Informed Consent

Title of Research Project: Increasing Cardiac Rehabilitation Participation among Medicaid Enrollees

Principal Investigator: Diann E. Gaalema, Ph.D.

Sponsor: National Institutes of Health

You are being invited to take part in this research study because you are eligible to participate in cardiac rehabilitation and are enrolled In Medicaid or a similar state supported insurance program. This study is being conducted by the University of Vermont at the University of Vermont Medical Center.

We encourage you to ask questions and take the opportunity to discuss the project with anybody you think can help you make this decision.

Why is This Research Study Being Done?

Participation in cardiac rehabilitation has been shown to significantly reduce hospital admissions and even the chance of death for people that have stable heart failure or recently experienced a major cardiac event, such as a heart attack, stent procedure, bypass surgery or heart valve replacement. Despite these known benefits of cardiac rehabilitation the majority of people do not attend. Medicaid covers all the medical costs of attending cardiac rehabilitation. However, even with these costs covered attendance at cardiac rehabilitation remains low for people who are enrolled in Medicaid.

The goal of this research is to examine if reducing barriers and providing financial incentives can increase participation in cardiac rehabilitation for people enrolled in Medicaid.

How Many People Will Take Part In The Study?

We expect about 130 patients eligible for cardiac rehabilitation will take part in this study.

What Is Involved In The Study?

Overall, this study will last approximately 5 years. Your participation in the study will last for one year. This study will assess participation rates in cardiac rehabilitation. Study related assessments will be conducted at the beginning of the study, at four months, and at one year later. All study visits will take place at the Cardiac Rehabilitation Facility at 62 Tilley Drive in South Burlington. If you enroll in this study you will be asked to complete the assessments mentioned above even if you decide not to complete the cardiac rehabilitation program.

Study Groups: If you agree to participate in this study you will be assigned by chance ("randomized") to one of two study groups (A or B). You have an equal chance of being in either group. Both groups will undergo the same set of assessments (described below).

Group A (Control Group): If you are assigned to Group A you will receive $100 each for completing your baseline, your four month and your one year follow up assessments (maximum $300). You will otherwise not receive any specific study interventions but you will be invited to participate in cardiac rehabilitation.

Group B (Intervention Group): If you are assigned to Group B you will also receive up to $300 for completing assessments (intake, four months and one year), plus $20 for attending a cardiac rehabilitation orientation meeting and $20 for attending an initial personalized exercise session. In addition you can earn money for completing subsequent cardiac rehabilitation exercise sessions. Attending the first session would earn you $4 and at each session the amount you earn would increase by $2 up to a maximum of $50 per session. We expect participants in this group to earn an average of about $930 although you could earn up to $1488 if you attend all of your exercise and assessment visits on schedule.

Assessments: During each of the three assessments (baseline, four months, one year) you will be asked to complete a stress test and answer a variety of questions (described below).

A) Clinical Review: During the baseline assessment a cardiovascular exam will be performed to determine if you are an appropriate candidate for the exercise portion of the program. At each assessment your medical history will be reviewed. This review will be supplemented by having you fill in questionnaires that describe your "quality of life" and a "life satisfaction questionnaire". This "Clinical Review" session will take approximately 30 minutes and will directly precede your stress test.

B) Symptom Limited Exercise Tolerance Test, "Stress Test": This test will be performed on a treadmill at the Cardiac Rehabilitation Facility. You will be monitored by a highly experienced physician during the entire procedure. You will begin at a very easy pace and the speed or elevation of the treadmill will increase every 2 minutes until you stop exercising. Most people stop this test for fatigue but the physician may stop the test for medical reasons such as chest pain. All patients entering into cardiac rehabilitation perform this test whether or not they are in a research study (Total time: about one hour).

