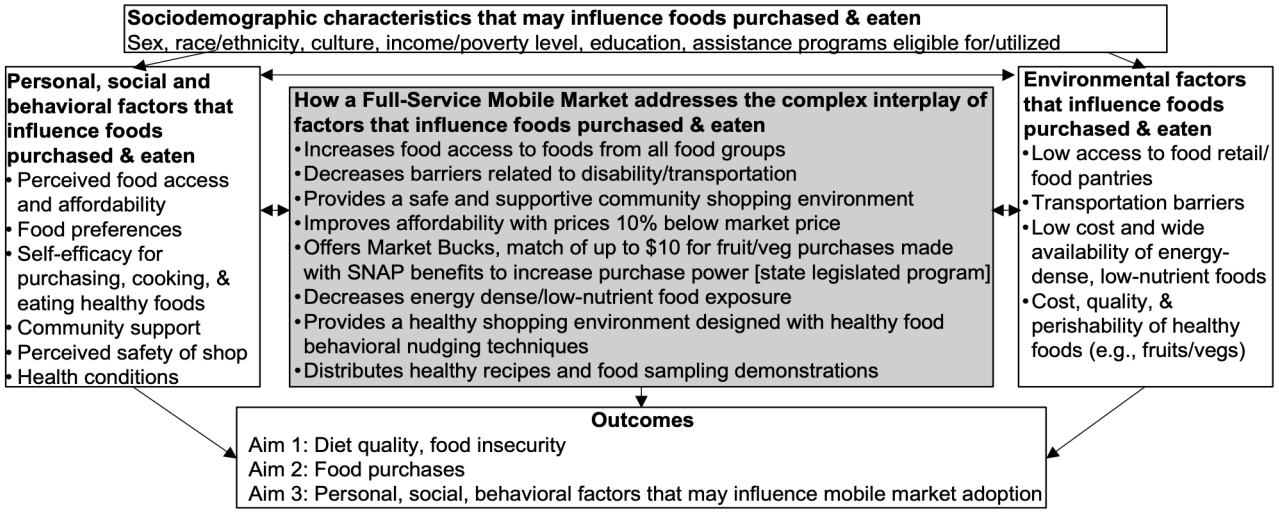
readings consistent with stages 1 and 2 of hypertension.[62] We also found 82% of market customers had BMI values classified as overweight or obese as compared to 72% nationally.[63]

The Twin Cities Mobile Market was designed to provide a shopping environment that promotes affordability, healthy food access, and diet quality. Implementation and design features include: (1) Attention to cultural food preferences based on input from community forums and customer requests;[59,64] 90% of customers reported in 2019 intercept surveys that the market was meeting their cultural needs. (2) Food stocking practices that focus on all food groups (e.g. fruits, vegetables, dairy, protein, grains) and limited inclusion of foods for which limited consumption is recommended (e.g. salty snacks, chips, desserts, sugar-sweetened beverages [SSBs]) aligned with behavioral nudging and choice architecture techniques that promote healthy food choices.[65,66] (3) Low food pricing, on average 10% below prices at local supermarkets. (4) Multiple payment options include cash, credit, debit, and EBT/SNAP. (5) Incentives for produce purchases through the state-funded Market Bucks program are provided and match SNAP produce purchases up to $10.[58] (6) Healthy recipes and food sampling demonstrations. (7) A safe, welcoming environment with exceptional customer service and opportunities for interacting with other customers/neighbors.[64] (8) Recurring weekly market stop times set in conjunction with community sites to maximize participation. (9) Ongoing engagement with community site partners to address needs and concerns in real time. In addition, this shopping environment also reduces need to go elsewhere to meet dietary needs, thereby minimizing exposure to unhealthy foods that comprise 32% of household food expenditures.[67,68] Of note, one theme that emerged from four focus groups with customers (N=29) was that the mobile market shopping environment helped customers make healthy food purchases by eliminating temptation to buy unhealthy foods.[64] Increasing healthiness of purchases across food groups may impact diet outcomes beyond fruit and vegetable intake (as studied by prior mobile market research[50–56]) but also other key diet outcomes including sodium, saturated-fat, SSB intake and overall diet quality.[69,70] Thus, to extend our preliminary focus group and survey findings, we will measure diet quality and these important diet outcomes with 24-hour recalls, considered to be one of the most rigorous self-report measures of food intake.[71]

Theoretical underpinnings. Aligned with the social cognitive theory[72] and social ecological framework,[73] there is a complex interplay between environmental, personal, social, and behavioral factors[72,73] that influence food choices, food purchases, food insecurity, and diet quality.[74–79] As depicted in **Figure 1** (next page), the full-service mobile market addresses these factors in various ways to support positive outcomes. Specifically, a full-service mobile market alters the community food environment to reduce factors linked to unhealthy food intake, including: low food access; [11,12,28,74,75,80–82] lack of transportation;[31–33] wide accessibility of low-cost, energy-dense, low-nutrient foods;[36–38,83] high cost of healthy foods;[34,35,83] and poor quality of healthy foods.[84,85] Full-service markets designed with behavioral nudging

and choice architecture promote healthy choices (e.g., by placing fruits/vegetables at eye level at market entry and having minimal presence of foods for which minimal consumption is recommended).[65,66] Moreover, the market also addresses personal, social, and behavioral factors that may influence market adoption and food purchasing by targeting perceived food access and affordability,[64,74,80,84,85] self-efficacy for and knowledge of purchasing, cooking, and eating healthy foods,[64,74,75] and food preferences.[75,76,86] The market also provides a supportive community[64,75,77] and safe shopping environment.[64,85] Thus, the market has strong potential to improve diet quality, food security, and food purchases, while addressing personal,

Figure 1. Theoretical model guided by the social ecological framework and social cognitive theory



Note: Social cognitive theory and social ecological framework posit complex interplay between environment, personal, social and behavioral factors to influence outcomes. Full-Service Mobile Markets address these factors in many ways as depicted above.

social, behavioral, and environmental factors that may influence market shopping adoption. These potential impacts warrant rigorous research evaluation of the full-service mobile market.

2.2 Preliminary Data:

Preliminary studies led by the Principal Investigator provide evidence of feasibility, premise, and justification for the proposed study and aims.

Mixed-Method Mobile Market Feasibility Research [IRB study number: STUDY00000812]. A mixed-method feasibility CBPR study involved 4 focus groups (n=29) of full-service mobile market customers and a cross-sectional study (n=45). Focus groups were used to inductively assess mobile market impact as perceived by customers and to inform future research. Themes from focus group findings indicated customers reporting improved affordability, purchase patterns, and dietary intake. For example, this theme is exemplified with the quote: *"I find that it's better to go shopping on the bus . . . I find it better than going to the grocery store 'cause I don't buy no junk. I stick with the food that I'm going in there for. Or I am buying more vegetables or I am buying more fruit. So that is one thing that the bus does help me with. Stick to the right diet."* [64] Focus group findings on research acceptability were incorporated into the subsequent cross-sectional study. The cross-sectional study assessed feasibility of measuring key outcomes (**Table 1**) in market customers and in non-customers recruited from market waitlist sites. All participants completed psychosocial measures and were trained to collect, annotate, and mail their food purchase receipts using an established protocol of the time;[87–89] 87% returned their receipts in the 2-week collection period. Rates of participation in receipt collection improved during the study (80% for the first 30 participants and 100% for the last 15) due to adaptations in the protocol. Purchasing outcomes of this feasibility study included median proportion of total purchases that were fruits/vegetables and SSBs. While cross-sectional outcomes trended in the right direction (**Table 1**), we realized that comparison of the proportion of spending by food category does not address the different quantity that can be purchased at the market because of the 10% market price discount. Thus, for the proposed study, we will use objective, annotated receipt collection that we found feasible to implement, but we will enhance our purchasing outcome to robustly measure purchase quantity by assessing total (edible) servings purchased of fruits, vegetables, and SSBs to eliminate the market price discount as a potential confounder. We also demonstrated capacity to measure fruit and vegetable intake, food insecurity, and personal, social, behavioral, and environmental factors; we observed trends in expected directions for most outcomes (**Table 1**). This preliminary study provided us with ample feasibility and acceptability data to inform the proposed trial.

Table 1. Feasibility of measuring key outcomes

Aim/Outcome	**Mixed-Method Feasibility CBPR** (N=45) Customers	Non-Customers	*p*
Aim 1a. Diet quality	Mean FV servings (SD)[a]		
	4.3 (3.7)	2.9 (2.6)	0.20
Aim 1b. Food Insecurity	Food insecurity prevalence[b]		
	78%	67%	0.41
Aim 2. Food purchases from all food sources[c]	Median % of food purchases on FV[d]		
	11%	3%	0.04
	Median % of food purchases on SSB[d]		
	2%	3%	0.44
Aim 3. Example measurement of personal, social, behavioral, environmental factors	Mean self-efficacy for healthy cooking[f]		
	10.9 (3.7)	12.2 (3.8)	0.27
	Mean social connectedness (SD)[f]		
	25.9 (8.4)	25.0 (9.1)	0.74
	Mean health related quality of life[f]		
	2.5(0.9)	2.9 (0.9)	0.14

Notes. FV=Fruit/vegetable. SSB=Sugar sweetened beverage. [a]Measured with a validated FV screener (excluding juice & fries).[133,134] [a]Assessed with a validated two-item measure.[135] [c]Participants were trained to collect, annotate, and mail all food purchase receipts for 2 weeks with a standardized protocol.[87–89] [d]Variable was skewed; median non-parametric test assessed for differences. [f]Higher scores indicate higher traits measured with validated measures.[102,104,109,136]

Customer Intercept Surveys [IRB study number STUDY00004137]. In an ongoing, repeated cross-sectional study, we are using brief customer intercept surveys to assess whether increased mobile market frequency (from biweekly to weekly) alters food access, food security, and diet intake at existing market stops. In

June-July 2019, we surpassed our recruitment goal of 200 by recruiting 302 participants. Adjusted general linear and logistic regression models were used to evaluate associations between how long customers had been shopping at the mobile market and fruit and vegetable intake and odds of food insecurity (**Table 2**). We found longer market use was associated with higher fruit and vegetable intake and lower odds of being food insecure, supporting the scientific premise of the proposed study. We also found 85% of customers identified as food insecure and 90% felt their cultural food preferences were met at the market. Results further support proposed trial feasibility.

