Attachment UUU

Title:	**Development of the Diabetes Homeless Support (D-Homes) Program – Part Three**
Drug or Device Name(s):	Not applicable (N/A)
FDA IND/IDE	N/A
NCT Number	NCT05258630
Sponsor:	The National Institute Of Diabetes And Digestive And Kidney Diseases of the National Institutes of Health under Award Number K23DK118117
Protocol Date:	05/19/23
Revision Date(s):	

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PROTOCOL SYNOPSIS

Study Title	**The Diabetes Homeless Medication Support (D-Homes) Program – Part Three**
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. 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. 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. We will consider the study feasible if we enroll 75% of those screened who meet inclusion criteria, and 75% of enrolled participants complete at least one follow-up. We will consider 50% session attendance as indicative of feasibility. We will consider the intervention acceptable if 70% of participants are satisfied and would recommend it to others. The goal of the current study is to conduct a randomized pilot trial of the D-HOMES program. D-HOMES is a coaching-based collaborative care intervention tailored to DH using behavioral activation, motivational interviewing and psychosocial support to improve medication adherence. We will compare this to brief diabetes education and referral to meet medical and psychosocial needs. Our team's central hypothesis is that medication adherence, glycemic control, health care use/cost will improve with D-HOMES more than in our comparison. This pilot trial is under-powered to assess efficacy and focuses on recruitment, retention, blinding, and randomization procedures.
Study Objective(s)	**Primary**

	• To conduct a randomized pilot trial of the D-Homes intervention **Secondary** • To refine efficacy measures for future D-Homes evaluation
Test Article(s)	D-HOMES behavioral intervention to support medication adherence
Study Design	Randomized pilot trial
Subject Population **Key Criteria for Inclusion and Exclusion:**	We will enroll adults (age ≥ 18 yrs.) with type 2 diabetes who have experienced homelessness. **Inclusion criteria:** 1. Age 18 yrs. or older 2. English-speaking 3. Recent homelessness by federal definition (HEARTH ACT) a. Any housing instability in the last 12 mo. (includes supported housing or worry about paying rent) b. Significant housing instability in the last 24 mos. (includes any stay in shelter, outside, or places not meant for human habitation) 4. Self-reported diagnosis of type 2 diabetes with A1c ≥7.5%, later verified in medical record and study point-of-care lab. test 5. Plan to stay in local area or be reachable by phone for the next 24 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 people.
Number Of Subjects	Total Number of Subjects: 54 Total Number at Hennepin Healthcare: Unknown Total Number of Sites: 1 (Hennepin Healthcare)
Study Duration	Each subject's participation will last 24-30 weeks. The entire study is expected to last up to 24 months.
Study Phases **Screening** **Intervention**	1. Screening: screening for eligibility and consent, baseline assessment 2. Randomization to: a. Intervention: study intervention with weekly coaching support in person and/or by phone x 12 week

	b. Comparison: one-time diabetes education session
Follow-Up	3. Follow-up 1: 12-16-week follow-up assessments and A1c Follow-up 2: 24-30-week follow-up assessments and A1c
Efficacy Evaluations	• Satisfaction with trial, recruitment, retention rates • Hemoglobin A1c measured by point-of-care fingerstick or venipuncture • Self-reported medication adherence • Self-reported psychological wellness • Self-reported diabetes self-management, distress • Height, weight, blood pressure
Safety Evaluations	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 values during assessment visits
Statistical And Analytic Plan	We hypothesize a satisfactory, feasible, acceptable intervention with adequate recruitment and retention rates. We may see early indicators of improvement in efficacy measures of adherence, glycemic control, and wellness among intervention participants compared to comparison. We will consider the study feasible if we screen 50% of those referred, enroll 75% of those screened who meet inclusion criteria, and 75% of participants complete follow-up. We will consider 70% session attendance as indicative of feasibility. We will consider the intervention acceptable if 70% of participants are satisfied and would recommend it to others. We will use generalized linear models to compare changes in A1c and medication adherence over time in intervention vs. comparison groups according to the ARMS-D measure of diabetes medication adherence while controlling for baseline differences and changes in housing status over time. Adherence will also be examined with pharmacy refill data (continuous medication gap for non-insulin diabetes medications 0-1.0).[92] We will use an intention-to-treat approach including all randomized participants; multiple imputation[93] will generate data for those lost to follow-up. Similar modeling approaches will compare psychological wellness, and other biometric and patient-reported outcomes.
Data And Safety Monitoring Plan	Dr. Vickery (PI) will work closely with study staff to monitor the quality of data collected at assessment. This pilot trial (N=54), 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 ASSESSMENT PROCEDURES

