Sensing Physiological Symptoms of Opioid Withdrawal and Cravings in Patients With Opioid Use Disorder (Closed-Loop)

NCT06487533

May 2, 2024

IRB Approved Template
MUST BE APPROVED
FOR SITES BEFORE USE
May 02, 2024

RESEARCH SUBJECT CONSENT FORM

TITLE: Sensing Physiological Symptoms of Opioid Withdrawal and Cravings in Patients with Opioid Use Disorder

PROTOCOL NO.: SBM-OWP-09
WCG IRB Protocol #20241756

SPONSOR: Spark Biomedical, Inc.

INVESTIGATOR: Name
Address
City, State Zip
Country

STUDY-RELATED PHONE NUMBER(S): Number
24-Hour Number

RESEARCH CONSENT SUMMARY

You are being invited to take part in a research study. Below contains key information that will help you decide whether to join the study. This document begins with a brief summary of the research project with later sections outlining all necessary details.

What should I know about participating in research?

- Someone will explain this research study to you.
- Taking part in this research is voluntary. The choice to participate is up to you.
- You do not have to participate.
- Your choice to participate or not won't be held against you, nor negatively impact the care you receive.
- You can choose to stop the study at any time.
- If you don't understand, ask questions.
- You can ask all the questions you want before you decide.

How long will I be in this research?

Participation in this research will last approximately 14 days and include one in-person visit on each day of the study while you are in inpatient detoxification treatment.

Why is this research being done?

The purpose of this research is to measure changes in your body's signals (such as heart rate, heart rate variability, skin temperature, motion, cortisol levels) to understand how it behaves during opioid withdrawal and cravings. Two wearable devices, the

EmbracePlus device and the Corti Wearable, will be worn by participants throughout the study to gather biometric data. Data from this research study will be used to create an algorithm to accurately detect opioid withdrawal and cravings.

How many people are expected to take part in this research?

About 20 adults (18+ years) will participate in this research study.

What happens to me if I agree to take part in this research?

If you decide to participate in this research study, you will experience the following:

- Research staff will collect information about your medical and psychiatric history (including thoughts about or previous attempts to commit suicide), the medications that you currently take and plan to take as part of your treatment and measure your height and weight.
- Research staff will conduct clinical interviews and ask you to complete questionnaires that will assess your experience of withdrawal and craving symptoms and stress.
    - Clinical Opiate Withdrawal Scale (COWS) will take around 5 minutes for authorized healthcare staff to complete.
    - Short Opiate Withdrawal Scale-Gossop (SOWS-Gossop) is 10 questions and will take about 5 minutes to complete.
    - Opioid Craving Visual Analog (OC-VAS) is only 1 question and takes less than 2 minutes to complete.
    - Stress Monitoring and Response Tool (SMART) contains 23 questions and will take about 7-10 minutes to complete.
- You will be asked to provide a sample for a urine drug screen to detect Amphetamines, Buprenorphine, Benzodiazepines, Cocaine, Ethyl Glucuronide, Fentanyl, Synthetic Marijuana, Ecstasy, Methamphetamines, Methadone, Opiates / Morphine, Oxycodone, Cannabinoid (Marijuana), Tramadol, and Xylazine.
- You will be asked to wear two devices for each day of the study.
    - The EmbracePlus Smart watch will be placed on your wrist and worn daily to collect information on data which includes heart rate, changes in heart rate, temperature, skin temperature, sleep length, and quality of sleep.
    - The Corti Wearable will be placed on your forearm and worn throughout the day, except when showering or bathing to measure 4 different proteins from your sweat.
- You will meet every morning with one of the study staff to look at the skin that is in contact with the devices, to replace the 2 devices, and to discuss your medications, withdrawal symptoms, and your participation in counseling and therapy activities.

Could being in this research hurt me?

Although not everyone will experience these, the most common risks or discomforts that you may expect from taking part in this research include:

- Dermal (skin) irritation
- Erythema (redness where device is touching the skin)
- You may find it difficult or tiresome to comply with assessments administered throughout the study.
- You may find it difficult to comply with the 24-hour requirement of wearing the watch device on your wrist and the second device on your forearm.

We will carefully check daily for these possibilities and teach you about wearing the devices to help decrease these situations. There is also the possible loss of confidentiality of your research information.

Will being in this research benefit me?

The research team cannot promise any personal benefits from participating in this study. However, others may benefit from the knowledge gained from this study.

What other choices do I have besides taking part in this research?

You may choose not to take part in this research. You will receive standard of care treatment for opioid use dependence and withdrawal regardless of whether you take part in this study.

What else should I know about this research?