Table 2. Year 1 Customer Survey (N=302) Outcomes

Aim/Outcome	Length of mobile market shopping
Aim 1a. FV intake[a]	β=0.26, SE:0.10, p=0.01
Aim 1b. Odds of food insecurity in last year[b]	OR=0.77; 95% CI=0.60-0.997

Notes. Models were adjusted for sociodemographic characteristics. FV=Fruit / vegetable. [a]Assessed with two questions found to rank individuals based on overall FV intake in population-based surveys.[137] [b]Assessed with a two-item validated measure.[135] *Manuscript in press at Appetite.*

Point-of-Sales [IRB study number STUDY00000051]. We analyzed mobile market point-of-sales data by food group for 2016.[59] This data showed half of full-service mobile market sales were for fruits and vegetables, with all food groups contributing to the other half.[59] This work demonstrates our capacity to collect and analyze key implementation and process data that measure reach, adoption, and maintenance of mobile market shopping.

Summary of Preliminary Studies and Relevance to Aims. Aim 1. We have demonstrated feasibility of measuring diet intake (Aim 1a) and trends indicate better fruit and vegetable intake in customers (compared to non-customers) and in long-term market shoppers. We will increase the rigor of diet assessment in this trial by using interviewer administered diet recalls successfully used by Co-Investigator Harnack in the same communities.[90] Diet recalls allow for assessment of overall diet quality using the validated Health Eating Index-2015 (HEI-2015)[69,70] in addition to other diet outcomes. With our preliminary work, we also demonstrated feasibility of measuring food insecurity (Aim 1b) and found lower odds of being food insecure with longer market use. We will expand these data with our proposed trial by using the United States Department of Agriculture (USDA) gold standard food insecurity measure that will allow us to delineate 4 levels of food security (e.g., very low, low, etc).[91] **Aim 2.** We have demonstrated our ability to collect purchase receipt data, which has also been successfully done in research led by Dr. Harnack.[92,93] **Aim 3.** We have demonstrated our ability to measure personal, behavioral, social and environmental factors that may influence mobile market adoption and our ability to collect and analyze qualitative data. **Process data.** We have demonstrated our capacity to collect and analyze transaction and sales data that are important process evaluation measures of market reach, adoption, and maintenance.[59]

2.3 Existing Literature:

Please see sections 2.1 and 2.2 above.

3.0 Study Endpoints/Events/Outcomes

3.1 Primary Endpoint/Event/Outcome:

Diet quality. Trained research staff certified in collecting dietary recalls using Nutrition Data System for Research software will collect three 24-hour dietary recall interviews (2 weekdays, 1 weekend day) from each participant at each measurement period (baseline and follow up). Dietary recall data will be used to calculate the Health Eating Index-2015 Score. HEI-2015 is a scoring system designed to measure adherence to the 2015-2020 Dietary Guidelines for Americans (2015-2020 DGA). [69,70]

3.2 Secondary Endpoint(s)/Event(s)/Outcome(s):

Food insecurity. Food insecurity in the past 6 months will be measured with the gold-standard, 18-item food security screening module of the USDA, which will allow for assessment of both binary food insecurity (yes, food insecure; no, food secure) and level of food security (very low, low, marginal, and high food security).[91] We will also use newly developed and validated nutrition insecurity measures to assess ***nutrition insecurity*** in the past 6 months, which helps us understand fuller contexts around choices people may make when money is tight (e.g., compromise nutrition for a full stomach).[137]

Fruit & Vegetable purchasing outcomes: Participants will record their fruit and vegetable purchases using forms in a provided booklet, and mail their booklets to the researchers in prepaid addressed envelopes, which will be used to measure:

- Average weekly servings of fruits and vegetables purchased
- Total number of trips
- Store types visited

Mobile Market shopping patterns: Participants randomized to the intervention sites will participate in a "Market Members" program, which tracks their purchases at the Mobile Market (i.e. number of transactions, items purchased, dollars spent).

Personal, social, behavioral, and environmental factors that may influence mobile market adoption. These factors include:

- Neighborhood Healthy Food Availability (4 item scale; α=0.89);[99]
- Social Connectedness (8 item scale, α=0.92);[102]
- Health-related quality of life (4-items);[103–107]
- Self-efficacy of Healthy Cooking (4 item scale, α=0.85).[109]
- Self-efficacy for eating and cooking fruits and vegetables (4 item scale, α=0.90).[108]
- Everyday Discrimination Scale (6 item scale α=0.77 + 2 follow-up items)[139-140]

Mobile market features that could influence market shopping adoption will be measured at follow-up for participants who were located at intervention site locations. These factors include:

- Perceived convenience of market service
- Whether the market meets participant cultural food needs
- Perceived affordability of market food prices
- Would you recommend the market to a friend (yes/no)?
- Satisfaction of the market's: (a) location and timing; (b) selection of food items available; (c) prices; (d) customer service; and (e) overall shopping experience (not at all satisfied to very satisfied) will also be measured.

Qualitative interview questions. Qualitative interviews will be conducted with a subsample of intervention participants (high and low adopters). Interviews will be audio recorded and occur in person or by phone. Main interview questions will inductively explore factors that influenced market shopping and shopping adoption.

4.0 Study Intervention(s)/Interaction(s)

4.1 Description:

Intervention and waitlist control. Following baseline participant data collection, sites will be randomized to receive the full-service mobile market intervention or serve as the wait list control.

The Full-Service Mobile Market start-up involves two key components.
(1) Initial community engagement: Prior to randomization, community sites will begin engagement activities aligned with CBPR best-practices.[115–117] These activities include regular meetings with site location staff to develop logistical plans for research activities and market intervention. Following randomization, site group assignment will be revealed for participants and the UMN research team after baseline data collection for the wave is complete, continued site engagement will occur to finalize logistics, including selection of time for the weekly market stop. Resident meetings will be held to introduce how the market works (e.g., when it will come, foods / prices to expect, payment forms accepted). The market schedule will be advertised in community sites (e.g., elevators, community rooms, resident newsletters). Based on our ongoing work, this initial community engagement takes two-weeks to two months, is critical to launching new sites, and is essential for building/maintaining rapport and trust. These activities will be repeated for waitlist sites after follow-up data collection in each Wave.

As a note, this community engagement occurs at new Mobile Market sites that are starting up unrelated to the trial as well – thus, this step (aside from the randomization) is not different than would/does occur normally with mobile market start-up at a new location.

(2) Full-service mobile market implementation (the beginning of the intervention): After initial community engagement, the intervention will begin. Specifically, the market will visit intervention sites weekly. The market will carry items from all food groups including

fresh, frozen and canned fruits and vegetables, whole grains, dairy / dairy substitutes, proteins (e.g., frozen meat/fish, beans, eggs), and dry goods (e.g., cooking oil, spices). Foods will be priced below the cost of local supermarkets (~10% below) and purchases can be made with cash, SNAP/EBT, or credit/debit. The state funded Market Bucks program will provide a dollar-for-dollar match, up to $10, for produce purchases made with SNAP benefits. Customers will be able to enroll in a "Market Members" loyalty card program that provides incentives for shopping more frequently (e.g. $5 off every third trip) and all customers will be asked at the point of sale if they are a Member. Community engagement will continue during this time; market staff will check in with site partners regularly to ensure smooth service, addressing any challenges and capitalizing on opportunities (e.g., community events to promote the market) in real time. Intervention site participants will be contacted monthly (e.g., sent a newsletter on the market offerings/sales) in addition to retention contacts described above.

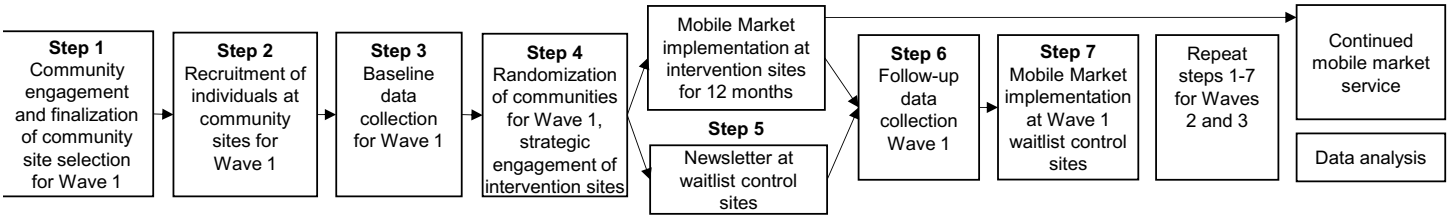
As a note, this the start-up and implementation of the mobile market occurs at new Mobile Market sites that are starting up or that are receiving ongoing service unrelated to the trial as well – thus, this step (aside from the randomization) is not different than would/does occur normally with mobile market start-up at a new location.

Waitlist control. Sites randomized to the waitlist will not receive market service prior to follow-up data collection. After follow-up Wave 1 data collection, Wave 1 waitlist sites will participate in community engagement and then receive the market. After follow-up Wave 2 data collection, Wave 2 waitlist sites will do the same. After follow-up Wave 3 data collection, Wave 3 waitlist sites will do the same. The use of a waitlist control was purposeful and informed by our community partners. We will be in communication with waitlist site participants during the 6-month implementation period at the intervention sites, as described above to ensure up-to-date contact information and to facilitate engagement/retention.

5.0 Procedures Involved

5.1 Study Design:

We will use a cluster randomized trial design. We will recruit 12 community sites ("clusters") in low-income neighborhoods and/or adjacent to low-income housing residences with 22 participants per site. To enhance feasibility, we will conduct the study in three waves, with 4 community sites in wave



2, and 4 community sites in wave 3. For each wave, following participant baseline data collection that will occur at the same time across the sites of the wave, we will randomize sites to receive the full-service market intervention or serve as a waitlist control. Sites randomized to receive the market will begin weekly service immediately following 2 months of strategic community engagement led by the community partner at The Food Group with the Mobile Market (see section 4 above). After 6 months of market operation, follow-up data collection will occur for outcome measurement followed by qualitative interviews with a subset of intervention participants (high and low adopters). The RE-AIM (reach, effectiveness, adoption, implementation, maintenance) framework guides our evaluation.[87–89] This process will be repeated for Wave 2 and 3 sites. Intervention sites will continue to receive the market during and after the follow-up data collection period. The waitlist sites for Waves 1, 2, and 3 will receive the intervention following final data collection for the wave.

5.2 Study Procedures:

Recruitment of sites: See details in IRB protocol section 9.0 and 12.

Recruitment of individuals from sites recruited for the trial. See details in IRB protocol section 9.0 and 12. See also "eligibility screening script" document.