Study Phase	**Eligibility screening**	**Consent, Baseline visit #1**	**Run-in, Baseline visit #2**	**Follow-up visit #1**	**Follow-up visit #2**
Visit Number		**1**	**2**	**3**	**4**
Study Weeks, approximate	**0**	**1**	**2-3**	**12-16**	**24-30**
Confirm communication preferences	X	X		X	X
Review Inclusion/Exclusion Criteria	X	X	X		
Informed Consent		X			
Demographics/Medical History/Medication List		X	X		
Medical records and insurance access permissions		X			X
Biometrics: BP, Height, Weight, Hemoglobin A1c (fingerstick/venipuncture)		X	X	X	X
Medication review		X	X	X	X
Self-report survey measures:					
Mental Health Inventory (MHI-5)[115]			X	X	X
Health-related Quality of Life Short Form (SF-12)[116]			X	X	X
Problem Areas in Diabetes (5-item PAID)[113]			X	X	X
Diabetes self-management questionnaire (DSMQ)[105]			X	X	X
Adherence to Refills and Medications Scales-Diabetes (ARMS-D)[111]			X	X	X
Self-reported medication adherence (Adherence Starts with Knowledge, ASK-12)[106]			X	X	X
Basic needs survey[107]		X		X	X
Lifetime housing status		X			
Current housing status, 30 day recall		X		X	X
Use of substances (ASSIST)		X		X	
Self-reported health care use (NHANES)		X		X	X
Discrimination in Medical Settings Scale [117]		X			
Client Satisfaction Questionnaire (CSQ-8) [95]				X	

TABLE 2: SCHEDULE OF STUDY TREATMENT PROCEDURES

Intervention group,	**Comparison group,**
10 weekly coaching offered over 12 weeks Session #1 in-person on day of baseline assessment visit 2 Sessions #2-10 offered in-person or via phone/video Monthly booster calls from 12-24 weeks	1 educational session (15-30 min.) offered in-person on day of baseline assessment visit 2 Monthly calls to retain contact from weeks 3-30

2 BACKGROUND INFORMATION AND RATIONALE

OVERVIEW

This protocol is for the third and final part of a set of studies with an overall goal to develop and pilot test the Diabetes Homeless Medication Support (D-Homes) program. D-Homes is 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 part 2 (HSR #20-4863). Part 2 was a single arm treatment development trial that tested the feasibility and acceptability of study procedures and refined the D-Homes treatment manual through test cases (n=10-15). We found the D-Homes manual and study procedures are feasible and acceptable to DH as measured by self-report and post-treatment interview but that treatment engagement lessened for participants with the highest degrees of housing instability.

This protocol describes part 3, a fully randomized pilot study in concordance with study Aim 3.

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**

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)

significant early hyperglycemia despite later glucose normalization.[25] While homelessness and unstable housing are increasingly recognized for 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

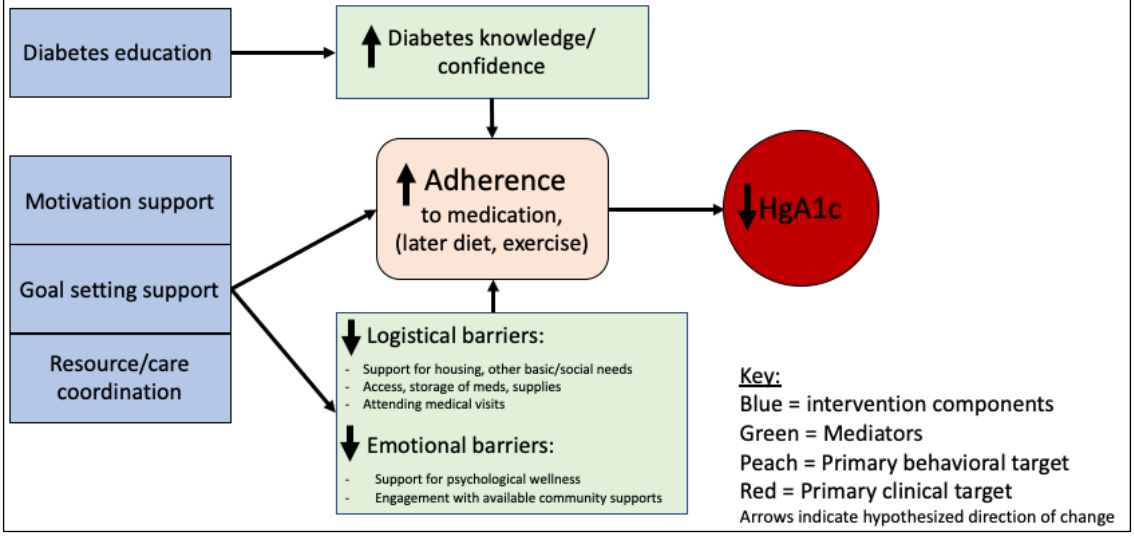
homeless,[49] and has improved medication adherence in non-homeless people with diabetes[50,51] including when delivered by trained, non-mental health professionals to low-income populations.[52] We will use BA first and employ MI when participants demonstrate ambivalence to change.

