UTHealth
The University of Texas
Health Science Center at Houston

CONSENT TO TAKE PART IN RESEARCH

Simple Study Title:	Link2Care
Full Study Title:	"mHealth to Increase Service Utilization in Recently Incarcerated Homeless Adults" HSC-SPH-15-0632
Study Sponsor:	National Institute of Health
Principal Investigator:	Dr. Michael Cannell (University of Texas School of Public Health) Dr. Jennifer Gonzalez (Meadows Mental Health Policy Institute) Dr. Michael Businelle (University of Oklahoma Health Sciences Center
Study Contact:	James Barnes Research Coordinator 214-713-0504.

You are invited to take part in a research study. This consent form has important information about this study to help to decide whether or not to take part in this study. Your decision to take part is voluntary. You may refuse to take part or choose to stop taking part at any time. A decision not to take part or to stop being a part of the research project will not change the services available to you at The Bridge Homeless Recovery Center or UTHealth. We are doing this study to evaluate the impact of providing smartphones with and without a new smartphone app on contacts with Bridge care managers, future homelessness, and arrest/incarceration. If you decide to be part of this research study, you will have to respond to The Bridge a total of five times over 6 months to take part in surveys. You may be issued a smart phone, on which you would take surveys. Each visit will take 1 to 1 1⁄2 hours. During these visits, you will answer questions on an electronic tablet and in person with the research staff. If in-person visits are not possible, follow-up visits may be completed in the community, by phone, or by sending a link through text or e-mail.

What is the purpose of this research study? The purpose of this research study is to evaluate the impact of a new smartphone app on contacts with Bridge care managers, future homelessness, and arrest/incarceration. This study will also aim to identify factors that predict future homelessness and arrest. The National Institutes of Health is paying for this study to becompleted.

A description of this clinical trial is available on http://www.clinicaltrials.gov, as required by U.S. Law. This will not include information that can identify you. After the study has ended, website will include a summary of the results. You can search this website at any time. The ClinicalTrials.gov Identifier is NCT03399500.

Who is being asked to take part in this study? You have been invited to be screened and potentially join this research study because you were recently released from the Dallas County Jail or the Dallas City Jail and are currently enrolled in The Bridge Homeless Recovery Program. This is a local study that will enroll a total of 462 people at The Bridge in Dallas. Only U.S. Citizens may participate in this study.

What will happen if I take part in this study? We will ask you to sign this consent form andcomplete a number of questionnaires on a computer tablet and potentially a study-provided smartphone. The research staff will also contact you by telephone or email to provide appointment reminders, troubleshoot problems with your smart phone, or to obtain follow -upinformation.

If you are interested and qualify to take part in this study, we will enroll you in the study today. If you meet the inclusion criteria for this study, we will ask you to return to The Bridge after your initial visit 4 times to complete questionnaires. The first two visits must be in-person so we may assign you a smart phone if you are randomized to receive one. The remaining three in-person follow-up visits may be completed by phone or online. Questionnaires will cover many topics including questions about your health, demographic information, alcohol and other drug use, your neighborhood, stress, mood, and social support.

If you agree to take part in this study, you will be randomized (similar to flipping a coin) during your second visit to receive either:

1. The usual Bridge care management program.
2. The usual Bridge care management program plus a smartphone.
3. The usual Bridge care management program plus a smartphone that is pre-loaded with an app that is programmed to offer to connect you with your care manager multiple times each week.

There is a 66% chance you will receive a smartphone and a 33% chance that you will not receive a smartphone. Participants who receive smartphones will be asked to complete questionnaires on the phone each day. The smartphone will ring and vibrate 30 minutes after your usual wake up time and alert you to complete the questionnaire. You will respond to questionnaires by using the smartphone touch screen and the phone will collect your location (e.g., GPS coordinates) multiple times each day. This information will be used for future studies. These questionnaires will take about 5 minutes to complete.

You will use a study smartphone or your personal smartphone to complete assessments through an encrypted mobile application and all data will be automatically saved and sent to the study server. Your Google Play Store account will be used to download the Insight app (we will help you to create a Google account if you do not already have one). You will not be able to access the phone settings via an app blocker, Google Play Store, or delete the Insight App on the phone. Only the research staff will have the password to access those functions. If at your third visit you have completed 50% or more of the daily surveys, the app blocker will be removed from your phone.

If you receive a smartphone, at the conclusion of your time in the study, the Insight app, and all app data will be removed from the phone, and the phone will be yours to keep. At the conclusion of your time in the study, the study data will be removed from your phone and all data collection through the Insight application will end. Researchers will delete the app from your personal device once you complete the study.

If you do not complete 5 or more smart phone assessments in a row, and have not been responsive to the research team after repeated contact attempts, we will send you a text message. This text message will inform you that your cell phone service will be terminated if you

do not contact the research team within one week. After this week without contact, your phone service will be disconnected. If your phone service is disconnected because you did not complete assessments, you will not receive a replacement phone.

