Diabetes Homelessness Medication Support Single Arm Treatment Development Trial

NCT04678284

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Title of Research Study: Development of the Diabetes Homeless Support (D-Homes) Program

Study Team Contact Information:
For questions about research appointments, the research study, research results, or other concerns, call or email the study team at:

- Investigator: Dr. Katherine Diaz Vickery / (612) 873-6852 / katherine.vickery@hcmed.org
- Study staff: (651) 508-3741 / DHomes@hhrinstitute.org

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KEY INFORMATION

We are asking you to be in our research study because you have diabetes and have experienced homelessness. This research study is being done to design a diabetes support program specifically for people who have experienced homelessness and to test if and how it works.

What will I need to do to be in this study?
You will be asked to complete the following visits over a period of 16 weeks (4 months):

Assessment Visit #1 + Assessment Visit #2
• We will ask you questions about your overall health, medication history, diabetes, wellness, substance use, basic needs, and housing status. • We will also review your medical and/or health insurance claims information. • We will ask for a fingerstick hemoglobin A1c test.
Coaching Sessions #1-10
• Your diabetes wellness coach will get to know you and help you set goals related to your diabetes.
Final Assessment Visit
• Same activities as Assessment Visit #1 + Assessment Visit #2. • We will also interview you about your experience participating in the research study.

Will being in this study help or hurt me in any way?
We can't be sure you'll experience help in any way from our study, but your participation may help future patients with diabetes. You may experience some discomfort during the study related to potentially sensitive questions we may ask and the fingerstick blood test. There is also a risk of loss of confidentiality.

What happens if I do not want to participate in this research?
You do NOT have to participate in this research. Choosing not to participate will not affect your healthcare nor be held against you. You can choose to participate and later change your mind.

What do I get to help me participate?
We provide compensation to help overcome the inconveniences to you of participating in this study.

INTERESTED IN PARTICIPATING? PLEASE READ ON FOR MORE DETAILED INFORMATION.

1. *SITE OF THE RESEARCH STUDY. Where will this study be done?*

- Hennepin County Health Care for the Homeless
- Hennepin Healthcare, and
- Hennepin Healthcare Research Institute

You will work with the research team to schedule in-person Assessment Visits at one of these locations most convenient to you. Your Diabetes Coaching Sessions may occur at one of the locations listed above or where you're currently staying, over the phone, or by video. You and the coach will decide this together based on your preferences.

2. ELIGIBILITY. *Who is being asked to be part of this research study?*

To be part of this study, you must:

- be 18 years or older
- have a type 2 diabetes diagnosis in your medical record
- have experienced homelessness or unstable housing in the past 12 months
- speak English
- plan to stay in the local area or be reachable by phone for the next 16 weeks
- be willing to work on diabetes self-care, including how you get and take your medication
- be able to provide informed consent
  - not be experiencing active psychosis or intoxication
  - not have a legal guardian
- not be pregnant or breastfeeding

3. FREEDOM TO PARTICIPATE AND WITHDRAW. *Is being part of this research study voluntary? Can you decide to stop being in this research study at any time?*

Being part of this research study is your choice. You do not have to be part of this study.
You can agree to be in the study now and change your mind later. Your decision to not be in the study or to stop being in the study will not affect your regular health care, and your doctor's attitude toward you will not change.

4. PROCEDURES. *What procedures will be done for this research study?*

You will be asked to complete the following visits over a period of 16 weeks:

Assessment Visit #1 + Assessment Visit #2	1 hour x 2 visits
These **<u>in-person</u>** visits will include a medical history interview, health screening (e.g., blood pressure, height, weight, and fingerstick hemoglobin A1c), and completion of study surveys. You will also be asked to provide access to your medical records and/or health insurance claims information so that we can collect information about your past year: • Medications and refills • Physical, mental, and substance use conditions • Primary care visits • Hospitalizations	

• Emergency department visits • Mental health provider visits • Substance use treatment visits • History of hemoglobin A1c test results • History of blood pressure, height, and weight	
Diabetes Coaching Sessions #1-10	30 min x 10 visits
These **in-person, phone, or video** coaching sessions will focus on getting to know you, what's important to you, and helping you to set goals to improve your diabetes and overall health and wellness. These sessions will be audio recorded. The first session will occur on the same day as Assessment Visit #2.	
Final assessment	2 hours x 1 visit
At the **in-person** Final Assessment visit, you will complete the same procedures from Assessment Visit #1 and Assessment Visit #2. We will access your medical records and/or health insurance claims information to update the information collected during Assessment Visit #1 and Assessment Visit #2. You will also be briefly interviewed about your experiences while in the study. This interview will be audio recorded.	

