CONSENT TO PARTICIPATE IN RESEARCH
Affect Therapeutics, Inc.

TITLE: Demonstration of a Digital Care Program for Methamphetamine Use Disorder

PROTOCOL NO.: R43DA055394
IRB Protocol #20215696

SPONSOR: NIDA

INVESTIGATOR: Kristin Muhlner, BA
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SUB-INVESTIGATORS: Jeff DeFlavio, M.D., Frank Muensch, Ph.D.

STUDY-RELATED PHONE NUMBER(S): 571-350-8559 (24 hours)

PARTICIPANT ID: _____

Introduction

Thank you for your interest in our research study to examine a program that uses an experimental smartphone app and other services to treat methamphetamine use disorder. You may be eligible to participate in this study if you are at least 18 years old and you are seeking treatment for methamphetamine use disorder. Being in this study is entirely voluntary. Please discuss any questions you have about the study with study staff. You may talk to your family and friends about it and take your time to make your decision.

Information in this form will be useful for deciding whether or not to be in the research study. If you decide to participate you must sign this form to show that you want to take part. If you participate, you would be one of about 90 people in Arizona who will be involved, and you would be in the study program activities for about 8 weeks. Your choice to be involved (or not to be involved) in this research study is entirely voluntary. If you choose not to participate or to stop participating, there will be no penalty or loss of benefits to which you are otherwise entitled.

Who Is Doing this Study?

Kristin Muhlner, CEO of Affect Therapeutics, Inc, is the Principal Investigator of the research study.Kristin Muhlner and Jeff DeFlavio, M.D are also co-owners and developers of the Affect app. Please feel free to ask any questions about this.

The study will examine the effects of technology-based treatment for methamphetamine use disorder. The study uses a smartphone app provided by Affect Technologies, Inc. The study sponsor is the National Institute on Drug Abuse (NIDA), which is a research agency of the federal government; NIDA is also providing funds to do the research work.

Why Is this Study Being Done?

The purpose of this study is to understand if a digital technology—the Affect app—and program services can help individuals who use methamphetamine ("meth") to stay in treatment to reduce or stop meth use.

Is there Any Cost to Me If I Participate?

You do not have to pay anything to be in this study for the activities and procedures that are provided as part of the program. If you require healthcare or other services that you would have needed regardless of your participation in the study, costs of such services are your responsibility or the responsibility of your insurance or Medicaid.

How Long Will I Be in the Research Study?

- You will be involved in the study using the Affect app for 8 weeks.
- You will receive a follow-up telephone contact from the research team for an interview at 4 weeks after the 8-week program.

What Will Happen If I Take Part in this Research Study?

If you agree to be in the study, you will be asked to download and use the Affect app and participate in program activities and procedures. These are described in this Consent form. Before you sign this form, Affect personnel will ask you to complete an oral quiz over the phone to make sure you understand the Consent form and the study. After the quiz, they will tell you if you are eligible to be in the study and will answer your questions about participation. Your voluntary involvement in the study will include activities and procedures outlined below.

Study Activities and Procedures

- Study personnel will determine your study eligibility by asking you questions and requesting that you complete two online questionnaires and an oral quiz about this Consent form conducted before you sign. If you are not eligible, you cannot be in or continue in the study. If you are eligible and agree to be involved, you will be able to sign the consent and enroll in the study as follows:
- Several assessments will occur to get baseline information.
- The 8-week program requires that you download and use the Affect app to participate in the therapeutic activities (such as counseling sessions).
- There will be weekly drug tests that you do yourself using a urine test kit that we provide. You present test results via private videochat (Zoom) with Affect personnel.
- The Principal Investigator (Kristin Muhlner) and a study Research Associate will have your permission to obtain and review your clinical and administrative records during the 8-week program.
- You will be contacted by study personnel for the follow-up telephone interviews about 4 weeks after the 8-week study intervention.

