Cover page added for Clinicaltrials.gov

Meals for Me: Managing Diabetes at Home

IRB Proposal with Protocol & Statistical Analysis Plan. Last update: June 21, 2023

Clinical Trials No: STUDY00002808-2022

# 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

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

1. Assess the impact of medically-tailored meals program on diabetes management and mental health in comparison to usual care without such program for older adults.
2. Assess the differential impact of two delivery models being considered for payment by the health system on diabetes management and mental health: once-a-week frozen drop shipment model versus more frequent warm meal

delivery model that is more complex to implement but allows for human connection and easier meal preparation.

## 3 Study Background

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Diabetes is prevalent and often accompanied by mental health conditions.[1–3] Recent estimates suggest 28% of adults over 65 have diabetes[4], and 18% of older adults who had difficulty paying medical bills reported symptoms of depression.[5] The magnified challenges of supporting diabetes when mental health conditions such as depression co-present have been recognized.[6,7]

Home-delivered meals have begun to be assessed for their utility in improving health of recipients. The U.S. health system is beginning to pay for such services, usually for up to a month after discharge from hospitals.[8] Recently, delivery of medically tailored meals (MTMs) has begun to be tested to support chronic condition management at home, especially for older adults.[9,10] One dominant model for delivering MTMs by industry providers (e.g., Mom's Meals) is a box of frozen meals drop-shipped once every week or two weeks. Meals on Wheels (MOW) organizations also provide these services but usually with delivery of ready-to-eat meals 3-5 times a week. Both kinds of programs have been shown to reduce hospitalizations suggesting improvements in health for those receiving the meals.[9,11]

The drop shipment of frozen meals is optimized for delivery logistics and doesn't deliver nor require human connection. In contrast, the MOW's model is optimized for participant needs, with the participant receiving frequent meals that are ready-to-eat, delivered by a person directly with varying degrees of interaction. Qualitative assessments have highlighted the benefits perceived by participants of the daily delivery model.[12] Because of changing funding environments, MOW organizations have also begun to test a frozen drop-ship delivery model for its relatively easier implementation.[13,14] Neither model has been assessed, however, for how much benefit they provide to the participant including how many meals are actually eaten, health outcomes or other benefits of the human connection during delivery. Here, we aim to assess the benefits of medically-tailored meals on these measures as well as compare the differences in benefit from the two delivery models.

This project is done in partnership with Meals on Wheels Central Texas (MOWCTX).

**References**

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5. Cheruvu VK, Chiyaka ET. Prevalence of depressive symptoms among older adults who reported medical cost as a barrier to seeking health care: findings from a nationally representative sample. *BMC geriatrics*. 2019;19(1). doi:10.1186/s12877-019-1203-2

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13. Hewitt M, Nowak M, Gala L. Consolidating home meal delivery with limited operational disruption. *European Journal of Operational Research*. 2015;243(1). doi:10.1016/j.ejor.2014.10.045

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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:** We will conduct a randomized controlled trial to assess impact of medically tailored meal (MTM) delivery on Hemoglobin A1C and mental health. The trial has two phases of 6 months each, for a total of 12 months.

**Phase 1:** Randomized controlled trial, 6 months, with 3 arms as described below, with measurements at baseline, 3 months, and 6 months.

Arm 1: Waitlisted Control

- Educational materials

Arm 2: "Daily Warm" MTM in-person delivery

- Educational materials
- Meal preparation instructions
- 10 MTM delivered in-person 3-5X a week.
- Each delivery day, one meal is warm, the other is frozen. Depending on the participant's availability (3-5 days/week), more frozen meals will be given one day to account for a total of 10 meals every week.
- Meals are delivered to the participant's home by trained volunteers and/or paid delivery drivers who provide human interaction.

Arm 3: "Weekly Frozen" MTM drop shipment

- Educational materials
- Meal preparation instructions
- 10 MTM delivered 1X a week
- Each week all meals are frozen.
- Meals are shipped to the participant's home with no human interaction.

**Phase 2:** Three parallel arms, including the waitlisted control, will receive the standard MOWCTX model, which includes a lower number of meals delivered daily (1 instead of 2 a day), case management to help with social needs, and access to helpful services (e.g., home repair, pet care). Measurements will be taken at 6 (the same as in Phase 1), 9 and 12 months.