Baseline Data collection: The consent forms will be mailed to interested and eligible participants in advance of the baseline data collection visit. The process of informed consent will take place at baseline data visits in a private and confidential space [using a privacy screen if needed]. Data collection will occur at baseline (after site recruitment but before site randomization is known to sites, participants, research staff, the PI, and non-statistician University co-investigators) and again at follow-up (after 6 months of mobile market service at sites randomized to the intervention) for all sites. Data collection will occur simultaneously at intervention and waitlist sites to minimize the threat of temporal trends (e.g., changes in community, policy, or economic climate). Data collection will occur onsite or in nearby community locations and over the telephone. Mobile market purchasing data collection will occur during and after the intervention through the end of data collection for participants at sites randomized to receive the mobile market first. Implementation process data collection will occur throughout the trial and participant process data collection will occur after the 6 month implementation of the mobile market intervention. If sites do not have adequate privacy, we will create a private space with privacy screens. The surveys will be completed by participants using a Health Sciences registered iPad using a secure web-based REDCap survey. In case of technical failure, paper-pen back-up surveys will be available. If this is needed, paper-pen surveys will be entered into a secure REDCap database[118] by two study staff and verified for accuracy. Diet recall data will be entered in Nutrition Data System for Research (NDSR) software by trained staff. The data will be stored on

secure University laptops and backed-up to secure BOX data servers. Paper files will be stored in secured, locked file cabinets. See the table below for a broad overview of timeline of data collection and measurement. Details for each of the measures is provided below the table.

	Screening	Baseline	6 month intervention	Follow-up data collection	Qualitative interviews
Eligibility and study interest	x				
Informed Consent		X			
Diet Quality (measured with 3 dietary recalls - one in person, and 2 in the next three weeks by phone)		X		X	
Food security		X		X	
Fruit & Vegetable form completion for 4 weeks		X		X	
Personal, social, behavioral, and environmental factors survey		X		X	
Demographics		X			
Randomization**		X			
Adverse Events		X	X	X	
Mobile market shopping purchases (intervention participants only)			X		
Quantitative measures of mobile market factors that may influence shopping adoption (intervention participants only)				X	
Qualitative interviews with a subset of intervention participants (high & low adpoters)					X
Process measures			X	X	

** Randomization occurs after site recruitment for the Wave is complete (about 2 months prior to the end of data collection for the wave. Sites (and the participants attached to those sites) will be randomized to receive mobile market service or to the waitlist (to receive mobile market service after data collection for the wave is complete). After randomization, the study statistician will be unblinded to site names by being provided access to the key that matches sites with their assigned numbers. This will inform him which sites were randomized to the intervention and waitlist control. The study statistician will inform the mobile market co-investigator of the sites randomized to the intervention approximately 2 months prior to the end of data collection to allow time for the mobile market to plan for market routes and schedules. Participants, site locations, the PI, and other UMN trial investigators and staff will be blinded to (i.e., not be informed of) site randomization results until after baseline data is collected. The mobile market co-investigator will explicitly instruct the market drivers (who will help plan the routes with the new stops for the trial sites) that the knowledge of sites is strictly confidential until after baseline data collection is complete and contact between mobile market staff (aside from the Mobile Market co-investigator) and research team, PI, and University staff will not occur during this time to reduce any potential for unintentional disclosure.

Diet quality will be measured through 24-hour dietary recall interviews. Trained staff certified in collecting diet recalls using Nutrition Data System for Research (NDSR) will collect three 24-hour recall interviews (2 weekdays, 1 weekend day)

from each participant at both measurement periods (baseline, follow-up). At each measurement, the first recall will be conducted in-person during data collection visits; the second two recalls will be by phone. NDSR,[94] a diet analysis software developed and maintained by the University of Minnesota Nutrition Coordinating Center (led by co-investigator Harnack) will be used to collect recalls. The multiple-pass interview technique will be used to prompt for complete recalls and descriptions.[95] A Food Amounts Booklet adapted from Van Horn et al.[96] will be provided to participants for use in estimating food and beverage amounts (attached).

To measure diet quality, Healthy Eating Index-2015 (HEI-2015) total and components scores will be calculated from the recall data. The HEI-2015 is a scoring system to measure adherence to the 2015-2020 Dietary Guidelines for Americans (2015-2020 DGA).[69,70] The HEI-2015 total score is the sum of 13 subcomponents that measure adequacy (Total Fruits, Whole Fruits, Total Vegetables, Greens and Beans, Whole Grains, Dairy Products, Total Protein Foods, Seafood and Plant Proteins, and Unsaturated:Saturated fats) and moderation (Refined Grains, Sodium, Added Sugars, and Saturated Fats). All subcomponents are scored from 0-5 or 0-10 based on intake between minimum and maximum standards. Moderation components are reverse scored so higher scores reflect lower intake. A higher HEI-2015 score (out of 100) represents greater consistency with the 2015-2020 DGA. Additional diet outcomes from recall data include mean daily intake of: energy, fruits and vegetables (servings/day), added sugar (% calories from added sugar) and sodium (mgs/day)..[69,70] See dietary recall protocol.

Food insecurity. Food insecurity in the past 6 months will be measured with the gold-standard, 18-item food security screening module of the USDA, which will allow for assessment of both binary food insecurity (yes, food insecure; no, food secure) and level of food security (very low, low, marginal, and high food security).[91] We will assess for change in prevalence of food insecurity and level of food security from baseline to follow-up (e.g., change in % very low food security from baseline to follow-up), as assessed in other community-based food intervention studies aiming to improve food security.[97,98] We will also use newly developed and validated measures to assess ***nutrition insecurity*** in the past 6 months, which helps us understand fuller contexts around choices people may make when money is tight (e.g., compromise nutrition for a full stomach).[137] These measures will be collected via REDCap, which makes the skip patterns invisible and easy for participants.

Fruit & Vegetable purchasing outcomes: Participants will record the fruits and vegetables that they buy along with the date and place of purchase using forms in provided booklets, and mail these booklets to the researchers in prepaid addressed envelopes, which will be used to measure:

Average weekly servings of fruits & vegetables. The purchase quantity (volume, weight, quantity) of fruits and vegetables from the forms will be entered into NDSR. Using these data, NDSR will calculate the edible

servings for each item. This process accounts for and eliminates the inedible portions of foods (e.g., peels, pits). The edible servings purchased will be summed and averaged to obtain the average servings of fruits and vegetables purchased weekly across all purchase locations. See Fruit & Vegetable Purchasing data collection protocol and Fruit & Vegetable purchasing booklets for participants attachments.

Descriptive purchasing variables measured with data from the fruit & vegetable forms. Total number of trips and store types visited will be measured using the data from the fruit & vegetable forms. See the Fruit & Vegetable Purchasing Data Collection Protocol and Fruit & Vegetable purchasing booklets for participants attachments.

Shopping adoption. Intervention participant shopping adoption will be measured in 2 ways: (A) average monthly dollars spent and frequency of shopping at the mobile market during the implementation period and 3 months post-implementation as measured by purchases with customer loyalty cards (see Mobile Market purchasing data protocol attachment); and (B) self-reported average frequency of mobile market shopping each month (see process survey attachment).

Quantitative measures of personal, social, behavioral, and environmental factors. At baseline and follow-up, surveys with validated psychosocial measures will be used to measure factors that may influence mobile market adoption. These factors include: Neighborhood Healthy Food Availability (4 item scale; α=0.89);[99] Social Connectedness (8 item scale, α=0.92);[102] Health-related quality of life (4-items);[103–107] Self-efficacy of Healthy Cooking (4 item scale, α=0.85);[109] Self-efficacy for eating and cooking fruits and vegetables (4 item scale, α=0.90);[108] and Everyday Discrimination Scale (6 item scale α=0.77 + 2 follow-up items).[139-140] Item responses will be coded and summed so a higher scale score indicates a higher trait (e.g., higher access to affordable quality foods). See psychosocial survey attachment.

Other data to be collected

Participant information, demographic information, and potential confounding variables. Participants will self-report by survey age; sex; income level (<10,000, 10,000 to <15,000, etc); education level (some high school, graduate equivalent degree [GED], some college, etc.); receipt of SNAP, WIC, free or reduced price school lunches, other food programs and medical assistance; household size; ethnicity; race (American Indian or Alaskan Native, Asian, Black or African American, Native Hawaiian and Other Pacific Islander, White; selecting all that apply); and diet/weight related health conditions. See attached surveys (Note: Most of these questions are in the demographics survey; the health related questions are in the psychosocial survey and the household size questions are in the food security survey.)

Process data. Aligned with the RE-AIM framework,[112–114] we will collect process measures during and immediately following the intervention to assess

reach, adoption, implementation, and maintenance. See table below.

Process Measures (RE-AIM alignment)	**Collection Method**	**Data collected**	**Who / When**	**Analysis**
Site mobile market operation implementation fidelity **(I)**	Assessments for deviations in scheduled operation (e.g., related to weather, traffic, repairs), stocking practices, and pricing.	• Documented deviations (see Fidelity Bus Operations Data Collection Protocol)	Regularly monitored by study staff during the implementation period	Descriptive
Site sales: use and reach by site **(R, A)**	The cloud-based, electronic, point-of-sale, cash register records all *sales* transactions.	• Date, time, site of sale, payment type, and foods items/categories sold for all transactions (data to be collected **are not identifiable or linked to participants** – rather this data will be used to describe sales at intervention sites and make comparisons to waitlist and other non-research sites)	Downloaded monthly by study staff during the implementation period	Descriptive. Total sales and sales by food category for intervention sites
Contamination and dose—**self-reported (R, A)**	Survey will include questions to assess market dose and contamination exposure	• Shopping frequency • Length of time shopping at the mobile market (in months) (see Process Follow-up Survey)	Study participants at follow-up data collection	Descriptive and as described in Aim 1 analysis plan
Contamination and dose—**objective (R, A)**	Fruit and vegetable purchase data collection	Number of trips to Mobile Market	Study participants at baseline and follow-up data collection	Descriptive and as described in Aim 1 analysis plan
Intervention participant market purchases **(R, A, M)**	Point of sale system with customer loyalty program (Market Members) to track purchases [a]	• Frequency of purchases • Dollars spent on market purchases • Number and types of items purchased (see Mobile Market purchasing protocol)	Intervention site participants during the implementation period	Descriptive and as described in Aim 2 analysis plan
Key features and suggestions for improvement from intervention participants **(A, I)**	Open-ended qualitative process survey and interviews about key features that make the market helpful and suggestions for improvement	• Open-ended responses (see process survey) • Qualitative interview transcripts (see qualitative question guide)	Intervention site participants at follow-up data collection and intervention site participants selected for interviews	See Aim 3

Notes: [a]*Intervention* site participants will all be enrolled in the Market Member program as part of their participation in the study. All Mobile Market customers, regardless of whether they are at a research site or are participating in the research study, can enroll in thid program and receive nominal discounts ($5 off) every 3-4 shopping trips (see Mobile Market purchasing data collection protocol attachment).