To help us stay in touch with you throughout your time in the study, we will request detailed locator information during your initial visit, and update it every 15 days by phone call or text. This information will be stored in a locked file cabinet, and we will not share this information w with anyone outside of the study team. We will use all the information you provide, including phone calls, text messages, e-mails, and social media handles, to locate you and remind you of follow-up visits. For social media contacts, you will be contacted using private or direct messages on social media if you consent to be contacted using this mode on the locator form. No 'friend' requests will be accepted in order to further protect your confidentiality.

Visit 1: During your visit today, we will determine if you are eligible to participate in the study. If eligible, you will complete questionnaires and we will make an appointment for you to return to The Bridge within the next 3 days. If you are eligible to participate in this study, today's visit will take up to 2 hours to complete and you will be paid $30 for completing the assessment today.

Visit 2: This visit will take less than 1 hour to complete and you will receive $30 as payment. AfterVisit 1, you will come back to the Bridge in about 3 days to be randomized into one of the study conditions where you may be assigned a smartphone. You will have 14 days from your scheduledVisit 2 date to be randomized. If you are not randomized within the 14 day period, you will not be allowed to continue in the research study. If you receive a smartphone, we will show you how to use the phone to complete questionnaires, how to use the app features to make calls, and how tokeep track of how many assessments you complete. You will receive 3 referral coupons that you can pass on to others who are interested in the study. You will receive $20 on your study card when someone who brings in one of your coupons completes their first visit. If you have used all your initial referral coupons, you may be given an additional 3 coupons. Coupons are only valid while you are active in the study. You can be compensated for a total of 6 successful referrals.

Visits 3, 4, and 5: These visits will occur 1, 3, and 6 months after today's visit (Visit 1). You will have 14 days from your scheduled Visit 3 and 4 dates and 30 days from your scheduled Visit 5 date to complete the visit. You are able to complete visits 5 days prior to your scheduled Visit date if there is a serious or personal time conflict. During these visits, you will be asked to complete questionnaires. These visits will take about 1 hour to complete and you will receive $50 for completing each of these visits (up to $150 if you attend all 3 follow-up visits).

If you are randomized to receive a smartphone, you will have the opportunity to earn additional payment every 15 days for completing daily surveys on the phone. You will not receive payment for phone surveys until you confirm or update your locator information (we will attempt to contact you every 15 days). Your level of payment for these daily surveys will depend upon the number of surveys that you complete within each 15-day period. If you complete at least 13 surveys within a 15-day period, you will receive $50, if you complete at least 11-12 surveys within a 15-day period, you will receive $30, and if you complete at least 7-10 surveys within a 15-day period, you will receive $20. You will be able to track the number of surveys you have completed by clicking a button on the phone. If you complete less than 7 surveys during a 15- day period, you will not receive payment for that cycle.

If you decide to take part in this research study, you will not incur any additional costs. If you receive a bill that you believe is related to your taking part in this research study, please contact Dr. Gonzalez (470-333-8749).

You will be paid for taking part in this research study. The table below shows the amount of compensation you can receive for completing each assessment.

	Compensation (Usual Care)	Compensation (Smartphone Groups)
Visit 1 (Today)		
Questionnaire	$30	$30
Visit 2 (Within 3 Days)	$30	$30
Visit 3 (1-Month Follow-Up)		
Questionnaire	$50	$50
Phone Assessments	N/A	Up to $50 every 15 days for survey completion ($100)
Visit 4 (3-Month Follow-Up)		
Questionnaire	$50	$50
Phone Assessments	N/A	Up to $50 every 15 days for survey completion ($200).
Visit 5 (6-Month Follow-Up)		
Questionnaire	$50	$50
Phone Assessments	N/A	Up to $50 every 15 days for survey completion ($300).
TOTAL:	**Up to $210**	**Up to $810**

The Bridge Homeless Recovery Program: Your decision to participate in this study will not impact any services that you receive from The Bridge as part of the Homeless Recovery Program. You will continue to receive daily access to the shelter, meals, showers, mail, your case manager, Metro Care, housing assistance, disability/veteran's benefits assistance, job readiness training, legal aid, bus passes, and any other services available regardless of whether you enroll in this study.

What choices do you have other than this study? The only alternative is not to take part in this study. You do not have to take part in this research to receive standard care management services at The Bridge.

What are the risks of taking part in this study? Some of the questions that we ask and collecting information on your location may make you feel uncomfortable. If this happens, you may take a break or stop participating in this study at any time. In addition, any time information is collected, there is a potential risk for loss of confidentiality. We will make every effort to keep your information confidential; however, this cannot be guaranteed. There is always a risk of breach of confidentiality with any research study. All members of the research team are required to undergo extensive training about how to keep information confidential. We will label your data

with an ID number. We will keep the file linking your ID number with your personal information (such as your name) in a separate, locked filing cabinet.