Each Arm: "Daily Warm MOWCTX Standard"

- Meals are delivered 2-4x a week, depending on participant's availability and delivery route.
- Each delivery day includes a1 warm MTM and can include 1 or more frozen meals to account for a total of 5 meals/week.
- Meals are delivered to the participant's home by trained volunteers and/or paid delivery drivers who provide human interaction.
- As per MOWCTX standard approach, participants will be assigned a case manager for additional support, as needed.
- Welcome packet will be provided by the case manager, menu and educational materials sent monthly through the mail by MOWCTX (as part of their normal business model).

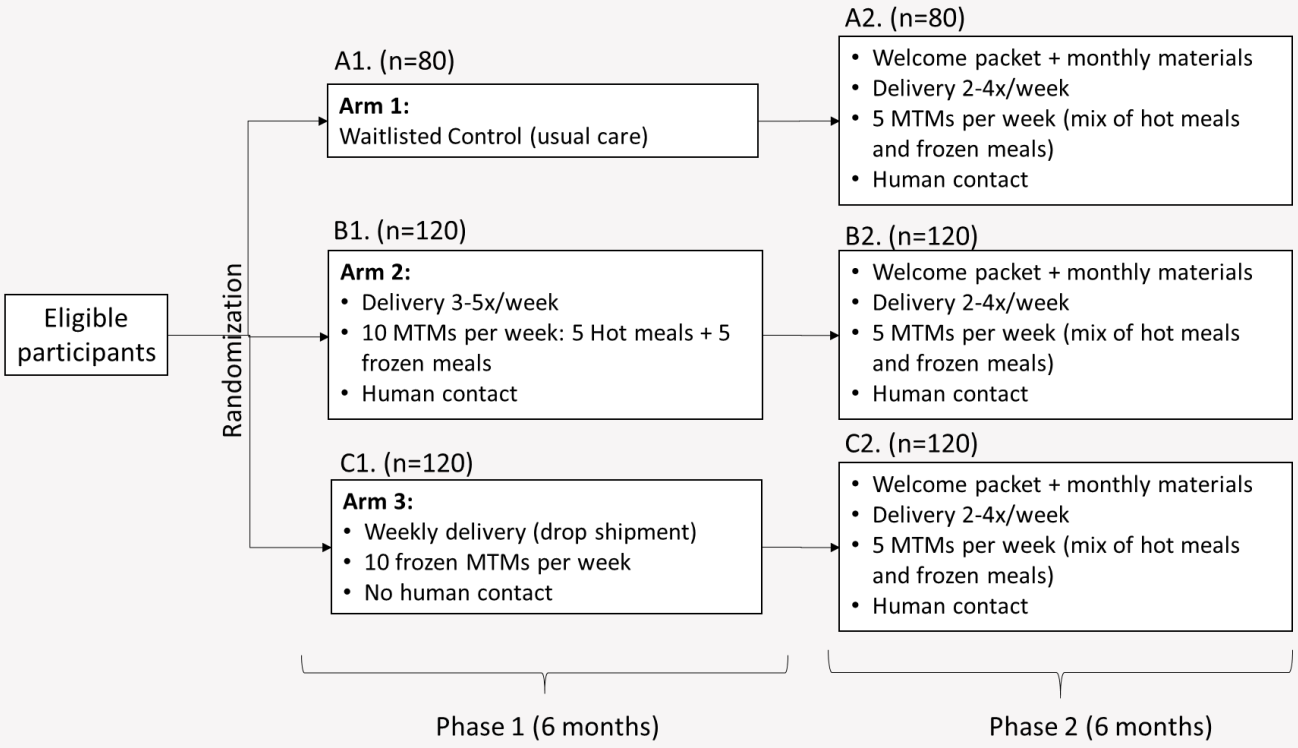


**Figure 1: Trial Design.** MTM = medically tailored meals

**Randomization:** Three-way randomization of eligible MOW clients to waitlisted control (n=80), and the two active arms (n=120 each) in 2:3:3 ratio. Eligible participants who are members of the same household will have one person as the index participant who be randomized to one of the three arms, and the other household member(s) will be allocated to that same arm.

**Blinding/Masking:** Assessments are made in participant homes or an identified central site such as Dell Medical School.