5.3 Randomization: The sites recruited for the trial will be randomized to mobile market service first or the waitlist control (to receive mobile market service after the data collection for each wave is complete). The randomization will be completed by the study statistician who will be blinded to the study site location names. After randomization, the study statistician will be unblinded to site names by being provided access to the key that matches sites with their assigned numbers. This will inform him which sites were randomized to the intervention and waitlist control. The study statistician will then inform the mobile market co-investigator of the sites randomized to the intervention approximately 2 months prior to the end of data collection to allow time for the mobile market to plan for market routes and schedules. Participants, site locations, the PI and other UMN trial investigators and staff will be blinded to (i.e., not be informed of) site randomization results until after baseline data is collected. Of note, only the project manager and the study

statistician will be aware of the key (the link between the site names and the assigned site numbers that will be used in analysis) until analysis is complete.

Intervention/waitlist control: The intervention, Twin Cities Mobile Market service will be provided in the communities recruited for the trial. This service will be the same service provided to other community sites with ongoing Mobile Market service. Service will be available to anyone in the community regardless of trial enrollment. Intervention sites will receive mobile market service following two months of strategic community engagement. Waitlist control sites will receive mobile market service after follow-up data collection for the wave is complete. More detail is provided in IRB protocol section 4.1.

Data analysis: Data will be analyzed by research staff to answer study related research questions and to determine the individuals who are the high and low adopters of mobile market shopping for qualitative interviews related to the study's third aim. See details in IRB protocol section 17.

The following actions will be taken if a participant misses a study visit:

- The study team must attempt to contact the participant and reschedule the missed visit as soon as possible, counsel the participant on the importance of maintaining the assigned visit schedule, and ascertain whether the participant wishes to and/or should continue in the study.
- Before a participant is deemed lost to follow-up, the investigator or designee must make every effort to regain contact with the participant, where possible, by text, email, telephone calls, and if necessary, a certified letter to the participant's last known mailing address. These contact attempts will be documented in the participant's contact log. Should the participant be unreachable for 5 consecutive attempts by phone or text without response/reply followed by a certified letter without response, the participant will be considered to have withdrawn from the study.

5.4 Follow-Up: The data collection process will be identical to that of baseline data collection with a few exceptions, noted below. There is not long-term follow-up data collected.

Quantitative measures of mobile market features. Features of the market that could influence market shopping adoption will also be measured at follow-up data collection for the participants at sites randomized to receive mobile market services first (vs. waitlist service to start after final data collection). These features include perceived convenience of market service (not at all convenient to very convenient); whether the market meets participant cultural food needs (yes/no); perceived affordability of market food prices (not at all affordable to very affordable); and whether they would recommend the market to a friend (yes/no). Customer satisfaction of the market's: (a) location and timing; (b) selection of food items available; (c) prices; (d) customer service; and I overall shopping experience

(not at all satisfied to very satisfied) will also be measured. See process survey attachment.

Qualitative interview questions. Qualitative interviews will be conducted with a subsample of intervention participants who are high and low mobile market adopters after the intervention is complete (see section 11 for specifics of how participants would be selected for the interviews). Interviews will be audio recorded with a digital voice recorder and occur in person or by phone. Main interview questions will inductively explore factors that influenced market shopping and shopping adoption. Interviews will unfold consistent with qualitative methodology and allow the participants to shape the flow and content.[110] Probing and clarifying questions will be asked as needed.[110,111]. See qualitative interview guide attachment.

5.5 Individually Identifiable Health Information: This research study will collect participants' names, contact information, dietary intake data, fruit and vegetable purchasing data and minimal self-reported health information (i.e. has a doctor ever told you that you have the following conditions or health problems (with yes, no response options): high blood pressure or hypertension, high cholesterol or hyperlipidemia, diabetes, heart disease, depression or anxiety, overweight/obesity.

6.0 Data Banking

6.1 Storage and access: Deidentified data will be stored in the PI's secure Box storage for future use by other researchers not on the research team. Data will be available 2 years following study completion ending 15 years after study start.

6.2 Data: Deidentified dataset.

6.3: Release or sharing: Outside researchers who request to use the deidentified data would have to have IRB approval documented with the PI prior to sharing of the dataset via a secure box file. Additionally, publishing of these data may be required. Federal funders (e.g. National Institutes of Health), granting agencies (e.g. Bill & Melinda Gates Foundation), and journal publishers (e.g. PLoS) increasingly require datasets be made publicly available—often immediately upon associated article publication. If this is the case, all data published will be fully de-identified.

7.0 Sharing of Results with Participants

7.1 General, group level (aggregate) survey results (e.g., means of participant scores) will be shared with participants and others as appropriate (e.g., academic research audiences, community groups). These group level study results will be conveyed in both peer-reviewed and lay publications (e.g., infographic/newsletter). The Community-Centered Dissemination Toolkit will be used to guide development of materials.

8.0 Study Duration

8.1 The duration for participant involvement in trial procedures is less than 1 year. Enrollment per wave is expected to take approximately 3 months. The duration anticipated to complete all study procedures and data analysis is approximately 5 years.

9.0 Study Population

9.1 Inclusion Criteria:

To achieve the proposed study aims, communities and human subjects from those communities will be recruited and data about operational procedures and costs will be collected.

Community site selection (see letters of support of interested site locations):
In order to be eligible to participate in this study, a community site (e.g., public housing hi-rise, low-income senior living residence) must meet the following criteria:
(a) locale for low-income populations that experience difficulty in accessing healthy, affordable foods (e.g., public housing residences; low-income senior housing) or a community center in a low-income, low-food access (0.5 mile) census tract;
(b) willingness to be randomized to the intervention or waitlist control;
(c) located over 0.5 miles apart from other trial sites;
(d) willingness to allow for recruitment and data collection to occur in onsite community rooms;

Process for initial contact with sites:
Steph Wagner at The Food Group with the Twin Cities Mobile Market regularly receives calls from site locations across the Twin Cities that may be interested in having the mobile market come. As these calls comes in, she will provide information on the mobile market service in general and also that there is a research study opportunity. She'll provide the sites a site flyer. She will connect any interested sites with the Mobile Market researchers for specific questions related to the research, if any, prior to the formal conversation, as outlined in the attached site screening script (below).
Flyer for site recruitment: We have created a flyer for sites (attached) interested in mobile market service study to provide information on the mobile market research study. This site flyer would serve as a preview to a more formal conversation about being both a mobile market site and research site. It should be noted that the site recruitment flyer lists the contact information for Co-Investigator Wagner given her position of regularly receiving this type of call at the Mobile Market currently. She will refer sites to the researchers for research specific questions as they arise prior to a formal conversation as outlined with the screening script.

Site screening script:

For sites that may be interested, a research team member and Co-Investigator Wagner will go through a formal conversation using the site screening script to guide the conversation. Please see the site screening script attached.

When sites would like to join:
If an interested site were to be interested, eligible and decide to participate, a letter of support would be written documenting this decision. This letter of support will be provided to the UMN IRB following signature.

Sites meeting site eligibility criteria will be recruited in three waves, with 4 sites in wave 1, 4 sites in wave 2, and 4 sites in wave 3. After baseline data collection for each Wave, stratified randomization of sites by type (e.g., randomization within public housing, low-income senior living sites) will be conducted to ensure balance between groups. See support letters from sites on the market waitlist meeting the aforementioned criteria.

Human subject recruitment will occur in the participating communities.

In order to be eligible to participate in this study, an individual must meet the following criteria:

(a) being aged 18 years or older;
(b) identifying as the primary food shopper in their household;
(c) being able to speak English or American Sign Language (ASL);
(d) living within a half mile of the community site location; and
(e) reporting to be likely or somewhat likely to shop at the market in response to: "how likely would you be to shop regularly at the Twin Cities Mobile Market if it came to your neighborhood each week (response options: likely to unlikely).
(f) willing and able to participate in all study data collection activities
- Please note: we may be amending these inclusion criteria and this protocol and all documents to include individuals who speak other languages once the community sites are selected and the other languages are known.

9.2 Exclusion Criteria: An individual who meets any of the following criteria will be excluded from participation in this study:

(a) planning to move in the next 12 months
(b) not currently shopping at the mobile market
(c) not having a phone number or mailing address
(d) presence of a condition or abnormality that would prohibit participation in the study or the quality of the data

9.3 Screening: Screening will occur in person or via phone using the eligibility screening script (attached). Participants will self-report answers to these questions. Participants will be asked to provide verbal consent prior to conducting the initial

screen. Participants who consent to proceed with the screening process will be documented by study staff.

If participants are found to be potentially eligible after phone screening, they will be invited to the study for a full written consent process that covers the remainder of the study, as described in this protocol.

10.0 Vulnerable Populations

10.1 Vulnerable Populations:

Population / Group	Identify whether any of the following populations will be targeted, included (not necessarily targeted) or excluded from participation in the study.
Children	Excluded from Participation
Pregnant women/fetuses/neonates	Included/Allowed to Participate
Prisoners	Excluded from Participation
Adults lacking capacity to consent and/or adults with diminished capacity to consent, including, but not limited to, those with acute medical conditions, psychiatric disorders, neurologic disorders, developmental disorders, and behavioral disorders	Included/Allowed to Participate
Non-English speakers	Included/Allowed to Participate
Those unable to read (illiterate)	Included/Allowed to Participate
Employees of the researcher	Included/Allowed to Participate
Students of the researcher	Included/Allowed to Participate

Undervalued or disenfranchised social group	Targeted Population
Active members of the military (service members), DoD personnel (including civilian employees)	Included/Allowed to Participate
Individual or group that is approached for participation in research during a stressful situation such as emergency room setting, childbirth (labor), etc.	Excluded from Participation
Individual or group that is disadvantaged in the distribution of social goods and services such as income, housing, or healthcare.	Targeted Population
Individual or group with a serious health condition for which there are no satisfactory standard treatments.	Included/Allowed to Participate
Individual or group with a fear of negative consequences for not participating in the research (e.g. institutionalization, deportation, disclosure of stigmatizing behavior).	Included/Allowed to Participate
Any other circumstance/dynamic that could increase vulnerability to coercion or exploitation that might influence consent to research or decision to continue in research.	Excluded from Participation

10.2 Additional Safeguards:

- This study is not recruiting based on pregnancy status. Rather, it is possible that a pregnant women would meet all criteria for inclusion in the study, given the nature of this research, there is no anticipated harm to pregnant women or the fetus, should she elect to enroll in the research.

