Consent to Participate in a Research Study

Title of Research Study: Development of an Integrated Depression and Behavioral Risk Factor Reduction Intervention for Secondary Prevention Following Acute Coronary Syndrome: **The Healthy Heart Habits Study**

Investigator Team Contact Information:
For questions about research appointments, the research study, research results, or other concerns, call the study team at:

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KEY INFORMATION ABOUT THIS RESEARCH STUDY

The following is a short summary to help you decide whether or not to be a part of this research study. More detailed information is listed later in this form.

What is research?
Doctors and investigators are committed to your care and safety. There are important differences between research and treatment plans:

- The goal of research is to learn new things in order to help groups of people in the future. Investigators learn things by following the same plan with a number of participants, so they do not usually make changes to the plan for individual research participants. You, as an individual, may or may not be helped by volunteering for a research study.
- The goal of clinical care is to help you get better or to improve your quality of life. Doctors can make changes to your clinical care plan as needed.

Research and clinical care are often combined. One purpose of this informed consent document is to provide you clear information about the specific research activities of this study.

What should I know about a research study?
- Someone will explain this research study 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 any questions you may have before you decide.

Why am I being asked to take part in this research study?
We are asking you to take part in this research study because you have had a cardiac event (heart attack or unstable angina) in the past 2-12 months, you have depressed mood, and you are willing to work on changing at least one cardiac health behavior.

Why is this research being done?
1. We are doing this study to develop and pilot test a program to support patients who have had a cardiac event with depression to improve their mood and make behavior changes to improve their physical health.
2. We are doing this study because people who have had a cardiac event with depression are known to have poor health outcomes compared to other cardiac event patients.
3. The program we develop through this research may help to treat patients who experience cardiac events in the future.

Where will this study be done?
This research study will be done at Hennepin Healthcare and its research arm Hennepin Healthcare Research Institute. Your in-person study contacts will occur at the Hennepin Healthcare or in your home. Most coaching sessions will be over the phone. Assessments may be conducted over the phone.

How long will the research last?
We expect that you will be in this research study for approximately twelve weeks.

What will I need to do to participate?
You will be asked to participate in two assessment visits and up to ten coaching sessions in person and by phone. The coaching sessions will focus on goal-setting and things you like to do. We will also ask you questions using surveys and interviews about if and how the program may be working for you. Participants who are working to quit smoking may be asked to provide a breath sample. More detailed information about the study procedures can be found under: 4. PROCEDURES

Is there any way that being in this study could be bad for me?
This is considered a low risk research study. Please see details related to risks in section 5 below. More detailed information about the risks of this study can be found under: 5. RISKS, DISCOMFORTS, AND INCONVENIENCES.

Will being in this study help me in any way?
We cannot promise any benefits to you or others from your taking part in this research. You will have access to no cost coaching focused on improving mood and health. You will also be offered a variety of tools to help you improve your health at no cost. Possible benefits include improvements in health behaviors you choose to work on. These may include taking your

medications as prescribed by your health care team, choosing healthy foods, getting more physical activity, and quitting tobacco use. You may also experience improved mood as your coach will be applying an established method for improving mood.

What happens if I do not want to participate in this research?
You do not have to participate in this research. If you decide not to be in this study, other common medicine / treatment can be used to treat your heart disease and/or depression. This can be obtained through your regular doctors.

DETAILED INFORMATION ABOUT THIS RESEARCH STUDY

The following is more detailed information about this study in addition to the information listed above.

1. SITE OF THE RESEARCH STUDY
Where will this study be done?

This research study will be done at Hennepin Healthcare and its research arm Hennepin Healthcare Research Institute. Your in-person study contacts will occur at Hennepin Healthcare Research or in your home. Most coaching sessions will be over the phone. Assessments may be conducted over the phone.

2. PURPOSE OF THIS RESEARCH STUDY
Why is this research study being done?

This research study is being done to help us pilot test a program to help cardiac event patients with poor mood to improve their mood and make changes to improve their physical health. This group is known to have poor health outcomes compared to other patients who have experienced a cardiac event. We hope to develop a program to better support this group of people. This study will recruit 20 people over one year to try out our planned program and improve it. After that improvement process, we hope to test how it works with a larger number of people sometime in the future.

3. ELIGIBILITY
Who is being asked to be part of this research study?

To be a part of this study you need to be 18-75 years old, live within 1.5 hours of Hennepin Healthcare, be fluent in English, have a had a recent diagnosis of acute coronary syndrome (including unstable angina, ST and non-ST elevation myocardial infarction, these terms are commonly referred to as 'heart attack' or 'unstable angina'), have significant depressed mood, and have the need and desire to work on improving one of four health behaviors targeted in this study. We also exclude people who would be unlikely to be able to engage in treatment or who are currently attending other treatment that duplicates the components of this program

4. PROCEDURES

What procedures will be done for this research study?

