UT Austin IRB Approved
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The University of Texas at Austin

Consent to Participate in Research

Basic Study Information

Title of the Project: mHealth Intervention (iCAN) to Connect and Empower People Experiencing Homelessness to Improve Health Outcomes and Meet Social Needs: A RCT
Principal Investigator: Leticia Moczygemba, PharmD, PhD, University of Texas College of Pharmacy
Study Sponsor: Agency for Healthcare Research and Quality

Invitation to be Part of a Research Study

You are invited to be part of a research study. This consent form will help you choose whether or not to participate in the study. Feel free to ask if anything is not clear in this consent form.

Important Information about this Research Study

Things you should know:

- The purpose of the study is to understand the impact of a mobile health intervention, iCAN, that has been designed to help homeless individuals with care coordination, on health and social need outcomes.
- In order to participate, you must be 18 years old or older, be currently homeless, own a cell phone with service or access to wifi, be prescribed 2 or more medications, have a diagnosis of at least two chronic health conditions, have had 2 or more hospitalizations or emergency room visits in the last 6 months, be able to read health information, and be aware of your surroundings.
- If you choose to participate, you will be expected to stay in touch with the study team for 6 months by attending in-person study visits 1, 3, 5, and 6 months after enrollment.
- You will be randomly assigned (like the flip of a coin) to receive either the iCAN study phone or no phone. You have a 1 in 2 chance of receiving the iCAN study phone.
- Risks or discomforts from this research are not greater than everyday life.
- The possible benefits of this study include being reminded to take your medications and being prepared for your appointments. You may also gain from contributing to the existing knowledge base regarding mobile technology interventions.
- Taking part in this research study is voluntary. You do not have to participate, and you can stop at any time.

Please take time to read this entire form and ask questions before deciding whether to take part in this research study.

What is the study about and why are we doing it?

The purpose of the study is to measure the impact of a mobile health intervention, iCAN, on health outcomes such as number of emergency room and hospital visits, medication adherence, and social support and attainment of social needs such as obtaining housing or employment. We are doing the study to understand how iCAN helps in coordinating health and social services for people experiencing homelessness and how that impacts the outcomes listed above.

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What will happen if you take part in this study?

If you agree to take part in this study, you will be asked to:

- Spend about 30 minutes checking in to the study, which will include you and I reading this form. I will also answer any questions you have about the study. Then, I will ask you questions about you, your health, the support you get, and how you use technology. You will also be asked to sign forms that indicate your health information can be shared with the study team.
- After checking into the study, you will be randomly assigned (like the flip of a coin) to receive either the iCAN study phone or no phone. You have a 1 in 2 chance of receiving the iCAN study phone.
- If you are assigned to the iCAN group the you will be expected to:
    - Receive training on the intervention. This training will include a detailed description of the intervention, strategies to use to keep the study phone safe and charged, what to do if you have a question or concern, and how to report problems. This will take 30 – 45 minutes.
    - Participate in an intake assessment by the iCAN case manager within 2 - 3 days of enrollment. She will call you on your study phone. The case manager will also call 2 - 3 days after a hospital or emergency room visit to see if you need help with coordinating services. You can also text the study case manager with questions about navigating services. Responses to text messages will occur within 2 - 3 days, therefore the case manager should not be texted for emergencies.
    - Respond to text messages as requested on a daily basis for the duration of the six-month study. You should expect to receive three to five messages per day and spend no more than 15 minutes per day responding to text messages.
    - Leave your phone turned on to the extent possible. Research staff will use GPS technology to remotely locate your telephone, when needed to help you access services, during the hours of 8am-5pm, Monday-Friday for the duration of the six-month study.
    - Attend study visits 1, 3, 5, and 6 months after enrollment. At each study visit, you will be asked questions about you, your health, the support you get, and how you use technology. 1 and 5 month visits will take about 15 – 20 minutes and the study visits at 3 and 6 months will take 30 – 45 minutes.
    - All of the visits will take place at the site of enrollment, via telephone, or at an organization agreed upon by you and the study staff member.
- If you are NOT assigned to the iCAN group you will be expected to:
    - Attend study visits 1, 3, 5, and 6 months after enrollment. At each study visit, you will be asked questions about you, your health, the support you get, and how you use technology. 1 and 5 month visits will take about 15 – 20 minutes and the study visits at 3 and 6 months will take 30 – 45 minutes.
    - All of the visits will take place at the site of enrollment, via telephone, or at an organization agreed upon by you and the study staff member.