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 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 conduct a randomized pilot trial of the D-Homes intervention. This will support our ultimate goal to determine the efficacy of this 10-session behavioral activation and motivational interviewing support program for DH in a future, fully-powered study. The outcomes we will use to assess this pilot phase of our work will be participant satisfaction, our ability to recruit and retain participants, the acceptability and process of the comparison group, and follow-up until a 24-week final assessment visit.

3.2 Secondary Objectives (or Aim)

The secondary objectives will be to refine efficacy measures for future D-Homes evaluation

We will:

- Assess the acceptability of patient-reported outcome measures to detect changes at follow-up visits #1 and #2 (24-30 weeks).
- We will establish and refine laboratory testing protocols for use of a consistent point-of-care A1c machine which our team will control

4 INVESTIGATIONAL PLAN

4.1 General Schema of Study Design

This is a randomized pilot trial to inform development of the D-HOMES behavioral treatment, see Tables 1 and 2 above. The intervention, see Figure 2 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) referral from Health Care for the Homeless, Hennepin Healthcare, supportive housing providers, or other community organizations, (2) snowball sampling using advertisements (flyers, video), word of mouth, and referrals via community partners and previous participants, (3) community advertisement using flyers in places such as bus stops, libraries, and shelters, and (4) invitation letters and follow-up calls to eligible patients at Hennepin Healthcare, (5) invitation letters and follow-up phone calls to eligible Hennepin County clinic patients at Health Care for the Homeless and other willing sites. Per review by the County's internal research review committee (IRRC), these letters and calls will be generated by county employees and handed over to research staff once interested participants are identified, (6) tabling events with study flyers and snacks at Hennepin Healthcare, Health Care for the Homeless facilities, supportive housing or community partners such as libraries, shelters, and drop-in homeless service centers. Potential subjects will be screened in-person or 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 in both the intervention and comparison groups.

4.1.2 Study Intervention

This study will be offered to willing participants as an adjunctive to usual diabetes care. No prescriptions will be changed by study staff. Throughout the study, 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 treatment sessions or requested to end their sessions early. Since the emphasis of this pilot trial 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

Participants will be randomized to either the intervention or a control group (1:1). Randomization will be stratified by housing type (unstable (e.g., shelter, staying outside) vs.

more stable (e.g., worry about rent payment, supportive or transitional housing)). Randomization will occur after baseline assessment visit #2 via REDCap. Staff who conduct who conduct the follow-up assessment visits will be blind to condition.

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. Intervention participants 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. Intervention participants will receive monthly booster calls from coaches after weekly coaching ends through week 24 post enrollment. Comparison participants will engage in a one-time diabetes education session. Comparison participants will receive monthly check-in calls by study staff to update contact information beginning at 6 weeks through week 24. All participants will also complete a two follow-up assessment visits. To maximize participation, these follow-up visits can occur 1 week after intervention and up to 30 weeks after enrollment.

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

Enrollment for the study will continue until 54 participants have been enrolled.

HHRI will serve as the only site for this study.

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

This study focuses on adults experiencing type 2 diabetes who have experienced recent homelessness per the HEARTH Act definition (Box). 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 2 of this study (HSR#20-4863). See *Consent Quiz*.

