USC Keck School of Medicine
Department of Emergency Medicine

Study Title: Trial to examine using mHealth with social support to improve diabetes self-care for ED patients

Principal Investigator: Elizabeth Burner, MD MPH

EXPERIMENTAL SUBJECT'S BILL OF RIGHTS

You have been asked to participate as a subject in a medical experiment. Before you decide whether you want to participate in the experimental procedure, you have a right to the following information:

CALIFORNIA LAW REQUIRES THAT YOU MUST BE INFORMED ABOUT:

1. The nature and purpose of the study.
2. The procedures in the study and any drug or device to be used.
3. Discomforts and risks reasonably to be expected from the study.
4. Benefits reasonably to be expected from the study.
5. Alternative procedures, drugs, or devices that might be helpful and their risks and benefits.
6. Availability of medical treatment should complications occur.
7. The opportunity to ask questions about the study or the procedure.
8. The ability to withdraw from the study at any time and discontinue participation without affecting your future care at this institution.
9. Be given a copy of the signed and dated written consent form for the study.
10. The opportunity to consent freely to the study without the use of coercion.

I have carefully read the information contained above and I understand fully my rights as a potential subject in this study.

Date: _____ Time: _____

Signature: _____
(Research Participant)

INFORMED CONSENT

TITLE: **Trial to examine using mHealth with social support to improve diabetes self-care for ED patients**

PRINCIPAL INVESTIGATOR: **Elizabeth Burner MD MPH**

DEPARTMENT: **Emergency Medicine**

We invite you to take part in a research study. Please take as much time as you need to read the consent form. You may want to discuss it with your family, friends, or your personal doctor. If you find any of the language difficult to understand, please ask questions. If you decide to participate, you will be asked to sign this form.

This research study is sponsored by the National Institute of Diabetes and Digestive and Kidney Disease. They provide funding to cover the costs of conducting this study.

WHY IS THIS STUDY BEING DONE?

This study is about the use of mobile phones in diabetes care. The study is called TExT-MED FANS (Trial to Examine Text-Based mHealth for Emergency department patients with Diabetes with Family And friends Network Supporters). We hope to learn if an education program can be delivered by text message. We want to know if this will help patients manage their diabetes. We also want to learn the effects of involving family or friends in their loved one's diabetes care.

You are invited as a possible participant because you have diabetes and an elevated HbA1C test. About 170 patients and 170 family members or friends (1 for each patient) will take part in this study at USC.

WHAT IS INVOLVED IN THE STUDY?

If you agree to take part, you will complete the initial visit and then you will be randomized (like flipping a coin) to one of two groups: the TEXT-MED FANS intervention or TExT-MED with traditional social support. You will also complete follow-up visits after 6 months and 12 months. You will also take a phone survey at 3 months and 9 months.

Both the intervention and control group patients will receive the TExT-MED program. This means you will receive daily text messages. The messages are educational and motivational. Messages will be delivered in English or Spanish, as you prefer. If you are in the intervention group, your family member or supporter will also receive text messages about diabetes. Messages will be delivered in English or Spanish, as they prefer. If you are in the control group your loved one will still receive the information, but not by text messages. The only difference between the groups is the texts sent to your family member or supporter.

Initial visit:

This will take about 30 minutes and you will be asked to do the following:

- Fill out questionnaires that will ask about your mobile phone and texting habits, your diabetes habits and your social support
- Get a finger stick to check your chronic blood sugar level
- Measure your height and weight
- Identify a close friend or family member to be your supporter

Follow-up visits:

- At 3 months, you will be contacted by phone and complete surveys about your current diabetes management.

- At 6 months after the initial visit, you will return for an appointment and you will be asked to do the following:
    - Complete questionnaires about your mobile phone and texting habits, your diabetes habits, your social support, and your satisfaction with the program
    - Check your height and weight
    - Repeat the finger stick test

- At 9 months, you will be contacted by phone and complete surveys about your current diabetes management.

- You will return at 12 months after the initial visit and you will be asked to do the following:
    - Complete questionnaires about your mobile phone and texting habits, your diabetes habits, your social support, and your satisfaction with the program
    - Check your height and weight
    - Repeat the finger stick test

While in the study, you will continue to get routine care. You will also receive the TExT-MED intervention. This means that daily educational and motivational text messages will be delivered on your mobile phone. Messages will be in English or Spanish, whichever you prefer. The supporter you identified will also receive text messages regarding diabetes if you are in the intervention group.

Interview:

After the program is complete, we will ask the patients in the intervention group to come to the hospital for an interview. This will only be done once. We will also ask the supporters from the intervention group to come for a single, separate interview. We hope to find out

more about how this intervention affects your everyday life. We will audio-record these interviews. If you do not wish to be audio recorded, you cannot participate in this final interview.

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

Possible risks and discomforts you could experience during this study include:

- Blood draw - a small amount of discomfort when the finger stick is performed. Aseptic technique will be used to minimize the small risk of local infection.
- Questionnaires - some of the questions may make you feel uneasy or embarrassed. You can choose to skip or stop answering any questions that make you uncomfortable.
- Loss of confidentiality - people who are not connected with this study may learn your identity or your personal information. To prevent this, all of your information will be kept in a locked study area only accessible to study personnel.