1. Outcome assessors are research associates (RAs) who will take direct biomedical measures (A1C, Blood Pressure). Participants self-report other measures directly through a tablet. However, given prior experiences, we anticipate cases where the RAs will need to assist them in answering questions. RAs are blinded for all measures at baseline and 3 months. At the end of each assessment, however, a set of questions are asked that are different for each of the three arms on food intake and preferences, and for arm 2, for the experience of delivery. Thus, baseline and 3-month assessments will be blinded to group assignment. But at the end of the 3-month assessment RAs will no longer be blinded. To minimize influence of unblinding, we will actively cross-assign RAs after the 3-month measurement. We will also setup the online self-administered surveys specific to certain arms in a way that will reduce the likelihood of RAs accidentally identifying participants in different arms.

2. Participant and program staff who are not part of the research assessment process are unblinded.
3. Principal investigator and biostatistician are blinded to participant allocation.

**Outcomes & Data collection:**
Research assistants will collect data through direct measure and through surveys for self-reported data either at the participant's home or at a central location such as Dell Medical School or other identified location Section 11 describes research and data collection procedures.

- Primary Outcome: glycated hemoglobin (HbA1c)
- Secondary Outcomes: Blood Pressure, general physical and mental health, quality of life, diabetes distress, loneliness, depression, anxiety
- Exploratory: Health care utilization (such as, hospitalizations, ED and doctor visits, food/medication trade-off, care delay), food consumption

The table below provides an overview of the outcome measurements to be assessed and the population descriptors.

**Table 1.** Outcome measurements to be assessed and population descriptors

| Outcome | Indicator or Measure | Tool | Type | Time points |
|---|---|---|---|---|
| Diabetes management | Hemoglobin A1c | Fingerstick POC | Direct measure | B, 3m, 6m, 9m, 12m |
| Physical health | Blood pressure | Digital automatic BP monitor | Direct measure | B, 3m, 6m, 9m, 12m |
| | Physical health & quality of life | SF12-Physical health questions | Self-reported | B, 3m, 6m, 9m, 12m |
| Mental health | Diabetes-related distress | Diabetes Distress Screening 2-items (DDS2) | Self-reported | B, 3m, 6m, 9m, 12m |
| | Mental health & quality of life | SF12-Mental health questions | Self-reported | B, 3m, 6m, 9m, 12m |
| | Loneliness | 3-item UCLA Loneliness | Self-reported | B, 3m, 6m, 9m, 12m |
| | Depression | PHQ-8 | Self-reported | B, 3m, 6m, 9m, 12m |
| | Anxiety | GAD-7 | Self-reported | B, 3m, 6m, 9m, 12m |
| Health care utilization & access | DM medications | Customized | Self-reported | B, 3m, 6m, 9m, 12m |
| | Hospitalizations | Customized | Self-reported | B, 3m, 6m, 9m, 12m |
| | Emergency room visits | Customized | Self-reported | B, 3m, 6m, 9m, 12m |
| | Hypoglycemia episodes | Customized | Self-reported | B, 3m, 6m, 9m, 12m |

| | | | | |
|---|---|---|---|---|
| | Visits to the doctor, behavioral health, social services | Customized | Self-reported | B, 3m, 6m, 9m, 12m |
| | Care delay due to cost | Customized | Self-reported | B, 3m, 6m, 9m, 12m |
| | Food/basic needs trade-offs | Customized | Self-reported | B, 3m, 6m, 9m, 12m |
| | Medication underuse due to cost | Customized | Self-reported | B, 3m, 6m, 9m, 12m |
| Food security | Food security scores | USDA 6-item Food security questionnaire | Self-reported | B, 3m, 6m, 9m, 12m |
| Food consumption and satisfaction | Dietary assessment | Diet Screener (DSQ) | Self-reported | B, 3m, 6m, 9m, 12m |
| | Non-program meal consumption | Customized - Non-program meals | Self-reported | B, 3m, 6m, 9m, 12m |
| | Program hot meal consumption (Phase 1 Arm 2 only; Phase 2 all arms) | Customized | Self-reported | 3m, 6m, 9m, 12m |
| | Program frozen meal consumption (Arms 2, 3) | Customized | Self-reported | 3m, 6m |
| | Program snack consumption, Overall program food consumption, Satisfaction, Comments (Phase 1 Arms 2 and 3; Phase 2 all arms) | Customized | Self-reported | 3m, 6m, 9m, 12m |
| Value of human connection | Perceived positiveness from having MOW volunteer/driver checking in on them. (Phase 1: Arm 2 only. Phase 2: All arms.) | Customized | Self-reported | 3m, 6m, 9m, 12m |
| **Descriptors** | **Measures** | **Tool** | **Type** | **Time points** |
| Demographic data & social needs | E.g., Age, time of DM diagnosis, household information, Housing Insecurity; Transportation Barriers; Financial Strain | Customized | Self-reported | Baseline |
| Usual healthcare & health status | Usual healthcare received, insurance, health status and comorbidities | Customized | Self-reported | Baseline |
| Isolation and social connection | Isolation and social connection | Lubben Social Network Scale (LSNS-6) | Self-reported | Baseline |

