Diabetes Homelessness Medication Support Single Arm Treatment Development Trial

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Title:	**Development of the Diabetes Homeless Support (D-Homes) Program – Part Two**
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PROTOCOL SYNOPSIS

Study Title	**Development of the Diabetes Homeless Support (D-Homes) Program – Part Two**
Funder	NIH-NIDDK
Clinical Phase	N/A
Study Rationale	More than eight million Americans each year experience unstable housing and/or homelessness; this includes 44% of all adults seen at community health centers. The chronically homeless have a 5- to 10-fold increased risk of premature death and high health care costs (driven by acute emergency department and hospital visits). Diabetes prevalence is approximately the same among the homeless versus general population (8%), but **people with type 2 Diabetes who experience Homelessness**, herein abbreviated as **DH**, have worse glycemic control and are hospitalized for diabetes complications a decade earlier and with more frequency than their housed peers. Most DH are of minority race and/or ethnicity. Poor glycemic control can induce "metabolic memory," or long-term vascular stresses which persist despite later glucose normalization. Managing diabetes while homeless presents a unique set of barriers including food insecurity, low social support, lack of safe medication storage/refrigeration. Almost half of people who are homeless have comorbid mental illness and/or substance use disorders. Prescription medications are a cornerstone in the management of type 2 diabetes and avoidance of complications. Diabetes medication adherence is low in housed populations, and limited evidence suggests it is as low or lower among DH; adherence is highly correlated with all-cause hospitalization and mortality. A tailored intervention to improve medication adherence in DH could have substantial public health impact through reduction of the disparities in morbidity and mortality faced by DH. The study goal is to develop and pilot test a collaborative care intervention tailored to DH using motivational interviewing and psychosocial support to improve medication adherence. Our team's central hypothesis is that medication adherence (and eventual glycemic control, health care use/cost) will improve with an intervention tailored to the unique context of DH.
Study Objective(s)	**Primary** • To develop and pilot test a behavioral intervention tailored to DH using behavioral activation, motivational interviewing and psychosocial support to improve medication adherence **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. English-speaking 3. Homelessness by federal definition in the last 12 mo. 4. Self-reported diagnosis of type 2 diabetes, later verified in medical record 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. Inability to provide informed consent (e.g., presence of a legal guardian, prisoners) 2. Active psychosis or intoxication precluding ability to give informed consent 3. Pregnant or lactating females. 4. Patients who choose to opt out of research.
Number Of Subjects	Total Number of Subjects: 15 Total Number at Hennepin Healthcare: Unknown Total Number of Sites: 1 (Health Care for the Homeless)
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 point-of-care fingerstick
Safety Evaluations	Not applicable in this single arm trial
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=15), does not meet NIH criteria requiring a Data Safety Monitoring Board (DSMB), however Drs. Vickery, Busch, and Connett 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

2 BACKGROUND INFORMATION AND RATIONALE

OVERVIEW

This protocol is part 2 of a set of studies with an overall goal 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 people experiencing homelessness and diabetes (DH). 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.

This work builds upon part 1 (HSR#19-4622) during which we completed Aim 1 activities to develop the initial Diabetes Homeless Medication Support (D-Homes) treatment manual through focus groups with DH at various levels of glycemic control and interviews with their multi-disciplinary providers. 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 treatment manual through test cases (n=15). With a hypothesis that the D-Homes manual and study procedures will be feasible and acceptable to DH as measured by self-report and post-treatment interview.

Eventually, part 2 will be followed by a fully randomized pilot study in concordance with study Aim 3, a fully randomized pilot trial. Approval of this activity from the IRB will be sought before these activities begin.

