Cambridge Health Alliance
A COMMUNITY OF CARING

INFORMED CONSENT AND AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION FOR RESEARCH

We try to make this form easy to understand. But it may have words or ideas that are not clear to you. Please ask the study doctor or study staff to explain anything you do not understand.

You may take this form home with you to discuss with family or friends before you decide whether to be in this study.

Study Title: Integrating Mindfulness into the Patient-Centered Medical Home (Phase 3)

Funding Title: Mindfulness Influences on Self-Regulation: Mental and Physical Health Implications

Your name (Participant):	**Today's Date:**

Not including this study, are you taking part in any research now? ☐ **Yes** ☐ **No**

Name of Principal Investigator: Zev Schuman-Olivier, MD

Name of Co-Investigator(s):

Consent form version date or number: Version 10

Name and telephone number of study contact to call with questions: Lexie Comeau
Tel: 617 - 806- 8735

CHA IRB Number: CHA-IRB-1002/08/14 **IRB Approval Date:** January 13, 2020 **IRB Expiration Date:** October 6, 2020	**Study Sponsor(s):** NIH Science of Behavior Change Initiative/National Center for Complementary and Integrative Health (UH3AT009145)

You are invited to take part in a research study done by Dr. Schuman-Olivier and other people who work with this doctor.

Taking part in this study is voluntary. You can choose to take part or not. If you take part in the study, **you may leave the study at any time for any reason**. If you don't want to take part, it does not change any part of the standard health care you will receive at Cambridge Health Alliance.

If you decide to take part in this study, you will be asked to sign this form. You will be given a copy of the signed form. Please keep your copy for your records. It has information, including important names and telephone numbers, for future reference.

Introduction

Mindfulness is paying attention, on-purpose, to the present moment in a non-judgmental way. Mindfulness training can help people to lower stress and to manage life's challenges more easily. Mindfulness training can help relieve anxiety, depression, and pain. It can also increase feelings of well-being, especially if you have a chronic illness. Learning to be mindful requires regular practice. Regular practice has lasting effects on the brain. It can help you increase self-control, especially in your health behaviors, and decrease craving for habits, such as tobacco smoking, overuse of alcohol or prescription drugs. With just a few weeks of daily practice, many people can lower their daily stress and feel happier.

This program aims to bring tools for self-healing to CHA patients in their primary care health centers.

The National Institutes of Health (NIH) is providing funding for this research through its Science of Behavior Change Initiative.

Purpose for the Study

This research study compares how different mindfulness training formats affect health behavior change. In this study you will fill out surveys about your health and wellness, and track your health behaviors and any mindfulness practice you do. This study will test the effects of different lengths of time of mindfulness practice on your health behaviors, health and wellness.

New Findings

We will tell you about new findings that may cause you to change your mind about being in this study.

Reasons why you have been invited to be in this study

To take part in this study, you have to meet the following criteria:

- You are currently a patient at Cambridge Health Alliance (CHA).
- You have access to a compatible smartphone
- You are willing to use a smartphone application every day for a portion of the study
- You are willing to attend two in-person computer task sessions
- You are able to fill out the study questionnaires on a compatible electronic device on a daily basis

Period of Participation (how long you will be in this study)

If you choose to be part of this research study, **you will participate for 24 weeks (six months total).**

You will either take part in a **CHA mindfulness group for 8 weeks soon after you enroll**

OR

You will be given information about other mindfulness resources and local mindfulness programs and placed on a **6-month waiting list** for a CHA mindfulness group.

We ask you NOT to participate if you expect to be hospitalized in the next 2 months for a health problem. We will ask you NOT to participate if you expect to go to jail in the next 2 months. In addition, we do not recommend this program for women in the third trimester (week 27 or later) of pregnancy.

Regardless of whether you are in a mindfulness group right away or on the 6-month waiting list, this study has **five (5)** components for all participants:

1. You will be asked to fill out **three (3)** long sessions of surveys (45 minutes each): at the beginning of the study, after 8 weeks, and after 24 weeks.

