Study Name:	HEALTH IMPROVEMENT PROJECT – PROVIDENCE (HIP-P)
NCT Number:	NCT02886234
Grant Title:	MINDFULNESS TRAINING TO IMPROVE ART ADHERENCE AND REDUCE RISK BEHAVIOR AMONG PERSONS LIVING WITH HIV
Grant #:	R34AT008930
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Principal Investigators:	Michael P. Carey, PhD and Elena Salmoirago-Blotcher, MD, PhD The Miriam Hospital Providence, RI 02906
Content:	Consent Form

Study Volunteer Initials

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

207815
Committee #

Name of Study Volunteer

Health Improvement Project – Providence
Pilot Trial

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 a study staff member 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 study staff member 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. WHY IS THIS STUDY BEING DONE?

The purpose of this research is to study the effects of a mindfulness program with a health and wellness program for people living with HIV. Both programs will be delivered over the telephone. You are being asked to take part in this study because you are a patient at the Immunology Center. This research is being done for two reasons: (1) to figure out if these programs can successfully be delivered over the telephone, and (2) because we do not know if these programs will be helpful to patients at the Immunology Center. This study is sponsored by the U.S. National Institutes of Health (NIH).

Taking part in the study is completely voluntary and will **not** change your relationship with your doctor or affect the quality of your care at The Miriam Hospital or at other places where you receive services. This Form explains the study and describes what will be expected of you if you decide to take part. Please ask any questions that you have.

2. HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

About 50 of people will take part in this study.

3. WHAT IS INVOLVED IN THE STUDY?

First, you will be asked several questions to find out if you are eligible to be in the study. These questions will include your personal information (such as your age) as well as information about your health and medical history, and your involvement in other research studies. Your answers will be identified by a Research Identification Number (RIN), not your name.

If you are eligible, you will be invited to participate in the study. The study staff member will review the purpose of the study, how the study will be carried out, what you will be expected to do, and the possible risks and possible benefits of being in the study. Any questions you have about any of these things will be answered before you decide whether you wish to take part in the study.

If you decide to be in the study, you will sign and date this form before any study activities begin. We will ask for your name and contact information so that we can reach you throughout the study.

Your participation in the study will take about 6 months. Below is a chart of all study activities and when they will occur as well as a description of what each of these activities involves.

	Before the program	**During the program**	**Within 2 weeks after the program ends**	**12 weeks (+/- 2 weeks) after the program ends**
Self-administered Survey	X		X	X
Monthly Phone Calls for Pill Counts	X	X	X	X
Biological Samples	X		X	X
Randomization	X			
Weekly Phone Calls		X		
Daily Skills Practice		X		
Semi-Structured Interview			X	X

Before the Program: During an initial visit to the Immunology Center, you will be asked to complete a self-administered survey, receive training in pill counting, provide biological samples, and be randomized to receive one of two health promotion programs. This visit will take about one and a half hour.

Computerized Survey: You'll begin by taking a self-administered survey on a computer in a private room at the Immunology Center. The survey includes questions that we and other researchers, have used in other projects. Many people find the questions to be interesting, and the computer is set up to be easy to use. We will show you how to use the computer, and will be nearby to provide help if you need it. The survey asks about your health-related thoughts, feelings, and behaviors, including sexual behavior and substance use. This survey is completely confidential, and your name will not be associated with your survey. Your privacy will be protected.

Pill Count: Study staff will also ask you to bring your medications that you take by mouth (in pill form) with you to this first visit. We will teach you how to count your pills out loud using a pill knife and sliding the pills into a pill tray. You will be provided with a pill knife, pill tray, and other materials to help with this process. You will practice counting your pills at this visit and will be called twice within two weeks after this visit to count your pills with study staff on the phone.

Because it is important for the program to start on time we ask that you complete these first two calls in a timely manner. If study staff are unable to reach you to complete the first two pill count calls within 60 days of study enrollment you will unfortunately be removed from the study. Telephone pill counts will continue throughout the study on a once a month basis.