SIGNFICANCE

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. However, the total number of people experiencing homelessness (Box) is likely much higher[19] with an estimated 7 million additional people living "doubled up" with family/friends in 2014.[20] New data recently established that 44% of all adults, and 37% of adults with diabetes, at US community health centers experience unstable housing.[3,4] All-cause mortality rates among people experiencing homelessness in the U.S. are 4.5 to 9.6-times higher than the general population. Premature death often results from preventable chronic diseases including diabetes (2%) and its related comorbidities, e.g. heart disease (16%).[21] While diabetes *prevalence* among the homeless and general population is comparable (≈8% in both),[22] there is evidence indicating large disparities in diabetes *outcomes*. Patients with type 2 Diabetes who are Homeless, herein abbreviated DH, have worse glycemic control[23] and are hospitalized for diabetes-related complications a decade earlier than their housed peers.[24] New data finds unstably housed adults have over five times the odds of diabetes-related emergency or hospital visit.[4] This is of particular concern given "metabolic memory," **or long-term vascular stresses which persist after significant early hyperglycemia despite later glucose normalization.[25]** While homelessness and unstable housing are increasingly recognized for

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)

their impact on diabetes control, including by the American Diabetes Association,[26,27] there is a paucity of solution-driven research. Thus, there is an urgent need to develop novel treatments to improve glycemic control in DH as they move across the spectrum of unstable housing.

Medication adherence is a complex behavior critically linked to improved overall and diabetes-specific outcomes. The rate of adherence for all long-term therapies averages 50% in the general (non-homeless) U.S. population due to barriers at various levels including: (i) patient, (ii) medication/disease, (iii) system, and (iv) socioeconomic.[28] Among privately insured populations, non-adherence to diabetes and related cardiovascular medications is associated with poor disease control (e.g., higher hemoglobin A1c and blood pressure), as well as increased risk of all-cause mortality and visits to the hospital and emergency department, and total health care costs.[29,30] In low-income populations, cost-related non-adherence is common,[31] and non-adherence is correlated with poor glycemic control.[32] In fact, every 10% improvement in diabetes medication adherence reduced hemoglobin A1c by 0.16%.[33] *The importance of medication adherence is recognized by NIH with an active FOA to improve medication adherence (PA-18-722).*[34]

Poor diabetes outcomes among the homeless is caused by low medication adherence. Non-adherence to medications across disease types is a known concern for homeless people especially when they are young (age <40 yrs.), have comorbid mental health/substance use disorders, experience food insecurity**[35]** and frequent the emergency department. Despite high rates of overlapping **physical and behavioral co-morbidities,[36]** 36% of US homeless adults report unmet needs for prescription medications.[37] Small studies find lower medication adherence in homeless patients when directly compared to housed peers.[38] DH patients specifically report challenges obtaining, storing, and retaining medication (especially insulin), and stigma surrounding the possession/use of needles.[39,40,41,42]

Existing evidence-based models targeting medication adherence to improve diabetes will be the starting point for our novel intervention. We will draw from such interventions which target patient and system-level factors[43] to improve diabetes self-care activities, including medication adherence, for historically disadvantaged groups. The overarching theoretical model guiding treatment development is the **Information Motivation Behavioral Skills model.**[44] Our proposed treatment is also consistent with the **Collaborative Care Model**, a care management approach designed for individuals with multiple chronic conditions with known success improving diabetes outcomes in patients with depression.[45,46] The Collaborative Care Model frequently uses Motivational Interviewing as the counseling approach, as we plan to in this study.[47] **Behavioral Activation (BA)** is another counseling approach that complements motivational interviewing. Behavioral intervention is empirically supported to address medication adherence in a population with high levels of underlying psychiatric disease (especially depression) and/or psychosocial stress.[96-99] BA is easier to train than other empirically-supported counseling treatments and can be delivered with fidelity by bachelor's level practitioners.[100-101] BA is appropriately complemented by motivational interviewing, a person-centered, evidence-based approach to behavior change focused on participants' values and preferences and overcoming expected ambivalence to change.[48] It is particularly appealing to groups with historic disadvantage and minority race,[48] including the homeless,[49] and has improved medication adherence in non-homeless people with diabetes[50,51] including when delivered by trained, non-mental health professionals to low-income populations.[52] We will use BA first and employ MI when participants demonstrate ambivalence to change.