5. COMPENSATION FOR PARTICIPATION. ***Will you be paid for being part of this research study?***

If you complete every part of this study, the total amount you will be paid is up to $215. A detailed reimbursement schedule is included in the table below:

	Assessment Visit		**Diabetes Coaching Sessions**										**Assessment Visit**
	1	2	1	2	3	4	5	6	7	8	9	10	Final
Assessment Reimbursement	$10	$20	-	-	-	-	-	-	-	-	-	-	$45
Travel/phone Reimbursement	$10	$10*	$10*	$10	$10	$10	$10	$10	$10	$10	$10	$10	$20

*If Assessment Visit #2 and Diabetes Coaching Session #1 will occur on the same day, you will receive just one $10 reimbursement.

Reimbursement will be provided after each in-person visit. Reimbursement for phone or video coaching sessions will be provided at your next in-person assessment visit or diabetes coaching session. Alternatively, you may pick your reimbursement up at a secure location you choose or have it mailed to you.

6. STUDY TEAM COMMUNICATION. ***How will the study team communicate with you?***

In addition to phone calls, your coach and other members of the study team may contact you by text, email, or social media if you provide permission to do so. These forms of communication can help us stay in touch, but they are not always secure. Although it is unlikely, there is a possibility that information you include in a text, email, or on social media may be accessed by individuals outside of the research study team. Please initial next to the methods you feel comfortable with us using to contact you. You do not have to give permission for any of these!

_____Text

_____Email

_____Social media

You will also be asked to provide contact information for other individuals who would know how to get in touch with you, such as friends, relatives, and medical and social service providers you work with. We will contact these individuals only to request updated contact information for you. We will not share information about you with them. We will not contact these individuals unless we can't find you using your direct contact information and only if you have given permission for us to do so.

Please initial here if you agree to this method of getting in touch with you: _____

7. RISKS, DISCOMFORTS, AND INCONVENIENCES. ***What are the possible risks, side effects, discomforts, or inconveniences of this research study?***

You may feel uncomfortable answering some assessment questions and talking with your coach as part of this study. For example, you will be asked some potentially sensitive questions related to your mood and health as part of this study.

You may also experience some discomfort as a result of the fingerstick blood test, including soreness, swelling, and bruising.

There is also a risk of loss of confidentiality. We describe the steps that will be taken to protect your confidentiality in Section 11 below.

8. REPRODUCTIVE AND PREGNANCY ISSUES. ***What is important to know about being a part of this study and pregnancy?***

There are no known reproductive or pregnancy issues with being in the study. If you are currently pregnant or lactating, you may not participate in the study. However, if you become pregnant during the study, you may continue your participation.

9. ***HEALTH BENEFITS. What are the possible health benefits to you or to others from your being part of this research study?***

We cannot promise any benefits to you or others from taking part in this research. Your participation in this study may help patients with diabetes in the future.

You may experience improved physical and emotional health as a result of the free diabetes wellness coaching sessions. However, this is not guaranteed.

10. ALTERNATIVE TREATMENTS. ***What treatments or procedures are there for you if you decide not to be part of this research study?***

If you decide not to be in this study, you may continue seeing your regular health care provider at clinic or health system you choose.

11. CONFIDENTIALITY. ***Who will know that you are part of this research study? How will your information be used and protected?***

Private Health Information

Your personal information will be treated in strict confidence to the extent allowed by law. But we will have to share some of your information with others as part of the study. If you agree to be part of this study, you will also be allowing Dr. Vickery and other members of the study team to view and use some of your private health information as need for the purposes of this study as described in this consent.

Information collected from you during (1) study visits or from your medical record or health insurance claims AND that may identify you (also called **private health information**) will only be shared with:

- The members of the research team involved in this study, which includes Hennepin Healthcare providers, their staff, and others who may join the research team
- External researchers and data analysts at the University of Minnesota
- External research consultants approved by the research team
- Hennepin Healthcare Research Institute and Hennepin Healthcare System, Inc.
- The National Institutes of Health; and
- You, if you request to see your study data. You may request your study data at your Final Assessment visit. The study team will arrange to get your data to you by pickup or mail.

We will collect private health information from your medical record and/or health insurance claims data from the past year and throughout the 16-week duration of the study. This data will be stored in HIPAA-compliant electronic locations or locked in file drawers at Hennepin Healthcare Research institute. Anyone obtaining access to your private health information must agree to protect your information in a similar HIPAA-compliant manner as required by this consent even if federal privacy laws no longer apply.