Biological Samples: At this first visit, you will also be asked to provide several biological samples for testing for viral HIV load and for sexually transmitted infections. The samples may include blood, urine, oral swab, and rectal swab. The samples you are asked to provide will depend upon whether you are a man or a woman. We will test these samples for chlamydia, gonorrhea, syphilis, and trichomonas as well as for the level of HIV in your blood (viral load).

Randomization: Lastly, you will be "randomized" to receive either the mindfulness or the health and wellness program. Randomization means that you are put into a group by chance. It is like flipping a coin – heads means you get one program, tails means you get a different program. However, instead of a coin we will use a computer to determine which program you will receive. Neither you nor the Project Director will choose what program you will be in. You will have an equal chance of being placed in each one. You will be randomized once the first two pill count calls are completed. At that time you can chose to come in and pick up your program materials or we can mail them to you.

During the Program: You will receive 8 weekly telephone calls from a health coach or instructor. Both of the programs were designed using input from patients from the Immunology Center, and were designed to be interesting as well as informative. Both programs are completed over the telephone and take the same amount of time. The only difference between the programs is what is talked about.

Weekly Phone Call: You will be asked to schedule one telephone session each week with a coach at a time that is convenient for you. Each telephone session will take about 30 minutes. The coach's voice will be audiotaped and reviewed by the researcher team for quality control (that is, we want to make sure that the coaches are following the program guidelines). Your voice will not be recorded. After the completion of this study, the recordings are erased. The coaches will do their best to schedule phone calls at times that are convenient to you. We ask that you respect that the instructors are holding a timeslot for you and to complete the call when you have scheduled it or to **kindly provide 24 hours notice** that you will need to reschedule the call. **If you miss two weeks in a row of calls you may be removed from the coaching portion of the study.** (If this is the case you will still be contacted for pill counts and follow-up assessments).

Daily Practice: Between weekly program sessions you will be asked to listen to an audio file or CD that will guide you through skills you have learned so far for 15 minutes each day. You will also be asked to keep track of the number of times you listen to the audio practice each week using a log that you will mail back weekly using a pre-stamped envelope.

After the Program: You will be asked to come to the Immunology Center two times after the telephone program is complete.

Within two weeks of the program ending: After you have completed the telephone program you will be asked to come to the Immunology Center (1) to complete another survey and a brief interview, and (2) to provide a blood sample to be tested for HIV viral load. This survey will be

similar to the one that you completed prior to the program, but shorter. This visit will take about one hour.

About 12 weeks after the program ends: You will be asked to come to the Immunology Center (1) to complete another survey and a brief interview, and (2) to provide biospecimens to be tested for STIs and HIV viral load. The samples you are asked to provide will depend on if you are a man or a woman. This survey will be similar to the one that you completed prior to the program, but somewhat shorter. This visit will take about one hour.

Finally, we ask your permission to review your medical chart in the Immunology Center to see if you have had a new infection during the 6 months you were in the study. We use information from the surveys, samples, and charts to measure the value of our health promotion programs.

You will be compensated $40 cash at the conclusion of Visit #1, $40 cash at the conclusion of Visit #2, and $50 cash at the conclusion of Visit #3. You will receive $10 for each of the telephone pill count phone calls (seven calls for a total of $70). Compensation earned from telephone pill counts will be paid the next time you come to the Immunology Center. If you would like to receive your $10 sooner, an office pickup can be arranged with research staff. Thus, over the course of the entire research project, you may earn $200 ($40 + $40 + $50 + [7 x $10]) if you complete all research-related assessments.

4. HOW LONG WILL I BE IN THE STUDY?

You will be in this study (enrolled) for about 6 months. Some participants with extenuating circumstances may be enrolled for up to 7.5 months if there are delays to beginning the program.

There is a small possibility that, after the study begins, we may need to ask you to leave the study. The reasons we might do this are the following:

- The study is cancelled by our sponsor (the NIH), or by the Hospital Institutional Review Board (IRB). An IRB is a committee that monitors safety events reported by the investigators in order to protect your rights and welfare as a research participant.
- You are experiencing a high level of emotional distress that needs the attention of medical professionals.
- The Research team decides it is in your not in your best interest to participate.