2. You will be asked to fill out twelve (12) short surveys: one Mindfulness Practice/Resource survey **every week** for the first 8 weeks, one Action Plan survey after 7 weeks, and one Action Plan Follow Up survey after Week 9, Week 10, and Week 16.

3. You will be asked to attend **two (2) in-person** 45-minute computer task sessions before Week 1 and between Weeks 8 and 9

4. You will be asked to fill out **daily surveys** tracking your eating, drinking, exercise, and mindfulness practice for **sixteen (16) days** during Weeks 0-2, and for **eight (8) days** during week 8.

5. You will be asked to install a step-counting application on your smartphone and carry your smartphone on you for **sixteen (16) days** during Weeks 0-2, and for **eight (8) days** during week 8.

Procedures (what will happen during this study)

You will participate in this study for 24 weeks. In order to take part in this study you will need a referral from your primary care provider or mental health provider. During the study you will be asked to fill out surveys. **These surveys will be online on a secure, confidential website.** Your answers to the surveys will be confidential.

In this study, you will be **randomly placed** in a **mindfulness group** or on a **6-month waiting list**.

The mindfulness group will meet each week for **8 weeks**. This group will last for 2 hours each week. These weekly sessions will be billed to your insurance, and you may have a co-pay. The mindfulness group will meet at a local primary care health center. This group will also have a full day-long session on a weekend. This weekend session will not be billed to your insurance.

The waiting list group will be given information about local mindfulness programs and electronic tools. **The waiting list group will be on a 6-month waitlist for a CHA mindfulness group**. If you are on the waiting list, **you will be able to join a group at CHA after 6 months provided you complete all of the surveys and health behavior tracking completely and on time.** You cannot choose whether you will be in a primary care mindfulness group or on the waiting list.

Informed Consent Session:
You have met with a CHA behavioral care provider and are eligible for this study. That is why you have been asked to fill out this informed consent form. You will get a copy of this form for your records. If you have any questions during this time, please ask one of the study staff during the Informed Consent Session. You can also call our study staff at 617-591-6055 or email (MINDFULPC@challiance.org).

You will also be asked to complete an Informed Consent Assessment. This assessment has important questions to show that you understand the risks and benefits of this study. You can ask the study staff questions about the study at any time during the Informed Consent Session. You may correct your answers on this assessment. **You must score a 90% on the assessment in order to enroll in the study.**

Baseline Survey Session (Duration: 1 hour):
After you complete the informed consent process, you will be asked to fill out a series of surveys. **You must fill out the surveys before you can be randomly placed into the mindfulness group right away or on the 6-month waiting list.** You will fill out the surveys online at your primary care center. We will ask you questions about your past experience with mindfulness. We will also ask you about your health and stress and your use of alcohol and other drugs. You will be paid for your time completing this survey.

Mindfulness Introduction Session (Duration: 1 hour):
After you fill out the informed consent and first session of surveys, you will meet in a group of about 10 – 20 people. The group will be led by a member of the MINDFUL-PC study team and a Mindfulness Group Leader. In this visit, you will learn about the 8-week Mindfulness group.

Scheduling Phone Call (Duration: 10 minutes):
After you fill out the informed consent form and first session of surveys, and go to the orientation session, **you will be randomly assigned to either an 8-week mindfulness group or a 6-month waiting list for a group.** We will call you to let you know whether you will be in a group or on the wait list. During this phone call we will help you schedule your study sessions and will be happy to answer your questions.

Computer Task Session 1 (Duration: 45 minutes): All participants will participate in this visit. You will be paid for your time completing this visit.

