Fred Hutchinson Cancer Research Center

Consent to take part in a research study:

Mi Vida Saludable en el Valle

Adaptation and Evaluation of an Online and eHealth Diet and Physical Activity Program to Improve Cardiometabolic Health in Rural Latino Adults

Principal Investigator: Rachel Ceballos, PhD
Fred Hutchinson Cancer Research Center
206-667-7806

Co-Investigator: Heather Greenlee, ND, PhD
Fred Hutchinson Cancer Research Center
206-667-4502

Community Project Manager: Genoveva Ibarra
Fred Hutch Center for Community Health Promotion
509-837-6359
509-840-5203

Important things to know about this study.

You are invited to participate in a research study. The purpose of this research is to understand the best way to teach Latino adults with a history of hypertension, diabetes, cardiovascular disease, cancer, or obesity how to eat a healthy diet and maintain ≥150 minutes per week of moderate-to-vigorous physical activity. People who agree to join the study will be asked to attend up to 6 study online sessions over a period of 3 months, as described in the study procedures section of this consent form. The goal of any research study is to answer questions. We are doing this research study to answer these questions:

1. Can online group sessions and electronic health (eHealth) communications (including text messages, newsletters and a website) be used to promote healthy eating and physical activity in Latino cancer survivors who live in a rural area?
2. Do online group sessions and eHealth communication intervention cause changes in diet quality and minutes per week of moderate-to-vigorous physical activity?
3. Is there a difference in the changes in diet quality and minutes per week of moderate-to-vigorous physical activity when comparing results from participants who receive one online group session and eHealth

FHCRC IRB Approval
SEP 24 2021
Document Released Date

communications compared to participants who receive the eHealth communication and six biweekly online group sessions?

We would like you to join this research study.
We are doing this study to understand how to create an effective education program for Latinos living in rural areas who have a history of hypertension, diabetes, cardiovascular disease, cancer, or obesity. We want to know how to address the needs of Latinos residing in Lower Yakima Valley. Since you have self-identified as Hispanic/Latino, speak Spanish fluently, are 18 years or older, and have a history of hypertension, diabetes, cardiovascular disease, cancer, or obesity, we would like to ask you to join this research study. We will enroll up to 40 people.

You do not have to be in this study. You are free to say yes or no, or to drop out after joining. There is no penalty or loss of benefits if you say no. Whatever you decide, your regular medical care will not change.

What research tests and procedures are part of this study? / What will happen in this study? If you decide to join this study, we will do these tests and procedures:

Baseline Data Collection: Before any data collection, a community health educator or promotor(a) will explain to you the study activities, rights and responsibilities. After signing the informed consent form online, you will receive:

1. A link to an online medical records release form for your permission to access and collect information from your medical recorded related to your diagnoses and treatment.
2. A link to an online questionnaire to collect information about your demographics (age, gender, ethnicity, etc.), medical history, height, weight, current health status, health behaviors, quality of life, and medication use.

Data Collection at Home: We will mail you a study data collection package with information and materials and devices, along with written instructions (some will include links to video instructions) on how to completer the data collection procedures. We will also be available by phone to answer any of your questions:

1. Actigraph accelerometer device, also known an accelerometer, to collect data on your physical activity during an average week.
2. A questionnaire to report the frequency of food consumption and portion sizes over a 2-week period of time.
3. Materials to return the accelerometer to us by mail.

Telephone-based Data Collection: You may be randomly selected to complete three phone interviews about the foods you ate and beverages you drank during the past 24 hours. Each phone call will take 20-30 minutes to complete. All participants will receive a phone call reminder to complete all collection procedures and to return the materials to us in the pre-stamped and addressed return mailers provided to you.

