The University of New Mexico Health Sciences Center

Consent and Authorization to Participate in a Research Study

Key Information for Home-based prediabetes care in Acoma Pueblo

You are being invited to take part in a research study about educational life style interventions to reduce risk factors for type 2 diabetes.

WHAT IS THE PURPOSE, PROCEDURES, AND DURATION OF THE STUDY?

By doing this study, we hope to learn if educational intervention delivered by a community health representative (CHR) improves the health of people at higher risk for diabetes. Your participation in this research will last about two years.

WHAT ARE THE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

You may consider participating in this study as you have risk factors for diabetes. For a complete description of benefits, refer to the Detailed Consent.

WHAT ARE THE KEY REASONS YOU MIGHT NOT CHOOSE TO VOLUNTEER FOR THIS STUDY?

We respect your choice of not joining for your personal reasons or your work schedule. For a complete description of the risks, refer to the Detailed Consent.

Lifestyle changes are necessary to lower the risk of getting diabetes and you may feel that you can do it on your own.

DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits or rights you would normally have if you choose not to volunteer.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

The person in charge of this study is Principal Investigator Drs. Bouchonville, Shah and their associates of the University of New Mexico Health Sciences Center, Department of Internal Medicine. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study, the office number is 505-272-4658.

If you have any questions or concerns about your rights as a volunteer in this research, contact staff in the University of New Mexico Health Sciences (UNMHSC) Human Research Review Committee (HRRC) between the business hours of 8AM and 5PM, Mountain Standard Time (MST), Monday-Friday at 505-272-1129.

UNIVERSITY OF NEW MEXICO HEALTH SCIENCES CENTER
CONSENT TO PARTICIPATE IN RESEARCH

Home-based prediabetes care in Acoma Pueblo

INTRODUCTION: You are being asked to take part in a study of home-based diabetes care (HBDC). Drs. Bouchonville and Shah at the University of New Mexico Health Sciences Center (UNMHSC) and their research associates are conducting this study. The National Institute of Health (NIH) will pay for the study. Leadership of the Acoma Pueblo and doctors from Acoma IHS hospital are collaborating on this study. This study is being done to find out if a home-based diabetes care program can help prevent diabetes and its complications in members of Acoma families who are at risk for diabetes. Our purpose is to first invite about 300 Acoma members for this study. We will then invite about 150 volunteers with early forms of diabetes based on testing results and all of them will receive HBDC. Volunteers will be randomly divided (like the flip of a coin) into two treatment groups. Community Health Representatives (CHRs) from Acoma will work with the HBDC group while the other group will receive their usual care by Acoma IHS hospital. The usual care group will be invited after 12 months of their screening to get HBDC. The HBDC portion of the study will last approximately 4 months. We will check in with study volunteers once more after 12 months to check about your health status.

What will happen if I participate: If you agree to join the study, you will be asked to read and sign this Consent Form. After you sign the consent form, some or all of the following things may happen:

(1) We will ask you questions using surveys about your overall health, your background, the health of you and your family, medication use, habits and your knowledge about diabetes related issues using a diabetes quality of life survey. We will also conduct a brief survey called 'patient activation measure (PAM)' to gauge your knowledge, skills and confidence, tools important for managing your own health. You may refuse to answer any questions at any time during the interview. The questions will take about 25 minutes to complete.
(2) We may measure your height, weight, blood pressure and waist and hip areas.
(3) Blood may be taken from a vein in your arm and from a finger stick to measure, glucose levels and glucose control, kidney function, cholesterol levels, and electrolytes (salts in your body). Approximately, three tablespoons of blood will be taken. This sample will be sent to the Acoma-Canoncito-Laguna Hospital laboratory and not outside of your community.
(4) A sample of your urine may be collected to measure protein, which can be an early sign of kidney disease. This sample will be sent to the Acoma-Canoncito-Laguna Hospital laboratory and not outside of your community.
(5) We will give the results to you and to your doctors/nurses at the Indian Health Service (IHS) Hospital. If there are abnormal results, we can refer you to a doctor if you want us to do so. No additional tests will be performed on your samples without expressed written consent from you, the Acoma Tribal Council and the research review committees at UNMHSC and the Indian Health Service.
(6) We will not store your blood and urine samples. Rarely, we may ask you for an additional blood sample. In the rare event (less than 1%) that a sample is lost, broken or wrongly labeled we may ask you for an additional blood sample.

