Clinicaltrials.gov cover page

Official Title of the study

Kidney Health: Eat Well, Live Well

NCT number

NCT05970341

Date of the document

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Unique Protocol ID:

STUDY00002253

Principal Investigator:

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GENERAL STUDY INFORMATION

Use for greater than minimal risk studies and minimal risk studies that fit into one or more expedited categories (see Section 5.3 of our Policies & Procedures for details regarding expedited research).

Do NOT submit this form if the study will qualify for exempt review, instead submit HRP-UT902 IRB Proposal – Exempt Submission Form found in the document Library.

If you are only using secondary data that will not be initially collected solely for this research project, use HRP-UT903 Template IRB Proposal Secondary Use form instead.

For studies following a multi-center or sponsor protocol, please use this guidance to assist in your completion of this form.

For questions regarding definitions, policies, or terms referenced below see the policies and procedures manual.

Please note, Word online does not support Word checkboxes. Please download the file and use your desktop version of Microsoft Word.

1 Review Type (Choose one)

*Click on the check box (or double click and type an "X" if using Google Docs) the **one** review type that in the investigator's opinion applies.*

Please note: Expedited Review does not refer to the timeliness of the review of your protocol, but specific categories of research defined by ORHP. If you would like help determining which type of review is most appropriate for your study please contact the Office of Research Support and Compliance: https://research.utexas.edu/ors/about-ors/contact-us/.

Investigator's assessment of review does not preclude the IRB from alternate determinations. In cases where the investigator and the IRB's determination conflict, the IRB's determination should be considered accurate.

A ☐ **Full Board Review – Greater than Minimal Risk Research**

B ☒ **Expedited Review – Minimal Risk Research**

2 Research Hypothesis

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Can lowering barriers to resources, providing instrumental support and empathetic connection improve diet and reduce kidney injury in low-income patients with CKD 2 and 3 over 6-months/26 weeks.

1. Can kidney injury, cardiovascular risk, diet and mental health improve by (a) lowering barriers to improving diet by providing resources (direct delivery of fruits and vegetables (F&V) and grocery store eGiftcards) (b) providing instrumental support (educational materials, recipes and as-needed practical

food purchase and preparation help) and (c) providing empathetic connection over the telephone through a dedicated “Health Partner” (Intervention).
2. Does the more easily implemented part of the program lead to improvements in kidney injury, cardiovascular risk, mental health and diet, with just the provision of grocery store eGiftcards, educational materials and recipes without the more operationally complex provision of customized delivery of F&V and the dedicated health partner(Control).

3 Study Background

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Chronic kidney disease (CKD) is diagnosed and monitored mainly through abnormal urine albumin levels and a persistent reduction in the estimated glomerular filtration rate (eGFR). These markers are used to stage it from 1 to 5, reflecting disease progression. Detection in early stages (1-3) can greatly improve disease prognosis by enabling early intervention and delaying, or even avoiding, kidney replacement therapy, like dialysis, or kidney transplant when it progresses to CKD stages 4 and 5 (end-stage kidney disease, ESKD). At early stages, however, CKD usually remains undetected; it is not systematically screened for in primary care practice and is asymptomatic, with little to no impact on the individual’s quality of life (National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), 2021). ESKD, on the other hand, disrupts individuals’ lives and their families’, in addition to being expensive for them and the health care system. Recently, based on usage in clinical trials, urine Albumin:Creatinine ratio (uACR) has been included in CKD guidelines as a marker for monitoring kidney damage in primary care (National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), 2021). Therefore, healthcare payers have also begun assessing the benefit of measuring and reducing this marker.

At any CKD stage, metabolic acidosis can be a serious CKD-related complication (Raphael, 2019). For some individuals, an oral alkali treatment, generally sodium bicarbonate tabs, can be included as part of the pharmacological treatment to help regulate acid-base balance in the blood (National Kidney Disease Education Program, 2014). The addition of sodium can, however, increase the chances of cardiovascular disease (CVD) complications, especially given that CKD often presents with other chronic conditions, such as diabetes and hypertension, with the latter being the leading cause of CKD mortality (National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), 2021). Diet therapy has been considered a key component of disease management mostly in ESKD to support electrolyte and mineral balance during kidney replacement therapy. More recently, however, dietary intake has been studied as a means to support the reduction in renal acid load in early CKD stages and potentially improve kidney-related outcomes (van Westing et al., 2020).

Randomized trials conducted with patients diagnosed with CKD have demonstrated that increasing the consumption of alkali-inducing fruits and vegetables can positively impact biomarkers of CVD, adding the benefit of CVD protection, on top of protecting kidney function similarly to sodium bicarbonate (Goraya et al., 2012, 2014, 2019, 2021). In their initial study, Goraya et al. (2012) showed that a fruits and vegetables intervention among patients with CKD stage 1 or 2 successfully reduced urine Albumin:Creatinine ratio (uACR) better than usual care and sodium bicarbonate after just one month. Following that study, the same team (Goraya et al., 2014) showed a reduction in uACR and preservation of eGFR in patients with CKD stage 3 who received a fruits and vegetables intervention

and were followed for 3 years. These studies demonstrated that fruits and vegetables consumption can protect kidney function. Further studies also support the need to adopt a more comprehensive approach to eating patterns, such as making healthier food choices in the overall diet (Pereira et al., 2020; Wesson et al., 2020). Together with other lifestyle changes, improved dietary patterns can have a compounded effect to delay or avoid dialysis (Quintela et al., 2021). Experts in the field have made the case for more pragmatic trials in CKD, so that such programs can be evaluated and reach people in the context of their lives (De Boer et al., 2016).

Here, we propose a 6-month program aimed at supporting patients to change their eating habits to reduce the likelihood of kidney injury. We aim to reduce barriers to trying healthier, kidney-friendly foods through the direct provision of fruits and vegetables and grocery store eGiftcards. We will provide instrumental support, including education to support a better understanding of kidney disease and the role of healthy eating in slowing its progression, recipes customized to provided resources and food preparation tips. Finally, we will provide empathetic relational support through a dedicated "Health Partner" who will connect via telephone. The program will be assessed with a 2-arm randomized controlled trial, with primary outcome of Urine Albumin to Creatinine ratio (uACR), cardiovascular risk via Hemoglobin A1C and blood pressure, mental health and diet.

This project is a partnership with the Harris Health system in Houston with co-investigators: Karen Tseng (Sr. VP & Chief Integration Officer), Dr. Meroë Morse (Baylor's Integrative Internal Medicine-Primary Care, Smith Internal Medicine Clinic), Dr. Rob Wesley (Site Director & Associate Director of Medicine Subspecialties-LBJ Outpatient Center UT Medicine Clinic and Associate Professor of Medicine, McGovern School UT Health), and Dr. Jaime Rueda (Internal Medicine and Pediatrician at Smith & MLK Clinics and Assistant Professor at Baylor College of Medicine).