Self-reported questionnaires on health care resource utilization (such as doctor visits, ER visits, hospitalizations, and medication use) have been shown to be acceptable proxies when medical claims and administrative data are unavailable, particularly for shorter recall periods than yearly (Allin et al., 2013; Leggett et al., 2016; Moura et al., 2021; Short et al., 2009).

Allin, S., Bayoumi, A. M., Law, M. R., & Laporte, A. (2013). Comparability of self-reported medication use and pharmacy claims data. Health Reports, 24(1), 3–9. https://doi.org/10.1177/1742395320985913

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Moura, C. S., Payette, Y., Boileau, C., Abrahamowicz, M., Pilote, L., & Bernatsky, S. (2021). Agreement in the CARTaGENE cohort between self-reported medication use and claim data. Chronic Illness. https://doi.org/10.1177/1742395320985913

Short, M. E., Goetzel, R. Z., Pei, X., Tabrizi, M. J., Ozminkowski, R., Gibson, T. B., Dejoy, D. M., & Wilson, M. G. (2009). How accurate are self-reports? An analysis of self-reported healthcare utilization and absence when compared to adminstrative data. Journal of Occupational and Environmental Medicine, 51(7), 786–796. https://pubmed.ncbi.nlm.nih.gov/19528832/

## 5 Data Analysis

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

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

The analytic plan is described for the primary outcome measures HbA1c (an objective indicator for diabetes management) and for PHQ-8 (a patient-reported measure of depression symptoms, part of mental health-related outcomes). Each of the remaining self-reported secondary outcome measure will be examined relying on similar model testing procedures. Only the index participant's data will be included in the primary analyses.

The two types of outcomes measures (objective and patient reported on mental health) inform questions around potential 'losses' and 'gains' in each phase and across phases.

We will rely on linear mixed effect regressions with random person intercepts to analyze the outcome that are continuously distributed and measured repeatedly within each phase. These methods readily accommodate drop-out, variations in schedule of assessments that produce uneven spacing.

**In Phase 1**, time will be modeled as days elapsed from baseline. Group assignments (arms) and person-level variables such as gender and age will be modeled in the second level to address questions of interest.

Figure 1: A1 *versus* C1

- We expect "weekly frozen" (C1) to make negligible, if any, difference in mental health relative to the waitlisted control group (A1), especially in the case of PHQ-9 (depression symptoms), GAD-7 (anxiety symptoms) and SF-12 Mental Health subscale.

Figure 1: B1 *versus* C1

- Phase 1 models will also elucidate the health benefits of "daily warm" (B1) versus "weekly frozen" (C1) related to both the objective (HbA1C and blood pressure) and patient-reported mental health.

**In phase 2**, all groups will be switching to the MOWCTX standard delivery (1 hot meal, 3-4x/week, plus 1-2 frozen meals for a total of 5 meals/week), informing *estimates* for potential 'losses' and 'gains' that are observable from the switch. Hence, group assignments will still be modeled as the original Phase1 group assignments, but inferences will be distinct. The effect of primary interest to study questions is the fixed cross-level interaction of time with the grouping indicator (dummy indicators will be reserved for the active arms).

**Phase 2 models** will be fitted to data twice: once starting with 6-month assessments and once starting with baseline assessments. If the maximal effects of phase 1 are evident at 6-months for majority of outcome measures, which we expect will be the case, modeling data from the maximal gains at 6-months to assess changes at 9- and 12-months in the phase 2 of the program will be sufficient to inform targeted estimates.