You will participate in a baseline assessment visit at the start of your participation. This will include medical history interview and completion of study surveys. This visit will occur at Hennepin Healthcare or in your home if you are unable to travel. This assessment will take about 45 minutes.

You will participate in up to ten coaching sessions over a 12 week period. The first will occur in person immediately after your baseline assessment. The second will occur a week later and will also be conducted in person. These first two sessions will take about 50 minutes to complete. The remaining sessions (up to 8) are done by phone and should take about 20-30 minutes. The coaching sessions will focus on improving your mood and chosen health behavior. These sessions will be audio recorded. Your coach may text or email you between sessions if you provide permission to do so.

After 12 weeks you will complete a post-treatment assessment during which you will answer questions and compete a survey. Immediately following the post-treatment assessment you will be participate in a brief qualitative interview regarding your experiences in the study. This interview will be audio recorded. The assessment and qualitative interview will together take about an hour and can be completed at Hennepin Healthcare, in your home, or by phone.

5. RISKS, DISCOMFORTS, AND INCONVENIENCES

What are the possible risks, side effects, discomforts, or inconveniences of this research study?

a) You may feel uncomfortable answering some assessment questions and talking with your coach as part of this study. You will be asked about some potentially sensitive issues related to your mood, smoking history, diet, exercise, medication adherence, and/or medical history as part of this study.

b) *If you work on smoking as a health behavior goal and quit smoking*, you may feel withdrawal symptoms such as mood swings, anxiety, irritability, decreased concentration, restlessness, excessive hunger, and trouble sleeping. These symptoms are not dangerous and usually only last about one to two weeks after quitting.

c) *If you work on smoking as a health behavior goal you may be offered nicotine replacement (nicotine patch and/or lozenge) to help you quit.* There are some side effects to these products. Side effects of nicotine replacement includes: mouth irritation (nicotine lozenges), skin irritation (nicotine patch), dizziness, rapid heartbeat, or upset stomach. You may have vivid or strange dreams and you could also have an allergic reaction to nicotine replacement. The study team will determine if nicotine replacement is appropriate for you and at what dose. You will be provided with the full medication package insert instructions if you are provided with nicotine replacement.

You cannot use nicotine replacement in this program if you are pregnant, trying to get pregnant, or breastfeeding a child. If you find that you are pregnant, you should stop using nicotine replacement and inform your provider immediately.

d) *If you are working on physical activity as a health behavior goal*, there could be some risks of injury from increased activity. This study focuses on increased steps per day from more walking, thus risk of injury is low. After a cardiac event your doctor may have specific recommendations regarding physical activity for you and we will make recommendations for increased activity within these limitations. The study team will discuss all recommendations to increase physical activity to determine if appropriate for your medical status.

6. REPRODUCTIVE AND PREGNANCY ISSUES
What is important to know about being a part of this study and pregnancy?

There are no known reproductive or pregnancy issues with being in the study. See risks to using nicotine replacement during pregnancy in section 5c above.

7. HEALTH BENEFITS
What are the possible health benefits to you or to others from your being part of this research study?

We cannot promise any benefits to you or others from your taking part in this research. You will have access to no cost coaching focused on improving mood and health. You will also be offered a variety of tools to help you improve your health at no cost. Possible benefits include improvements in health behaviors you choose to work on. These may include taking your medications as prescribed by your health care team, choosing healthy foods, getting more physical activity, and quitting tobacco use. You may also experience improved mood as your coach will be applying an established method for improving mood.

8. ALTERNATIVE TREATMENTS
What treatments or procedures are there for you if you decide not to be part of this research study?

You do not have to participate in this research. If you decide not to be in this study, other common medicine / treatment can be used to treat your heart disease and/or depression. This can be obtained through your regular doctors.

9. CONFIDENTIALITY
Who will know that you are part of this research study?

Any information that could be used to identify you will be treated in strict confidence to the extent allowed by law. Nevertheless, some uses and disclosures of your information are necessary to conduct the study. If you agree to be part of this study, you will also be allowing

the uses and disclosures of your private health information as needed for the purposes of this study as described in this consent.

"Private health information" means information that identifies you and is collected:

- during this study;
- from your past and current medical records maintained by your regular health care providers (including, if applicable, Hennepin Healthcare), to the extent the information is relevant to this study or to your eligibility for this study; or
- from any payment records relating to items or services furnished to you during this study.

