The University of Texas at Austin

Official Title of the study: Empathy in Action: Sunshine Calls for Life With Diabetes

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Consent to Participate in Research

Basic Study Information

Title of the Project: Empathy in Action
Principal Investigator: Maninder Kahlon, PhD, Vice Dean, Health Ecosystem Dell Medical School; Assoc Professor, Population Health
Study Sponsor: Episcopal Health Foundation

Invitation to be Part of a Research Study

You are invited to be part of a research study. This consent form will help you choose whether or not to participate in the study. Feel free to ask if anything is not clear in this consent document.

Important Information about this Research Study

Things you should know:

- The purpose of the study is to determine if a program that delivers phone calls by a dedicated partner can support diabetes self-management behaviors and reduce Hemoglobin A1C (HbA1c) in patients with diabetes.
- In order to participate, you must be 21-70 years old, have an HbA1c of 7.5 or higher at baseline measurement, and at least one visit with Lone Star Circle of Care within the past 12 months (in-person or telehealth). You also need to answer all questions in the PHQ-9 survey during your enrollment visit to the clinic.
- Exclusion criteria: currently pregnant, undergoing cancer treatment, diagnosis of end-stage renal disease or serious mental illness diagnosis, moderate to severe cognitive impairment, or receiving systemic treatment with prednisone or immunosuppressant therapy following an organ transplant. Not responding to the PHQ-9 survey in its entirety at the enrollment visit.
- If you choose to participate, you will be randomly assigned to one of two different groups. These groups are the intervention group or the control group. The intervention group will receive short calls (5-10 minutes) each week, and given the choice to have more or less frequent calls throughout the program. The control group will not receive weekly phone calls. Both groups will have HbA1c, blood pressure, and survey measures completed at scheduled research visits. These will occur at baseline, months 3, 6, 9, and 12 at a Lone Star Circle of Care clinic site or at Dell Medical School at The University of Texas at Austin. Each visit will take about 1-2 hours.
- Risks or discomforts from this research include:

    1. Finger stick blood sample for HbA1c blood testing: The risks of obtaining a blood sample are minimal, similar to any time blood is collected and include pain, bleeding, bruising, infection, and skin irritations (from cleaning agents used to sterilize the skin or bandages).
    2. Blood Pressure: Participants may experience mild discomfort in their arm when the cuff is inflated.
    3. Discomfort: There is potential to feel discomfort sharing personal information about yourself. You do not need to answer any question that might make you feel uncomfortable. You can stop the surveys at any time.

4. Loss of confidentiality: There is a potential for accidental release of confidential information. Procedures are in place to minimize this risk.

- The possible benefits for the intervention arm of this study include improved glucose control and improved mental health. These possible benefits would not be available to those in the control arm.
- Taking part in this research study is voluntary. You do not have to participate, and you can stop at any time.

More detailed information may be described later in this form.

Please take time to read this entire form and ask questions before deciding whether to take part in this research study.

What is the study about and why are we doing it?

The purpose of the study is to determine if a program that delivers empathetic and relationship-oriented phone calls by a friendly caller can support diabetes self-management behaviors and reduce Hb A1C in patients with diabetes at Lone Star Circle of Care (LSCC), a federally qualified health center (FQHC).

What will happen if you take part in this study?

If you agree to take part in this study, you will be asked to:

All Groups:

- Complete a series of measurements including HbA1c, blood pressure, and survey questions about your feelings of anxiety and depression. Biomedical measures (HbA1c and blood pressure) will be measured at a Lone Star Circle of Care clinic, Dell Medical School at The University of Texas at Austin, or another community-based site. All other measures will be collected at the same time on an electronic tablet (or paper copy upon your request). These measures will be collected at baseline, 3, 6, 9, and 12 months. Each visit will take about 1-2 hours to complete.
- Next, you will be randomly assigned to be in one of two groups. Which group you end up in is entirely up to chance, like a coin toss.