You will be guided by a research staff member to install an activity tracking application on your phone which will be later used in the study. The study staff will show you how it works. Then, you will be asked to do the following computer tasks:

- **A heartbeat detection task:** you will be asked to sit quietly and count your heartbeat. During this time, you will be asked to place your hands on a small pad called the Kardia Mobile Device. This device will count your heartbeat during each trial. (Duration: 5 minutes)
- **A choice task:** you will choose between two different options given at different times. (Duration: 1 minute)
- **An attention task:** you will press a key on the keyboard based on numbers that appear on the screen. (Duration: 20 minutes)

Daily Behavior Tracking Surveys Part 1 (Duration: 15 minutes per day): You will fill out daily behavior surveys for **sixteen (16) days** during study Weeks 0-2. You will be paid for your time completing these surveys. This includes:

- Filling out an online questionnaire about Food, Activity, and Sleep Tracking (FAST) daily. Duration: 8 minutes
- Filling out an online diary about mindfulness practice. Duration: 5 minutes
- Activity tracking by keeping your phone on your body at all times (except when entering water). The phone could also be carried in a bag when you are moving from one place to another. Duration: 2 minutes

8-Week Mindfulness Training Group:
If you are in the 8-week Mindfulness group, you will meet at your primary health care center. You will meet in groups of about 10 people with a behavioral health care provider or primary care provider. There will be one meeting a week for 8 weeks. Each meeting will be 2 hours long. During the second half of your group, there will be a 7-hour long session on the weekend. This will be at a location near the primary care center. This course will teach skills to help you regulate your feelings, body sensations, and thinking. You will also learn simple mindful movement exercises that you can do to help your body feel better. You will be asked to practice these skills for up to 30-45 minutes a day, every day during the 8-week long mindfulness training group.

Daily Behavior Tracking Surveys Part 2 (Duration: 15 minutes per day): You will fill out daily behavior surveys for at least seven (7) days during Week 8-Week 9. You will be paid for your time completing these surveys.

This includes:

- Filling out an online questionnaire about Food, Activity, and Sleep Tracking (FAST) daily. Duration: 8 minutes
- Filling out an online diary about mindfulness practice. Duration: 5 minutes
- Activity tracking by keeping your phone on your body at all times (except when entering water). The phone could also be carried in a bag when you are moving from one place to another. Duration: 2 minutes

Create an Action Plan Worksheet (Duration: 20 minutes):
You will be asked to fill out an Action Plan Worksheet about a health goal that you want to work on. This will take place during Week 7. You are encouraged to share this worksheet with a healthcare provider or person who may help you in accomplishing the goal. You will be asked to complete a brief survey about the goal that you made. You will be paid for your time completing this survey.

Weekly Practice/Resource Surveys (Duration: 10 minutes per week)
Every week during the first 8 weeks of the study, you will be asked to fill out two short surveys online. These surveys will ask about any mindfulness practice that you've done for that week, or any mindfulness resources that you've used in the community for that week. You can fill out the surveys at home or at a local CHA primary health care center. You will be paid for your time if you complete all of the surveys, and you will still receive partial payment if you complete both surveys during at least 6 of 8 weeks.

Participant Engagement Call (Duration: 3-5 minutes, Weeks 2, 4, 6, and 8):
You will be called by a member of the study staff during study weeks 2, 4, 6, and 8. This will be a short outreach call to provide you support as you participate in the study. During this call, the study staff can help you answer any questions, help you with problems you may have in filling out the surveys, and hear about anything that you would like to share with the study staff. If you don't answer this phone call, the study staff will leave a message.

8-Week Survey Session (Duration: 1 hour):
After 8 weeks, you will be asked to fill out more surveys online. You can fill out the surveys at home or at a local CHA primary health care center. These surveys will ask about your health and stress, and your use of alcohol and other drugs. You will be paid for your time completing this survey.

