Attachment UUU

Title:	*Expanding the Diabetes Homelessness Medication Support (D-Homes) program to Spanish speaking Hispanics*
Short Title	D-Homes Spanish Aim 2
Sponsor:	National Institute of Diabetes and Digestive and Kidney Diseases (R03DK133553-01)
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PROTOCOL SYNOPSIS

Study Title	Expanding the Diabetes Homelessness Medication Support (D-Homes) program to Spanish speaking Hispanics
Funder	National Institute of Diabetes and Digestive and Kidney Diseases (R03DK133553-01)
Clinical Phase	N/A
Study Rationale	**People experiencing homelessness die on average 10 years earlier than their housed peers due to poorly controlled chronic physical and behavioral health conditions.** The Hispanic community has disproportionately higher rates of both homelessness and diabetes. They have higher age-adjusted prevalence of diagnosed diabetes (1.6 times), earlier complications, and more diabetes-related death than non-Hispanic whites. Homelessness and unstable housing are common and increasing among Hispanic people. Access and insurance barriers compound individual challenges leading to even lower rates of medication adherence than general U.S. population.
Study Objective(s)	**Primary** • To pilot test a behavioral intervention tailored to Spanish-speaking adults who have type 2 diabetes who have experienced homelessness or unstable housing using behavioral activation, motivational interviewing and psychosocial support to improve medication adherence (n=10-12) **Secondary** • To improve diabetes control (HgA1c)
Test Article(s)	Behavioral intervention to support medication adherence
Study Design	Single arm treatment-development trial
Subject Population Key Criteria for Inclusion and Exclusion:	We will enroll adults (age ≥ 18 yrs.) with type 2 diabetes who are experiencing homelessness. **Inclusion criteria:** 1. Age 18 yrs. or older 2. Preferred language of Spanish 3. Experience of homelessness per the HEARTH Act (2011). 4. Self-reported diagnosis of type 2 diabetes, later verified in medical record and via A1c blood test 5. Plan to stay in local area or be reachable by phone for the next 16 weeks 6. Willingness to work on medication adherence and diabetes self-care

	Exclusion criteria will include conditions raising risk for coercion or limitation of capacity to ethically consent to research: **1.** Active intoxication (appears to be under the influence) **2.** Active psychosis or dementia **3.** Active legal commitment (per search of publicly available civil court records). **4.** Pregnant or lactating at the start of the study. This is aligned with previous studies by this team (K23DK118117, IRB # 19-4622).
Number Of Subjects	Total Number of Subjects: 10-12 Total Number at Hennepin Healthcare: Unknown Total Number of Sites: Assessments and coaching will primarily occur at Communidades Latinas Unidas En Servicio (CLUES) service centers (see Letter of Support in Attachments) or at Hennepin Healthcare.
Study Duration	Each subject's participation will last 16 weeks. The entire study is expected to last one year.
Study Phases **Screening** **Intervention** **Follow-Up**	(1) Screening: screening for eligibility and obtaining consent, baseline assessment (2) Intervention: study intervention with counselor support approximately weekly in-person and/or by phone x 12 weeks (3) Follow-up: final assessment
Efficacy Evaluations	• Self-reported medication adherence • Self-reported psychological wellness • Self-reported diabetes self-management, distress • Hemoglobin A1c measured by venipuncture at Hennepin Healthcare Lab or using at-home A1c test kit and reporting the results to research staff
Safety Evaluations	Capacity to consent for this at-risk patient population will be assessed using a quiz. Adverse events will be tracked as below.
Statistical And Analytic Plan	The primary endpoint of this study is the feasibility and acceptability of the program to participants in this treatment development phase. We will summarize themes in the end-of treatment interview, assess satisfaction via structured survey, and assess treatment dose received via frequency, length, and type of communications with study staff. We will conduct exploratory analyses on our eventual primary behavioral endpoint of medication adherence and compare this with change in our eventual primary clinical endpoint of point-of-care Hemoglobin A1c during this same time frame. We will refine our

	use of patient-reported outcomes and administrative claims data for use in the future, planned randomized pilot trial.
Data And Safety Monitoring Plan	Dr. Vickery (PI) will work closely with study staff to monitor the quality of data collected at assessment. This treatment development study (N=10-12), does not meet NIH criteria requiring a Data Safety Monitoring Board (DSMB), however Drs. Vickery and Busch will oversee a detailed safety monitoring plan.

TABLE 1: SCHEDULE OF STUDY PROCEDURES

Study Phase	**Eligibility screening**	**Consent, Baseline visit 1**	**Run-in, Baseline visit 2**	**Treatment sessions**										**Follow-up visit**
Visit Number				**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	
Study Weeks	**0**	**1**	**2-3**	**2-3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13-16**
Confirm communication preferences	X	X		X				X					X	
Review Inclusion/Exclusion Criteria	X	X	X											
Informed Consent		X												
Demographics/Medical History		X	X											
Medical records request/ abstraction		X	X											X
Vital Signs: BP, HR		X	X											X
Height and Weight		X	X											X
Hemoglobin A1c		X	X											X
Medication review		X	X											X
Self-report survey measures		X	X											X
Satisfaction with intervention														X

1 BACKGROUND INFORMATION AND RATIONALE

1.1 Introduction

The overall goal of this project is to expand our team's existing evidence-informed programs to specifically target medication adherence to improve diabetes care among Spanish-speaking Hispanic adults experiencing homelessness or unstable housing in Minnesota and beyond. We plan a sequential exploratory mixed methods study design for treatment development familiar to our team from prior work (K23DK118117) with ongoing input from our community-engaged research team (Fig 2).

Aim 2. This protocol is part 2 of a set of studies with an overall goal to pilot test a collaborative care intervention using motivational interviewing and behavioral activation alongside education and psychosocial support to improve medication adherence tailored to the experiences of Spanish-speaking people experiencing homelessness and diabetes (DH-SH). Our team's central hypothesis is that medication adherence and diabetes self-care (and eventual glycemic control, health care use/cost) will improve with an intervention tailored to the unique context of DH-SH.

This work builds upon part 1 (IRB-FY2022-431) during which we completed Aim 1 activities to modify research and intervention tools from the Diabetes Homeless Medication Support (D-Homes) study to make them more culturally appropriate for Spanish-speaking patients. Data from this phase has identified barriers and strategies for medication adherence, patient values regarding medication, and treatment preferences and informed development of this part 2 application.

