Study Name:	Mind Your Heart Study
NCT number:	NCT03571581
Grant Title:	Mindfulness Training to Promote Medication Adherence in Patients with Chronic Heart Failure
Grant #:	R21HL140492
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Principal Investigator:	Elena Salmoirago-Blotcher, MD, PhD

Lifespan Affiliate Site where research will be conducted

☐ Rhode Island Hospital	☒ The Miriam Hospital
☐ Bradley Hospital	☐ Newport Hospital
	☐ Gateway Healthcare

Agreement to Participate in a Research Study And Authorization for Use and Disclosure of Information

_____ _____

Committee # Name of Study Volunteer

Exploring the role of Mindfulness Training in the promotion of medication adherence in heart failure outpatients

You are being asked to take part in a research study. All research studies at Lifespan hospitals follow the rules of the state of Rhode Island, the United States government and Lifespan. Before you decide whether to be in the study, you and the researcher will engage in the "informed consent" process. During this process, the researcher will explain the purpose of the study, how it will be carried out, and what you will be expected to do if you participate. The researcher will also explain the possible risks and benefits of being in the study and will provide other information. You should feel free to ask any questions you might have. The purpose of these discussions is for you to decide whether participating in the study is the best decision for you.

If you decide to be in the study, you will be asked to sign and date this form in front of the person who explained the study to you. This form summarizes the information you discussed. You will be given a copy of this form to keep.

1. Nature and Purpose of the Study. You are being asked to take part in a research project because you are 18 years old or older and have been diagnosed with heart failure. This is a preliminary experimental study designed to explore whether mindfulness training can improve the ability to take medications regularly. Mindfulness training involves learning to focus the attention and become aware of body sensations, emotions, and thoughts as well as of events happening in the environment surrounding you at each given moment.

We expect to enroll 50 patients into this study. Your participation in this research study, should you enroll, will last 6 months.

The study is sponsored by the National Heart, Lung, and Blood Institute.

2. Explanation of Procedures. If you take part in this study, you will:

a) Attend one screening/baseline visit. This visit will take place at the **Coro Center, Centers for Behavioral and Preventive Medicine, 1 Hoppin Street, 3rd Floor, Providence, RI 02903.** This first visit will take approximately 1 hour and 30 minutes to be completed.
   - During the visit, we will confirm that you are eligible to participate in the study. If you are not eligible, you will not be enrolled in the study.

- Once enrolled, we will ask you to complete a series of study surveys including tests of memory and thinking ability, we will measure your body weight and blood pressure, and conduct a "walk test".
- The walk test measures your ability to exercise. You will walk back and forth in the hallway at the CORO center for 6 minutes at a normal pace. You will be permitted to slow down, to stop, and to rest as necessary. The research assistant will give you a demonstration before you start. There are no known side effects associated with this test.
- At this visit, the research staff will give you a special pill bottle that helps us track if you are taking your medications regularly. The research assistant will teach you how to use the pill bottle.

b) During the following weeks, you will begin the mindfulness training. An especially trained mindfulness instructor will supervise you during the mindfulness sessions. S/he will first contact you over the phone to introduce herself/himself, to schedule the first session, and to answer questions you may have. You will then receive one session of mindfulness training each week for a total of 8 weeks. All sessions will be phone delivered and will include a series of brief exercises in which you will learn to focus your attention on different objects (e.g., sensations in the body, breath, and sounds). You will be able to practice at your own pace and to stop whenever you need to.

- You will be encouraged to participate in as many sessions as possible.
- During mindfulness classes, the instructor will obtain a digital recording of his/her own voice during to monitor the accuracy of the sessions. These recordings will be used for research purposes only and will be destroyed once the study is over.
- In addition to attending classes, you will practice mindfulness exercises at home at least three times a week with the aid of a CD or MP3 containing exercises sequences similar to those you learned in class. We will ask you to keep track of the number of minutes you practice your exercises in a diary that will be given to you.

c) In addition, we will ask you to do the following:

- Attend 2 follow-up visits approximately 3 and 6 months since you enrolled in the study. At each visit, you will complete study surveys, complete cognitive assessments using a laptop computer, we will measure your blood pressure and body weight, and you will complete a walking test. We anticipate that each visit will last about one hour.
- All visits will be conducted at the Centers for Behavioral and Preventive Medicine situated at the Coro Center (1 Hoppin Street, 3rd Floor, Providence RI 02903).
- You will receive compensation for your time. You will receive a $50 compensation once you completed the study assessments (baseline, 3, and 6 months after enrollment) (total, $150).

