A Pilot Trial to Prevent Hospital Readmission of Patients with Diabetes

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Title of research: A Pilot Trial to Prevent Hospital Readmission of Patients with Diabetes

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Why am I being invited to take part in this research?

We invite you to take part in a research study because you have been admitted to the hospital and you have diabetes.

What should I know about this research?

- Someone will explain this research to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Who can I talk to about this research?

If you have questions, concerns, or complaints, or think the research has hurt you, contact:

Shaneisha Allen, Study coordinator
215-707-9731

Dr. Daniel J. Rubin
Lewis Katz School of Medicine at Temple University
3322 N. Broad Street
Philadelphia, PA 19140
Office: 215-707-4746 (24 hours)

This research has been reviewed and approved by an Institutional Review Board. You may talk to them at (215) 707-3390 or e-mail them at: irb@temple.edu for any of the following:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research subject.
- You want to get information or provide input about this research.

Why is this research being done?

People with diabetes are more likely to come back to the hospital (readmitted) after being discharged than people without diabetes. There are no proven ways specifically for patients with diabetes to help them stay out of the hospital. Based on other research and our own experience, we have built the Diabetes Transition of Hospital Care Program ("My Temple Extra Care Service") to prevent readmissions. The My Temple Extra Care Service involves extra support around hospital discharge, adjusting diabetes medicines, diabetes education, and close follow-up after discharge. Also, we have made a questionnaire that predicts a person's risk of readmission, but it has not been confirmed in patients who followed in real time. This research is being done for two reasons: (1) To find out if we can prevent readmissions with the My Temple Extra Care Service, and (2) To confirm how good the questionnaire is at predicting readmission risk in patients with diabetes.

How long will I be in this research?

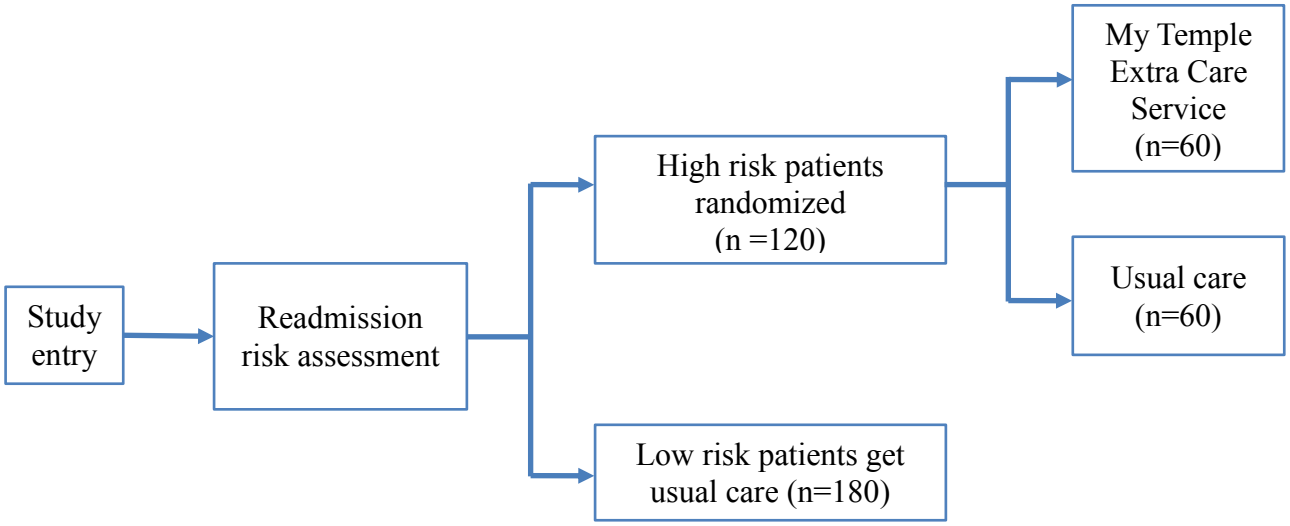
We expect that you will be in this research during your hospital stay and 3 months after your discharge.

How many people will be studied?

We expect up to 300 people will take part in the research.

