

Use of a Telehealth Intervention to Decrease Readmissions  
in Cirrhosis: A Randomized Controlled Trial

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**UNIVERSITY OF PENNSYLVANIA  
RESEARCH SUBJECT  
INFORMED CONSENT AND HIPAA  
AUTHORIZATION FORM**

**Title of the Research Study:**      **Use of A Telehealth Intervention to  
Decrease Readmissions in Cirrhosis: A  
Randomized Controlled Trial**

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You are being asked to take part in a research study. This is not a form of treatment or therapy. It is not supposed to detect a disease or find something wrong. Your participation is voluntary which means you can choose whether or not to participate. If you decide to participate or not to participate there will be no loss of benefits to which you are otherwise entitled. Before you make a decision you will need to know the purpose of the study, the possible risks and benefits of being in the study and what you will have to do if you decide to participate. The research team is going to talk with you about the study and give you this consent document to read. You do not have to make a decision now; you can take the consent document home and share it with friends, family doctor and family.

If you do not understand what you are reading, do not sign it. Please ask the researcher to explain anything you do not understand, including any language in this form. If you decide to participate, you will be asked to sign this form and a copy will be given to you. Keep this form, in it you will find contact information and answers to questions about the study. You may ask to have this form read to you.

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### **What is the purpose of the study?**

Cirrhosis affects more 600,000 adults, results in more than 150,000 hospitalizations, causes more than 60,000 deaths, and is the reason for 6000 liver transplants each year in the US. It is also very costly. The number of people who have cirrhosis who need to be readmitted to the hospital has been increasing at a faster than in people with other types of diseases. The investigators of this study have developed a new mobile communication monitoring system to detect early symptoms and signs, to help prevent a patient from being readmitted. All study participants will be randomly assigned into one of the two study groups. Random assignment means that you are put into a group by chance to compare controls (current discharge standard of care) to mobile monitoring. This study will allow us to improve the telehealth program we created and decrease readmissions on a large scale.

This will be the first study to look at readmissions using a patient centered approach and the first to use telehealth to decrease readmissions in cirrhosis patients.

Those meeting inclusion criteria will be randomized to one of two arms: current discharge standard of care (control) or mobile monitoring and social support. This study is only being done at the University of Pennsylvania and we plan on having 213 cirrhotic patients to be randomized to receive telehealth treatments and 213 cirrhotic patients will be randomized to receive standard of care.

In this study, you will receive routine care for your condition from your study doctor. If you agree to join this research study, you will receive routine care plus additional surveys and materials that are discussed below.

### **Why was I asked to participate in the study?**

You have been asked to participate in this study because you have either been admitted to the hepatology service at the Hospital of the University of Pennsylvania for cirrhosis or you are being seen in the Gastroenterology clinic for cirrhosis and have been admitted to an outside hospital in the last 30 days and meet all inclusion and exclusion criteria.

**How long will I be in the study?**

You will be in the study for up to 90 Days post-discharge for both treatment groups. If you are enrolled in the control group and choose to receive telehealth text messages after the 90 days, you will be in the study for up to 180 days.

**Where will the study take place?**

You will be completing study required tasks while at home post-discharge from the hospital.

**What will I be asked to do?**

If you decide to take part in this study you will be randomized (by chance, like a flip of a coin) to receive telehealth monitoring or standard of care at discharge from the hospital.

If you are randomized to the telehealth system, you will be followed for 90 Days and will receive text messages on your cell phone daily asking you questions to monitor your vital signs, whether you are taking your medications, and about how you are feeling. Weekly messages will be sent asking you to answer short health-related questions via text. Daily text messages will be received in the morning and evening. You may receive additional messages from your nurse or physician to review your information if there is a question or a concern. You will also be asked to complete two initial study questionnaires prior to discharge and at the end of 90 days. One will be thoughts about your health over the month prior and the other will assess your level of satisfaction with your care. You will also need to complete the satisfaction survey in the middle of the study. A family member or friend will have access to the platform and be educated about alarm symptoms and signs to serve as another layer of support for you

Examples of clinical parameters, which will be monitored and trigger a phone call include: Temperature greater than 100.4 or less than 96, Heart Rate greater than 15 from baseline, SBP greater than 15 mm Hg from baseline; change in weight greater than 2 kg or greater than 5 lbs; change in encephalopathy or new asterixis, medication adherence if less than 80% over 3 days, less than 1 bowel movement daily or greater than 5 bowel movements.

On telehealth you will be given a scale and a blood pressure device so that you can report these readings to us.

