Partners HealthCare System
Research Consent Form

Subject Identification

General Consent Form Template
Version Date: January 2019

Protocol Title: Mindfulness-Based Cognitive Therapy Delivered via Group Videoconferencing for Acute Coronary Syndrome Patients with Deprssive Symptoms: An Open Pilot Trial

Principal Investigator: Christina Luberto, PhD

Site Principal Investigator:

Description of Subject Population: Acute Coronary Syndrome (ACS) patients with depressive symptoms

About this consent form

Please read this form carefully. It tells you important information about a research study. A member of our research team will also talk to you about taking part in this research study. People who agree to take part in research studies are called "subjects." This term will be used throughout this consent form.

Partners HealthCare System is made up of Partners hospitals, health care providers, and researchers. In the rest of this consent form, we refer to the Partners system simply as "Partners."

If you decide to take part in this research study, you must sign this form to show that you want to take part. We will give you a signed copy of this form to keep.

Key Information

Taking part in this research study is up to you. You can decide not to take part. If you decide to take part now, you can change your mind and drop out later. Your decision won't change the medical care you get within Partners now or in the future.

The following key information is to help you decide whether or not to take part in this research study. We have included more details about the research in the Detailed Information section that follows the key information.

Why is this research study being done?

This is a pilot study. Pilot studies are done on a small group of subjects to learn if a larger study would be useful. Specifically, this research is being done to determine if a virtually-delivered group mindfulness program can be used to help patients after an acute cardiac event. Researchers are trying to determine if the intervention and its' research components are acceptable and feasible. Results of this research study will inform changes to the intervention and research procedures for a future research study.

How long will you take part in this research study?

If you decide to join, it will take you about 6 months to complete this research study.

What will happen if you take part in this research study?

If you decide to join this research study, you will be asked to participate in an 8-week mindfulness program using videoconferencing. There will be one session per week, for eight weeks, and each session lasts approximately 1.5 hours. You will be asked to complete short surveys after each session and practice what you learned during each session between sessions. You will also be asked to complete a series of questionnaires and submit blood samples one week before and after the intervention and 3 months after the intervention. Once the intervention is over, we may ask you to participate in a 30-60-minute exit interview about your experiences in the intervention. More information about your participation in this study can be found in the "Who will take part in this research?" and "What will happen in this research study? sections of this form.

Why might you choose to take part in this study?

We cannot promise any benefits to you from taking part in this research study. However, possible benefits may include sharing and receiving support from other patients and learning ways to improve your coping skills and well-being. Others who have experienced an acute cardiac event may benefit in the future from what we learn in this study.

Why might you choose NOT to take part in this study?

Taking part in this research study has some risks and requirements that you should consider carefully.

Important risks and possible discomforts to know about include mild discomfort from completing study questionnaires and participating in intervention sessions. You may also experience mild discomfort when providing a blood sample.

As with all studies there is a small risk of a breach in confidentially. We will take all available precautions to maintain confidentiality and minimize this risk.

A detailed description of side effects, risks, and possible discomforts can be found later in this consent form in the section called "What are the risks and possible discomforts from being in this research study?"

Other things to consider are the time commitment required to complete the invention sessions, questionnaires, dried blood spot sample collection and an exit interview.

What other treatments or procedures are available for your condition?

The program in this research study aims to improve mood, quality of life, and coping skills. Other treatments available to improve mood and quality of life include psychotherapy, cognitive-behavioral therapy, and psychiatric medications.

If you have questions or concerns about this research study, whom can you call?

You can call us with your questions or concerns. Our telephone numbers are listed below. Ask questions as often as you want.

Christina Luberto, PhD, is the person in charge of this research study. You can call her at 617-643-**9453, Monday-Friday, 9:00am-5:00pm.** You can also call **Sydney Crute, the RA for the study at (617)724-5657, Monday-Friday, 9:00am-5:00pm** with questions about this research study.

If you have questions about the scheduling of appointments or study visits, call **Sydney Crute, the RA for the study at (617)724-5657.**

If you want to speak with someone **not** directly involved in this research study, please contact the Partners Human Research Committee office. You can call them at 857-282-1900.

You can talk to them about:

- Your rights as a research subject
- Your concerns about the research
- A complaint about the research
- Any pressure to take part in, or to continue in the research study

Detailed Information

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.

Why is this research study being done?

We are doing this research to evaluate the acceptability and feasibility of a virtually-delivered group mindfulness program for adults who have experienced acute coronary syndrome (ACS), which refers to an acute cardiac event such as a heart attack or unstable angina.

