Official Title:	Text messaging to improve adherence to repeat colonoscopy
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Date of the Document:	• October 23, 2023

Participant Name: _____ Last4SSN: _____ Date: _____

Title of Study: Text messaging to improve adherence to repeat colonoscopy

Principal Investigator: Peter Liang VA Facility: New York Harbor VA

KEY SUMMARY INFORMATION ABOUT THIS STUDY

You are being invited to take part in a research study that is being funded by the NATIONAL CANCER INSTITUTE (NCI). Before you decide to take part, it is important for you to know why the research is being done and what it will involve. This includes any potential risks to you, as well as any potential benefits you might receive. Taking part in this study is completely voluntary.

Our records indicate that you are due soon for a repeat colonoscopy. The purpose of this colonoscopy is to keep you up-to-date with colorectal cancer screening. Colorectal cancer is one of the most common cancers in both men and women, but you can substantially reduce your risk by getting a routine colonoscopy.

The reason I am reaching out is because we would like to include you in our research study, which is called "Text messaging to improve adherence to repeat colonoscopy in the VA: a pilot study." This study involves a VA texting messaging program called "Annie" to improve adherence to repeat colonoscopy. The purpose of this study is to test a text messaging intervention and see if it will increase colonoscopy attendance for those who are due.

If you agree to participate and you fall into the intervention group, you will be sent a series of text messages containing instructions and motivational messages, which will be sent starting 7-14 days before and until the day of the colonoscopy.

WHAT IS THE STUDY ABOUT AND HOW LONG WILL IT LAST?

The purpose of this study is to test a text messaging intervention and see if it will increase colonoscopy attendance for those who are due.

Your participation in this research will last about 2 weeks (14 days).

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

You may benefit from this research. If you were planning to cancel your colonoscopy or did not know how to do the bowel prep, the text messaging intervention may help you to prepare for and attend the procedure. Obtaining a colonoscopy has been proven to lower the risk of colorectal cancer, which is a potential benefit to you. In addition, if this intervention is shown to be effective, then it may be adopted at other institutions and increase colonoscopy uptake in the general population.

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

You may not like receiving text messages. You may feel text messages are inconvenient or intrusive, or that you're receiving too many messages.

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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 the study is Dr. Peter Liang at the Manhattan VA. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study, please contact the study research coordinator, Ms. Anika Zaman, at (646) 236-3894.

DETAILED INFORMATION ABOUT THE STUDY

WHAT IS THE PURPOSE OF THIS STUDY?

The purpose of this study is to test a text messaging intervention and see if it will increase the amount of colonoscopy attendance for those who are due.

HOW LONG WILL I BE IN THE STUDY?

Your individual participation in the project will take 2 weeks (14 days) to complete.

WHAT WILL HAPPEN IF I TAKE PART IN THE STUDY?

If you decide to participate in the study, you will be randomly placed into 1 of 2 group. There's a 50% chance that you will be in the intervention group and receive text messages. If you're in the text messaging group, you will receive text messages on your mobile/cell phone starting 7-14 before your scheduled colonoscopy and until the day of the procedure. The text messages will consist of instructions and motivational messages for the colonoscopy.

If you're not in the intervention group, you will not receive text messages but will receive standard medical care. Standard medical care includes bowel preparation instruction from a GI nurse and reminder call prior to your procedure.

WHAT IS EXPECTED OF ME IF I TAKE PART IN THIS STUDY?

What Do I Have to Do to Use Annie?
You need to know about your responsibilities and the risks associated with using Annie.

Both the health care provider and/or physician who registers you for Annie and a staff member from research will speak with you about how Annie will be used as part of your personal care plan.

WHAT POSSIBLE RISKS OR DISCOMFORTS MIGHT I HAVE IF I TAKE PART IN THIS STUDY?

The risks in participating in this study are: discomfort, or inconvenience because text messages may be considered too numerous or intrusive. Please note that any time you can stop your participation in the study and request to be unenrolled from Annie. There is also a small risk of breach of confidentiality, and all necessary precautions will be taken to prevent this. To ensure that there is no breach in confidentiality, all patient information will be kept in password protected devices and encrypted folders on the VA network.

