Protocol Title: Wellness with Culturally Optimized Messages for Ethnic-diverse Latinos (Welcome)
Principal Investigator: Josiemer Mattei Faculty Advisor (if PI is a student):
Description of Study Population: Hispanic/Latino adults 25-65y living in MA
Version Date: July 12, 2022

Key Information

The following is a short summary of this study to help you decide whether or not to participate. More detailed information is listed later on in this form.

Why am I being invited to take part in a research study?

We have invited you to take part in a research study because you are an adult between the ages of 25-65 years that self-identify as Latino/Hispanic and who have lived in Massachusetts for the past 12 months, do not plan to move from the area in the next 6 months, with no major chronic conditions, non-pregnant, willing to receive text messages in your phone, and able to understand a conversation in Spanish or English and answer questions without help. It is your choice whether or not to participate. If you choose to participate, you may change your mind and leave the study at any time. Refusal to participate or stopping your participation will involve no penalty or loss of benefits to which you are otherwise entitled.

* Someone will explain this research study to you.

- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You may discuss your decision with your family, your friends and/or your doctor.
- You can ask all the questions you want before you decide.

Why is this research being done?

Researchers at the Harvard University's T.H. Chan School of Public Health are conducting a study with the aim of identifying Latino/Hispanic cultural factors that can help with healthy eating in this community, and of studying similarities and differences by group of origin. This information will be used to design educational, nutritional programs that are appropriate to the Latino culture, which aim to help prevent chronic illnesses such as diabetes and cardiovascular diseases.

What will I be asked to do?

You will be asked to complete the procedures in four appointments (every 2 months) conducted by video calls within a period of 6 months. For the first 4 months, you will receive text messages daily with messages on healthy eating in the cellphone number that you provide. During the course of the study, you will receive reminders about the study. At each of the appointments, you will be asked questions on your health, lifestyle, diet and to take body and blood pressure measures with equipment that will be sent to your home address, following proper instructions. You may be invited

(at random) to one last conversation about your opinion of the program at the end of the study. You will be asked to provide the name of 3 contacts to help us reach you in case we cannot contact you on your phone.

How long will I take part in this research?

Your participation in this research study will conclude once you complete the procedures in four appointments conducted by Zoom calls (one initial appointment, one in 2 months, one in 4 months, and one in 6 months) within a period of 6 months. We expect that it will take about 1-2 hours to complete the procedures of the first call, and 1 hour for the other 3 calls. You may take a break during the appointment if you wish so. If for any reason you decide not to complete the study at the time of the call, you may choose to complete the questionnaire within the next 2 weeks. You may be invited (at random) to one last conversation about your opinion of the program at the end of the study that would last 30-60 minutes. This conversation will be audio-recorded. More detailed information about the study procedures can be found under the *"What can I expect if I take part in this research?"* section.

Is there any way being in this study could be bad for me?

The risks and discomforts of this study are minimal. Some sections of the interview may ask questions about personal feelings and emotions that may upset some participants. A potential adverse risk is breach of confidentiality of the information reported. All efforts to protect confidentiality will be done.
More detailed information about the risks of this study can be found under the *"What are the risks and possible discomforts?"* section.

Will being in this study help me in any way?

There are no direct benefits to you from your participation in this research. We cannot promise any benefits to others from your participation in this research. However, possible benefits to others may include benefiting from other research studies, policies, and programs for healthy eating and for prevention of chronic diseases created based on the information that you and other study participants have provided.

What happens if I do not want to be in this research?

Participation in research is completely voluntary. You can decide to participate or not to participate. Your alternative to participating in this research study is to not participate.

Detailed Information

Please find below more detailed information about this study.

About this consent form
Please read this form carefully. It provides important information about participating in research. You have the right to take your time in making decisions about participating in this research. If you have any questions about the research or any portion of this form, you can ask us at any time. If you decide to participate in this research, you will be asked to sign this form. A copy of the signed form will be provided to you for your record.