Furthermore, we will continue working closely with community providers in this area and our 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 in their annual consent process through the health system will contacted about the study although they will be allowed to participate if they reach out to study staff in response to flyers or other community invitations.

4.5 Inclusion and Exclusion Criteria

4.5.1 Inclusion Criteria

Inclusion criteria:

1. Age 18 yrs. or older
2. English-speaking
3. Recent homelessness by federal definition (HEARTH ACT)
    a. Any housing instability in the last 12 mo. (includes supported housing or worry about paying rent)

   b. Significant housing instability in the last 24 mos. (includes any stay in shelter, outside, or places not meant for human habitation)
4. Self-reported diagnosis of type 2 diabetes, later verified in medical record
5. Verification of hemoglobin A1c value at or above 7.5% by study-administered test at baseline 1 visit
6. Plan to stay in local area or be reachable by phone for the next 24 weeks
7. 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 people.

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 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, A1c results, 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 months. If patients are found not to have diabetes at this point, they will be excluded from the study. We will also process their point-of-care A1c after visit #1 to ensure eligibility.

If patients are confirmed to be eligible based on medical record review, we will proceed with baseline visit 2 which can be done remotely or in-person.

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

- Review Inclusion/Exclusion Criteria
- Informed Consent, HIPPA authorization
- Demographics/Medical History/Medication list
- Release of information for health systems used in last 12 mo.
- Release of information for insurance claims data in the last 12 mo.
- Biometrics: BP, height and weight, hemoglobin A1c (A1c)
    - Alc testing involves the collection of a 1.5 μL blood sample via fingerstick or venipuncture
- Patient-reported outcome survey items (See Table 1)

5.2 Study Intervention

For participants randomized to the intervention group, they will be offered 10 coaching sessions over 12 weeks. These will be conducted in-person, via secure video, and/or by phone-based per participant preference and COVID-19 safety protocols. The treatment will center on providing diabetes education, motivational and goal-setting support, and resource and care coordination (Figure 2).

In-person assessment visits will be conducted at private spaces convenient to the participant including Hennepin Healthcare, Health Care for the Homeless sites, or at participant homes (see *Home Visit Protocol*).

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 that may include the participants home

Video visits will be conducted via a secure Zoom or Teams link (using HHRI, Hennepin Healthcare, and/or Hennepin County HIPAA secure technology) or Facetime if the participant is using an Apple device.

Phone visits will be conducted via a study or office phone or the PI's work phone. If participants have no working phone, a study phone will be issued to participants and will sign a Study Issued Cell Phone/Tablet Agreement (See *Phone/Tablet Agreement*).

Psychological approaches of behavioral activation and motivational interviewing will be used along with provision of educational materials and tools to support behavior change (See *Tools and Education Materials*). Coaches will tailor which tools and educational materials are given to which participants 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 tools ranges from $4.99 (glucose log book) to $17.91 (Adhesives for Continuous Glucose Monitor).

Approved communication channels will be used to support participant's goal setting (e.g. reminders) and arrange study related visits.

Participants will be offered up to 10 treatment visits over 12 weeks and monthly booster calls from weeks 12-24.

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 medication adherence and 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)
- Assess existing diabetes care team; refer 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, calendar; see *Tools and Education Materials* 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 to maintain long-term diabetes adherence goals

5.2.6 Intervention group booster calls

Interventionists will offer monthly booster calls after the end of the intervention period (approx. 12-14 weeks post-enrollment), and prior to the follow-up assessment visit #2. Contact will be limited to a once-monthly to reinforce planned behavioral activation goals, update participant contact information, and arrange final follow up visit.

5.2.7 Comparison Group

Participants randomized into the comparison group will receive one 15 to 30-minute diabetes education session. Interventionists (coaches) will read the content of 3 diabetes educational handouts about (1) general descriptions of type 2 diabetes, (2) healthy eating, and (3) physical activity. Handouts are produced in alignment with American Diabetes Association guidelines by a community group (https://learningaboutdiabetes.org/) and have been used in previous diabetes behavioral trials[118] with participants in low-income situations. Participants will receive a standard pillbox at this visit. Participants will receive a resource sheet with referral information to establish health care, mental health support, or to access local resources for housing, food, and other basic needs.