Betz, M., Steenes, A., Peterson, L., & Saunders, M. (2021). Knowledge Does Not Correspond to Adherence of Renal Diet Restrictions in Patients With Chronic Kidney Disease Stage 3-5. *Journal of Renal Nutrition*, *31*(4), 351–360. https://doi.org/10.1053/j.jrn.2020.08.007

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4 Design and Methodology

Provide information regarding study design or data collection methodologies. Details regarding protocol specific research procedures will be discussed in a later section.

To input text, click in the light grey area below.

Design: Two-arm randomized trial. Arm 1 is intervention ("program") and arm 2 is control (usual care). Arm 2 will receive a monetary amount at the end of the 6 months to their preferred grocer.

Randomization: 1:1 ratio, stratified by diabetes mellitus type 2 diagnosis prior to enrolment.

Blinding: Outcome assessors, principal investigator, and biostatistician are blinded to participant allocation. Participant and other staff are unblinded.

6-month/26 week, 2-arm Randomized Controlled Trial

- **Arm 1:** Program + Usual Care
  Program contains following components provided in different combinations and frequencies over 26 weeks.
  1. Kick-off phone call plus a welcome package hand delivered in person by the RA at the baseline visit (after measurement completion) that will contain educational materials and resources (once after enrolment)
  2. Bags with fruits and vegetables (F&V) delivered at preferred times to the participant's preferred location.
  3. SMS texts to remind of upcoming F&V deliveries, with links to access recipes.
  4. Electronic Gift cards (eGiftcards) to a grocery store chosen by the participant among available options.

5. A personal health partner who connects on the phone and via SMS text with the participant.

- **Arm 2:** Materials Control + Usual Care
    1. Welcome package that includes same educational materials and resources: same as given to Arm 1. (Any intervention program-specific information will be removed.)
    2. Recipes: compiled from the same ones that Arm 1 received, but hand delivered at the beginning of the program by the RA at the baseline visit (after measurement completion (one-time).
    3. eGiftcards to a grocery store chosen by the participant among the same available options delivered after the 6 month measurement visit.

Description of usual care:

Patients in this study will be recruited from clinics within the Harris Health system. In this system usual care for patients with CKD not requiring kidney replacement therapy includes having access to primary care physicians by face-to-face or virtual (TeleHealth) appointments and on an as-needed basis by phone or through Harris Health's online portal.

To support disease management, physicians can refer patients to Patient Educators (PtEd) [Registered Nurses (RN)], Registered Dietitians (RDs), and Case Managers [RNs and/or Social Workers (SWs)].

- The Outpatient Center is designed exclusively for outpatients requiring specialty and diagnostic and surgical care. Non-medical support at clinic site includes a Food Farmacy [which includes services by RDs, PtEd, and Community Health Workers (CHWs)] and the "Nourish Teaching Kitchen" (delivered in partnership with University of Texas School of Public Health).
- The Smith Clinic and the Martin Luther King Jr. Health Center (MLK) are similar in their services to patients. They have an internal medicine clinic, which provides general primary care, along with multi-specialty clinics. It also has diagnostic imaging (such as Magnetic Resonance Imaging and ultrasound), full-service pharmacy with clinical pharmacists that provide support to patients with DM2 and hypertension, and laboratory services. They offer counseling, social services, and nutrition and health education, such as classes on diabetes and on basic nutrition.

Outcomes:

- Primary Outcome: Urine Albumin:Creatinine Ratio (uACR).
- Secondary Outcomes: Food intake, diet quality, Hemoglobin A1C, Blood Pressure, and mental health (depression, anxiety)

Measurements and tools:

The table below summarizes the tools and methods for data collection (for outcomes and population descriptors) and the time points during the study.
All self-report will be conducted using a tablet with study staff available as necessary for help.

Outcome	Indicator or Measure	Time points	Tool	Approach
Demographics & Behavioral Patterns				
Demographics	Includes -Gender, age, ethnicity, race, household size, income, age at CKD diagnosis, other conditions -Relationships: other food programs (e.g., Harris Health's Food Farmacy, SNAP, WIC), where shop, social/wellbeing institutions & Harris Health. - Diabetes diagnosis (for stratification)	Baseline	Customized	Self-report
Social Needs	Housing, transportation, paying for household necessities	Baseline	PRAPARE (within demographics survey)	Self-report
Biomedical Measures				
Kidney Injury	Urine albumin:creatinine ratio (UACR)	Baseline, 3, 6 mos	Single urine sample	Sample collection sent to Lab for analysis
		From 18 mo prior to 15 mo post enrollment, as available	Electronic Health Records	Data exchange
	Estimated Glomerular Filtration Rate (eGFR)	From 18 mo prior to 15 mo post enrollment, as available	Electronic Health Records	Data exchange
CVD risk & Diabetes	Hemoglobin A1C	Baseline, 3, 6 mos	Finger stick on portable device	Direct measurement
		From 18 mo prior to 15 mo post enrollment, as available	Electronic Health Records	Data exchange
CVD risk & Hypertension	Blood Pressure	Baseline, 3, 6 mos	Automatic blood pressure cuff	Direct measurement
		From 18 mo prior to 15 mo post enrollment, as available	Electronic Health Records	Data exchange
Anthropometric measures	Measured Weight	Baseline, 6 mos	Weight Scale	Direct measurement
	Height	Baseline	Customized or Electronic Health Records	Self-report or data exchange