Computer Task Session 2 (Duration: 45 minutes): All participants will participate in this visit. You will be paid for your time completing this visit.
You will be asked to do the following computer tasks:

- **A heartbeat detection task:** you will be asked to sit quietly and count your heartbeat. During this time, you will be asked to place your hands on a small pad called the Kardia Mobile Device. This device will count your heartbeat during each trial. (Duration: 5 minutes)
- **A choice task:** you will choose between two different options given at different times. (Duration: 1 minute)
- **An attention task:** you will press a key on the keyboard based on numbers that appear on the screen. (Duration: 20 minutes)

Action Plan Follow-Up Surveys (Duration: 5 minutes, 3 times):
During study weeks 9, 10, and 16 you will be asked to complete a short survey about the health goal that you created during Study Week 7. You will be paid for your time completing these surveys.

6-Month Survey Session (Duration: 1 hour):
After six months, we will ask you to fill out more surveys online. You can fill out the surveys at home or at a local CHA primary health care center. These surveys will ask about your health and stress and your use of alcohol and other drugs. You will be paid for your time completing this survey.

Optional Action Plan Interview:
At the end of your 6-month study participation, you may be reached by e-mail or phone about whether you are interested in sharing about your experience with the program. You may decline this invitation if you do not wish to share your experience. You will be paid for your time completing this interview.

Electronic Medical Records:
We will collect data from your electronic medical records. This will be from the year before this study and the year after this study. This is to study the long-term effects of the mindfulness practice. We look at your prescribed medications and health information. This information includes blood pressure, height, and weight. This information also includes your health-related behaviors, your mood, and the visits that you made to the hospital and to your primary care provider. We may continue to collect this data for up to 3 years after you start the study. You can choose to leave the study and remove our access to your data at any time.

Audio Recording of Group Sessions

Some group sessions during the course may be audio recorded. This is so that we can monitor the way the group leader teaches each session. Audio will not be linked to any personal or identifying information.

I agree to be audio recorded during group sessions.

Check the box to indicate your agreement to be audiotaped during group sessions. Checking the box is the same as signing your name in agreement.

☐ I agree ☐ I do not agree

If you are placed on the 6-month waiting list during this study, you will be able to take the 8-week group after you finish the study.

Possible Risks, Discomforts, Side Effects, and Inconveniences

The following are possible risks and side-effects if you participate in this study:

- Some of the questions that you will be asked are personal. You might feel stressed or embarrassed. You may ask to see the questions before you decide to participate in this study. If you get upset or stressed, you can call the study staff. The research coordinator will contact your behavioral health care provider if needed.
- You may spend extra time learning mindfulness techniques.
- You may feel anxious because of the difficulties in this mental training program.
- This training includes gentle movement. You may feel physical discomfort during the gentle movement.
- You might not benefit from the program.
- You will be asked to carry your smartphone throughout your day. This may cause you inconvenience.
- Despite strong efforts to maintain your confidentiality, your protected health information (PHI) might be exposed. All digital information collection and transfer using the internet carries the risk of loss of confidentiality due to privacy breach. For this reason, during orientation session, study staff will instruct you on how to disable GPS location tracking, photo sharing, and push notifications. Study staff will do this in order to limit the level of information that the activity tracking software can collect.
- Eye strain from performing computer tasks

Unknown Side Effects:

There may be side effects that are unknown at this time. Members of the study team will monitor you for any side effects. It is also important that you tell the study staff right away about any unusual events or changes in your health.

We will be happy to answer any questions you have about these risks and/or side effects. Please talk with a study team member if you have questions or concerns.

Alternatives to Participation

Participating in this study is voluntary. You may choose not to participate in this study and continue to receive standard care. Whether or not you are enrolling in the study will not affect your health care at CHA. However, you cannot participate in this training without consenting to the study.

Benefits (good that may come from being in this research)

Potential benefits to you from being in this study are:

- You can learn skills for controlling behavior and improving well-being.
- You may feel more joy and gratitude.
- You may feel less depression, anxiety, stress, insomnia and pain.
- You may have less of a need for symptom-relieving medication like benzodiazepines and opioids.
- You may find that you smoke fewer cigarettes and drink less alcohol.
- You may feel less stress about a chronic illness.
- You will have an opportunity to track your own health behaviors. What we learn from your health behaviors may help others in the future.