This protocol addresses Aim 2, to test patient perceptions of the feasibility and acceptability of study procedures and refine the D-Homes Spanish treatment manual through test cases (n=10-12) with a hypothesis that the D-Homes manual and study procedures will be feasible and acceptable to DH-SH as measured by self-report and post-treatment interview.

1.2 Significance

Homeless people in the US face disproportionate risk for premature death in part due to poorly controlled chronic diseases including diabetes. One and a half million unique US adults access homeless shelters annually.[1] People experiencing diabetes and homelessness develop complications 10 years earlier[6] and die prematurely compared to their housed counterparts.[8] Our region has accessible health insurance, health care, and prescriptions; however individual level barriers persist that are amenable to behavioral interventions.

Box. Defining Homelessness:
Many definitions of homelessness exist. We adopt that of the U.S. government which includes people who:
- Lack "fixed, regular, adequate nighttime residence"
- Stay at emergency shelters, temporary living facilities, other places not meant for human habitation
- Will imminently lose their primary residence

(HEARTH Act, 2011)

Substantial evidence links medication adherence as a leading modifiable health behavior driving poor diabetes outcomes in low-income and homeless populations.[11-13,15] Behavioral support for improved medication adherence among DH is the focus of our

team's **ongoing K23 award**. We've used qualitative data and multi-stakeholder input to develop a tailored behavioral intervention (the Diabetes Homeless Medication Support program [**D-Homes**]); pilot testing of this new intervention is ongoing. D-Homes offers 10 coaching sessions over 12 weeks targeting glycemic control via improved medication adherence. Coaching includes diabetes education and structured goal setting targeting medication adherence and psychological wellness.
Despite COVID-19-related challenges, we have successfully recruited 34 DH, 4 of whom identified as Hispanic. To date the existing K23 award (IRB # 20_4863) has required English fluency for enrollment due to limited resources.

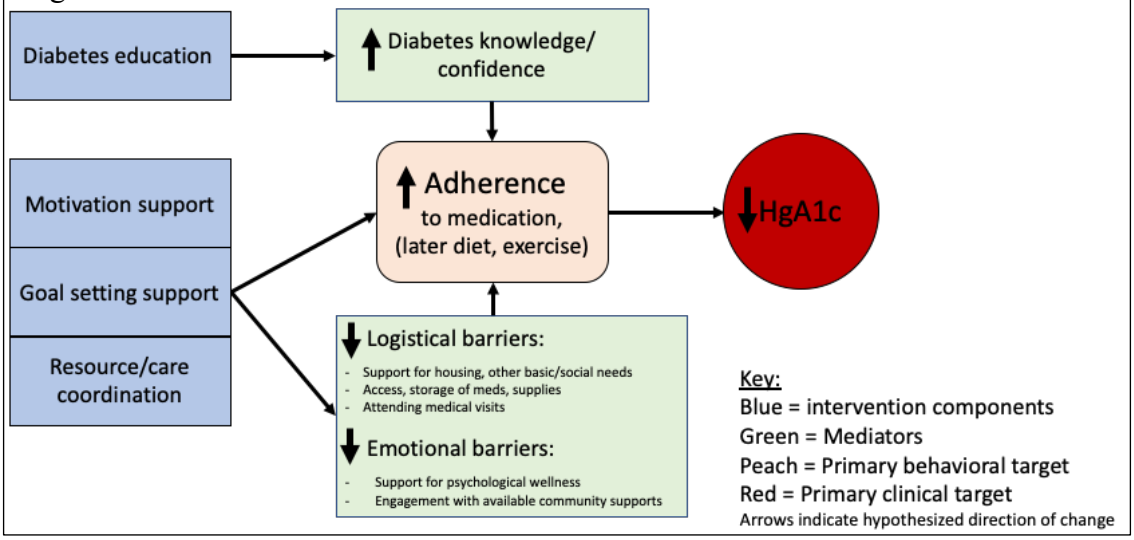
The Hispanic community has disproportionately higher rates of *both* homelessness and diabetes. They have higher age-adjusted prevalence of diagnosed diabetes (1.6 times),[21] earlier complications, and more diabetes-related death than non-Hispanic whites.[22,23] Furthermore, Spanish-speaking Hispanic adults with diabetes demonstrate significantly lower medication adherence than their English-speaking Hispanic or non-Hispanic white counterparts.[25] Further, Hispanic people face "hidden homelessness" as they frequently share housing ("double up") and rely on informal shelter settings both of which are underestimated in homeless counts.[29,30] Language barriers and widespread fear of utilizing public services like shelter due to undocumented status drive these differences.[31] Moreover, emerging evidence suggests worsening of health care, medication, and housing access since the COVID-19 pandemic among Hispanics.[32]

There is a *critical need* to include Spanish-speaking Hispanics in our ongoing D-Homes work to accurately reflect the demographics of DH nationally and locally. This R-03 application will extend the D-Homes work by adapting study materials for people experiencing **D**iabetes and **H**omelessness who are **S**panish-speaking **H**ispanics (**DH-SH**) and collecting feasibility and acceptability data in this population. This will parallel the study procedures familiar to our team from our prior work with English-speaking DH (IRB # 20_4863).

1.3 Name and Description of Intervention

The behavioral intervention tested in this protocol is the Expanding the Diabetes Homelessness Medication Support (D-Homes) program to Spanish speaking Hispanics (DHomes-Spanish). This will be a 12-week in-person, video, and/or phone-based support program centered on providing diabetes education, motivational and goal-setting support, and resource and care coordination (Figure 2). Psychological approaches of behavioral activation and motivational interviewing will be used along with provision of educational materials and tools to support behavior change, see Section 3. for details.

Figure 2. D-HOMES Treatment model



1.4 Selection of Treatment Dosages

Treatment doses are similar to a multiple health behavior change intervention currently underway by Dr. Andrew Busch ("Development of an Integrated Depression and Behavioral Risk Factor Reduction Intervention for Secondary Prevention following Acute Coronary Syndrome," 1R03HL136540), primary mentor on this study. This is also in line with current literature about behavioral interventions to support improved diabetes self-management via medication adherence and psychosocial wellness.[94] During this treatment development phase we will monitor and adjust the number and duration of planned sessions based on the data from case study participants. This will inform Aim 3 randomized pilot future steps.

1.5 Relevant References *See Section 10 for References.*

1.6 Compliance Statement

This study will be conducted in full accordance with all applicable Hennepin Healthcare Research Institute Policies and Procedures and all applicable federal and state laws and regulations including 45 CFR 46. All episodes of noncompliance will be documented.