	BMI	Baseline, 6 mos	----	Derived
		From 18 mo prior to 15 mo post enrollment, as available	Electronic Health Records	Data exchange
Eating Habits & Diet				
Food intake	30-day food frequency questionnaire (screener)	Baseline, 3, 6 mos	Dietary Screener Questionnaire in the NHANES 2009-10	Self-report Self-administered
Diet quality	Estimates of individual mean dietary intake	Baseline, 3, 6 mos	Calculated (from DSQ)	Derived
Food security	Access to food	Baseline, 6 mos	USDA Food Security Questionnaire	Self-report
Food Preparation, Diet & Health self-assessment	Who shops, who prepares food, self and household assessment of diet and health.	Baseline, 3, 6 mos	Customized	Self-report
Mental Health, Social Support & Quality of Life				
Depression	Depression symptoms	Baseline, 3, 6 mos	Patient Health Questionnaire 8 items (PHQ-8)	Self-report
Anxiety	Anxiety symptoms	Baseline, 3, 6mos	General Anxiety Disorder (GAD-7)	Self-report
Perception of aloneness/ Loneliness	Loneliness	Baseline, 3, 6mos	3-item UCLA loneliness scale	Self-report
Social support network & Isolation	Frequency of connection with friends and family who can be relied on.	Baseline, 6 mos	Lubben Social Network scale	Self-report
Quality of Life	Perceived Quality of life (general) Mental & Physical	Baseline, 6 mos	Short Form-12 (SF-12)	Self-report
Healthcare Utilization				
Health care utilization	Prescribed meds, Medical visits, hospitalization, ER, care delay due to cost, med-food tradeoff, medication underuse due to cost	Baseline, 3, 6 mos	Customized survey	Self-report
	History of visits to clinic (both primary care and specialty care), visits to the ER, and hospitalizations	From 18 mo prior to 15 mo post enrollment, as available	Electronic Health Records	Data exchange
Kidney Disease & Role of Diet Perceptions				
Perception of kidney disease, role of diet, actionability.	Understanding of having kidney disease; having some control over trajectory; perception of role of medical treatment & diet in improving disease.	Baseline, 6 mos	Modified "Brief Illness Perception Questionnaire"	Self-report
Program Components				

Interactions with dedicated health partner & program evaluation	Perception of utility of partner overall and specific aspects; program satisfaction; community organization interaction.	6 mo (intervention arm only)	Customized survey	Self-report

5 Data Analysis

Describe the data analysis plan, including any statistical procedures or power analysis.

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Our primary outcome of interest is Urine Albumin:Creatinine ratio (uACR) and secondary outcomes are Food intake through Dietary Screener Questionnaire, Hemoglobin A1C, Blood Pressure, self-efficacy, and mental health (depression, anxiety). Because comorbidity of *diabetes mellitus* (DM), particularly type 2, can affect responsiveness to the intervention, we will rely on stratified randomization of patients from the clinics by DM type 2 diagnoses.

We will test differences in the trajectory of uACR over the course of six-months with three assessments (baseline, 3- and 6-months) for those who participate in the program versus those who do not. We will rely on linear mixed effect regressions with random terms to model individual differences in both the intercept and change terms, accounting for the clustering effect of the clinic sites. We will predict these trajectories using the following person-level covariates: grouping indicator, terms to capture DM comorbidity, and age. The cross-level interaction of grouping indicator with time will constitute the effect of interest.

To explore if program's impact on uACR varies for those with DM comorbidity, we will test three terms: the DM indicator, its interaction of time, and intervention X DM X time term. Given their exploratory nature, alpha for these terms will be lowered to 0.025. In order to assess the dose-response relationships, we will examine Pearson correlations among uptake of program elements with primary and secondary outcomes from baseline to 6-month assessments.

STUDY ELEMENT IDENTIFICATION

6 Study Elements

Click on the check box (or double click and type an "X" if using Google Docs) each procedure included in your study.

A full description of all study procedures should be provided in the Procedures (Details) section below and/or the applicable supplement form.

☒	Bio-specimens	☐	Biometrics	☒	Registry or Repository
☐	Focus Group	☐	Genetic Analysis	☐	Genomic Data Sharing
☐	International Research	☒	Interview/Survey	☐	MRI
☒	Protected Health Information	☐	Observation	☐	Radioactive Material/PET/Nuc. Med
☒	Record Review	☒	Sensors (Externally Placed)	☐	Sensors (Inserted)
☐	Video/Audio Recording	☐	X-Ray/CT		

7 Study Intervention

Click on the check box (or double click and type an "X" if using Google Docs) if you will implement any of the following interventions.

A full description of all study interventions should be provided in the Procedures (Details) section below and/or the applicable supplement form.

☒	Behavioral	☐	Device	☐	Drug/Biologic

8 Clinical Trial

Click on the following check box (or double click and type an "X" if using Google Docs) if the research meets the below definition of a clinical trial.

☒ **This study meets the definition of a clinical trial according to clinical trials.gov in that it involves one or more human subjects who are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.**

9 Additional Oversight

Click on the check box (or double click and type an "X" if using Google Docs) each activity that requires oversight from additional UT committees.

☐	**Energy introduced to the subject (electrical, magnetic, light)**	☐	**Human embryonic, human induced pluripotent, or human totipotent stem cells; or human gametes or embryos**	☐	**Radiation exposure without direct clinical benefit**

☒ **Biological Samples, Biohazards, Recombinant DNA, or Gene Transfer**

If biological samples are used and stored on UT campus IBC approval is needed.

a ☒ **Biological samples collected will not be stored on UT sites and another agency has responsibility for biospecimen safety.**

b **IBC Protocol Number**

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10 Alternatives to Participation in This Study

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The alternative to participation is usual care at Harris Health clinics, the clinic system where we will be recruiting participants for this study. Participation in the study is voluntary; if the individual chooses not to participate in the research study, it will not affect the care they receive from Harris Health.

STUDY PROCEDURE DESCRIPTION

11 Procedure Description

Describe all study procedures, including a step-by-step outline of what participants will be asked to do or how data will be used. Be sure to describe all of the following in detail, as applicable:

- Provide a description of all research procedures being performed and when they are performed, in sequential order.
- All research measures/tests that will be used and state if questions or measures are standardized or published (upload copies of all surveys, scripts and data collection forms)
- Secondary data or specimens that will be obtained, how they will be collected, and how they will be used
- Where each activity will take place, the duration of each, and who will perform each activity
- Include time commitment of participants

To input text, click in the light grey area below.

This randomized trial study will have a total duration of 6 months.

The procedures will take place at the following site: Harris Health System clinics (for example, LBJ Hospital Outpatient Center, Martin Luther King Jr. Medical Center, and Smith Clinic) in Houston, TX.

This project is a partnership with the Harris Health system in Houston with co-Principal Investigators Esperanza "Hope" Galvan (Senior Vice President and Chief Health Officer, Harris Health System), and co-Investigators Dr. Rob Wesley (Site Director & Associate Director of Medicine Subspecialties- Harris Health's LBJ Outpatient Center UT Medicine Clinic and Associate Professor of Medicine, McGovern School UT Health Houston), and Dr. Jaime Rueda (Internal Medicine and Pediatrician at Harris Health's Smith & MLK Clinics and Assistant Professor at Baylor College of Medicine).

1. **Arm 1** (Intervention):

Intervention components:

F&V Bag Delivery with associated recipes.