Randomization: After completing the data collection mentioned above, you will participate in one of two study groups:

1. **6 Online Group Sessions of Mi Vida Saludable en el Valle and electronic Health (eHealth) Communication for 3 months.** If you are randomized to the six online sessions study group, you will participate in 6 nutrition and physical activity classes held every other week for 3 months. Sessions will each last for about 120 minutes and will be streamed via Zoom. Sessions will include cooking and physical activity education, cooking hands-on sessions, exercise classes and activities. If you are unable to attend the class, you will be able to access a recorded copy on the study website. You will also receive eHealth communications including supportive text messages twice a week, links to newsletters via text, and access to a nutrition website. You will receive the text messages on your cell phone or tablet and you will have the option to respond to the text messages. Study staff will measure your use of the website using Google analytics software. Text messages will be sent using a computer program called REDCap. Your cell phone number will be stored on the secure Fred Hutch computer servers.

2. **1 Online Group Session of Mi Vida Saludable en el Valle and electronic Health (eHealth) Communication for 3 months.**
   If you are randomized to the one online session study group, you will participate in one nutrition and physical activity class at the start of the three month project period. The session will last for about 120 minutes and will be streamed via Zoom. Sessions will provide an introduction to healthy cooking and physical activity education. If you are unable to attend the class, you will be able to access a recorded copy on the study website. You will also receive eHealth communications including supportive text messages twice a week, links to newsletters via text, and access to a nutrition website. You will receive the text messages on your cell phone or tablet and you will have the option to respond to the text messages. Study staff will measure your use of the website using Google analytics software. Text messages will be sent using a computer program called REDCap. Your cell phone number will be stored on the secure Fred Hutch computer servers.

Start-Up Package: Study staff will contact you over the phone to inform you of your group assignment. Following this phone call, we will mail you a study package that will include a schedule of study activities and a Fitbit device to monitor your daily physical activity throughout the study with detailed instructions on how to use the Fitbit. You will also receive a binder with written materials needed to participate in the online session(s).

Monthly Phone Call: Each month, study staff will call you to ask about your use of the Fitbit and help you fix any technical issues you may have with the device. We will also ask you some questions about COVID-19.

Reminders: You will receive reminders about completing data collection and participating in the online session(s) via text messages, email and phone calls, depending on your preference.

Follow-up Data Collection (3 months): After 3 months, data collection procedures will be repeated. We will send you a link to an online questionnaire to collect information about your current health status, weight, health behaviors, quality of life, medication use, and your thoughts on participating in the study. If you prefer, we can ask you the questions over the phone.

We will mail you a data collection package similar to one you received at baseline, including an accelerometer device for you to wear for a continuous 7 days and food frequency questionnaire. You will be asked to return the accelerometer by mail using the provided pre-stamped and addressed individual return mailers.

If you were selected at the beginning of the study to complete phone interviews on foods and beverages, we will also contact you by phone to complete three interviews about the foods you ate and beverages you drank during the past 24 hours. Each phone call will take 20-30 minutes to complete.

Finally, we will ask you about your experience in the study during a brief phone interview.

How will this study help me?

We do not know if being in this study will help participants. The study procedures could cause side effects such as feeling uncomfortable by study questions or an unintentional injury from physical activity, as described below in this form. The study will provide information on healthy nutrition and physical activity for cancer survivors.

You do not have to join this study. We will give you details about the purposes, procedures, risks and possible benefits related to this study. We will explain other choices that you have. We will also give you any other information that you need in order to make an informed decision about joining this study.

Below is a more complete description of this study. Please read this description carefully. You can ask any questions you want to help you decide whether to join the study. If you join this study, we will give you a signed copy of this form to keep for future reference.

How long will I be in this study?
We think you will be in this study for about 4-5 months.

The study principal investigator or your doctor may take you out of this study at any time. This would happen if:

- They think it is in your best interest to drop out.
- You are unable or unwilling to follow study procedures.
- The whole study is stopped.

If you are thinking about dropping out of this study, please tell us. We will talk to you about any other follow-up or testing that would help you.
If you leave the study, your test results and information cannot be removed from the study records.

Risks of being in this study
There are some potential risks with participating in this study. These potential risks are listed below. There may be some unknown risks linked with being in this study that are not listed.

Survey Questions: You may feel uncomfortable, embarrassed, or self-conscious about answering the study questions. The study staff's questions are to better assist Latino cancer survivors in the future. You do not have to answer any part of the questionnaires or other assessments; you may ask to skip questions that may make you feel uncomfortable. Study staff will also discuss how information will be kept confidential.