- You may be contacted after the study by a research team member to validate study results.

How long will you be in this study and how many people will be in the study?

Participation in this study will last for six months. You will be expected to attend study visits in person at this site 1, 3, 5, and 6 months after enrollment. We will enroll up to 120 participants in this study.

What risks and discomforts might you experience from being in this study?

There are some risks you might experience from being in this study. They are:

1. Potential breach of confidentiality.
2. If you are assigned to the iCAN group, large amounts of personal information may be collected including texts, pictures, locations, and search histories on the Smartphone that you use. The data is not being used for research purposes.
3. If you are assigned to the iCAN group, potential theft of or damage to the study Smartphone. We will provide you with a hard plastic case for your phone and a device that can attach the phone to your body in order to reduce these risks. Also, if you lose a phone, a new phone will be issued one time during the study.

The researchers will let you know about any significant new findings (such as additional risks or discomforts) that might make you change your mind about participating in this study.

How could you benefit from this study?

You might benefit from being in this study because the iCAN intervention is specifically designed to provide medication reminders, appointment reminders, and information to help you stay safe and healthy. Therefore, participating in this study may benefit you by helping you to remember to take your medications and to keep your appointments. You may also benefit from contributing to the existing knowledge base regarding mobile technology interventions.

What will happen to the samples and/or data we collect from you?

As part of this study we will collect background information about you including age, gender, employment status, income level, housing status, and insurance coverage. We will also collect information on your health history and current health status, social support, recent emergency room and hospital use, and use of technology. Upon enrollment into the study, you will be assigned an ID number that will be used on all research materials. Your name will be included only on a list linking participant names to ID numbers. This list will be stored in a password protected document on UTBox. All data collected as part of this study will be destroyed no later than five years after study completion.

How will we protect your information?

We will protect your information by the following steps:

1. You will have control over the amount of information you choose to share.
2. Upon enrollment into the study, you will be assigned an ID number that will be used on all research materials. Your name will be included only on a list linking participant names to ID numbers. This list will be stored in a password protected document on UTBox.
3. Your name will only appear on the informed consent document and linking documents. The informed consent documents will be stored in a separate, locked file cabinet. The linking document will be stored on UT Box, an encrypted software platform.
4. At the end of the study, research staff will delete the Google account created for and used in this study. If you would like to retain the Google account for your personal use, research staff will help you to change your password.

Your name and any other information that can directly identify you will be stored separately from the data collected as part of the project**.**

Information about you may be given to the following organizations:

- Agency for Healthcare Research and Quality (Study Sponsor)
- Representatives of UT Austin and the UT Austin Institutional Review Board
- Sunrise Navigation Center, Trinity Center, or Charlie Center (this depends on your enrollment site)

A description of this study will be available on http://www.ClinicalTrials.gov as required by US 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.

Under certain situations, we may break confidentiality. If, during the study, we learn about child abuse or neglect, we will report this information to the appropriate authorities including the police and/or the Texas Department of Family and Protective Services. If the research staff should become concerned that you are in danger of harming yourself or others, your confidentiality will be broken. We are required to notify the proper authorities in order to keep you and others safe.

We plan to publish the results of this study. To protect your privacy, we will not include any information that could directly identify you.

The data or samples that we will collect about you will not be shared with any other researchers.

What will happen to the information we collect about you after the study is over?

We will keep your research data to use for secondary analyses related to mHealth. Your name and other information that can directly identify you will be deleted from the research data collected as part of the project. The data or samples that we will collect about you will not be shared with any other researchers.

What if we learn something about your health that you did not know?

As part of this study, we may learn medically relevant information about you. If we learn something that you and your doctor did not know, we will contact you via the contact information your provide at baseline to describe the new information. We will also provide information on who you can contact for assistance.

How will your health information be used and shared during the study?

As part of this research study, we will ask you to share identifiable health information with us and/or permit us to access existing information from your healthcare records. New health information may also be created from study-related tests, procedures, visits, and/or questionnaires. This type of information is considered “Protected Health Information” that is protected by federal law.

What type of health information will be used or shared with others during this research?