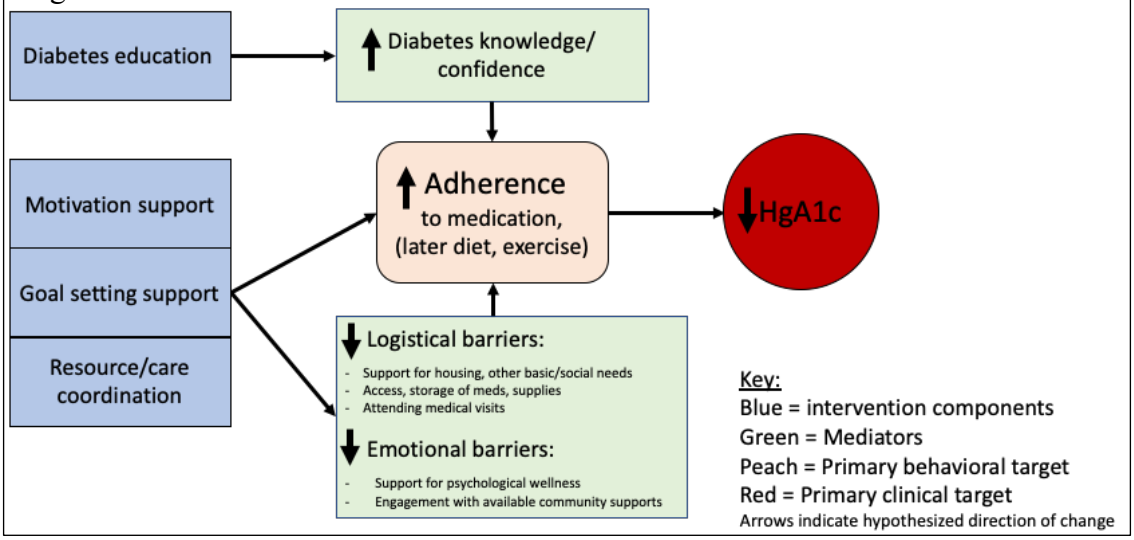
We will also integrate education using content consistent with the latest diabetes care guidelines.[26] And we will offer problem-solving to address psychosocial needs (including food and housing) modeled after clinic-based approaches for homeless veterans.[53,54] *These evidence-based interventions*

offer a starting point for a new intervention which will be tailored to the unique context of DH through the iterative, multi-stakeholder process described below.

2.1 Name and Description of Intervention

The behavioral intervention tested in this protocol is the Diabetes-HOmEless Medication Support (D-HOMES) program. 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



2.2 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.

2.3 Relevant References *See Section 10 for References.*

2.4 Compliance Statement

This study will be conducted in full accordance of all applicable Hennepin Healthcare Research Policies and Procedures and all applicable Federal and State laws and regulations. All episodes of noncompliance will be documented and reported according to the Prompt Reporting Guidelines, Attachment EEE, of the Hennepin Healthcare IRB Policies and Procedures.

The investigators will perform the study in accordance with this protocol, will obtain informed consent and will report unanticipated problems involving risks to subjects or others and SAEs in accordance with The Hennepin Healthcare 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.

3 STUDY OBJECTIVES

The purpose 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 people experiencing homelessness and diabetes (DH).

3.1 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. 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 interview.

3.2 Secondary Objectives (or Aim)

The secondary objectives will be to edit Aim 3 randomized pilot trial protocols and treatment manual instructions to optimally support participants. We will:

Clarify recruitment and retention strategies for DH

Assess the acceptability of patient-reported outcome measures and laboratory testing protocols

Finalize plans to use administrative claims and health care record data

Determine adequate incentive amounts and adequate timing of distribution

Refine protocols for distribution of phones and other tools to support intervention participation and behavior change

4 INVESTIGATIONAL PLAN

4.1 General Schema of Study Design

This is a single arm pilot trial to inform development of the D-HOMES 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 people experiencing type 2 diabetes and homelessness (DH). The goal of this treatment development phase of our work is to refine approaches and protocols for further study of our program.