Other information that may be important for you to consider so you can decide whether to take part in this research is that there may be unknown risks to a fetus or embryo. Therefore you cannot participate in this study if you are pregnant, planning to become pregnant or breast feeding while in this study.

DETAILED RESEARCH CONSENT

You are being invited to take part in a research study. A person who takes part in a research study is called a research subject, or research participant.

What should I know about participating in research?

- Someone will explain this research study to you.
- Taking part in this research is voluntary. The choice to participate is up to you.
- You do not have to participate.
- Your choice to participate or not won't be held against you, nor negatively impact the care you receive.
- You can choose to stop the study at any time.
- If you don't understand, ask questions.

- You can ask all the questions you want before you decide.

How long will I be in this research?

Researchers expect that your participation will last 14 days and include an in-person visit on every day of the study.

Why is this research being done?

The purpose of this research is to measure changes in your body's signals (such as heart rate, changes in heart rate, skin temperature, motion, cortisol levels) to understand how it behaves during opioid withdrawal and cravings. Two wearable devices, the EmbracePlus device and the Corti Wearable will be worn throughout the study to gather biometric data. Data from this clinical trial may be used to create an algorithm to detect opioid withdrawal and cravings. About 20 subjects will take part in this research.

What happens to me if I agree to take part in this research?

The picture below shows what will happen during the study.

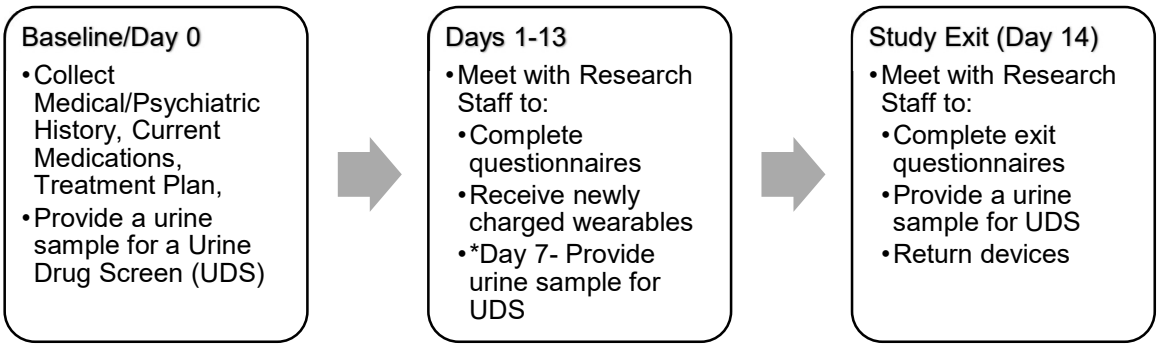

Figure 1: Study Flow

Baseline

After signing this Informed Consent form, the first step will be for research staff to ask you some questions to see whether you qualify to be included in the study. The following will happen during the prescreening and baseline assessment at the residential treatment center:

- Research staff will collect information about your medical and psychiatric history (including thoughts about or previous attempts to commit suicide), the medications that you currently take and plan to take as part of your treatment and measure your height and weight.

- Research staff will conduct clinical interviews and ask you to complete questionnaires that will assess your experience of withdrawal and craving symptoms and stress.
    - Self-Report Opioid Use
    - Clinical Opiate Withdrawal Scale (COWS) will take around 5 minutes for authorized healthcare staff to complete.
    - Short Opiate Withdrawal Scale-Gossop (SOWS-Gossop) is 10 questions and will take about 5 minutes to complete.
    - Opioid Craving Visual Analog (OC-VAS) is only 1 question and takes less than 2 minutes to complete.
    - Stress Monitoring and Response Tool (SMART) contains 23 questions and will take about 7-10 minutes to complete.
    - Columbia-Suicide Severity Rating Scale contains 6 questions and will take about 5 minutes to complete.
- You will be asked to provide a sample for a urine drug screen to detect any of the following substances: Amphetamines, Buprenorphine, Benzodiazepines, Cocaine, Ethyl Glucuronide, Fentanyl, Synthetic Marijuana, Ecstasy, Methamphetamines, Methadone, Opiates / Morphine, Oxycodone, Cannabinoid (Marijuana), Tramadol, and Xylazine.

Days 1 – 14
The two wearable devices that will be worn daily on Days 1 – 14 of the study include the EmbracePlus Smart Watch and the Corti Wearable (Figure 2).

Figure 2: (Left) EmbracePlus Smart Watch, and (Right) Corti Wearable

The EmbracePlus Smart watch will be worn on the wrist and provide measurements of heart rate, changes in heart rate, temperature, electrodermal activity (electrical characteristics of the skin), body motion, and sleep metrics (sleep duration and sleep quality).