What are the benefits to taking part in this study? If you agree to take part in this study, there may or may not be direct benefits to you. The researchers cannot guarantee that you will benefit from taking part in this research. However, the knowledge gained from this study will help us understand how we can use technology to increase contact with your case manager, increase service use, and ultimately reduce homelessness and arrest.

Can you stop taking part in this study? Your decision to take part is voluntary. You may decide to stop taking part in the study at any time. A decision not to take part or to stop being a part of the research project will not change the services available to you at The Bridge. If you withdraw from the study, any information you provided before that date may be used by the research team.

What happens if you are injured during the study? If you suffer any injury as a result of taking part in this research study, please understand that nothing has been arranged to provide free treatment of the injury or any other type of payment. However, all needed facilities, emergency treatment and professional services will be available to you, just as they are to the community in general. You should report any injury to Dr. Gonzalez (470-333-8749) and to the Committee for the Protection of Human Subjects at (713) 500-7943. You will not give up any of your legal rights by signing this consent form.

What are the costs of taking part in this study? If you decide to take part in this research study, you will not incur any additional costs. If you receive a bill that you believe is related to your taking part in this research study, please contact Dr. Gonzalez (470-333-8749).

How will privacy and confidentiality be protected? Your privacy is important and your participation in this study will be kept confidential. However, absolute confidentiality cannot be guaranteed.

If you sign this document, you give permission to UTHealth to use and disclose (release) your health information. The health information that we may use or disclose for this research includes obtaining information from your case manager at The Bridge about the number and duration of case management or counseling sessions that you completed and any crisis services or referrals that you were provided. We will also request records from a Dallas County employee to determine if you are re-arrested in the next 12 months. We will share your name and date of birth to obtain this information, but no additional information that you provide to us over the course of the study will be shared with this Dallas County employee or the Dallas County Jail. The research team will search the Dallas City Jail records portal to identify new arrests.

If you are paid $600 or more during a calendar year, your personal information will be reported to the IRS. During your baseline visit, we will ask for your citizenship status**,** social security number and if you are an employee of the University of Oklahoma Health Sciences Center. This information is confidential and will not be used by the research team. Only people who identify as U.S. Citizens may participate in this study.

The smartphone that you may be provided will also keep track of the number of minutes that you used the app to call your case manager or other services (if applicable).

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a

court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

Please understand that research study data will be sent to the research collaborators at other Universities. The data that will be shared will not include your name but may include your initials, date of birth, date of study visits, and date of study procedures. People who receive your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect your health information and may share your information with others without your permission, if permitted by laws governing them.

You will not be personally identified in any reports or publications that may result from this study. If all information that does or can identify you is removed from your health information, the remaining information will no longer be subject to this authorization and may be used or disclosed for other purposes.

Representatives of the organizations listed below will see your name and other personal identifiers when they review your research records and medical records for the purposes of verifying study data: Representatives of UTHealth and the University of Oklahoma Please note that you do not have to sign this Authorization, but if you do not, you may not participate in this research study. UTHealth and Memorial Hermann may not withhold treatment or refuse treating you if you do not sign this Authorization.

You may change your mind and revoke (take back) this Authorization at any time. Even if you revoke this Authorization, researchers may still use or disclose health information they already have obtained about you as necessary to maintain the integrity or reliability of the current research. To revoke this Authorization, you must contact Dr. Jennifer Gonzalez (Meadows Mental Health Policy Institute, 2800 Swiss Ave Dallas, Texas 75204) and / or Dr. Michael Businelle (University of Oklahoma Health Sciences Center, 655 Research Parkway, Suite 400 Oklahoma City, OK 73104). This Authorization will expire 15 years after the end of the study.

You will not be personally identified in any reports or publications that may result from this study. Any personal information about you that is gathered during this study will remain confidential to every extent of the law. A special ID number will be used to identify you in the study and only the research team will know your name. Please note that we will request records from a Dallas County employee to determine if you are re-arrested in the next 12 months. We will share your name and date of birth to obtain this information, but no additional information that you provide to us over the course of the study will be shared with this Dallas County employee or the Dallas County Jail.

Who can I contact if I have questions about the study? If you have questions at any time about this research study, please feel free to contact Dr. Jennifer Gonzalez at 470-333-8749 as they will be glad to answer your questions. You can contact the study team to discuss problems, report injuries, voice concerns, obtain information in addition to asking questions about the research.

The Committee for Protection of Human Subjects at the University of Texas Health Science Center has reviewed this research study. You may contact them for any questions about your rights as a research subject, and to discuss any concerns, comments, or complaints about taking part in a research study at (713) 500-7943.

SIGNATURES

Sign below only if you understand the information given to you about the research and you choose to take part in this research study. Make sure that all your questions have been answered. If you decide to take part in this research study, a copy of this signed consent form will be given to you.

Printed Name of Subject	Signature of Subject	Date	Time

Printed Name of Person Obtaining Informed	Signature of Person Obtaining Informed Consent	Date	Time