4.1.1 Screening Phase and Baseline Assessment

Recruitment protocols are summarized in section 9.5 below but will involve (1) invitation to aim 1 research participants who indicated interest in future research, and (2) referral from Health Care for the Homeless, Hennepin Healthcare, or shelter staff, (3) snowball sampling using advertisements and referrals via community partners and previous participants, (4) community advertisement using flyers in places such as bus stops, libraries, and shelters, and if needed (5) invitation letters and follow-up calls to eligible patients at Hennepin Healthcare, (6) tabling events with study flyers and snacks at Hennepin Healthcare or Health Care for the Homeless facilities and in public community spaces such as libraries, shelters, and community organizations.

Potential subjects will be screened by phone using the protocol inclusion and exclusion criteria. See Appendix A.

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.

4.1.2 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.

4.1.3 Follow-up

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.

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

4.3 Study Duration, Enrollment and Number of Sites

4.3.1 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. This is a maximum of 16 weeks duration per participant.

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

Enrollment for the study will continue until 15 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. Health Care for the Homeless will offer space in the community for study related activities to minimize burden on participants (See Appendix B for letter of support with addresses list).

4.4 Study Population

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

This study focuses on 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 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 (HSR#19-4622). See Appendix C.
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.

4.5 Inclusion and Exclusion Criteria

4.5.1 Inclusion Criteria

Inclusion criteria:

1. Age 18 yrs. or older
2. English-speaking
3. Homelessness by federal definition in the last 12 mo.
4. Self-reported diagnosis of type 2 diabetes, later verified in medical record
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

4.5.2 Exclusion Criteria

1. Inability to provide informed consent (e.g., presence of a legal guardian, prisoners)
2. Active psychosis or intoxication precluding ability to give informed consent
3. Pregnant or lactating females.
4. Patients who choose to opt out of research.

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

5 STUDY PROCEDURES

5.1 Qualifying Visit

5.1.1 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:
    - Health-related Quality of Life (EQ-5)[102]
    - Kessler K-6 measure of psychological distress[103]
    - Mental Health Inventory (MHI-5)[115]
    - Health-related Quality of Life Short Form (SF-12)[116]
    - Diabetes Distress Scale (17-items)[104]
    - Problem Areas in Diabetes (PAID)[113]
    - Illness Intrusiveness Scale[112]
    - Treatment Burden questionnaire[114]
    - 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.

5.2 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 (Figure 2). 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 Health Care for the Homeless clinical spaces at sites convenient to participants (see Appendix B for letter of support including addresses of sites) or at HHRI/HHS.

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.

In-person treatment visits will be arranged at private spaces convenient to the participant that may include the participants home (see Appendix D for safety protocol related to home visits).

Video visits will be conducted via a secure Zoom or Teams link (using HHRI, Hennepin Healthcare, and/or Hennepin County HIPPA secure technology). Health Care for the Homeless maintains private spaces within local shelters and drop-in centers. They also have secure tablets on rolling stands for telehealth use in shelter clinics and hotels. These will be used for assessment and treatment visits in cooperation with HCH staff. If needed, an HHRI supported tablet may be added to further facilitate video visits. This may take place in adjacent, private rooms at a shelter, hotel, or apartment facility (e.g. participant in their own room or in a clinic exam room and research staff in a private office or exam room) or may be conducted by dropping off a tablet for participant use and collected later. See Appendix E for Study Issued Cell Phone/Tablet Agreement.

Phone visits will be conducted via a study or office phone or using the secure TelemedIQ app of study team members. If phone minute compensation below is insufficient to support participant phone access or a participant mentions they have no working phone, a study phone will be issued to participants. Participants receiving a phone will sign a Study Issued Cell Phone/Tablet Agreement (See Appendix E).

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. See Appendix F for a sample list of tools and educational materials that might be provided. Which tools and educational materials are given to which participants will be decided by the coach depending on participant need as well as the 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 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 follow-up 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.

5.2.1 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

5.2.2 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] She 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

5.2.3 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

5.2.4 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

5.2.5 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

5.2.6 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

5.3 Part 2 of the Study *Details of Part 2 of the study (Aim 3 randomized trial protocols) will be submitted in a future amendment.*

5.4 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.

5.5 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.

5.6 Rescue Medication Administration *Not applicable in this behavioral trial.*

5.7 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.