Intervention Group:

- If you are randomly assigned to the intervention group, you will receive 6 months of friendly phone calls between you and a dedicated partner. The calls will be short (5-10 minutes) and will provide you an opportunity to discuss whatever you wish to share. In addition, they may provide support for your diabetes health goals on exercise, nutrition, sleep, and taking your medication on a regular basis.
- Calls will occur 3x a week in the first month and once a week in months 2-6. After the first week, you can adjust calls to a maximum of 5x a week or a minimum of 2x a week for the first month. In months 2-6 you will also have the option of switching to a call every other week from your dedicated partner if you would like to. Calls average 10 minutes or less.
- If part of the intervention group, you have the option of choosing between a health-promoting tool (pedometer or weigh scale) in the first week of the program, which you will receive within the first month. If these options are not applicable to you due to health

or other limitations, you will be provided the option between a fitness band with handles or an exercise program for the upper body. You will receive printed diabetes self-management information that will be mailed to you after randomization. You will also receive a healthy living item selected by your assigned caller at two time points during the study (months 3 and 5).

- In addition to health incentives, you will also receive a letter from your caller twice during the study. These letters will be physically mailed to you between months 2 and 5.
- If the caller feels the participant could benefit from a pre-selected list of YouTube videos, that includes people talking about their life with diabetes, the caller may decide to share it with them via text.
- If you are randomly assigned to the intervention group, you will also receive monthly text messages during months 7-12 from your dedicated partner as simple reminders of tips discussed during the first 6 months.
- During your 12-month (last) measurement visit, you will be asked to complete a Program Improvement survey with your other survey questions.

Control Group:

- If you are assigned to the control group, you will not receive the phone calls or any text message reminders about the program, and continue with your normal routine. You may receive reminder text messages about your upcoming measurement appointments.
- If part of the control group, your choice of health-promoting tool and healthier living items will be offered as final questions of the 6-month assessment. The tool will be mailed to you at month 7 along with printed diabetes self-management information. You will receive 2 healthier living items the first at month 8 and the second at month 10.

All Groups:

- Finally, regardless of which group you are assigned to, all participants will be asked to meet with a member of the research team to complete the same series of health assessments and survey questions. These will happen every 3 months for up to 12 months, and will be measured at a Lone Star Circle of Care clinic, Dell Medical School at The University of Texas at Austin, or another community-based site at one time.

The UT research team may text you to contact you regarding the study. This will be done to schedule times for measurement collection and to send reminders. In addition, educational YouTube videos may be sent via text.

How long will you be in this study and how many people will be in the study?

Participation in this study will take place over a period of 12 months and include up to 300 participants, 150 in the intervention group and 150 in the control group. Regardless of which group you are assigned to, all participants will spend approximately 5-10 hours of their time (1-2 hours per visit at baseline, 3, 6, 9, and 12 months) talking to our research team for enrollment and data collection over the 12 months. If in the intervention group, you will spend additional time on the phone as part of the intervention:

- Week 1: 30 minutes or less
- Weeks 2-4: 50 minutes or less per week
- Months 2-6: 10 minutes or less per week

What risks and discomforts might you experience from being in this study?

There are some risks you might experience from being in this study, including:

- Finger stick blood sample for HbA1c blood testing: The risks of obtaining a blood sample are minimal, similar to any time blood is collected and include pain, bleeding, bruising, infection, and skin irritations (from cleaning agents used to sterilize the skin or bandages).
- Blood Pressure: An inflatable cuff will be placed on your arm and a machine will measure your blood pressure and heart rate, after you have been sitting down for 10 minutes. You may experience mild discomfort in your arm when the cuff is inflated.
- Discomfort: There is potential to feel discomfort sharing personal information about yourself. You do not need to answer any question that might make you feel uncomfortable. You can stop the surveys at any time.
- Loss of confidentiality: There is a potential for accidental release of confidential information. Procedures are in place to minimize this risk.

