Attachment UUU

Title:	*Development of a multiple health behavior change intervention for cardiovascular risk reduction among people experiencing homelessness: The CV-HOMES study (Aim 2)*
Drug or Device Name(s):	Not applicable (N/A)
NCT	NCT06025721
Sponsor:	The C2DREAM Study (P50MD017342) via the National Institute for Minority Health and Health Disparities (NIMHD).
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Protocol Synopsis

Study Title	*Development of a multiple health behavior change intervention for cardiovascular risk reduction among people experiencing homelessness: The CV-HOMES study (Aim 2)*
Funder	National Institute on Minority and Health Disparities (P50MD017342): C2Dream pilot grant
Clinical Phase	N/A
Study Rationale	**People experiencing homelessness die on average 10 years earlier than their housed peers due to poorly controlled chronic physical and behavioral health conditions. Cardiovascular (CV) disease is a leading cause of death among people experiencing homelessness resulting from modifiable health behaviors.** High risk behaviors are more common among people experiencing homelessness with high rates of smoking (e.g., 73-79%) and low rates of fruit/vegetable intake (e.g., 64% <5 servings/day) and inadequate physical activity (e.g., 46% do not meet recommended guidelines). Access and insurance barriers compound individual challenges leading to even lower rates of medication adherence than general U.S. population.
Study Objective(s)	**Primary** • Assess the feasibility and acceptability of CV-HOMES, a behavioral activation based coaching program targeting multiple health behaviors, for people who have experienced homelessness in a single arm treatment development trial (n=8). • Assess the feasibility of measuring cardiovascular risk in this population at 2 time points.
Test Article(s)	One-on-one behavioral activation based coaching intervention to support behaviors to improve cardiovascular health
Study Design	Single arm treatment-development and feasibility trial
Participant Population **Key Criteria for Inclusion and Exclusion:**	**Patient inclusion criteria** are: (1) Moderate to high CV risk defined as self-reported diagnoses by a medical professional of high blood pressure, high cholesterol, prediabetes, type 2 diabetes, or heart disease. (2) Experience of homelessness per the HEARTH Act which includes living in a supported housing facility (2011). (3) English-speaking, (4) and willingness to engage in coaching about changes to ≥1 health behavior related to cardiac risk that align with patients' personal CV risk behaviors. Medical diagnoses and medications will be confirmed in medical records after enrollment. **Patient exclusion criteria** will include conditions raising risk for coercion or limitation of capacity to ethically consent to research: (1) active intoxication, (2) active psychosis or dementia, (3) active legal commitment (per search of publicly available civil court records) or (4) pregnancy or lactation. This is aligned with previous studies by this team (K23DK118117). We will further confirm capacity to consent using a brief quiz (see attachments).
Number Of Participants	Total Number of Participants: 8

	Total Number at Hennepin Healthcare: 8 Total Number of Sites: 1
Study Duration	Each participant will be enrolled for 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	• Cardiovascular health as measured by the American Heart Association's Life's Essential 8 score.[18] This includes:
	  ○ Self-reported cardiovascular health behaviors (eating better, being more active, taking medications as prescribed, quitting tobacco, getting healthy sleep)
	  ○ Blood pressure and body mass index (height, weight)
	  ○ Cholesterol and Hemoglobin A1c measured by point-of-care fingerstick or veinous blood draw
	  ○ Skin carotenoid measurement by VEGGIE METER
	• Self-reported medication adherence
	• Self-reported psychological wellness
	• Self-reported drug and alcohol use
	• Self-reported health care use

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 cardiovascular health. We will refine our use of patient-reported outcomes for use in a future 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=8), does not meet NIH criteria requiring a Data Safety Monitoring Board (DSMB), however Drs. Vickery and Busch will oversee a detailed safety monitoring plan.

TABLE 1: SCHEDULE OF STUDY PROCEDURES

Study Phase	**Eligibility screening**	**Consent, Baseline assessment**	**Treatment sessions**										**Follow-up visit**
Visit Number			**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	
Study Weeks	**0**	**1**	**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											
Informed Consent		X											
Demographics/Medical History, experiences of discrimination		X											
Vital Signs: BP, HR		X											X
Height and Weight		X											X
Point of care LDL and blood glucose		X											X
Skin Carotenoids		X											X
Medication review		X											X
Self-report survey measures		X											X
Satisfaction with intervention													X

1.1 Introduction

The overall goal of this project is to expand our team's existing evidence-informed programs to specifically target multiple health behavior change to decrease the cardiovascular (CV) health risk of people experiencing homelessness in Minnesota and beyond. This is relevant to health disparities given the disproportionate number of Black, Indigenous, and other people of color (BIPOC) who are homeless. We plan a sequential exploratory mixed methods study design for treatment development familiar to our team from prior work (K23DK118117) with ongoing input from our community-engaged research team (Fig 2).