Who can I talk to?
If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at:
Josiemer Mattei, PhD, MPH
Principal investigators (in English or Spanish)
Assistant Professor, Department of Nutrition, Harvard T.H. Chan School of Public Health
Phone: 617-432-3017; Email: jmattei@hsph.harvard.edu

This research has been reviewed by the Harvard Longwood Medical Area Institutional Review Board (IRB). If you wish to speak with someone from the IRB, you may contact the Office of Human Research Administration (OHRA) at 617-432-2157 (or toll-free at 1-866-606-0573) or at irb@hsph.harvard.edu for any of the following:

- If your questions, concerns, or complaints are not being answered by the research team,
- If you cannot reach the research team,
- If you want to talk to someone besides the research team,
- If you have questions about your rights as a research participant, or
- If you want to get information or provide input about this research.

Participation is voluntary
You are invited to take part in this research because you are an adult between the ages of 25-65 years that self-identify as Latino/Hispanic and who have lived in MA for the past 12 months, do not plan to move from the area in the next 6 months, with no major chronic conditions, non-pregnant, willing to receive text messages in your phone, and able to understand a conversation in Spanish or English and answer questions without help. It is your choice whether or not to participate. If you choose to participate, you may change your mind and leave the study at any time. Refusal to participate or stopping your participation will involve no penalty or loss of benefits to which you are otherwise entitled.

How many people will take part in this research?
About 75 people will take part in this research.

What can I expect if I take part in this research?
As a participant, you will be expected to complete the following:

1. You will be randomly assigned to a study group of which healthy eating messages you will receive. Your group assignment is by chance (i.e.: flip of a coin).

2. You will be asked to take measurements of your waist and hip by using a measuring tape, blood pressure in one of your arms using a blood pressure monitor, and your weight using a scale. This equipment will be sent to you, along with detailed instructions on how to use it. Throughout the study period, you will be asked to report them to the research assistant at the interview. You do not have to return the instruments to the Study.
3. A research assistant will administer a questionnaire that asks you questions on your age, sex, education, income, work, health care, medical diagnoses, smoking, alcohol use, physical activity, sleep, psychological and social scales, dietary behaviors and diet attitudes and satisfaction. Your answers will be entered electronically in the interviewer's computer. You may refuse to answer any particular question or any of these questionnaires without any consequence. The questionnaire will be completed by phone and/or video using Zoom. There will be a total of 4 appointments to complete this questionnaire (initial, at 2, 4 and 6 months, respectively). We will try to contact you up to 10 times to get it for these follow-up appointments; if we do not reach you, we will consider you as no longer interested in the study. You will be asked to provide the name of 3 contacts to help us reach you in case we cannot contact you on your phone.
4. You will receive daily texts during the first 4 months of the study in the cellphone number(s) that you provide to us today. Messages will include nutritional guidance, recipes, and basic nutrition information. Some messages will provide a link that will direct you to a secure website where you can access the content. You may contact us with questions and comments to these texts only as you want to, with no obligation to do so. During the last 2 months of the study, you will not receive daily text messages but will continue to have access to the material provided. After the 6 months of the study, we will select at random about 10-20 participants. If your name is selected, we might contact you to invite you to complete an interview of 30-60 minutes to hear your thoughts and opinions about the study. This is an optional component and you would get additional compensation for this.
5. It is feasible that in the future, we plan other similar research studies on lifestyle and diseases. If you were to meet the selection criteria and qualify for those studies that we would propose in the future, we may invite you to participate on such. We will ask you if you agree to be contacted with information about how to join other studies.
6. Because the study will have follow-up calls, we will ask you to provide at least 2 points of contact that will help us locate you. By signing this consent form, you agree that we inform these persons that you are part of this study (no more details) and that they are your contact.

You may choose to opt out of some parts of the research study without any penalty.

The research team at your Study Site (Harvard Chan School) will collect information about you. This form calls such information your "Personal Information" and it will include your name, contact information, sociodemographic and lifestyle information, and the results of any tests, surveys or procedures described in this informed consent form. It may also include information about your past and present health conditions and medications, emotional feelings, race or ethnicity.