The researchers will let you know about any significant new findings (such as additional risks or discomforts) that might make you change your mind about participating in this study.

How could you benefit from this study?

You may or may not benefit from participation in this study. Possible benefits in the intervention arm of this study may include improved glucose control and improved mental health. These benefits would not be available to those in the control arm.

What will happen to the samples and/or data we collect from you?

As part of this study we will collect information about your health (blood pressure, blood sugar level by HbA1c) and wellbeing (using surveys that measure things like depression, anxiety, etc.) In addition to this, we will also ask you basic demographic information, as well as information about your medications and healthcare visits. At the end of the study, we will ask you for your opinion about the study itself and how you felt about participating.

All research information will be collected at Lone Star Circle of Care clinic sites, Dell Medical School at The University of Texas at Austin, or other community-based sites, by a trained member of the research team or a Lone Star Circle of Care staff member. Data collection will be private, and information will be confidential.

How will we protect your information?

We will protect your information by using a secure database. Only research staff have access to this database. Both research staff and Lone Star Circle of Care staff will have access to your identifying information, such as name, address, and phone number. This is necessary in order for Lone Star Circle of Care to provide the services being studied as part of this research. Lone Star Circle of Care will not have access to individual survey responses collected by the UT Austin research members.

Information about you may be given to the following organizations:

- Representatives of UT Austin and the UT Austin Institutional Review Board
- Other collaborating organizations: Lone Star Circle of Care

We may share your data with other researchers for future research studies that may be similar to this study or may be very different. The data shared with other researchers will not include information that can directly identify you.

We plan to publish the results of this study. To protect your privacy, we will not include any information that could directly identify you.

Under certain situations, we may break confidentiality. If during the study, we learn about child or elder abuse or neglect, or that someone is a clear, serious, and direct harm to self or others, we may report the information to the appropriate authorities, including the police, the Texas Department of Family and Protective Services, and/or an emergency medical facility.

A description of this study will be available on http://www.ClinicalTrials.gov as required by U.S. Law. This web site will not include information that can identify you. At most, the web site will include a summary of the results. You can search this web site at any time.

What will happen to the information we collect about you after the study is over?

Your name and other information that can directly identify you will be deleted from the research data collected as part of the project during the data entry process. At the end of the study The University of Texas at Austin might stay in touch with you to determine interest in media opportunities.

How will your health information be used and shared during the study?

As part of this research study, we will ask you to share identifiable health information with us and/or permit us to access existing information from your healthcare records. New health information may also be created from study-related tests, procedures, visits, and/or questionnaires. This type of information is considered “Protected Health Information” that is protected by federal law.

What type of health information will be used or shared with others during this research?

The following types of information may be used for the conduct of this research:

☒ Complete health record		
☐ Information about sexually transmitted diseases	☐ Diagnosis & treatment codes	☐ Discharge summary
☐ History and physical exam	☐ Consultation reports	☐ Progress notes
☒ Laboratory test results	☐ X-ray reports	☐ X-ray films / images
☐ Photographs, videotapes	☐ Complete billing record	☐ Itemized bill

☐ Information about drug or alcohol abuse	☐ Information about Hepatitis B or C tests	☒ Information about mental health
☒ Other physical or mental health information (specify): Behavioral health visits and PHQ9 scores in the past year (12 months before study to study end)		

Where will you get my records?

For this study, we will obtain records from the following healthcare providers:

- Lone Star Circle of Care

Who will use or share protected health information about me?

The covered entities listed above are required by law to protect your identifiable health information. By signing this document, you authorize them to use and/or share your health information for this research. The health information listed above may be used by and/or shared with the following people and groups to conduct, monitor, and oversee the research:

- Principal Investigator and Research Staff
- Health Care Providers at Lone Star Circle of Care
- Institutional Review Boards

If your health information has been disclosed to anyone outside of this study, the information may no longer be protected under this authorization.