The investigators will perform the study in accordance with this protocol, will obtain consent and assent, and will report unanticipated problems involving risks to subjects or others in accordance with Hennepin Healthcare Research Institute IRB Policies and Procedures and all federal requirements. Collection, recording, and reporting of data will be accurate and will ensure the privacy, health, and welfare of research subjects during and after the study.

All study materials have been translated into Spanish and back translated by credentialed, native Spanish speaking, staff members to verify accuracy of translation. All of these translations have been verified by participants in Aim 1 of this study. The consent form and HIPAA documentation were professionally translated.

2 STUDY OBJECTIVES

The purpose of the study overall is to improve the health of Spanish-speaking people with type 2 diabetes who are experiencing homelessness or unstable housing to complement the work of our team with English-speaking people. The purpose of the aim of the study is to develop and pilot test a collaborative care intervention using motivational interviewing and behavioral activation alongside education and psychosocial support to improve medication adherence tailored to the experiences of Spanish-speaking people experiencing homelessness and diabetes (DH-SH).

2.1 Primary Objective (or Aim)

The primary objective of this study is to determine whether a 10-session behavioral activation and motivational interviewing support program is feasible and acceptable to DH-SH. The outcomes we will use to assess this treatment development phase of our work will be our ability to recruit and retain participants, the dose of treatment we can deliver (i.e., participant's attendance and follow-up with scheduled sessions and treatment activities), and participants' report of their satisfaction and overall experience during participation in a structured survey and qualitative post-treatment interview.

2.2 Secondary Objectives (or Aim)

The secondary objectives will be to edit randomized pilot trial protocols and treatment manual instructions to optimally support participants. We will:

1. Clarify recruitment and retention strategies for DH-SH
2. Assess the acceptability of patient-reported outcome measures and laboratory testing protocols
3. Finalize plans to use administrative claims and health care record data
4. Determine adequate incentive amounts and adequate timing of distribution
5. Refine protocols for distribution of phones and other tools to support intervention participation and behavior change

3 INVESTIGATIONAL PLAN

3.1 General Schema of Study Design

This is a single arm pilot trial to inform development of the DHomes-Spanish behavioral treatment, see Table 1 above. The intervention, see Figure 1 above, targets diabetes education, motivation and goal-setting support, as well as resource and care coordination for Spanish-speaking people experiencing type 2 diabetes and homelessness (DH-SH). The goal of this treatment development phase of our work is to refine approaches and protocols for further study of our program.

3.1.1 Screening Phase and Baseline Assessment

Recruitment protocols are summarized in section 8.4 below but will involve (1) invitation to aim 1 research participants who indicated interest in future research, (2) referral from CLUES (3) phone calls to eligible patients at Hennepin Healthcare. Potential subjects will be screened by phone using the protocol inclusion and exclusion criteria.

Congruent with other trials in this area,[49] we will conduct a 2-week run-in period to ensure participants are able to follow-up. During this time two baseline assessment visits will be scheduled. The second baseline assessment visit will be scheduled to correspond to the first treatment visit whenever possible.

3.1.2 Study Intervention

This study will be offered to willing participants as an adjunctive to usual diabetes care. During the screening and run-in period, participants will be encouraged and supported to continue seeing their regular health care team. If they do not have one, support will be given to help the participant schedule a primary care or endocrinology appointment at Hennepin County Health Care for the Homeless, Hennepin Healthcare, or another clinic/health system per participant preference.

3.1.3 Follow-up and post-treatment interview

To be eligible for follow-up, subjects must either have completed their planned coaching sessions or requested to end their coaching sessions early. Since the emphasis of this treatment development study is feasibility and acceptability, those ending early will be given particular attention so that their insights and experiences can shape future adaptations to the intervention and study design. Follow-up will be done in the form of a post-treatment interview.

3.2 Allocation to Groups and Blinding *Not applicable to this phase of the study.*

3.3 Study Duration, Enrollment and Number of Sites

3.3.1 Duration of Study Participation

Participants will be screened and recruited for a 2-week run-in period. They will engage in 10 weekly sessions over 12-weeks with our interventionist (“diabetes wellness coach”), and they will have a 4-week period within which to complete any missed visits and their final assessment visit, where they will complete assessment questions and the post-treatment interview. This is a maximum of 16 weeks duration per participant.

3.3.2 Total Number of Study Sites/Total Number of Subjects Projected

Enrollment for the study will continue until 10-12 participants have been recruited or when enough data has been gathered to inform future steps of treatment development.
HHRI will serve as the only site for this study. CLUES will offer space in the community for study related activities conducted by HHRI staff to minimize burden on participants (See letter of support).

3.4 Study Population

3.4.1 Use of Vulnerable Populations and Patients Who Opt Out of Research

This study focuses on Spanish-speaking adults experiencing type 2 diabetes and homelessness. This is justified given the premature morbidity and mortality of this population from diabetes and related comorbidities. While not formally considered a vulnerable population, DH-SH are a population requiring special attention with regard to safety and respectful engagement in research. A consent quiz will be used to ensure that no individuals unable to consent are recruited similar to protocols used in part 1 of this study (IRB-FY2022-431). Furthermore, we will continue working closely with community providers in this area and a multi-stakeholder team to ensure we achieve cultural congruence with the ways we approach and engage this population in research as well as with the planned study protocols. No patients who have chosen to opt out of research will be included in this study.

3.4.2 Inclusion and Exclusion Criteria

Inclusion Criteria

1. Age 18 yrs. or older
2. Preferred language of Spanish
3. Experience of homelessness per the HEARTH Act which includes living in a supported housing facility or worry you cannot pay rent in the next 2 months (2011).
4. Self-reported diagnosis of type 2 diabetes, later verified in medical record and by A1c test
5. Plan to stay in local area or be reachable by phone for the next 16 weeks
6. Willingness to work on medication adherence and diabetes self-care

Exclusion Criteria

1. Active intoxication (appears to be under the influence),
2. Active psychosis or dementia, or
3. Active legal commitment (per search of publicly available civil court records)
4. Pregnant or lactating at the time of enrollment.

This is aligned with previous studies by this team (K23DK118117, IRB # 19-4622). We will further confirm capacity to consent using a brief quiz in Spanish.

Subjects that do not meet all the enrollment criteria may not be enrolled. Any violations of these criteria will be reported in accordance with IRB Policies and Procedures.