Aim 2. Assess the feasibility and acceptability of CV-HOMES for people who have experienced homelessness in a single arm treatment development trial (n=8). We hypothesize feasibility (e.g., recruitment, treatment engagement, retention) and acceptability (of study procedures and CV-HOMES treatment). This will include examining changes in the American Heart Association's Life's Essential 8 score as our targeted clinical outcome.

1.2 Relevant Literature and Data

People experiencing homelessness are disproportionately Black, Indigenous, and other people of color. For example, in Minnesota in 2018 an estimated 37% of adults experiencing homelessness identified as African American (compared to 6% of Minnesota adults) and 12% identified as American Indian (compared to 1% of Minnesota adults).[1] This results directly from structural racism in the form of discrimination in housing,[2] education, and employment leading to a substantial wealth gap between BIPOC and white Minnesotans.

People experiencing homelessness die on average 10 years earlier than their housed peers due to poorly controlled chronic physical and behavioral health conditions. Barriers to optimal health exist at multiple levels and throughout the life course of people experiencing homelessness.[3] In previous work we demonstrated disproportionately high rates of CV health conditions among Minnesotans who were homeless (e.g., in 2018 27% reported hypertension, and 11% heart disease). We also found high rates of behavioral health conditions (e.g., in 2018 57% reported a mental health diagnosis and 42% substance use). There CV conditions and behavioral health comorbidities overlap significantly.[4]

CV disease is a leading cause of death among people experiencing homelessness resulting from modifiable health behaviors. High risk behaviors are more common among people experiencing homelessness with high rates of smoking (e.g., 73-79%)[5] and low rates of fruit/vegetable intake (e.g., 64% <5 servings/day) and inadequate physical activity (e.g., 46% do not meet recommended guidelines).[6] Access and insurance barriers compound individual challenges leading to even lower rates of medication adherence than general U.S. population.

Current permanent supportive housing (Housing First) models offer substantial opportunity to reduce homelessness but fail to achieve health improvements. Minnesota's 2022-2023 Affordable Housing Plan commits more than $3 billion to affordable housing solutions aimed at ending homelessness.[7] The National Academy of Medicine concluded "no substantial published evidence as yet to demonstrate that PSH improves health outcomes or reduces health care costs."[8] A large trial in Canada specifically demonstrated that Housing First models of general support did not lead to sustained CV risk reduction over usual care,[9] suggesting that housing is necessary but not sufficient to change CV risk. This demonstrates a critical need to establish health behavior change models to reduce CV risk that are adjunctive to housing support.

Wellness coaching tailored to the overlapping physical, behavioral, and social needs of people experiencing homelessness offers promise to reduce health disparities.

1.3 Name and Description of Intervention

Intervention content. Behavioral activation (BA) is an empirically supported counseling treatment has its underpinnings in the behavioral model of depression. BA seeks to reconnect participants with sources of positive reinforcement via collaborative values-based goal-setting.[12] The core activity in BA is the careful setting of between session goals and a structured review of those goals in the following session. BA is distinct from many other empirically supported depression treatments in that providers without mental healthcare backgrounds can be trained to deliver BA with fidelity. BA has been successfully leveraged to simultaneously target health behavior engagement and mood amelioration in a variety of medical populations,[13,14] including research by our team. For example, Dr. Busch is conducting an ongoing RCT of a BA based treatment targeting mood and smoking cessation post-cardiac event, Dr. Vickery is leading an on ongoing randomized trial targeting medication adherence and psychological wellness in people with diabetes who are homeless, and both just published an open trial of multiple health behavior change in cardiac patients with depression. CV-HOMES will build off of these three existing manuals.[10] **The CV-HOMES manual will target ≥ 1 health behaviors to reduce CV risk (quitting or reducing tobacco use, medication adherence, physical activity, healthy eating, or sleep), psychological wellness, and referrals to meet social and behavioral needs.**

Consistent with our prior work, CV-HOMES will be delivered via 8-10 sessions spanning 12 weeks. Sessions 1-2 (50 minutes each) will be completed in-person whenever possible and sessions 3-10 (30 minutes each) will be completed in-person or by phone or videoconference per participant preference. CV-HOMES will be delivered by a bachelor's level providers (e.g., social worker, health educator) or higher providers. We will use 1-2 of such providers already employed in our research labs (Ella Strother, Jill Carter). Dr. Vickery will participate in coaching the first few participants and train and supervise interventionists throughout the trial with support from Dr. Busch as needed. Interventionists will be referred to as a "wellness coaches" per Quorum team feedback from our previous work. We will also notify the patient's primary care provider and any other patient requested providers (e.g., cardiologist, psychiatrist) of their study involvement.