Randomization: After your initial screening, if you qualify for the study and agree to participate you will be assigned to the "HBDC group" or the "usual care group." Randomization is like the flipping of a coin to determine if you are assigned to HBDC or usual care group. Additionally, a member of your family who meets study criteria will be allowed to participate in the study and will

receive the same treatment and procedures as you. We will do following procedures for baseline screening:

Blood and urine tests will be repeated in all volunteers and education material for diabetes, kidney disease, heart disease, nutrition, and diet and lifestyle changes will be provided. If you are assigned to the **usual care group,** you will receive educational materials provided by the IHS clinic as needed. If you are assigned to the **HBDC group**, Acoma CHRs will provide you with education on healthy lifestyles (diet, exercise, alcohol abuse and smoking). Various educational materials will be provided to you on management of overweight, obesity, diabetes, blood pressure and fat intake, including, home blood pressure monitoring, pamphlets, videos, and material prepared by the investigators, and motivational text messages.

Your Study Related Visits:

All volunteers will receive HBDC. Some will receive it right away and some will receive after a delay of 12 months. If you are assigned to the usual care group, you will receive care according to your primary care team at the Acoma IHS hospital. Study surveys and blood and urine tests will be repeated at six and twelve months and we will contact you 12 months after your initial screening to do the delayed HBDC. If you are assigned to the HBDC group, you will be scheduled at a time of your choice for about 8 visits over four month period for home visits, (about 1hour for first visit and 30 minutes thereafter) with CHRs. CHRs will talk about improving your diet, increasing your physical activity, and will work with you to get you to your healthy weight; You are encouraged to participate in all visits. CHRs will give you updates on your progress and will also help you create a healthier home to support your nutrition and physical activity. You will be also asked to attend a 30 to 60 minutes group session with 5-8 other volunteers once at the start of the study and another at the end of the study. During the group session, we will talk about myths about diabetes, lifestyle changes, goal setting and other educational information. Also, we may ask you to take part in a weekly total of 150 minutes of exercise at Acoma wellness center on your own time of choosing. We may obtain the following measurements at each visit for a total of twelve visits over twelve months: weight, waist circumference, and blood pressure. We will measure diabetes marker in your blood using machines that give instant results. A CHR in consultation with an Acoma dietician will conduct a diet evaluation, including a diet history and stick to past dietary instructions by the Acoma wellness program.

We will provide cell phone coverage specifically for motivational text messaging for about 4 months, paid by the project. A private company expert in text messages will generate text messaging reminders and educational applications for your phone. You will interact with them by text messaging. This information will be used to promote follow-up to both medical and healthy lifestyle interventions. Volunteers in the HBDC group will receive weekly text messages from the CHR and will be requested to send a text response within 24 hours.

RISK AND DISCOMFORTS: There are some small risks to your health if you take part in the study.

1. You may have mild pain when we draw your blood. There is a small risk of bleeding, bruising (less than 10%) and infection (less than 1%) in the area where we put the needle.

2. There is no risk when giving a urine sample.

3. We have established a process to protect the confidentiality of your information. However, accidental disclosure of confidential study information may occur. This could affect your ability to obtain a job and/or health insurance.

4. Participation in our study may pose no more than minimal risk as all of the lifestyle treatment options included in the study fall within the current standard of care at Acoma IHS.

5. The risk is very minimal to receive/respond to the text message and group session of education as they are basically a motivational messages.

How will my information be kept confidential?
Your name and other identifying information will be maintained in locked files, available only to authorized members of the research team, for the duration of the study. For any information entered into a computer, the only identifier will be a unique study identification (ID) number. Any personal identifying information and any record linking that information to study ID numbers will be destroyed when the study is completed. Information resulting from this study will be used for research purposes and may be published; however, you will not be identified by name in any publications.

Information from your participation in this study may be reviewed by the UNM Clinical and Translational Science Center, federal and state regulatory agencies, and by the UNM Human Research Review Committee, which provides regulatory and ethical oversight of human research. There may be times when we are required by law to share your information. However, your name will not be used in any published reports about this study.

What are the benefits to being in this study?
There may or may not be direct benefits to you from being in this study. However, your participation may help healthcare providers better understand and/or treat others who are at risk for type 2 diabetes. One possible benefit of participating in this study is that you may be able to prevent diabetes. The interventions used in this study have been shown to be very effective for preventing diabetes and the complications of diabetes including kidney, eye, and nerve damage.

What other choices do I have if I don't participate?
Taking part in this study is voluntary so you can choose not to participate.

Will I be paid for taking part in this study?
HBDC group: You will be given a $25.00 gift card for each of the 3 data collection visits (blood and urine tests) in which you participate. You will also receive a $10.00 gift card at the end of each of the 2 group sessions you attend to assist with travel. If you complete all visits, you will receive $95.00 in gift cards.

