Addressing COVID-19 Testing Disparities in Vulnerable Populations Using a Community JITAI (Just in Time Adaptive Intervention) Approach: RADx-Underserved Populations (RADxUP) Phase III

NCT 07074171

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University of Texas Health Science Center at Houston

INFORMED CONSENT FORM TO TAKE PART IN RESEARCH

HSC-SPH-20-1372

Influencing Factors of COVID 19 Testing: Main Study 2024

INVITATION TO TAKE PART

You are invited to take part in a research project called, "Influencing Factors of COVID 19 Testing: Main Study 2024" led by Dr. Maria Fernandez of the University of Texas Health Science Center at Houston (UTHealth). The project is funded by the National Institutes of Health. Your participation is completely voluntary. You may stop at any time. Whether or not you take part in the study will not change the services available to you from the University of Texas Health Science Center at Houston (UTHealth).

Your participation in this study is completely confidential, and we will not use your name at any time or share any personal information outside of this project. The study will happen at two different times, two months apart. We will meet with you today and ask you questions and provide you with information. In two months, we will reach out to you and ask you some additional questions. As a token of our appreciation for your time, we will provide a $50 gift card incentive when today's meeting is over and a $35 gift card incentive when the follow-up meeting is completed by phone or in person two months from now.

This research project has been reviewed by the Committee for the Protection of Human Subjects (CPHS) of the University of Texas Health Science Center at Houston as HSC-SPH-20-1372.

PURPOSE

The purpose of this research study is to evaluate the effectiveness of a text message-based intervention about COVID-19 testing by recruiting door to door in neighborhoods and in community settings. We will ask you for information about COVID-19 testing and vaccination behaviors and attitudes to learn about the reasons people decide to test or vaccinate for COVID-19 and the reasons

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they don't test. We will compare the difference between giving participants COVID-19 home tests and text message-based education versus no home tests and no text message-based education. We will also ask about how people are connected with each other socially through organizations and communities.

WHAT HAPPENS IN THIS STUDY

You will be asked a series of questions that I will read to you word by word as written. I will record your response for you. If you have any questions throughout our time, please feel free to ask and I will try to clarify. After the questions, I will provide information to you about COVID 19 testing and answer any questions you have. I will obtain your phone number and email address so that we can contact you in two months in order to ask you some questions over the phone at that time.

TIME COMMITMENT

The total amount of time you will take part in this research study is no more than 1.5 hours. The first hour will be to complete the first visit (although it may be shorter and may be broken up and completed by phone). The second 30 minutes will be at the follow-up visit, 2 months after the first visit.

BENEFITS

If you agree to participate in the program the benefits will include improved access to COVID-19 tests and information. The information from this study may benefit other people in the future and may help improve your health, that of your family and others.

RISKS AND/OR DISCOMFORTS

The risks of participating in this study are that more knowledge of COVID-19 risks and complications, as well as knowledge of positive results, if self-tests are provided and used by participants, might cause some distress. Also, there is a chance that information shared with the study team and approved partners could accidentally be shared with people or organizations that are not approved. We have set strict rules to minimize this risk. It is also possible that you may get tired when we are asking you questions about your health or when

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you are completing questionnaires. You do have the right to refuse to answer.

ALTERNATIVES

At this moment, the only alternative is to not take part in this study.

STUDY WITHDRAWAL

Your decision to take part is voluntary. You may change your mind at any time and let the UTHealth contact person know in writing that you wish to be removed from the study.

If you stop participating in this study, the information already collected about you will still be used in the data analysis. However, no further information will be collected without your permission.

CONFIDENTIALITY

Please understand that the University of Texas Health Science Center at Houston, authorized third parties, and the sponsor of this research may review the information from this study for the purposes of verifying research data, and will see personal identifiers.

For this study, the data we share for research purposes will not hold information that can easily identify you. We will share your data with the Duke Clinical Research Institute ("DCRI") in North Carolina. Duke was chosen by the NIH to hold the data from all RADx-UP studies. Duke will keep your data securely. We plan to transfer and keep these non-identifiable data in a secure database for COVID-19 research at the NIH. Other researchers may use these data for studies, other than the ones stated in this consent form. We will not ask your permission before sharing these data because they are non-identifiable.

You will not be personally identified in any reports or publications that may result from this study.

QUESTIONS

If you have questions at any time about this research study, please feel free to contact Maria Fernandez at [redacted] as she will be glad to answer your questions. You can contact the study team to discuss problems, voice concerns, obtain information, and offer

input in addition to asking questions about the research.

Do you agree to participate in this study?

Yes_____No _____

Can UTHealth contact you for future projects or research opportunities?

Yes_____No _____

Signature of Participant _____

Date of Consent_____(MM/DD/YYYY)

CPHS STATEMENT: This study HSC-SPH-20-1372 has been reviewed by the Committee for the Protection of Human Subjects (CPHS) of the University of Texas Health Science Center at Houston. For any questions about research subject's rights, or to report a research-related injury, call the CPHS at [redacted]