If you are randomized to the control group, you will receive the current discharge standard of care. You will also be asked to complete an initial study questionnaire prior to discharge. Cirrhotic patients receive a discharge summary with discharge information

about their follow-up appointments, current medications and contacts to call for any medical questions. If you are enrolled in the control group, you will be able to get the telehealth messages at the end of 90 days if you choose to.

### **What are the risks?**

Study inclusion poses no more than minimal risk to the study participants. There should be no adverse events associated with the collection of vital signs, medication records, or symptom logs. Patients and caregivers will have clear instructions as to how to reach the team in the event that it is after hours. This intervention results in no more than minimal risk compared to things are done for your routine follow up care. There is a risk of a breach of confidentiality, meaning your personal information may be released if there is a breach, however we have procedures in place to minimize this.

### **How will I benefit from the study?**

You may not receive benefit from taking part in this study. Data obtained will allow for identification of factors associated with readmissions in cirrhotic patients and offers an opportunity to correct these factors in the future. The data obtained will also allow for better future interventions to lessen readmissions.

### **What other choices do I have?**

Your alternative to being in the study is to not be in the study.

If you choose not to be in the study you will receive standard of care post-discharge treatment.

### **What happens if I do not choose to join the research study?**

You may choose to join the study or you may choose not to join the study. Your participation is voluntary.

There is no penalty if you choose not to join the research study. You will lose no benefits or advantages that are now coming to you, or would come to you in the future. Your therapist, social worker, nurse, or doctor will not be upset with your decision.

If you are currently receiving services and you choose not to volunteer in the research study, your services will continue.

### **When is the study over? Can I leave the study before it ends?**

The study is expected to end after all participants have completed all visits and all the information has been collected. The study may be stopped without your consent for the following reasons:

- The PI feels it is best for your safety and/or health—you will be informed of the reasons why.
- You have not followed the study instructions
- The PI, the sponsor or the Office of Regulatory Affairs at the University of Pennsylvania can stop the study anytime

You have the right to drop out of the research study at any time during your participation. There is no penalty or loss of benefits to which you are otherwise entitled if you decide to do so. Withdrawal will not interfere with your future care.

If you no longer wish to be in the research study, please contact the study coordinator or PI listed on this consent form.

**What information about me may be collected, used or shared with others?**

- Name, address, electronic mail address, telephone number, date of birth
- Social Security number
- Medical Record Number
- Personal and family medical history
- Results from physical examinations, tests or procedures

**How will confidentiality be maintained and my privacy be protected?**

We will do our best to make sure that the personal information obtained during the course of this research study will be kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

**Electronic Medical Records and Research Results**

What is an Electronic Medical Record and/or a Clinical Trial Management System?

An Electronic Medical Record (EMR) is an electronic version of the record of your care within a health system. An EMR is simply a computerized version of a paper medical record.

A clinical trial management system (CTMS) is used to register your information as a participant in a study and to allow for your research data to be entered/stored for the purposes of data analysis and any other required activity for the purpose of the conduct of the research.

If you are receiving care or have received care within the University of Pennsylvania Health System (UPHS) (outpatient or inpatient) and are participating in a University of Pennsylvania research study, information related to your participation in the research (i.e. laboratory tests, imaging studies and clinical procedures) may be placed in your existing EMR maintained by UPHS. Information related to your participation in clinical research will also be contained in the CTMS.

If you have never received care within UPHS and are participating in a University of Pennsylvania research study that uses UPHS services, an EMR will be created for you for the purpose of maintaining any information produced from your participation in this research study. The creation of this EMR is required for your participation in this study. In order to create your EMR, the study team will need to obtain basic information about you that would be similar to the information you would provide the first time you visit a hospital or medical facility (i.e. your name, the name of your primary doctor, the type of insurance you have). Information related to your participation in the study (i.e. laboratory tests, imaging studies and clinical procedures) may be placed in this EMR.

Once placed in your EMR or in the CTMS, your information may be accessible to appropriate UPHS workforce members that are not part of the research team. Information within your EMR may also be shared with others who are determined by UPHS to be appropriate to have access to your EMR (e.g. health insurance company, disability provider, etc.).

### **Why is my information being used?**

Your information is used by the research team to contact you during the study. Your information and results of tests and procedures are used to:

- do the research
- oversee the research
- To see if the research was done right.

## **Who may use and share information about me?**

We will not use your name or your identity for publication or publicity purposes. All information obtained during this study including hospital records, personal data, and research data will be kept confidential unless release is required by law. For the purpose of this scientific analysis and, if applicable, publication, this data is circulated in a way so that your identity will not be revealed.