WILL YOUR INFORMATION BE KEPT PRIVATE?

We will keep your records for this study confidential as far as permitted by law. However, if we are required to do so by law, we will disclose information about you. The University of Southern California's Institutional Review Board (IRB) may review your records. The IRB is a research review board that reviews and monitors research studies to protect the rights and welfare of research participants. We may publish the information from this study in journals or present it at meetings. If we do, we will not use your name. Audio recordings will be transcribed and then destroyed after your name is removed.

You will be asked to sign a separate HIPAA Authorization for Research form authorizing the access, use, creation, and disclosure of your health information.

WHAT ARE THE POSSIBLE BENEFITS OF TAKING PART IN THIS STUDY?

You may not receive any direct benefit from taking part in this study. However, the knowledge gained from your participation may help future patients with diabetes.

WHAT OTHER OPTIONS ARE THERE?

You may choose to not participate in this study and continue with your regular care.

ARE THERE ANY PAYMENTS TO YOU FOR TAKING PART IN THE STUDY?

You will be paid a total of $280 in gift cards. At enrollment, you will receive $20. After the 3 month phone survey, you will receive $5. At the 6-month follow-up, you will receive $50. After the 9 month phone survey, you will receive $5. At the 12-month follow-up, you will receive $100. At the interview visit, you will receive $100. These payments are meant to cover your time, travel and additional phone costs you have from the text-messages.

If you receive more than $600 per year for taking part in one or more research studies, you may be required to pay taxes on that money. This does not include any payments you receive to pay you back for expenses like parking. You may receive an Internal Revenue Service (IRS) Form 1099 if you receive more than $600 in one year for taking part in one or more research studies.

WHAT ARE THE COSTS?

You may exceed your monthly texting allowance on your plan due to participation in the study.

All research tests and procedures provided to you for this study are being paid for by the sponsor. Neither you and/or your health plan/insurance company will be charged for the cost of any research tests or procedures that are being done for this study. If you require any routine tests or procedures to treat your illness that are not related to this study (meaning you would normally receive them if you were not participating in this study), you and/or your health plan/insurance company will be billed for the costs of the routine tests and procedures in the same way as if you were not in a study. You will also be responsible for any co-payments and deductibles that are standard for your health plan/insurance coverage. Some health plans will not pay these costs for people taking part in studies. Check with your health plan or insurance company to find out what they will pay for. If you have any questions about which tests or procedures will be billed to you and/or your health plan/insurance company, ask the study doctor.

WHAT HAPPENS IF YOU GET INJURED OR NEED EMERGENCY CARE?

If you think you have been hurt by taking part in this study, tell the study doctor immediately. If you require treatment because you were injured from participating in this study, treatment will be provided. You or your health plan/insurance will be billed for the cost of this treatment.

There are no plans to offer any type of payment for injury. However, by signing this form you have not given up any of your legal rights.

WHAT ARE YOUR RIGHTS AS A PARTICIPANT, AND WHAT WILL HAPPEN IF YOU DECIDE NOT TO PARTICIPATE?

Your participation in this study is voluntary. Your decision whether or not to take part will not affect your current or future care at this institution. You are not giving up any legal claims or rights. If you do decide to take part in this study, you are free to change your mind and stop being in the study at any time. You will not lose any rights if you decide to stop being in the study. If the withdrawal must be gradual for safety reasons, the study doctor will tell you.

WHOM DO YOU CALL IF YOU HAVE QUESTIONS OR CONCERNS?

You may contact Elizabeth Burner, MD at 323-226-6667 with any questions, concerns, or complaints about the research or your participation in this study. If you feel you have been hurt by taking part in this study, please contact Elizabeth Burner, MD at 323-226-6667. If you have questions, concerns, or complaints about the research and are unable to contact the research team, contact the Institutional Review Board (IRB) Office at 323-223-2340 between the hours of 8:00 AM and 4:00 PM, Monday to Friday. (Fax: 323-224-8389 or email at irb@usc.edu).

If you have any questions about your rights as a research participant, or want to talk to someone independent of the research team, you may contact the Institutional Review Board Office at the numbers above or write to the Health Sciences Institutional Review Board at LAC+USC Medical Center, General Hospital Suite 4700, 1200 North State Street, Los Angeles, CA 90033.

You will get a copy of this consent form.

AGREEMENT:

I have read (or someone has read to me) the information provided above. I have been given a chance to ask questions. All my questions have been answered. By signing this form, I am agreeing to take part in this study.

Name of Research Participant	Signature	Date Signed (and Time*)

I have personally explained the research to the participant using non-technical language. I have answered all the participant's questions. I believe that he/she understands the information described in this informed consent and freely consents to participate.

Name of Person Obtaining Informed Consent	Signature	Date Signed (and Time*)

** If a study procedure is done on the same day the informed consent is signed, the time and date are required. No study procedures may be done before the participant has signed the informed consent.*