Usual care group: You will be given a $25.00 gift card for each of the 4 data collection visits (blood and urine tests) in which you participate. You will also receive a $10.00 gift card at the end of each of the 2 group sessions you attend to assist with travel. If you complete all visits, you will receive $120.00 in gift cards.

What will happen if I am injured or become sick because I took part in this study?
If you are injured or become sick as a result of this study, University of New Mexico Health Sciences Center (UNMHSC) will provide you with emergency treatment, at your cost.

No commitment is made by the UNMHSC to provide free medical care or money for injuries to participants in this study.

In the event that you have an injury or illness that is caused by your participation in this study, reimbursement for all related costs of care will be sought from your insurer, managed care plan, or other benefits program. If you do not have insurance, you may be responsible for these costs. You will also be responsible for any associated co-payments or deductibles required by your insurance.

It is important for you to tell the investigator immediately if you have been injured or become sick because of taking part in this study. Dr. Bouchonville's direct office number is (505) 272-9447 and your provider in Acoma can also reach Dr. Bouchonville via the Physician Access Line Service (PALS) at (505) 272-2000 outside of business hours. If you have any questions about these issues, or believe that you have been treated carelessly in the study, please contact the Human Research Review Committee (HRRC) at the (505) 272-1129 for more information.

How will I know if you learn something new that may change my mind about participating?
You will be informed of any significant new findings that become available during the course of the study, such as changes in the risks or benefits resulting from participating in the research or new alternatives to participation that might change your mind about participating.

Can I stop being in the study once I begin?
Yes. You can withdraw from this study at any time without affecting your access to care at UNMHSC.

The investigators have the right to end your participation in this study if they determine that you no longer qualify to take part, if you do not follow study procedures, or if it is in your best interest or the study's best interest to stop your participation. The sponsor may also stop the study at any time. **All data collected from you will be destroyed if you withdraw from the study at any point.**

HIPAA Authorization for Use of Your Protected Health Information (HIPAA)
As part of this study, we will be collecting health information about you and sharing it with others in the form of aggregated data. However, this information is "protected" because it is identifiable or "linked" to you.

Protected Health Information (PHI)
By signing this Consent Document, you are allowing the investigators and other authorized personnel to use your protected health information for the purposes of this study. This information may include your medical and family health history.

In addition to researchers and staff at UNM and other groups listed in this form, there is a chance that your health information may be shared (re-disclosed) outside of the research study and no longer be protected by federal privacy laws. Examples of this include disclosures for law enforcement, judicial proceeding, health oversight activities and public health measures.

Right to Withdraw Your Authorization
Your authorization for the use of your health information for this study shall not expire unless you cancel this authorization. Your health information will be used as long as it is needed for this study. However, you may withdraw your authorization at any time provided you notify the UNM investigators in writing. To do this, please send a letter notifying them of your withdrawal to:

Matthew Bouchonville MD
MSC 10 5550
1 University of New Mexico
Albuquerque, New Mexico 87131

Please be aware that the research team will not be required to destroy or retrieve any of your health information that has already been used or shared before your withdrawal is received.

Refusal to Sign
If you choose not to sign this consent form and authorization for the use of your PHI, you will not be allowed to take part in the research study.

What if I have questions or complaints about this study?
If you have any questions, concerns or complaints at any time about the research study, Dr. Matthew Bouchonville, MD, or his associates will be glad to answer them at (505) 272-4658.

If you would like to speak with someone other than the research team, you may call the Human Research Review Committee (HRRC) at (505) 272-1129. The HRRC is a group of people from UNMHSC and the community who provide independent oversight of safety and ethical issues related to research involving human participants.

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

What are my rights as a research participant?
If you have questions regarding your rights as a research participant, you may call the Human Research Protections Office (HRPO) at (505) 272-1129 or visit the HRPO website at https://hsc.unm.edu/research/hrpo.

Consent and Authorization
You are making a decision whether to participate in this study. Your signature below indicates that you read the information provided (or the information was read to you). By signing this consent form, you are not waiving any of your legal rights as a research participant.

I have had an opportunity to ask questions and all questions have been answered to my satisfaction. By signing this consent form, I agree to participate in this study and give permission for my health information to be used or disclosed as described in this consent form. A copy of this consent form will be provided to me.

	/
Name of Adult Participant (print)	Signature of Adult Participant
Date	

I have explained the research to the participant and answered all of his/her questions. I believe that he/she understands the information in this consent form and freely consents to participate.

	/

Name of Research Team Member

Signature of Research Team Member

Date