Risks of the usual care you receive (e.g., the colonoscopy) are not risks of this study. Those risks are not included in this consent form. You should talk with your health care providers if you have any questions about the risks of usual care.

WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

We do not know if you will get any benefits from taking part in this research study. However, a possible benefit is that the text messaging intervention may help you to prepare for and attend the procedure. Obtaining a colonoscopy has been proven to lower the risk of colorectal cancer, which is a potential benefit to you. In addition, if this intervention is shown to be effective, then it may be adopted at other institutions and increase colonoscopy uptake in the general population.

WHAT OTHER CHOICES DO I HAVE IF I DO NOT WANT TO JOIN THIS STUDY?

You do not have to participate in this research study if you do not want to. If you choose to not participate, you will still receive that same standard of care.

HOW WILL MY PRIVATE INFORMATION BE PROTECTED?

To ensure that there is no breach in confidentiality, all patient information will be kept in password protected devices and encrypted folders on the secure VA network. Paper consent forms will be kept in locked cabinets instead locked offices.

We have obtained a Certificate of Confidentiality from the Federal Government. This helps protect your privacy by allowing us to refuse to release your name or other information outside of the research study, even by a court order. The Certificate of Confidentiality will not be used to prevent disclosures to local authorities of child abuse or neglect, or harm to self or others. The Certificate does not prevent you or a member of your family from releasing data about yourself or your involvement in this study.

We will include information about your study participation in your medical record.

A description of this 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 the results. You can search this website at any time.

Your information that is collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

Health Insurance Portability and Accountability Act (HIPAA)

There are rules to protect your private information. Federal and state laws and the federal medical Privacy Rule also protect your privacy. By signing this form, you provide your permission called your 'authorization,' for the use and disclosure of information protected by the Privacy Rule.

The research team working on the study will collect information about you. This includes things learned from the procedures described in this consent form. The study team may also collect other information including your name, address, date of birth, and information from your medical records such as the results of your colonoscopy.

The research team may also need to disclose the information to others as part of the study progress. Others may include the following: VA Cooperative Studies Program (CSPCC); CSP Clinical Research Pharmacy Coordinating Center (CSPCRPCC); CSP Site Monitoring; Auditing and Review Team (SMART); CSPCC's Human Research Committee (HRC); Food and Drug Administration, Office (FDA), Office of Human Research Protections (OHRP), the VA Office of Research Oversight (ORO), the Government Accountability Office (GAO; Sponsors; Contractors, Affiliates as appropriate)l the VA Institutional Review Board, and the local VA medical facility Human Research Protections Program (HRPP).

Your health information disclosed pursuant to this authorization may no longer be protected by Federal laws or regulations and may be subject to re-disclosure by the recipient.

While this study is being conducted you will have access to your research related health records

This will not affect your VA healthcare, including your doctor's ability to see your records as part of your normal care and will not affect your right to have access to the research records after the study is completed.

You can revoke this authorization, in writing, at any time. To revoke your authorization, you must write to the Release of Information Office at this facility, or you can ask a member of the research team to give you a form to revoke the authorization. Your request will be valid when the Release of Information Office receives it. If you revoke this authorization, you will not be able to continue

to participate in the study. This will not affect your rights as a VHA patient to treatment or benefit outside of the study.

If you revoke this authorization, Dr. Peter Liang and his research team can continue to use information about you that was collected before receipt of the revocation. The research team will not collect information about you after you revoke the authorization.

Treatment, payment or enrollment/eligibility for benefits cannot be conditioned on you signing this authorization. This authorization will expire at the end of the research study unless revoked prior to that time.

WHAT ARE THE COSTS TO ME IF I TAKE PART IN THIS STUDY?

