CHA Cambridge Health Alliance	**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 a member of the study team 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 research study.

Study Title: Effects of Primary Care Group Buprenorphine Treatment on Stress, Anxiety, and Opioid Use.

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): Richa Gawande, PhD, Alaine Fredericksen, LICSW, Randi Sokol, MD, Alexandra Oxnard MD, David Roll, MD, Ellie Grossman, MD, Benjamin Cook, PhD, Todd Griswold, MD, Nancie Rouleau, PhD, Laura Holland, MD, Paula Gardiner, MD, Colleen Labelle, CARN, Annalee Wells, MD, Sarah Moore, PhD, Mark Albanese, MD, Roger Weiss, MD, Timothy Creedon, PhD.

Consent form version date or number: Version 1.2

Name and telephone number of study contact to call with questions:
Thomas Fatkin, Study Coordinator (617-806-8567, stressreductionstudy@challiance.org)

CHA IRB Number: CHA-IRB-1114/06/19	**Study Sponsor(s):** NIH/NCCIH

Key Information

- You are invited to take part in a study called “Effects of Primary Care Group Buprenorphine Treatment on Stress, Anxiety, and Opioid Use”
- Taking part in this study is voluntary. You have the choice to take part or not. You may leave the study at any time for any reason.
- You will be asked to participate in the study for 24 weeks. You will be asked to complete surveys and a computer task before your first group, and then again at 4, 12, and 24 weeks. You will also be asked to complete weekly surveys throughout the 24 week study.
- You will be randomly assigned to participate in a group for at least 4 weeks with the option to continue up to 24 weeks. The groups aim to help you lower your stress, decrease your anxiety and depression, feel less isolated and more supported, and help you manage your opioid use.
- You may not benefit from this program. You may have moments where you feel stressed, embarrassed, or anxious due to being in a group. You may spend extra time learning stress and anxiety reduction techniques and be asked to practice skills at home between groups. You may have physical discomfort from gentle movement in groups. Despite strong efforts to maintain confidentiality, it is possible that your protected health information (PHI) may be exposed.
- You can choose at any point to return to standard care options that are approved by your primary care clinical team.

Introduction

Please read this form carefully. This form tells you about a study called Effects of Primary Care Group Buprenorphine Treatment on Stress, Anxiety, and Opioid Use. This study is being conducted by researchers at Cambridge Health Alliance, in Cambridge, Massachusetts. The primary care sites involved include CHA Central Street Care Center, CHA Revere Care Center, Lynn Community Health Center, Boston Medical Center, and North Shore Community Health. You will participate in this study at your primary care site. If you choose to take part in this study, you will be asked to sign this form. You will be given a copy of the signed form for your records.

Taking part in this study is voluntary. You have the choice to take part or not. If you take part in this study, you may leave 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 your primary care site.

Having the support of a group can help people lower stress and anxiety, while feeling less isolated and more supported. Learning stress and anxiety reduction techniques in a group can be beneficial to people's well-being and help decrease anxiety and depression. This program aims to bring stress reduction tools to patients with opioid use disorder who are currently receiving buprenorphine/naloxone treatment. It is not, however, guaranteed that you will experience these benefits.

The National Institutes of Health (NIH) is providing funding for this research. If you have any questions about the research or about this form, please ask us.

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

Purpose for the Study

This study will offer a weekly group with other people who are prescribed buprenorphine for opioid use disorder, which may focus on education, stress reduction, anxiety reduction, supporting each other, and/or talking about recovery. During groups, you will NOT be forced to talk about difficult past events and can choose to pass at any time you feel uncomfortable. You will be randomly assigned to one of the groups at your site, and groups will be focused on helping you reduce stress or anxiety, maintain sobriety and live well in recovery. The study will examine how the different groups affect your well-being, your substance use, your relationships, and your ability to continue with treatment at your primary care site. Approximately 210 participants will be enrolled in this study between January 2020 and July 2021.

Reasons why you have been invited to be in this study

You have been invited to participate in this study because you are a patient who is receiving a prescription of buprenorphine from a prescriber at a participating healthcare system. Your provider or nurse care manager may have referred you to this study.

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

- You are between 18 and 70 years of age.
- You have a diagnosis of opioid use disorder and are prescribed buprenorphine from a prescriber at one of the participating healthcare systems (Cambridge Health Alliance, Lynn, North Shore, Boston Medical Center).
- You understand English well enough to understand procedures and questionnaires and provide informed consent.
- You are able to fill out weekly surveys on either on an electronic device (like an iPad) at your primary care site or a computer or an electronic device at home.