Costs for participating in this study: Some of the services you will receive are being performed only because you are participating in this research study. Examples of these 'research only' services include the study visits and the walk test. These services will be paid for by the study and will not be billed to you or your health insurance company.

Contact Information: If you have questions about the study or concerns about side effects/problems, you can contact Ms. Kristen Walaska, Project Director at 401-793-8022 or the Principal Investigator, Dr. Elena Salmoirago-Blotcher at 401-793-8325.

3. Discomforts and Risks:

- Mindfulness training is safe. Only patients having current severe depression or psychosis may sometimes experience psychological distress during sessions. Some psychological discomfort, usually mild and transitory, may rarely happen in subjects that do not have these problems. A member of the study staff will contact you weekly to ask you about any problem or discomfort you might be experiencing during and between the training sessions. These phone calls should take no more than 5 minutes.
- No side effects have been signaled with the performance of the walk test.
- Some questions in the study questionnaires may make you uncomfortable. You may refuse to answer any of those questions and you make take a break at any time when completing those questionnaires.
- Another risk of being in this study is a loss of your personal information. This is very unlikely to happen, and we will do everything to make sure that your information is protected.

4. Benefits: There may be no benefit to you for being in this study. However, mindfulness training has been shown to reduce stress and anxiety in patients with a variety of chronic medical conditions, and you may feel more relaxed and calmer as a result of your participation. Also, the knowledge gained from this study may also help others with your condition in the future.

5. Alternative Therapies: There are currently no recommended treatment to improve the ability to take medications regularly. You can, however, discuss any issue with your medications with your primary care physician.

6. **Refusal/Withdrawal:** It is up to you whether you want to be in the study. You are not required to enroll or participate. If you decide to participate, you can always change your mind and quit at any time. If you decide not to be in the study, or if you quit later, you will still be able to get the health care services you normally get. If you join, but later on the researcher or your doctor feels being in the study is no longer good for you, they may choose to take you out of the study before it is over. If new information becomes available that might change your mind about whether you want to stay in the study the researcher will share this information with you as soon as possible. If you choose to participate the Principal Investigator can withdraw your participation at any time during the study with or without your consent for the following reasons:

- You receive a traumatic brain injury.
- You are diagnosed with a neurologic disease.
- You are found to be a current regular (daily) user of narcotics and / or antipsychotic medications.
- For other safety, behavioral, or administrative reasons.
- In addition, the sponsor may choose to end the study at any time, for reasons unrelated to health care.

Follow-up after Withdrawal of Consent

If you leave the study, it would still be useful for us to know how you do over the next 6 months. We would appreciate if you would permit us to get follow-up information about your health from your doctor or your medical record.

____ If I withdraw from the study, you have my permission to collect information about my health from my doctor or medical record.

_____ I do not give my permission for you to continue to collect information about me if I stop participating in the study.

_____ _____

Signature of study volunteer Date

You have the right to change your mind at any time regarding follow-up after withdrawal. If you decide to quit the study, please tell the head researcher Elena Salmoirago-Blotcher.

7. Medical Treatment/Payment in Case of Injury

A research injury is any physical or mental injury or illness caused by being in the study. If you are injured by a medical treatment or procedure you would have received even if you were not in the study that is not a research injury. To help avoid research injury and added medical expenses, it is very important to follow all study directions carefully. If you do experience a research injury, Lifespan or the study doctor can arrange medical treatment for you. Such treatment will be paid for as described below.