The Corti Wearable will be worn on the forearm and provide biochemical metrics from your sweat, including cortisol, melatonin, tumor necrosis factor alpha, and interleukin-6. These devices will be worn continuously except for during showering or bathing.

Study Schedule of Activities
Each morning, you will meet with research study staff to receive newly charged devices. Study personnel will measure your opioid withdrawal symptoms and collect information on your medications, engagement in recovery therapies, and stress using the SMART tool. You will also be asked about your opioid withdrawal and cravings, using the SOWS-Gossop and Opioid Cravings Visual Analog Scale, three times daily.

On Days 7 and 14, you will also be asked to provide a sample for a urine drug screen to detect any of the following substances: Amphetamines, Buprenorphine, Benzodiazepines, Cocaine, Ethyl Glucuronide, Fentanyl, Synthetic Marijuana, Ecstasy, Methamphetamines, Methadone, Opiates / Morphine, Oxycodone, Cannabinoid (Marijuana), Tramadol, and Xylazine.

Throughout the study, you will be monitored for any adverse events (side effects).

Study Exit will occur on Day 14. You will return all wearable devices to the study personnel. You will be asked to provide input on the usability of the wearable devices during your treatment.

Follow-Up by Push Notification, Telephone or Email
You (or in the event the research team is not able to reach you, your emergency contact) may be contacted by push notification (electronic request), phone call, and/or email as needed to discuss any issues that come up or to see if you have experienced any adverse events (side effects) or medication changes.

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

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

- Wearing the two wearable devices when required by the study protocol
- Following the study-specific instructions provided by the research team
- Providing the research team with any new information related to your medical history and current clinical treatment (e.g., new medications, changes in existing medication dosage, new medical issues, etc.)
- Promptly reporting any side effects to the research team

ALL SITES: The following risk information from [START] through [END] cannot be altered without submission of supporting documentation and/or Sponsor approval of changes. Submitted changes without appropriate documentation will be reverted during Board review.

[START]

Could being in this research hurt me? What will researchers do to help protect me from these potential risks?

Although not everyone will experience these, the most common risks or discomforts that you may expect from taking part in this research include:

- Dermal (skin) irritation
- Erythema (redness where device is touching the skin)
- You may find it difficult or tiresome to comply with assessments administered throughout the study.
- Temporary pain or discomfort due to wearing the sensor
- Allergic contact dermatitis (red, itchy rash due to an allergy)
- There may be unknown risks from your participation in the study.

[END]

The research team will try to minimize these risks by:

- Training you on how to use the wearable devices.
- Meeting with you daily to assess any issues with the device or protocol.

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

No. The wearable devices you will use during the study are provided at no cost.

Will being in this research benefit me?

The research team cannot promise any personal benefits from participating in this study. However, others may benefit from the knowledge gained from this study.

What other choices do I have besides taking part in this research?

You may choose not to take part in this research. You will receive standard of care treatment for opioid use dependence and withdrawal regardless of whether you take part in this study.

Who will have access to my research records?

There are reasons why information about you may be used or seen by the researchers or others during or after this study. Examples include:

- Government agencies, such as the National Institute of Health and the US Food and Drug Administration,
- the research study sponsor,

- authorized auditors, and/or
- the Institutional Review Board (IRB) may need the information to make sure that the study is done in a safe and proper manner.

What happens to the information collected for this research?

The research team will keep the information collected about you during the research. Your name and other information that can directly identify you will be stored securely and separately from the research information collected from you.

The results of this study may be published in an article or presentation but will not include any information that would let others know who you are. 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.

The research team may use or share your research information for future research studies. If your information is shared with other researchers, it will be de-identified, which means that it will not contain your name or other information that can directly identify you. This research may be similar to this study or completely different. The research team will not ask for your additional informed consent for these studies.

How will the researchers protect my information?

Even with every safeguard, breach of confidentiality is always a potential risk for any research that collects information about you. The research team protects your information from disclosure to others to the extent required by law. The research team cannot promise complete secrecy. Although the research team will do their best to protect your information during collection, storage, and analysis, it's possible that unauthorized people might gain access to your information.

Here are the steps that have been taken to help protect you from these potential risks. All research information collected will be stored electronically on the cloud; the term "cloud" refers to large computers located in different parts of the world where individuals may keep and remotely access their personal and professional files. Each cloud service has its own policies and methods for preventing unauthorized individuals from accessing files stored on their cloud servers. The cloud service used to store files associated with this research study meets state and federal clinical research data privacy and confidentiality protection requirements.