You will be responsible for any text message costs resulting from the research text messages that you receive. Message and data rates are particular to your mobile plan. Each participant will receive $40 in the form of a gift card or check from NYU Grossman School of Medicine. You will receive the option of either receiving a check in the mail or Amazon gift card after completion of study participation.

If you usually pay co-payments for VA care and medications, you will still pay these co-payments for VA care and medications that are not part of this study.

WHAT WILL HAPPEN IF I AM INJURED BECAUSE OF MY BEING IN THE STUDY?

No injuries are expected from this research. However, if you think you have been injured as a result of taking part in this research study, please contact the study research coordinator, Ms. Anika Zaman, at (646) 236-3894.

If you are injured as a result of taking part in this study, the VA will provide necessary medical treatment at no cost to you unless the injury is due to non-compliance by a study participant with study procedures or if the research is conducted for VA under contract with an individual or non-VA institution.

DO I HAVE TO TAKE PART IN THE STUDY?

Your participation is completely voluntary. This means that you do not have to participate in this research study unless you want to. Your decision whether or not to participate in this study will not affect your relationship with your medical providers at the Department of Veterans Affairs (VA).

You may withdraw or take back your permission to use and share your health information at any time for this research study. If you withdraw your permission, we may keep and analyze any data that has already been collected up to the time of your withdrawal request.
To withdraw your permission, send a written notice to the principal investigator. Upon receiving your request to withdraw from the study, we will notify you that you have been withdrawn from the study within 3 business days. No other information related to you will be collected from the time of your withdrawal request. Consent forms will be kept for the minimum amount of time as required by regulations. If you withdraw your permission, you will not be able to stay in this study.

Your permission to use or share your personal health information for this study will never expire unless you withdraw it.

WHO DO I CONTACT ABOUT THIS STUDY IF I HAVE QUESTIONS?

If you have questions, concerns or complaints regarding your participation in this research study or if you have any questions about your rights as a research subject, you should speak with the study research coordinator, Ms. Anika Zaman, at (646) 236-3894.

If you have questions about your rights as a study participant, or you want to make sure this is a valid VA study, you may contact the VA NYHHS Institutional Review Board (IRB) at 212-686-7500 (Ext. 7470). This is the Board that is responsible for overseeing the safety of human participants in this study. You may also contact the Research Compliance Officer at 212-686-7500 (Ext. 7443), if you have questions, complaints or concerns about the study or if you would like to obtain information or offer input. If you want to speak to someone who is not a member of the study to discuss problems, ask non-clinical questions or to voice concerns, you may call the local VA Patient Advocate in Brooklyn at 718-836-6600 (ext. 3308) or 718-630-3510; or New York at 212-686-7500 (ext. 7080).

WILL I BE TOLD NEW INFORMATION ABOUT THIS STUDY?

During the course of this study, we may find more information that could be important to you. This includes information that might cause you to change your mind about being in the study. We will notify you as soon as possible if such information becomes available.
Federal laws and policies provide you with protection from discrimination by health insurance companies, group health plans, and most employers based on your genetic information. A federal law called the Genetic Information Nondiscrimination Act (GINA) generally will protect you in the following ways:

- Health insurance companies and group health plans may not request your genetic information obtained from this study.

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- Health insurance companies and group health plans may not use your genetic information obtained from this study when making decisions regarding your eligibility or premiums.
- Employers with 15 or more employees may not use your genetic information obtained from this study when making a decision to hire, promote, or fire you or when setting the terms of your employment.

Be aware that this Federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. It also does not prohibit discrimination on the basis of already known genetic disease.

AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

Dr./Mr./Ms_____ _____ has explained the research study to you. You have been told of the risks or discomforts and possible benefits of the study. You have been told of other choices of treatment available to you. You have been given the chance to ask questions and obtain answers.

By signing this document below, you voluntarily consent to participate in this study and authorize the use and disclosure of your health information in this study. You also confirm that you have read this consent, or it has been read to you. You will receive a copy of this consent after you sign it.

I agree to participate in this research study as has been explained in this form.		
_____ Participant's Name	_____ Participant's Signature	_____ Date

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