

VERMONT CENTER ON BEHAVIOR AND HEALTH

University of Vermont

Healthy Lifestyle Program (HeLP)

Incentives and Case Management to Improve Cardiac Care

NCT03759873

Study Protocol

Version 10.03.19

Consent to Participate in Research

Title of Research Project: Incentives and Case Management for Cardiac Care

Principal Investigator: Diann Gaalema, PhD

Sponsor: National Institutes of Health

Introduction

You are being invited to take part in this research study because you are receiving care due to an underlying cardiac condition or a major cardiac event. This study is being conducted by the University of Vermont at the UVM Medical Center.

Please ask questions and take time to discuss the study with anybody you think can help you make this decision.

Key Information to Help You Decide Whether or Not This Study Is Right for You

It is important for cardiac patients to make needed changes to their behavior and get the medical care they need. This is especially important in cardiac patients. However, many people struggle to make these changes and get the care they need. The purpose of this research is to study how cardiac patients recover, and access care. Can we help patients change behaviors and access the care they need?

- We will have all patients come to three assessments, spread over one year.
- Each assessment takes about two hours and we look at your physical and mental health.
- We will be randomly putting patients into groups. Each group receives different levels of interventions. Patients may receive no intervention, one intervention, or two interventions.
- One intervention will be a case manager to help manage heart health-related care. The other will be financial incentives for completing outpatient cardiac rehabilitation.
- The goal of this research is to examine if these interventions can help patients with their cardiac care.
- Patients will be followed for one year. This is an optional, volunteer research study.
- We will ask about your mental and physical health frequently. Some of the questions may make you uncomfortable. You can choose not to answer questions.
- We will have you do an exercise tolerance test to make sure you are healthy enough to be in the study. There is a very small chance of complications from this test (less than 1 in 1000). Very skilled clinicians oversee these tests and it is actually riskier to not exercise after getting a cardiac diagnosis.

The information above is only a summary of the study. To learn more, it is important to read the additional detailed information below. A complete list of the risks is given in the following pages. If you decide to take part in the research, we will ask you to provide written consent at the end of this document.

Why Is This Research Study Being Conducted?

- Many cardiac patients struggle to make changes in their behavior.
- Little is known about whether earning incentives or having a case manager can help.

What Is Involved In The Study?

- In this study we are looking for patients who are receiving care due to an underlying cardiac condition or a major cardiac event. We will be randomly assigning patients to one of four groups and following them for one year. We are interested in how people recover. Do they go to outpatient rehabilitation? How often do they go back to the hospital?
- You would be in the study one year. All study visits take place at 62 Tilley Drive in South Burlington. The outpatient rehab is a clinical program. If you take part in those sessions we will use that clinical information for this study. All other assessments and procedures involved are for research only.
- Everyone who agrees to be part of this study will have three assessments. One happens a few weeks after you consent to be in the study, one 4 months later and the last at 12 months. These assessments take about 2 hours and you earn \$100 each time you complete one.
- At each assessment we will have you do four things:
 - Meet with a doctor. They will review your medical record and make sure you are healthy enough to complete the visit (30 minutes).
 - Complete an "Exercise Tolerance Test." You walk on a treadmill at a slowly increasing speed until you choose to stop (usually in 5-10 minutes). Total time 30 minutes.
 - Breathe into a cardboard tube attached to a small machine. This will measure if you have recently come into contact with carbon monoxide (CO). CO can be bad for heart health. CO can come from cigarette smoke, car exhaust, faulty heaters, and other sources.
 - Complete a series of questionnaires and computerized tasks. We will ask you basic information such as age, gender, and education. Also we will ask about your physical, cognitive, and mental health (including thoughts of suicide). We will also ask your views on exercise, your social support, and time and costs to attend treatment. One computerized task will measure how fast you can react. The other will measure how much you value money now compared to getting money later. Total time one hour.
- You will also be randomly put into one of four groups.
 - All four groups do the three assessments listed above. We expect all groups will benefit as your health will be closely checked on at these assessments.
 - Group 1. Usual care.
 - You have a 1/7 chance of being in this group.
 - You do not get an intervention.
 - Group 2. Case management only.
 - You have a 2/7 chance of being in this group.
 - You are immediately given a case manager.
 - They will be available by phone (9AM-7PM) to help you.