- F&V bags will be delivered to each participant's preferred delivery location (e.g. home or work) and time (morning, after-work, etc.), within limits of grocery deliverer.
- SMS texts (sent through a secure, HIPAA-compliant platform) will be used to inform participants of upcoming F&V bag deliveries and its content, as well as provide links to recipes customized to the items in the bag.
- F&V bag content will be predetermined every week to include 2 kidney-friendly vegetables sufficient for 2 meals for 4 people (family meals), fruit, and 1 kidney-friendly snack (e.g. dried fruit). The total cost is estimated at $20.00, excluding delivery, for prices in June 2022.

eGiftcards for a grocery store (named "*Healthy Eating Card*" for the participant)

- Sent via SMS text (or email if SMS text is not possible for the participant).
- The choice of grocery store will be obtained at the beginning of the study from a list of options (e.g., Walmart, H-E-B, Kroger).

Dedicated health partner:

- A consistent program staff ("health partner") will call the participant on a preferred phone number to build a relationship based on empathy, support the participant's journey, answer specific questions about the program and help the participant get answers for practical shopping and food preparation questions.
- Health partners will answer basic health-related questions that are available in the educational materials provided. No medical guidance or

advice will be provided – as these arise, health partners will recommend the participant call their clinic or physician. Questions will be answered on the phone or via SMS texts using a secure, HIPAA-compliant tool. A curated list of resources will be available for the Partner to share with the participant as needed—some examples appended.

- Participants will receive phone calls from the dedicated health partner 2 times a week for 4 weeks, then every other week for 8 weeks with the option to increase or decrease how frequent these phone calls are during the program. The schedule for calling is outlined in more detail in the next section below (under "**Intervention Protocol**").
- Based on our experience with such telephonic 'lay' support, we expect the average duration of calls to be less than 15 minutes.

Share learnings with groups (Optional activity):

- During the program, the Health Partner will encourage participants to identify an institution, group, or community of interest to them (e.g., ask to speak at a religious gathering, or at an association, a club, a community center or other) where they could share with others their own learned expertise on navigating their kidney disease. This will be optional and choosing not to do this activity will not affect their ability to participate in the overall study.

Intervention Protocol

- **Week 1-2 (2 weeks):**
  - Welcome Packet: During the baseline visit after measurement collection, the Research Staff will hand the participant a welcome packet including educational and motivational written materials, as well as a recipe book.
  - Welcome Call: Participants will be contacted by the Program Staff to introduce them to the program and ensure understanding. This call is expected to last 10-20 minutes.
- **Weeks 3-10 (8 weeks):**
  - Weekly F&V Bags with recipes: Participants will receive one produce bag delivered every week for 8 weeks, for a total of 8 bags.
  - eGift cards for Grocery Store: At the start of week 7, participants will receive one eGift card for a grocery store of $30.00 value.
  - Phone calls with a Dedicated Partner: Participants will receive 2 calls a week from their dedicated partner in weeks 3-6. At the end of week 6, calls will shift to once every 2 weeks by default, but participants will be asked if they prefer increasing the frequency to once a week or decreasing to once every 4 weeks.

- **Weeks 11-18 (8 weeks):**
  - Bi-weekly F&V Bags with recipes: Participants will receive one produce bag delivered once every 2 weeks for 8 weeks, for a total of 4 bags.
  - eGift cards for Grocery Store: during weeks 11-18, participants will receive two eGift cards of $40.00 each, sent 4 weeks apart, for a total of $80.00.
  - Phone calls with a Dedicated Partner: once every 2 weeks by default, but participants will be asked if they prefer increasing the frequency to once a week or decreasing to once every 4 weeks.
- **Weeks 19-26 (8 weeks):**
  - eGift cards for Grocery Store: during weeks 19-26, participants will receive two eGift cards of $60.00 each, sent 4 weeks apart, for a total of $120.00.
  - Phone calls with the Dedicated Partner: once every 2 weeks by default, but participants will be asked if they'd prefer increasing frequency to once a week or decreasing to once every 4 weeks.

2. **Arm 2** (Control): Participants randomized to this arm will receive usual care, which was described in section #4 in the protocol.
   - Welcome Packet: During the baseline visit after measurement collection, the Research Staff will hand the participant a welcome packet including educational written materials, as well as a recipe book.
   - Welcome text: Soon after randomization, Program Staff will contact participants allocated to this arm to inform them of their allocation and share expectations for the next 6 months.
   - eGiftCards for Grocery Store: A $250 eGiftCard to the participant's preferred grocer will be provided after the 6 month measurement visit.

Research Measures Procedures (both arms)

All study data will be collected during an in-person visit to a clinic within the Harris Health network, or other nearby convenient location, at 0 (baseline), 3, and 6 months of the study. Baseline visit may last a maximum of one hour, with subsequent visits being shorter. Data collection visits will follow the steps and procedures below:

1. Consenting (max. 30 min)
   a. This process is detailed later. It happens over the phone and outside of the data collection visit.
2. Enrolment (at baseline) or check-in (during subsequent visits) (max. 5 min)

a. At enrolment, research staff will check in advance whether consent was received electronically (DocuSign), if not, will obtain it in writing, and ask questions to verify identity and register in the study. Research staff will also answer any questions the participant may have and make sure the participant still agrees to participate in the study since the time of initial consent.

3. Biomedical measures (max. 10 min):
   a. A single urine sample will be collected on site in a sterile container following Labcorp and Harris Health standardized protocols and collected by a Labcorp courier for analysis within 24 hours of collection.
   b. Height, weight, blood pressure and Hemoglobin A1C will be measured by trained research staff, who will record them through the REDCap platform.
4. Questionnaires (surveys) (max. 20 min)
   a. Other self-reported measures will be collected from participants through online, surveys using the REDCap platform on a mobile device (tablets) that will be provided to them at the time (self-administered) or read aloud (structure interview) by trained research staff and recorded onto the tablet in REDCap.

Data collection tools are described in Item #4 of this protocol.

SUBJECT POPULATION

12 Protected Subject Populations

Click on the check box (or double click and type an "X" if using Google Docs) each population, if they are specifically studied for this research.

☐ Active military personnel	☐ Children	☐ Decisionally impaired adults
☐ Emancipated minors	☐ Fetuses	☐ Individuals with limited English proficiency
☐ Neonates	☐ Pregnant Woman	☐ Prisoners
☐ UT Students	☐ UT or Seton Staff/Employees	

13* Research Participant Information

Describe the research population.

**For multiple research populations (e.g., teachers, students, and parents), copy this section as necessary to describe your population.*

a Participant Group Name

To input text, click in the light grey area below.