CV-HOMES goal setting structure: Between session goal setting will focus on pleasant/valued activities to improve mood and goals directly aimed at improving relevant health behaviors. The patient and coach will collaboratively agree on goals that are individualized for the patient's context. Goals are set in manageable increments (to increase self-efficacy through early success), and reviewed in detail to problem-solve any barriers encountered. All goals are explicitly written down (e.g., to-do list, daily planner) or otherwise scheduled (e.g., entered into cell phone calendar). As needed and with permission, study staff will send an automated email or text message between sessions to remind the patient to complete their goals.

Health behavior (i.e., quitting or reducing tobacco use, medication adherence, physical activity, healthy eating, or sleep) goals will be set alongside mood-focused goals using the process above, as has been successfully done in previous studies.[13] If multiple health behaviors are relevant for a patient, they will be targeted sequentially. That is, coaching will initially focus on one behavior and if sufficient progress is made, the participant and coach will collaboratively decide if goals should be set targeting a second and/or third health behavior. We chose sequential targeting because simultaneous targeting of multiple health behaviors is cognitively demanding for the patient and

associated with increased drop-out.[15] Tools will be provided to participants to support health behavior goals (see Session 2 below).

The content of goals will be integrated to maximize both mood improvement and health behavior change. For example, for a participant trying to quit smoking, goals will be set to avoid contact with smoking triggers.

Treatment Fidelity. Coaches will complete treatment fidelity checklists. All sessions will be audio recorded. Dr. Vickery will monitor fidelity via review of all recordings and provide feedback to coaches during weekly supervision meetings. Audio recordings will be stored securely.

Baseline only measures. At baseline we will collect demographics to describe the sample. We will also collect the Discrimination in Medical Settings scale[16] given the high degree of discrimination found in previous data with this population and congruent with the larger C2DREAM grant.

Primary outcomes of this proof-of-concept, single arm, treatment development pilot trial are feasibility (e.g., recruitment, treatment engagement, retention) and acceptability (of study procedures and CV-HOMES treatment via satisfaction survey and post-treatment interview). Secondary outcomes will include efficacy measures we plan to use in a future randomized pilot study and eventual R01 randomized trial. Outcomes will be collected during screening and at a baseline and post-treatment assessment visits. We will examine feasibility by tracking success of planned methods of recruitment. We will track the ratio of invitations to screenings and screenings to enrollments. We will also examine treatment engagement and retention via the number of attended assessment visits and coaching sessions. We will use the 8-item Client Satisfaction Questionnaire and a 20 minute qualitative post-treatment exit interview to track acceptability of activities as has worked well in several prior trials by our team.[17]

1.4 Selection of Treatment Dosages

Treatment doses are similar to a multiple health behavior change intervention currently underway by Dr. Andrew Busch ("Development of an Integrated Depression and Behavioral Risk Factor Reduction Intervention for Secondary Prevention following Acute Coronary Syndrome," R03HL136540; "Multisite feasibility of BA-HD: An integrated depression and behavioral risk factor reduction coaching program following acute coronary syndrome," R34HL165716), primary mentor on this study. This is also in line with the prior work of our team in diabetes with a similar population (D-HOMES, K23DK118117) which has been acceptable to participants. During this treatment development phase we will monitor and adjust the number and duration of planned sessions based on the data from participants if needed.

1.5 Relevant References *See references at end of document.*

1.6 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 Participants 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 Participants during and after the study.

2 STUDY OBJECTIVES

The purpose of the study is to develop and pilot test a multiple health behavior intervention using behavioral activation to improve cardiovascular health for people who have experienced homelessness with elevated cardiovascular risk.

2.1 Primary Objective (or Aim)

The primary objective of this study is to determine whether a 10-session behavioral activation support program is feasible and acceptable to people with cardiovascular risk who have experienced homelessness. 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.

2.2 Secondary Objectives (or Aim)

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

- Clarify recruitment and retention strategies for people with cardiovascular risk who have experienced homelessness
- Assess the acceptability of patient-reported and biometric outcome measures including point of care laboratory protocols
- Refine protocols for incentives and tools to support intervention participation and behavior change

3 INVESTIGATIONAL PLAN

3.1 General Schema of Study Design

This is a single arm pilot trial to inform development of the CV-HOMES behavioral treatment, see Table 1 above. The intervention targets cardiovascular health and psychological wellness using goal-setting support, as well as resource and care coordination for people experiencing elevated cardiovascular risk and homelessness. The goal of this treatment development phase of our work is to refine approaches and protocols for further study of our program.