- Because the study will be recruiting in the community, no prisoners will be included.
- No individuals less than 18 years of age are included based on inclusion criteria.
- We do not anticipate enrolling individuals with impaired capacity to consent. Assessment of capacity to consent will be informally made during routine interactions with participants. No specific assessment or documentation of capacity is required under those circumstances.
- American Sign Language speakers will be allowed to participate in this study, though they will not be specifically targeted for recruitment. If an ASL speaker indicates interest in the study while we are conducting recruitment, we will contact a certified interpreter to facilitate communication. An interpreter will be used for all study visits and be available to the participant if they have questions regarding any written forms. We will have an interpreter translate our consent form into a video, a link to which will be provided on the English consent form. In addition, if preferred by the participant, we will allow ASL speakers to conduct their follow-up dietary recalls in person with an interpreter rather than requiring these to be conducted by phone and will allow the interpreter to interpret the iPad written survey questions as read by a study staff member and the participant's responses so they can be entered. Additional non-English speakers may be targeted for recruitment at a later time, but the languages are not yet known. We will amend this protocol/procedures and all related documents once the languages are solidified to add this inclusion criterion and related supporting documentation (e.g., consent form in selected languages etc) and will wait to receive IRB approval related to this modification prior to enrolling participants who do not speak English.
- This study will not be targeting recruitment of individuals who are not literate. However, if an individual who is not able to read wants to participate, study staff will assist with completion of surveys, forms, etc. to ensure that the sample is inclusive of and represents all individuals that wish to use the mobile market including any that may not be literate. Participants who are illiterate may not be known, research staff will not be asking a direct question about literacy to potential participants. However, if it is made known to us that the participant is illiterate we will take extra care to go through the consent form and read it to the potential participant. An unbiased witness (non-study team member) will be present to attest that the consent form was described accurately. He/she will also sign the consent form.
- Employees of the researcher: If an employee of the researcher presents as a potential participant eligible for this study, they will be seen for consenting and treatment by a member of the study team who is not the researcher. They will

be told during consenting that their decision whether to participate will not affect their professional relationship with the researcher.

- Student of the researcher: If a student of the researcher presents as a potential participant eligible for this study, they will be seen for consenting by a member of the study team who is not the researcher. They will be told during consenting that their decision whether to participate will not affect their professional relationship with the researcher nor will it have an impact on their graduation status, GPA, future job or internship opportunities or any other academic or professional status.
- This study will recruit individuals who are disadvantaged in the distribution of social goods and services such as income, housing or health care and/or who may identify as an undervalued or disenfranchised social group. In particular, the mobile market aims to serve those who live in low-income, low food access communities; thus, it is critically important that the population the mobile market is trying to reach is included in the study, as it will ensure the results represent the target population. Caution was taken to provide appropriate levels of compensation for participants given their income level, so as to not be coercive while also providing appropriate compensation for the time spent in research activities. Levels were set in conjunction with community partner. When possible, diverse and multilingual research staff will be hired to reflect the individuals in the community site locations.
- Active members of the military (service members), DoD personnel (including civilian employees): Members of the military may not be known, research staff will not be asking a direct question about military status to potential participants. We do not anticipate vulnerability for this group to be increased by participating in this study.
- Individual or group with a serious health condition for which there are no satisfactory standard treatments: Participants with a serious health condition for which there is not satisfactory standard treatment will be fully informed of the potential risks and benefits of the research study. We do not anticipate vulnerability for this group to be increased by participating in this study.
- Individual or group with a fear of negative consequences for not participating in the research (e.g. institutionalization, deportation, disclosure of stigmatizing behavior): Individuals with a fear of negative consequences for not participating in the research (e.g. institutionalization, deportation, disclosure of stigmatizing behavior) are not targeted but may be enrolled. All participants will be fully informed that the study is completely voluntary and that they may withdraw participation at any time.

10.3 If research includes potential for direct benefit to participant, provide rationale for any exclusions indicated in the table above:

Prisoners are excluded as they will not have access to the mobile market while in custody. Children are excluded as they are not the primary food purchasers in this household, which is whom this intervention is targeted for – they may still benefit

if their parent/guardian enrolls in the study. We are not including people in a stressful time sensitive situations like being in the emergency room or while in labor, as they are not the target population of the mobile market; these individuals would be eligible to participate when the stressful situation has resolved if meeting eligibility criteria.

As a reminder: Non-English speakers, with the exception of ASL speakers, will be excluded from participation at this time. However, they may be targeted for recruitment at a later time, but the languages are not yet known. We will amend this protocol and all related documents once the languages are solidified to add this inclusion criterion and related supporting documentation and will wait to receive IRB approval related to this modification prior to enrolling participants who do not speak English.

11.0 Number of Participants

11.1 Number of Participants to be Consented:

Targeting enrollment at 264 participants in full-data collection.

For qualitative interviews, these will happen with a smaller subsample of participants enrolled. Specifically, the qualitative sample will be derived from purposive sampling of extremes[119,120] in market adoption. Thus, participants selected for interviews will be from the highest and lowest quintiles of market shopping as measured by the number of trips to the Mobile Market during the final two months of the intervention period. The estimated number of interviews is 24 for low adopters and 24 for high adopters (48 total) selected from across intervention sites;[121] however, the qualitative sample size will only be set after saturation has occurred during analysis and coding of the qualitative data.[121]

For our primary outcome, with our planned sample size of 264 divided between 12 clusters, we anticipate 80% power to detect a difference of 5.0 HEI points between the intervention and control groups. This calculation assumes an attrition rate of 15%, so that our final analytic sample size is 224 individuals, and a conservative ICC of 0.01. If attrition is higher or recruitment is slower, a final analytic sample of n=160 individuals will provide 80% power to detect a difference of 6.0 HEI points, which is still within the range of plausibility for the effect size of this intervention. Furthermore, smaller effects will be detectable even with this smaller sample if the ICC is closer to the value 0.004 observed in previous studies. Additionally, for our secondary outcomes, an even smaller sample would be acceptable for analysis. For example, for the third aim, we are aiming for 24 high mobile market shopping adopters and 24 low mobile market shopping adopters (final sample size will be determined once saturation is reached).

12.0 Recruitment Methods

12.1 Community and Participant Recruitment process:

Community recruitment process:

When: After grant is awarded. Process will begin approximately 2-5 months into the grant.

Where: At/around the Twin Cities in low-income/low food access communities meeting site inclusion criteria.

Strategies: Mobile market staff will work with their ongoing community partners, sites on their waitlist (interested in service when capacity to expand is available), and new potential partners to recruit sites meeting inclusion criteria to receive mobile market service as part of the trial (depending on randomization, as either intervention or waitlist control sites). While the sites will be specifically recruited for the trial, the mobile market service at these sites will be normal mobile market service (i.e., the same service that is currently ongoing at other community site locations that are not part of the trial). At the trial site locations of this trial, anyone will be able to shop at the mobile market, not just those enrolled in the trial.

Participant recruitment process:

When: After recruitment of community sites

Where: At/around the community sites recruited for the trial before randomization of communities to mobile market service or waitlist control is known to sites, participants, research staff, the PI, and non-statistician University co-investigators.

Strategies:

- working closely with community site staff to get the information to community members
- posting flyers and tabling in central locations around recruited site locations
- attending resident meetings (e.g., resident council in public housing buildings)
- sending trial information along with community newsletters/ updates
- bringing the mobile market to each site for an informational event

Retention strategies:

- providing contact throughout the study to retain up-to-date contact information (e.g., calls/text messages/emails, reminder letters, seasonal cards, monthly newsletters),
- continuing to collect data in a convenient location
- providing culturally and linguistically competent staff

12.2 Source of Participants: Community – specifically, community members in/around the 12 sites recruited for mobile market service as part of the trial will be recruited. See recruitment for details.

12.3 Identification of Potential Participants:

- See recruitment strategies for how potential participants will be identified (section 12.1). As additional information:
    - No recruitment will occur based on information contained in private/protected records.
    - When in-person recruitment occurs, the research staff will make initial contact by saying hello and offering to speak with potential participants when they pass by.
    - When recruitment occurs by flyer posting or newsletter, the participant will make the initial contact to reach the research staff. [Note, if information is sent via community newsletter, the information in the newsletter would be created by the research team but would be included in the normal sending of the community newsletters, such that the research staff would not have access to the community members names or addresses and the potential participant receiving the information would need to make the first contact to the research staff.]
    - Following the intervention period, a subset of participants from intervention sites who are either the highest or lowest users of the Twin Cities Mobile Market will be invited to participate in an additional interview. This will be participants who are in the highest and lowest quintile based on the number of trips made to the Mobile Market in the final two months of the intervention period. Each of these individuals will be invited during their follow-up data collection visit.

12.4 Recruitment Materials:

See attached recruitment materials:

- flyers (to be hung in common areas at community sites)
- door hangers (which can be delivered to all units within a community housing site)
- newsletter text (which could be included in a community site's newsletter or other communications with residents)
- handout (which could be distributed during tabling or other community event)
- screenshot of the study website (http://z.umn.edu/mobilemarketstudy; link is included on other recruitment materials)

12.5 Payment:

- Compensation (up to $200 across measurement periods) will be offered. An additional $20 will be provided to participants selected to participate in the qualitative interviews. More specifically:
    - Each participant will receive an incentive for specific data collection activities at baseline and follow-up data collection [$200 total; $100 at baseline and $100 at follow-up]. Specifically, participants will be given $20 for completing the psychosocial survey and first dietary recall at the in-person data collection visit, $10 for completing the second dietary recall, and $15 for completing the third dietary recall. Participants will be given $10 for each week of fruit & vegetables purchase booklet collection (for weeks 1-4) and $15 additional dollars in the final week (week 4) of fruit & vegetable purchase booklet collection, if participants collected and returned purchase receipts for the entire month. One Greenphire ClinCard pre-paid debit card will be provided at in-person measurement and the other payments will be reloaded onto the debit card after completion of the study activities (see Clincard information form attachment for information we will collect in order to provide payments). For participants selected for qualitative interviews, qualitative interview participation will result in participants receiving an additional $20 payment loaded to their debit card. We plan to recruit 264 and complete qualitative interviews with 48 individuals already enrolled in the study. Qualitative interviews will occur during the follow-up period of each Wave.
- No Research Experience Points will be awarded.