The research population is individuals at risk for progressing to late stage kidney disease. 1) Those diagnosed with chronic kidney disease (CKD) stages 2, 3a, and 3b, as defined by eGFR ≥ 30 and <90 mL/min/1.73 m^2. 2) Those with Albuminaria as defined by ACR > 30 mg/g even if they are at CKD stage 1 or undiagnosed, but not if they have already advanced kidney disease (stage 4 or greater).

b Minimum Age

To input text, click in the light grey area below.

18 years old

c Maximum Age

To input text, click in the light grey area below.

None

d Inclusion Criteria

To input text, click in the light grey area below.

- Adult (18 years of age or older)
- Primary care visit at either one of the three partner clinics from Harris Health [Smith Clinic, Harris Health Outpatient Center (located on the LBJ campus), or Martin Luther King Jr. Health Center (MLK)] and a primary care patient within Harris Health System
- Have had at least 1 visit in the past 18 months with prior history in the clinic (i.e., not first visit)
- Diagnosis of CKD (Stage 2, 3a, and 3b) as defined by estimated Glomerular Filtration Rate (eGFR) ≥ 30 and <90 mL/min/1.73 m^2 OR CDK 1 or undiagnosed with urine Albumin Creatinine Ratio ≥ 30 mg/g
- Within the past 12 months, the most current serum K^+ ≤ 4.6 mEq/L
- English or Spanish speaking
- Ability to participate in the program at least 6 months
- Ability to clean, prepare, refrigerate/freeze food products that are given to them
- Have access to receive SMS text messages

- Location of preferred produce bag delivery within an available delivery zone

e Exclusion Criteria

To input text, click in the light grey area below.

- CKD 4, ESRD or on dialysis.
- Taking certain medications chronically (more than twice a week for 90 days) that may interfere with K^+ metabolism (such as non-steroidal anti-inflammatory drugs (NSAIDs), as self-reported during enrollment screening
- Taking mineralocorticoid receptor antagonists
- Taking Warfarin
- Diagnosis of any specific kidney conditions (such as polycystic kidney disease, glomerulonephritis, Lupus associated with Nephritis, Antineutrophil cytoplasmic antibody (ANCA)-associated vasculitis (AAV)) that would contraindicate study participation as determined by physician
- Medical history of organ transplant that would contraindicate study participation as determined by physician
- Received immunotherapy for primary or secondary kidney disease within 6 months prior to enrolment
- Diagnostic of heart failure conditions Class IV in the New York Heart Association (NYHA) functional classification
- Had myocardial infarction, unstable angina, stroke, or transient ischemic attack (TIA) within 12 weeks prior to enrolment
- Had coronary revascularization (PCI, CABG) or valvular repair within 12 weeks prior to enrolment
- On active hospice care as self-reported during enrollment screening
- Diagnosis of active malignancy requiring treatment that would contraindicate study participation as determined by physician
- Has decompensated cirrhosis as determined by physician
- Cognitive impairment that would contraindicate study participation as self-reported during enrollment screening

f Additional Population Information

To input text, click in the light grey area below.

14 Total Sample Size

To input text, click in the light grey area below.

332 recruited for 150 retained in each arm.

15 Sample size rationale

To input text, click in the light grey area below.

To detect a small to moderate sized standardized effect (f = .09) for the intervention by time term at the end of phase 1, we assumed a moderate correlation for rank-order stability in uACR over time of r= .30. To have 80% power at alpha = .05, we need to retain 150 individuals in each arm if we configure an attrition rate of 10%. Hence, we plan to recruit 166x2 = 332 total individuals. This sample size permits us to capture moderate effect sizes previously reported for dietary interventions in this population. Aggregate numbers from the clinics indicate that these numbers are feasible to recruit. Regarding correlations, we have 90% power to detect correlations as small as r = .26 and 80% power to detect correlations as small as r = .23 within each group (N = 150) at alpha = .05. These are fair to moderate effect sizes that bear on the power of any follow-up mediation analyses or dose-response relationships.

SCREENING AND RECRUITMENT

16 **Identification and Screening**

Click on the check box (or double click and type an "X" if using Google Docs) if true.

☒ **This study involves obtaining information or biospecimens for the purpose of screening, recruiting or determining eligibility of prospective subjects prior to informed consent by either:**

1. Oral or written communication with the prospective subject or LAR
2. By accessing records containing identifiable private information or stored identifiable biospecimens.

17 **Identification and/or Screening Procedures**

Describe the identification and/or screening procedures below.
To input text, click in the light grey area below.

1. **Screening #1 – Electronic Health Records (by Harris Health - HH):** During the period of recruitment, Harris Health will produce an EHR report for HH credentialed research staff to identify, on a recurring basis, potentially eligible patients at each participating clinic using the inclusion and exclusion criteria within their electronic health records. Patients that clearly meet the inclusion criteria without "flags" from the exclusion criteria will be added to a pool of potentially eligible study participants. Patients whose medical history appointed to potential "flags" from the exclusion criteria will be streamed into step 2 below.

2. **Screening #2 – Physician assessment, if needed (by HH clinicians who are on study personnel):** For patients that had "flags" in their medical history (especially pertaining to the exclusion criteria), research staff credentialled and trained by HH will share those patients' charts with a physician in the patient's circle of care so that a physician assessment of eligibility can be completed—particularly related to life expectancy, relevance of the program to the patient, and any concerns related to medication use and past medical history. Based on the physician's assessment, patients will then be moved to the pool of potentially eligible study participants (and into step #3 below) or excluded.
3. **Contacting potentially eligible study participants:** Study staff credentialed at HH will then contact those individuals in the final pool by phone, SMS texting, letter or email to inform about the study and to ask whether they would be interested in participating.
4. **Screening #3 and consenting, if eligibility is confirmed (by study staff):** Study staff will check for eligibility related to having access to receive SMS text messages, preferred produce delivery location residing within a delivery zone, being able to clean, prepare, refrigerate/freeze food products adequately at home, and to participate in the program for at least 6 months (screening #3). If eligibility is confirmed, the study staff will invite them to join, initiate the consent process, and answer any questions they may have. Those who are interested and eligible will be asked to read and sign the consent form via DocuSign (if they have access and are able to do so), and will be informed of the next steps, including scheduling the first visit to the clinic for baseline data collection. If a signature for the consent form cannot be obtained virtually through DocuSign, it will be obtained physically, in person, during the first visit to a clinic for baseline data collection. Research staff will also answer any questions the participant may have and make sure the participant still agrees to participate in the study since the time of initial consent.

18 **Recruitment Overview**

Click on the check box (or double click and type an "X" if using Google Docs) all recruitment methods utilized for this research.

☒	E-mail	☒	Flyer
☒	In-Person	☒	Letter
☐	Social Media	☐	Research Pool
☒	Telephone/Text	☐	Snowball Sampling

☐ **Web-post**

☐ **Word of Mouth**

19 **Describe the recruitment process, including where recruitment will take place.**

Describe the recruitment procedures below.
To input text, click in the light grey area below.