Rationale for excluding pregnant people: People who are pregnant may have less control over their A1C and typically receive guidelines from their provider on diet and exercise during pregnancy. Though we do not think participation in this study poses a risk to pregnant people, we do not think we can accurately measure the effect of our program in this population.
Retain participants who become pregnant during the study:

Risk of withdrawing care: We have opted to retain participants who become pregnant after enrollment because a) we do not think interaction with a diabetes wellness coach poses greater than minimal risk and b) prematurely withdrawing the care of the diabetes wellness coach from a vulnerable population (pregnant people who are experiencing homelessness) poses a greater risk than continued participation.
Mitigation of risk: Our diabetes coaching is designed to adapt to the unique goals of each participant, and we recognize that people who become pregnant during the study will likely be working on their diabetes control with their care team. In the case that a participant becomes pregnant, we will ask the participant to sign a release of information so we can communicate with their OB, midwife, or other provider overseeing their pregnancy to ensure DHomes coaching goals align with the diet and wellness goals established by the provider.

4 STUDY PROCEDURES

4.1 Recruitment

Participants will be recruited from the clients of CLUES. In 2020, CLUES provided direct rental assistance to over 2,700 households and secured housing for 74 individuals and families that were experiencing homelessness. This will be supported by a sub-contract between CLUES and HHRI to provide appropriate training and support for patient screening and recruitment. We will utilize strategies refined in our previous studies with similar populations to send flyers and informational letters to eligible participants and follow-up with personal phone calls. We will also encourage personal invitations from trusted staff (e.g. case managers, social workers) who can provide warm hand-offs to the study team in-person or by phone or video.

In the case that we cannot successfully recruit all participants from CLUES, we have also requested a weekly BOE report from HCMC. We have asked the Analytics Center for Excellence to use the existing social indicators associated with homelessness such as housing or food insecurity, Spanish Language, department, upcoming appointment dates, and lab data to generate rosters of patients who meet enrollment criteria but who have not opted out of research participation. We also will create a list using SlicerDicer including the same criteria as the BOE list report where we will filter out people who decline to participate in research. We will contact eligible patients by phone—a method we've used successfully in the past to recruit unstably housed individuals. Care will be taken to ensure research staff emphasize the voluntary nature of participation and emphasize that the choice to participate will not impact receipt of health care at HCMC or other health systems.

4.2 Qualifying Visit

4.2.1 Eligibility, screening visit

As outlined in Table 1, before consent, interested participants will complete a phone screening. This will cover inclusion and exclusion criteria and briefly describe the intervention to ensure the participant is aware and willing to commit to study.

5.1.2 Baseline Assessment and run-in

After the screening visit, after the participant's signed consent at baseline assessment visit 1, the medical record will be accessed. Participants' diabetes diagnosis, past 12 mo. HgA1c, medication list, frequency of refills, primary care team, and pattern of clinic/emergency department/hospital visits will be abstracted and recorded for the previous 12 mos. If patients are found not to have diabetes at this point, they will be excluded from the study.

If patients are confirmed to be eligible based on medical record review, we will proceed with baseline visit 2. This will be an in-person visit scheduled to correspond with study visit #1.

As outlined in Table 1 above, the screening visit and baseline assessment visits will collect:

- Informed Consent, HIPPA authorization
- Review Inclusion/Exclusion Criteria
- Demographics/Medical History
- Release of information for health systems used in last 12 mo.
- Release of information for insurance claims data in the last 12 mo.

- Vital Signs: BP, HR
- Height and Weight
- Point of care Hemoglobin A1c (HgA1c)
- Medication review, self-reported and later verified in EHR
- Primary/diabetes care team review
- Patient-reported outcome survey items:
    - Medical History
    - Health care Utilization
    - Education
    - Mental Health Inventory (MHI-5)[115]
    - Health-related Quality of Life Short Form (SF-12)[116]
    - Problem Areas in Diabetes (PAID)[113]
    - Diabetes self-management questionnaire (DSMQ)[105]
    - Adherence to Refills and Medications Scales-Diabetes (ARMS-D)[111]
    - Self-reported medication adherence (Adherence Start with Knowledge, ASK-12)[106]
    - Basic needs survey[107]
    - Current and lifetime housing status
    - Use of substances
    - Brief Trauma Questionnaire[108]
    - Self-reported health care use

Since a goal of this treatment development trial is to refine both the flow of the initial baseline assessment visits as well as which patient-reported instruments are best tolerated, not all participants will receive all survey items. Informed consent and HIPAA authorization

will always be collected at baseline assessment visit 1. However, we will adjust when other data are collected across the first two baseline visits based on participant and assessment surveyor feedback.

4.3 Study Intervention

This will be a 10 session, 12-week in-person, video, and/or phone-based support program with assessment for 2 weeks before and 2 weeks after treatment visits. The treatment will center on providing diabetes education, motivational and goal-setting support, and resource and care coordination. Modality of treatment delivery will be adapted based on logistics by study team considering participant preference as well as safety with regard to the COVID-19 pandemic.

In-person assessment visits will be conducted within CLUES spaces convenient to participants, in HHRI/HHS clinical spaces, or in participants' homes if they request.
All in-person assessment and treatment visits will follow current guidance from HHRI and Hennepin Healthcare about social distancing and use of personal protective equipment.

Video visits will be conducted via a secure Zoom or Teams link (using HHRI, Hennepin Healthcare, and/or Hennepin County HIPPA secure technology).
Phone visits will be conducted via a study or office phone or using the secure TelemedIQ app of study team members.

Psychological approaches of behavioral activation and motivational interviewing will be used along with provision of educational materials and tools to support behavior change. Tools/materials will be distributed with travel and cell phone minute renumerations as above. We have included a sample list of tools and educational materials that might be provided in Cayuse. Which tools and educational materials are given to which participants will be decided between the coach and participant aligned with specific goals that are mutually set. E.g.) A participant with 10 medications per day may benefit from a pillbox with AM and PM slots. E.g.) A participant with many appointments for behavioral and physical health care providers may benefit from a pocket calendar. Financial value of gifts ranges from $2.99 (hand sanitzer) to $32.95 (lock boxes).

In order to facilitate retention with this population, we will ask participants to provide multiple modalities by which we may contact them, including phone, email, and social media.