The mindfulness program is a manualized, group intervention with 8 weekly 1.5-hour sessions and 30 minutes of daily home practice. It is designed to teach mindfulness skills to improve mood, coping, and quality of life. The program will also include education about cardiac health. The intervention will be conducted via a secure videoconferencing system (meaning virtually, face to face), with a group of no more than 10 participants. This study will examine if MBCT adapted for ACS patients and delivered via videoconferencing will be feasible and acceptable, and if it may be useful in helping ACS patients who have depressive symptoms.

In total, we will run approximately 2 groups in this study in its entirety.

Who will take part in this research?

We are asking you to take part in this research study because you have experienced an ACS at some point in your life and reported some depressive symptoms. About 20 people will take part in this research study, which is being conducted at Massachusetts General Hospital. The National Institutes of Health/National Center for Complementary and Integrative Health is paying for this research.

What will happen in this research study?

If you decide to take part in this research study, you will be asked to participate in a mindfulness intervention; complete survey questionnaires about your mood and health before and after the program, and 3 months after the program; complete brief surveys about the program after each session; self-collect dried blood spot samples to measure inflammation; and you may be asked to participate in an individual exit interview after the intervention is over. It will take you about 6 months to complete this research study. As part of the study, you will be assigned your own

study identification number. This code is how you will be identified by study staff on study-related documents and samples to help protect your privacy.

Before the intervention starts you will be asked to complete surveys assessing your mood and health and asked to send us a dried blood spot sample to assess biomarkers of inflammation, which are CRP, IL-6, and TNF-a. Details about these methods are described below.

During the intervention you will be asked to participate in a group mindfulness training program virtually via videoconferencing. There will be 8 weekly 1.5-2 hour sessions and 30 minutes of home practice per day. You will also be asked to complete brief surveys on your thoughts about each session after that session is over. Further details are described below.

Following your completion of the intervention you will be asked to complete the same surveys about your mood and health again, provide another dried blood spot sample, and may be asked to participate in an individual exit interview. Further details are below.

At 3 months following your completion of the intervention you will be asked to complete the same surveys about your mood and health again and provide another dried blood spot sample.

Study intervention: The study intervention is a group mindfulness training program that teaches ways to cope with stressors to improve mood and quality of life. The program will consist of eight virtual sessions once a week over the course of 8 weeks (1.5-2 hours each). The intervention will be conducted by an experienced instructor who has utilized this program before and is comfortable with content. You will be asked to spend at least 30 minutes each day practicing the techniques taught in each session. We will send you audio recordings via a secure email link or Dropbox, to help with your home practice. You will be asked submit a record of your mindfulness practice before the next session. Throughout the intervention sessions, the instructor will address any barriers or problems you may be having with daily practice and help to problem solve them with you. During each session, we will ask all participants to agree to keep information discussed during the sessions private and not share others' personal information outside of the group. The study staff cannot guarantee that other members will follow this rule. This intervention is being delivered as a psychoeducational program and not as a clinical group. We will also extract data from your electronic health record to assess your medical and demographic characteristics (e.g. medical diagnoses, medications, cardiac rehab attendance).

Videoconferencing delivery: All sessions will take place virtually using a secure, HIPAA-compliant videoconferencing platform called Zoom. The platform will be set up so that when you are looking at the screen during each session, you will see other members of the group and the provider(s) and they will see you as well. A member of the study team will work with you to get you trained and set up in using the videoconferencing platform and will be available for

assistance throughout the study. The videoconferencing delivery allows you to participate from your own home. We ask that you use headphones during the sessions to maintain the group's privacy, and to participate from a quiet and private place.

All sessions will be audio-visually recorded to help inform future research. Given that audio-video files contain personally-identifying information, they will be labeled with your study ID number and not with any personally-identifying information. All audio-video files will be stored on a password-protected drive on a secure Partners' network immediately following each intervention session and will be destroyed 7 years following the completion of the study. A file linking your name to your study ID number will be kept separately in a password-protected file on a secure Partner's network.

Survey questionnaires: You will be asked to complete surveys before and after the intervention, at 3 months after the intervention, and each of the intervention sessions. All study surveys will be labeled with a study ID number, not with any personally identifying information. We will store the surveys in our access-restricted computer network or locked storage cabinets and only study staff will be able to access them. Surveys completed through email will be recorded on REDCap, a secure data collection platform.