Figure 1: Arm 2, B1 → B2

- We expect that Arm 2 shows some 'loss' in objective measures (HbA1c and blood pressure) moving from B1 to B2, but do not expect this group to show changes in mental health outcomes

Figure 1: Arm 3, C1 → C2

- We expect to observe 'gains' on mental health outcomes in Phase 2 (6-12 months) in Arm 3 switching from "weekly frozen" shipment to standard MOWCTX's meals delivery.
- The 'gains' on objective outcomes (HbA1c and blood pressure) for Arm 3 ("weekly frozen") may be limited.

Figure 1: C1 → C2 *versus* B1 'gains'

- Arm 3 'gains' on objective outcomes (HbA1c and blood pressure) may be more variable relative to the gains observed for participants in Arm 2 ("daily warm") in phase 1.

Figure 1: A2 *versus* B1

- Finally, we will estimate whether the 'gains' in both mental health and objective measures observed in the waitlisted control during Phase 2 is inferior to the maximal gains we expect to observe in Arm 2 in phase 1.

**At 12-months**, we have the opportunity to compare these groups on overall objective and mental health outcomes. This particular comparison informs whether there is an advantage of being exposed to 'frequent' contact over the prior year versus only half the year. If mental health support available in the "daily warm" delivery model maximizes the reductions in HbA1c and blood pressure ('gains') from delivered meals, we would expect such effects to be evident at 12-months.

## 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**

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

## 10 Alternatives to Participation in This Study

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

For those not eligible to the regular MOWCTX program, there are no other alternatives to participation. While the alternative to participation in this study for some individuals would be the usual Meals on Wheels Central Texas program, eligibility to the regular MOWCTX program is, however, different from the eligibility to this present study

## 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.*

After eligibility is confirmed and consent is obtained, participants will be randomized to one of the three arms (as described in Section #4 of the protocol).

**Phase 1 (6 months)**

- Arm 1: Waitlisted control
  - Receives educational materials on such topics as healthy eating for diabetes.

- Arm 2: "Daily Warm" MTM in-person delivery
  - Receives the same educational materials as Arm 1, in addition to materials on meal planning and instructions.
  - All participants randomized to this arm will receive a total of 5 hot, 5 frozen, and 5-10 snacks per week. Meals and snacks offer approx. 1200 kcal per day.
  - The frequency and type of meals change as the following, depending on the participant's availability:
    - 5x/week delivery: Receives daily 1 hot, 1 frozen, and 1-2 healthy snacks Mon-Fri.
    - 4x/week delivery: Receives 1 hot + 1 frozen meal each delivery day, plus 2 extra frozen meals on one day.
    - 3x/week delivery: Receives 1 hot + 1 frozen meal each delivery day, plus 4 extra frozen meals on one day.
  - MOWCTX's trained volunteers and/or paid delivery drivers delivering the meals will have a brief social interaction ("check-in") with the participant.

- Time required: approx. 5-15min. for participant to receive food and interact.

- Arm 3: "Weekly Frozen" MTM drop shipment
  - Receives the same educational materials as Arm 1, in addition to materials on meal planning and instructions
  - Receives once a week 10 frozen medically tailored meals and 5-10 healthy snacks (with the goal of providing 2 meals and 1-2 snacks for 5 days of the week). Meals and snacks offer approx. 1200 kcal per day.
  - Meals are shipped to the participant's home.
  - No human interaction.
  - Time required: approx. 3 min. for participant to collect the box once a week.

**Phase 2 (6 months)**

- All arms receive standard MOWCTX home meal delivery:
  - Everyone receives 5 meals/week, delivered 2-4x a week, depending on participant's availability and delivery route. Planned to offer approx. 600 kcal per day.
  - Each delivery day includes one hot MTM plus one or more cold bags (with healthy snacks), plus enough frozen meals to account for a total of 5 meals:
  - Meals are delivered Monday to Friday at the participant's home during a delivery window set by MOWCTX.
  - MOWCTX's trained volunteers and/or paid delivery drivers delivering the meals will have a brief social interaction ("check-in") with the participant.
  - Participants will have access to a case manager to assist with additional resources within the community and for additional support if needed (e.g., grocery shopping assistance, home repairs, and pet care).
  - Time required: approx. 5-15 mins. for the participant to receive food and interact.