- You are NOT participating in another research study.
- Either you have used non-prescribed opioids (e.g. Oxycodone, Vicodin, Percocet, Fentanyl, Heroin, etc.), non-prescribed benzodiazepines (e.g. Xanax, Klonopin, Ativan, etc.), non-prescribed stimulants (e.g. Adderall, Crystal Meth), non-prescribed cannabis, cocaine, OR alcohol in the past 90 days OR you have an anxiety or stress disorder.

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

You will be screened during your first visit to determine whether you are eligible for this study. You will be compensated for this visit even if you are not eligible to join the study.

If you are found to be eligible for the study, you will be randomly placed in one of two groups with different approaches to stress and anxiety reduction, maintaining sobriety, and helping you to live well in recovery. You will be expected to participate in your assigned group for 60-90 minutes a week for at least four weeks. After 4 weeks, you will have the option to continue with the group that you're in, or consider a change to another form of treatment. You will be able to continue as part of the study for up to 24 weeks.

You will be expected to complete a survey and computer session before your first group and then again at 4, 12, and 24 weeks. These sessions may last up to 90 minutes and you will be paid for time completing study tasks. You will also be expected to complete weekly surveys for the first 24 weeks of the study, which may last about 7 minutes each week.

We ask you NOT to participate if you expect to be hospitalized in the next 24 weeks for a health problem. We will ask you NOT to participate if you expect to go to jail in the next 24 weeks. You may participate in this study if you are pregnant. No other experimental treatments or participation in other investigational trials are allowed during the study.

Procedures (what will happen during this study)

This study has 5 components: group sessions, surveys, urine toxicology testing, screening session, and computer tasks.

1) Group Sessions: You will be asked to attend a weekly group for 60-90 minutes each week at your primary care center for 4 weeks. The groups are regular groups designed for people in early recovery where you can learn some skills to help you reduce stress and anxiety, prevent relapse and the return of depression, and cope better with pain and cravings. Groups are billed to insurance like any other clinical group. Depending on who the provider is and your insurance type, you may have a co-pay. We will do our best to let you know what the co-pay may be, but it is your responsibility to ask your insurance company to confirm.

You may have the option at some point in the study of joining a more focused 16-hour intensive group which may meet for 2 hours every week over 8-weeks OR for around 60-90 minutes every week for 16 weeks, depending on your site. The timing of this group for you will be subject to availability and scheduling, but you will not be required to join this group in order to participate in the study. These group sessions may substitute for standard group participation requirements for your buprenorphine treatment—you will have the opportunity to discuss your individual treatment plan details with your healthcare providers.

2) Weekly Surveys: You will fill out weekly surveys that ask questions about your substance use in the past week and your use during the past week of the skills you have learned about in group.

3) Urine Toxicology Testing: You will participate in a urine toxicology test at least every 2 weeks or more frequently as required by your clinical treatment team (*may be weekly if required by your prescriber*).

4) Screening Session: After you sign the informed consent form, you will participate in a 30-40 minute long screening session to determine your eligibility for the study. The session will include a 25-minute psychiatric diagnostic interview, a 3 minute long survey, and may include a 10-minute cognitive assessment.

5) Computer Tasks and Survey Session: After you sign the informed consent form and if you are determined to be eligible to participate in the study, you will participate in a 1.5-hour computer task session 4 times: at the beginning of the study before you start group, after 4 weeks of group, at 12 weeks, and at 24 weeks. Each visit will be conducted at your primary care clinic.

At these visits, you will do the following:

- On the computer, you will do:
  - **An attention task:** You will press a key on the keyboard based on numbers that appear on the screen. This task will be done on a study computer. (Duration: 25 minutes)
  - **A choice task:** You will choose between two different options given at different times. This task will be done on a study computer. (Duration: 1 minute)
- You will be asked to **count your heartbeat** for about 3 minutes.
  - During this time, you will be asked to place your hands on a small pad called the Kardia Mobile Device. This FDA-approved device will count your heartbeat during each trial.
  - The anonymized readings from this device will be transmitted to an iPad and written down by hand by the research coordinator.
  - The Kardia Mobile Device will NOT be used diagnostically to detect irregular heartbeats or abnormalities. Only heart rate will be measured during this task.
- You will be asked to fill out surveys on a computer or iPad for 45 minutes.
- You will be able to take a short break if needed during the session.