You can stop the study at any time. However, if you decide to stop taking part in the study, we encourage you to talk to the Project Director and your medical doctor first.

5. WHAT ARE THE RISKS OF THE STUDY?

We do not expect any significant risks from your participation in this study. It is possible that you may experience some distress during the programs when talking about your health, but this is unlikely. Mindfulness training is safe. Only patients having current severe depression or psychosis may sometimes experience psychological distress during mindfulness sessions. Some psychological discomfort, usually mild and transitory, may rarely happen in participants that do not have these problems. To help with any distress you may experience, the instructors will ask you during each call how you are feeling during the call and during your daily practice. The instructors are trained and experienced on how to help with distress. You may also contact our staff at any time if you experience discomfort during or between sessions. You are always able to stop the program at any time.

It is also possible that you may feel uncomfortable answering some questions. You are always able to "pass" (i.e., not answer) any question or topic that is uncomfortable for you.

You will be asked to report on personal and sensitive information such as your age, sexual behavior, and substance use. One risk is a breach of confidentiality. This is possible, but very unlikely. Our research team is are well-trained and we are required to protect your information very carefully. We take many steps to protect the information you share with us. For example, all information collected as a part of this study will be identified by a Research Identification Number (RIN). We use this instead of your name when we save the data. Research staff will be responsible for collecting, handling and shipping the biological samples to the designated lab for analysis; no other people will have access to these samples. Samples will be prepared and stored in locked freezers in a locked room until they are sent for testing. All research team members are required to maintain confidentiality.

The urine, rectal, and throat biological samples will be self-collected. The blood sample will be collected by a trained phlebotomist. Taking swabs involves no major risk. Blood will be taken by inserting a needle into a vein in your arm and withdrawing a sample of blood, the same procedure you have probably experienced at regular doctor visits. You may experience mild discomfort associated with blood collected, including minor pain during blood drawing and perhaps some bruising. In rare circumstances you may experience fainting or local infection. These risks will be minimized by having a skilled phlebotomist perform the blood draw.

Data from this project will be stored separately from identifying forms. Thus, your answers on surveys and from interviews will NOT be connected to your name or other identifying information. When your participation in the study ends, the locator information we collected (such as your name, telephone number, and address) will be destroyed. All electronic data are stored on a secure hospital server in a project-specific folder that only the research team can access. Password protected thumb drives will be used for transferring data. Once the data are uploaded to a secure hospital server the data will be deleted from the thumb drive. We hope to share the results of the research at research meetings and in publications in professional journals. When we present or publish our results, we will only present results averaged across all participants or quotations that do not identify you. Your name will never be used.

6. ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

If you agree to take part in this study, there may or may not be direct benefit to you. It is possible that the two programs we are studying (the mindfulness program and the health and wellness program) will help you to improve your health behaviors and disease management. In our previous research, many participants have reported that they enjoyed participating. In addition, some participants have told us that completing the self-administered survey, which asks participants to reflect on their health behaviors, was helpful. Being tested for sexually transmitted infections may be a benefit to you because this testing can identify infections that you have do not know about. Some infections do not have symptoms but can cause health problems. We also hope the information learned from this study will benefit other patients living with HIV improve their health.

7. WHAT OTHER OPTIONS ARE THERE?

Instead of being in this study, you may get training in mindfulness and health and wellness at other locations. Further, you can receive general health promotion information for people living with HIV from websites such as AIDS.gov and your doctor here at the Immunology Clinic. Your decision about to participate in this study will not, in any way, change your relationship with your doctor or affect the quality of your care at The Miriam Hospital or at other places where you receive services.

Please talk to your medical doctor about these and other options.

8. WHAT ARE THE COSTS?

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 biological samples being taken for the study and programs. Those services will be paid for by the study and will not be billed to you or your health insurance company.

There is also no charge to you for the counseling (coaching) provided by telephone. However, you will need to provide your own phone and to pay any phone charges that you incur as a result of using your phone to participate in this study.