While study visits may occur by phone, email and social media communications will be limited to content only related to arranging details of when/where and how to connect with participants. This may involve coordinating details to give a participant a study phone. This is necessary since we anticipate participants will have a higher than average likelihood of their phone service ending due to unpaid bills. If phone service is shut off, email and social media platforms continue to be used by participants through the phone's wifi capabilities. Participants will provide their email addresses, usernames and preferred platforms and provide signed consent to be contacted in these ways. Privacy concerns and appropriate use

of email and social media to arrange for other communication with study team will be noted in the consent.

We will also ask participants to identify two people who know them well and would know how to reach them in the event that we are not able to contact them by phone, email, or social media. Similarly, we will ask participants to identify medical and social service providers who would know their current address or have up-to-date contact information for them. Participants will be asked to sign appropriate releases of information to allow medical and social service providers to share this information with the study team.

4.3.1 Visit 1

The first visit will immediately follow the baseline #2 visit and be conducted in person whenever possible. The goals of the first visit are to (a) establish rapport, (b) assess baseline diabetes self-care behaviors, (c) describe the rationale for the treatment. The interventionist will get to know the participant and discuss things of importance in their life. She will complete a detailed assessment of prescribed diabetes medications and use of pharmacies and health care clinics/hospitals supplementing with data from the medical record as needed. The interventionist will also:

- Review boundaries for sessions, confidentiality, and mandated reporting
- Educate the patient on the rationale of behavioral activation and motivational interviewing
- Assess co-morbidities (e.g. mental illness, substance use disorder, heart disease) and contextual factors (e.g. housing status, social supports, food security) of influence
- Assess existing diabetes care team; refer to HCH or Hennepin Healthcare if no team in place.
- Assign self-monitoring goals per behavioral activation

4.3.2 Visit 2

The goals of the second visit are to complete a values assessment and provide relevant/needed health behavior tools. The interventionist will use a list to prompt the values assessment based on the Valued Living Questionnaire.[96] They will:

- Identify participant values
- Provide health behavior tools as desired/needed (e.g., pill boxes, warm socks; see Appendix F for details)
- Identify valued activities goals to promote diabetes medication adherence and psychosocial wellness specific to the participant's values and context
- Problem solve foreseeable barriers to behavior change goals

4.3.3 Visits 3-5

The goals of visits 3-5 will be to advance the practice of behavioral activation and motivational interviewing to promote improved diabetes knowledge/confidence, and reduced logistical and emotional barriers specifically related to medication and other diabetes adherence. During these visits the interventionist will:

- Review engagement in health and wellness-promoting valued activities

- Identify valued activities goals to promote diabetes medication adherence and psychosocial wellness specific to the participant's values and context
- Problem solve foreseeable barriers to emergent behavior change
- Assess for inclusion of diet, exercise goals to enhance diabetes adherence goals

4.3.4 Visits 6-8

The goals of visits 6-8 are to continue to support behavior change related to diabetes medication adherence. During these visits the interventionist will:

- Introduce advanced or challenging valued activity goals
- Explore ways to increase synergy between psychosocial wellness and diabetes health behavior goals

4.3.5 Visits 9-10

The goals of visits 9-10 are to emphasize maintenance of behavior change achieved during earlier weeks and plan for sustainability. During these visits the interventionist will:

- Plan and implement strategies for long-term maintenance of diabetes adherence goals

4.3.6 Final Assessment

The final assessment visit will be completed within 4 weeks of completion of visit 10 or upon early termination. This will be completed by a research staff member who is distinct from the interventionist. The staff person will assess:

- Vital Signs: BP, HR
- Height and Weight
- Hemoglobin A1c
- Medication review
- Self-report survey measures
- Satisfaction with intervention

The staff person will also conduct the post-treatment interview.

4.4 Unscheduled Visits

Contact between the study team and participant during the 16-week intervention period will be encouraged. This will include reminders of study-related assessments and visits. The interventionist will work with the patient to set treatment goals related to improved diabetes care. These may include between-visit text messages, calls, e-mails, or private messages on secure social media platforms per the participant's preference. These will be done with input and agreement by the participant. The interventionist will also respond to participant-initiated between visit communications. Should communications become too frequent or surpass agreed upon treatment boundaries, the interventionist will be guided to set boundaries and limit contact by Drs. Vickery and/or Busch.

4.5 Concomitant Treatment

All prior and concomitant diabetes care in the year prior to the screening visit and through the end of the study will be recorded with patient input as well as review of medical records (with signed consent). Care for relevant co-morbidities (mental illness, substance use disorder, cardiac disease, etc.) will also be recorded.

4.6 Subject Completion/Withdrawal

Subjects may withdraw from the study at any time without prejudice to their care. They may also be discontinued from the study at the discretion of the Investigator for lack of adherence to study treatment or visit schedules and AEs. If the Investigator becomes aware of any serious, related adverse events after the subject completes or withdraws from the study, they will be recorded in the source documents and on the case report form.

4.6.1 Early Termination Study Visit

Any participant who withdraws will have no further study visits.

5 STUDY EVALUATIONS AND MEASUREMENTS

5.1 Screening

We will use two screening methods. First, CLUES staff may identify potential participants from their clients who fulfill all eligibility criteria using the screening script as a guideline. Second, a phone screening will be conducted with patients to confirm study eligibility before each interview. If a potential participant cannot be contacted by phone before the interview, this screening survey will be conducted in-person prior to obtaining informed consent to ensure study eligibility. The screening survey will assess:

- Eligibility based on type 2 diabetes diagnosis and glycemic control via last known HbA1c
- Housing status
- Age
- Gender
- Race
- Ethnicity
- Preferred language
- Communication preferences

On all interview participants, the participant characteristics and experience will be collected using REDCap. This will help to refine instruments for use in future phases of the research. Study staff will orally administer the survey questions in a private area.