3.1.1 Screening Phase and Baseline Assessment

Recruitment protocols are summarized in section 9.5. Screening will be conducted by phone or in-person as requested by participants. It will focus on ensuring they meet inclusion criteria and assessing current health behaviors to inform which behaviors might be targeted by wellness coaches. Baseline assessment will consist of informed consent, self-reported survey items, and biometric data including cholesterol, A1c, and skin carotenoid measurement via VEGGIE METER. Blood samples for cholesterol and A1c will be collected by fingerstick and measured on the DCA Vantage, Cholestech, A1c Now Professional, or CardioChek Plus Analyzer (1-3 drops of blood). If the POC machines using small amounts of blood are malfunctioning, veinous blood draws (100 microliters) may be scheduled and collected for the study at the Healthcare for the Homeless or

Hennepin Healthcare labs. Participants will be informed of results in lab letter after appointment (2023.12.21 CV-Homes.LabLetter).

3.1.2 Study Intervention

This study will be offered to willing participants as an adjunctive to usual clinic-based health care. During the screening 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 cardiology appointment at Hennepin County Health Care for the Homeless, Hennepin Healthcare, or another clinic/health system of their choosing.

3.1.3 Follow-up

Participants who have completed their planned coaching sessions or requested to end their coaching sessions early will be contacted for a follow-up assessment. Participants will be informed of results in lab letter after appointment (2023.12.21 CV-Homes.LabLetter). Since the emphasis of this treatment development study is feasibility and acceptability, those ending early will be given particular attention during their post-treatment interview so that their insights and experiences can shape future adaptations to the intervention and study design.

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

3.3 Study Duration, Enrollment and Number of Sites

3.3.1 Duration of Study Participation

Participants will be screened and recruited over 1-2 weeks. They will engage in 10 weekly sessions over 12-weeks with our interventionist (“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.

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

Enrollment for the study will continue until 8 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. Catholic Charities offers space in the community for study related activities to minimize burden on participants. The study team will connect with other housing and community partners to identify community spaces if necessary.

3.4 Study Population

3.4.1 Use of Vulnerable Populations

This study focuses on adults experiencing moderate or high CVD risk and homelessness (CVH). This is justified given the premature morbidity and mortality of this population. While not formally considered a vulnerable population, CVH are a population requiring special attention regarding 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 Dr. Vickery’s other studies.

Furthermore, we will continue working closely with staff at Catholic Charities, other community partners, 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.

3.5 Inclusion and Exclusion Criteria

3.5.1 Inclusion Criteria

Inclusion criteria:

1. Age 18 yrs. or older
2. English-speaking
3. Have experienced homelessness or housing insecurity in the past 2 years
4. Self-reported diagnosis of moderate or high CVD risk, defined as being told by a medical professional that the participant has hypertension, hypercholesterolemia, prediabetes, type 2 diabetes, or heart disease
5. Plan to stay in local area or be reachable by phone for the next 16 weeks
6. Willingness to work on one or more CVD risk reduction behavior change identified during the screener. The behavior change meet specified qualifying criteria for each CVD risk behavior (below; also see Assessment table for exact wording of screening questions). (i.e., If the patient uses combustible tobacco products, they qualify and must be willing to work on quitting tobacco. If the participant qualifies for the study because they get less than 6 hours of sleep per night. They must be willing to work on getting more sleep as the focus of coaching.)
    a. Quitting tobacco: Any use of combustible tobacco in the last 30 days
    b. Taking prescription medications: Having daily prescriptions and reporting missed doses some, most, or every time they were due in the last 7 days; or wanting help getting prescription medications (e.g. medications advised in the past but not currently receiving).
    c. Getting healthy sleep: Sleeping <6 hours or >9 hours per night
    d. Moving your body: <3 days per week with 30 minutes or more of moderate physical activity
    e. Eating healthy: <5 days per week following healthful eating plan, getting 5 or more servings of fruits and vegetables, or >2 days per week eating high fat foods.

3.5.2 Exclusion Criteria

1. Active intoxication
2. Active psychosis
3. Presence of a legal guardian
4. Pregnant or lactating people

Patients who do not meet all enrollment criteria will not be enrolled. Any violations of these criteria will be reported in accordance with IRB Policies and Procedures.

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

Retain participants who become pregnant during the study:

Risk of withdrawing care: We have opted to retain participants who become pregnant after enrollment because a) we do not think interaction with a wellness coach poses greater than minimal risk and b) prematurely withdrawing the care of the wellness coach from a vulnerable population (pregnant people who are experiencing homelessness) poses a greater risk than continued participation.

