Effects of RME on Engagement in Buprenorphine Treatment

NCT05184907

Informed Consent Document

Version Date: 12/20/2022

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

Study Title: Effects of Remote Motivational Enhancement on Engagement in Buprenorphine Treatment

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; Kathleen Moore, PhD

Name of Co-Investigator(s): Holly Hills, PhD, Khary Rigg, PhD, Amanda Sharp, PhD

Consent form version date or number: Version 4.0, Date: December 20, 2022

Name and telephone number of study contact to call with questions:
Cassandra Harding, Project Coordinator (857-366-0748, charding@challiance.org)

CHA IRB Number: CHA-IRB-21-22-19	**Study Sponsor(s):** CDC

Key Information

- You are invited to take part in a study called "Effects of Remote Motivational Enhancement on Engagement in Buprenorphine Treatment"
- 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 12 weeks. You will be asked to complete online surveys before beginning the study, and then again at 2, 4, and 12 weeks. The study team will continue to collect research data from your electronic health record at Bicycle Health through 24 weeks, but you will not be required to complete any study-related activities or assessments beyond 12 weeks.
- You will be randomly assigned to either the Motivational Coaching group or the Information-only group. If you are assigned to the Motivational Coaching group, you will have the opportunity to meet with a motivational coach up to 3 times to discuss your recovery goals and develop an action plan. If you are randomly assigned to the Information-only group, you will review information with your healthcare provider and have the opportunity to learn about goal setting and develop an action plan.
- You may not benefit from this intervention. If you are randomly assigned to participate in the coaching intervention, you may have moments where you feel stressed or anxious. Some of the assessment questions may increase anxiety or feelings of guilt. Despite strong efforts to maintain your confidentiality, if you participate in the online study assessments, as with any activity on the internet, it is possible that your protected health information (PHI) may be exposed.
- You may benefit from this intervention regardless of which group you are assigned. Some of the expected benefits include an increased sense of accountability in your mental well-being, more social support and access to social services, and less stress.
- You can choose at any point to return to standard care options that are recommended by your clinical team at Bicycle Health.

Introduction

Please read this form carefully. This form tells you about a study called “Effects of Remote Motivational Enhancement on Engagement in Buprenorphine Treatment.” This study is being conducted by researchers at Cambridge Health Alliance (CHA), in Cambridge, Massachusetts and at the University of South Florida (USF) in Tampa, Florida. Bicycle Health is not involved in the research activities and will only serve as the recruitment site for this study.

Taking part in this study is voluntary. You have the choice 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 may receive at Bicycle Health.

If you decide to take part in this study, you will be asked to sign this form. We will give you 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.

The Centers for Disease Control and Prevention (CDC) 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 new findings that may cause you to change your mind about being in this study.

Purpose for the Study

The purpose of this research study is to support your recovery and help you set goals related to your individual social service needs, mental health symptoms, and/or overall stress and wellness during your recovery from opioid use disorder (OUD). This study will examine how remote motivational enhancement (RME) sessions with coaches and creating an action plan can impact your connection with support services, mental health providers, and your overall stress level during recovery compared to creating an action plan without motivational coaching support and information only.

Approximately 130 participants will be enrolled in this research study.

Reasons why you have been invited to be in this study

The reason why you have been invited to be part of this research study is because you are a patient at Bicycle Health and have completed computerized screening about the status of your mental health, social vulnerability, stress level and recovery status. One of your treatment providers at Bicycle Health may have referred you to this study because they think you may benefit from setting an action plan goal for getting additional support in one of the following areas, including your mental health, stress reduction, and/or social service support. This action plan goal will help you be clear about what help you need from your Bicycle Health providers and help you access additional resources, case management services, or mental health referrals if you need and want them.

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

- You are at least 18 years of age.
- You have completed online mental health and social vulnerability screenings.
- You are a current patient of Bicycle Health receiving Opioid Use Disorder (OUD) treatment with buprenorphine/naloxone (Suboxone)
- You understand English well enough to understand procedures and questionnaires and provide informed consent.
- You have access to the internet and an electronic device with adequate data capacity to complete questionnaires and meet with motivational coaches virtually.
- You can fill out surveys on a computer or an electronic device at home.

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

If you choose to participate in this research study, you will first be screened to determine whether you are eligible for this study.

If you are found to be eligible for the study, you will be randomly assigned to either meeting with a motivational coach ("motivational coaching group") or receiving information from your healthcare provider ("information-only group"). You will be asked to complete study assessments throughout the first 12 weeks of the study. At study week 24, the research team will collect buprenorphine prescription data from your electronic health record at Bicycle Health, but you will not be required to engage in any research assessments beyond 12 weeks.

You will be expected to complete online surveys at the start of the study (baseline), week 2, week 4, and week 12. The baseline survey session may last up to 15 minutes, the survey session at week 2 may last up to 20 minutes, the survey session at week 4 may last up to approximately 40 minutes and the final survey session at week 12 may last up to 1 hour. You will be paid for time spent completing study tasks at week 2, 4 and 12.

