UMASS CHAN MEDICAL SCHOOL

COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS IN RESEARCH

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Title: RAE (Realize, Analyze, Engage)- A Digital Biomarker Based Detection and Intervention System for Stress and Craving During Recovery from Substance Use Disorder: Phase II

Grant No.: R44DA046151

Sponsor: National Institutes of Health – National Institute on Drug Abuse, ContinueYou, LLC

Investigator: Stephanie Carreiro, MD

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Daytime phone number: 508-421-1400

Consent Version: 6/28/2022

You are being invited to take part in a research study. Someone will explain this research to you. This form helps to sum up their explanation.

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KEY INFORMATION

You are being invited to participate in a research study because you are currently in treatment for a substance use disorder (SUD). If you have questions or don't understand something, please ask.

Taking part in this research is voluntary and completely up to you. You are free to say no or to leave the research at any time. There will be no penalties or changes in the quality of the health care you receive, and you will not lose any benefits to which you are otherwise entitled.

The main question this study is trying to answer is whether the RAE system (a mobile phone app and a connected wearable sensor) can improve treatment outcomes for individuals who are in treatment SUD.

If you join this research, you will be randomly assigned (like pulling a name out of a hat) to receive either:

- Usual Care (Control)
- RAE + Usual Care (Intervention)

In either group, you will still receive the same care you otherwise would with a treatment provider and you will also receive a Garmin smartwatch. However, if you are randomized into the "RAE + Usual Care" group, you will also be given access to the RAE Health app. You will participate in a baseline visit where we will collect some basic information about you, and you will be asked to fill out several surveys. You will be guided through set up of the RAE app and smartwatch and will receive a demonstration on the technology. You will be asked to use the RAE system for 30 days; at the end you will receive additional surveys to fill out. You may also be asked to participate in a brief interview. At 3, 6, and 12 months after the study, we will send you additional surveys for you to fill out to see how you are doing.

You may not want to be in this study if you are uncomfortable with:

- Talking about substance use disorder with researchers
- Wearing a sensor and using a mobile app
- Sharing your private information with researchers, including:
    - Your medical and substance use history, or information about stress and drug craving
    - Data from a mobile phone app and a wearable sensor
- Allowing us to review the results of your urine drug screen and assessments collected by your treatment program
- Sharing any data entered in the app. The RAE app is a commercial product, owned and operated by a private company (ContinueYou, LLC). Any data that would be collected as part of routine use of the RAE app (including potentially identifiable information that you use to create login credentials and data from your wearable sensor) may be stored by RAE Health as outlined in the company's privacy policy. This policy is shown when you first open the app, and **you are required to agree to these terms in order to set up an account before you can use the app.** If you don't agree to any of the terms in the RAE Health privacy policy, you should not participate in this study. A copy of the RAE

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Health privacy policy will also be provided to you before you consent to enrolling in the study.

Risks:

- You may become upset or uncomfortable answering questions about drug use, craving, and stress. If this occurs, you can decline to answer any question or can ask to stop a study-related interview at any time.
- The sensor could irritate your skin or cause physical discomfort. This is unlikely, and if it occurs, we expect this would resolve if you simply take the sensor off.
- We will take steps to protect your personal information. However, there is a risk of breach of confidentiality. If the breach involves information that you would not want shared (e.g., that you have used drugs, that you are pregnant), this could be damaging to you. For example, it could make it harder for you to get or keep a job or insurance, or there could be legal consequences. We believe the chance these things will happen is very small, but we cannot make guarantees. There is a theoretical risk that the biometric data could be used to identify substance use. However, we think that this is unlikely because the app is only programmed to detect stress and craving. If we (the study team) learn that you may want to hurt yourself or others, or are severely depressed, we will take steps to share this information with someone who can get you help.

Benefits:

- Your participation will help us to gain knowledge that may help better treat others with substance use disorder in the future
- The RAE system may help support your recovery process
- We cannot promise any direct benefits to you from this research.

Alternatives: Your alternative is to not take part in the research. You do not need to be in the study to receive treatment for your condition.

Conflict of Interest: The principal investigator collaborates with RAE Health as an academic partner and has received funds from RAE to conduct similar studies in the past. Dr. Carreiro has also received an investigator-initiated grant in 2015 from RAE Health for preliminary data collection that led to this NIH award and has no other financial COI. Specifically, aside from receiving the NIH funds from the UMass Chan subcontract of the grant, the PI does not receive any funding from RAE Health for research, consulting, or any other activities, and receives no financial benefit from the app.

If you think you might like to participate in this research, please continue reading to learn more about the details of this study.

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STUDY DETAILS

How many people will take part in this research?

About 300 people will take part here at UMass Chan Medical School.

How long will I be in this research?

You will be asked to wear the sensor and use the RAE app (if applicable) for 30 days. After that, we will continue to send you surveys at 3, 6, and 12 months after beginning the study to see how you are doing.

What happens if I say yes, I want to be in this research?