Some of these benefits may not help you directly. However, what we learn from this research may help others in the future. There is no guarantee you will benefit from being in this study.

Costs

You will not have any costs from being in this study. The time related to study survey visits and procedures will be given to you at no cost. **Costs for the mindfulness group treatment will be billed as usual to you or your insurance. Co-pays for group treatment will follow standard procedure for your insurance provider.**

In order to participate, you must have a diagnosis that will make you eligible to be covered by insurance for group visits. Some examples include: anxiety disorder, depression, insomnia, pain syndrome, or adjustment disorder related to chronic illness (e.g. diabetes, heart disease, etc.). If your insurance provider does not cover group treatment, you may not be able to participate in the study.

This study requires you to have a compatible smartphone. This study requires you to use the smartphone application each day.

Payment

You could be paid a total of $350 for filling out all the surveys, attending the computer task sessions, and doing the daily behavior tracking:

Payment 1 @ Pre-treatment: $20 for completing baseline survey
Payment 2 @ Week 0: $30 after Pre-Computer Tasks visit
Payment 3 @ Week 8: Up to $**112** for:
Daily Behavior tracking during Week 0-2 ($72)
Week 8 Surveys ($20)
Completion of Weekly Mindfulness Surveys Weeks 1-8 ($20)

Payment 4 @ Week 9: Up to **$93** for:
Post-Computer Tasks Visit ($30)
Daily Behavior tracking during Week 8-9 ($36)
Mid-Study High Completion Bonus ($27) if you complete the baseline survey, week 8 survey, at least 75% of your daily behavior tracking, and both computer visits.
Payment 5 @ Week 26: Up to **$80** for:
6 Month Survey ($20)
Action Plan ($15)
All three Action Plan Follow-Up Surveys ($15)
Final Completion Bonus ($30) if you complete the Action Plan, all three Action Plan Follow-Up Surveys, and the 6 Month survey.
Payment 6 Post-Study: $15 for Action Plan Interview.

Study-Related Injury

If you get hurt or get sick as a direct result of being in this study, emergency treatment will be given to you. All needed emergency care is available to you, just as it is to the general public. Any needed medical care is available to you at the usual cost. You or your insurance carrier will have to pay for any such medical care.

Cambridge Health Alliance has not set aside any money to pay for a research-related injury or illness. There are no plans to pay for your treatment if you get hurt or sick as part of this study.

Voluntary Participation

Taking part in this study is voluntary. If you do not take part you will not be punished or lose benefits that you have the right to receive. The quality of your medical care will be the same at Cambridge Health Alliance whether you take part in the study, refuse to take part, or decide to leave the study.

If you choose to take part and then decide to stop, tell a member of the research team. It may not be safe for you to suddenly stop being in this study. The study team will help you stop safely.

Any information collected from you before the date you leave the study will be used in the research study.

The research team may decide that you can no longer be in the study. This could be for several reasons, including:

1. You have had a bad reaction to the study.
2. You did not follow all the study rules.

Privacy / Confidentiality

There are laws (state and national) that protect your health information to keep it private. We follow those laws. Your identity, medical records, and study data will be kept confidential, except as required by law.

We will protect all of your health information, including your Protected Health Information or "PHI." Your PHI is your individually identifiable health information.

If you take part in this study, you agree to let the research team use your medical information. Do not take part in this study if you do not want the research team to access your health information.

We will follow these guides:

- The research team will view your health information only during the life of this study.
- We will not include any information that could identify you in any publication.

- At the end of the study, we will remove all of your identifiable information (name, address, telephone number, *etc.*) from the study database.

We will make every effort to keep your information private, but we cannot guarantee it. The Cambridge Health Alliance Institutional Review Board (IRB) is responsible for protecting the safety and welfare of people who take part in research studies at our hospital. IRB staff may ask to look at any research records to make sure the study team is following the laws and rules to protect you. Certain government agencies, including the Office for Human Research Protections and the U.S. Food and Drug Administration (regulates drug and device studies), may also look at records that identify you.