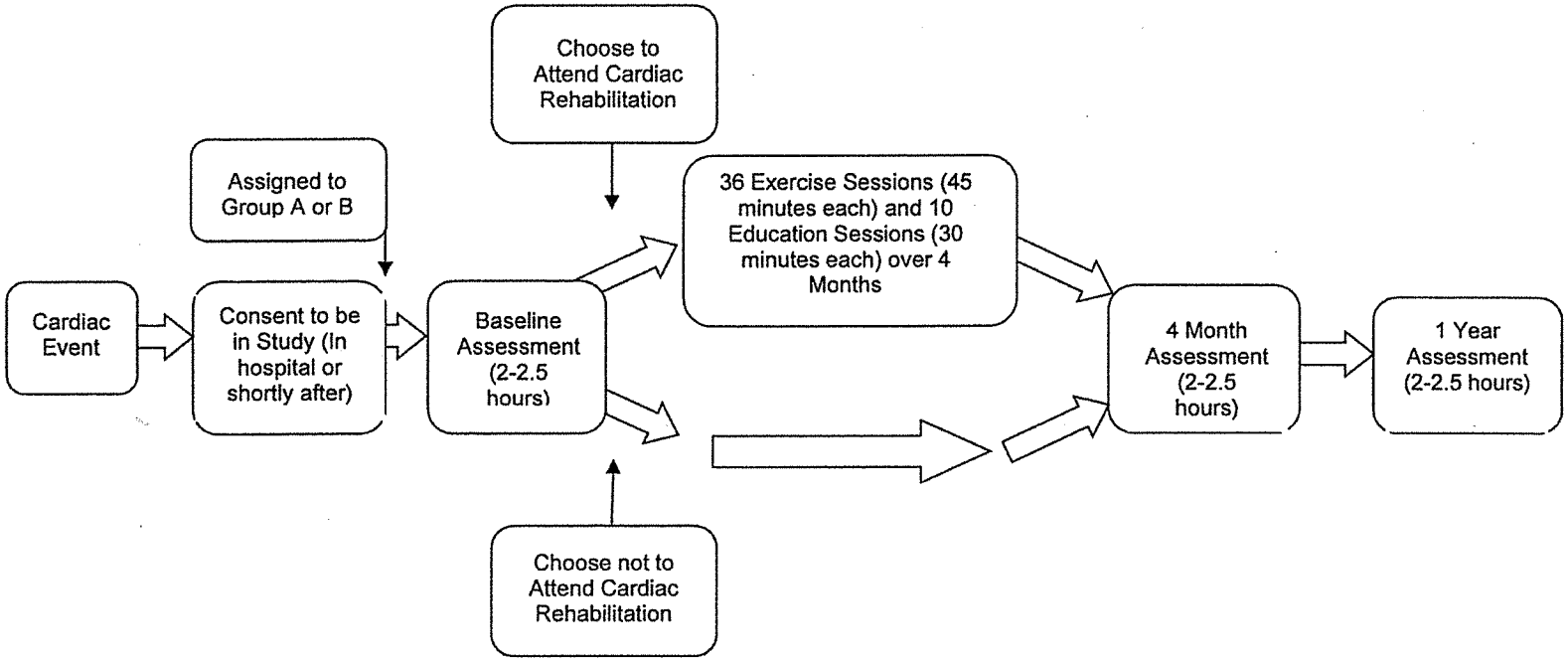
C) Behavioral Assessments. You will be asked to complete a series of questionnaires. Topics covered will include basic information such as age, gender, and education, your physical and mental health, a general estimate of intelligence, your views on exercise, and time and costs involved in attending treatment. One questionnaire will ask about your current mood, including recent thoughts of suicide. Mood is often related to how successful people are at

exercising. Additionally you will be asked to complete two computerized tasks. One task measures decision making by asking you to choose between different amounts of money at different time periods and the other task measures your ability to make quick decisions and keep from responding when given a signal not to (Total time: between 1 and 1.5 hours). You can ask study staff for feedback on how you performed on any of these questionnaires or tasks.

Description of the Exercise Protocol:
- Participants assigned to Groups A & B will be encouraged to complete the exercise sessions provided as part of cardiac rehabilitation. If you are in Group A you will receive regular encouragement from cardiac rehabilitation staff to complete all of the recommended sessions, but you will not receive any financial incentives for doing so. If you are in Group B you will also receive the same staff encouragement plus you will receive incentives for completing these cardiac rehabilitation sessions. Everyone in Groups A & B who attend these sessions will be asked to complete a consent form that is specific to participating in cardiac rehabilitation.
- The exercise program consists of 36 exercise sessions that gradually increase in difficulty guided by an exercise counselor. Exercise sessions will be about 45 minutes in length and will be scheduled 2-3 times a week over a 4 month period. You will be closely supervised by an exercise specialist during these sessions and the intensity of exercise will be tailored to your fitness level. The goal is for each session to eventually include 25 minutes of treadmill walking and 5-10 minutes on a cycle ergometer, arm ergometer, or rower.
- You will also be offered weekly 30 minute educational sessions that will take place on exercise days, including stress management (5 sessions), healthy nutrition (2 sessions), medication use, symptom recognition, and the importance of risk factor control.

Cost Analysis:
As part of this study we will be measuring the costs associated with your participation in cardiac rehabilitation as well as other medical costs incurred during your time in this study. We will collect this information from the University of Vermont Medical Center which will include billing information and direct and indirect costs.

In Summary: if you agree to participate in this study, you will be asked to have an exercise stress test and complete behavioral assessments three times: when you start the study, at four months and at one year. Your time in the study would be one year.


Choose to Attend Cardiac Rehabilitation
Assigned to Group A or B
36 Exercise Sessions (45 minutes each) and 10 Education Sessions (30 minutes each) over 4 Months
Cardiac Event
Consent to be in Study (In hospital or shortly after)
Baseline Assessment (2-2.5 hours)
4 Month Assessment (2-2.5 hours)
1 Year Assessment (2-2.5 hours)
Choose not to Attend Cardiac Rehabilitation

What Are The Risks and Discomforts Of The Study?