Baseline Visit (Day 0): You will be assigned into a study group by chance (like pulling names out of a hat). 150 people will be in the Usual Care group and 150 will be in the RAE + Usual Care group. You cannot choose your study group. You will be given a brief training session on how to set up and use the technology. If you give us permission, we will also meet with your treating provider to train them on how to use the technology as well. You will also be asked to fill out several surveys about your medical and substance use history and standardized surveys about your quality of life. This visit will occur in person or via secure videoconference (Zoom), and we expect it to take **less than one (1) hour**.

Active Study Period (Day 0-30):.

If you are selected to the RAE + Usual Care group: You will be asked to use the RAE system (mobile app plus sensor) for one month and will need to wear the sensor at all times, except when it needs to be charged. The sensor will collect data about you and will try to predict when you are experiencing stress or a drug craving. The app will send you a notification if it detects stress or craving, and you will be prompted to answer a series of questions about how you are doing at that moment. You will also be offered several short app-based activities to possibly reduce stress (which you can accept or decline). Activity options include journaling, guided deep breathing, or calling/texting someone in your support system.

You will also continue to receive standard of care treatment from your SUD treatment program.

If you are selected to the Usual Care group: You will also receive standard of care treatment from your SUD treatment program.

Exit Visit (30 Days Post-Enrollment): You will be asked to complete several surveys about your experience in the study and how you are doing overall. We expect this visit to take **less than 30 minutes**.

You may be asked to participate in an optional exit interview. The interview would be voice recorded, and we will ask you not to mention private information about yourself or others

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(specifically others you are in treatment with). We expect the optional interview to take **less than 45 minutes.**

Follow-Up Surveys (3, 6, and 12-Months Post-Enrollment): You will be emailed surveys at these time periods which will ask some brief questions about your continued treatment, sobriety and need for hospitalizations. You will again be asked to complete the standardized surveys about your quality of life. We expect each follow up to take **less than 30 minutes in total to complete**.

Table 1: Schedule of surveys

Visit	**Intake**	**WHOQOL**	**BASIS**	**BAM**	**Perceived Stress and Craving**	**PHQ-9**	**Exit Survey**	**System Usability Scale**	**Follow up**
Baseline	X	X	X	X	X	X			
Exit		X	X	X	X	X	X	X	
3 month		X	X	X	X	X			X
6 month		X	X	X	X	X			X
12 month		X	X	X	X	X			X

The RAE Health app is considered an investigational device. This means that it is not approved by the Food and Drug Administration (FDA).

- We will be collecting data of the effects of RAE using several standardized questionnaires described above.
- Currently RAE is only available to research participants; in the near future RAE may be available as a subscription through your treatment provider outside of the research context
- You will continue to have access to RAE at the end of the 30-day study period to use if you wish

Will you be collecting any specimens from me?

We will not be directly collecting any specimens from you. The research will not include whole genome sequencing.

Will it cost me any money to take part in this research?

You or your insurance will not have to pay for tests and procedures that are done for research purposes only. You will not be charged for the Garmin smartwatch, or for access to the RAE

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app. You will be responsible for costs associated with routine use of your mobile phone, including the cost of data plans and/or internet access.

You or your insurance will be billed for all routine medical and diagnostic costs that are part of the standard of care for treating your condition. This may include the cost of tests, procedures, or medicines to manage any side effects. You will be responsible for any deductibles, co-payments, or co-insurance payments that your coverage normally requires.

Will I be given any money or other compensation for being in this study?

You will be compensated for your time; the study compensation will be valued at up to $159. This will be broken down as follows:

- You will be allowed to keep the study sensor (Garmin Vívosmart 4 ®) which is a retail value of $99.
- You are able to receive up to $60 over the course of the study for completing the research-related surveys.
    - You will be compensated $15 each time you complete a set of surveys at 1, 3, 6 and 12 month follow ups (Shown in Table 1 above)
    - The retail gift cards will be sent to you electronically, either via text or email. If you would prefer a physical gift card, please let study staff know and we will mail it to you.
- At this time, we do not think that the results of the research (even if identifiers are removed) will lead to commercial profit. In the event it does, there are no plans to share profits with you.

What happens if I am injured because I took part in this research?

If you are injured while in the study, seek treatment and contact the study doctor as soon as you are able.

The UMass Chan Medical School does not provide funds for the treatment of research-related injury. If you are injured as a result of your participation in this study, treatment will be provided. You or your insurance carrier will be expected to pay the costs of this treatment. No additional financial compensation for injury or lost wages is available.

You do not give up any of your legal rights by signing this form.

What are my responsibilities if I take part in this research?

If you take part in this research, you will be responsible for:

- Using the RAE app and sensor for 30 days
- Completing the surveys for the baseline, exit and follow-ups at 3, 6, and 12- months after enrollment
- Following our (the study doctor and research staff) directions

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- Telling us (the study doctor and research staff) about all prescriptions, over-the-counter medications, and vitamins or herbal supplements you are taking, and about all of your health issues
- Telling your other health care providers that you are in a research study.

What happens if I say yes, but I change my mind later?