Mitigation of risk: Our coaching is designed to adapt to the unique goals of each participant, and we recognize that people who become pregnant during the study will likely be working on their cardiovascular health with their care team. In the case that a participant becomes pregnant, we will ask the participant to sign a release of information so we can communicate with their OB, midwife, or other provider overseeing their pregnancy to ensure coaching goals align with the diet and wellness goals established by the provider.

4 STUDY PROCEDURES

4.1 Qualifying Visit

4.1.1 Eligibility, screening visit

As outlined in Table 1, before consent, interested participants will complete a phone or in-person 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.

4.1.2 Baseline Assessment

The baseline assessment will begin with the participant's signed consent. 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.
- Primary care team
- Biometric data including height, weight, blood pressure, skin carotenoids, hemoglobin A1c, and cholesterol levels.
    - Fingerstick (1-3 drops; collected by study staff) will be collected, run on point-of-care machines (e.g. Cholestech, DCA Vantage, A1C Now, CardioChek Plus), and then disposed of appropriately following the biometrics protocol for CV-Homes. In case of machine malfunction, veinous blood samples (100 microliters) will be scheduled for study participants and collected at HCH or Hennepin Healthcare labs.
    - Skin carotenoids will be measured using reflection spectroscopy by a non-invasive machine called the VEGGIE METER. As confirmed via email, the VEGGIE METER is a patented and validated piece of technology that has been used in NIH- funded research. There is a standard protocol for use which will be followed.
- Patient-reported outcome survey items and physiological measures: See Table 2

After consent and HIPPA authorization are obtained, study staff will access participants' medical records to confirm a diagnosis of one of the qualifying CVD risk conditions. If patients are found not to qualify at this point, they will be excluded from the study.

Table 2. Measurement and classification of Life's Essential 8 composite measure of CV health.[18]

LE8 Item	Measure	Scoring
Physical Activity	Measurement: Self-reported minutes of moderate or vigorous PA per week NHANES PAQ-K questionnaire	Metric: Minutes of moderate- (or greater) intensity activity per week Scoring: **Points. Minutes** 100 ≥150 90 120–149 80 90–119 60 60–89 40 30–59 20 1–29 0 0
Diet	Measurement: Self-reported daily intake of a DASH-style eating pattern; MEPA	Quantiles of DASH-style diet adherence: **Points MEPA score (points)** 100 15–16 80 12–14 50 8–11 25 4–7 0 0–3
Nicotine Exposure	Measurement: Self-reported use of cigarettes or inhaled NDS; NHANES SMQ	Metric: Combustible tobacco use or inhaled NDS use; or secondhand smoke exposure Scoring: **Points Status** 100 Never smoker 75 Former smoker, quit ≥5 y 50 Former smoker, quit 1–<5 y 25 Former smoker, quit <1 y, or currently using inhaled NDS 0 Current smoker Subtract 20 points (unless score is 0) for living with active indoor smoker in home; NHANES seems to define current as 30 days
Sleep health	Measurement: Self-reported average hours of sleep per night Example tools for measurement: "On average, how many hours of sleep do you get per night?"	Metric: Average hours of sleep per night Scoring: **Points Level** 100 7–<9 90 9–<10 70 6–<7 40 5–<6 or ≥10 20 4–<5 0 <4 Consider subtracting 20 pts if untreated or undertreated sleep apnea
Weight	BMI (weight [kg]/height [meters] squared on scales, stadiometers)	Metric: BMI (kg/m2) Scoring: **Points Level**

		100 <25 70 25.0–29.9 30 30.0–34.9 15 35.0–39.9 0 ≥40.0 Clinicians may want to assign 100 points for overweight individuals (BMI, 25.0–29.9 kg/m2) who are lean with higher muscle mass.
Blood pressure	Resting systolic and diastolic BP via standard measurement	Metric: Systolic and diastolic BPs (mm Hg) Scoring: **Points Level** 100 <120/<80 (optimal) 75 120–129/<80 (elevated) 50 130–139 or 80–89 (stage 1 hypertension) 25 140–159 or 90–99 0 ≥160 or ≥100 Subtract 20 points if treated level
Blood glucose	Blood analyzed via point of care/lab testing	Metric: HbA1c (%) Scoring: **Points Level** 100 No history of diabetes and HbA1c <5.7 60 No diabetes and HbA1c 5.7–6.4 (prediabetes) 40 Diabetes with HbA1c <7.0 30 Diabetes with HbA1c 7.0–7.9 20 Diabetes with HbA1c 8.0–8.9 10 Diabetes with Hb A1c 9.0–9.9 0 Diabetes with HbA1c ≥10.0
Total cholesterol	Blood analyzed via point of care/lab testing	Metric: Non–HDL cholesterol (mg/dL) Scoring: **Points Level** 100 <130 60 130–159 40 160–189 20 190–219 0 ≥220 If drug-treated level, subtract 20 points
LE8 Total Score	**Average of all 8 category scores (100-80 high CVH; 79-50 moderate CVH; 49-0 Low CVH)**	

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 based on participant and assessment surveyor feedback.