Comparison group participants will be contacted by the study staff (non-interventionists) once-monthly starting 4 weeks after their education session through the final assessment visit. Booster calls will update participant contact information and remind them of the timeline for follow-up assessments.

5.2.8 Follow-up Assessments

The follow-up assessments will be completed by a blinded research staff member. The staff person will assess:

- Vital Signs: BP
- Height and Weight
- Hemoglobin A1c
- Medication review
- Patient-reported measures, see Table 1 for timeline and specific measures

5.3 Unscheduled Visits

Contact between the study team and participant during the 24-week study period will be encouraged. This will include reminders of study-related assessments and coaching visits.

The interventionist will work with intervention participants 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.

Study staff will respond to participant-initiated communications from comparison group participants. They will refer participants to locally available resources on the handout for any expressed needs.

Should communications become too frequent or surpass agreed upon boundaries with any participants, staff will be guided to set boundaries and limit contact by Drs. Vickery and/or Busch.

5.4 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 via self-report.

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

5.6 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 adverse events (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.

5.6.1 Early Termination Study Visit

Any participant who withdraws will be contacted by the PI to be offered the opportunity to complete any outstanding assessment visits with compensation.

6 STUDY EVALUATIONS AND MEASUREMENTS

6.1 Screening and Monitoring Evaluations and Measurements

Our pre-consent phone screening will closely parallel the phone screenings used in previous parts of this study. This has been 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 24-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 *DH Aim 3 Screener Script* for question structure.

During the baseline and follow-up assessment visits data will be collected using the following procedures:

Demographics/ Medical History	Participants will be given a verbal survey at either the Baseline 1 or Baseline 2 visit to add to data collected in pre-consent screening. Topics will include: health insurance, education, medical history, and current living situation.
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 • History of hemoglobin A1c: Mo./year, results of tests After the follow-up assessment visits, we will review and abstract any changes in: • Medication list, dose, frequency, and prescriber • History of medication refill frequency • History of hemoglobin A1c: Data and results of tests
Insurance company claims data	We will collect data from health insurers including Minnesota Medical Assistance. We will work directly with Hennepin County per instructions of the 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 explore the feasibility of using pre-established protocols to examine hospitalizations for hyper and hypoglycemia.[109]
Biometric data	The following biometric data will be collected from participants at baseline and both follow-up assessment visits. See *Biometric Data* for detailed information on how these will be measured: • Blood pressure • Height • Weight • Hemoglobin A1c--Participants will receive a copy of their results. See *HgA1c Result* for A1c results sheet.
Medication review	Patients will be asked to bring a list of 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.
Patient-reported survey measures	Formal assessment surveys will be collected at Baseline and follow-up assessment visits as described in Table 1.
Satisfaction with intervention	At the 16-week 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]

6.2 Efficacy Evaluations

Although our study is not fully powered to detect efficacy, we will collect the following eventual efficacy measures to prepare for later, fully-powered testing at baseline and both follow-up assessment visits (Table 1):

- Hemoglobin A1c (primary)
- Adherence to diabetes medications (ARMS-D) (secondary)
- Adherence to all medications (ASK-12) (secondary)
- Diabetes self-care (DSMQ) (secondary)
- Difficulties with diabetes management (PAID) (secondary)

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 follow-up assessment visits. See Section 8 for details.

7 STATISTICAL CONSIDERATIONS

7.1 Primary Endpoint

The primary endpoint of this study is the satisfaction of participants in this pilot randomized trial (via CSQ-8).

The feasibility and acceptability of study protocols for recruitment, retention, and randomization are also important. We will assess this by measuring our ability to recruit and retain participants, and the assessment and treatment visits we can deliver (i.e., participant's attendance and follow-up with scheduled sessions and treatment activities). 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 consider the study feasible if we enroll 75% of those screened who meet inclusion criteria, and 75% of enrolled participants complete at least one follow-up. We will consider 50% session attendance as indicative of feasibility. We will consider the intervention acceptable if 70% of participants are satisfied and would recommend it to others.

We will also analyze our primary clinical endpoint of change in A1c between intervention and comparison groups between baseline follow-up visit #1 (approx. 12-16 weeks)

if it changes from baseline to between intervention.

7.2 Secondary Endpoints

Secondary endpoints will include the following changes from baseline to follow-up visit #1 (approx. 12-16 weeks) between intervention and comparison groups.