- They will answer questions about symptoms and medications and help make appointments.
- Group 3. Incentives only.
 - You have a 2/7 chance of being in this group.
 - You earn incentives (gift cards) by completing outpatient rehab visits.
 - Completion means finishing your recommended exercises for that day.
 - There is one orientation session and 36 exercise sessions
 - You can earn \$20 for attending an orientation meeting.
 - You can earn \$10 for completing your first, one-on-one exercise visit.
 - After that you can earn money for completing additional sessions. The next session earns you \$12. Each session after that increases by \$2 each time.
 - The maximum is \$40 per session.
 - You would probably earn about \$850 in this group total.
 - You could earn up to \$1220 if you completed all of your exercise visits on schedule.
- Group 4. Case management plus incentives.
 - You have a 2/7 chance of being in this group.
 - You get both of the interventions given to Groups 2 and 3.
- We will also look at your hospital records for the year you are in the study. We will look to see if you went to the hospital and if so, why.
- Any private information collected for this study will not be used or distributed for future research.

What Are The Risks and Discomforts Of The Study?

- Exercise testing is a common procedure but is not risk-free. The risks of this test are roughly 1 death in every 10,000 tests. Risk of an issue requiring hospitalization is less than 1 in 1,000 tests. You will be closely and constantly monitored by a physician and exercise technician. They are highly trained to deal with cardiac problems that might happen during these tests. If a serious event occurs they will provide medical support until emergency medical personnel arrive.
- There is a risk that someone might get access to your confidential information. Professional standards for protecting the confidential information will be used to minimize this risk.
- You may feel uncomfortable answering some of our questions. We always ask questions in a private setting and you can choose not to answer questions.
- If you report suicidal thoughts we will have you talk with a lead study investigator. They will talk with you about your thoughts and connect you with crisis services if necessary.

What Are The Benefits of Participating In The Study?

- There may be no benefits to you from being in this study. However, cardiac participants who get appropriate care tend to be healthier.

What Other Options Are There?

- You may choose not to participate in this study and your care at University of Vermont Medical Center will not be affected.

Are There Any Costs?

- There is no cost to you to participate in this study.

What Is the Compensation?

- Compensation will be given for your time in the study.
- You will earn \$100 for each assessment you complete, up to \$300. You can also be reimbursed for transportation to assessments, up to an additional \$50 per assessment.
- If you are in one of the two incentive groups you can earn up to \$1220 in gift cards.
- You can get your incentives as you earn them.
- If you leave the study you will be given the amount you have earned up to that point.

Can You Withdraw or Be Withdrawn From This Study?

- You may withdraw yourself from this study at any time.
- The researcher may withdraw you from this study at any time.

What About Confidentiality of Your Health Information?

What health information will be used and disclosed for this study?

The health information we plan to collect for this study is listed below.

- Information that identifies you, such as name, address, phone number, age, and sex
- Medical history and examinations
- Reports from cardiac rehabilitation visits
- Information about the cause and costs of hospital visits that occur while you are in the study
- Responses to questionnaires

Who is disclosing your health information for this research study?

- The University of Vermont Medical Center
- Other doctors' offices and hospitals where you may receive medical care while this study is active.

Who will use your health information in this study?

Our research team will use your health information. We may also share it with those who assist with the conduct of the research or oversight of the activities for this study. The representatives from the institutions, organizations, and agencies are listed below.

- The University of Vermont and its Committees on Human Research
- Officials from agencies and organizations that provide accreditation and oversight of research
- The University of Vermont Medical Center
- An independent data and safety monitoring board that oversees this study
- The sponsor of this study, the National Institutes of Health

Your health information is protected by a federal law called the Health Information Portability and Accountability Act (HIPAA). Once your health information is shared outside of the University of Vermont Medical Center, we cannot guarantee that these laws will continue to

apply. As a result, your health information could be further disclosed for other purposes. In the absence of a Certificate of Confidentiality, it is also possible for a court or other government official to order the release of study data. The confidentiality of your health information cannot be guaranteed if you agree it may be used in this study.