Dried blood spot samples: We will ask you to provide dried blood-spot samples one week before and after the intervention, and 3-months following the intervention, which you will collect yourself at home (3 blood samples total). To collect a dried blood spot sample, research staff will mail you a dried blood spot collection kit, containing the necessary materials needed to self-collect a dried blood spot sample. You will also receive a video link via email and/or written instructions explaining how to do the dried blood-spot procedure. One week before the start of the intervention, a trained member of the research team will address any question you may have and will guide you in collecting a dried blood-spot sample via a videoconference call or phone call. The research team will be available for any other questions you may have along the way.

To collect the dried blood spot sample we will ask you to prick your finger with a lancet and produce 5-10 drops of blood onto a piece of filter paper. You will then allow the blood to dry overnight, document the date the sample was taken on the filter paper, and mail the sample to study staff the next morning. The study staff will include your study ID number on the filter paper. You should not write your name on the paper. This will keep your blood sample confidential. If study staff receive your sample later than 2 weeks following the date indicated on the filter paper, we will ask you to take and send a new sample. We may also ask you to submit another sample if the quality of the first sample is not appropriate for analysis. It is possible that your sample could get lost in the mail. Study staff will minimize this risk by communicating with you about when samples are sent and received, and by only labeling your sample with your study ID number to maintain confidentiality in the event the sample is lost in the mail.

After study staff receives your sample, it will be mailed to the Laboratory for Human Biology Research at Northwestern University for storage and/or processing. It may also be stored in the MGH Clinical Research Center Lab.

Collecting a dried blood spot sample may cause mild, temporary pain. This pain may be relieved by placing an icepack on the site of dried-blood spot collection. Your study status will not change if, at any point during the study, you are unable or unwilling to provide a dried blood spot sample.

Why dried blood spot sample collection? A dried blood spot sample is a valid way to measure biomarkers of inflammation that are related to cardiac health and depressive symptoms. We are only exploring are the CRP, IL-6 and TNF- α biomarkers. The dried blood samples will allow us to explore possible changes in inflammatory biomarkers throughout the intervention, which could help us develop better treatment programs to improve cardiac health and mood in the future. The dried blood spot method allows you to collect the samples yourself at home without having to come to the hospital. The dried blood spot samples will not be used to explore any other biological information, such as genetic biomarkers, other than the inflammatory markers specified above. The samples will be destroyed after they are processed for the study.

Exit interviews: After the intervention program is over, you may be asked to participate in a 30-60 minute exit interview either by phone or by video conference with study staff. These interviews will ask about your thoughts and experiences with the MBCT program and research procedures. The interviews will be audio-or video recorded and stored securely in a password-protected computer on a secure Partner's drive, and labeled with your study ID number and not with any personally-identifying information.

Communicating with study staff: Study staff will attempt to contact you about session scheduling and survey completion and blood spot reminders through phone calls and email. Following the completion of this consent form we will review your preferred contact methods. Please note that the Partners standard is to send email securely. This requires you to initially set up and activate an account with a password. You can then use the password to access secure emails sent to you from Partners HealthCare. If you prefer, we can send you "unencrypted" email that is not secure and could result in the unauthorized use or disclosure of your information. If you want to receive communications by unencrypted email despite these risks, Partners HealthCare will not be held responsible. Your preference to receive unencrypted email will apply to emails sent from this research group/study only.

Partners Alert System: Partners has an electronic system that lets your study doctors know if you are admitted to a Partners Hospital, or if you visit a Partners Hospital Emergency Department. We want to make sure the study doctors know about any possible problems or side effects you experience while you are taking part in the study. A notation that you are taking part

in this research study may be made in your electronic medical record. Information from the research that relates to your general medical care may be included in the record. Please ask your study doctor if you have any questions about what information will be included in your electronic medical record.

How may we use and share your samples and health information for other research?

The samples and information we collect in this study may help advance other research. If you join this study, we may remove all information that identifies you (for example, your name, medical record number, and date of birth) and use these de-identified samples and data in other research. It won't be possible to link the information or samples back to you. Information and/or samples may be shared with investigators at our hospitals, at other academic institutions or at for-profit, commercial entities. You will not be asked to provide additional informed consent for these uses.

Do you agree to let us store and use your samples and health information for other research related to cardiac health and mood? You may still participate in this study either way.

YES NO Initial _____

The researchers may conduct other studies on cardiac health and mood in the future. If you would like, the researchers could include your name on a list to contact about future studies.

Do you agree to let us store your name and contact information to inform you about other studies you may be eligible for in the future?

