e-Motivación: Developing and Pilot Testing an App to Improve Latinos' Screening Colonoscopy Rates
PI: Sarah J Miller, Psy.D.
NCT04987788
Document Date: 5-3-2023

Form Version Date: July 11, 2022

STUDY INFORMATION:

Study Title: e-Motivación: Developing and Pilot Testing an App to Improve Latinos' Screening Colonoscopy Rates [Aim III]

Principal Investigator (Head Researcher): Sarah Miller, PsyD

Physical Address: 17 East 102nd Street, New York, NY 10029

Mailing Address: 1 Gustave L Levy Place Box 1130, NY, NY 10029

Phone: 212.824.7783

SUMMARY OF THIS RESEARCH STUDY:

In medicine there are many unanswered questions. A research study is when scientists try to answer a question about something that we don't know enough about. Participation in a research study may or may not directly help you or others. Participation is entirely voluntary. It is completely up to you whether or not you take part. You can also change your mind at any time and it will not affect your ability to get medical care within the Mount Sinai Health System.

The purpose of this research study is to test an app designed for patients who have received a referral for a screening colonoscopy and identify as Latino/a/x. The app operates in both English and Spanish and has two main functions. First, it provides information on colorectal cancer screening. Second, it helps patients decide whether or not they want to have a colonoscopy. Our intent is to understand if the app is a helpful tool that can help increase screening colonoscopy rates among Latinos.

If you choose to participate, you will be asked to answer some questions about you and your health. You will then be asked to either engage with an app about colorectal cancer OR view a general health video. In six months, the research team will review your medical record to determine whether you received a colonoscopy.

The main risks to you if you choose to participate are: 1) potential emotional discomfort engaging with an app centered on colorectal cancer and colonoscopies; 2) the possibility of a breach of confidentiality.

You may also benefit from participation in this research if you learn something new about your health.

If you are interested in learning more about this study, please continue to read below.

PARTICIPATION IN THIS RESEARCH STUDY:

This research study will be fully explained to you by a member of the study team. Feel free to ask all the questions you want before you make a decision about whether or not to participate. Any new

information that develops during this research study that might make you change your mind about participating will be given to you promptly.

You may qualify to take part in this research study because you: 1) self-identify as Latino/a/x; 2) speak English or Spanish; 3) received a physician referral for a screening colonoscopy; 4) have access to a device (e.g., smartphone, computer, tablet) with working Internet; 5) have no hearing or vision impairment; 6) have not participated in an early phase of the study.

Funds for conducting this research are provided by the National Institute on Aging at NIH.

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.

LENGTH OF TIME AND NUMBER OF PEOPLE EXPECTED TO PARTICIPATE:

Your participation in this research study is expected to last 6 months. Your engagement in the study will last 30-45 minutes. Then, 6 months after enroll in the study, the study team will review your medical chart to assess the colonoscopy completion status.

The number of people expected to take part in this research study at Mount Sinai is 80.

DESCRIPTION OF WHAT'S INVOLVED:

If you agree to participate in this research study, the following information describes what may be involved.

- Complete a 5-minute survey administered by a research coordinator, over the phone or in-person. The research coordinator will ask you questions about you (e.g. age, gender, and race) AND some information about your medical history (e.g. family history of colorectal cancer);
- You will be asked to engage with a new app about colorectal cancer OR watch a video about health; Our recommendation is to use a Wi-Fi Internet connection
- Whether you will be asked to engage with the app or watch the video online will be determined by chance alone, like flipping a coin. Neither you nor the study team, nor your doctor will choose what task you will be asked to perform. You will have an equal chance of being directed to the App or video;
- In 6 months, the study team will access your medical chart to assess the completion of the screening colonoscopy, completion status (completed, rescheduled, or cancelled), date of completion (if applicable), preparation quality (if applicable), receipt of patient navigation (in person or digital), reasons for not completion (if applicable).
- You will receive a $25 gift-card as compensation for your time and efforts.

USE OF YOUR DATA AND/OR SPECIMENS:

In the future, your identifiable information may be removed from the private information and/or samples that are collected as part of this research. After this removal, the information and/or samples could be used for future research studies or shared with other research teams for future research studies. You will not be informed of the details of specific research that is done with your medical information and biospecimens. That means that a research project might be done that you would not consent to if provided with the details of that research project.