4.2 Intervention structure

This will be a 10 session, 12-week in-person, video, and/or phone-based support program with assessment for 2 weeks before and 1 week after treatment visits. The treatment will center on providing CVD health education, with a focus on behaviors to address modifiable risk, goal-setting support, and resource and care coordination. Modality of treatment delivery (in-person, phone, or video platform) will be adapted based on logistics by study team considering participant preference as well as safety in case of changes in the status of COVID-19 in our community.

In-person assessment and treatment visits will be conducted in private spaces at Catholic Charities' facilities, at sites convenient to participants, 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. Video visits will be conducted via a secure Zoom or Teams link (using HHRI or Hennepin Healthcare HIPPA secure technology). Phone visits will be conducted via a study cellphone or office phone or using the secure TelemedIQ app of study team members.

Psychological approaches of behavioral activation and motivational interviewing will be used along with provision of educational materials and tools to support behavior change. Which educational materials are given to which participants will be decided by the coach depending on participant need, learning preferences, and the specific goals that are mutually set.

Participants will each receive a tool of approximately $20 commercial value. Tools will be chosen by coaches and participants collaboratively to reinforce health behavior change goals. E.g. A participant with 10 medications per day may benefit from a pillbox with AM and PM slots, and a participant with many appointments for behavioral and physical health care may benefit from a pocket calendar. Some participants who choose to work on quitting smoking may select tools of nicotine lozenges or patches (see safety protocol, pregnancy in inclusion/ exclusion criteria). These tool choices are based on extensive qualitative development work with patients and providers (R03HL136540, Aim 1 interviews of this project).

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 secondary contacts.

While study visits may occur by phone, email communications will be limited to content only related to arranging details of when/where and how to connect with participants or sharing resources or educational materials with permission. Participants will provide their email addresses and provide signed consent to be contacted in this way. Privacy concerns and appropriate use of email 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 if we are not able to contact them by phone or email. Similarly, we will ask participants to identify medical and social service providers who would know their current contact information for them. Participants will be asked to sign appropriate releases of information to allow medical and social service providers to share this information with the study team.

4.2.1 Wellness coaching content

Session 1 will acclimate the patient to the coaching program and inform future goal setting. Coaches will collaboratively identify an initial health behavior target (i.e., eating better, being more active, taking medications as prescribed, quitting tobacco, or getting healthy sleep; the patient must be currently below recommended guidelines and willing to work on improvement), and provide self-monitoring activities to track mood and health behaviors. **Session 2** will include review of patient self-monitoring of mood, activities, and target health behavior, emphasizing mood/behavior relationships, a structured values assessment to identify life areas that the participant cares deeply about; this was adapted by our Quorum team for people experiencing homelessness. Values will be used to set 2-4 goals that can be completed before the next session Starting at session 2, participants will work with coaches to identify an affordable, commercially available behavior change tools related to their relevant health behavior and tailored to patient preferences and comorbidities as above. **Session 3-10** will follow the same format to assess wellness (mood), activity, and relevant health behavior between sessions, review adherence to goals from the previous session, address barriers, and choose 2-4 new between session goals. Starting in session 4 the collaboratively discussions will consider adding 1-2 relevant health behaviors.

In addition to the coaching tools submitted in the IRB, coaches will provide audio, video, or written materials based on participant interest and preferred learning style. These materials will be selected from the American Heart Association (https://www.heart.org/en/healthy-living/healthy-lifestyle/lifes-essential-8) and American Diabetes Association (https://diabetes.org/) directly or other respected partners who create easy-to-read handouts aligned with recommended guidelines (e.g., https://learningaboutdiabetes.org/ or https://www.diabeteseducator.org/living-with-diabetes/Tools-and-Resources).

4.2.2 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. See list of measures in Table 2 and Assessment Table.

4.3 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 CV health. 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 with guidance from Drs. Vickery and/or Busch.

