IRB APPROVED
Feb 18, 2021

CONSENT TO PARTICIPATE IN RESEARCH

TITLE: Field Study of a Digital Therapeutic Platform to Facilitate Treatment for Methamphetamine-Primary Stimulant Use Disorder

PROTOCOL NO.: IRB Protocol #20210518

SPONSOR: Affect Therapeutics, Inc.

INVESTIGATOR: Michael Zito, MD
SITE(S): Affect Therapeutics, Inc.
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STUDY RELATED PHONE NUMBERS: (626) 246-6230

Who Is Doing this Study?

Mike Zito, M.D., a professor at the University of California at Los Angeles (UCLA), is the Principal Investigator conducting the research. The research will examine the effects of technology-based therapeutic services for methamphetamine use disorder. The study uses the "app" provided by Affect Technologies, Inc., which is the study sponsor. You are being considered as a participant in this study because you are at least 18 years old and you are seeking treatment for methamphetamine use disorder. This Consent document provides information to enable your decision about participating in the research study. Your choice to be involved (or not to be involved) in this research study is entirely voluntary.

Why Is this Study Being Done?

The purpose of this study is to find out if an investigational digital technology—the Affect app—and related services can help individuals who use methamphetamine to stay in treatment in order to reduce or stop methamphetamine 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 therapeutic 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.

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

If you consent to take part in the study, you will be asked to download and use the Affect app and participate in therapeutic activities and study procedures. These are

described in this consent. Before you sign this consent, the person authorized by the researcher will ask you to complete an oral quiz over the phone to make sure you understand the consent and the study. After that, they will tell you if you are eligible to participate and will answer your questions about participation. Your involvement in the study will include activities and procedures as described below.

General Activities and Procedures

- Study personnel will determine your study eligibility by asking you questions and requesting that you complete two online questionnaires (completed) and an oral quiz about this consent form conducted before you sign. If you are not eligible for the study, you cannot participate in or continue in the study. If you are eligible, you will be able to sign the consent and enroll in the study as follows:
- You will complete several initial assessments to begin participation (baseline).
- You will participate in the 8-week program, which involves downloading and using the Affect app and participating in the related therapeutic activities (such as counseling sessions) and other study procedures, including weekly drug tests that you do yourself using saliva swabs. You will present the results of the swab test via videoconferencing (over secure/encrypted Zoom) with Affect personnel.
- You will allow the research Principal Investigator (Mike Zito, M.D.) and authorized representative (a Research Associate) to obtain and review your clinical and administrative records during the intervention period, which will be 8 weeks.
- You will be contacted by study personnel for three follow-up telephone interviews at 1, 3, and 6 months after the 8 week intervention.

These procedures are described below:

Baseline Information Participation

- Participate in telephone and online assessments during eligibility screening (already done), which ask about your demographics (age, race/ethnicity, etc.), drug use, past history of drug treatment, health-risk behaviors, criminal justice history, health and social functioning, as well as knowledge about methamphetamine use and treatment for methamphetamine use disorder. *Takes about 30 minutes.*
- Provide contact/locator information so that you can be contacted for follow-up interviews. You will be asked to provide your address(es) and phone number(s), as well as contact information for two individuals (family members, friends, or acquaintances) who are likely to know your whereabouts over time. Research staff may contact these individuals when attempts to contact you directly have been unsuccessful. No information will be shared with these contacts about you or your participation in this study except so say that "participants in a health study are being contacted." In addition, your birthday

date will be confidentially recorded. Research staff will search commercial/agency databases to get your current contact information or status. Some of the information may already be public. For information that is not public, your agreement to participate means that you will allow the database owners and agencies to provide information about you with research staff for research purposes. *See below under "Clinical and Administrative Records" for details.*

Intervention and Related Therapeutic Activities

The App Digital Therapeutic Platform

Participants interact with the app to learn new non-drug behaviors and coping skills through working with the Affect curriculum. The curriculum with app tasks combines principles from cognitive behavioral therapy (CBT) and contingency management (CM), which are common treatment modalities useful for individuals with methamphetamine use disorder. The app helps motivate individuals to engage with program activities (especially the app-based tasks), doing so at their own convenience. This is especially important during times when clinic presentation is difficult due to circumstances such as the COVID pandemic or other interference in travel and gathering activities; distance from care; and need to manage work/childcare responsibilities, etc.

App tasks and activities. The app provides brief, engaging, incentivized 'tasks' that are designed to guide and support behavior change to avoid drugs, prevent relapse, and seek social activities and other 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 $0.50 each. Tasks are monitored by the app and the Care Team for timely, satisfactory completion and verification. The Affect app supports interactions in team efforts to build peer support, helping to rebuild behavior patterns that have lapsed as a result of drug use. The app's functions respond to individual needs at different stages of recovery, such as focusing on avoiding triggering factors in early stages and addressing emerging issues during recovery such as sleep issues and incipient craving.