Loss of confidentiality: A risk of taking part in this study is the possibility of a loss of confidentiality. Loss of confidentiality includes having your personal information shared with someone who is not on the study team and was not supposed to see or know about your information. We'll try to protect your information, but we can't guarantee privacy. The plans for keeping your information private are described in the 'confidentiality' section of this consent form.

Physical injury: There is a risk of unintentional injuries that may occur while cooking, performing physical activity. You will be asked to increase your physical activity during the 3 months of the study. This increased physical activity may cause unintentional soreness, joint pain or exercise related injuries.

Gas and bloating: Recommended dietary changes may include gas and bloating due to increased fiber consumption.

Inconvenience: The timing and frequency of the phone calls, online sessions, text messages, and emails may be inconvenient to your schedule.

Other risks: There may be other risks of taking part in this research study that we don't know about. If we learn about other risks, we will let you know what they are so that you can decide whether or not you want to continue to be in the study.

What are the benefits?
We do not know if this study will benefit participants. We hope the information we learn will help cancer survivors in the future.

Although the study may not benefit participants directly, we hope the information we learn will improve our knowledge about the best way to teach cancer survivors about maintaining a healthy diet and engaging in regular moderate-to-vigorous physical activity.

You have other choices besides this study.
You do not have to join this study. You are free to say yes or no. Your regular medical care will not change. Enrollment in this study may exclude you from other research studies.

If you do not join this study, you have other choices. Each of these choices has risks and benefits. You should talk to your doctor or healthcare provider about them.

Your other choices may include:

- Following your physician's or treatment team's directions for diet, exercise, and other health maintenance and improvement activities.
- Other research studies.
- Standard exercise programs.
- Exercising on your own.
- No exercise programs.
- Seeing a dietitian on your own.
- Taking healthy eating and cooking classes on your own.

Protecting your Privacy as an Individual and the Confidentiality of Your Personal Information

Some people or organizations may need to look at your research records for quality assurance or data analysis. They include:

- Researchers involved with this study.
- Institutional Review Boards (IRB), including the Fred Hutchinson Cancer Research Center IRB. An IRB is a group that reviews the study to protect your rights as a research participant.
- Fred Hutchinson Cancer Research Center
- US National Institutes of Health, National Cancer Institute, Office for Human Research Protections, Food and Drug Administration, and other agencies as required.
- Office of Human Research Protections (OHRP)

We will do our best to keep the personal information in your medical record confidential. But we cannot guarantee total confidentiality. Your personal information may be given out if required by law. For example, workplace safety rules may require health workers to contact you about lab tests. Or a court may order study information to be disclosed. Such cases are rare.

We will not use your personal information in any reports about this study, such as journal articles or presentations at scientific meetings.

A description of this clinical trial 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.

This research is covered by a Certificate of Confidentiality from the U.S. government. This Certificate helps protect the confidentiality of information about people who join this study. If you join the study, the Certificate means that generally we would not have to give out identifying information about you even if we were asked to by a court of law. We would use the Certificate to resist any demands for identifying information.

We could not use the Certificate to withhold research information if you give written consent to give it to an insurer, employer, or other person.

This protection has some limits. We would voluntarily provide the information:

- To a member of the federal government who needs it in order to audit or evaluate the research.
- To the funding agency and groups involved in the research, if they need the information to make sure the research is being done correctly.
- To the federal Food and Drug Administration (FDA), if required by the FDA.
- To someone who is accused of a crime, if he or she believes that our research records could be used for defense.
- To authorities, if we learn of child abuse, elder abuse, or if participants might harm themselves or others.

Will you pay me to be in this study?
If you complete this study, we will give you at $25 gift card after completing all assessments during the baseline data collection and returning the accelerometer to study staff via the provided return mailers. We will also give you a $25 gift card after completing the 3-month follow-up data collection procedures. You will get to keep your Fitbit device, which is approximately of a $100 value. If you drop out of the study, or if we take you out of this study, you will not receive the gift card for the 3-month follow-up, but you will be able to keep the Fitbit.