All meals are planned and approved by MOWCTX's Registered Dietitian Nutritionists.

As a standard of practice, MOWCTX screens (runs background checks) and trains their volunteers and paid drivers delivering the meals. These volunteers and drivers will not be engaged in research (i.e., will <u>not</u> do consent, collect data, or data analysis). We will not collect data on them as part of the research.

**Data collection procedure during visits:**

Baseline (0) and subsequent measurement collection (3, 6, 9, and 12 months) will occur at a central site or at participant's home. The initial baseline visit will take approximately 45 minutes, while subsequent measurements will be shorter (20-30 minutes each). The research team members will follow the steps and procedures below for data collection:

1. Enrollment/Baseline (5-10 mins)
    a. Research team member will obtain written consent if consent has not already been received electronically.
    b. HbA1c will be measured by trained research staff to ascertain eligibility. Once confirmed, the research staff will proceed with collecting other data measures. If participant does not meet A1c inclusion criterion, research staff will not collect any further data and will provide compensation for the visit. This information will be recorded in HIPAA-secure REDCap database.

2. Baseline and subsequent measurements:
    a. Biomedical measures (~10 mins): BP and HbA1c will be measured by trained research staff and will be recorded in HIPAA-secure REDCap database.

Participants will self-report other measures through self-administered online surveys in REDCap using a tablet. Given prior experience, we expect that RAs may need to help some individuals answer questions. If needed, research staff may give hard copies of the surveys for the participant to look at in the event they have a limitation where this may be needed or they may need to read the questions aloud to the participant if they have a limitation that does not allow for them to read it themselves.

## 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.*

Older adults, 55 and over, living in the Austin city limits with poorly controlled diabetes.

### Minimum Age

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

55

### c Maximum Age

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

90

### d Inclusion Criteria

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

- Adult 55-90
- Hemoglobin A1c ≥7.5
- Living in Austin city limits and within a MOWCTX daily delivery route
- Interested and available to receive meals during delivery window time
- Has access to a freezer and a microwave
- Pass a MOWCTX background check

### e Exclusion Criteria

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

- Participated in MOW program in previous 3 months.
- Has any of the following: dementia or cognitive impairment, diagnosis of heart failure, cirrhosis, or active cancer
- Is receiving hospice care

- Does not pass a MOWCTX background check

**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.*

We aim to recruit a total of 400 people who will be randomized to account for an estimated attrition of 20%. This would optimize the ability to retain the number of participants in each arm, shown below, that supports the statistical analysis with adequate power.
Total N = 320
Arm 1: Waitlisted Control, n=80
Arm 2: Daily warm, n=120
Arm 3: Weekly frozen, n=120

**15 Sample size rationale**

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

Our target sample sizes (after attrition) in the active arms (2 and 3), each 120, and 80 in the waitlist (for a total of N=320) permits us to test both targeted effects supporting causal inference in phase 1. The potential loss/gain estimates we will inform from the switch to daily warm delivery of a single meal in phase 2. As described in the data analysis section, the study is powered to detect meaningful cross-level interactions of time with dummy variables capturing group assignments in phase 1. We have 80% power to detect at alpha =.05 fixed interaction effects of f = .08 with minimal attrition. Even with 20% attrition we can still detect fixed interaction effects of size f= .09. These are meaningful small to moderate size effects.