If you decide to leave this research, contact the research team so that the investigator can remove you from the protocol. If you decide to stop, we may ask if we can contact you for safety reasons or to follow your health. We may also ask you if we can collect data from your medical records and your routine medical care. You may ask us to destroy your information at any time. However, we will not be able to destroy any research data that has already been created. We also will not be able to destroy data that have already been shared outside of UMass Chan.

Can I be removed from the research without my approval?

The person in charge of this research study can remove you even if you want to continue. This may happen if:

- It is in your best interest
- You have a side effect that requires stopping the research
- You need a treatment not allowed in this research
- The research is canceled by the FDA or the sponsor
- You are unable to use the research device
- You are unable to keep your scheduled appointments

We will tell you about any new information that may affect your health, welfare, or choice to stay in this research.

How will my information be stored and when will it/they be destroyed?

We will remove your name and any other information that could directly identify you from your data. We will replace this information with a code number. We will create a master list linking your code number to your name. We will keep this list separate from your data. We will keep paper documents under lock and key. We will keep electronic health information and research data on secure computer networks. These computer networks have many levels of protection.

De-identified data will be entered into the Principal Investigator's data-bank (data repository). There is no limit on the length of time we will store your de-identified data. However, we will destroy the master list of identifiers when the data analysis for the study is complete.

It is possible that we might use the de-identified research data in other future research. We may also share data with researchers and companies that are not part of UMass Chan. In these cases, we will not share your name or other information that identifies you directly, and we will not come back to you to ask for your consent.

Who has access to my information?

Signing this document means you allow us, the researchers in this study, and others working with us to use some protected health information for this research study.

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At Aware Recovery Care, you will be providing urine samples for drug testing as part of your treatment program. We will not have direct access to these samples, but we will be able to view the results. As part of the research, Aware Recovery Care or any other healthcare facility where you are treated may disclose the following information:

- Demographic and identifying information like your name, date of birth, address, telephone number, and your email address
- Related medical information like family medical history, and current and past medications or therapies
- Information about drug testing and drug use
- All tests and procedures that will be done in the study

Your health information and research records will be shared with the study team and with individuals and organizations that conduct or watch over this research, in order to conduct the study and to make sure it is conducted as described in this form. Information and records may be shared with:

- The research sponsors
- People and companies who work with the research sponsor
- Federal and state government agencies, such as the Food and Drug Administration and state auditors
- The UMass Chan Medical School and UMass Memorial Health, including their Institutional Review Board (IRB) and research, and compliance offices
- Health care providers who provide services in connection with this study
- People and companies who work with UMass Chan and UMMH on activities related to the research

We will protect your identifiable information from disclosure to others to the extent required by law, but we cannot promise complete secrecy. We are legally required to disclose information about child abuse, abuse of the elderly or disabled, you potentially harming yourself or others, and certain reportable diseases. Any disclosure carries the potential for re-disclosure. Once your protected health information is disclosed, it may no longer be protected by federal privacy laws.

Your authorization does not have an expiration date. If you change your mind, you have the right to revoke your authorization in writing or using the contact information at the beginning of this form. If you revoke your authorization, you will not be allowed to continue to participate in the study. We will not collect any new information about you. However, information that we have already collected will stay in the study database and cannot be removed in order to maintain the integrity of the research. Your information may still be used and disclosed if you have an adverse event.

You do not have sign this authorization. If you choose not to sign, it will not affect your treatment, payment, or enrollment in any health plans, or affect your eligibility for benefits. You will not be allowed to participate in the research study.

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We may publish the results of this research. However, we will keep your name and other identifying information confidential.

Because the National Institutes of Health (NIH) funds this research, this study has **a Certificate of Confidentiality.** The Certificate keeps us from sharing your identifiable sensitive information collected for the research unless you allow us to do so. It also keeps us from being forced to release information that may identify you, as part of a court, legislative, administrative, or other proceeding. There are times when the Certificate cannot be used. For example, we cannot refuse to give information to government agencies that oversee or fund research, such as the NIH or Food and Drug Administration (FDA). The Certificate also does not stop us from giving information to local government agencies, law enforcement personnel, or others if we suspect you or someone else is in danger or if we are required to do so by law.

The Certificate does not stop you from giving out information about yourself or your participation in the research. If you give an insurer, employer, or someone else your permission for us to release information, we will do so. 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.

Will you share any results with me?

It may be several years before the results of the research are available. If you would like us to try to reach you at that time, please let us know. We will ask for your contact information.

We can share your individual results with you if you ask. However, because these are research tests, they are for your interest only. They cannot tell you about your health or diagnose any condition. They will be available at the end of your active study period (30 days).

Who can I talk to?

If you have questions, concerns, or complaints, or think this research has hurt you or made you sick, talk to the research team at the phone number listed on the first page.

This research is being overseen by an Institutional Review Board. An IRB is a group of people who perform independent review of research studies. You may talk to them at (508) 856-4261 or irb@umassmed.edu for any of the following:

Your questions, concerns, or complaints are not being answered by the research team.

You cannot reach the research team.

You want to talk to someone besides the research team.

You have questions about your rights as a research participant.

You want to get information or provide input about this research.

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