1. Forming and contacting a pool of potentially eligible participants at the partnering Harris Health clinics: After review of the Electronic Health Records (Screening #1) and a physician assessment (Screening #2, if applicable), patients will be added to a pool of potentially eligible participants.
2. The study team will contact potentially eligible patients by phone, email, mail, and/or text, to determine their interest in participating and for further screening for eligibility on an ongoing basis until planned recruitment numbers are reached.
3. Those individuals will then be asked questions related to Screening #3, as explained earlier, as the last step in confirming their eligibility. If the patient is interested and eligible, the research staff will read through the consent form with the patient and answer any questions. The patient will then sign the consent form electronically via DocuSign, if able to do so, and be informed of the next steps. Those who are interested and deemed eligible will then be scheduled for a baseline visit at one of the Harris Health clinics, where consent will be checked (or obtained in writing if electronic signature was not received) and data collection procedures will be performed.

OBTAINING INFORMED CONSENT

20 **Consent Overview**

Click on the check box (or double click and type an "X" if using Google Docs) all applicable items.

☒ **Obtaining Written Informed Consent**

☐ **Requesting a Waiver of Documentation of Informed Consent**

☐ **Requesting a Waiver of Informed Consent**

☐ **Requesting an Alteration of the Required Elements of Informed Consent**

☐ **Obtaining Child Assent**

☐ **Obtain Consent Using a Short Form with a Witness**

21 **Consent and Assent Processes**

Provide a detailed description of the consent process including who will obtain consent, where, and when consent will occur in such a manner that participants have sufficient time for adequate consideration.

To input text, click in the light grey area below.

Those who demonstrated interest in the study will receive a call to invite them to join the study. After final eligibility is confirmed (Screening #3), the research staff will read the consent form and answer any questions the individual may have. They will follow-up with an email to the participant to ask them to sign the form electronically (via DocuSign), if they are able to do so. If an electronic signature is not possible or not received by the time of the first visit to the clinic, it will be obtained physically (in person) during the participant's in-person enrollment and prior to start of baseline data collection. At both points, all study procedures will be discussed in detail with the participant and all questions will be answered. Patients will be made aware that participation is fully voluntary, and that they may change their mind at any time if they no longer choose to participate, without any negative consequence to their care by Harris Health system. These procedures will be the same at all sites.

22 **Consent and Translation**

Click on the check box (or double click and type an "X" if using Google Docs) to indicate that consent will be translated.

☒ **The study population will likely include participants whose limited English speaking status requires translation of the consent form.**

Translation Process

Click on the check box (or double click and type an "X" if using Google Docs) that best describes the translation process, either 21 or 22.

23 ☐ **The consent documents will be translated by a certified translator.**

24 ☒ **A non-certified translator will translate the consent documents.**

If selected, complete the next two questions below.

i **Describe the translator's qualifications**

To input text, click in the light grey area below.

Two English-fluent and native-Spanish speakers within Factor Health research personnel. One will translate and the other will review and confirm translation.

ii ☒ **Another individual will confirm that the translation is accurate and appropriate.**

Waiver of Documentation of Informed Consent

To approve a waiver of documentation of informed consent, one of the following options below must be justified by the researcher.

Only complete the sections below if requesting a waiver of documentation of informed consent. *If not requesting a waiver of documentation of consent, skip to 27.*

Please choose one waiver option and provide additional information as prompted. The Office of Research Support and Compliance recommends using Waiver Option 2 in most cases.

25 **Waiver Option 1**

Provide confirmation for the following criteria and follow the additional instructions.

Additional Instructions:
1. Include this choice in the informed consent form.
2. Articulate the destruction process for signed consent forms in the privacy and confidentiality section.

Click on the check box (or double click and type an "X" if using Google Docs).

a ☐ **The only record linking the subject and the research would be the consent document.**

b ☐ **The principal risk would be potential harm resulting from a breach of confidentiality.**

c ☐ **Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern.**

26 **Waiver Option 2**

Provide confirmation for the following criteria and follow the additional instructions.

Click on the check box (or double click and type an "X" if using Google Docs).

a ☐ **The study is minimal risk.**

b ☐ **Written consent would not be required outside the research context.**

27 **Waiver Option 3**

Provide confirmation for the following criteria and provide additional information as requested.

Click on the check box (or double click and type an "X" if using Google Docs).

a ☐ **The subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm**

b **Describe the cultural group or community.**

To input text, click in the light grey area below

c ☐ **The research presents no more than minimal risk of harm to subjects.**

d ☐ **There is an appropriate alternative mechanism for documenting that informed consent was obtained.**

e **Describe mechanism for documenting that informed consent was obtained**

To input text, click in the light grey area below

Waiver or Alteration of Informed Consent

To approve a waiver or alteration of informed consent all of the following criteria below must be justified by the researcher.

Only complete the sections below if requesting a waiver of informed consent. *If not requesting a waiver or alteration of consent, skip to 31.*

28 **The research involves no more than minimal risk to the subjects.**

To input text, click in the light grey area below

29 **The waiver or alteration will not adversely affect the rights and welfare of the subjects.**

To input text, click in the light grey area below

30 **The research could not practicably be carried out without the waiver or alteration (it is impracticable to perform the research if obtaining informed consent is required and not just impracticable to obtain consent).**

To input text, click in the light grey area below

31 **If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format.**

To input text, click in the light grey area below.

Deception and Debriefing

Only complete the sections below if requesting an alteration of informed consent that involves deceiving research participants. *If this study does not involve deception, skip to 35.*

See IRB Policies and Procedures Section 15 for a description of deception.

Click on the check box (or double click and type an "X" if using Google Docs).

32 ☐ **It is appropriate to provide additional pertinent information to the subject after research activities are complete (e.g., the researcher needed to deceive to subject to the nature of the study).**

33 ☐ **Research participants will have the opportunity to withdrawal their data during the debriefing.**

34 **Describe the nature of deception and why it is necessary to conduct the research.**

To input text, click in the light grey area below.

35 **Describe debriefing procedures.**

To input text, click in the light grey area below.

BENEFITS

36 **Benefits to Society**

Describe the scientific and societal benefit(s) below.

To input text, click in the light grey area below.