YES NO Initial _____

Will you get the results of this research study?

You and/or your doctor should not expect to get information about the results of the research study or the results of your individual participation in the research study. We will study samples and information from many people. It could take many years before anyone knows whether the results have any meaning. There is a small chance that we could find out something from the

study that might be important to your health. If this happens, we may contact you to find out if you would like to learn more. However, even if we find something important to your health, we cannot guarantee that you will be contacted.

What are the risks and possible discomforts from being in this research study?

You may experience mild distress from completing surveys or participating in the intervention. You may also experience mild discomfort associated with the dried blood spot procedure. As stated above, study staff will work with you to ensure that you are comfortable with providing dried blood spot samples. You may choose not to provide dried blood samples at any point during the study, for any reason, by informing study staff. Opting out of providing dried blood spot samples will not affect your study status. Similarly, you may choose not to complete any of the survey items without penalty.

In the event of a psychological emergency, confidentiality may be suspended if you are at risk or hurting yourself or someone else. Confidentiality may also be suspended in suspected cases of abuse or neglect of a child, elder, or person with a disability.

Through the surveys and intervention sessions, the researchers will monitor your mood symptoms. If the study staff have any concerns about your symptoms, they will discuss these with you. If the researchers require you to exit the study, they will let you know why.

We will require every participant to agree to respect the confidentiality of other group members. We will ask you to wear headphones during the group and not to repeat group discussions to others or outside of the group. However, because this program will be delivered virtually, we cannot guarantee that other group members will not share the content of the groups.

As with any research study, there may be other risks that are currently unknown. It is possible that certain unknown risks could be serious.

What are the possible benefits from being in this research study?

We cannot guarantee that you will receive any benefits from this study. You may receive benefits from being in a group with other ACS patients to share and receive support. You may also benefit from learning mindfulness skills to reduce stress and improve well-being, and from learning information about cardiac health.

By participating in this research study, you may enhance the understanding of mind-body interventions in ACS patients with depressive symptoms. This intervention may have widespread

implications for the types of resources available that may ultimately improve the health and well-being of ACS patients with depressive symptoms.

What other treatments or procedures are available for your condition?

You may be able to access the following treatments to improve mood, coping, and quality of life outside of this study:

a. Psychotherapy
b. Cognitive-behavioral therapy
c. Psychiatric medications.

Can you still get medical care within Partners if you don't take part in this research study, or if you stop taking part?

Yes. Your decision won't change the medical care you get within Partners now or in the future. There will be no penalty, and you won't lose any benefits you receive now or have a right to receive.

We will tell you if we learn new information that could make you change your mind about taking part in this research study.

What should you do if you want to stop taking part in the study?

If you take part in this research study, and want to drop out, you should tell us. We will make sure that you stop the study safely. We will also talk to you about follow-up care, if needed.

Also, it is possible that we will have to ask you to drop out of the study before you finish it. If this happens, we will tell you why. We will also help arrange other care for you, if needed.

Will you be paid to take part in this research study?

Yes. You will receive $10 for the surveys completed one week before and after and 3 months after the intervention (for a total of $30); $5 for completing each of the 8 post-session surveys (for a total of $40); $15 for completing an individual exit interview; and $20 for each dried blood (for a total of $60). Therefore, the maximum amount you may receive for completing all parts of the study is $145.

We will be using an approved, outside vendor (Forte Research) to make these payments to you via a reloadable credit card-based system, called Forte Payments. This secure system is similar to a gift card or credit card.

You will be given a Forte Payments Visa card when you enroll in the study. Once the card is activated, the study team will add a payment after you complete each interview/survey. The payment should be available to you within a day. You may use the card anywhere Visa cards are accepted, such as at a grocery store.

We will need to collect your Social Security number to make these payments, and it will be shared securely with Forte, the company that runs the card-based system. Payments are considered taxable income. If you receive more than $600 a year from Partners HealthCare, Partners will issue a 1099 form to you and to the Internal Revenue Service for income reporting purposes. You may choose not to give us your social security number. If so, we cannot pay you for participating in the study.

Prior to completion of a survey you will be asked to sign an agreement form, acknowledging your understanding of the Forte payment system. We will mail this form to you and ask that you send it back. When mailing the agreement form is not feasible, we will ask you to complete the form electronically via REDCap with study staff.

What will you have to pay for if you take part in this research study?

There are no costs to either you or your insurance company for participating in this study.

What happens if you are injured as a result of taking part in this research study?