The following individuals may use or share your information for this research study:

- Dr. Khungar and Dr. Forde and their study team (other University staff associated with the study)
- The University of Pennsylvania Institutional Review Boards (the committees charged with overseeing research on human subjects) and University of Pennsylvania Office of Regulatory Affairs
- The University of Pennsylvania Office of Human Research (the office which monitors research studies)
- Authorized members of the University of Pennsylvania and the University of Pennsylvania Health System and School of Medicine workforce who may need to access your information in the performance of their duties (for example: to provide treatment, to ensure integrity of the research, accounting or billing matters, etc.).
- Other research personnel with access to the databases for research and/or study coordination and as otherwise approved by the IRB

Your study doctor may tell your family doctor about your taking part in the study and ask them for medical information about you. A description of this clinical trial 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 the website at any time.

## **Who, outside of the School of Medicine, might receive my information?**

If required by law and/or necessary for oversight purposes, your information may be shared with:

- The Department of Health and Human services
- The National Institutes of Health
- The Office of Human Research Protections



Records of the patient's participation in this study will be held confidential except as disclosure is required by law or as described in this informed consent document Information. Once your personal health information is disclosed to others outside the School of Medicine, it may no longer be covered by federal privacy protection regulations.

The Principal Investigator or study staff will inform you if there are any additions to the list above during your active participation in the trial. Any additions will be subject to University of Pennsylvania procedures developed to protect your privacy.

### **How long may the School of Medicine use or disclose my personal health information?**

Your authorization for use of your personal health information for this specific study does not expire.

Your information may be held in a research database. However, the School of Medicine may not re-use or re-disclose information collected in this study for a purpose other than this study unless:

- You have given written authorization
- The University of Pennsylvania's Institutional Review Board grants permission
- As permitted by law
- You have the right to revoke HIPAA authorization by sending a written notice to the study team.

### **What if I decide not to give permission to use and give out my health information?**

Then you will not be able to be in this research study. You will be given a copy of this Research Subject HIPAA Authorization describing your confidentiality and privacy rights for this study.

By signing this document, you are permitting the School of Medicine to use and disclose personal health information collected about you for research purposes as described above.

### **Will I have to pay for anything?**

The study material used in this study will be given to you to use free of charge. You or your usual health care payer will be responsible for any other health care costs. Any medical care or intervention required as a direct result of study inclusion will be provided to the subject at no cost to you.

However, if you do choose to receive study communications via text messages, standard text message charges may apply.

**Will I be paid for being in this study?**

Yes. You will receive \$25 30 days after enrollment and another \$25 after 90 days, for a total of \$50. All study payments will be sent by check via US Mail.

**What information will I need to provide to receive compensation and how is that information protected?**

To mail your financial payments, we will need to collect your name and address. Since all university payments must be reported to the Internal Revenue Service (IRS), we will also need to collect your social security number (SSN). Your information will be kept in a secured, password-protected file at the University of Pennsylvania. Your information will be transmitted and stored using very secure systems. The network servers where your data are stored sit behind firewalls that do not allow unauthorized access and are physically located in a secure server room that can only be accessed by critical staff members. The investigator and staff involved with the study will keep your personal information collected for the study strictly confidential. All of these personnel will have completed research and confidentiality training.

**Who can I call with questions, complaints or if I'm concerned about my rights as a research subject?**

Contact Dr. Khungar 215-687-0223 for any of the following reasons:

- if you have any questions about your participation in this study,
- if at any time you feel you have had a research-related injury or a reaction to the study drug,

If a member of the research team cannot be reached or you want to talk to someone other than those working on the study, you may contact the Office of Regulatory Affairs with any question, concerns or complaints at the University of Pennsylvania by calling (215)-8982614.

Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

When you sign this form, you are agreeing to take part in this research study. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer. Your signature also means that you are permitting the University of Pennsylvania to use your personal health information collected about you for research purposes within our institution. You are also allowing the University of Pennsylvania to disclose that personal health information to outside organizations or people involved with the operations of this study.

A copy of this consent form will be given to you.

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Name of Subject (Please Print)	Signature of Subject	Date
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Name of Person Obtaining Consent (Please Print)	Signature	Date
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Also Required: For subjects unable to give authorization, the authorization is given by the following authorized subject representative:

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Authorized subject representative (Signature)	_____	Authorized subject     Date representative (Print)
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Provide a brief description of above person authority to serve as the subject's authorized representative.

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