UMASS CHAN MEDICAL SCHOOL

COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS IN RESEARCH

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Title: Re-Engineered Discharge for Diabetes Care Transitions (REDDCAT2): Screening and Addressing Social Determinants of Health Needs at Hospital Discharge (STUDY00002129)

Protocol No.: 1R01NR021826-01A1

Sponsor: National Institutes of Health/ National Institute on Nursing Research

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Consent Version: 0.3

Document Date: 10/17/2024

You are being invited to take part in a research study. Someone will explain this research to you. This form helps to sum up their explanation.

KEY INFORMATION

You are being invited to participate in a research study because you are an adult inpatient at a University of Massachusetts (UMass) Memorial Health hospital with type 2 diabetes.

If you have questions or don't understand something, please ask.

Taking part in this research is voluntary and completely up to you. You are free to say no or to leave the research at any time. There will be no penalties or changes in the quality of the health care you receive, and you will not lose any benefits to which you are otherwise entitled.

We are doing this research to test a computer-based screening tool and a care coordination protocol to help people with type 2 diabetes who report unmet social determinants of health.

Social determinants of health (SDOH) are the conditions in the environments where people are born, live, learn, work, play, worship, and age that affect a wide range of health, functioning, and quality-of-life outcomes and risks. – *Office of Disease Prevention and Health Promotion*

Examples of SDOH include factors such as housing, transportation, education, job opportunities, income, and access to healthy food, clean air and water, and health care services.

If you join this research, you will be asked to complete a screening survey about your health. Then, you will be randomly assigned (like pulling a name out of a hat) to one of two groups:

- Those in Group 1 will be partnered with a patient navigator whose role will be to review the results of the screening survey and help you coordinate your care before you leave the hospital and for 90 days after. Together, you will form an action plan intended to help you address personal, social, or community factors affecting your health. You can expect your navigator to contact you every 2 weeks, though this can be adjusted based on your preference.
- Those in Group 2 will receive treatment as usual. A list of community-based resources will be provided.

Participants in both groups will complete surveys at the beginning of the study and again at 30 and 90 days after leaving the hospital. We will make reminder calls to participants in both groups about data collection.

We will collect information from your medical record for as long as 90 days after you leave the hospital.

You may not want to be in this study if you are uncomfortable with:

- The fact that neither you nor your doctor will get to pick which group you are in
- Sharing your private information with researchers

Risks: We will take steps to protect your personal information. However, there is a risk of mental or emotional discomfort associated with answering questions about social and community factors that may affect your health. There is also a risk of breach of confidentiality.

There may also be risks that we do not know yet.

Benefits:

All participants will contribute to science, by using a tool designed to identify important SDOH needs.

Those assigned to the intervention group will contribute to a protocol that improves communication between patients and providers. Your participation will help researchers understand how to reduce SDOH needs among diabetes patients following a hospital stay. You may benefit from improved quality of life and quality of care.

We cannot promise any benefits to you if you take part in this research.

Alternatives: There is a standard of care for all patients in the hospital with diabetes. This often includes a referral to Endocrinology and/or Social Work, as needed. If you would like to learn more about your diabetes or community programs after you leave the hospital, you can talk to your primary care team. Your alternative is to not participate.

If you think you might like to participate in this research, please continue reading to learn more about the details of this study.

STUDY DETAILS

Why is this research being done?

The purpose of this research is to test an intervention that combines social needs screening and navigation support to improve health among hospitalized patients with diabetes.

How many people will take part in this research?

About 412 people will take part here at UMass Memorial Health Care/ UMass Chan Medical School.

How long will I be in this research?

You will be in this study for 90 days following your discharge date from the hospital.

What happens if I say yes, I want to be in this research?

- In this study, we will ask you to respond to questions about personal, social, community, and societal factors that have the potential to impact your health. These questions will be asked either over the telephone, in person by a member of our research team, or via a secure link sent to your email address. If we are in person and you are comfortable using a computer, you may choose to read the questions for

yourself; otherwise, the questions can be read to you. We will ask you for some demographic information (such as age, gender, racial/ ethnic background, education, household income, and internet use) before we ask the survey questions. Answering all of the questions will probably take you about 1 hour.