4.4 Concomitant Treatment

All prior and concomitant primary care and cardiovascular care will be reviewed as needed to support study goals. Care for relevant co-morbidities (mental illness, substance use disorder, cardiac disease, etc.) will also be noted and encouraged as it aligns with participant psychological wellness or CV health (e.g., follow-up with psychiatry or cardiology).

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

4.6 Participant Completion/Withdrawal

Participants 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 participant completes or withdraws from the study, they will be recorded in the source documents and on the case report form.

4.6.1 Early Termination Study Visit

Any participant who withdraws will be contacted by Dr. Vickery to assess their desired level of participation. A final assessment visit with compensation will be offered to those who are willing to ensure we collect data about why the intervention or protocol did not meet their needs. Participants will have the right to decline this visit if they desire.

5 STUDY EVALUATIONS AND MEASUREMENTS

5.1 Screening and Monitoring Evaluations and Measurements

Our pre-consent phone screening (included in data collection materials) will closely parallel the phone screening used by Dr. Busch in a prior, similar study (HSR#17-4351). This was efficient and well-tolerated by participants in that study. The primary goal will be to ensure eligibility and interest in study participation.

During the baseline and final assessment visits, study staff will read questionnaire items out loud to participants and record information directly into REDCap. See our Assessment Table for a list of all measures.

5.2 Efficacy Evaluations

Efficacy is not the intended goal of this treatment development study. However, eventually the goal will be to impact patient CV health. The primary behavioral target to achieve this impact will be Life Essential 8 CV health composite measure. We will also examine specific behavior change for targeted health behaviors (e.g., Both of these endpoints will be measured, as detailed above, at the baseline and 12-week assessment visits during this single arm pilot.

5.3 Pharmacokinetic Evaluation *Not applicable*

5.4 Safety Evaluation

Participant 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, blood sugar, or heart rate values at baseline or final assessment visits. See Section 8 for details.

6 STATISTICAL CONSIDERATIONS

6.1 Primary Endpoint

Primary outcomes The primary endpoint of this study is the feasibility and acceptability of the program to participants in this treatment development phase. We will assess this by measuring our ability to recruit and retain participants, the dose of treatment we can deliver (i.e., participant's attendance and follow-up with scheduled sessions and treatment activities), and participants' report of their satisfaction and overall experience during participation in a structured survey (CSQ-8) and qualitative post-treatment interview. Secondary outcomes will include measures we plan to use in a future randomized pilot study (see Assessment Table).

Clinical Outcomes will occur at baseline and post-treatment. Our primary target is a composite measure of cardiovascular health developed by the American Heart Association, Life's Essential 8 (see Table 2).[18] All biometric data and self-reported items will be collected and stored in REDCap.

6.2 Statistical Methods

6.2.1 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). We will also collect data using the Discrimination in Medical Settings scale, which has been piloted in previous and current work (D-HOMES; D-HOMES-Spanish).[16]

6.2.2 Efficacy Analysis

The primary purpose of this study is feasibility and acceptability. This will be assessed using the following data:
Qualitative data Analysis of audio recordings of post-treatment interviews will be completed by listening to files and taking detailed notes to highlight satisfaction, treatment experience, and suggested changes of intervention participants.
Survey data from the Client Satisfaction Questionnaire (CSQ-8) will be summarized using descriptive statistics. Exploratory analyses by race and gender 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.

6.2.3 Pharmacokinetic Analysis *Not applicable.*

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

6.3 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]

7 STUDY MEDICATION

Participants who choose to work on quitting smoking with their coach will be provided with nicotine lozenges or patches. They will work closely with Dr. Vickery on dosages and will follow the CV-Homes safety protocol if participants mention adverse reactions. The study team will provide the first supply of Nicorette lozenges or patches up to $20 in value. Then, the PI or coach will work to support the patient in connecting with other sources of lozenges or patches through options such as their clinic, Health Care for the Homeless, or Quit Partner MN.

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

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

Drs. Vickery and Busch will collaboratively gather any information needed to investigate the event and determine subsequent action. Any subsequent action will be documented and reported to the HHRI IRB and/or C2DREAM grant leaders and/or 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, behavioral health walk-in center, and psychiatric emergency room. If non-urgent physical health needs arise in participants, study staff will provide written resources about health care available through Health Care for the Homeless and Hennepin Healthcare. If staff identify that a participant has a high A1c or high cholesterol level, they will encourage the participant to visit their primary care physician or provide a resource sheet so that the participant can select a clinic to visit. If a participant wants to use nicotine patches to quit smoking, coaches will educate the participant on proper use of the patch and symptoms to be aware of such as skin irritation, dizziness, rapid heartbeat, or upset stomach that may arise if a person smokes while using the patch. Coaches will

encourage participants to reach out to their primary care provider or regular clinic prior to using the patch if they have any concerns or significant comorbidities and if they experience symptoms such as chest pain or if they become pregnant.