13.0 Withdrawal of Participants

13.1 Withdrawal Circumstances: The following are the circumstances under which participants would be withdrawn from the research without their consent:

- If they are lost to follow up
- If they behave inappropriately toward study staff
- If they show signs of diminished capacity to consent

13.2 Withdrawal Procedures: Participants will be informed that if any point they no longer wish to be in the study, they may withdraw from the study. If a participant tells the research staff they would like to withdraw from the study, the research staff will ask for and document reason for withdrawal. Any data provided by the participant will continue to be used in the study, unless they formally request that data is not used. No further data will be collected from a participant who withdraws from the study.

13.3 Termination Procedures: This study may be temporarily suspended or prematurely terminated if there is sufficient reasonable cause (see stopping rules on the DSMP). Written notification, documenting the reason for study suspension or termination, will be provided by the suspending or terminating party to the funding agency and regulatory authorities. If the study is prematurely terminated or suspended, the PI will promptly inform the IRB and will provide the reason(s) for the termination or suspension. The study may resume once concerns about safety, protocol compliance, and/or data quality procedures are addressed and satisfy the funding agency and IRB. If the study is terminated, the study team will notify the participants of the study termination.

Data collected for the study prior to the study termination will be handled in the following manner:

- If the study is terminated due to safety reasons, the data related to AEs will be evaluated.
- If the study is terminated for any other reason, the regulatory and/or institutional document/data retention policies will apply.

14.0 Risks to Participants

14.1 Foreseeable Risks:

Data Risks and Protections: To follow participants from baseline data collection to follow-up data collection, identifiable information (e.g., names, contact information including phone, address, and other forms if available) and sensitive information (e.g., self-report of health conditions) will be collected. This collection of identifiable and/or sensitive data does pose a potential risk of a data breach. The risk of a system-wide data breach of the secure HIPAA compliant University of Minnesota Health Sciences Academic Health Center (UMNHSACH) computer/network serve is low. To minimize this potential but rare risk, all data linked to participants will be coded with a non-identifiable study ID number. Identifiable information (names, addresses, etc) will be stored on a secure password protected file on a secure UMNHSACH server and will only be accessible to those the PI has given permission. Participant forms will only contain the study ID number. De-identified data will be stored separate from identifiable information and will be accessible only to those with explicit permission of the PI and a secure password. Even with a password to the server, permission is required to access file level data. All passwords will conform to the requirements of the University of Minnesota for maximum security, which includes two factor identification.

Data collected in the field from participants will be collected primarily via REDCap surveys administered using an iPad at data collection visits. The surveys will be directly entered into the secure REDCap Database and all other windows will be closed while a participant has an iPad. If there is a technical failure with the wi-fi or iPads, paper-pen surveys will be completed. The paper-pen surveys will be entered

into the secure REDcap Database by two different study staff and verified for accuracy. Data for this study will be entered into a REDCap database, which uses a MySQL database via a secure web interface with data checks used during data entry to ensure data quality. REDCap includes a complete suite of features to support HIPAA compliance, including a full audit trail, user-based privileges, and integration with the institutional LDAP server. The MySQL database and the web server will both be housed on secure servers operated by the University of Minnesota Health Science Academic Health Center's Information Systems group (AHC-IS). The servers are in a physically secure location on campus and are backed up nightly, with the backups stored in accordance with the AHC-IS retention schedule of daily, weekly, and monthly tapes retained for 1 month, 3 months, and 6 months, respectively. Weekly backup tapes are stored offsite. The AHC-IS servers provide a stable, secure, well-maintained, and high-capacity data storage environment, and both REDCap and MySQL are widely-used, powerful, reliable, well-supported systems. Access to the study's data in REDCap will be restricted to the only specific members of the study team by username and password and permission of the PI.[118] The REDCap database will be downloaded daily while data collection is ongoing and weekly when data collection is not actively occurring by the project manage. The REDCap data downloads will be stored on secure, password protected Box file.

Survey Risks and Protections: During the survey, residents will be asked to report on their household's own food security. It is possible that these questions could elicit an emotional response. Because we expect our study population is at high risk for food insecurity, we plan to offer all participants a handout that lists contact information for Hunger Solutions (an organization that helps people identify local food shelves and food assistance programs they may quality for and assistance with signing up for assistance.) Assistance contacting this organization or using their website to find local food shelves will also be provided, as appropriate.

Full-Service Mobile Market Intervention Risks and Protections: The full-service mobile market intervention is a community level intervention that already exists in the Twin Cities metropolitan area (there are 24 current weekly stops). While the full-service mobile market intervention will be newly available to the community sites participating in the proposed trial, the risk of participation in the mobile grocery store is minimal and equal to participation in mobile market service not associated with the trial. For example, participants of the trial will have the same opportunity to use the mobile market as will their neighbors who may or may not be in the trial. In addition, the mobile market staff on the full-service mobile market will not know (or have access to data to know) whether customers are participants in the trial or not; thus, accidental disclosure of study participation by staff will not be possible.

14.2 Reproduction Risks: Not applicable.

14.3 Risks to Others: Not applicable.

15.0 Incomplete Disclosure or Deception

15.1 Incomplete Disclosure or Deception:

- Not Applicable.

16.0 Potential Benefits to Participants

16.1 Potential Benefits:

The research participants may not see a direct benefit as a result of participation in the proposed study. However, research participants may benefit if they utilize the full-service mobile market, which may increase affordable food access, dietary intake, food security, and food purchasing outcomes. The mobile market will operate at the site locations recruited for this study after randomization/start-up for intervention sites and after final data collection for waitlist sites until the trial is complete. Then the sites will remain mobile market stops if they are well utilized and the community partners continue to wish to have mobile market service.

17.0 Statistical Considerations

17.1 Data Analysis Plan: See section 17.3

17.2 Power Analysis:

Power calculation. For the primary outcome of change in HEI scores, power is computed based on a t-test at the individual client level, but the sample size is inflated for the group randomization design by a factor of *1+(m-1)*ICC* where *m* is the average cluster size and ICC is the intracluster correlation. In Co-Investigator Harnack's study with participants similar to the proposed study (i.e., from the same communities with similar income and diversity levels), the HEI SD was 11.2.[90] In our preliminary customer intercept survey study, we found an ICC of 0.0004. Therefore, to be conservative, we assume an SD of 12 and an ICC of 0.01. Under these assumptions with a two-sided type I error rate of 5%, this study will have 80% power to detect a mean difference of 5.5 HEI points between intervention and control participants with an average cluster size *m* of 20 and number of clusters *k* of 12 for a total of 264 participants (132 per group). This calculation assumes an attrition rate of 20%. Detection of a 5.0 point difference in HEI is clinically significant, as it corresponds to a lower risk of cardiovascular mortality and lower risk of all-cause mortality.[122] Additionally, given our conservative approach, we may ultimately be adequately powered to detect even smaller differences in HEI scores between intervention and control sites.

17.3 Statistical Analysis:

Aim 1: The primary analysis will compare the mean within-person, baseline to follow-up change in HEI-2015 between the mobile market and waitlist control groups. Changes in HEI-2015 will be modeled via a Generalized Estimating Equation (GEE) linear model to account for the possible correlation of outcomes within community sites. Food insecurity, as measured by the U.S. Adult Food Security Survey Module, will be analyzed similarly. Baseline characteristics of randomized

groups will be summarized to assess whether any chance imbalances between groups are scientifically meaningful. If necessary, imbalanced variables will be adjusted for in outcome analyses. For variables with > 10% missing values, we will compare characteristics between individuals with missing and non-missing values and perform multiple imputation if needed.[123] Since several hypotheses on different outcomes are of interest, we will focus mainly on reporting confidence intervals rather than null hypothesis significance testing, an approach in line with current recommendations.[124] If the overall intervention effect is sufficiently large (i.e., of similar clinically meaningful size that we are powered to detect), we will use exploratory analyses to assess the presence and magnitude of possible treatment-covariate interactions, where again the focus will remain on identifying interactions of a clinically meaningful magnitude rather than those that achieve a pre-determined significance threshold. In particular, we will investigate the influence of sex as a biological variable by assessing whether intervention effects vary by sex. While the primary analyses will be conducted within an intent-to-treat (as randomized) framework, we will also perform dose-adjusted analyses to investigate the association between frequency and volume of use of the mobile market and the outcomes of interest, and whether these usage measures mediate the effects of the intervention.[125] For process and implementation measures taken at the site level, the focus will be mainly on creating meaningful descriptive statistics and visualizations.

Aim 2: The main purchasing outcomes will be the average number of servings of fruits and vegetables purchased each week. These outcomes will be treated as continuous variables and modeled using mixed effects regression models with random effects for participant, site, and time. Initially, we will fit separate models for each outcome (average fruit, and vegetable servings purchased each week); we will also consider joint outcome models that use the vector of servings (fruit, vegetables) as the outcome. These models will be used to assess whether temporal trends in food purchases are different between study groups, and whether any differences in trends identified are modified by other baseline covariates, including sex as a biological variable. If any outcomes are zero-inflated, we will consider regression models which accommodate this, e.g., negative binomial regression. Similar approaches will be used to analyze intervention effects on other purchasing outcomes. Further, we will perform exploratory analyses to identify trends and patterns in intervention site participant mobile market purchases (tracked with customer loyalty cards) over the 6 month intervention period.

Aim 3: Quantitative statistical procedures and analysis. We will use mixed effects (i.e., repeated measures) models similar to those in Aim 2 to quantify associations between personal, social, environmental, and behavioral factors and the quantitative shopping adoption outcome measures for intervention group participants. We will construct both univariate and multivariate models to consider the independent and joint effects of each of these explanatory factors, along with exploring other potential predictors of shopping adoption (e.g., sociodemographic

characteristics, dietary quality, food insecurity). We will also perform additional analyses to quantify joint associations between baseline factors, shopping adoption, and perceived mobile market features at follow-up.