5.2 Demographics, Medical History, and Medication use – patients

During the baseline and final assessment visits data will be collected using the following procedures:

Demographics/Medical History	Participants will be given a written survey at either the Baseline 1 or Baseline 2 visit to add to data collected in pre-consent screening. If patients prefer, these questions will be asked verbally by the assessor. Topics will include: health insurance, education, medical history, and current living situation. This will also include the Brief Trauma Questionnaire.[108]
Medical record request/abstraction	Signed release of information forms will be collected for participants at their primary care clinic/preferred health system and at Hennepin Healthcare and Hennepin County affiliate clinics. Once signed consent is obtained, EPIC records at Hennepin Healthcare will be directly accessed for abstraction with signed consent. Release of information (ROI) forms will be collected for outside health systems patients have used. ROI forms will be sent, via secure e-mail or fax, to Health Information Management offices at outside health systems. Return of information will occur via secure file transfer system preferred by the recipient organization. Returned records will be abstracted by study staff. After the Baseline 1 visit, we will abstract the past 12 mo. of: • Medication list, dose, frequency, and prescriber • Comorbidities (including physical and behavioral health) • History of medication refill frequency • Number of visits to primary care: Overall and related to diabetes • Number of visits and length of stay in the hospital: Overall and related to diabetes • Number of visits to the emergency department: Overall and related to diabetes • Number of visits to behavioral health providers, as relevant • History of hemoglobin A1c: Data and results of tests • History of blood pressure, height, and weight

	After the 12-week visit, we will review and abstract any changes in: • Medication list, dose, frequency, and prescriber • History of medication refill frequency • Number of visits to primary care: Overall and related to diabetes • Number of visits and length of stay in the hospital: Overall and related to diabetes • Number of visits to the emergency department: Overall and related to diabetes • Number of visits to behavioral health providers, as relevant • History of hemoglobin A1c: Data and results of tests
Insurance company claims data	During this case study phase of the project, we will refine our procedures for obtaining and formulating insurance company claims data. We expect most records to be from Minnesota Medical Assistance. We will work directly with Minnesota Department of Human Services Medicaid office to securely obtain records at the end of the study on all participants. Signed consents will be sent via secure fax or secure file transfer process. Pharmacy and health care claims data detailing medication refill patterns as well as clinic, hospital, and emergency department use across all health systems will be abstracted. We will follow pre-established protocols to examine hospitalizations for hyper and hypoglycemia.[109]
Biometric data	The following biometric data will be collected from participants. See Appendix G for detailed information on how these will be measured: • Blood pressure • Heart rate • Height • Weight • Hemoglobin A1c--Participants will receive a copy of their results. See Cayuse for A1c results sheet.
Medication review	Patients will be asked to bring all their medications to the Baseline 2 assessment visit. All dates, doses,

	frequencies, and prescriber information will be recorded. If patients forget, they will be asked to name this information and it will be confirmed within their medical record.
Self-report survey measures	Formal assessment surveys will be collected at Baseline Assessment 1 and/or Baseline Assessment 2 and 12-week assessment visits used as follows: 1. Mental Health Inventory (MHI-5)[115] 2. Health-related Quality of Life Short Form (SF-12)[116] 3. Problem Areas in Diabetes (PAID)[113] 4. Diabetes self-management questionnaire (DSMQ)[105] 5. Adherence to Refills and Medications Scales-Diabetes (ARMS-D)[111] 6. Self-reported medication adherence (Adherence Start with Knowledge, ASK-12)[106] 7. Basic needs survey[107] 8. Current and lifetime housing status 9. Use of substances 10. Brief Trauma Questionnaire[108] 11. Self-reported health care use
Satisfaction with intervention	At the final assessment visit, the assessor (who is not the interventionist) will collect input about the participant's experiences during the intervention. Participant satisfaction will be assessed by the Client Satisfaction Questionnaire, an 8-item measure developed in the mental health field,[95] and a qualitative post-treatment interview focused on experiences during participation from screening through final assessment visit. See interview guide.

5.3 Efficacy Evaluations

Efficacy is not the intended goal of this treatment development study. However, eventually the goal will be to impact patient diabetes control as measured by Hemoglobin A1c. The primary behavioral target to achieve this impact will be medication adherence. Both of these endpoints will be measured, as detailed above, at the baseline and 12-week assessment visits during this single arm pilot.

5.4 Safety Evaluation

Subject safety will be monitored by adverse events and early termination of interview participation. All adverse events and protocol deviations will be reported to Dr. Vickery as soon as possible and she will report them to the IRB in accordance with HHRI policy.

6 STATISTICAL CONSIDERATIONS

6.1 Primary Endpoint

The primary endpoint of this study is the feasibility and acceptability of the program to participants in this treatment development phase. We will assess this by measuring our ability to recruit and retain participants, the dose of treatment we can deliver (i.e., participant's attendance and follow-up with scheduled sessions and treatment activities), and participants' report of their satisfaction and overall experience during participation in a structured survey (CSQ-8) and qualitative post-treatment interview. In addition to above outcomes, we will carefully track the number and types of between-treatment communications with participants (who initiated communication; form of communication: text, calls, e-mails, etc.).

We will conduct exploratory analyses to define our eventual primary behavioral endpoint of medication adherence e.g.) Change from baseline to 12-weeks in the ASK-12 questionnaire or Change from baseline to 12-weeks in ARMS-D questionnaire to help inform the next phase of the study. We will compare this with change in our eventual primary clinical endpoint of Hemoglobin A1c during this same time frame.

6.2 Secondary Endpoints

Secondary endpoints will include the following changes from baseline to 12-week visit:

Overall change in patient-reported outcome measures: E.g.) Change in overall DSMQ score and changes in sub-scales E.g.) Change in Diabetes Distress score, E.g.) Change in health-related quality of life and psychological distress

Change in medication refill pattern from the electronic health record abstraction and insurance claims

Change in blood pressure, BMI

Safety and tolerability of the treatment based on Adverse Events and participant withdrawal

Exploratory analyses will examine the impact of different algorithms on claims data variable specification to define medication adherence, health care use (clinic, hospital, and emergency department), as well as to categorize when use related to diabetes overall and specifically to hypo- and hyperglycemic events necessitating hospitalization.

6.3 Statistical Methods

6.3.1 Baseline Data

Baseline and demographic characteristics will be summarized by standard descriptive summaries (e.g. means and standard deviations for continuous variables such as age and percentages for categorical variables such as gender).

6.3.2 Efficacy Analysis

The primary purpose of this study is feasibility and acceptability. This will be assessed using the following data:
Qualitative data Analysis of audio recordings of post-treatment interviews will be completed by listening to files and taking detailed notes to highlight satisfaction, treatment experience, and suggested changes of intervention participants.
Survey data from the Client Satisfaction Questionnaire (CSQ-8) will be summarized using descriptive statistics. Exploratory analyses by race, gender, and housing circumstances will be done to look for any patterns.
Communication and treatment contact data will also be examined by creating summary counts of the number and types of communication (by modality and initiator), total minutes of completed treatment, and any notes from treatment sessions.
Clinical outcome analyses will focus on exploratory analyses to determine any evidence as to whether DHomes-Spanish had clinically meaningful effects. We will assess planned future primary behavioral and clinical outcomes of medication adherence (ASK-12) and point of care Hemoglobin A1c as detailed above. We will use t-tests to assess changes in these continuous variables in exploratory post-treatment analyses.
We will additionally use chi-squared tests (for categorical variables) and t-tests (for continuous variables) to examine within participant effect sizes and response rates (using standard cut offs) on the secondary end points listed above. We will analyze data in an intent-to-treat manner.
Exploratory analysis of electronic medical record and administrative claims data will examine the impact of various algorithms for constructing pharmacy-record adherence measures and health care use variables. We will use these analyses to define protocols for use in our Aim 3 randomized pilot.