# 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. **Interest:** Potentially eligible participants will be identified through various recruitment venues and sites (as described in Section 19) where older adults who are low income can be reached and where those with unmanaged diabetes can be easily identified. Those who express their interest in the study will be put on an interest list.
2. **Screening #1 + reading consent:** Research staff contacts via text and phone call those on the interest list to give more information on the study, confirm interest, conduct initial screening and proceed to reading the consent form.
    a. **Screening #1:** Once RA confirms interest, they will obtain their 1) name, 2) age, 3) address (which will be shared with MOWCTX post-call to confirm they live within the delivery route zones), 4) availability during the week and the meal delivery window, 5) confirmation that they are the household participant who will receive and eat the meals, 6) willingness to undergo a MOWCTX background check (noting that they have to pass to be eligible), and 7) access to a freezer and a microwave. The RA will also review the exclusion criteria, such as any prior MOWCTX program participation and disease diagnoses.
    b. Once the participant has shown interest and confirms they can receive the meal during the delivery time window (after #4 and #5 above), the RA will let them know that for the study, it is important to make sure they are the ones that will receive and eat the meals. If at this time, the individual shares that it is a household member who should receive the meal, the RA will schedule a follow up phone call with the household member who will then be screened to see if they are eligible for the program. **Reading the consent form:** If the individual is deemed eligible after Screening #1 (with the exception of the background check, which will be screened for after the initial assessment of interest call takes place), the RA will proceed to reading the consent form and scheduling an enrollment visit (contingent on a passed background check). The RA will also inform the individual of the three criteria that still need to be confirmed for full eligibility and enrollment into the study: 1) living in a MOWCTX daily delivery route (via the address, to be checked by the RA using the delivery map provided by

MOWCTX – edge cases will need to be checked after the phone call and RA to call the person back), 2) the HbA1c level criterion, which will be checked during the first data collection visit, and 3) passing the background check conducted by MOWCTX. The consent form will be sent to the participant, via DocuSign, if they are willing to share an active email address. If they wish to sign in-person at the first enrollment visit, that will be an option for them.

**NOTE:** If the participant does not live within MOWCTX daily delivery zones, the participant will be notified during the phone call using the delivery map provided by MOWCTX, if it is an edge case, the person will be notified via a subsequent text and/or phone call that they do not meet this eligibility criterion prior to coming in for an enrollment visit.

3. **Screening #2 (pass background check completed by MOWCTX)** The background check will be conducted prior to a baseline visit that takes place in the potential participant's home. This is a standard Meals on Wheels practice to ensure the safety of research staff. Once MOWCTX confirms whether they have passed or not with the research team, the person will be contacted again to confirm enrollment visit (next step).
4. **Screening #3 (Written consent + HbA1c):** At the time of the enrollment visit, the research team member will obtain written consent, if person has not completed e-signature of consent form via Docusign. Once written consent has been confirmed or obtained, research staff member will collect HbA1c measure to confirm that eligibility criterion.
5. **Complete and confirm enrollment:** The research team member will call and/or text and let the individual know whether they have been successfully enrolled into the study (if deemed fully eligible) or that they could not be enrolled due to not meeting all eligibility criteria

## 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.*

Our lab team and MOWCTX will generate an interest of potentially eligible participants by engaging and outreaching to groups, sites, and organizations who serve low income individuals. Our recruitment efforts will focus on adding low income individuals onto our interest list. The table below provides examples of potential recruitment sites and strategies.

| **Strategy** | **Potential sites** |
|---|---|
| Referrals onto program interest list via clinic system | CommUnity Care Health Centers<br>WellMed medical group – dual eligibles<br>People's Community Clinics |
| Direct member outreach | United Health Care (UHC)'s Medicaid member list |
| Outreach via older adult housing and centers | Housing Authority of the City of Austin (HACA) senior housing, other housing sites and centers who serve older adults |
| MOWCTX wait list | MOWCTX |

Posters, flyers, emails, phone calls and/or texts with an invitation to participate will be posted at these locations or sent to listservs. In addition, some organizations may outreach to the member/patient base to assess general interest through a script provided by the research team (see script attachment). Once someone has indicated interest and provided permission, the organization will provide their contact information to the research team to schedule a time to obtain consent and screen the individual for enrollment.

If multiple people from the same household indicate interest, both individuals will be screened as normal. If only one meets eligibility criteria, only one will be enrolled into the study as a unique case. The first person from that household that meets all eligibility criteria and completes their baseline measurement will serve as the index participant. The index participant will be the participant that is randomized to one of

the three arms. The other member(s) of the household will be household participants, and they will be allocated to the same arm the index participant was randomized into.

# 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.*

1. Research team members will contact by phone and/or text the individuals who indicated interest in the study via recruitment strategies and will further explain the study to confirm interest.
2. When interest is confirmed, the research team member will read through the consent form over the phone. They will allow as much time as the person needs to ask any questions they may have. They will also explain that the research is voluntary and they are not required to participate and may withdraw at any time for any reason. If the potential participant agrees to participate, they will be sent the consent form via DocuSign to obtain an e-signature. If the person does not have email, or wishes to sign in-person, they will do so at the in-person enrollment visit that will be scheduled with the research team member. A copy of the unsigned consent form will also be provided at the time of the enrollment

visit for everyone (regardless if they signed via DocuSign or sign in-person) as making a copy of the signed copy at home visits or central sites may be difficult. If the participant would like a copy of the signed consent form, a copy will be mailed or provided at the next in-person visit.