The clinical care that you receive at the Immunology Clinic and The Miriam Hospital are considered "routine clinical services." These are services that you would have received even if you were not participating in the research study. Such "routine clinical services" will continue to be handled as they would be if you were not in this study. Thus, these routine clinical services will be billed to your health insurance company, and you will be responsible for paying any deductibles, co-payments, or co-insurance that are a normal part of your health insurance plan. If you do not have health insurance, you will be responsible for those costs.

9. MEDICAL TREATMENT / PAYMENT IN CASE OF INJURY

A research injury is any physical or psychological injury or illness caused by your participation in the study. If you are injured by a medical treatment or procedure that you would have received even if you were not in the study, that is not a research injury. To help avoid research injury and potential added medical expenses, it is important to follow all study directions carefully. If you experience a research injury, Lifespan, or the study doctor, are available to arrange for medical treatment for you. The cost of your 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 costs of treating you could be billed to your insurer. If your health insurance will not cover such costs, then 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.

10. WHAT ARE MY RIGHTS AS A STUDY VOLUNTEER?

Taking part in this study is completely voluntary. You may choose to take part or not. If you do join the study, you may leave the study at any time. Leaving the study will not result in any penalty or loss of benefits to which you are entitled.

An Independent Monitoring Committee, an independent group of experts, will monitor the study throughout the study. We will tell you about the new information from this or other studies that may affect your health, welfare, or willingness to stay in this study.

11. WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about this study or research-related concerns or problems, please contact:

Dr. Michael Carey, PhD **401-793-8218**
Centers for Behavioral and Preventive Medicine 1 Hoppin Street, Coro West, Suite 309
The Miriam Hospital Providence, RI 02903

Dr. Carey is the lead Researcher, and is in charge of this research study.

Signing this form does not take away any of your rights protected by law. If you have any concerns or complaints about this study, or if you 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.**

12. WHAT ABOUT CONFIDENTIALITY?

Your research records will be treated as private health care records and will be protected according to Lifespan privacy practices and policies and consistent with state and federal laws. Federal law requires that we get your permission to use your information for research, or to release your information to someone outside of Lifespan (for example, to another doctor whom you are seeing). By signing this consent form, you are agreeing to be in this research study and you are permitting the use and disclosure of your health information for the purpose of conducting the research, providing treatment (for example, if you are found to have a sexually transmitted infection), 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, then you must cancel permission **in writing**. You may do this 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 his research staff;
- The study sponsor: the National Institutes of Health, which is a division of the United States Department of Health and Human Services;
- Doctors, nurses, laboratories and others who provide services to you or the sponsor in connection with this study;
- The section of the U.S. government that is paying for the study and others they hire to oversee, administer, or conduct the research;
- The United States Department of Health and Human Services, the Office of Inspector General, and the Office of Civil Rights;
- People who volunteer to be patient advocates or research volunteer protectors;
- Members of the hospital's administrative staff responsible for reviewing, approving and administering clinical trials and other healthcare or research activities.
- Accrediting Organizations.

There are laws that 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

the names of individuals diagnosed with positive STI results to be reported to the Health Department. Additionally, 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 effect 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.

You will not be allowed to see or copy the information described in this form as long as the research study is open. You may see and copy the information when the study is completed.

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.

To further protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, we cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. We will use the Certificate to resist any demands for information that would identify you, except as explained below.

A Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

The Certificate of Confidentiality does not prevent us from disclosing voluntarily, without your consent, information that would identify you as a participant in the research project under the following circumstances.

1. If officials of the Department of Health and Human Services were concerned that the research team was acting inappropriately, these officials might audit our research records to (a) protect your rights as a research participant, and (b) to make sure that this research is being conducted ethically and as promised. If such an audit were conducted, Dr. Carey might be required to share the research records with the auditors. However, the auditors are required to protect your privacy.

2. If you told us that you intend to harm yourself or to harm another person, or if you report child abuse or neglect, we would act to protect you, the other person, or the child.

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 4/26/2018**.**

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 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 Time signed

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

_____

_____