This study will test the effectiveness of a multicomponent intervention aimed at increasing kidney-friendly food (including fruit and vegetable) consumption among individuals diagnosed with early stages (non-dialysis) chronic kidney disease as one strategy to delay disease progression and improve biomarkers of CVD. The study is done in close partnership with Harris Health, the major health system in Houston providing for the under and uninsured, who plans to continue to deliver the program to their patients in the long term if results are positive. By sustaining the program, families who receive their services will continue to benefit, positively impacting them in the long term. In addition, it will also add to the growing body of evidence on the need for health care systems to pay for interventions that support people's health and delay disease progression in the community where they live, play, and work (instead of solely focusing on occasional clinical or pharmacological services).

Benefits to Participants

Click on the applicable check box (or double click and type an "X" if using Google Docs).

37 ☒ **There is no anticipated direct benefit to participants.**

38 ☐ **There are anticipated benefits to participants.**

39 **If applicable, describe the potential direct benefits to participants.**

To input text, click in the light grey area below.

RISKS

40 **Describe the risks associated with each activity in this research**

To input text, click in the light grey area below.

To study participants:

- Accidental loss of confidentiality: Questionnaires and sample collection at an in-person clinic can pose the risk of accidental breach of confidentiality.
- Urine sample: There are no known risks from providing a urine sample.

- Fingerstick blood sample for HbA1c testing: The blood sample for this point-of-care test is only a very small drop from a lancet, posing minimal risks to the participant. Nonetheless, some potential risks include pain at the location, bleeding, bruising, infection, and skin irritations from cleaning agents used to sterilize the skin or bandages.
- Blood Pressure with a pressure cuff: Participants may experience mild discomfort in their arm when the cuff is inflated.
- COVID-19 transmission: There is a risk of transmission of coronavirus disease (COVID-19).

41 Describe how each risk is mitigated/minimized.

To input text, click in the light grey area below.

- Accidental loss of confidentiality: Study visits will be conducted in a private space to ensure privacy. Participants will be flowing through data collection points at the clinic in a way that reduces people (other than research staff) unwillingly seeing others' information, such as booking time slots and directing people to separate spaces/rooms in the clinic. Samples and data will be handled and stored to protect privacy and confidentiality. All forms and samples will be labeled with a unique identifier for each subject and research staff will follow ethics training in assuring privacy and confidentiality, such as not discussing participants' information or results in public areas. All data will be kept in a secure, locked environment only accessible to people who are on our research team. Any paper study documents will be stored in a secure lock bag or cabinet, with access granted only to the research study staff. Only the investigators and study staff will have access to the databases linking the study subjects to their identifiers. Databases, the texting tool and the web learning platform will be kept on secure, HIPAA-compliant servers.

If participants choose to take part in the optional activity where they share their learnings and insights gained during this health journey (by speaking at a neighborhood meeting, to a congregation, at their children's school or community center, for example) there may be a risk of breach in confidentiality, in their identity or privacy. Participants will be informed about this risk, and a reminder that this activity is completely optional, and that choosing not to take part in this portion of the study will not affect their participation in the overall study.

The dissemination of data will not contain any patient identifiers and will only be shared as aggregated results.

- Fingerstick blood sample for HbA1c testing and Blood Pressure equipment: To minimize risks of biohazard and contamination for HbA1c, only staff trained on the proper technique in doing this collection will be obtaining this measurement to maintain safety and minimize discomfort. Only trained staff will obtain blood pressure readings to minimize discomfort for the individual during measurement.

- COVID-19 transmission: The study activities will only occur when this type of human research is allowed by the University of Texas at Austin and by Houston, Harris County, and Texas regulations related to COVID-19 and in-person interactions. All UT Austin and local and state regulations regarding personal protective equipment (such as masks) and other measures to reduce risk will be followed.

Data Safety Monitoring

For additional information regarding data safety monitoring boards and data safety monitoring plans, please see Section 21 of our Policies and Procedures.

Click on the check box (or double click and type an "X" if using Google Docs).

42 ☒ **In the investigator's opinion, this study is minimal risk and does not require a Data Safety Monitoring Plan (DSMP) or a Data Safety Monitoring Board (DMSB).**

PLEASE NOTE: The IRB may determine minimal risk studies do require data safety monitoring under certain circumstances (e.g., if there is a known risk with an expected frequency).

43 ☐ **This study does not have a Data Safety Monitoring Board, but researchers have an internal plan/policy to monitor for safety.**

Complete Data Safety Monitoring Details (44-51).

44 ☐ **This study has a Data Safety Monitoring Board (DSMB).**

Complete Data Safety Monitoring Details (44-51) or upload this study's Data Safety Monitoring Board's charter.

Data Safety Monitoring (Details)

45 **How is safety information collected?**

To input text, click in the light grey area below.

46 **When will safety data collection start (for each participant or for the whole study, as applicable)?**

To input text, click in the light grey area below.

47 **How frequently will safety data be collected?**

To input text, click in the light grey area below.

48 **Who will review the data for safety?**

To input text, click in the light grey area below.

49 **How frequently will data be monitored for safety concerns?**

To input text, click in the light grey area below.

50 **What data will be reviewed?**

To input text, click in the light grey area below.

51 **State the frequency or periodicity of the review of cumulative data?**

To input text, click in the light grey area below.

52 **State any conditions that would trigger an immediate suspension of the research.**

To input text, click in the light grey area below.

As this is a minimal risk study that provides food, eGift cards, and phone calls we do not expect any conditions that would trigger an immediate suspension of the research.

Early Withdrawal

Only complete this section if there are planned conditions under which a participant will be withdrawn from the study. *If not applicable, skip to 56.*

Include this information in your consent form.

53 **List the criteria for withdrawing individual participants from the study (e.g., safety or toxicity concerns, emotional distress, inability to comply with the protocol, or requirements from study sponsor).**

To input text, click in the light grey area below.

54 **Describe any necessary procedures for ensuring the safety of a participant who has withdrawn early.**

To input text, click in the light grey area below.

55 **Describe any pre-specified criteria for stopping or changing the study protocol due to safety concerns.**

To input text, click in the light grey area below.

REQUIRED DISCLOSURES

Required Consent Disclosures

Identify each element below that may require additional information to be disclosed in the consent form.

Click on the check box (or double click and type an "X" if using Google Docs).

56 ☐ **It is reasonable that researchers could discover or suspect child or elder abuse.**

57 ☐ **It is reasonable that researchers could learn of an incident that could require reporting under Title IX.**

58 ☐ **It is reasonable that researchers could discover incidental findings or other information of medical interest about a participant's previously unknown condition.**

59 **Articulate methods for addressing and reporting incidental findings, if applicable.**

To input text, click in the light grey area below.

PRIVACY AND CONFIDENTIALITY

60 **Privacy**

Describe how you will protect the identity and privacy of study participants during each phase of research. Privacy focuses on the individual participants rather than data. In this section, researchers should focus on issues such as where research activities take place and how participant involvement is protected from non-participants.