What are my responsibilities?

As a participant, you are responsible for answering all questions with true and accurate answers to the best of your knowledge and ability.

What are the risks and possible discomforts?

The risks and discomforts of this study are minimal. The procedures used in this study are not considered to carry any significant risks. Some sections of the interview (i.e.: the psychosocial questions) may ask

questions about personal feelings and emotions that may upset some participants. Interviewers are trained on cultural sensitivity and how to minimize any discomfort, including handling sensitive questions and emotional reactions. Slight discomfort may occur when taking clinical measurements. Assistants conducting the interviews have been trained to guide you during the measurement, to make the experience as comfortable as possible.

A potential adverse risk is breach of confidentiality of the information reported which may include the information of the people you provide as contacts. All efforts to protect confidentiality will be done, including removing personal identifiers and protecting data with passwords and locks. Data on criminal or civil records, or any sensitive or personal information that may lead to such, will not be collected. There are minimal to no risks for receiving the intervention text messages. If you decide to answer to messages there is a minimal risk of a breach of confidentiality of the information contained in those messages.

Are there any benefits from being in this research study?
There are no direct benefits to you from your participation in this research. We cannot promise any benefits to others from your participation in this research. However, possible benefits to others may include benefiting from other research studies, policies, and programs for healthy eating or prevention of chronic diseases based on the information that you and other study participants have provided.

What happens if I say yes, but I change my mind later?
You can leave the research at any time, and it will not be held against you. If you decide to leave the research, you may do so at any time. There will be no penalty to you. If you decide to leave the research study, contact the investigator so that the investigator can discontinue all procedures and mark down your non-participation so that you are not contacted again about the study in the future. Before this, you will be asked to explain why you are discounting the study; if the decision is regarding a part, but not the whole study, we will ask if you agree to undergo follow-up procedures or data collection that you are comfortable with.

If you stop being in the research, already collected data may not be removed from the study database.

If you withdraw from the whole study, you will no longer be able to participate in the study. No new information or samples will be collected about you or from you by the study team. Your withdrawal has no effect on the lawfulness of the data processing that occurred prior to your withdrawal.
Your Study Site may still, after your withdrawal, need to report any safety event that you may have experienced due to your participation to Harvard University and other entities involved in the study. Your personal information, including coded information, that has already been collected up to the time of your withdrawal will be kept and used to guarantee the integrity of the study, to satisfy any legal or regulatory requirements related to ensuring public health, including ensuring high standards of quality and safety of health care and of medicinal products or medical devices, and/or for any other purposes permitted under applicable data protection and privacy laws.

Your personal information (including coded information) will not be used for further scientific research. However, if permitted by applicable law, your Personal Information may be anonymized so that the information does not identify you personally. This anonymized information may be used for further research.

Will I be compensated for participating in this research?
You will receive up to a total of $100 in the form of multiple Visa gift cards given as a $25 gift card in each of the four visits (first, 2 months, 4 months, 6 months), as compensation for completing the study. The gift card will be given regardless of how many steps are completed or if you leave the study during the visit. If your name is selected at random to be invited to participate in one last chat or interview about your opinions of the program, you will receive an additional $20 gift card.

What will I have to pay for if I participate in this research?
It will not cost you anything to participate in this research.

What happens if I am injured as a result of participating in this research study?
If physical injury resulting from participation in this research should occur, Harvard's policy is not to provide compensation.

If I take part in this research, how will my privacy be protected? What happens to the information you collect?
Every effort will be made to ensure that your participation in this study, and all records related to your participation, will remain confidential. There is a very small possibility that the interviewer may know you, at which case you can request to have another interviewer or decline participation without penalty. The principal investigator of this study, Dr. Josiemer Mattei, will train and require all study personnel, including interviewers, to refrain from quoting or identifying any participant. Only authorized members of the research team will have access to the electronic and paper-based files and will be trained to keep all information confidential. When not in use, the paper-based files will be kept in a locked file cabinet, in a locked office. Electronic files will be kept on password-protected computers or programs. For data analyses, we will give each participant a unique identification number as part of a coding system to link the information you provide. These data and the link between the research code and the identifiers will be kept in separate locked file drawers and in a password-protected computer. Your name and other personal identifying information will not be associated with the information you provide. Any results of this research study that become published or presented at meetings will be presented grouped for all participants; your identity will not be revealed.