- Psychological wellness (SF-12, MHI-5)
- Adherence to diabetes medications (ARMS-D) (secondary)
- Adherence to all medications (ASK-12) (secondary)
- Diabetes self-care (DSMQ) (secondary)
- Difficulties with diabetes management (PAID) (secondary)

Secondary endpoints will also include change from baseline to follow-up visit #2 (approx. 24-30 weeks) of A1c to assess sustained change of our primary endpoint.

We will also complete exploratory analyses on the change from baseline to follow-up visit #2 of:

- Adherence to diabetes medications (ARMS-D)
- Adherence to all medications (ASK-12)
- Diabetes self-care (DSMQ)
- Difficulties with diabetes management (PAID)

Exploratory analyses will further measure changes from baseline to follow-up visits #1 and #2 of other self-reported and claims-measures will be assessed including housing status, substance use, and other biometric measures (BP, BMI). Exploratory analyses will also compare self-reported adherence measures (ARMS-D and ASK-12) to measures built from medication refill patterns in insurance claims.

7.3 Statistical Methods

Statistical support for this trial will be provided by Dr. Connett and Mr. Evans via the Biostatistical Design and Analytics Center (BDAC) at UMN.

7.4 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).

7.4.1 Efficacy Analysis

We will use summary statistics (mean, standard deviation) to examine CSQ-8 scores for all participants. We will use t-tests to examine the differences in CSQ-8 scores between the intervention and comparison groups; we hypothesize no difference. We will also examine the experiences of White vs. Black, Native American, and Hispanic participants. We will also generate summaries of the age, gender, and race/ethnicity of people at the highest and lowest quintiles of CSQ-8 scores.

We will use generalized linear models to compare changes in A1c and medication adherence (ARMS-D and ASK-12) over time in intervention vs. comparison groups. We will control for baseline differences and changes in housing status over time. Adherence will also be examined with pharmacy refill data which we will compare to self-report (ARMS-D and ASK-12).[92] We will use an intention-to-treat approach including all randomized participants; multiple imputation[93] will generate data for those lost to follow-up. Similar modeling approaches will compare psychological wellness, blood pressure, and health care use outcomes.

7.4.2 Pharmacokinetic Analysis *Not applicable.*

7.4.3 Safety Analysis

We will complete quarterly data reviews to examine safety events in the intervention and comparison groups. Dr. Connett will advise us if any changes to the existing study protocol are needed to ensure patient safety.

7.5 Sample Size and Power

This sample size is appropriate for the goal of feasibility and acceptability of the intervention. This is in line with ongoing studies by Dr. Busch (HSR#17-4351) as well as the current literature.[110]

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

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 any reported safety events and determine subsequent action. Any subsequent action will be documented and reported to the HHRI IRB and the Program Officer at NIH.

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 (See *Resource List*). 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 (See *Resource List*).

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 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 Randomization will occur at the 2nd baseline visit, and will be done using a pre-generated randomization schedule in REDCap. Randomization will be stratified into 2 strata based on severity of housing instability: "unstable" (e.g., living in shelter, staying outside) and "more stable" (e.g., history of homelessness that's now resolved, worry about rent payment, subsidized housing).

9.1.2 Blinding Staff who conduct the follow-up assessment visits will be blind to condition.

9.1.3 Unblinding Multiple staff members will be trained in how to complete the outcome assessments. In the event that a staff member is unblinded during the first follow-up assessment visit, a different blinded assessor will complete the 24-week visit.

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. If needed due to Covid-19, we will follow our HHRI-approved e-consent procedures (see *Consent/Assent Documents*).

Data from self-reported survey items administered during screening interviews and assessment visits will be entered and stored in REDCap. If needed (e.g. no available wifi at community screening event), paper copies will be used. Physical copies such paper 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 will be audio recorded and reviewed during coach supervision meetings with Drs. Vickery and Busch. 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, 12/31/2024.

Since assessment visits may 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, 12/31/2024. 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. If request for data is received, we 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 which will not include PHI.

9.4 Regulatory and Ethical Considerations

9.4.1 Data and Safety Monitoring Plan

This treatment development study (N=54), does not meet NIH criteria requiring a Data Safety Monitoring Board (DSMB) due to the small sample size and 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 support with a goal of improved diabetes self-management which can reduce their morbidity from this disease. Free counseling related to psychological wellness may reduce depression symptoms, stress, and 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 this study.

