Title:	*Expanding the Diabetes Homelessness Medication Support (D-Homes) program to Spanish speaking Hispanics*
Short Title	D-Homes Spanish Aim 2
Sponsor:	National Institute of Diabetes and Digestive and Kidney Diseases (R03DK133553-01)
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Study Team Contact Information:
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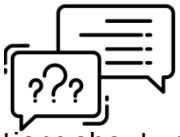
- Study staff: (651) 508-3741 / DHomes@hhrinstitute.org

Supported By: National Institutes of Diabetes and Digestive and Kidney Disease, niddk.nih.gov

KEY INFORMATION

Do you want to be in our research study? It's for people like you with type 2 diabetes who have experienced homelessness or housing instability. We want to see if and how a diabetes support program we made specifically for people who have experienced homelessness works.

What will I need to do to be in this study? You will be asked to have visits/calls over 4 months:

Assessment Visit #1 (1h, today)		
 Consent	 A1c check, BP, weight, etc.	 Questions about your health, life
Assessment Visit #2 (1h, in 1-2 weeks)		
 Questions about you		
Diabetes Wellness Coaching Sessions, #1-10		
 10 x coaching (30 min., weekly)	 Pillbox/other tool	 3 x calls (monthly)
Assessment Visit #3 (1h, in 12-16 weeks)		
 A1c check, BP, weight, etc.		 Questions about your health, life

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. Your participation may help future patients with diabetes.

You may experience some discomfort during the study related to the blood tests. You also might not like some sensitive questions we ask. There is also a risk of loss of confidentiality. We will work with you to minimize the chance that risks happen to you.

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 support your participation in this study. Payments will be provided on a study provided Visa debit card. If you are uncomfortable using a debit card, you may opt to receive cash payments.

If you complete every part of this study, the total amount you will be paid for assessment visits is $110. A detailed payment schedule is included in the table below:

	Assessment Visits		
	#1	#2	#3
Assessment Payment	$20	$30	$60

Participants will receive a monthly stipend to support their phone bill. You will be paid up to $60 over 3 months.

	Monthly Stipend		
Use your own phone with monthly stipend	Mo. 1	Mo. 2	Mo. 3
	$20	$20	$20

For in-person study visits, participants will also receive arranged transportation, a parking voucher, or bus tokens.

Do you agree to receive your compensation on a study provided debit card?
____Yes _____No

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

1. ***SITE OF THE RESEARCH STUDY. Where will this study be done?***
   - Comunidades Latinas Unidas En Servicio (CLUES)
   - Participants' homes
   - 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. If working with a Diabetes coach, coaching sessions may occur in-person at one of the locations listed above, by phone, or by video 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 by a medical provider
- have an A1c value greater than or equal to 7.5%
- have experienced homelessness or unstable housing in the past 12-24 months
- speak Spanish
- 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 hemoglobin A1c drawn from your vein at Hennepin Healthcare lab or using at-home A1c Kit), 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.

Participant Responsibilities: If you take part in this research, you will be responsible for:

- Remaining in contact with the study team and alerting us to changes in contact information
- Coordinating with the study team to schedule all study visits, and attending those visits according to the schedule described above
- Completing study questionnaires and A1c tests at assessment visits

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 for assessment visits is $110. A detailed payment schedule is included in the table below:

	Assessment Visits

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

For participants using their own personal phone, they will receive an additional monthly stipend to support their phone bill of $20/month. You will be paid up to $60 over 3 months.

	Monthly Phone Use		
	#1	#2	#3
Phone Payment	$20	$20	$20

Payment will be available on a debit card. Study staff will add money to this debit card at each assessment and each month for phone payments. For those who are uncomfortable using a debit card, cash payment will be available.

For in-person study visits that occur outside of your place of residence, such as Hennepin Healthcare or community sites, you will also receive arranged transportation, a parking voucher, or bus tokens.

6. BLOOD SAMPLES. ***How will blood samples be used?***

Your blood samples will be used only for measuring your A1c. Your blood samples will not be retained. Your blood samples will not be used for commercial profit. This study will not include any genetic testing.

7. 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. This is not required, but it helps us keep in touch with you!

_____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.

If you provide permission for us to reach out to a secondary contact, please know that the research staff member will disclose that they are trying to reach you because of your participation in a research study. Details of the study will not be shared.

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

We will ask your permission to reach out to organizations that you list as places you frequent or services providers you have frequent communication with. Examples of such organizations/individuals are a case worker, housing providers, a substance use treatment facility, or someone else from whom you receive services. If you give us permission to contact these service providers, we would only tell them that you are involved in a diabetes program and that we and ask them to help us get in touch with you. In order for them to provide us with your contact information, we will need to present them with a release of information that you have signed.

Please initial here if you agree to sign a release of information for this purpose: _____

8. 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 can skip any question you do not wish to answer.

You may also experience some discomfort during your blood draws from your arm, 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.

9. 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 in coaching but will not be scheduled for the final assessment. There are no risks to continuing with coaching for the pregnant person or the fetus.

10. ***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 education or diabetes wellness coaching sessions. However, this is not guaranteed.

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

There are no alternative treatments. 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.

12. 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 needed for the purposes of this study as described in this consent.

Information collected from you during 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 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.

External researchers and data analysts at the University of Minnesota will receive de-identified data containing **no** private health information in order to assist with data analysis.

We will collect private health information from your medical record and/or health insurance claims data from the past year and throughout the 30-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 in writing at (*Dr. Vickery, 701 Park Avenue S2.311, Minneapolis, MN 55415*). 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). If we learn about excessive use of alcohol or use of controlled substances for non-medical reasons during pregnancy, we may be required or permitted by Minnesota law or Hennepin Healthcare policy to report this information to the Hennepin County Child Protection Agency.

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.

13. 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).

14. 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.

15. PROCEDURES FOR ORDERLY DISCONTINUATION OR WITHDRAWAL 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 or asking you to participate in a final assessment. If you agree to that limited participation, we will note that in your records. Completion of this final session is your choice.

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

- 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.

16. CONTACT INFORMATION FOR QUESTIONS. ***Who should you contact if you have questions?***

This research has been reviewed and approved by an IRB within the Human Research Protection Program.

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 [to be updated once registered] Scan the QR code to the left 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 12 ("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

INTERPRETER STATEMENT:

A qualified interpreter was present for the duration of the consent process for this research study. The interpreter has the necessary skills to provide interpretation between the participant's language and English. A full and complete interpretation of the exchange between the researcher obtaining consent and the participant occurred.

The interpreter was present in the following manner:

- ☐ in-person
- ☐ by phone
- ☐ by videoconference