YOUR RESPONSIBILITIES IF YOU TAKE PART IN THIS RESEARCH:

If you decide to take part in this research study you will be responsible for the following things:

- *Reviewing and electronically signing this Informed Consent Form;*
- *Completing a 5-minute interviewer-administered survey to provide information about you (e.g. age, gender, and race) AND some relevant information on your medical history (e.g. family history of* colorectal cancer*);*
- *Using a device of your choice (smartphone, laptop, or tablet);*
- *Opening a link that will randomly direct you to the app that we are testing OR to a video with health-related content;*
- *Completing the tasks in the app OR watching the online video*

COSTS OR PAYMENTS THAT MAY RESULT FROM PARTICIPATION:

Being in this research study will not lead to extra costs to you, if you access the app or watch the video using a Wi-Fi Internet connection. You will not be reimbursed for your travel, time or any other cost that may be required for getting the screening colonoscopy to which you have been referred.

Taking part in this research study may lead to added costs to you, *if you do not have access to a Wi-Fi Internet connection to engage with the app or watch the video. Costs of consuming mobile data vary and depend on your carrier.*

If you agree to take part in this research study, we will pay you $25 *Target gift-card* for your time and effort. *The gift card will be sent to you via email, regular mail, or text, if you participate remotely, as soon as you complete the tasks described in this form. The gift card will be handed to you directly, in case you participate in-person.*

Tax law may require the Mount Sinai Finance Department to report the amount of payment you receive from Mount Sinai to the Internal Revenue Service (IRS) or other agencies, as applicable. Generally,

this reporting would take place if you receive payments that equal $600 or more from Mount Sinai in a calendar year. You would be responsible for the payment of any tax that may be due.

POSSIBLE BENEFITS:

It is important to know that you may not get any benefit from taking part in this research. Others may not benefit either. However, possible benefits may be gaining new knowledge about your health.

REASONABLY FORESEEABLE RISKS AND DISCOMFORTS:

- Psychological risks – You could experience temporary mild to moderate discomfort arising from engaging with an App centered on colorectal cancer and colonoscopies.
- Risk of loss of private information – The app will not collect any protected health information **(**PHI) or personally identifiable information (PII) for study data. Users will be given a random PIN to access the app.. The risk of a breach of confidentiality always exists, but there are procedures in place to minimize the risk.
- Economic risks – If you access the app or video on Wi-Fi, you should not incur any additional costs. If you do not access the app or video via Wi-Fi, you may incur additional costs from your mobile carrier (e.g., data usage). Group Risks – Although we will not give researchers your name, we will give them basic information such as your race, ethnic group, and gender. This information helps researchers learn whether the factors that lead to health problems are the same in different groups of people. It is possible that such findings could one day help people of the same race, ethnic group, or gender as you. However, they could also be used to support harmful stereotypes or even promote discrimination.
- Privacy Risks – Your name and other information that could directly identify you (such as email address or phone number) will never be placed into a scientific database. However, there is a small chance that someone could trace it back to you. The risk of this happening is very small, but cannot be reduced to zero. A break in security may pose a risk to potential misuse of your private information that could lead you to experience other harms, such as stress, anxiety, stigmatization, or embarrassment from revealing information about your health conditions.

OTHER POSSIBLE OPTIONS TO CONSIDER:

You may decide not to take part in this research study without any penalty. The choice is totally up to you.

IN CASE OF INJURY DURING THIS RESEARCH STUDY:

If you believe that you have suffered an injury related to this research as a participant in this study, you should contact the Principal Investigator.

This does not prevent you from seeking payment for injury related to malpractice or negligence. Contact the investigator for more information.

ENDING PARTICIPATION IN THE RESEARCH STUDY:

You may stop taking part in this research study at any time without any penalty. This will not affect your ability to receive medical care at any of the Mount Sinai Health System hospitals or to receive any benefits to which you are otherwise entitled.

If you decide to stop being in the research study, please contact the Principal Investigator.

If you stop being in the research study, already collected information may not be removed from the research study database and will continue to be used to complete the research analysis. However, if you withdraw your consent to be involved in the interventional portion of the study (engaging with the App or watching the video), the study team will not access your medical chart for purposes related to the study.

If you decide you don't want your data to be used for research anymore, you can contact the study team and ask to have your data removed from future use. If data have already been shared without your identity, it won't be possible to retrieve them because no one will know who you are. Data that have already been used will not be affected by your decision. Any data that are still linked to your identity by a code the researcher has will be withdrawn so that no future sharing of your data will take place.