More information about the study procedures is provided below:

Baseline Information Participation

- There will be telephone and online assessments during eligibility screening, which will ask about your age, birthday date, race/ethnicity, drug use, past history of drug treatment, health-risk behaviors, criminal justice history, health, social functioning. and about your awareness of the effects of meth use and treatment for meth use. *This will take about 30 minutes.*
- Research staff will ask you to provide locator information so that you can be contacted for a follow-up interview and. You will be asked to provide your current address (where we will send urine test kits) and your smartphone number.
- Research staff will ask you to provide contact information for two individuals (family members, friends, or acquaintances) who would be able to get in touch with you. Research staff may contact these individuals if they cannot contact you directly. No information will be shared with these contacts about you or your participation in this study except to say “participants in a health study are being contacted.”
- Research staff will search available databases to get additional information about you that may already be public. Your agreement and consent to participate means that you permit database owners to provide information about you to Affect staff for research purposes.

Program Activities

The App. As a participant, you will interact with the app to learn new non-drug behaviors and coping skills (like how to avoid relapse). The program includes app tasks combining cognitive behavioral therapy (CBT) and contingency management (CM), which are common treatments for people who use meth. The app helps motivate people engage with program activities (especially the app-based tasks), doing so at their own convenience. This makes it easier to stay involved during difficult times such as the COVID pandemic and avoids problems like traveling to a clinic, also making it possible to manage work/childcare responsibilities.

App Tasks and Activities. The app provides brief, interesting 'tasks' that are designed to guide and support behavior change to avoid drugs, prevent relapse, and seek activities and behaviors that involve life without drugs. Some of the tasks are coaching experiences to encourage participation. Daily tasks are tracked in the app; to promote participation in the tasks, the completion of a task when assigned is rewarded at $0.25-0.50 each. Tasks are monitored by the app and the Care Team for completion. The Affect app supports interactions in team efforts to build peer support, helping to rebuild positive behavior patterns. The app's functions respond to needs at different stages of treatment and recovery, such as focusing on avoiding triggering factors in early stages and addressing issues during recovery such as sleep problems and craving.

Therapeutic Services for Treatment of Meth Use. You will be involved in therapeutic services that include:

- Contingency Management (CM), providing monetary incentives for drug tests (voluntary urine samples) negative for stimulants and for completion of tasks and attendance in counseling sessions.
- The CBT-based therapy delivered via the Affect app builds skills deal with cravings, using such techniques as app-promoted deep breathing exercises, daily physical exercise, and help in making and sticking to a relapse prevention plan.
- Periodic individual counseling with clinical personnel and more frequent group therapy, both via telemedicine; counseling sessions are arranged by texts from the Care Team and presented by the app as a reminder. Individual and group therapy sessions occur over Zoom, which is integrated into the Affect app.
- Referral to a psychiatrist for medication support, if needed, and remote/virtual interaction with a psychiatrist or addiction-certified physician at least once monthly during the study.

Follow-Up Interview. Affect researchers will contact you by phone for a follow-up interview about 4 weeks after your participation in the 8-week intervention.

Are There Potential Risks or Discomforts that I Might Experience from this Study?

- There are no physical risks associated with the interviews or questionnaires, nor with the activities as part of the Affect treatment program.

    - *If at any time you feel that you are in danger of harming yourself or others because of your condition, you must contact the study staff who will refer you for treatment. In an emergency, you need to call 911.*

- It is possible that you might feel uncomfortable discussing your drug use or other topics during interviews or in group therapy/counseling sessions. You may choose not to answer those questions, and you may pause a therapy session if it causes discomfort.
- Because this study involves the use of some personal information, there is a small chance that a loss of confidentiality may occur. The Affect Care Team and the research personnel are well trained in confidentiality and know how to reduce the possibility of this happening (see the section below: *"Will information about me and my participation be kept confidential?"*).

Are There Any Potential Benefits If I Participate?

You may receive benefit from being in this study if it helps you reduce or stop meth use, and that may result in improved well-being. Results of this study may lead to improved treatment for people struggling with meth use. If proven effective, the Affect program may be widely used, potentially helping people stay in treatment and leading to better health outcomes for people with meth problems.

What Other Choices Do I Have If I Choose Not to Participate?

If you chose not to participate, you may seek other treatment services available in the community. If you request, the Affect staff will provide a list of providers or services that include other programs of usual treatment offered to people with meth use problems.

Will I Be Paid for Being a Research Participant?

You are not paid for becoming a participant, but you are eligible for compensation/rewards earned from doing app tasks and for results of drug tests showing no meth present. Your eligibility for the study must be confirmed, and you must remain eligible, as described above, to be compensated. If eligibility requirements are not met, you will not be allowed to enroll in or continue in the study, and you cannot receive compensation/reward.