At the start of the study, you will receive cookware to assist you in reaching the diet and physical activity goals of the intervention. We will provide the ingredients needed to cook a meal during the hands-on cooking portion of the online sessions (one or six depending on which group you are randomized to), which will be available to pick up at a convenient local grocery store or delivered to your home, depending on your preference.

How much will this study cost me?
There may be some extra costs for being in the study. These costs may include expenses for childcare during the online sessions, if you need childcare during the sessions.

What if you get sick or hurt after you join this study?
For a life-threatening problem, call 911 right away or seek help immediately. Contact your study doctor when the medical emergency is over or as soon as you can.

For all other medical problems or illness related to this research, immediately contact the Community Project Manager, Genoveva Ibarra at 509-837-6359. They will treat you or refer you for treatment. You or your health insurance will have to pay for the treatment. There are no funds to pay you for a research-related injury, added medical costs, loss of a job, or other costs to you or your family. State or national law may give you rights to seek payment for some of these expenses. You do not waive any right to seek payment by signing this consent form.

You or your insurer will be billed for treatment of problems or complications that result from your condition or from standard clinical care. You would not lose any legal right to seek payment for treatment if you sign this form.

What will my information be used for?
Your medical information will be used for the purposes of this study. Your information, including medical records relating to diagnoses and surveys you participate in for this study, will be used to understand how well the study activities work at helping people change their diet and physical activity behaviors.

In addition, be aware that by agreeing to participate in this study, your information could be used for future research studies or sent to other investigators for future research studies without additional consent from you. These future research studies will be reviewed by an oversight group known as an institutional review board (IRB) if required by law. The information that identifies you will first be removed from your information.

The online sessions will be video, and audio recorded for viewing by other study participants and to be used for research purposes. During the recordings, you may be recorded, including your voice on video, photographic, digital, electronic or any other medium and any comments or questions made during the sessions. Do you give permission for us to use your image, or video, or voice when presenting research results or promoting similar studies? (circle one)
YES **NO** Initials: Date:

Is it OK for researchers to contact you in the future to ask you to participate in future research studies? (circle one)
YES **NO** Initials: Date:

Your rights

- You do not have to join this study. You are free to say yes or no. Your regular medical care will not change.
- If you join this study, you do not have to stay in it. You may stop at any time (even before you start). There is no penalty for stopping. Your regular medical care will not change.
- If you get sick or hurt in this study, you do not lose any of your legal rights to seek payment by signing this form.
- During the study, we may learn new information you need to know. For example, some information may affect your health or well-being. Other information may make you change your mind about being in this study. If we learn these kinds of information, we will tell you.

For more information

If you have questions or concerns about this study, you can talk to your doctor anytime. Other people you can talk to are listed below.

If you have questions about:	**Call:**
This study (including complaints and requests for information)	206-667-7806 (Dr. Rachel Ceballos) 509-837-6359 (Genoveva Ibarra, Community Project Manager)
If you get sick or hurt in this study	206-667-7806 (Dr. Rachel Ceballos)
Your rights as a research participant	206-667-5900 or email irodirector@fredhutch.org (Director of Institutional Review Office, Fred Hutchinson Cancer Research Center)

Signature

Please sign below if you:

- have read this form (or had it read to you);
- had the opportunity to ask any questions you have;
- had the opportunity to discuss the research with the person obtaining consent; and
- agree to participate in this study.

Participant (age 18+)

Printed Name	Signature	Date

If you served as an interpreter or impartial witness during the consent process, sign below to indicate you attest to the accuracy of the presentation and the participant's apparent understanding of and willingness to participate in the research.

Impartial Witness or Interpreter:

Printed Name	Signature	Date

Researcher's statement

I have discussed the research study, including procedures and risks, with the person signing above. A copy of the signed consent form will be given to the participant.

Person obtaining consent signature:

Printed Name	Signature	Date

Protocol: IR# 10270
Current consent version date: 09/21/2021
Previous consent version date: 04/21/2021
Copies to: