



**Nourishing the Community Through Culinary Medicine- Acres Homes**

**NCT06096506**

**Version Date: 03/15/2024**

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**IRB NUMBER: HSC-SPH-23-0810**  
**IRB APPROVAL DATE: 03/15/2024**

## ADULT CONSENT TO TAKE PART IN RESEARCH

**Full Study Title:** Nourishing the Community through Culinary Medicine - Acres Homes

**Protocol No:** HSC-SPH-23-0810

**Study Sponsor:** MD Anderson Cancer Center

**Principal Investigator:** Natalia Heredia, PhD, MPH, Assistant Professor, Health Promotion and Behavioral Sciences, Center for Health Promotion and Prevention Research, UTHealth Houston School of Public Health

**Study Contact:** Natalia Heredia, PhD, MPH, [REDACTED]

You are being invited to take part in a research study because you are a patient at the UT Physicians clinics that serve the Acres Homes neighborhood of Houston. Your decision to take part is voluntary. You may refuse to take part or choose to stop taking part, at any time. The purpose of this study is to see how well a virtual hands-on healthy cooking class works to help patients with diabetes and high body weight change their eating habits, improve their blood sugar and ultimately, their health. This program may help participants develop healthy cooking skills and improve related eating habits.

If you choose to participate in this study, you will be asked to complete an online pre- and post-survey, participate in five online cooking classes, and complete lab work at UT Physicians clinics within three months of starting the program and six months after completing the program. The total amount of time you will be in this study is approximately 15 minutes to complete the surveys, 90-minutes for each weekly class (plus time for grocery shopping), and up to 30 minutes for homework activities per week.

There are potential risks involved with this study that are described in later this document. Some known risks include cuts and burns due to cooking, and potential allergic reactions to foods.

There may be potential benefits to you such as an increase in your awareness about healthy cooking and nutrition for yourself and your family.

If you do not want to be in the study, there are no other choices except not to take part in the study.

If you decide to take part in the study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your usual benefits. Your decision will not affect your future relationship with the University of Texas Health Science Center at Houston (UTHealth Houston) or UT Physicians Clinics.

If you are interested in participating, please continue to read below.

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**What is the purpose of this research study?**

The purpose of this research study is to see how well Nourishing the Community Through Culinary Medicine - Acres Homes works at treating people with diabetes and high body weight change their eating habits, improve their blood sugar and ultimately, their health.

National Cancer Institute (NCI) (via MD Anderson Cancer Center) is paying UTHealth Houston for their work on this study.

A description of this clinical trial will be available on <http://www.clinicaltrials.gov>. 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.

**Who is being asked to take part in this study?**

You are being asked to take part in this research study because you have diabetes and high body weight. This study is being conducted at two UT Physicians Clinics. About 130 people will take part in the study in Houston.

**What will happen if you take part in this study?**

What to expect as a participant:

- You will be asked to complete an online survey before and after the program.
- You will participate in, five online classes lasting 90-minutes that include:
  - Hands-on cooking virtual cooking classes
  - Links to watch additional cooking technique and recipe videos
  - Nutrition education and activities lead by UTHealth Houston registered dietitians and trained UTHealth Houston staff
- Your lab results (blood sugar, blood pressure, weight, cholesterol) will be securely shared with us by your UT Physicians clinic. Participants will need to complete laboratory work at UT Physicians clinics no more than 3 months prior to enrollment and a follow-up appointment about 3 months after enrollment. This frequency of visit to the clinic is part of your standard of care and will not be covered by the study. If you fail to report to your follow-up appointment you will be contacted via telephone to make an appointment for laboratory work.
- You may be asked to complete an optional interview.

*Interviews/Questionnaires/Surveys*

As part of this study, you will be asked to complete surveys. While survey questions are mandatory, if you are unsure, you can select “Don’t know” or “Refuse to answer” the question. You will be asked to complete an online survey before and after the program that includes questions about:

- Dietary intake, dietary habits, cooking skills/behaviors, food availability, home nutrition environment, food purchasing habits, food beliefs, diabetes management, and other related behaviors.
- Your age, gender, level of education, race/ethnicity and participation in government programs.
- Each survey takes about 15 minutes. The optional interview takes about 30 minutes.

**How long will you be in the study?**

If you agree to take part, your participation will last for 5 weeks and will involve five 90-minute classes.

**How will your information be used?**

Your information (data) may be used for a variety of research purposes. The results will be used to determine if virtual cooking classes can be effective in improving cooking skills, health outcomes, and dietary behaviors.

**What choices do you have other than this study?**

If you do not want to be in the study, there are no other choices except not to take part in the study.

**What are the risks of taking part in this study?**

There are both risks and benefits to taking part in this study. It is important for you to think carefully about these as you make your decision. There are potential risks related to taking part in this study.

- Knives will be used raising the risk for minor cuts.
- Stove tops, ovens, and other kitchen equipment will be utilized raising the risk for minor burns.
- Food items containing known allergens may be utilized raising the risk for allergic reaction.

*Interviews/Questionnaires/Surveys*

You may get tired or bored when we are asking you questions or you are completing questionnaires. You do not have to answer any question you do not want to answer.

*Breach of Confidentiality*

There is the risk that information about you may become known to people outside this study.

**What are the benefits to taking part in this study?**

There is some evidence in people with diabetes that the NCCM Study can promote cooking and healthy eating, improve diet- and cooking-related attitudes and behaviors, and lower blood sugar levels. However, we do not know if this will happen in everyone with diabetes. This study may help the researchers learn things that may help other people in the future.

**Can you stop taking part in this study?**

Your participation in this study is voluntary. You may decide to stop taking part in the study at any time. To withdraw from the study, please contact Natalia Heredia, PhD, MPH at [REDACTED].

The PI or MD Anderson can stop the study at any time. The PI or MD Anderson may stop your participation in the study if your condition worsens, the study is stopped, you do not meet all the requirements of the study, or the study is not in your best interest. If your participation in the study is stopped, your doctor will discuss other options for your treatment.

If you stop participating in this study, the information already collected about you will still be used in the data analysis. However, no further information will be collected without your permission.

While taking part in this study, the study team will notify you of new information that may become available and could affect your willingness to stay in the study.

**What are your costs for taking part in this study?**

There is no cost to participate in the program. You will receive grocery store gift cards (\$200 total) in order to purchase foods needed to participate in class. If the grocery cards do not cover the cost of groceries, you will be responsible for the additional costs incurred.

**Will you be paid for taking part in this study?**

You will receive a \$25 gift card for completing a survey before the classes begin. You will receive an additional \$25 gift card for completing a survey after completing the program. Participants will not be compensated for completing the surveys if they received \$25 gift cards for completing the surveys in a prior study cohort.

Participants will receive a \$40 grocery card per class (5 classes for a total of \$200) to purchase ingredients for the cooking sessions. Participants who are repeating a class will not receive a \$40 grocery card if they received one for the same class in a prior study cohort. Participants who are absent for a session will not receive a \$40 grocery card for the following session until they confirm with a staff member that they plan to attend the following session. Participants who are absent for 2 or more consecutive sessions will not receive a \$40 grocery card until they attend another session.

**How will your privacy and confidentiality be protected?**

Your privacy is important and your participation in this study will be kept confidential. However, absolute confidentiality cannot be guaranteed.

If you sign this document, you give permission to UTHealth Houston to use and disclose (release) your health information. The health information that we may use or disclose for this research will be used only by the study team and includes height, weight, blood pressure, triglycerides, and cholesterol.

All identifiable information (e.g., your name, medical record number, or date of birth) will be removed from the private information (data) collected in this study. After we remove all identifiers, the data may be used for future research or shared with other researchers without your additional informed consent.

If you are not comfortable with the use of your data in future research, you may not want to participate in this study.

Please note that you do not have to sign this Authorization, but if you do not, you may not participate in this research study. UTHealth Houston and UT Physicians may not withhold treatment or refuse treating you if you do not sign this Authorization.

You may change your mind and revoke (take back) this Authorization at any time. Even if you revoke this Authorization, researchers may still use or disclose health information they already have obtained about you as necessary to maintain the integrity or reliability of the current research. To revoke this Authorization, you must contact Natalia Heredia, PhD, MPH in writing at [REDACTED].

This Authorization will expire 15 years after the end of the study.

**Whom can you contact if you have questions about the study?**

If you have questions at any time about this research study, please feel free to contact Natalia Heredia, PhD, MPH at [REDACTED] as she will be glad to answer your questions. You can contact the study team to discuss problems, report injuries, voice concerns, obtain information in addition to asking questions about the research.

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The Committee for Protection of Human Subjects (CPHS) at the University of Texas Health Science Center has reviewed this research study. You may contact them for any questions about your rights as a research subject, and to discuss any concerns, comments, or complaints about taking part in a research study at [REDACTED].

**Are you interested in being contacted for future research studies?**

Please check the appropriate box to indicate your preference. If you are interested in participating in future studies, the research team will retain information that will identify you, such as your name, phone number, mailing address, and/or email address.

☐ Yes, I am interested in being contacted for future research studies.

☐ No, I am not interested in being contact for future research studies.

**SIGNATURES**

Sign below only if you understand the information given to you about the research and you choose to take part in this research study. Make sure that all your questions have been answered. If you decide to take part in this research study, a copy of this signed consent form will be given to you.

Printed Name of Subject	Signature of Subject	Date	Time
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Printed Name of Person Obtaining Informed Consent	Signature of Person Obtaining Informed Consent	Date	Time
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