The unidentifiable data may be available upon request to other researchers via a secured, password-protected sharing website, at no cost to them. The information provided to users will *not* be used for commercial purposes, and will *not* be redistributed to third parties. Any data sharing will follow appropriate institutional policies, as well as local, state and federal laws and regulations including the Health Insurance Portability and Accountability Act (HIPAA). Users must agree to the conditions of use governing access to the public release of data, including restrictions against attempting to identify study participants, destruction of the data after analyses are completed, reporting responsibilities, restrictions on redistribution of the data to third parties, and proper acknowledgement of the data resource.

However, confidentiality cannot be absolutely guaranteed. Data collected, including your identifiable information, may be seen by the Harvard University's Institutional Review Board (IRB) that oversees the research. We may also share your information related to this study with other parties with the right to review the records from this study, including translators, transcribers, thesis committees, FDA, and/or other federal agencies as applicable. This may occur to ensure that this study is being properly conducted and following all applicable regulations and laws. Your identity will be revealed only as required by law.

Your Personal Information will be treated in compliance with applicable data protection laws. Harvard University is the controller of your Personal Information collected for this study.[1]

Your Personal Information needed for the research will be saved, analysed and, if necessary, transferred outside of Harvard University. Before we transfer your Personal Information, we will replace your name with a unique code and remove information that directly identifies you. This is called your "Coded Information" in this form. It is sometimes called "pseudonymised data" by data protection laws. Harvard University and some of the other people using your Personal Information, including your Coded Information, may be based in countries other than your country, including the United States. Data protection and privacy laws in these countries may not offer the same level of protection as those in your own country. Harvard, and those working with Harvard, will take steps to maintain the confidentiality of your Personal Information. If your Personal Information is transferred by the Study Site from the EU, EEA, and/or Switzerland to other countries that have not yet been found by European regulators to meet requirements for protection of Personal Information, the Study Site has in place standard EU data transfer agreements to protect your Personal Information.

Efforts will be made to limit the use and disclosure of your personal information, including research study records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this organization, funding agencies, and other collaborating institutions.

The individuals and groups listed above will access your Personal Information (including your Coded Information) to conduct and manage this study, and to comply with legal or regulatory requirements, including to:

- determine if you are eligible for this study;
- verify that the study is conducted correctly and that study data are accurate;
- answer questions from IRB(s), independent ethics committee(s) (IECs), or government or regulatory agencies;
- contact you during and after the study (if necessary);
- follow-up on your health status, including using publicly available sources should the study team be unable to contact you using information held on file;
- protect your vital interests or the interests of your pregnant partner (for example, a critical medical situation, such as providing information to an emergency department of a hospital where you are being treated); and
- answer your data protection requests (if any).

Your Personal Information may also be used by the individuals and groups listed above to:

- Publish summaries of the study results in medical journals, on the internet or at educational meetings of other researchers. You will not be directly identified in any publication or report of the study. But, some journal representatives may need access to your Coded Information to verify the study results and ensure the research meets the journal's quality standards. Also, journals may require that genetic and other information from the study that does not directly identify you be made available to other researchers for further research projects.
- Comply with regulatory requirements mandating that data collected in research studies such as this one be made available to other researchers not affiliated with your Study Site or [Harvard]

[1] Controller status should be evaluated on a case by case basis depending on the precise roles of the parties in the study.

(including through publication on the internet or in other ways). However, information that could directly identify you will not be made available to other researchers.