- Then, you will be assigned to 1 of 2 groups at random; this means you have a 50-50 chance of being in either group. Neither you nor the research team will be able to choose groups.
- If you are assigned to the first group (called intervention), a patient navigator, who is a member of the research team, will meet with you before you leave the hospital to discuss the results of the survey you completed. Together, you will make an action plan to address coordinate your care based on your results. The navigator will contact you approximately every 2 weeks during the 90-day period following your discharge date. The navigator will check in and help you meet your goals. The navigator will notify your primary care team that you are in the study and add progress notes to your health record.
- If you are assigned to the second group (called treatment as usual), you will continue to receive the same care from your health providers without change. A list of community resources will be provided to you.
- While you are in the study, we will look at clinical values (i.e. hemoglobin A1c), other medical conditions you have, medications, insurance type, and number and description of emergency department visits and hospital admissions. We will review what is in your medical record starting when you were admitted to the hospital and for the 90 days after you leave the hospital. If you are not admitted to the hospital while you complete this survey, we will not collect this information. The ways we will protect your privacy and confidentiality are described in a separate section later in this form.
- If hemoglobin A1c values are not available in your medical record at the beginning or end of the study, the study team will invite you to meet for an in-person research visit at am UMMHC location. At this visit, a finger stick test will be performed, which will measure your HbA1c in real-time.

Could being in this research hurt me?

- You might experience mental or emotional discomfort while participating in the study. You might feel uncomfortable answering questions that ask about your health and about social factors in your life. You do not have to answer any question that you do not wish to, and you have the option of withdrawing from the study at any time.
- ***There is a risk that someone could get access to the data we have stored about you. If those data suggest something serious about your health, it could be misused. We believe the chance these things will happen is very small, but we cannot make guarantees.***
- In addition to these risks, taking part in this research may harm you in unknown ways.

Will being in this research help me in any way?

- The primary goal of this research is to collect information about the scientific questions asked in this study. Your being in this study may help the investigators learn what social factors put people at the highest risk of being hospitalized and how best to address them.
- You will receive no direct benefit from being in this study.

Will it cost me any money to take part in this research?

- No, there is no cost to you.

Will I be given any money or other compensation for being in this study?

Yes, you will receive up to $50 for your time and participation. You will be paid as follows:

- $10 after completing baseline data collection (at the start of the study)
- $15 after completing data collection 30 days after your hospital discharge
- $25 after completing data collection 90 days after your hospital discharge

If you decide to stop your participation in the study early, you will be paid only for the study activities you completed.

In order to receive a stipend for study participation, you will need to give us private information like your name, address and phone number. We will then share this information with the business offices and companies that need it to process the payment. You will need to provide your social security number and complete a W-9 (tax form) if you receive:

- $300 or more from a single study within a single calendar year at UMass Chan, or
- $600 or more in a calendar year across multiple research studies at UMass Chan.

The Medical School may report the payment to the IRS and send you a 1099 form for tax purposes. The business offices and companies will keep the information as part of their financial records. The research team will destroy this information no later than six years after study closure.

What happens if I am injured because I took part in this research?

If you are injured while in the study, seek treatment and contact the study doctor as soon as you are able.

The UMass Chan Medical School does not provide funds for the treatment of research-related injury. If you are injured as a result of your participation in this study, treatment will be provided. You or your insurance carrier will be expected to pay the costs of this treatment. No additional financial compensation for injury or lost wages is available.

You do not give up any of your legal rights by signing this form.

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

If you take part in this research, you will be responsible to:

- Follow the directions of the study doctor and research staff.
- Tell your study doctor and staff about all prescriptions, over the counter medications, and supplements you are taking, and about health issues that resulted in a visit to the hospital or emergency department.
- Tell your other health care providers that you are in a research study.

What happens if I say yes, but I change my mind later?

If you decide to leave this research, please contact the research team so that we can document your decision. All future outreach and research activities will stop as a result.

Can I be removed from the research without my approval?