6.4 Sample Size and Power

This sample size (n=10-12) is appropriate for the goal of treatment development and protocol refinement. This is in line with ongoing studies by Dr. Busch (HSR#17-4351) as well as the current literature.[110]

7 SAFETY MANAGEMENT

7.1 Clinical Adverse Events

Clinical adverse events (AEs) and serious adverse events (SAEs) will be closely monitored throughout the study in accordance with HHRI IRB definitions and policies.

7.2 Adverse Event Reporting

Unanticipated problems related to the research involving risks to subjects or others that occur during this study and SAEs will be reported to the IRB in accordance with IRB Prompt Reporting Guidelines. AEs that are not serious but that are notable and could involve risks to subjects will be summarized and submitted to the IRB at the time of continuing review.

Dr. Vickery will be responsible for completing Adverse Events Forms should an event occur. She will report Serious Adverse Events to the HHRI IRB within 24 hours of having received notice of the event.

Drs. Vickery and Busch will collaboratively gather any information needed to investigate the event and determine subsequent action. Any subsequent action will be documented and reported to the HHRI IRB and the Program Officer at NIH.

Adverse event reports will be reviewed annually with the HHRI IRB to ensure participant safety.

7.3 Investigator Reporting of a Serious Adverse Event to Sponsor

Reporting to the National Institutes of Health will be completed as required by their policies or advised by HHRI IRB staff.

7.4 Medical Emergencies

If non-urgent psychological distress arises in participants during study related activities, study staff will provide a handout about local mental health resources, including a 24-hour support line and psychiatric emergency room. If non-urgent physical health needs arise in participants, study staff will provide written resources about health care available through Health Care for the Homeless and Hennepin Healthcare.
If an emergency physical or behavioral health situation arises, study staff will arrange for immediate clinical support from PI (Dr. Vickery), Health Care for the Homeless clinical staff (who have a walk-in treatment model), the Hennepin County mental health crisis team (COPE Line, available by phone or in-person 24hrs./day, 7 days/week), or emergency medical services as appropriate. This event will be written up and reviewed by the PI (Dr. Vickery) and primary mentor (Dr. Busch) within 48 hours of the event and reported to the IRB if needed. Study staff will use the suicidal ideation checklist to guide their decision making about the order of who to contact. This checklist will be used to fill out the SAE form if necessary.

If measured blood pressure surpasses SBP>180 or DBP>100 or pulse>150 or if blood sugar measurement takes place within a study visit and falls <60 or >400/error, study staff will page Dr. Vickery who will provide clinical assessment of symptoms and make referral or arrangement for immediate transfer to appropriate treatment as needed.

As deemed necessary by the primary mentor and/or HHRI IRB, issues related to patient safety will be reviewed with mental health or medical professionals at HCMC not affiliated with the study who will provide recommendations for withdrawal from the study, referrals for additional care, or other necessary action.

8 STUDY ADMINISTRATION

8.1 Data Collection and Management

We will assign study ID numbers to all participants. Study IDs will be used on all study documents. Consent forms will be stored separately and will not be associated with study IDs when stored. Tracking forms will ensure each enrolled participant has a completed consent form.

Data from paper surveys administered during screening interviews and assessment visits will be entered and stored in REDCap. Physical copies of the surveys will be stored in a locked file drawer separate from consent documents. Electronic health record access will take place in Hennepin Healthcare EPIC or via faxed paper copies of medical records from other health systems. Data from electronic health records will be extracted by a trained research staff member and entered into standard forms using REDCap.

All treatment sessions and final close-out interviews will be audio recorded. Notes about treatment plans and notes summarizing main themes about satisfaction, treatment experience, and suggested changes will be created. Notes will remove all 18 HIPPA personal identifiers if mentioned. Notes will use only subject ID numbers and will contain no personal identifiers. Once audio recordings are uploaded to the HHRI-maintained computer network, they will be deleted from the audio recording equipment. Audio recordings will be destroyed on or before the end of the grant period.

Since assessment visits will be conducted at locations away from the research offices of the PI, extreme care will be taken to keep study materials in the possession of research staff at all times. Immediately after visits, consent forms, hemoglobin A1c results, audio equipment, and other study materials will be returned to the secure research offices of Hennepin Healthcare Research Institute. Each office has a locked door in a badge-access-only wing of the Institute. Signed consent documents will further be stored in a locked file drawer whose key will be stored in a separate locked key box.

Study data, including all audio recordings will be stored and analyzed on Dr. Vickery and her staff's HHRI-maintained computer network. This network is robust, secure, and has state-of-the-art back-up and password protections. Dr. Vickery and staff will comply with any necessary software, hardware, and data storage updates to maintain the security of this system under the direction of the HHRI IT Department.
The identifiers will be destroyed on or before the completion date of the grant. The other data will be retained for three years.

8.2 Confidentiality

All data and records generated during this study will be kept confidential in accordance with HHRI Institutional policies and HIPAA on subject privacy. The PI and other site personnel will not use such data and records for any purpose other than conducting the study. Confidentiality will be maintained by numerically coding all data, disguising identifying information, and keeping data in secure electronic locations or locked in file drawers. All electronic data will be numerically coded and stored on a password protected computer in a secure research space. All paper forms will be stored in locked file cabinets in a locked room. Names of participants will be stored separately. Participant information will be accessible only to HHRI-trained research staff, who are pledged to confidentiality and complete training in the ethical conduct of research (i.e., both HIPAA and CITI trainings). Identifying information will not be reported in any publication.

No identifiable data will be used for future study without first obtaining IRB approval. The investigator will obtain a data use agreement between the provider (the PI) of the data and any recipient researchers (including others at Hennepin Healthcare) before sharing a limited dataset (PHI limited to dates and zip codes).