Collection of identifiable private information or identifiable biospecimens

We will collect data from your electronic medical records. This will be from the year before this study and up to 1 year after you start the study. We look at your prescribed medications and health information. This information includes contact information, medication names and dosages, blood pressure, height, weight, urine toxicology results, your health-related behaviors, your mood, and the visits that you made to the hospital and to your primary care provider. You can choose to leave the study and remove our access to your data at any time. The study team will have access to your data up until the date of your withdrawal from the study.

Participant Engagement Call (Every other week):

You will be called by a member of the study staff every other week during the 24 week study. This will be a short (5 minute) 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 any 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.

Possible Risks, Discomforts, Side Effects, and Inconveniences

The following are possible risks and side effects associated with your participation in this study:

- Some questions that you will be asked are personal. You might feel stressed or embarrassed. You may ask to see the questions before you participate in the study. If you get upset or stressed, you can call the research staff. The research coordinator can call a behavioral health provider if needed.
- You may spend extra time learning techniques and doing study tasks.
- You may have physical discomfort from any gentle movement that you do in your group.
- You may feel anxious being in a group or due to what you learn or do in group.
- You might not benefit from this program.

- 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.
- Group members will be asked to keep what you share confidential, but they may not. You may be invited to share your experiences, but you will not be forced to share personal information in group and can always ask to speak privately with a clinician afterwards if there is something you feel you want to discuss but feel worried to do so in group.
- You might experience eye strain from performing computer tasks.

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 any study-related questions or concerns.

Alternatives to Participation

Participation is **voluntary.** Whether or not you enroll in this study will not affect your health care at your primary care site. You may choose not to participate in the study and return to standard care options that are approved by your primary care clinical treatment team.

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

Potential benefits to you from being in this study are:

- You may learn about others who have similar problems as you do, helping you feel less alone
- You may feel increased accountability in your recovery by being in group
- 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 can learn skills for controlling behavior and improved well-being
- You may feel less depression, anxiety, craving, panic, stress, and pain
- You may feel more joy and gratitude

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 the study.

Costs

You will not have any additional costs from being in this study. The time related to research study visits will be given to you at no cost. Costs for group treatment sessions will be billed as usual to you or your insurance. Co-pays for group treatment will follow standard procedure for your insurance providers.

As with standard treatment, you will have to pay for your own transportation and parking to attend weekly group treatment sessions. However, the study team can provide up to $10 to reimburse you for transportation/parking costs for the baseline study session before the group starts, the first four weeks of your group (*if you do not already have transportation or if there are parking costs*), and for attending each of the 4-week, 12-week, and 24-week, in-office study sessions with computer tasks. The study staff can work with your clinical treatment team to determine if transportation assistance can be provided for your clinical group treatment sessions. Receipts from parking or proof of transportation expense will need to be provided to study staff who can add the transportation reimbursement to your payment card at the next research study visit.

Payment

You will be paid up to $228:

- $20 for screening/consent visit
- $40 for baseline surveys/computer task
- $40 at 4-week study visit
- $40 at 12-week study visit

- $40 at 24-week study visit
- Up to $48 for a completion bonus at the 24-week visit. You will get this bonus only if you have completed your baseline, 4-week, 12-week, and 24-week study visit, and at least 90% of your urine testing visits and 75% of your weekly surveys. This bonus could range from $36 to $48 depending on your weekly survey completion (at a rate of $2/week for 24 surveys completed).

You will receive payments **5 times** during the study:

Payment 1: $20 for Screening/Consent visit
Payment 2: $40 at Baseline survey/computer visit
Payment 3: $40 at 4-week study visit
Payment 4: $40 at 12-week study visit
Payment 5: Up to $88 at 24-week study visit

You will receive a prepaid card that may be reloaded as the study progresses. Study staff will fill the card with the amount of your study payment after your screening/consent, baseline, week 4, week 12, and week 24 visits. If you are provided with a reloadable card, the study staff will ask you to disclose your personal information (e.g., name, address, social security number) to PNC bank, which is required to keep this confidential information for anti-money laundering purposes.

Each time you finish a study visit you will also get to draw from a giant fishbowl filled with prizes. The fishbowl will include gift cards at multiple levels with prizes as high as $100. After you have completed all the required tasks (surveys and computer tasks) during your baseline study visits, then you will get to draw from the fishbowl until you receive a prize worth at least $1. At weeks 4, 12 and 24, you will get to draw a prize from the fishbowl for each two-week period in which you have completed both the weekly surveys for the 2 weeks and at least one urine screen. At week 4 you may have up to 2 draws from the fishbowl. At week 12 you may have up to 6 draws from the fishbowl. At week 24 you may have up to 12 draws from the fishbowl, depending on how many weeks you completed your surveys and urine screens.

