Information Sheet

Title: Using artificially intelligent text messaging technology to improve American Heart Association's Life's Essential 8 Health Behaviors: UH3 Trial

Co-Principal Investigators: Michael Ho, MD, PhD; Sheana Bull, PhD, MPH

Protocol: 24-0025

Version date: 1/31/2024

The University of Colorado at Anschutz Medical Campus in collaboration with Denver Health is conducting a research study to see if chatbot and text messages could help patients gain better control of the American Heart Association's Life's Essential 8 lifestyle factors (blood glucose, cholesterol, blood pressure, physical activity, weight, sleep, diet, and smoking).

You are receiving this letter because you have been identified as a patient at Denver Health. We plan to send participants chat and text messages to serve as resources on how to manage blood pressure, control cholesterol, reduce blood sugar, be active, eat and sleep better, lose weight, and stop smoking. In this study, we hope to follow you and other patients over 2 years.

Please review the information sheet in this packet. If you would like to join the study, you can text the word "HEART" to XXX-XXX-XXXX or scan the QR code in this packet to opt into receiving messages. If you do not wish to participate, please complete the opt-out form and send it in the self-addressed and stamped envelope, included in this packet.

Thank you for your consideration. Sincerely,

Pamela N Peterson, MD MSPH
Staff Cardiologist
Site Principal Investigator
Denver Health Medical Center

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INFORMATION ON THE STUDY

What is the title of this research study?
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Why is this research study being conducted?
Half of patients in the US over 45 have two or more chronic medical conditions. Managing these conditions can be difficult, and if not done correctly it can lead to increased medical risk or even death. Our study plans to learn if sending different chatbot and text messages, serving as reminders or encouragement, may help patients improve healthy behaviors to manage chronic cardiovascular conditions.

How does the study work?
Our research team will identify patients with chronic cardiovascular conditions that have one or more risk factors address in the Life Essential 8 from the American Heart Association. Our research team will confirm that you would like to receive text messages by you texting the word "heart" to XXX-XXX to opt in. We will also send one text message asking if you want to receive text messages. If we do not hear from you we will call you to ask if you would like the receive the text messages. Once you are in the study you will be randomized into one of three arms by our study team: generic, interactive chatbot, or interactive chatbot with pharmacist support. You will receive 5 messages for 9 weeks on different health topics and they type of message will change based on each arm.

If you choose to not take part in the study now, please "opt out" by filling out and mailing back the enclosed form. No data will be collected by the study team if you decide to opt out now.

At any time, participants can text STOP to stop receiving the messages. The data that would otherwise be collected by your healthcare provider will continue to be viewed by the Chat for Heart Health team after the intervention.

What if I don't have a cell phone?
Only patients that have a cell phone with texting capabilities can take part in the study.

What are you going to measure?
We are interested to learn if text messages and chat bots are better than current methods to help patients improve their heart health. We will measure patients' overall Life's Essential 8 scores, and see if it improves after messages are sent.

These measures are mostly results form your doctor's visits. Results may include blood pressure levels and blood pressure control. We will also monitor patients for emergency department visits and hospitalizations. An additional measure will include a short survey that will be sent to patients via text message at the beginning and end of the study.

Study Duration
This study will start in XX and will end by XX. We will only enroll patients between XX and XX.

What is the process to "opt out" of the research study?
To "opt out" means you do not want to be enrolled in this research study. To opt out of the study, you need to fill out the enclosed form.

Who is paying for this study?
This research is being paid for by a grant from the National Institutes of Health (NIH) Health Care Systems Research Collaboratory.

Financial Disclosure

One of the Principal Investigators (PIs) involved in this project, Dr. Sheana Bull, founded and owns Clinic Chat, the company responsible for sending messages as part of the intervention. The company was established with a licensing agreement to the University of Colorado (CU). This project represents a work that is a derivative of the original infrastructure and content for the Clinic Chat chatbot system. Clinic Chat grants the University of Colorado a non-exclusive, royalty-free license to use, reproduce, transmit, perform, and distribute this derivative work solely for its own internal use, or for educational and research purposes of University.