8.3 Regulatory and Ethical Considerations

8.3.1 Data and Safety Monitoring Plan

This treatment development study (N=10-12), does not meet NIH criteria requiring a Data Safety Monitoring Board (DSMB) as we expect it to be considered minimal risk by the HHRI IRB. However, we have a detailed data safety and monitoring plan. Dr. Vickery will have primary responsibility for monitoring all procedures for data collection, analysis, and storage. Any adverse events, breaches of confidentiality, or other data or safety issues that arise will be discussed during weekly visits with Dr. Busch (primary mentor) or sooner if required. If needed, Dr. Busch will locate representatives independent of the study team for input.

All issues related to patient safety (e.g., psychiatric distress) will be reviewed with medical and mental health professionals at Hennepin Healthcare not affiliated with the study who will provide recommendations for withdrawal from the study, referrals for additional care, or other necessary action.
If requested by NIH or our local IRB, a DSMB will be convened.

8.3.2 Risk Assessment

Discomfort or distress when completing assessment and treatment procedures. Some participants may feel uncomfortable or distressed answering personal or private questions during assessment or treatment. Some participants may also feel uncomfortable or distressed due to the collection of physical measures (e.g., weight). In previous studies, when individuals did report discomfort in these situations, it was mild.

We minimize discomfort or distress with three key approaches: (1) clearly explaining the study and emphasizing the optional nature of participation, (2) conducting all treatment

sessions and assessment visits in private settings, (3) staff training about the sensitivity of chronic health conditions and the specific circumstances of homelessness including how to offer appropriate support.

Physical discomfort during or after blood draw. Participants may experience discomfort or bruising during or after their blood draw. We try to address this risk by sending participants to the lab for draws from phlebotomists. Alternatively, we will provide participants with home A1c kits and instruction on how to use the kits.

Confidentiality or loss of privacy. We will collect potentially sensitive information about participants; if released inappropriately, participants may experience embarrassment or distress. The seriousness of the consequences would depend on the nature of the information revealed and to whom the information was revealed. See Section 8.1 detailing the numerous steps we take to protect participant confidentiality. We therefore think the risk of a breach of confidentiality is low.

Worsening of mental illness, depression, and emergent suicidality. Circumstances of homelessness can be high stress. Although there is no evidence to suggest this would be exacerbated from trial participation, it is possible that a minority of participants will experience worsening of mental illness, depression, or episodes of suicidality during this study. See Section 7.4 above for our detailed safety plan to address this risk.

8.3.3 Potential Benefits of Trial Participation

Potential benefits for participants include free diabetes management support with a goal of improved diabetes self-management which can reduce their morbidity from this disease. Free counseling related to psychosocial wellness may improve participants' quality of life. Furthermore, there may be indirect benefits for participants in knowing they have helped promote research to develop an intervention that could help other people at later times.

8.3.4 Risk-Benefit Assessment

Overall, we expect the potential benefits to participants to outweigh the low risks of study participation.

8.4 Recruitment Strategy

Recruitment of participants will begin with subjects from part 1 (IRB-FY2022-431). In that study 10 of the 10 consented participants agreed to be contacted about future phases of this work. Participants provided their preferred contact information which will be used to invite them to participate.

As a second approach, recruitment of participants will be done via personal invitations by CLUES and/or Hennepin Healthcare staff who often have long-standing, trusted relationships with their clients.

As a third approach, we will include use the electronic health record system at Hennepin County Medical Center (HCMC). We will ask staff in the HCMC Analytics Center for Excellence to use the existing homeless indicator,[49] Spanish as preferred language, department, and lab data to generate rosters of patients who meet enrollment criteria but who have not opted out of research participation. We will contact eligible patients phone call—a method we've used successfully in the past to recruit unstably housed individuals. Care will be taken to emphasize the voluntary nature of participation and to emphasize that the choice to participate will not impact receipt of health care at HCMC or other health systems they may visit.

8.5 Informed Consent/Assent and HIPAA Authorization

We will collect signed consent and HIPAA authorization from all participants. The consent will also include HIPAA authorization to review their electronic health record at Hennepin Healthcare and any other systems where they have gotten care in the last year. We will also ask them to sign consent for us to obtain claims data for one year before and one year after study participation from their insurance provider.

Staff will review consent documents with participants and monitor their comprehension using teach back methods.

After presentation of key features of the document, research staff will administer a 4-question consent quiz to confirm comprehension from all patient participants. This will be a written quiz but administered orally to participants who request it. Participants must answer all questions on the consent quiz correctly to consent. Research staff may administer the quiz up to 2 times, providing feedback for incorrect answers prior to the second administration.

Any and all questions will be answered by study staff and the voluntary nature of participation will be emphasized.

Participants will be given up to thirty minutes to make the decision to participate and more time if requested. Those requesting more may be invited to reschedule their baseline enrollment visit.

The consent form is written at the sixth-grade reading level or below.
If any participant appears to be under the influence of drugs or alcohol or unstable from a mental health perspective, or otherwise unable to consent, or if they fail the consent quiz, we will politely exclude them from participating.

8.6 Payment to Subjects/Families

Participants will be paid for their participation in three ways:

(1) Reimbursement for travel, parking, and cell phone minutes/text messages for all assessment and treatment visits
(2) Payment for time, effort, and inconvenience of assessment visits

(3) Gifts in the form of tools and incentives to enhance behavior change goals

8.6.1 Reimbursement for travel, parking, and cell phone minutes/text messages

Participants will be reimbursed for travel/parking with two bus tokens or arranged transportation via transportation plus for each in-person visit. We will cover phone minutes/text messages for virtual or phone visits with $20 monthly payments (x3). Payments will be made in cash or using ClinCard. Reimbursement is summarized below:

Month 1 phone	Month 2 phone	Month 3 phone	**Total**
$20	$20	$20	**$60**

8.6.2 Payments to subject for time, effort, and inconvenience (i.e. compensation)

Participants will be additionally reimbursed for study assessment visits at each baseline visit and the final visit for their effort and inconvenience. This includes a blood draw at each visit. We will compensate participants $20 at baseline visit 1, $30 at baseline visit 2, and $60 for the final assessment visit. Compensation will be in the form of cash or ClinCard. Maximum total compensation will be $110.

Baseline visit 1	Baseline visit 2	Final visit	**Total**
$20	$30	$60	**$110**

The amount and form of these payments were set with input and approval by CLUES and are in line with compensation for DHomes-English.

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