How long will your health information be used for research?

Your permission to use your health information will not end until the study is completed. During this study, you will not have access to study data. You may ask for your data once study activities are complete. You have a right to receive a copy of the information in your medical record at any time.

What if you decide not to give permission for research use of your health information?

If you decide not to allow the use and disclosure of your health information, you may not take part in this study. Your decision will have no effect on your current or future medical care.

If you choose to stop taking part in this study in the future, you may cancel permission for the use of your health information. You should let the research team know that you are cancelling your permission. A member of the research team will assist you in making your decision effective. The study will continue to use the health information already collected for the study before you cancelled your permission, and you cannot get back information that was already shared with others.

Who can answer your questions about the use and disclosure of your health information?

If you have questions or concerns about the use and disclosure of your health information, you should ask a member of the study team at (802) 656-9874 or the Privacy Officer at The University of Vermont Medical Center, Inc, at (802) 847-2667.

Safeguarding Your Health Information

A record of your progress will be kept in a confidential form at the cardiac rehabilitation clinic. The security of your record will be maintained by the research team. The results of this study may eventually be published and information may be exchanged between medical investigators, but patient confidentiality will be maintained.

If your record is used or disseminated for government purposes, it will be done under conditions that will protect your privacy to the fullest extent possible consistent with laws relating to public disclosure of information and the law-enforcement responsibilities of the agency.

You will be required to provide your name and address each time you receive a payment. You will also be requested to provide your social security number if the amount of the payment is \$100 or if the total payments from UVM are equal to or greater than \$600. If you are not a US Citizen or Permanent Resident Alien you will be required to complete additional paperwork including your immigration status for payment. This information will be strictly confidential and will be used for tax

withholding and reporting purposes only and will allow the University to determine your US residency for federal income tax purposes.

Clinical Trials Registration

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.

What Happens If You Are Injured?

If you are injured or become ill as a result of being in this research, The UVM Medical Center, the hospital partner of the University of Vermont, will provide reasonable and usual medical care for that injury or illness. There will be no cost to you if the conditions listed below apply to your injury or illness. These conditions are:

1. The investigator determines that your injury or illness results from the research and not from your underlying condition or its usual treatment.
2. You let the investigator know about the injury or illness when you first notice it; and
3. You follow medical advice about proper treatment options for the injury or illness.

If the above conditions are not met, the UVM Medical Center may claim payments for your medical treatment from the study sponsor or your insurance company when these payments are allowed. If we bill your insurance for this care, you will be responsible for any associated co-payments or deductibles.

For an injury or illness that results from being in this study, The University of Vermont Health Network affiliate hospital where you are receiving care will not offer you any other payments, such as lost wages or expenses, except for your medical care. Even though you may receive medical care at no cost to you under certain conditions if you are in this study, The University of Vermont Health Network affiliate hospital and the University of Vermont do not admit to any responsibility for an injury or illness that results from being in the study.

If you agree to take part in this study and you sign this consent form, you are not giving up any of your legal rights.

Contact Information

You may contact Dr. Gaalema the Investigator in charge of this study, at 802-656-9874 for more information about this study. If you have any questions about your rights as a participant in a research project or for more information on how to proceed should you believe that you have been injured as a result of your participation in this study you should contact the Director of the Research Protections Office at the University of Vermont at 802-656-5040.

Statement of Consent

You have been given and have read or have had read to you a summary of this research study. Should you have any further questions about the research, you may contact the person conducting the study at the address and telephone number given below. Your participation is voluntary and you may refuse to participate or withdraw at any time without penalty or prejudice to your present and/or future care.

You agree to participate in this study and you understand that you will receive a signed copy of this form.

Signature of Subject Date

Name of Subject Printed

Signature of Principal Investigator or Designee Date

Name of Principal Investigator or Designee Printed

Name of Principal Investigator: Diann Gaalema
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