Therapeutic services for treatment of methamphetamine use disorder. Participants will be involved in therapeutic services that include:

- CM (providing monetary incentives for drug tests negative for stimulants).
- The digital therapy curriculum (based on CBT) delivered via the Affect app on smartphones; the curriculum builds skills to develop meaningful strategies to combat cravings, using such techniques as app-promoted deep breathing exercises, daily exercise, and help in making and sticking to a relapse prevention plan.
- Periodic individual counseling via telemedicine (TM) with clinical personnel and more frequent group therapy via TM; counseling sessions are arranged by texts from the Care Team advocate and also presented by the app as a reminder. Individual and group therapy sessions occur over Zoom, which is integrated into the Affect app download package.
- Referral to a psychiatrist for medication support, if needed.

Clinical and Administrative Records

Your progress during study participation will be tracked using your clinical and administrative records (e.g., treatment and medical records) over the entire study period beginning from your initial enrollment in the study. Depending on when you enroll in the study, we will collect these records for no more than six months after you complete the 8-week intervention. This may include information on your intervention activities, diagnoses, medications, interactions with physicians (such as keeping appointments), and drug test results. Some records may be obtained from other publicly accessible databases that contain this information, including California's Controlled Utilization Review and Evaluation System, the Department of Justice Automated Criminal History System, the Centers for Disease Control and Prevention National Death Index, and the California Outcomes Measurement System for Substance Use Disorder Treatment.

Follow-Up Interviews

You will be contacted by phone for three follow-up surveys at 1, 3, and 6 months after your participation in the 8-week intervention.

How Long Will I Be in the Research Study?

- You will be involved in the intervention with the Affect app for 8 weeks.
- You will receive three follow-up telephone contacts from the research team for interviews at 1, 3, and 6 months after the 8-week intervention.

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

- You are at minimal risk in this study. There are no physical risks associated with the interviews or questionnaires in this study, nor with the activities as part of the therapeutic intervention involving the Affect app.
- It is possible that during data collection interviews or in group therapy/counseling sessions you may feel uncomfortable discussing issues related to your drug use or other aspects of your life. You may choose not to answer those questions, and you may pause participation in a therapy session if it causes discomfort.
- As this study involves the use of your identifiable, personal information, there is a chance that a loss of confidentiality may occur. The Affect Care Team and the researchers are well trained in confidentiality and have procedures in place 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 some benefit from your participation in this study in the form of reduced methamphetamine use or cessation of use, as well as improved well-being; however there is no guarantee. Results from this study may lead to the development of improved treatment delivery for individuals struggling with methamphetamine use. If

proven effective, the intervention may be used in practice, potentially helping people stay in treatment and leading to better health outcomes for individuals with stimulant use disorder.

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

If you choose not to participate, you may seek other treatment services available in the community. If you choose not to participate, you may be able to receive cognitive behavioral therapy (CBT) and/or contingency management (CM) from other programs in the community. If you request, the Affect staff will provide a list of programs or services that include usual treatment offered for methamphetamine use disorder.

Will I Be Paid for Participating?

Before you are eligible for payments/rewards earned from doing app tasks and for meth-negative drug tests, your eligibility for the study must be confirmed as described above, and you must remain eligible. If all eligibility requirements are not met, you will not be allowed to participate/continue in the study and you will not receive payment/reward.

- You will be paid $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 $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).
- Scheduled drug tests: You will receive increasing rewards between $10-$30 for providing consecutive saliva samples *negative* for meth and other illicit stimulants; the maximum possible earned is $340 (from twice-weekly tests during the 8 weeks). 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 $30 for each of the three follow-up telephone interviews.
- Compensation will be in the form of deposits to CashApp, which will be downloaded at the onboarding when the Affect app package 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 will do their best 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.
- The research team, authorized personnel of the study sponsor (Affect Technologies), and authorized personnel of the FDA and the Institutional Review Board may 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 penalty or loss of benefits to which you are otherwise entitled.
- 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?

- **The research team:** If you have any questions, complaints, comments or concerns about the research, or you think this research may have made you sick, you can talk to the Principal Investigator, Mike Zito, M.D., at 310 478-3711.
- **The Institutional Review Board:** If you have questions about your rights as a research participant, or you have questions, concerns or complaints or you want to talk to someone other than the researchers, you may contact the organization overseeing this project, the Institutional Review Board: 855-818-2289 .

By Signing this Consent Form, I Confirm the Following:

- I have read this consent form.
- 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 by the sponsor and authorized persons.
- 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.

CONSENT TO BE CONTACTED FOR FUTURE RESEARCH

We would like to re-contact you after the study to invite you to participate in new studies that may be developed by the Principal Investigator or by Affect Technologies, Inc. Future studies would require a separate informed consent to be obtained from you; this consent, if you agree, only indicates your willingness to be contacted for possible future research. If you agree, please initial the first item below, or initial the second line to disagree:

- I agree to allow the research team to re-contact me after the study to invite me to participate in new studies in the future. _____(initials)

- I do NOT agree to allow the research team to re-contact me after the study to invite me to participate in new studies in the future. _____(initials)

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: Dr. Mike Zito

Signature of PI: Dr. Mike Zito

Name of Affect Care Team Coordinator: _____

Signature of Affect Care Team Coordinator: _____

Date: _____