Aim 3. Qualitative analysis procedures and analysis. Interviews will be transcribed verbatim and verified for accuracy.[126] Transcripts will be analyzed separately for high and low adopters using conventional content analysis[127] to identify major themes/subthemes. A team approach with two coders will facilitate analysis quality and rigor allowing for clearer and deeper understanding to be reached.[128] Prior to analysis, both coders will document personal preconceptions, topic knowledge, and feelings related to the study to facilitate objectivity.[128,129] Then, a two-step process will be used. First, transcripts will be reviewed to identify themes. Second, coders will independently read each transcript several times and code responses into the themes identified in step one using qualitative data analysis software.[127] Codes assigned by the coders will be compared, and discrepancies in coding will be discussed to reach consensus.[130,131] Next, the investigator team will compare themes and subthemes between high and low market adopters and assess for convergences and divergences between quantitative and qualitative findings. Similarities and differences will be detailed and supported with exemplar quotes. Additionally, as noted as part of the process evaluation, all intervention participants will answer open-ended qualitative questions about features that make the market helpful and suggestions for improvement. This opened-ended qualitative process data will provide further insights on mobile market implementation. This data will be analyzed apart from the qualitative interviews; however, content analysis and methods described above will be used to generate themes of findings from the data.[127]

17.4 Data Integrity:

Data collection is the responsibility of the study staff under the supervision of the study investigator. The investigator is responsible for ensuring the accuracy, completeness, legibility, and timeliness of the data reported. Data collected in the field from participants will be collected primarily via web-based REDCap surveys completed on iPads with paper-pen back-ups in case of technical failure. If needed the paper-pen surveys will be entered into the secure REDcap Database by two different study staff and verified for accuracy.

Data will be extracted from the REDCap study database and prepared for analysis in the statistical software R.[132] Data quality checks will be performed to identify potential data entry errors. A comprehensive data dictionary will be maintained as a standalone CSV, allowing variables to be read and properly labeled by any statistical software program.

18.0 Health Information and Privacy Compliance

18.1 Select which of the following is applicable to your research:

x My research does not require access to individual health information and therefore assert HIPAA does not apply. **The HIPCO office was contacted prior to submission to determine whether HIPAA would apply. We received the following guidance (also documented in a PDF submitted to ETHOS):**

" Lauren Popp from HIPCO confirmed that since your study is asking just a cursory question and not collecting PHI or doing anything clinical, HIPAA would not apply.

In your Protocol, you can just indicate that in the section about HIPAA Authorization (there is a check box for it) and you needn't worry about the Email or Text forms, etc."

☐ I am requesting that all research participants sign a HIPCO approved HIPAA

Disclosure Authorization to participate in the research (either the standalone form or the combined consent and HIPAA Authorization).

☐ I am requesting the IRB to approve a Waiver or an alteration of research participant authorization to participate in the research.

Appropriate Use for Research:

☐ An external IRB (e.g. Advarra) is reviewing and we are requesting use of the authorization language embedded in the template consent form in lieu of the U of M stand-alone HIPAA Authorization. Note: External IRB must be serving as the privacy board for this option.

18.2 Identify the source of Private Health Information you will be using for your research (Check all that apply)

☐ I will use the Informatics Consulting Services (ICS) available through CTSI (also referred to as the University's Information Exchange (IE) or data shelter) to pull records for me

☐ I will collect information directly from research participants.

☐ I will use University services to access and retrieve records from the Bone Marrow Transplant (BMPT) database, also known as the HSCT (Hematopoietic Stem Cell Transplant) database.

☐ I will pull records directly from EPIC.

☐ I will retrieve record directly from axiUm / MiPACS

☐ I will receive data from the Center for Medicare/Medicaid Services

☐ I will receive a limited data set from another institution

☐ Other. Describe:

18.3 Explain how you will ensure that only records of patients who have agreed to have their information used for research will be reviewed. Not applicable.

18.4 Approximate number of records required for review: Not applicable.

18.5 Please describe how you will communicate with research participants during the course of this research. Check all applicable boxes

☐ This research involves record review only. There will be no communication with research participants.

☐ Communication with research participants will take place in the course of treatment, through MyChart, or other similar forms of communication used with patients receiving treatment.

☐ Communication with research participants will take place outside of treatment settings. If this box is selected, please describe the type of communication and how it will be received by participants.

18.6 Access to participants: not applicable.

18.7 Location(s) of storage, sharing and analysis of research data, including any links to research data (check all that apply).

☐ In the data shelter of the Information Exchange (IE)

☐ Store ☐ Analyze ☐ Share

☐ In the Bone Marrow Transplant (BMT) database, also known as the HSCT (Hematopoietic Stem Cell Transplant) Database

☐ Store ☐ Analyze ☐ Share

☐ In REDCap (recap.ahc.umn.edu)

x Store ☐ Analyze ☐ Share

☐ In Qualtrics (qualtrics.umn.edu)

☐ Store ☐ Analyze ☐ Share

☐ In OnCore (oncore.umn.edu)

☐ Store ☐ Analyze ☐ Share

☐ In the University's Box Secure Storage (box.umn.edu)

x Store x Analyze x Share

☐ In an AHC-IS supported server. Provide folder path, location of server and IT Support Contact:

☐ Store ☐ Analyze ☐ Share

☐In an AHC-IS supported desktop or laptop.

Provide UMN device numbers of all devices:

HIPCO requires and will confirm that devices used in this manner are properly encrypted.

☐ Store ☐ Analyze ☐ Share

☐ Other.

Indicate if data will be collected, downloaded, accessed, shared or stored using a server, desktop, laptop, external drive or mobile device (including a tablet computer such as an iPad or a smartform (iPhone or Android devices) that you have not already identified in the preceding questions

☐I will use a server not previously listed to collect/download research data

☐I will use a desktop or laptop not previously listed

☐I will use an external hard drive or USB drive ("flash" or "thumb" drives) not previously listed

x I will use a mobile device such as an tablet or smartphone not previously listed:

We will purchase two study cell phones to be able to contact research participants with by text or phone. These cell phones will be password protected and contain no information besides participants names and phone numbers for communication. All contact information will be deleted at the end of each Wave. We will also have a digital voice recorder to record qualitative interviews. Upon completion of each interview the audio file will be moved to BOX immediately and then deleted from the recorder.

18.8 Consultants. Vendors. Third Parties. NA

18.9 Links to identifiable data: NA

18.10 Sharing of Data with Research Team Members. Any research related data will be stored and shared in a secure, password protected Box file and shared only with IRB-approved members of the study team.

18.11 Storage of Documents: NA

18.12 Disposal of Documents: NA

19.0 Confidentiality

19.1 Data Security:

Training. All study staff will be appropriately trained to this protocol and its requirements, including maintenance of participant confidentiality.

Authorization of access. Only designated IRB-approved staff will have access to the data.

Confidentiality. Individual participant information obtained as a result of this study is considered confidential. Information will be accessible to authorized parties or personnel only. All reports, and other records will be identified in a manner designed to maintain participant confidentiality. All paper study records will be kept in a secure storage area with limited access. Any paper-pen surveys will be entered into the electronic secure database (REDCap) and then stored in a locked space in a locked file cabinet within the School of Nursing. Any physical files that have identifiable data (e.g., consent form) will be secured and locked separately than files identified only with participant ID number. The consent form and other research study information will not be placed in the participants' medical, employment, or educational records.

Certificates of Confidentiality. Since this study will be funded by an NIH Grant, a Certificate of Confidentiality is automatically granted. All entities that are part of this study will be subject to the requirements of this Certificate.

Separation of Identifiers and data. Participants will be assigned a unique identifier assigned sequentially as they enroll. The Contact Log database that links participants' identifiable information to their identifier will be password protected accessible only to those who need the information to do their jobs.

Research databases in REDCap will contain the participant's unique ID number along with name and phone number to allow for text message reminders via REDCap's Twilio feature. However, these fields will be marked as "identifiers" within REDCap and only staff who need this information to do their jobs will be able to export these fields. All data files exported for analysis will not include identifiers.

All other research data will be identified only with the participant's unique ID number and will be stored in a separate database that will be password protected accessible only to those who need the data to do their jobs. The links will be destroyed after the completion of the study.

Data storage. Data for this study will be collected using web-based REDCap survey or with paper-pen that will be entered into a REDCap database, which uses a MySQL database via a secure web interface with data checks used during data entry to ensure data quality. REDCap includes a complete suite of features to support HIPAA compliance, including a full audit trail, user-based privileges, and integration with the institutional LDAP server. The MySQL database and the web server will both be housed on secure servers operated by the University of Minnesota Academic Health Center's Information Systems group (AHC-IS). The servers are in a physically secure location on campus and are backed up nightly, with the backups stored in accordance with the AHC-IS retention schedule of daily, weekly, and monthly tapes retained for 1 month, 3 months, and 6 months, respectively. Weekly backup tapes are stored offsite. The AHC-IS servers provide a stable, secure, well-maintained, and high-capacity data storage environment, and both REDCap and MySQL are widely-used, powerful, reliable, well-supported systems. Access to the study's data in REDCap will be restricted to the members of the study team by username and password. The electronic deidentified data will be downloaded from the Redcap and stored in Box in a password-protected file structure, password-protected server.

NDSR is a software program that will be used to collect dietary recall interviews from participants and assess nutritional quality of participant food purchases. For recalls, the data stored in NDSR is deidentified in that it will contain participant first name (so the interviewer can greet the participant by name), participant study ID number, date of dietary recall interview/fruit & vegetable form, participant sex, recall number (first, second, or third), dietary data, any notes about the recall interview/fruit & vegetable form, and staff who completed the recall. Similarly, for fruit and vegetable form data entry, the data stored in NDSR will contain participant study ID number, sex, date & location of purchase, which purchase form it was (i.e., week 1, 2, 3, or 4), dietary data, any notes about the form, and staff who completed the data entry. These deidentified dietary data will be extracted from NDSR and stored on Box.

We will also have a digital voice recorder to record qualitative interviews. Upon completion of each interview the audio file will be moved to BOX immediately and then deleted from the recorder.

We will collect participant purchasing data through the Market Members loyalty program. This loyalty program and the data it collects is for all mobile market customers who sign up for business purposes and not just for those enrolled in the study. UMN study staff will extract participant-specific purchase data from the larger mobile market loyalty database (that does not link to whether a person is in the study or study ID number) through the matching of participants to those in the larger database using unique customer numbers that are generated by the Market Members software that can be matched with our participant IDs. After the purchase data is extracted, the names and customer numbers will be removed and replaced with the participant study ID number. The purchase data linked to the participant ID

number will then be uploaded into REDCap or BOX. See the Mobile Market purchasing data protocol.

Password protection/encryption/physical controls: All electronic data will be stored in REDCap and Box. Audio files will be downloaded from audio recorders to Box immediately after the interview. Voice recordings and de-identified transcriptions of the audio will also be saved on Box. Password protected files / data sets will be stored and accessible through REDCap or Box for those research team members. Research team members will only be given access to the databases/files/documents that they need to complete their work.