- Improve the quality, design and safety of this study and other research studies.
- Conduct additional studies with the data collected in this study to advance scientific research and public health. At this time, we do not know the specific details of these future research projects. These projects may involve bringing together information from this study with information from other studies or sources outside typical research settings, such as data from coded electronic health records, health care cost and payment data, pharmacy data or patient engagement programs. If your Personal Information is used for additional studies, specific safeguards will be used to protect the data, which may include:
    - Using only your Coded Information rather than Personal Information that readily identifies you.
    - Limiting access to specific individuals who are obligated to keep the information confidential.
    - Using security measures to avoid data loss and unauthorized access.
    - Anonymizing the data by destroying the link to the Coded Information and your personal identifiers.
    - When required by applicable law, ensuring that the scientific research has the approval of IECs, IRBs, or other similar review groups.

Harvard University will retain your Personal Information (including your Coded Information) for the period necessary to fulfill the purposes outlined in this informed consent form, unless a different retention period is required or permitted by law.

If you provide someone else's Personal Information (for example, an emergency contact) you should make them aware that you have provided the information to us. We will only use such Personal Information in accordance with this informed consent form and applicable law.

Any type of abuse, neglect, criminal activity, or other illegal act witnessed by study personnel during the course of the study will be reported only in case of an emergency (i.e.: a life is threatened or under danger) or as required by the authorities.

What Rights do I have?

If you wish to exercise any of the rights described below, it is best to contact Longwood Medical Area IRB using the contact information provided.

- You have the right to see the information being collected about you in the study. To ensure integrity of the study, you will not be able to review some of the data until after the study has been completed. For example, if you are in a blinded study, neither the researchers nor you will be able to know the study arm in which you participated until after the study is over.
- You have the right to correct or update your Personal Information if it is inaccurate.
- You have the right to limit the collection and use of your Personal Information under certain circumstances (for example, if you think that the information is inaccurate).
- You have the right to receive your Personal Information in a structured, common computer format (for example, in a readable text electronic file or chart) for your own purposes or for giving it to others, as required by applicable data protection laws. You

may not have the right to receive your Personal Information that has been used for public interest purposes (for example, for reporting incidents of disease to public health officials) or in the exercise of official authority vested in the Study Site or [Harvard] (for example, responding to information requests from public agencies or monitoring drug safety)

- You have the right to request the deletion of your Personal Information if you are no longer participating in the study. However, there are limits on your ability to request deletion of your Personal Information. [Harvard] and your Study Site may keep and use some or all of your Personal Information if deletion would seriously impair the study (for example, if deletion would affect the consistency of study results) or if your Personal Information is needed to comply with legal requirements.
- You have the right to file a complaint with a data protection authority (http://ec.europa.eu/justice/data-protection/article-29/structure/data-protection-authorities/index_en.htm).

Can I be removed from the research without my OK?
The person in charge of the research study, Dr. Josiemer Mattei, or any of the study representatives designated by her, or the sponsor can remove you from the research study without your approval for any reason. Participants will be withdrawn from the research without consent if they present hostile or aggressive behaviors; lack of commitment to the study such as refusal or inability to answer the majority of the questions; are deemed disengaged, dishonest, or unreliable in their responses; pose any threats or endanger the wellbeing of the study staff; the study is discontinued; or there are changes to the study protocol that invalidates their eligibility. We will tell you about any new information that may affect your health, welfare, or choice to stay in the research.

What else do I need to know?
This research is being funded by funds from the Harvard TH Chan School of Public Health.

Statement of Consent
I have read the information in this consent form including risks and possible benefits. All my questions about the research have been answered to my satisfaction. I understand that I am free to withdraw at any time without penalty or loss of benefits to which I am otherwise entitled.

I consent to participate in the study.

I consent to participate in the study.
☐Yes ☐No _____ (initials)

If you consent to participate in the study:

1. **Do you agree to have us store your information for their possible use in research studies in the future?**
   ☐Yes ☐No _____ (initials)

2. **Do you agree to have a study representative from Harvard University contact you regarding possible participation in a future study if you qualify?**
   ☐Yes ☐No _____ (initials)

SIGNATURE

Your signature below indicates your permission to take part in this research

Name of participant	
Signature of participant	Date
Signature of person obtaining consent	Date
Name of person obtaining consent	