- You will be compensated $20 for completing the app familiarization interview (via telephone/Zoom) and $20 for completing the end-of-study interview.

- You have the opportunity to earn up to $0.50 for each of the tasks you complete (there are 5 possible tasks every day of the week in the 8-week program (the maximum possible amount is $140).
- You will receive varying rewards between $10-$30 for providing consecutive urine samples showing no meth or other illicit stimulants. If you have a test positive for meth or other stimulants, the value will reset to $0 until the second consecutive meth-free test, which will be compensated at $10.
- You will receive $20 for an end-of-study interview.
- You will receive $30 for the follow-up telephone interview.
- Compensation will be in the form of deposits to CashApp, which will be downloaded when the Affect app is downloaded onto your phone.

Will Information About Me and My Participation Be Kept Confidential?

- Any information that is obtained in connection with this study and that can identify you will remain confidential. It will be disclosed only with your permission or as required by law.
- The researchers are trained to make sure that your private information is kept confidential. Information about you will be handled as confidentially as possible.
- Transmission of responses to online web-based questionnaires and any other online survey data will be encrypted in compliance with data security policies.
- Study data will be electronically stored in dedicated, secure data storage. To reduce possible risks of security breach, research data will be stored electronically on a secure server that is encrypted and uses password protection.
- All the information about you, except this Informed Consent Form, will be identifiable only by a code number. The information that links your name with the code number will be securely stored, accessible only to the Principal Investigator and authorized Affect personnel. This link and any personal identifying information will be destroyed within six months after the completion of the study.
- All research and clinical staff receive training in protection of participant confidentiality.
- Data collected in this study will be used for research purposes only. Publications and/or presentations that result from this study will not identify you by name or other personal identifiers.
- The research team, authorized personnel of the study sponsor (Affect Technologies), the National Institute on Drug Abuse (NIDA), the U.S. Food and Drug Administration (FDA), and authorized personnel of the Institutional Review Board will have access to study data to monitor the study. No research records will be shared that contain identifiable information about you.

What Are My Rights If I Take Part in this Study?

- You may freely choose whether or not you want to be in this study, and you may withdraw your consent and discontinue participation at any time without repercussion.
- If you decide not to participate in this study, your decision will not affect or limit your access to other available treatment services to which you may be entitled.
- Once enrolled after meeting all inclusion criteria (and no exclusion criterion), you may refuse to answer questions that you do not want to answer and still remain in the study.
- You will be given access (as a web link) to a copy of the Participant's Bill of Rights, which you may access at your convenience and download for your reference.

Who Can I Contact If I Have Questions About this Study?

- Y*ou may contact the research team:* If you have any questions, complaints, or concerns about the research, you can talk to the Principal Investigator, Kristin Muhlner, at 571-350-8559 (24 hours).
- *You may contact the Institutional Review Board:* If you have questions about your rights as a research participant, or if you have questions, concerns, or complaints about the research or you want to talk to someone other than the researchers, you may contact the organization overseeing this project, the WCG IRB: 855-818-2289.

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.

By Signing this Consent Form, I Confirm the Following:

- I have read this Consent form, presented in English, which is a language that I read and understand.
- My questions have been answered to my satisfaction.
- I can leave the study at any time without giving a reason and without penalty.
- I agree to the collection, use, and analysis of my personal health information and study information collected as part of this study.
- I will have electronic access to this digital Consent form, signed and dated, which I may download to keep.
- I voluntarily agree to participate in this study.

SIGNATURE OF RESEARCH PARTICIPANT

Name of Participant_____

Signature of Participant_____

Date of Signature_____

You will be given digital access (i.e., a web link) to this Informed Consent to download and keep for your records or to access via the internet at any time.

SIGNATURE OF PERSON OBTAINING CONSENT

As the undersigned Principal Investigator (PI), I am responsible for the conduct of this study and I have delegated the explanation of this study and obtaining this Informed Consent to the Affect Care Team Coordinator.

Name of PI: Kristin Muhlner

Signature of PI: _____

Name of Affect Care Team Coordinator: _____

Signature of Affect Care Team Coordinator: _____