We will offer you the care needed to treat any injury that directly results from taking part in this research study. We reserve the right to bill your insurance company or other third parties, if appropriate, for the care you get for the injury. We will try to have these costs paid for, but you may be responsible for some of them. For example, if the care is billed to your insurer, you will be responsible for payment of any deductibles and co-payments required by your insurer.

Injuries sometimes happen in research even when no one is at fault. There are no plans to pay you or give you other compensation for an injury, should one occur. However, you are not giving up any of your legal rights by signing this form.

If you think you have been injured or have experienced a medical problem as a result of taking part in this research study, tell the person in charge of this study as soon as possible. The researcher's name and phone number are listed in the beginning of this consent form.

If you take part in this research study, how will we protect your privacy?

Federal law requires Partners to protect the privacy of health information and related information that identifies you. We refer to this information as "identifiable information."

In this study, we may collect identifiable information about you from:

- Past, present, and future medical records
- Research procedures, including research office visits, tests, interviews, and questionnaires

Who may see, use, and share your identifiable information and why they may need to do so:

- Partners researchers and staff involved in this study
- The sponsor(s) of the study, and people or groups it hires to help perform this research or to audit the research
- Other researchers and medical centers that are part of this study
- The Partners ethics board or an ethics board outside Partners that oversees the research
- A group that oversees the data (study information) and safety of this study
- Non-research staff within Partners who need identifiable information to do their jobs, such as for treatment, payment (billing), or hospital operations (such as assessing the quality of care or research)
- People or groups that we hire to do certain work for us, such as data storage companies, accreditors, insurers, and lawyers
- Federal agencies (such as the U.S. Department of Health and Human Services (DHHS) and agencies within DHHS like the Food and Drug Administration, the National Institutes of Health, and the Office for Human Research Protections), state agencies, and foreign government bodies that oversee, evaluate, and audit research, which may include inspection of your records

- Public health and safety authorities, if we learn information that could mean harm to you or others (such as to make required reports about communicable diseases or about child or elder abuse)
- Other:

Some people or groups who get your identifiable information might not have to follow the same privacy rules that we follow and might use or share your identifiable information without your permission in ways that are not described in this form. For example, we understand that the sponsor of this study may use your identifiable information to perform additional research on various products or conditions, to obtain regulatory approval of its products, to propose new products, and to oversee and improve its products' performance. We share your identifiable information only when we must, and we ask anyone who receives it from us to take measures to protect your privacy. The sponsor has agreed that it will not contact you without your permission and will not use or share your identifiable information for any mailing or marketing list. However, once your identifiable information is shared outside Partners, we cannot control all the ways that others use or share it and cannot promise that it will remain private.

Because research is an ongoing process, we cannot give you an exact date when we will either destroy or stop using or sharing your identifiable information. Your permission to use and share your identifiable information does not expire.

The results of this research study may be published in a medical book or journal, or used to teach others. However, your name or other identifiable information **will not** be used for these purposes without your specific permission.

Your Privacy Rights

You have the right **not** to sign this form that allows us to use and share your identifiable information for research; however, if you don't sign it, you can't take part in this research study.

You have the right to withdraw your permission for us to use or share your identifiable information for this research study. If you want to withdraw your permission, you must notify the person in charge of this research study in writing. Once permission is withdrawn, you cannot continue to take part in the study.

If you withdraw your permission, we will not be able to take back information that has already been used or shared with others, and such information may continue to be used for certain purposes, such as to comply with the law or maintain the reliability of the study.

You have the right to see and get a copy of your identifiable information that is used or shared for treatment or for payment. To ask for this information, please contact the person in charge of this research study. You may only get such information after the research is finished.

Informed Consent and Authorization

Statement of Person Giving Informed Consent and Authorization

- I have read this consent form.
- This research study has been explained to me, including risks and possible benefits (if any), other possible treatments or procedures, and other important things about the study.
- I have had the opportunity to ask questions.
- I understand the information given to me.

Signature of Subject:

I give my consent to take part in this research study and agree to allow my health information to be used and shared as described above.

_____	_____	_____
Subject	Date	Time (optional)

Signature of Study Doctor or Person Obtaining Consent:

Statement of Study Doctor or Person Obtaining Consent

- I have explained the research to the study subject.
- I have answered all questions about this research study to the best of my ability.

_____	_____	_____
Study Doctor or Person Obtaining Consent	Date	Time (optional)

Consent Form Version: 8/27/2020, Version 3