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Who can be in this study?
Our study will include patients at Denver Health and Salud Family Health Centers that have been diagnosed with a chronic cardiovascular condition including hypertension, hyperlipidemia, and diabetes.

Who will see my responses to the messages?
Only the study team will see your responses to the messages. We will not share your responses with anyone outside of the study team. Depending on the type of messages you receive, a pharmacist from Denver Health may reach out to you to offer support managing your chronic cardiovascular condition.

Who is responsible for the information provided by the chatbot?
The study team at the University of Colorado Anschutz Medical Campus has developed messages that reflect the advice of the American Heart Association to improve healthy behaviors.

Will it cost me money to participate in the study?
You may receive messages to help you improve healthy behaviors. Receiving and responding to these messages will cost the same as when you receive other text messages.

Are these messages from my doctor?
No, these are messages from a research team.

Will patients get paid to participate?
You will receive one $5 gift card for completing the survey sent to you via text when you opt into receiving text messages.
You will receive one $5 gift card for completing the survey sent to you via text at the end of receiving messages.

You may also get invited to participate in a phone interview after the intervention of approximately 30 minutes. This interview will be recorded. If you are invited and agree to participate in the interviews, you will receive a gift card of $30.

Do I have to be in this study?
You do not have to participate in this study if you do not want to. You can opt out or decide later to withdraw at any time. There will be no change in procedures performed compared to the standard care provided by your physician normally for your condition. To opt out, please complete the opt out consent form and send the enclosed letter.

Who do I contact with questions?
Please feel free to contact Michael Ho, MD, PhD, by phone at 303.724.5692 or by email at c4hstudy@cuanschutz.edu.

A description of this clinical trial will be available on http://www.Clinical Trials.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.

How will I know the messages are from the study?
All of our chat and text messages will state they are coming from the study.

Ready to join now?
To use the QR code:

1. Scan with the Camera app on your smartphone.
2. You will be redirected to messages with a preset message.
3. Hit “Send”.
4. You’re done!

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GENERAL QUESTIONS

What is COMIRB?

COMIRB, or Colorado Multiple Institutional Review Board, is the local Institutional Review Board that will review this study. The Institutional Review Board (IRB) is a group of people, including medical, scientific, and non-scientific members, who are not involved with the study and whose duty is to ensure the protection of the rights, safety, and well-being of patients enrolled in clinical trials. COMIRB is federally regulated and is designed to protect people in a research study. For more information, their website is www.ucdenver.edu/research/comirb. Their phone number is 303-724-1055.

What is the consent for?

The consent is to inform you, your legally authorized representative, or family members about the study and to obtain permission to continue data collection for the study.

The data we collect will be used for this study but may also be important for future research. Your data may be used for future research or distributed to other researchers for future study without additional consent if information that identifies you is removed from the data.

Certificate of Confidentiality

This study has been issued a Certificate of Confidentiality from the federal government to help protect your privacy. The Certificate prohibits the researchers from disclosing your name, or any identifiable information, document or biospecimen from the research, with the exceptions listed below. A certificate provides protections against disclosing research information in federal, state, or local civil, criminal, administrative, legislative or other proceedings.

These protections apply only to your research records. The protections do not apply to your medical records.

The researchers may disclose your name or identifiable information, document or biospecimen, under the following circumstances:

- To those connected with the research,
- If required by Federal, State or local laws,
- If necessary for your medical treatment, with your consent,
- For other scientific research conducted in compliance with Federal regulations,
- To comply with mandated reporting, such as a possible threat to harm yourself or others, reports of child abuse, and required communicable disease reporting, or
- Under other circumstances with your consent.

A Certificate of Confidentiality does not protect information you or a member of your family voluntarily release.

OPT-OUT CONSENT FORM

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Please complete if you **DO NOT** wish to take part in the above study.

Printed name of participant			
Signature of participant		Date	

Please return this self-addressed, stamped postcard by: **xx/xx/xxxx** to **no longer** be enrolled in the study.