If you have insurance and have a research injury that is not covered by the study, it is possible that some or all of the cost of treating you could be billed to your insurer. If your health insurance will not cover such costs, it is possible you would have to pay out of pocket. In some cases, Lifespan might be able to help you pay if you qualify for free care under Lifespan policy. However, Lifespan has no policy to cover payment for such things as lost wages, expenses other than medical care, or pain and suffering.

8. Rights and Complaints

Signing this form does not take away any of your lawful rights. If you have any complaints about this study, or would like more facts about the rules for research studies, or the rights of people who take part in research studies you may contact Janice Muratori in the Lifespan Office of Research Administration, at (401) 444-6246

9. Confidentiality and Research Authorization for Use and Disclosure of Your Health Care Information. Your research records will be treated as private health care records and will be protected according to Lifespan privacy practices and policies that are based on state and federal law. In particular, federal law requires us to get your permission to use or disclose (release your information to someone outside of Lifespan) your health information for research purposes. If you sign this form you agree to be in this research study and you permit the use and disclosure of your health information for the purpose of conducting the research, providing treatment, collecting payment and running the business of the hospital. This permission has no expiration date. You may withdraw from the study at any time. However, if you do not want the researchers to use or disclose any further information in this study you must cancel permission in writing and may do so at any time. If you cancel your permission, you will stop taking part in the study and no new information will be collected about you. However, if you cancel your permission, it will not apply to actions already taken or information already collected about you by the hospital or the researchers before you canceled your permission.

Generally, the entire research record and any medical records held by the hospital may be used and released for research purposes. The following people or businesses/companies/ might use, release, or receive such information:

- The researcher and their support staff;
- The study sponsor (National Heart, Lung, and Blood Institute);
- Doctors, nurses, laboratories and others who provide services to you or the sponsor in connection with this study;
- The United States Food and Drug Administration, the Department of Health and Human Services, the Office of Inspector General, and the Office of Civil Rights;
- Members of the hospital's administrative staff responsible for reviewing, approving and administering clinical trials and other healthcare or research activities.

There are times when the law might require or permit Lifespan to release your health information without your permission. For example, Rhode Island law requires researchers and health care workers to report abuse or neglect of children to the Department of Children, Youth and Families (DCYF) and to report abuse or neglect of people age 60 and older to the Department of Elderly Affairs.

All researchers and health care providers are required to protect the privacy of your health care information. Other people and businesses/organizations that are not health care providers are not required by law to do that, so it is possible they might re-release your information.

You have the right to refuse to sign this form and not participate in the research. Your refusal would have no affect on your treatment, charges billed to you, or benefits at any Lifespan health care site. If you do not sign, you will not be able to enroll in the research study and will not receive treatment as a study participant.

If you decide to quit the study after signing this form (as described in Section 6) no new information will be collected about you unless you gave us permission to do so. However, the hospital or the researchers may continue to use information that was collected before you quit the study to complete analysis and reports of this research.

Additionally, 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.

For more detail about your privacy rights see the Lifespan Joint Privacy Notice, which has or will be given to you.

SIGNATURE

I have read this informed consent and authorization form. ALL OF MY QUESTIONS HAVE BEEN ANSWERED, AND I WANT TO TAKE PART IN THIS RESEARCH STUDY.

By signing below, I give my permission to participate in this research study and for the described uses and releases of information. *I also confirm that I have been now or previously given a copy of the Lifespan Privacy Notice*

This informed consent document expires on _____.
DO NOT sign this document after this expiration date

The Researcher is required to provide a copy of this consent to you.

_____ _____ _____
Signature of study volunteer/authorized representative* Date and Time when signed

I WAS PRESENT DURING THE CONSENT PROCESS AND SIGNING OF THIS AGREEMENT BY THE STUDY VOLUNTEER OR AUTHORIZED REPRESENTATIVE

_____ _____
Signature of witness (required if consent is presented orally or at the request of the IRB) Date

_____ _____
Signature of Translator Date

_____ _____ _____
Signature of researcher or designate Date and Time when signed

* If signed by agent other than study volunteer, please explain below.

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