This consent to use your private health information does not expire, but you may revoke this consent by contacting Dr. Vickery. If you revoke your consent, you may no longer be able to participate in the study. Further, we cannot undo uses or sharing of your private health information that have already taken place relying on your prior consent.

We will not share any of your private health information with your medical or social service team unless you ask us to and give signed consent to do so.

Deidentified or Partially Deidentified Information
We may share data that does not include identifying information or that includes limited identifying information (including, dates and zip codes) for future research by this study team or with other investigators without your additional permission.

The findings of this study may also be used for scientific meetings, written reports, and publications, but none of your personal information (that could be used to identify you) will ever be shared.

Mandated Reporting
There is certain information that we may be required or permitted by law or policy to report if you share it with us. This includes information about child or vulnerable adult abuse or neglect. It also includes information about if you have had a communicable, infectious, or other disease required to be reported under Minnesota's Reportable Disease Rule (for example, tuberculosis or COVID-19).

Certificate of Confidentiality
To further help protect your privacy, we have a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, we cannot be forced (for example, by court order) to give out information that may identify you. We will use the Certificate to say no to any demands for information, except as explained below.

This Certificate does not keep us from taking steps to prevent serious harm from happening to you or others, including reporting to Child Protective Services or 911. Reporting to Child Protective Services or 911 only happens in special cases, such as when somebody says that they are being neglected or physically or sexually abused by a parent, or that they are feeling suicidal or plan to physically hurt someone else. These topics are not part of our research, but we are mentioning them so that you know how the Certificate works.

This Certificate does not prevent you from talking about yourself or this study to others if you choose.

12. COSTS ASSOCIATED WITH THE RESEARCH STUDY. ***Will your insurance provider or you be billed for any costs of the procedures done as part of this research study?***
Neither you nor your insurance provider will be billed for the costs of any of parts of this study. You will be billed in the regular way for any medicine, procedures, or treatments done as part of your routine medical care (e.g. diabetes visits).

13. NEW FINDINGS. ***Will you be told of any new information or new risks that may be found while this study is going on?***

In every research study, there may be risks we do not expect. You will be told about any important new information that may cause you to change your mind about being part of this study.

Research results that may be relevant to your healthcare, including your A1c results, will be shared with you by the study team.

14. PROCEDURES FOR ORDERLY WITHDRAWAL OR REMOVAL FROM THE STUDY. ***What would happen if you decide to stop being part of this study or if you are removed from this study?***

If you decide that you no longer wish to participate the study, you should contact the study team, at (651) 508-3741 or DHomes@hhrinsitute.org.

If you decide to stop being in the study, the study team may discuss with you a more limited participation in this study such as still collecting information from your medical records after you stop your direct participation. If you agree to that limited participation, we will note that in your records.

There are also instances when the study team may decide to end your participation in the study. This may happen if:

- You do not have a hemoglobin A1c result in the range for study participation
- staying in the study would be harmful to you or others in any way;
- you decide to stop being part of the study;
- you fail to attend multiple study sessions; or
- the study is canceled.

If you decide to stop being part of the study, or if you are removed from the study for any reason, you will be asked to complete the Final Assessment Visit. Completion of this final session is your choice. You may decline to complete this final session.

15. CONTACT INFORMATION FOR QUESTIONS. ***Who should you contact if you have questions?***
If you have any problems, concerns, or questions about your rights as a participant in this research study, want to obtain information, or want to offer input to someone other than the study doctor, please contact the Hennepin Healthcare Human Research Protection Office (HRPO) at HRPO@hhrinstitute.org or (612) 873-6881.

If you have any questions before signing this consent, please be sure to ask them now. During the study, if you have any questions, concerns, or complaints for the study doctor, please call Dr. Katherine Vickery at (612) 873-6852.

A description of this clinical trial is available at https://clinicaltrials.gov/ct2/show/NCT04678284?term=Katherine+vickery&draw=2&rank=1, as required by U.S. law. Scan the following QR code using your smartphone camera to be directed to the webpage:

This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

SIGNATURE PAGE

- I have either read the attached consent or it has been read to me.
- By signing this form, I do not give up any of my legal rights or release anyone involved in this research study from their responsibility for negligence.
- By signing this form, I agree to be part of this research study and consent to the use of my private health information as described in Section 11 ("Confidentiality") of the attached consent.
- A signed copy of this consent will be given to me.

_____

Subject's Printed Name

_____

Subject's Signature

_____

Date

I certify that a copy of this form has been provided to the above-named subject.

_____ _____

Explained by Printed Name, Title Signature

_____

Date