When will this authorization (permission) to use my protected health information expire?

This authorization will expire when the research study is closed, or there is no need to review, analyze and consider the data generated by the research project, whichever is later.

If you later decide that you do not want to share your medical information any longer, please contact the study team in writing to withdrawal your authorization. Contact information for the study team can be found at the bottom of this form.

How will we compensate you for being part of the study?

All participants, whether in intervention or control, will be provided a possible total of $250 for their participation in the study ($50 for completion of each measurement (5 total)). Gift cards will be distributed to the participants at the end of each completed measurement at baseline and months 3, 6, 9, and 12.

Who will pay if you are hurt during the study?

In the event of a research-related injury, it is important that you notify the Principal Investigator of the research-related injury immediately. You and/or your insurance company or health care plan may be responsible for any charges related to research-related injuries. Compensation for an injury resulting from your participation in this research is not available from The University of Texas at Austin.

What are the costs to you to be part of the study?

To participate in the research, you will need to travel to the research visit site [at Lone Star Circle of Care Clinics, Dell Medical School at The University of Texas at Austin, or other community-based sites].

Who can profit from study results?

Your samples may be used for commercial profit and there is no plan to share those profits with you.

Your Participation in this Study is Voluntary

It is totally up to you to decide to be in this research study. Participating in this study is voluntary. Your decision to participate will not affect your relationship with The University of Texas at Austin or Lone Star Circle of Care. You will not lose any benefits or rights you already had if you decide not to participate. Even if you decide to be part of the study now, you may change your mind and stop at any time. You do not have to answer any questions you do not want to answer. However, only during the enrollment visit (the first one), there will be one survey, the PHQ-9, that you will be required to answer all questions. It asks about how you have been feeling recently. Answering that survey in its entirety during your first visit will be required for your participation in the study to continue. It is not a requirement in other visits.

If you decide to withdraw before this study is completed, you will need to contact the research team through the number included at the bottom of this consent. Alternatively, you may contact Lone Star Circle of Care and they will let the University of Texas at Austin researchers contact you to verify your decision to withdraw from the study.

You may change your mind and take back the right to use your protected health information at any time. However, even if you take back this permission, the researchers may still use or disclose health information they have already collected about you for this study. For example, if the law requires it, the sponsor and government agencies may continue to look at your medical records to review the quality or safely of the study. If you take back this permission you may no longer be allowed to participate in the research study. To take back this permission, you must write to the Principal Investigator.

Is it possible that you will be asked to leave the study?

You may be asked to leave the study if it is determined by your healthcare provider or the research team that it is unsafe for you to continue.

Contact Information for the Study Team

If you have any questions about this research, you may contact:

Maninder “Mini” Kahlon
Phone: 512-495-5017
Email: mkahlon@austin.utexas.edu
Address: ATTN: Mini Kahlon, 1501 Red RiverSt. Austin, TX 78701

Julia Guerra
Phone: 512-228-4544
Email: julia.guerra@austin.utexas.edu

Maria Cowley-Morillo

Phone: 512-584-1376
Email: maria.cowleymorillo@austin.utexas.edu

Contact Information for Questions about Your Rights as a Research Participant

If you have questions about your rights as a research participant, or wish to obtain information, ask questions, or discuss any concerns about this study with someone other than the researcher(s), please contact the following:

The University of Texas at Austin Institutional Review Board
Phone: 512-232-1543
Email: irb@austin.utexas.edu

Please reference the protocol number found at the top of this document.

Your Consent

By signing this document, you are agreeing to be in this study. We will give you a copy of this document for your records. We will keep a copy with the study records. If you have any questions about the study after you sign this document, you can contact the study team using the information provided above.

I understand what the study is about and my questions so far have been answered. I agree to take part in this study.

_____
Printed Subject Name

_____
Signature Date

_____
Signature of Person Obtaining Consent Date