Withdrawal without your consent: The treating physician, study PI, study doctor, sponsor or study institutions may stop your involvement in this research study at any time without your consent. This may be because the research study is being stopped, the instructions of the study team have not been followed, the investigator believes it is in your best interest, or for any other reason. If data have been stored as part of the research study, they too can be destroyed without your consent.

CONTACT INFORMATION:

If you have any questions, concerns, or complaints at any time about this research, or you think the research has harmed you, please contact the Principal Investigator, Dr. Sarah Miller, at phone number 212.824.7783.

Form Version Date: July 11, 2022

This research has been reviewed and approved by an Institutional Review Board. You may reach a representative of the Program for Protection of Human Subjects at the Icahn School of Medicine at Mount Sinai at telephone number (212) 824-8200 during standard work hours for any of the reasons listed below. This office will direct your call to the right person within the Mount Sinai Health System:

- Your questions, concerns, or complaints are not being answered by the study team.
- You cannot reach the study team.
- You are not comfortable talking to the study team.
- You have questions about your rights as a research subject.
- You want to get information or provide input about this research.

DISCLOSURE OF FINANCIAL INTERESTS:

Sometimes, physicians/researchers receive payments for consulting or similar work performed for industry. Effective September 2014 Mount Sinai reviews only payments to an individual totaling more than $5,000 a year per entity when determining potential conflicts of interest. If you have questions regarding industry relationships, we encourage you to talk your physician/researcher or visit our website at http://icahn.mssm.edu/ where Mount Sinai publicly discloses the industry relationships of our faculty.

MAINTAINING CONFIDENTIALITY – HIPAA AUTHORIZATION:

As you take part in this research project it will be necessary for the study team and others to use and share some of your private protected health information. Consistent with the federal Health Insurance Portability and Accountability Act (HIPAA), we are asking your permission to receive, use and share that information.

What protected health information is collected and used in this study, and might also be shared with others?
As part of this research project, the study team at the hospital(s) involved in the research will collect your name, medical record number, telephone number, e-mail, age, place of birth, length of residency in the United States, ethnicity, nationality, race, preferred language, year of last colonoscopy (if applicable), self-reported colorectal cancer diagnosis, self-reported diagnosis of other gastrointestinal diseases, family history of colorectal cancer, gender, educational attainment, marital status, primary type of health insurance, self-reported household income.
The researchers will also get information from your medical record coming from the hospital or clinic where you have been referred for a screening colonoscopy, within the Mount Sinai Health System.

Why is your protected health information being used?
Your personal contact information is important to be able to contact you during the study. Your health information and the results of any tests and procedures being collected as part of this research study will be used for the purpose of this study as explained earlier in this consent form. The results of this study could be published or presented at scientific meetings, lectures, or other events, but would not

include any information that would let others know who you are, unless you give separate permission to do so.

The study team and other authorized members of The Mount Sinai Health System ("Mount Sinai") workforce may use and share your information to ensure that the research meets legal, institutional or accreditation requirements. For example, the School's Program for the Protection of Human Subjects is responsible for overseeing research on human subjects, and may need to see your information. If you receive any payments for taking part in this study, the Mount Sinai Finance Department may need your name, address, social security number, payment amount, and related information for tax reporting purposes. I*f the study team uncovers abuse, neglect, or reportable diseases, this information may be disclosed to appropriate authorities.*

Who, outside Mount Sinai, might receive your protected health information?
As part of the study, the Principal Investigator, study team and others in the Mount Sinai workforce may disclose your protected health information, including the results of the research study tests and procedures, to the following people or organizations: (It is possible that there may be changes to the list during this research study; you may request an up-to-date list at any time by contacting the Principal Investigator.)

- A collaborating research center and its associated research/clinical staff who is working with the investigators on this project, notably: the School of Medicine at the University of Virginia.
- The sponsoring government agency and/or their representative who need to confirm the accuracy of the results submitted to the government or the use of government funds: National Institute On Aging/NIH/DHHS.
- A Data Safety Monitoring Board or other committee that will monitor the study on an ongoing basis for safety.
- The United States Department of Health and Human Services and the Office of Human Research Protection.