## 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.*

Multiple English fluent and native Spanish speakers within research personnel. One will translate and the other will 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.*

Addressing nutrition through delivery of medically-tailored meals could improve chronic illness and potentially result in savings to the healthcare system. The study is done in partnership with Meals on Wheels Central Texas (MOWCTX), one of the largest meal-delivery organizations in the State, who plans to expand its program 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 impact of medically-tailored meals for health care systems to pay for interventions that support people's health 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.*

Individuals may or may not benefit from this study. Individuals participating in this study may see the anticipated direct benefit of improved glucose control, access to food and diabetes healthy diet, reduction of social isolation and loneliness, as well as improved anxiety and depressive symptoms.

# RISKS

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

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

- Accidental loss of confidentiality: Questionnaires and sample collection at an in-person visits can pose the risk of accidental breach of confidentiality.
- 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 confidentiality and privacy are maintained. 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 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 the research team. Any hard copy documents with data 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 REDCap, the database linking the study subjects to their identifiers and data that has been collected as part of this study. Databases will be kept on secure, HIPAA-compliant servers.

- 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 Austin, Travis 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.*

## 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.*

Participants may be withdrawn from the study if they are verbally abusive or inappropriate with research staff or if it is determined by a healthcare provider or the research team that it is unsafe for them to continue.

They may be also be asked to leave the study if conditions for delivery are not deemed safe by staff or delivery drivers, including but not limited to, mistreatment, harassment or other inappropriate behavior towards staff or delivery drivers either by the participant or by someone else at the participant's residence; repeated violation of the dog policy; dangerous structural conditions; or if illegal activities are carried in or around the residence.

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.*

There are no procedures in place to ensure the safety of a participant that is withdrawn for inappropriate behavior or because it was determined by a healthcare provider or research staff. This is a minimal risk study and being withdrawn poses no risk to the participant.

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.*

None

# 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.*

Given the population of interest is older adults, it is reasonable that researchers could discover or suspect elder abuse. If we learn during the study about elder abuse or neglect, we will report the information to the appropriate authorities, including the police and the Texas Department of Family and Protective Services.

# 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, UT Box.

Participant privacy will be maintained by conducting research visits in a private room or if in a large space, by providing adequate distance to ensure privacy. If participant chooses to complete surveys with a hard copy, it will be stored in a locked cabinet before and after measurement collection. In addition, paper copies of signed consent will be stored in locked cabinet and electronic copies will be stored on secure UT Box platform.

## 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. After the study ends, the University of Texas at Austin might contact participant/s to determine interest in media opportunities, which would be completely optional for them to do so. All data will be stored in the Dell Med REDCap database and/or on UT Box. These secure, HIPAA compliant databases can only be accessed with password and dual authentication. Hard copies of the measurements will be available to participants upon request. Any paper copies with identifiable information (such as written consent forms) will be stored in a locked cabinet until it is destroyed with the other data (two years after the end of the study).

**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.*

Due to the nature of the study, identifiable data will be shared with MOWCTX during the study. This is critical and necessary to be able to conduct the research study as MOWCTX needs to know demographic data in order to deliver the intervention. We will not record the addresses of ineligible participants and we will destroy the addresses on a monthly basis from our database if they are deemed ineligible. Non-aggregated and de-identified study data will be shared with MOWCTX after analysis for the purpose of improving care to the client population. Aggregated and de-identified data will be shared with MOWCTX and presented in public forums.

We may share data with other researchers for future research studies that may be similar to this study or may be different. The data shared with other researchers will not include information that can directly identify the participant.

## 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.*

Participants will be paid $50.00 for each measurement visit for a maximum of $250.00 for 5 visits.

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.*

Participants will be paid $50.00 for each measurement visit for a maximum of $250.00 for 5 visits.

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 small cost to travel to the study visit sites. This will vary from one participant to the next, but will be negligible for most.