By signing this consent, you are agreeing that your private health information may be disclosed to and used by:

- the psychology and medical doctors and other health care providers involved in this study;
- their staff;
- the research center (Hennepin Healthcare Research Institute);
- members of the Hennepin Healthcare Human Subjects Research Committee/Institutional Review Board;
- the sponsor of this study and its agents; and
- representatives from the United States Government and/or Food and Drug Administration (FDA).
- The findings of this study may be used for scientific meetings, written reports, and publications, but no information that could be used to identify you will be disclosed for these purposes.
- Private health identifiers might be removed and the de-identified information or biospecimens used for future research or distributed to another investigator without additional informed consent from you.

  Once your private health information has been disclosed to a third party, federal privacy laws may no longer protect it from re-disclosure. However, anyone obtaining access to your private health information under this consent must agree to protect your information as required by this consent.

This consent to use your private health information as described above does not expire. However, if you later change your mind, you can revoke this consent by writing to Dr. Andrew Busch saying that you no longer wish to allow your private health information to be used for this study. If you revoke your consent, you may no longer be able to participate in the study. Moreover, we cannot undo uses or disclosures of your private health information that have already taken place in reliance on your prior consent.

10. COSTS ASSOCIATED WITH THE RESEARCH STUDY

Will your insurance provider or you be billed for any costs of any treatments, medicines, or procedures done as part of this research study?

You will not be billed for any of the medicines/procedures/treatments connected with this study.

11. COMPENSATION AND MEDICAL TREATMENT FOR ANY STUDY-RELATED INJURY

If you are injured from being part of this research study, what should you do and who will pay for it?

It is felt that this research involves no more than minimal risk. In the unlikely event that you experience a study-related injury requiring treatment, all expenses for your treatment would need to be paid by you or your insurance provider.

12. COMPENSATION FOR PARTICIPATION

Will you be paid for being part of this research study?

You will receive $30 for each of the assessment visits ($30 at baseline assessment and $30 at post-treatment assessment). Additionally, you will receive $20 for participating in a qualitative interview following the post-treatment assessment. The <u>total</u> amount you will be paid for completing the whole study is $80. You will also be provided transportation or reimbursed for transportation costs.

13. NEW FINDINGS

Will you be told of any new information or new risks that may be found while this study is going on?

In every research study, there may be risks we do not expect. You will be told about any important new information that may cause you to change your mind about being part of this study.

14. FREEDOM TO PARTICIPATE AND WITHDRAW

Is being part of this research study voluntary? Can you decide to stop being in this research study at any time?

Being part of this research study is your choice. You do not have to be part of this study. You can agree to be in the study now and change your mind later. Your decision to stop being in the study will not affect your regular care. Your doctor's attitude toward you will not change.

If you decide to stop being in the study, the study doctor may discuss with you a more limited participation in this study such as still collecting information from your medical records after you stop your direct participation. If you agree at that time to such continued limited participation, that agreement will be noted in your records.

15. PROCEDURES FOR ORDERLY WITHDRAWAL OR REMOVAL FROM THE STUDY

What would happen if you decide to stop being part of this study or if you are removed from this study?

You may be taken out of the study by the researchers if:

- staying in the study would be harmful to you or others in any way;
- you decide to stop being part of the study; or
- the study is canceled.

If you decide to stop being part of the study, or if you are removed from the study for any reason, you will be asked to have a final visit with the study doctor. At this visit, the study doctor will ask you to fill out the final study survey and ask questions about your experience. We may invite you to participate in a modified protocol based on your specific needs.

16. CONTACT INFORMATION FOR QUESTIONS

Who should you contact if you have questions?

If you have any questions before signing this consent, please be sure to ask them now. During the study, if you have any questions, concerns, or complaints for the study doctor, please call Dr. Andrew Busch at (612) 873-4051.

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.

VOLUNTARY CONSENT FORM

- I have either read the attached consent or it has been read to me.
- By signing this form, I do not give up any of my legal rights or release anyone involved in this research study from their responsibility for negligence.
- By signing this form, I agree to be part of this research study and consent to the use of my private health information as described in Section 9 ("Confidentiality") of the attached consent.
- A signed copy of this consent will be given to me.

_____

Subject's Printed Name (or Legally Authorized Representative's)

_____

Subject's Signature (or Legally Authorized Representative's)

_____

Date

I certify that a copy of this form has been provided to the above-named subject.

_____ _____

Explained by Printed Name, Title Signature

_____

Date