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. In the case of suicidal ideation, study staff will use the SI Questionnaire to guide their approach to working with the participant and reach out to Dr. Vickery for support. These events 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.

All treatment sessions and post-treatment 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 Participant 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 study, 10/31/2024.

Since assessment visits will be conducted at locations away from the research offices, research staff will store all documents in a locked folder while moving between community locations and the office. Immediately after visits, consent forms, point of care test 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.

9.3 Confidentiality

All data and records generated during this study will be kept confidential in accordance with HHRI Institutional policies and HIPAA on Participant 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=8), does not meet NIH criteria requiring a Data Safety Monitoring Board (DSMB) and poses minimal risk to participants.

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 regular meetings with Dr. Busch. If needed, Dr. Busch will locate representatives independent of the study team for input.

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

If requested by NIH or our local IRB, a DSMB will be convened.

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 feel uncomfortable or experience minor bleeding or bruising as a result of the fingerstick or veinous blood draws. Some participants may also feel uncomfortable or distressed due to the collection of biometric data (e.g., weight). In previous studies by Drs. Vickery and 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.

Negative reaction to nicotine patch. Participants may choose to use the nicotine patch as part of coaching. Participants may experience skin irritation in the area where the patch is in contact with skin. They may also experience dizziness, rapid heartbeat, or upset stomach if the dose is too large or if they smoke while using the patch. They may also have vivid or strange dreams. Coaches will explain how to properly use nicotine patches and will encourage participants to reach out to their primary care providers before starting and if they experience chest pain or become pregnant while using the patch.

9.4.3 Potential Benefits of Trial Participation

Potential benefits for participants include free health coaching with a goal of improved cardiovascular health, which can reduce their morbidity and mortality if sustained. Free coaching related to psychological 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

Our primary method of recruitment will be referral from housing navigators or case managers working for Catholic Charities. This will begin with interview participants from Aim 1 who have already met study staff, provided their contact information, and indicated willingness to participate in coaching. We will also use snowball sampling to identify and screen interested people. We may also set up tabling events with study flyers and snacks at Catholic Charities' facilities or community spaces.

Potential Participants will be screened in person or by phone (see Assessment Table).

9.6 Informed Consent/Assent and HIPAA Authorization

We will collect signed consent and HIPAA authorization from all participants. The consent will also include HIPAA authorization to review their electronic health record at Hennepin Healthcare and any other systems where they have gotten care in the last year. Staff will review consent documents with participants and monitor their comprehension using teach back methods.

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

All questions will be answered by study staff and the voluntary nature of participation will be emphasized. Participants will be given up to thirty minutes to make the decision to participate and more time if requested. Those requesting more may be invited to reschedule their baseline enrollment visit. The consent form is written at the sixth-grade reading level or below.

If any participant appears to be under the influence of drugs or alcohol or unstable from a mental health perspective, or otherwise unable to consent, or if they fail the consent quiz, we will politely exclude them from participating.

If COVID-19 or other logistics necessitate, assessment and treatment visits will be conducted by phone or secure video platform (HHRI Zoom and/or HHRI or HCMC or Hennepin County Teams) and arrangements will be made for brief collection of biometrics in accordance with HHRI and/or Catholic Charities policy.

9.7 Payment to Participants/Families

Participants will be paid for their participation in several ways:

(1) For study visits that occur outside of participants' housing facility, reimbursement for parking or bus tokens will be provided.
(2) Monthly reimbursement for cell phone minutes or the use of a study provided phone

(3) Payment for time, effort, and inconvenience of assessment visits
(4) 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 that require patient travel will be paid via bus token or an HCMC parking voucher. Phone minutes/text messages for virtual or phone visits be reimbursed $20 per month.

Use your participant phone with monthly stipend	Mo. 1	Mo. 2	Mo. 3
	$20	$20	$20

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

Participants will be additionally reimbursed for study assessment visits at baseline and at the end of treatment for their effort and inconvenience. This includes a finger-stick blood draw at each visit. We will compensate participants $30 for their baseline visit and $60 for the final assessment. Compensation will be in the form of cash or ClinCard per their preference. Maximum total compensation will be $90. This is similar to other studies Dr. Vickery has completed with a similar population and congruent with recommendations from people with lived experience who advise this project. We have found this amount to be respectful while not being so high as to be coercive.

	Assessment visits	
	Baseline	Final
Assessment Payment	$30	$60

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.

We will also provide a $10 stipend if participants need blood re-drawn for either the baseline or final visit.

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