

Title: Personalized patient data and behavioral nudges to improve adherence to chronic cardiovascular medications (Nudge)

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The University of Colorado in collaboration with Denver Health is conducting a research study to see how well text messages could work to remind and encourage patients take medicines they have already been prescribed.

You are receiving this letter because you have been identified as a patient at Denver Health. We plan to send participants text messages to serve as reminders to fill your prescription for already prescribed cardiovascular related medications. In this study, we hope to follow you and other patients over 2 years.

Please review the information sheet attached in this packet. If you would like to join the study, you do not need to complete any forms. If you do not wish to participate, please complete the opt-out letter and send it in the self-addressed, stamped envelope, attached.

Thank you for your consideration.

Sincerely,



Pamela N Peterson, MD MSPH
Staff Cardiologist
Site Principal Investigator, Personalized patient data and behavioral nudges to improve adherence to chronic cardiovascular medications (The Nudge study)
Denver Health Medical Center

INFORMATION ON THE STUDY

What is the title of this research study?

Personalized patient data and behavioral nudges to improve adherence to chronic cardiovascular medications (The Nudge Study)

Why is this research study being conducted?

Half of patients with cardiovascular disease do not take their medications as prescribed. This behavior can lead to increased medical risk or even death. Our study plans to learn if sending different text messages, serving as reminders or encouragement, may help patients take their medication more often if they have had trouble keeping up with their medicines.

How does the study work?

Our research team will identify patients taking prescription medicine that have already been prescribed by their doctor. If a patient does not refill their prescription within 7 days of their recommended refill date, they may receive a text message intervention.

At any time, participants can text STOP to stop receiving text messages. For voice messages/phone calls, pressing 0 will also opt you out of the study. The data that would otherwise be collected by your healthcare provider will continue to be viewed by the Nudge Study team after the intervention.

What if I don't have a cell phone?

For patients that do not have a cell phone, a voice recording saying the same messages will be sent to your phone line instead.

What are you going to measure?

We are interested to learn if text messages are better than current methods to help patients refill medications that have been prescribed by their doctor. We will measure the proportion of days patients have their medication available, and see if it improves after text messages are sent.

We will also measure results from your doctor's visits that we would expect would improve if patients took their medications as prescribed. Results may include blood pressure levels and blood pressure control. We will also monitor patients for emergency department visits and hospitalizations.

Study Duration

This study will start in the fall of 2019 and will end in the summer of 2023. We will only enroll patients between the fall of 2019 and the summer of 2021.

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. In order to opt out of the study, you need to fill out the enclosed letter.

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.

Who can be in this study?

Our study will include patients at University of Colorado Hospital, the Denver VA, or Denver

Health that have been diagnosed with a chronic condition and are taking medications to treat the condition. Patients will enter the study if they do not fill their prescription after 7 days.

Will it cost me money to participate in the study?

You may receive messages to remind you to refill your medication(s) if you experience a delay. Rates for receiving a text message would cost the same as when you receive other text messages.

Are these messages from my doctor?

No, these are messages from a research team reminding you take prescriptions already prescribed to you.

Will patients get paid to participate?

You may 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 be in this study if you do not want to be. 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 303-724-8096 or by email at nudge@ucdenver.edu.

How will I know the messages are from the Nudge Study?

All of our messages will state they are coming from the Nudge study.

What is the opt out survey?

If you are choosing not to participate in the Nudge Study, we would like to learn about your reason(s) for deciding to opt out, with hopes to improve future research. Filling out this survey is completely voluntary. If you choose to fill out the survey, you can choose to only fill out some of the questions or complete the entire survey. Not participating in the Nudge Study or this survey will never affect your healthcare or your relationship with your doctor.

If you choose to opt out, we will not follow your prescription history. If you opt out, only your deidentified demographic information will be used.

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.