20.0 Provisions to Monitor the Data to Ensure the Safety of Participants

20.1 Data Integrity Monitoring.

Team meetings will occur regularly (at least monthly) with study investigators to discuss regular monitoring of study progress and study safety. At these meetings, the study team will discuss recruitment efforts, monitoring participant distribution and progress toward enrollment targets.

Data collected since the previous meeting will be discussed, and the team will review whether approved protocols are working well.

20.2 Data Safety Monitoring.

Please see the attached DSMP reviewed by the project officer at NINR. Any modifications to this DSMP will be submitted to NINR for pre-review prior to submission to the UMN IRB for review and approval.

21.0 Compensation for Research-Related Injury

21.1 Compensation for Research-Related Injury: In the event that research-related activities result in an injury, treatment will be provided to the participant (e.g., first aid, emergency treatment, and follow-up care as needed). Care for such injuries will be billed in the ordinary manner to the participant or the participant's insurance company.

21.2 Contract Language: Not applicable.

22.0 Consent Process

22.1 Consent Process:

- *Where the consent process will take place: The* consent forms will be mailed to interested and eligible participants in advance of the baseline data collection visit. The process of informed consent will take place at baseline data visits in a private and confidential space [using a privacy screen if needed]. Prior to beginning data collection, the trained research staff will read through the consent form with

each participant, answering any questions the participant has, and using teach back to make sure the participant understands what he/she/they is consenting to (e.g., time commitment, research methods inclusive of baseline and follow-up surveys, dietary recalls, fruit & vegetable data collection, risks, benefits, compensation, voluntary, etc as outlined in full in the consent form). Following this, if the participant is willing to consent and participate in the study, the research staff and participant will complete and sign the consent form. The participants may withdraw consent at any time throughout the course of the study. A copy of the signed informed consent document will be given to the participants for their records. The rights and welfare of the participants will be protected by emphasizing to them that their ability to shop at the mobile market will not be adversely affected if they decline to participate in this study.
Participants will also be provided with a Participant Guide that describes the study activities to help participants understand the study activities if/when they consent.

- *Any waiting period available between informing the prospective participants and obtaining the consent.* There will be no waiting period required between informing the prospective participants and obtaining the consent, unless participants wish to think about their decision. Participants will have the opportunity to carefully review the informed consent form and ask questions prior to signing. The participants will also have the opportunity to discuss the study with others or think about it prior to agreeing to participate if they wish.
- *Any process to ensure ongoing consent*. Participants will be informed that at any point in time, they are free to no longer be in the study and may choose to leave the trial. Formal written consent will take place only at the start of the study; however, at subsequent study encounters, interest in continued participation will be assessed at study visits.

22.2 Waiver or Alteration of Consent Process (when consent will not be obtained, required information will not be disclosed, or the research involves deception):

- Not applicable.

22.3 Waiver of Written/Signed Documentation of Consent (when written/signed consent will not be obtained):

- Not applicable.

22.4 Non-English Speaking Participants: We are currently allowing ASL speakers to participate in the study. There may be recruitment and inclusion of additional non-English speaking participants as part of this research study eventually, as we expand the study to community sites that have larger non-English speaking populations. The languages selected will be based on the communities we recruit for mobile market stops (anticipated languages are Spanish and Hmong). However, we will amend this

protocol with additional protocols/processes, safeguards, and certified translations of study materials like the consent forms, surveys, etc after we know what languages the trial will be completed in. We will make these modifications, submit for IRB approval, and await IRB approval prior to recruiting or enrolling participants who speak languages other than English.

22.5 Participants Who Are Not Yet Adults (infants, children, teenagers under 18 years of age):

- Not applicable – not recruiting individuals under 18 years of age (Participants will be asked upon screening if they are 18 years of age or over. If not 18 years of age or older they will not be able to participate in the study).

22.6 Cognitively Impaired Adults, or adults with fluctuating or diminished capacity to consent:

- We do not anticipate enrolling individuals with impaired capacity to consent. Assessment of capacity to consent will be informally made during routine interactions with participants. No specific assessment or documentation of capacity is required under those circumstances.

22.7 Adults Unable to Consent:

- Not applicable.

23.0 Setting

23.1 Research Sites:

- The trial investigator team is housed at the
    - University of Minnesota and
    - The Twin Cities Mobile Market of The Food Group. The Twin Cities Mobile Market that brings affordable, fresh and healthy food options to low income or low food access communities. The Mobile Market provides service in partnership with their community site partners.
- Recruitment will occur in the community in/around the community site partner locations recruited for the trial.
- Data collection will occur in the community meeting spaces in/around the community site partner locations (e.g., community meeting rooms, library meeting rooms). Data collection will also occur by phone and mail.
- Mobile market service for community site locations recruited for the trial will occur at the location agreed upon between the community site partner and the Twin Cities Mobile Market. Again, important to note, that this service will occur just as it does at ongoing sites currently receiving the mobile market with no affiliation with the trial and anyone within the community (regardless of their participation in the trial) will be able to shop at the mobile market.

- The Food Group does not engage in research outside of this grant. It provides food resources and services throughout the community. Thus, it does not have site specific regulations/customs related to research and will follow those at the University of Minnesota and will work with PI Horning and the UMN IRB for ethical oversight.

23.2 International Research:

- Not applicable.

23.3 Community Based Participatory Research:

- Twin Cities Mobile Market is the community partner of the study that has been involved in preliminary studies and during grant development. This involvement will continue and one of their staff is a co-investigator on the study. They will continue to advise to ensure the research is acceptable and aligned with their community values and priorities. All research related actions/materials (e.g., survey, flyer, etc) will be reviewed and adapted per their recommendations, as needed, and will be sent to the IRB for re-review if changes are made.
- As a result of participation at the level of co-investigator, Ms. Stephanie Wagner has completed the Human Research: Social / Behavioral or Humanist Research Investigators and Key Personnel training. She will complete the required HIPAA confidentiality training as well.
- Other mobile market staff will provide regular mobile market service at the community sites recruited for this trial. This service will be the same service they provide at their other community site locations that currently receive service (those that are active an ongoing, not part of the study) and service at the community sites of this trial will be open to the general public (not just those enrolled in the study). Because the staff's involvement is limited to providing a service that is currently being provided in the city, these mobile market staff will receive a training on research ethics and the process and protocols of the study by the researcher or designated research staff in case a participant self-identifies themselves to a staff member while on the mobile market and has a question about the research study. In this case, the mobile market staff will be trained to refer these individuals to the researcher if the question is about research.
- To align our work with community engaged research principles, we seek to make sure the research process is as smooth and friendly to potential research participants as can be. Thus, the Mobile Market in partnership with university research staff/investigator(s) will be hosting informal community meetings with ongoing customers at existing non-research sites. These individuals are NOT potential research participants to discuss what works on the mobile market, what could be improved to make mobile market service even better, and to inform the proposed research processes (e.g., review of flyers,

recruitment/retention plans, participant flow through data collection experience, data collection instruments for ease of use, etc.). Community members who take part in these meetings will receive a light meal (breakfast or lunch) and a $20 mobile market gift card for their time in the meeting and a t-shirt (if they have not already received one).

24.0 See letters of support from the grant. Multi-Site Research

24.1 Study-Wide Number of Participants: 264

24.2 Study-Wide Recruitment Methods: See plan for human subjects recruitment above – only UMN research staff will be conducting human subjects recruitment.

24.3 Study-Wide Recruitment Materials: See plan for human subjects recruitment above – only UMN research staff will be conducting human subjects recruitment.

24.4 Communication Among Sites:

- The Food Group and the UMN team will meet regularly. Depending on time in the study this meeting interval may vary from weekly (for instance when in active recruitment or mobile market launch) to biweekly or at most no longer than monthly (for instance when in data analysis phase) to discuss the trial activities and updates.
- The most current approved versions of the protocol and documents will be stored in a Box secured file (as well as in ETHOS).
- The initial, continuing review, and modification IRB approvals required will be documented and stored in the shared secure password protected Box file as well as within the ETHOS system.
- All modification submissions and approvals will also be communicated at meetings and through email. Until formal communication (by email or meeting minutes) of approvals of modifications, no modifications will be able to be implemented.
- Identifiable and research survey data is only being collected by the UMN research staff.
- The mobile market will be collecting real-time purchasing data as part of their Market Members program from all customers (not just those within the trial) as part of their mobile market program. The mobile market will provide a UMN research staff member access to this data to be able to extract the data for research participants only per the research participants consent with their consent form. The mobile market co-I nor mobile market staff will not be given the identifiable information of research participants, as it will not be needed to do their job.
- The mobile market will also collect process data related to overall sales of the mobile market at mobile market sites receiving service as part of the trial. This

data is not linked to individual customers. This data will be shared with UMN research staff by giving UMN research staff access to download the data from the mobile market's electronic cash register that collects point of sale data.

- De-identified data will be stored and shared in password protected secure box files and those who need access will be granted access to the files.
- All local site investigators will 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 university or local policy.
- All other reportable events in accordance with university or local policy.

24.5 Communication to Sites:

- Problems (inclusive of reportable events) will be communicated by the timelines as outlined in the DSMP document referred to in this protocol in section 20.2.
- Study progression will be communicated in regular meetings and email communication between UMN and Mobile Market staff.
- The closure of the study will be planned for and communicated in budget conversations, regular meetings and emails between UMN and Mobile Market staff.

25.0 Coordinating Center Research

Not applicable.

26.0 Resources Available

26.1 Resources Available:

- We are recruiting from community site locations that the mobile market bring service to. Thus, we are sampling from the community and the inclusion criteria requires the participant to live within a half mile of the community site location closest to them, which provides us with an ample population to recruit from.
- The grant will fund the time of the research team and mobile market staff for the intervention; the grant will also fund the intervention itself and all other research activities.
- Please see the attached facilities and resources attachment for facilities and resources.
- It is not anticipated that the study participants will need medical or psychological resources as a result of participating in the study. However, if such resources are requested by a participant, the research staff will make the appropriate referral.

- Because we expect our study population is at high risk for food insecurity, we plan to offer all participants a handout that lists food relief services (e.g., food shelves) and contact information for Hunger Solutions (an organization that helps people identify food assistance programs they may quality for and assistance with signing up for assistance.
- All persons who will assist with the research will receive training to the study protocols and procedures by the PI or designated research team member (e.g., project manager) and will be trained in all human subjects research ethics training. These individuals will all be added to the study team within ETHOS for IRB approval and review. The persons who assist with the research will also be given training on how to perform their role within the study by the PI or designated research team member and demonstrate they are proficient in the activities assigned.

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