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 your primary care site 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.

If you no longer want to participate in the assigned treatment group (“Group Discontinuation”), you may return to standard care options that are approved by your primary care clinical treatment team. You can leave the treatment group, but still remain in the study and complete study activities and be paid for your time, including for completing urine screens, weekly surveys, computer tasks and survey sessions.

If you choose to withdraw from the study completely (“Study Withdrawal”), you will no longer be expected to complete study activities listed above and you most likely will not be able to continue in the treatment group.

Any information collected from you before the date you leave the study will be used in the research study. If you wish to withdraw from the study, please notify the study staff either in writing or via email that you wish to do so.

The research team may decide that you can no longer be in the treatment group ("Group Discontinuation"). This could be for several reasons, including:

1. You have had a bad reaction to the study.
2. Your substance use worsens substantially requiring referral to a higher level of care.
3. You did not follow all the group rules.
   a. You breached the confidentiality of other people in the group by sharing their information outside of the group.
   b. You threatened others in the group or provided serious disruption to group.
   c. You were found to be sharing or selling your buprenorphine medication.

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

1. You threaten treatment staff or study staff.
2. You tamper with your urine toxicology screens.
3. You are unable to complete baseline survey sessions.
4. You are repeatedly too intoxicated to complete study assessments.
5. You meet study exclusion criteria.
   a. You are experiencing acute psychosis, mania, or suicidality with plan.
   b. You are judged to be cognitively unable to complete study surveys as determined by inability to complete this form, and by the cognitive screening process.
   c. You are currently participating in another experimental research study.
   d. You have previously participated in a related study.
   e. You expect to be medically hospitalized in the next 24 weeks.
   f. You expect to be incarcerated in the next 24 weeks.
   g. You are experiencing substance use severity likely requiring inpatient hospitalization.
   h. You are unable to participate in the group intervention without disrupting the group.

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 leads each session. Audio will NOT be linked to any personal or identifying information collected in other aspects of the study, including your name. Please indicate your agreement to be audio-recorded during group sessions.

I agree to be audio recorded during group sessions.

☐ I agree ☐ I do not agree

Future Contact

Sometimes the study team has information about other studies or opportunities that might interest you. Please indicate below whether you give permission for us to contact you about future studies or opportunities via email or phone. We will retain your phone number and e-mail address in a separate database from the study database.

□ I agree □ I do not agree

Social Media, Text, and Email Contact

The study team will ask you to provide your Facebook and Instagram handles, as well as the text, email, and home addresses for 3 close contacts who you are likely to stay in touch with. This is so that we can reach you regarding study surveys if you choose to discontinue treatment. Only private, direct messages will be sent to you through social media from the "Stress Reduction Study" Facebook account and "Stress Reduction Study" Instagram account. When reaching out to your 3 close contacts we will not mention this research study or the nature of the study. All of these conversations will be limited to scheduling study visits. We will also use email and text to contact you about scheduling study visits and about logistical issues related to the group intervention.

□ I agree □ I do not agree

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 any health information that identifies you. This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local proceeding. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the agency which is funding this project.

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 from the year before you enrolled in the study. during the life of this study, and for three years after you finish the study.

- We will not include any information that could identify you in any publication.
- Anonymous data from this study may be made available on a public database – it will never be made available in a way that can identify you.
- We will remove all of your identifiable information (name, address, telephone number, *etc.*) from the study database 7 years after the study has been completed.

We will make every effort to keep your information private, but we cannot guarantee it. The Cambridge Health Alliance Institutional Review Board (IRB) or the IRB at your primary care site 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. Additionally, the study staff may be required to disclose confidential information if it becomes clear that you risk harming yourself or others.

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

- Other researchers conducting this study
- Research collaborators
- 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.

- **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 Website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

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 or email 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:

The easiest way to reach the study team with questions is by email at stressreductionstudy@challiance.org.

You can also call study investigators if you have an urgent question or concern.

Zev Schuman-Olivier, MD (Principal Investigator)	617-591-6056
Thomas Fatkin (Research Coordinator)	617-806-8567

On nights and weekends, you may contact your healthcare provider if any urgent issues arise.

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-5:00pm:

IRB Chair: Dr. Lior Givon
Telephone: 617-499-8302

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

Confirmation from Person Obtaining and Documenting 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_____