Describe methods to ensure participants' privacy during identification, recruitment, screening, the consent process, the conduct of the study, and dissemination of data.

To input text, click in the light grey area below.

All data will be kept in a secure, locked environment only accessible to people who are on our research team. Electronic survey data will be stored in secure databases managed by the research team, such as REDCap and UT Box, approved by UT Austin for research purposes.

Some health status data of study participants will also be requested from Harris Health's electronic health record system based on participant consent and a data-sharing agreement with Harris Health. Data will be transmitted using secured UT Box folder accessible only to research staff and contain identifiers for appropriate data linkages (first and last name and date of birth) and information on the following, as available: uACR, eGFR, Hemoglobin A1c, Body Mass Index, blood pressure, history of visits to clinic (both primary care and specialty care), visits to the ER, and hospitalizations. Historical health data will be obtained for the 18 months before enrollment into the study and 15 months post-enrollment.

Data will be uploaded from the secure, password-protected Labcorp results portal into a secured UT Box folder accessible only to research staff and contain only two identifiers for appropriate data linkages (first and last name and date of birth) and the measured uACR results.

Any paper study documents will be stored in a secure lock bag or cabinet, with access granted only to the research study staff.

Study visits will be conducted in a private space to ensure privacy. Participant privacy will be maintained by conducting research visits in a private room for biomedical measures and dietary intake or, if in a large space due to the unavailability of private spaces, by providing adequate distance between participants in that same space. All self-administered surveys will be completed by participants using a mobile device (tablets) that can further ensure privacy while responding.

If participants choose to take part in the optional activity where they share their learnings and insights gained during this health journey (by speaking at a neighborhood meeting, to a congregation, at their children's school or community center, for example) there may be a risk of breach in confidentiality, in their identity or privacy. Participants will be informed about this risk, and a reminder that this activity is completely optional, and that choosing not to take part in this portion of the study will not affect their participation in the overall study. The dissemination of findings in

reports and publications will not contain any patient identifiers and will only be shared as aggregated results.

Confidentiality and Data Security Plan

Click on the check box (or double click and type an "X" if using Google Docs) that best describes the confidentiality and data security plan and provide additional details regarding how you will protect the confidentiality of data or address confidentiality concerns.

61 ☐ **Identifiers will be coded to protect confidentiality.**

61a **If true, state how data is coded and where identifiers are stored.**

To input text, click in the light grey area below.

62 ☒ **Identifiable data will be destroyed.**

62a **If true, describe destruction plan and timeline**

To input text, click in the light grey area below.

Identifiers will be destroyed at the end of the study after all data has been analyzed. All data for analysis will be kept in a dedicated and restricted UT Box folder, accessible only by research staff associated with the project. This secure, HIPAA compliant platform can only be accessed with password and dual authentication.

63 ☐ **Identifiable data will not be destroyed.**

63a **If true, provide rationale for retaining identifiable data indefinitely.**

To input text, click in the light grey area below.

64 **Data Access**

Click on the check box (or double click and type an "X" if using Google Docs) for each group of individuals that will have access to study data.

If you plan on creating a repository, complete the repository form as well.

☒	Study Team Members	☒	External Collaborators	☐	Data coordinating center
☐	Sponsor	☒	Future Sharing with other researchers		

☐ **Others**

Describe below. To input text, click in the light grey area below.

65 **Describe data sharing plan for each group checked above and state whether researchers plan on sharing identifiable, coded, or de-identified data**

To input text, click in the light grey area below.

No identifiable research data will be shared outside of the research team. Only de-identified data or aggregated results will be shared with external collaborators (Harris Health) and when presented in public channels of communications (journals, news, magazines, conferences, etc.). This includes collaborating sites Harris Health, Baylor College of Medicine and UTHealth Houston.

We may share de-identified data with other researchers for future studies to support advancement and comparison of evidence in the field. The data will be shared upon request. Information shared will only contain a study ID, selected demographic variables necessary for population comparison, and outcome variables—all potential personal identifiers will be removed.

Certificate of Confidentiality

Click on the check box (or double click and type an "X" if using Google Docs) to identify each element below that may require additional information to be disclosed in the consent form.

If a Certificate of Confidentiality is not applicable for this study, skip to 68.

66 ☐ **The study requires a Certificate of Confidentiality.**

67 ☐ **NIH has issued a Certificate of Confidentiality for this study.**

68 ☐ **A Certificate of Confidentiality has not been obtained, but there are plans to apply for one.**

COMPENSATION AND COSTS

Compensation

Click on the check box (or double click and type an "X" if using Google Docs).

69 ☒ **Subjects receive compensation.**

70 ☐ **Subject will not receive compensation.**

Skip to question 74 if subjects will not receive compensation.

71 **Total Amount of Compensation**

To input text, click in the light grey area below.

Research Compensation: Participants will receive up to US $150 total in compensation for the three data collection time points ($50.00 for each visit) being planned throughout the duration of the study.

Program Payments: Participants in the intervention group will also receive $230 in program payments, and participants in the control group will receive $250 in program payments.

72 **Type of Compensation**

Click on the check box (or double click and type an "X" if using Google Docs) for each form of compensation that will be provided.

☐	Cash	☐	Check	☒	Gift Card
☐	Course Credit	☒	ClinCard	☐	Tango Card
☐	Other				

Describe, To input text, click in the light grey area below.

73 **Proration Schedule**

To input text, click in the light grey area below.

Research Compensation: Participants will be paid $50.00 for each visit to the clinic at data collection points, for a maximum of $150.00 for 3 visits.

Program Payments: Participants in the intervention group will be paid $230 at the following timepoints- the start of week 7- $30; weeks 11-18- 2 payments of $40 sent 4 weeks apart, for a total of $80; weeks 19-26- 2 payments of $60 each, sent 4 weeks apart, for a total of $120.

Participants in the control group will be given their program payment of $250 after their 6 month measurement visit.

74 ☒ **Amount of compensation and its form is reasonable for this population for the activities requested of them.**

75 **Costs**

Click on the check box (or double click and type an "X" if using Google Docs) each applicable item regarding costs.

☐ **Participants will have no costs associated with this study**

☐	Standard of care procedures contributing to study data
☐	Research procedures not associated with standard of care
☐	Administration of drugs / devices
☐	Study drugs or devices
☒	Transportation and parking

76 **Describe all costs below.**

To input text, click in the light grey area below.

There is a cost to the participant that will be related to travel to the sites where data collection for the study will happen. The amount of costs will vary from their location in relation to the clinic, but only a small cost is anticipated and the study visits will take place at their regular clinic site.