5.7.1 Early Termination Study Visit

Any participant who withdraws will have no further study visits.

6 STUDY EVALUATIONS AND MEASUREMENTS

6.1 Screening and Monitoring Evaluations and Measurements

Our pre-consent phone screening will closely parallel the phone screening we completed for focus group participants in our Aim 1 study (HSR#19-4622). This was efficient and well-tolerated by participants in a variety of housing circumstances in that study. The primary goal will be to ensure eligibility and interest in study participation. We will also ensure participant will be reachable for the 16 week study time frame. We will assess diabetes history, housing history, medication use, communication preferences/access, and also collect basic demographic data, (e.g. age, gender). See Appendix A for script and question structure.

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 (including Health Care for the Homeless). 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 Appendix H 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 permission will be sought to confirm this 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. Health-related Quality of Life (EQ-5)[102] 2. Kessler K-6 measure of psychological distress[103] 3. Mental Health Inventory (MHI-5)[115] 4. Health-related Quality of Life Short Form (SF-12)[116] 5. Diabetes Distress Scale (17-items)[104] 6. Problem Areas in Diabetes (PAID)[113] 7. Illness Intrusiveness Scale[112] 8. Treatment Burden questionnaire[114]

	9. Diabetes self-management questionnaire (DSMQ)[105] 10. Adherence to Refills and Medications Scales-Diabetes (ARMS-D)[111] 11. Self-reported medication adherence (Adherence Start with Knowledge, ASK-12)[106] 12. Basic needs survey[107] 13. Current and lifetime housing status 14. Use of substances 15. Brief Trauma Questionnaire[108] 16. 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 interview focused on experiences during participation from screening through final assessment visit. See interview guide in Appendix I

6.2 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.

6.3 Pharmacokinetic Evaluation *Not applicable*

6.4 Safety Evaluation

Subject safety will be monitored by adverse events and rates of early termination of the study. We will also follow safety protocols in case we identify dangerous blood pressure, or heart rate values at baseline or final assessment visits. See Section 8 for details.

7 STATISTICAL CONSIDERATIONS

7.1 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 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 point-of-care Hemoglobin A1c during this same time frame.

7.2 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.

7.3 Statistical Methods

7.3.1 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).

7.3.2 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 end-of-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 D-HOMES 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.

7.3.3 Pharmacokinetic Analysis *Not applicable.*

7.3.4 Safety Analysis *Not applicable since there is no control group in this study.*

7.4 Sample Size and Power

This sample size 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]

8 STUDY MEDICATION (*Not applicable)*

8 SAFETY MANAGEMENT

8.1 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.

8.2 Adverse Event Reporting

Unanticipated problems related to the research involving risks to subjects or others that occur during the course of this study and SAEs will be reported to the IRB in accordance with IRB Attachment EEE: 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, Busch, and Connett 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.

8.3 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.

8.4 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 (Appendix P). 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 (Appendix P).
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.
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.

9 STUDY ADMINISTRATION

9.1 TREATMENT ASSIGNMENT METHODS

9.1.1 Randomization or Other Assignment

No randomization will occur in this single arm trial.

9.1.2 Blinding

There will be no blinding.

9.1.3 Unblinding

Not applicable

9.2 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, 12/31/2023.
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, 12/31/2023. The other data will be retained for three years.

9.3 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).

9.4 Regulatory and Ethical Considerations

9.4.1 Data and Safety Monitoring Plan

This treatment development study (N=15), 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 and immediately brought to the attention of Dr. Connett (biostats. co-mentor). Dr. Connett has served on numerous DSMBs for large NIH trials. If needed, Drs. Busch and Connett 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.

9.4.2 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 by Dr. Busch, 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.
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 9.2 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 8.4 above for our detailed safety plan to address this risk.

9.4.3 Potential Benefits of Trial Participation

Potential benefits for participants include free diabetes management treatment 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.