The person in charge of this research study can remove you even if you want to continue. This may happen if

- It is in your best interest
- You develop a medical condition that affects your participation in the study

We will tell you about any new information that may affect your health, welfare, or choice to stay in this research.

How will my information be stored and when will it be destroyed?

- We will remove your name and any other information that could directly identify you from your data. We will replace this information with a code number. We will create a master list linking your code number to your name. We will keep this list separate from your data.
- We will keep paper documents under lock and key. We will keep electronic health information and research data on secure computer networks. These computer networks have many levels of protection.
- There is no limit on the length of time we will store your data. We will destroy the master list of identifiers when the study is complete and results are analyzed.
- It is possible that we might use the research data in other future research. We may also share data with researchers and companies that are not part of UMass Chan. In these cases, we will not share your name or other information that identifies you directly, and we will not come back to you to ask you for your consent.

Who has access to my information?

Signing this document means you allow us, the researchers in this study, and others working with us to use some protected health information for this research study.

As part of the research, UMass Memorial Medical Center or any other healthcare facility where you are treated may disclose the following information:

- Demographic and identifying information like your name, date of birth, address, telephone number, and your email address
- Related medical information like family medical history, and current and past medications or therapies
- Information from physical examinations, such as blood pressure reading, heart rate, temperature, height/weight, and lab results

Your health information and research records will be shared with the study team and with individuals and organizations that conduct or watch over this research, in order to conduct the study and to make sure it is conducted as described in this form. Information and records may be shared with:

- The research sponsor
- People and companies who work with the research sponsor
- Federal and state government agencies, such as the National Institutes of Health
- The UMass Chan Medical School and UMass Memorial Health, including their Institutional Review Board (IRB) and research and compliance offices
- Health care providers who provide services in connection with this study
- People and companies who work with UMass Chan and UMMH on activities related to the research

We will protect your identifiable information from disclosure to others to the extent required by law, but we cannot promise complete secrecy.

Any disclosure carries the potential for re-disclosure. Once your protected health information is disclosed, it may no longer be protected by federal privacy laws.

Your authorization does not have an expiration date. If you change your mind, you have the right to revoke your authorization in writing or using the contact information at the beginning of this form. If you revoke your authorization, you will not be allowed to continue to participate in the study. We will not collect any new information about you. However, information that we have already collected will stay in the study database and cannot be removed in order to maintain the integrity of the research. Your information may still be used and disclosed if you have an adverse event.

<u>You do not have sign this authorization.</u> If you choose not to sign, it will not affect your treatment, payment, or enrollment in any health plans, or affect your eligibility for benefits. You will not be allowed to participate in the research study.

We may publish the results of this research. However, we will keep your name and other identifying information confidential.

Because the National Institutes of Health (NIH) funds this research, this study has a Certificate of Confidentiality. The Certificate keeps us from sharing your identifiable sensitive

information collected for the research unless you allow us to do so. It also keeps us from being forced to release information that may identify you, as part of a court, legislative, administrative, or other proceeding.

There are times when the Certificate cannot be used. For example, we cannot refuse to give information to government agencies that oversee or fund research, such as the NIH or Food and Drug Administration (FDA). The Certificate also does not stop us from giving information to local government agencies, law enforcement personnel, or others if we suspect you or someone else is in danger or if we are required to do so by law.

The Certificate does not stop you from giving out information about yourself or your participation in the research. If you give an insurer, employer, or someone else your permission for us to release information, we will do so.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Will you share any results with me?

It may be several years before the results of the research are available. Results of the research will be shared in summary form with participants. No personally identifiable information or individual results will be shared.

Who can I talk to?

If you have questions, concerns, or complaints, or think this research has hurt you or made you sick, talk to the research team at the phone number listed on the first page.

This research is being overseen by an Institutional Review Board. An IRB is a group of people who perform independent review of research studies. You may talk to them at (508) 856-4261 or irb@umassmed.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 participant.
- You want to get information or provide input about this research.

Signature Block for Capable Adults

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

Signature of adult research participant	Date
Printed name of adult research participant	
Signature of person obtaining consent	Date
Printed name of person obtaining consent	