We will ask that you NOT participate in the study if you expect the following:

- to be hospitalized in the next 12 weeks for a physical health problem
- if you expect to go to jail in the next 12 weeks
- if you are in your third trimester of pregnancy or plan to deliver within 12 weeks of study consent.
- Participation in other investigational studies is allowed during the study, including studies providing stress reduction, mental health, or social services, but only if you enroll in the other studies after week 2 of this current study.

Procedures (what will happen during this study)

As part of your participation in this study, the research team will need access to the computerized screening results that you completed online through MindWell for Bicycle Health. These MindWell screenings include the Computerized Adaptive Testing for Mental Health (CAT-MH) surveys, the Perceived Stress Survey (PSS), and the Brief Addiction Monitor (BAM) survey. The research team will only obtain these results after you have provided consent.

If you take part in this study, you will be asked to complete the following:

- Consent/Initial Screening Session: You will sign this informed consent form if you are interested and eligible to participate in the study. A Research Coordinator will review the inclusion and exclusion criteria for the study with you to determine if you are eligible to participate in the study.

After you are screened and have signed the informed consent form, you will be randomly assigned to either the Motivational Coaching group or the Information-only group, and you will be encouraged to schedule an appointment within 2 weeks with your Bicycle Health prescriber to receive information about your MindWell screening results.

Regardless of which group of the study you are assigned to, you will be asked to complete the following:

- Between weeks 1-2, you will watch a short video on goal-setting and describe up to 3 action plan goals (related to mental health, social services, and stress reduction/mental wellness services that you feel you want and need) and then follow-up surveys will ask about whether you have initiated or completed any of your action plan goals.
- Based on your MindWell screening results, Bicycle Health may provide you information about what might support your mental health, recovery, and social service needs with contact information for you to pursue additional support if needed either through a Bicycle Health Prescriber or Social Worker, case management, or referrals.

- You also will be asked to complete online surveys related to your demographic characteristics, mental health, addiction status, action plan and goal setting progress, treatment and service needs, and overdose history on a website at the start of this study (baseline) and then again at week 2, week 4 and week 12. Baseline surveys will take up to 15 minutes to complete, week 2 surveys may take up to 20 minutes to complete, week 4 surveys may take up approximately 40 minutes to complete, and week 12 surveys may take up to 1 hour to complete.

If you are assigned to the **Motivational Coaching arm of the study**, you will be asked to complete the following in addition to the activities listed above:

- Remote Motivational Enhancement (RME) Coaching Sessions: Participate in 1-3 video conferencing sessions with a motivational coach within 30 days of starting the study. The coach may also review your MindWell screening results with you and assist you in developing your action plan.

Support Calls and Text Messages:

You may be called by a member of the study staff at various times during the first 12 weeks of the study. This will be a short (5-10 minute) outreach call to provide reminders to complete study surveys. During this call, the study staff can help you answer any questions regarding study assessments or study activities and will assist you with any problems you may have in filling out the surveys. If you don't answer this phone call, the study staff will leave a message. A study team member may continue to call and leave several voicemails or reach out by email or text message for reminders or if they do not hear back from you.

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. There is a possible risk for worsening of underlying mental health symptoms or increased anxiety due to discussing your emotions during the assessments. If you get upset or stressed, you can call the research staff. The research coordinator can call a behavioral health provider at Bicycle Health if needed.
- You may spend extra time doing study tasks.
- 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.
- If you are randomly assigned to participate in virtual coaching:
    - You may feel anxious about sharing personal information with a motivational coach.

We will be happy to answer any questions you have about these risks. 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 Bicycle Health. You may choose not to participate in the study and return to standard care options that are approved by your clinical treatment team at Bicycle Health.

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

- You may feel increased awareness of how your decisions impact your mental well-being by engaging in monthly computerized surveys.

- You may feel increased accountability in your mental well-being by engaging in motivational coaching sessions if you are assigned to the intervention group.
- You may feel increased mental well-being by completing online assessments that will help guide you in goal setting and developing wellness and recovery-oriented action plans.
- You may become more engaged in your Suboxone treatment at Bicycle Health due to the enhanced social support and connection to social service and mental health services.
- You may feel less depression, anxiety, and stress.
- You may receive increased resources and access to the proper level of wellness education, support or mental health care.

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. All study-related visits and procedures will be given to you at no cost. If you meet with your treatment team at Bicycle Health or are referred to outside behavioral health care providers, costs related to your Bicycle Health standard care will be billed as usual to you or your insurance if you choose to pursue these referrals and visits.

Payment

You will be paid up to $120 in Amazon electronic gift cards if you complete all of the study surveys within 48 hours of receiving the survey emails.

- Survey Completion at week 2: **$25**
- Survey Completion at week 4: **$25**
- Survey Completion at week 12: **$50**
- Bonus compensation for completing week 2 survey within 48 hours of receiving the email with the survey links: **$5**
- Bonus compensation for completing week 4 survey within 48 hours of receiving the email with the survey links: **$5**
- Bonus compensation for completing week 12 survey within 48 hours of receiving the email with the survey links: **$10**

If you do not complete the study surveys within 48 hours after receiving the email notification, you will still be eligible to receive the survey completion payments (up to **$100**) for completing the study surveys even if it is outside of that time window. However, you would not be eligible for the additional bonus compensation (up to **$20**).