9.4.4 Risk-Benefit Assessment

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

9.5 Recruitment Strategy

Recruitment of participants will begin with subjects from part 1 (HSR#19-4622). In that study 21 of the 26 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, we will include additional recruitment via personal invitations by shelter and clinic staff who often have long-standing, trusted relationships with participants. We will also include staff at hotels where shelter clients with chronic disease have been

relocated during the COVID-19 pandemic. We will provide flyers to these staff to share with eligible patients and/or to post in appropriate areas of their facilities. The flyer will include an email and phone number to invite interested patients to contact the research staff (Appendix J, Appendix P).

As a third approach, we will use snowball sampling. We will ask community partners and previous participants to distribute our study flyer to or refer friends/acquaintances who might be interested.

As a fourth approach, we will post our recruitment flyer in locations frequented by those experiencing homelessness (e.g., bus stops, shelter bulletin boards, libraries).

As a fifth 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] 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 by letter with a follow-up phone call—a method we've used successfully in the past to recruit unstably housed individuals (Appendix K, Appendix L). Care will be taken to ensure letters 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.

If needed, as a sixth approach we will use convenience sampling at healthcare and community sites. Study staff will go to sites with informational materials (ADA and CDC flyers and pamphlets), study flyers and low-glycemic snacks in order to engage with community members about the study face-to-face, and may schedule baseline assessments with interested persons (Appendix P). Information sessions will include both one-on-one conversations and tabling sessions that take place at a variety of healthcare and community settings with permission from each site's leadership, including Hennepin Healthcare facilities, Healthcare for the Homeless clinics, libraries, shelters, and community or social service agencies.

9.6 Informed Consent/Assent and HIPAA Authorization

We will collect signed consent and HIPAA authorization from all participants (Appendix M, Appendix N). 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 (Appendix C). 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 twelve-grade reading level or below. We will be getting feedback on the consent form and plan to submit a modification at a reduced reading level at a later date.
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.
If COVID-19 or other logistics necessitate, baseline visits 1 and 2 and treatment visit 1 will be conducted by phone or secure video platform (HHRI Zoom and/or HHRI/HCMC or Hennepin County Teams). See Appendix O for our e-consent protocol.

9.7 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

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

Reimbursement for travel/parking for in-person visits and phone minutes/text messages for virtual or phone visits be reimbursed at $10 cash per visit. This will be given to participants who decline a cab ride to any in-person visits. We will provide a $20 bonus payment for participants who complete all 10 scheduled treatment sessions. Maximum travel and data/minutes reimbursement is summarized below:

Baseline visit 1	Baseline visit 2	Tx visit 1	2	3	4	5	6	7	8	9	10	Final visit	**Total**
$10	$10	$10	$10	$10	$10	$10	$10	$10	$10	$10	$10	$20	**$140**

Note: If Baseline 2 + Treatment visit 1 happen concurrently, total will be $130.
Payment for treatment sessions will occur at each in-person visit. Phone visits will be reimbursed at the next in-person treatment or assessment visit or mailed or picked up at a homeless drop-in center per participant preference.

Further, participants who receive a study phone to facilitate their participation will receive $20 for return of the study phone and charging equipment at the end of the study.

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

Participants will be additionally reimbursed for study assessment visits at baseline and 12-weeks for their effort and inconvenience. This includes a finger-stick blood draw at each visit. We will compensate participants $30 for the baseline visits ($10 at visit 1 and $20 at visit 2) and $45 for the final assessment visit. Compensation will be in the form of cash. Maximum total compensation will be $75.
The amount and form of these payments were set with input and approval by our multi-stakeholder research team of people with lived experience and multi-disciplinary providers.

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11 APPENDIX (ATTACHED SEPARATELY)

Appendix A—Patient Screening Survey
Appendix B—Health Care for the Homeless letter of support
Appendix C—Consent quiz
Appendix D—Home visit safety protocol
Appendix E—Phone/Tablet Agreement
Appendix F—Tools and Educational materials
Appendix G—Biometric data
Appendix H—A1c results sheet
Appendix I—Final Assessment Interview
Appendix J—Recruitment flyer
Appendix K—Recruitment letter
Appendix L—Recruitment phone script
Appendix M—HIPAA authorization
Appendix N—Informed consent
Appendix O—eConsent protocol
Appendix P—Recruitment Postcard Flyer