Only authorized and trained research-related personnel have access to this cloud. All access will be monitored and tracked. The research team will assign your information a random code, rather than your name or any other details that others could use to identify you. During the study, the code key that links your coded information to you will be secured and stored separate from your data by research staff. Once the study is

completed, this code key will be destroyed; as a result, it will be impossible for others to know the information came from you.

Information about a Certificate of Confidentiality for this research:
Spark Biomedical, Inc. has received a Certificate of Confidentiality from the government which will help protect the privacy of research subjects. The certificate protects against the involuntary release of information about you collected during the course of this research. The researchers involved in this study cannot be forced to disclose any information collected in this study in any legal proceedings.

However, you may choose to voluntarily disclose the protected information and this certificate does not prohibit such voluntary disclosure. Furthermore, the parties listed in the Confidentiality / Authorization section of this consent form may review our records under limited circumstances and this certificate does not prohibit such disclosure.

Who can answer my questions about this research?

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

This research is being overseen by WCG IRB. An IRB is a group of people who perform independent review of research studies. You may talk to them at 855-818-2289 or clientcare@wcgclinical.com if:

- You have questions, concerns, or complaints that are not being answered by the research team.
- You are not getting answers from the research team.
- You cannot reach the research team.
- You want to talk to someone else about the research.
- You have questions about your rights as a research subject.

What if I am injured because of taking part in this research?

The researchers have taken steps to minimize the risks of this study. Please tell the researchers immediately if you have any injuries or problems related to your participation in the study.

The research team may be able to assist you with obtaining emergency treatment, if appropriate, but you or your insurance company will be responsible for the cost.
The sponsor will pay any charges that are not covered by insurance policy, provided the injury was not due to your underlying illness or condition and was not caused by you or some other third party. No other payment is routinely available from the sponsor.

Will the researchers tell me if they learn of new information that could change my willingness to stay in this study?

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

Can I be removed from this research without my approval?

The person in charge of this research can remove you from this research without your approval. Possible reasons for removal include:

- It is in the best interest of your health and safety.
- You have a side effect that requires stopping the research activities.
- You need a treatment not allowed in this research.
- You become pregnant.
- The research is canceled by the FDA or the sponsor.
- You are unable or refuse to use one or both devices.
- You are unable or refuse to keep your scheduled research appointments.

What happens if I agree to be in this research, but I change my mind later?

You are free to leave the study at any time. If you leave the study before it is finished, there will be no penalty to you. If you decide to leave the study before it is finished, you need to contact the research team and coordinate a time to pick up the devices and complete the necessary paperwork.

If you choose to tell the researchers why you are leaving the study, your reasons may be kept as part of the study record. The researchers will keep the information collected about you for the research unless you ask us to delete it from our records. If the researchers have already used your information in a research analysis it will not be possible to remove your information.

Will I be paid for taking part in this research?

You will be paid up to $200.00 for your participation in this research: you will receive $100 for completing Day 7 and $100 for completing Day 14 of the procedure.

Statement of Consent:

Your signature documents your consent to take part in this research. You will receive a signed copy of this consent form.

Signature of adult subject capable of consent	Date
Signature of person obtaining consent	Date

****For Sites in California****

AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES

What information may be used and given to others?
The study doctor will get your personal and medical information. For example:

- Past and present medical records
- Research records
- Records about phone calls made as part of this research
- Records about your study visits.

Who may use and give out information about you?
The study doctor and the study staff. They may also share the research information with an agent for the study doctor, if applicable.

Who might get this information?
The sponsor of this research. "Sponsor" means any persons or companies that are:

- working for or with the sponsor, or
- owned by the sponsor.

Your information <u>may</u> be given to:

- The U.S. Food and Drug Administration (FDA),
- Department of Health and Human Services (DHHS) agencies,
- Governmental agencies in other countries,
- The institution where the research is being done,
- Governmental agencies to whom certain diseases (reportable diseases) must be reported, and
- Institutional Review Board (IRB)

Why will this information be used and/or given to others?

- to do the research,
- to study the results, and
- to make sure that the research was done right.

If the results of this study are made public, information that identifies you will not be used.

What if I decide not to give permission to use and give out my health information?
Then you will not be able to be in this research study.

May I review or copy my information?
Yes, but only after the research is over.

May I withdraw or revoke (cancel) my permission?
This permission will be good until December 31, 2070.

You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor. If you withdraw your permission, you will not be able to stay in this study.

When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

Is my health information protected after it has been given to others?
There is a risk that your information will be given to others without your permission.

Authorization:
I have been given the information about the use and disclosure of my health information for this research study. My questions have been answered.

I authorize the use and disclosure of my health information to the parties listed in the authorization section of this consent for the purposes described above.

AUTHORIZATION SIGNATURE:

Signature of Participant	**Date**