-Exercise testing is a common procedure with minimal risks, but the test is monitored by a physician and will be stopped if problems occur. These include fainting, dizziness, chest pain, irregular heartbeats, or a heart attack, although the latter is extremely rare. The risks of this test are roughly 1 death in every 10,000 tests performed and serious adverse effects such as a heart attack or serious irregular heart beat (arrhythmias) requiring hospitalization occur in less than 1 in 1,000 tests. Your blood pressure, heart rate and rhythm and breathing will be closely and constantly monitored by a physician and exercise technician trained in CPR, exercise testing and emergency treatment of cardiac arrhythmias.

- If you were not very active prior to embarking on this study, you may experience some mild soreness early on in your exercise program but this will be minimized by having you begin gradually.
- Regarding our questionnaires, you may feel uncomfortable answering some of the questions. We will work with you to minimize this discomfort and you do not have to answer any question that you do not wish to.
- There is a risk that confidential information might accidentally be disclosed. Professional standards for protecting confidential information (detailed below) will be used to minimize this risk.

How will my Confidentiality be Protected?

- Your confidentially will be respected and protected. All data will be coded by identification number assigned to you, and is known only by the investigators on this project. Your name will not be given out with any results. However, if you express thoughts of suicide we may need to break confidentiality. We will discuss these thoughts with you and depending on how you are feeling may call Crisis Services who are experts in helping people who are having suicidal thoughts.
- A record of your progress will be kept in a confidential form at the Tilley Drive Cardiac Rehabilitation program. The security of your record will be maintained by keeping paper files in a locked file cabinet and by keeping computer files in a password protected file on the University of Vermont Medical Center's computer network. The results of this study will eventually be published and information may be exchanged between medical investigators, but patient confidentiality will be maintained.
- The sponsor as well as the Institutional Review Board and regulatory authorities may be granted direct access to your original medical and research records for verification of clinical trial procedures and/or data. 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.
- Please refer to the separate Authorization Form that explains more specifically how your personal health information will be used.

- Your name, social security number and address will be disclosed one time to either the University of Vermont's Procurement Services Department or the University of Vermont Medical Center s Accounts Payable Department for purposes of reimbursing you for participation in this study. Your information will be coded and this code and the information will be kept under lock and key with only authorized personnel accessing the data. Please note that this compensation earned through the study may be taxable.

What Are The Benefits of Participating In The Study?
There may be no benefit to you for your participation. However, participants who participate in cardiac rehabilitation tend to be healthier and have a higher quality of life than those who do not.

What Other Options Are There?
You may choose not to participate in this study at all and your care at the University of Vermont Medical Center will not be affected. There are no other formal recovery programs for those recovering from heart trauma. However, you can participate in cardiac rehabilitation without being part of this study. Additionally you have the option of recovering on your own at home under the observation of your primary physician.

Are There Any Costs?
The study procedures will be provided at no cost to you.

Can You Withdraw or Be Withdrawn From This Study?
You may withdraw from the study at any time. If you wish to withdraw, please tell the staff right away. If you withdraw, it will not interfere with the future care you may receive at the University of Vermont Medical Center and data collected from you during the course of the study will be destroyed. Participation in this study may also be ended without your consent if there is an event that makes continued participation impossible. For example a physician may determine it is not advisable for you to continue the exercise program.

What Happens If You Are Injured?
University of Vermont Medical Center Policy: If you are injured or become ill as a direct result of participating in this research project, the University of Vermont Medical Center, the hospital affiliated with the University of Vermont, will provide reasonable and customary medical care for that injury or illness at no cost to you providing certain conditions are met. These conditions are:

1) It is the opinion of the investigator and/or sponsoring agency that the injury or illness is a result of the research;
2) For studies which provide treatment of a specific condition or disease, it is the opinion of the investigator and/or sponsoring agency that the injury is not associated with your disease/condition or with the expected complications of the usual therapies for the disease/condition;
3) You have followed all of the directions of the investigator;

4) You have notified the investigator of the injury or illness in a timely manner after onset; and
5) You have followed medical advice regarding the injury or illness.

Where applicable, reimbursement may be sought by the University of Vermont Medical Center directly from the Study Sponsor or your insurance company. The fact that the University of Vermont Medical Center provides free treatment or care to you as a result of a research-related injury or illness as just described is not an admission by the University of Vermont Medical Center or the University of Vermont that it is responsible for such injury or illness.

It is not the policy of the University of Vermont or the University of Vermont Medical Center to provide any further financial compensation in the event of an injury or illness. You should understand, however, that by acknowledging this you are not waiving or releasing any of your legal rights.

Contact Information

Please contact Dr. Diann Gaalema 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 Nancy Stalnaker, 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 project. 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.

This form is valid only if the Committees on Human Research's current stamp of approval is shown below.

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Signature of Subject **Date**

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Name of Subject Printed

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Signature of Principal Investigator or Designee **Date**

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Name of Principal Investigator or Designee Printed

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Committee on Human Research
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