9.5 Recruitment Strategy

We will use a variety of recruitment methods throughout our study to identify participants:

1. We will include use the electronic health record system at Hennepin Healthcare. We will ask staff in the Analytics Center for Excellence to use the existing homeless indicator,[49] 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 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 (see *Recruitment Materials: Letter*) 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.
2. We will recruit participants via personal invitations staff at local service delivery sites for people experiencing homelessness. This includes Health Care for the Homeless and other Hennepin County public health clinics and housing workers as

well as community organizations offering rent and housing support in our region. We will provide flyers to these staff to distribute to their clients and/or to post in appropriate areas of their facilities. The postcard flyer will include an email and phone number to invite interested patients to contact the research staff (see *Recruitment Materials: Flyer*). We will also support these partners to send letters (see *Recruitment Materials: Letter*) to eligible participants and to call them in follow-up. We will also support partners to share our recruitment video (see uploaded video file) with their patients, clients, and within their own communication channels. When interested participants are identified, they will be passed along to our study team via email or study phone.

3. 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.
4. We will use convenience sampling at health care and community housing sites. Study staff will go to sites with informational materials about diabetes, study flyers, hygiene kits, study-branded promotional materials (pillboxes, socks, etc.), and low-glycemic snacks in order to engage with community members about the study face-to-face. This may include screening on-site with fingerstick A1c testing, which is independent of research protocols, and scheduling of baseline assessments with interested persons. Our recruitment video may be played at these events. 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, housing facilities, and community or social service agencies.
5. We will post our flyer in locations frequented by those experiencing homelessness (e.g., bus stops, drop-in centers, shelter bulletin boards, libraries, etc.).

9.6 Informed Consent/Assent and HIPAA Authorization

We will collect signed consent and HIPAA authorization from all participants (see *Consent/assent documents*). 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 insurance 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 (see *Consent Quiz*). This quiz will be administered orally and 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.

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 a patient prefers to work remotely or Dr. Vickery deems remote work preferred for public health reasons, baseline visits 1 and 2, treatment visits, and outcome visits can be conducted by phone or secure video platform (HHRI Zoom and/or HHRI/HCMC or Hennepin County Teams). See *Consent/assent documents* 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 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 will happen at each in-person visit.

For in-person coaching or assessment visits at Hennepin Healthcare, participants will receive 2 bus tokens, $5 for street parking, or a parking voucher for the hospital ramp. In the case that a participant who has already screened into the study asks for transportation reimbursement prior to their first enrollment visit, we will mail them two bus tokens or arrange transportation for the participant.

We will provide monthly reimbursement for phone minutes/text messages. For participants using their own personal phone, they will receive a monthly stipend to support their phone bill. They will be paid up to $120 over 6 months either as a cash payment or via ClinCard. Participants without a personal phone will be provided with a study phone to use for the 6 months of the study (no stipend).

	Study phone provided for your use *OR*					
Use your own phone with monthly stipend	Mo. 1	Mo. 2	Mo. 3	Mo. 4	Mo. 5	Mo. 6
	$20	$20	$20	$20	$20	$20

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

Participants will be additionally compensated for all four study assessment visits for their effort and inconvenience. This includes a fingerstick blood draw with research staff or the option of a fingerstick or veinous blood draw at the CSC 2 lab at visits #1, 3, and 4. We will compensate participants with either cash or via ClinCard using the following schedule:

	Assessment Visits

	#1	#2	#3	#4
Assessment Payment	$20	$30	$40	$60

Maximum total compensation will be $150.

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. In the case that the specimen from visit #1,3, or 4 clots, we will offer an extra $10 to repeat the fingerstick or veinous blood draw at the lab. We will offer this $10 once for each assessment visit that requires a blood draw (three total).

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11 APPENDICES (ATTACHED SEPARATELY)

Study Protocol
Consent/assent document(s)
HIPAA authorization for research form
Data Collection Instruments: DH Aim 3 All Assessment Qs
Data Collection Instruments: DH Aim 3 Screener Script
Recruitment Materials: Flyer
Recruitment Materials: Letter
ACT checklist
Other Attachments
- Biometric Data
- Consent Quiz
- Home Visit Protocol
- Phone/Tablet Agreement
- Tools and Education Materials
- HbA1c Result
- Resource List
- Payment Tracker