You will only be paid for each assessment that you complete. You will be given your payment electronically via email at the end of each assessment.

Payment comes in the form of an electronic Amazon gift card which can be redeemed throughout the study. We will send a new gift card via email at each payment time point after the corresponding surveys are completed. Your email address and telephone number will be shared with the USF Study Coordinator in order to send you these gift cards. If there are payment questions or issues, the USF Study Coordinator will contact you via telephone.

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. If you have depression or mental health symptoms that worsen during the study, you will be referred to an appropriate level of mental health care through Bicycle Health. 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. You may refuse to participate or stop your participation in this research study at any time without penalty or loss of benefits. Withdrawal or refusing to participate will not affect your relationship with Cambridge Health Alliance or the treatment you receive at Bicycle Health.

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 choose to withdraw from the study completely ("Study Withdrawal"), you will no longer be expected to complete study activities listed above. 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 intervention group ("Group Discontinuation"). This could be for several reasons, including:

1. You have had a bad reaction to the study.
2. Your mental health symptoms worsen substantially requiring referral to a higher level of care.

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 are unable to complete screening and baseline survey assessments or lose access to the internet and you are unable to participate in the assessments offered on the internet.
3. You meet study exclusion criteria:
    a. You are non-English speaking.
    b. You are unable or unwilling to use a mobile device.
    c. You are experiencing acute psychosis, mania, suicidality, self-injurious behavior, or homicidal ideation.
    d. You are judged to be cognitively unable to complete study surveys as determined by inability to complete this form, and by the screening process.
    e. You expect to be hospitalized for a medical illness in the next 12 weeks.
    f. You expect to be incarcerated in the next 12 weeks.
    g. You are in your third trimester of pregnancy.

Collection of identifiable private information:

We will collect data from your electronic medical records at Bicycle Health regarding your buprenorphine prescription data and your MindWell screening survey data that includes your response to the Brief Addiction Monitor assessment, the Perceived Stress Scale assessment, and the CAT-MH (computerized adaptive testing for mental health) assessments . 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. If you do not withdraw from the study, the study team will have access to your data collected 24 weeks from your study start date that is stored in a study database for up to 7 years.

If all identifiers (name, date of birth, etc.) are removed, it is possible that the data collected for this study may be used for future research studies or distributed to another investigator for future research studies without your consent/permission.

Audio-Video Recording of Coaching Sessions

If you are randomly assigned to participate in the coaching intervention group of this study, some of your coaching sessions may be audio-video recorded. This is so that we can monitor the way the coaches are conducting the sessions with you. The audio-video recordings will be saved with your assigned study identification number, unique letter combination, date, and your motivational coach's identification number, but will NOT be linked to any other personal or identifying information collected in other aspects of the study. Please indicate your agreement to be audio-video recorded during group sessions.

I agree to be audio-video recorded during coaching sessions.

☐ I agree ☐ I do not agree

Text, Telephone and Email Contact

The study team will ask you to provide your email and telephone number to text and call you on. This is so that we can reach you regarding study surveys. We will use unencrypted email, telephone calls, and text messages to contact you about study assessments related to the group intervention, should you miss a study assessment.

I agree to be contacted via text message.

☐ I agree ☐ I do not agree

I agree to be contacted via telephone.

☐ I agree ☐ I do not agree

I agree to be contacted via unencrypted email.

☐ 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 your individually identifiable health information.

Additional privacy protections:

This research is covered by a Certificate of Confidentiality from the Centers for Disease Control and Prevention (CDC). This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

If you take part in this study, you agree to let the research team use your medical information from your Bicycle Health Electronic Health Record. Researchers will have access to your PHI through the Bicycle Health application and web platform. 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 for up to 24 weeks after enrolling in 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 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) 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 (at both Cambridge Health Alliance and the University of South Florida),
- The study sponsor (CDC) and any companies that the sponsor uses to oversee, manage, or conduct the study,
- Research collaborators (the University of South Florida (USF)
- Data and Safety Monitoring Board (this is an independent group of experts who monitor study participant data and safety while a study is taking place),
- Clinical staff not involved in the study, but involved in your regular treatment (i.e., Bicycle Health)
    - **Bicycle Health is not involved in the research**; however, your personal health information that is stored in Bicycle Health's applications may be shared with the research team.
    - The research team may share sensitive information stored in your study records with the Bicycle Health treatment team if you are at risk of harming yourself or others.
- 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 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 7 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 charding@challiance.org

You can also call study investigators if you have an urgent question or concern regarding the research study**:**
Zev Schuman-Olivier, MD (CHA Co-Principal Investigator): 617-591-6056
Cassandra Harding (CHA Project Coordinator): 857-366-0748

On nights and weekends, you may contact your Bicycle Health healthcare provider if any urgent treatment-related or mental health 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: Sarah Nelson
Telephone: 617-806-8702

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