What happens if I agree to be in this research?

First, we will get some information from your medical record and ask you a few questions about you and your health to predict your risk of readmission. If you are at high risk of readmission, then the treatment you get will be chosen by chance, like flipping a coin. Neither you nor the study doctor will choose what treatment you get. You will have an equal chance of being given one of two treatments: the My Temple Extra Care Service or usual care.



If you are chosen for the My Temple Extra care Service, then you will get the following:

1) Diabetes discharge instructions and education: Before leaving the hospital, a special nurse called a Navigator will review tips on how to best manage your diabetes. The Navigator

will also review your plan of care after discharge. In addition, you will be referred to the Temple Diabetes Center for more in-depth diabetes education after you leave the hospital.

2) Coordination of care: After leaving the hospital, a Navigator will help you follow through on your discharge instructions. This may include helping you get your medicines, schedule appointments to see your doctors, and find transportation to your appointments.

3) Adjustment of your diabetes medicine: Your A1C level will be checked with a routine blood test in the hospital if it has not been done recently. This would usually be done even if you do not participate in the study. The A1C level is like an average of blood sugars over the past 3 months. The diabetes medicine you take after discharge will be adjusted based on your A1C level as follows:
    a. If your A1C is less than 7%, then you will not change how you are taking your diabetes medicine at home.
    b. If your A1C is more than 7% and you have not been taking insulin at home, then you will take insulin at least once a day in addition to your other diabetes medicine. If you already take insulin at home, then the insulin will be adjusted by an Endocrinologist (Dr. Rubin or one of his partners). You may be asked to take insulin up to 4 times a day with or without your other diabetes medicine. If you have health insurance, then you will get the medicine as you normally do through insurance. If you do not have insurance, then the study may provide you with insulin depending on your needs.

4) Support after hospital discharge: A Navigator will call you 1-2 days after you leave the hospital to see how you are doing, ask if you need help, and go over your blood sugars. If you are having high or low blood sugar levels, then the Navigator will tell a study doctor so they can adjust your diabetes medicines. On the phone call, the Navigator will also find out if you need help from a Community Health Worker (CHW). A CHW is someone from the local community who works for Temple University Hospital and is trained to help patients with things such as transportation, food, housing, legal problems, and utility bills. Similar phone calls will be made every week for four weeks after you leave the hospital. Lastly, you will have at least one nursing visit from a local home care agency if it is covered by insurance to check on you at home and go over your medicines.

If you are chosen for usual care, then you will get the standard discharge instructions, diabetes education, and an A1C test in the hospital as well as 3 months after leaving the hospital. If needed, your hospital nurse will teach you how to use a glucometer and/or inject insulin. (The nurse would teach patients in either study group as well as patients not in the study). Your doctors will decide if you need diabetes education after you leave the hospital. Your doctors will also decide what you will take for diabetes after leaving the hospital. As with most Temple patients, a CHW will call you a few days after discharge to check on you, confirm your doctors' appointments, see if you have your medicines, and answer questions.

If you are in either high-risk group, then you will also:

1) Answer survey questions about you and your health while in the hospital.
2) Participate in a follow-up phone call to complete some surveys about your experience in the program and your health and review your blood sugars about 5 weeks after discharge from

the hospital. This call will take at least 30 minutes. Participants in the My Temple Extra Care Service may be asked to visit the Temple University Hospital General Clinical Research Center to do an interview about your experience in the program with someone on the research team. This interview will last about 30 to 45 minutes and will be recorded.

3) Have an A1C blood test done 3 months after leaving the hospital.

If you are at low risk of readmission, then we will ask about you and your health while you are in the hospital. About 5 weeks after discharge, we will call you to ask some survey questions. We will also check your Temple medical record to see if you have been back to the hospital or emergency department (ED). If you have not been readmitted at Temple, then we will ask if you have been to another hospital during the phone call.

Independently of the risk group you are placed in, the information we will be collecting from you and your medical record for this study includes social history, demographics, medical history (including HIV, substance abuse, and mental health), laboratory results, hospital diagnoses, and medications.

What are my responsibilities if I take part in this research?