Sometimes, we are required to share your study records with others, too, including:

- Other researchers conducting this study,
- The study sponsor and any companies that the sponsor uses to oversee, manage, or conduct the study,
- Clinical staff not involved in the study, but involved in your regular treatment,
- Insurance companies.

If any of these groups ask to look at your information, then we cannot prevent it from being shared. Once information is shared, we cannot guarantee any further confidentiality and privacy.

- **The data that is stored on the smartphone application and the computer tasks will be linked to a study e-mail address. The e-mail address will be made up of a Participant ID that is specific to the behavior-tracking portion of the study. This e-mail address will not be linked to any identifying information about you. Your name and health information will not be stored.** Only study staff have access to the confidential file that links your Participant ID with your identity, and this file is kept in a password-protected drive at CHA.
- **The smartphone application creators may have access to your smartphone application data but they will not know your identity. The activity tracking data may be accessible by our collaborators at Brown University, but they will not have access to any of your identifying data.** The heartbeat task data may be accessible by the software developers of Kardia Mobile Technology, but they will not have access to any of your identifying data.
- **Unsecure Wi-Fi can put your data at risk. We encourage you to use secure Wi-Fi if you decide to use Wi-Fi when completing study surveys.**
- **The study team may text you to schedule study sessions if you have already agreed to text-messaging in your patient electronic health record.**
- **Despite our best efforts to protect privacy and ensure confidentiality, data breaches can happen when you are using internet-based technology.**

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by US 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.

Period of Authorization

Your authorization on this research project will expire 10 years after completion of data gathering for the study. If you change your mind and want to withdraw your authorization please tell a member of the study team or write to the HIPAA Privacy Officer for Research, Cambridge Health Alliance, 1493 Cambridge Street, Cambridge, MA 02139. If you withdraw your authorization, you may no longer be allowed to participate in the study described in this form.

Getting Help (Contacts)

If you have questions about this study please ask a member of the study team. Some questions people have:

- What are the risks and benefits of being in this study?
- What other choices are available?
- What are my rights as a research participant?
- What should I do if I feel pressured to take part in this study?
- How is my health information used in this study?
- How will my health information be protected?

Call the study investigators for answers to any study-related questions or if you get hurt or sick as a result of being in this study. This is how to contact us Monday to Friday during regular business hours:

Zev Schuman-Olivier, MD (Principal Investigator) MINDFULPC@challiance.org
Lexie Comeau (Research Coordinator) 617-591-6055
Richa Gawande, PhD (Program Manager)

If you have questions about your rights as a study participant please contact either the IRB office or the Patient Relations Department. The offices are open Monday to Friday (not holidays) from 8:30am until 5:00pm:

IRB Chair: Dr. Lior Givon
Telephone: 617-665-1934

Patient Relations Manager: Lorraine Vendetti
Telephone: 617-665-1398

Signature of Consent

I, the study participant, have read this form or it has been read to me. I understand my part in this study and have had my questions answered to my satisfaction. I agree to take part in this research study.

_____ _____
Participant's Signature Date

I have informed the study participant, _____ of:
Participant's Printed Name

- The procedures, purpose, and risks related to participation in the above-described study;
- How his/her health information may be used, shared, and reported, and;
- His/her privacy rights.

The study participant has been provided with a signed copy of this form.

_____ _____
Signature of Researcher Obtaining Consent Date

_____
Printed Name of Researcher Obtaining Consent

_____ _____
Signature of Participant's Legally Authorized Representative Date

_____ _____
Printed name of Participant's Legally Authorized Representative Date

_____ Interpreter Role: ❒ CHA employee
Printed Interpreter Printed Name (if used) ❒ Other: _____

This form is valid only if it has the IRB stamp of approval.