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The following types of information may be used for the conduct of this research:

	☐ Complete health record	
☐ Information about sexually transmitted diseases	☒ Diagnosis & treatment codes	☐ Discharge summary
☐ History and physical exam	☐ Consultation reports	☐ Progress notes
☐ Laboratory test results	☐ X-ray reports	☐ X-ray films / images
☐ Photographs, videotapes	☐ Complete billing record	☐ Itemized bill
☒ Information about drug or alcohol abuse	☐ Information about Hepatitis B or C tests	☒ Information about mental health
☒ Other physical or mental health information (specify): Dates of emergency room or hospital visits		

Where will you get my records?

For this study, we will obtain records from the following healthcare providers:

- Integrated Care Collaboration

Who will use or share protected health information about me?

The covered entities listed above are required by law to protect your identifiable health information. By signing this document, you authorize them to use and/or share your health information for this research. The health information listed above may be used by and/or shared with the following people and groups to conduct, monitor, and oversee the research:

- Principal Investigator and Research Staff
- Health Care Providers at UT Health
- Institutional Review Boards
- Government/Health Agencies
- Others as Required by Law
- Study Sponsor Agency for Healthcare Research and Qualtiy
- Research Collaborators Sunrise Navigation Center

If your health information has been disclosed to anyone outside of this study, the information may no longer be protected under this authorization.

When will this authorization (permission) to use my protected health information expire?

The authorization will expire when the research study is closed, or there is no need to review, analyze and consider the data generated by the research project, whichever is later.

If you later decide that you do not want to share your medical information any longer, please contact the study team in writing to withdrawal your authorization. Contact information for the study team can be found at the end of this form.

How will we compensate you for being part of the study?

You will receive

1. $25.00 for completing the baseline questionnaire and enrolling in the study.
2. $10.00 for completion of the 1-month brief check-in.
3. $25.00 for completion of the 3-month questionnaires.
4. $10.00 for completion of the 5-month brief check-in.
5. $25.00 for completion of the 6-month questionnaires.
6. A 31-day Capital Metro unlimited bus pass downloaded on phone or can choose a paper bus pass (value is $41.25 per month X 6 months = $247.50) to facilitate attendance at follow-up visits. You must attend follow-up visits to get bus pass renewed.
7. For those in the iCAN group, the study cellphone with access to unlimited data, text, and calls (in the United States) for the six-month study period. Can keep phone after study, but unlimited data, text, and calls will end after the study period.

You will be responsible for any taxes assessed on the compensation.

What other choices do you have if you do not take part in this study?

The alternative is not to participate.

Your Participation in this Study is Voluntary

It is totally up to you to decide to be in this research study. Participating in this study is voluntary. Your decision to participate will not affect your relationship with The University of Texas at Austin, Sunrise Homeless Navigation Center, Trinity Center, or Charlie Center. You will not lose any benefits or rights you already had if you decide not to participate. Even if you decide to be part of the study now, you may change your mind and stop at any time. You do not have to answer any questions you do not want to answer.

If you contact us to withdraw from the study before it is completed, you can choose whether or not you are okay with us using the data you have provided us before you stopped the study or if you want us to delete all of your data.

You may change your mind and take back the right to use your protected health information at any time. However, even if you take back this permission, the researchers may still use or disclose health information they have already collected about you for this study. For example, if the law requires it, the sponsor and government agencies may continue to look at your medical records to review the quality or safety of the study. If you take back this permission you may no longer be allowed to participate in the study. To take back this permission, you must write to the Principal Investigator.

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Contact Information for the Study Team

If you have any questions about this research, or feel you may have been harmed due to participation, you may contact:

Leticia R. Moczygemba, PharmD, PhD
Phone: 512-232-6880
Email: lrmoczygemba@austin.utexas.edu
The University of Texas College of Pharmacy
2409 University Avenue, Stop A1930
Austin, TX 78712

Contact Information for Questions about Your Rights as a Research Participant

If you have questions about your rights as a research participant, or wish to obtain information, ask questions, or discuss any concerns about this study with someone other than the researcher(s), please contact the following:

The University of Texas at Austin Institutional Review Board
Phone: 512-232-1543
Email: irb@austin.utexas.edu

Please reference the protocol number found at the top of this document.

Your Consent

By signing this document, you are agreeing to be in this study. We will give you a copy of this document for your records. We will keep a copy with the study records. If you have any questions about the study after you sign this document, you can contact the study team using the information provided above.

I understand what the study is about and my questions so far have been answered. I agree to take part in this study.

_____
Printed Subject Name

_____
Signature Date

Signature of person obtaining consent

_____
Signature Date