If you take part in this research in either high-risk group, then you will be responsible for:

- Filling out surveys about you and your health
- Checking your blood sugar levels at least once a day if you do not take insulin, and twice a day if you do take insulin, and writing down the numbers
- Taking your medicine as directed
- Participating in the follow-up phone call
- Getting an A1C blood test 3 months after discharge

If you take part in this research in the My Temple Extra Care Service, then you may also be responsible for:

- Participating in an in-clinic visit for an in-depth interview
- Participating in at least 1 home visit by a visiting nurse and/or CHW, depending on insurance coverage and need

If you take part in this research in the low-risk group, then you will be responsible for:

- Filling out surveys about you and your health
- Participating in 1 follow-up phone call about 5 weeks after discharge
- Getting an A1C blood test 3 months after discharge

What other choices do I have besides taking part in this research?

Instead of being in this research, you can get the standard discharge process and care after you leave the hospital.

What happens if I agree to be in this research, but I change my mind later?

If you stop being in this research, already collected data may not be removed from the research database. You will be asked whether the investigator can collect data from your routine medical care. If you agree, this data will be handled the same as research data.

Is there any way being in this research could be bad for me?

Adjustment of diabetes medicines poses the usual risk of low blood sugars. However, your diabetes medicine will only be adjusted if you are in the My Temple Extra Care Service and your diabetes is uncontrolled based on a high A1C. You will be followed closely for 30 days after discharge and if your blood sugars are very high or low then your diabetes medicine will be adjusted.

You and your insurance company will be charged for the health care services that you would ordinarily be responsible to pay. In some cases, insurance will not pay for services ordinarily covered because these services were performed in a research study. You should check with your insurance to see what services will be covered by your insurance and what you will be responsible to pay. Because the study will only be using FDA-approved medicines and checking routine A1C blood tests, it is unlikely that your costs will be more than if a doctor was managing your diabetes outside the study.

Will being in this research help me in any way?

We cannot promise any benefits to you or others from taking part in this research. However, possible benefits include that the study interventions could improve your blood sugar control at home and make it less likely that you will return to the hospital within 30 days. Better blood sugar control may also help you feel better.

What happens to the information collected for this research?

To the extent allowed by law, we limit the viewing of your personal information to people who have to review it. We cannot promise complete secrecy. The IRB, Temple University, Temple University Health System, Inc. and its affiliates, and other representatives of these organizations may inspect and copy your information. The Department of Health and Human Services and its agents (if applicable), monitors, auditors, the IRB, and the will be granted direct access to the portion of your medical records which are related to this research study for verification of the research procedures and date. By signing this document you are authorizing this access. You will also need to sign a separate "Authorization to use and disclose your protected health information" to be a part of this research. We may publish the results of this research. However, we will keep your name and other identifying information confidential.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. 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.

Federal law provides additional protections of your personal information. These are described in an attached document titled "Authorization to use and disclose your protected health information".

Can I be removed from this research without my OK?

The person in charge of this research or the sponsor can remove you from this research without your approval. Possible reasons for removal include not following the instructions of research staff and not answering follow-up phone calls

What if I am injured because of taking part in this research?

If you are injured as a result of taking part in this research, immediately notify the research team and they will arrange for you to get immediate medical care. There is no commitment by Temple University, Temple University Health System or its subsidiaries to provide monetary compensation or free medical care to you in the event of a research-related injury. If you have a research-related injury, please contact Dr. Rubin at 215-707-4746 (24 hours). Someone is available to answer this phone number 24 hours a day, 7 days a week.

What will I be paid for taking part in this research?

If you agree to take part in this research, we will pay you for your time and effort. If you are in either the low-risk group or the high-risk group, then you will be given $50 after completion of the study. If you are in the My Temple Extra Care Service group and do the in-depth interview at the follow-up visit, then you will be given an additional $50. Federal tax law requires to you to report this payment as income to the Internal Revenue Service.

Signature Block for Adult Subject Capable of Consent

Your signature documents your permission to take part in this research.

Signature of subject	Date
Printed name of subject	
Signature of person obtaining consent	Date
Printed name of person obtaining consent	