In almost all disclosures outside of Mount Sinai, you will not be identified by name, social security number, address, telephone number, or any other direct personal identifier. Some records and information disclosed may be identified with a unique code number. The Principal Investigator will ensure that the key to the code will be kept in a locked file, or will be securely stored electronically. The code will not be used to link the information back to you without your permission, unless the Institutional Review Board allows it after determining that there would be minimal risk to your privacy. The Certificate of Confidentiality obtained from the Department of Health and Human Services will not be used to prevent disclosure to local authorities of child abuse and neglect, or harm to self or others. It is possible that a sponsor or their representatives, a data coordinating office, or a contract research organization, will come to inspect your records. Even if those records are identifiable when inspected, the information leaving the institution will be stripped of direct identifiers. Additionally, *the Office of Human Subjects Protection (OHRP) of the Department of Health and Human Services as well as the Food and Drug Administration (FDA) will be granted direct access to your medical records for verification of the research procedures and data. They are authorized to remove information with identifiers if necessary*

to complete their task. By signing this document you are authorizing this access. We may publish the results of this research. However, we will keep your name and other identifying information confidential.

For how long will Mount Sinai be able to use or disclose your protected health information?
Your authorization for use of your protected health information for this specific study does not expire.

Will you be able to access your records?
During your participation in this study, you will have access to your medical record and any study information that is part of that record. The investigator is not required to release to you research information that is not part of your medical record.

Do you need to give us permission to obtain, use or share your health information?
NO! If you decide not to let us obtain, use or share your health information you should not sign this form, and you will not be allowed to volunteer in the research study. If you do not sign, it will not affect your treatment, payment or enrollment in any health plans or affect your eligibility for benefits.

Can you change your mind?
You may withdraw your permission for the use and disclosure of any of your protected information for research, but you must do so in writing to the Principal Investigator at the address on the first page. Even if you withdraw your permission, the Principal Investigator for the research study may still use your protected information that was already collected if that information is necessary to complete the study. Your health information may still be used or shared after you withdraw your authorization if you should have an adverse event (a bad effect) from being in the study. If you withdraw your permission to use your protected health information for research that means you will also be withdrawn from the research study, but standard medical care and any other benefits to which you are entitled will not be affected. You can also tell us you want to withdraw from the research study at any time without canceling the Authorization to use your data.

It is important for you to understand that once information is disclosed to others outside Mount Sinai, the information may be re-disclosed and will no longer be covered by the federal privacy protection regulations. However, even if your information will no longer be protected by federal regulations, where possible, Mount Sinai has entered into agreements with those who will receive your information to continue to protect your confidentiality.

If as part of this research project your medical records are being reviewed, or a medical history is being taken, it is possible that HIV-related information may be revealed to the researchers. If that is the case, the following information concerns you. If this research does not involve any review of medical records or questions about your medical history or conditions, then the following section may be ignored.

Notice Concerning HIV-Related Information

If you are authorizing the release of HIV-related information, you should be aware that the recipient(s) is (are) prohibited from re-disclosing any HIV-related information without your authorization unless permitted to do so under federal or state law. You also have a right to request a list of people who may receive or use your HIV-related information without authorization. If you experience discrimination because of the release or disclosure of HIV-related information, you may contact the New York State Division of Human Rights at (888) 392-3644 or the New York City Commission on Human Rights at (212) 306-5070. These agencies are responsible for protecting your rights.

Certificate of Confidentiality:

To further protect your privacy, the researchers have obtained a Certificate of Confidentiality from the Department of Health and Human Services. This is intended to ensure that your identity as a participant in this research study will not have to be disclosed as a result from a subpoena, for the purpose of identifying you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings other than to the FDA or OHRP as identified above.

The research staff will not share any of your research information with anyone who is not a member of the study team, including any family members or friends, other than to those identified above. However, you should know that if we learn that you or someone else is threatened with serious harm, such as a child or an elderly person being abused, the investigators may notify the appropriate authorities if necessary to protect you or others. A Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. This means that you and your family must also actively protect your own privacy. If an insurer or employer learns about your research participation, and you agree that they can have your research information, then the researchers may not use the Certificate of Confidentiality to keep this information from them.

Form Version Date: July 11, 2022

ADULT PARTICIPANT:

Your signature below documents your permission to take part in this research and to the use and disclosure of your protected health information. A signed and dated copy will be given to you.

Signature of subject	Printed Name of Subject	Date	Time

PERSON EXPLAINING STUDY AND OBTAINING CONSENT:

Signature of consent delegate	Printed Name of consent delegate	Date	Time

WITNESS SECTION:

When a witness is required to observe the consent process, it should be documented below (for example, when subject is illiterate, visually impaired, or this document accompanies a short form consent).

My signature below documents that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the subject, and that consent was freely given by the subject.

Signature of Witness	Printed Name of Witness	Date	Time