BRIGHTVIEW INFORMED CONSENT FORM AND AUTHORIZATION TO USE AND DISCLOSE MEDICAL INFORMATION FOR

A Prospective Cohort Study of Contingency Management Using a Smartphone App Application in Patients with Substance Use Disorder

You are invited to participate in a medical research study. Your participation in this research study is strictly voluntary, meaning that you may or may not choose to take part. This study is being conducted by Dr. Shawn Ryan and his team at Brightview. We ask that you read this document carefully and ask any questions you may have before agreeing to be in the study. After reading the consent form, if you would like to participate, you will be asked to sign this form. You will be given a signed copy of your consent form to take home and keep for your records.

STUDY PURPOSE

The purpose of this research study is to test the acceptance and efficacy of a smartphone app (DynamiCare Rewards™) for patients with substance use disorder (SUD) who are in active treatment and recovery at BrightView centers. Patients will perform self-tracking of their recovery behavior (e.g., counseling attendance, abstinence from drugs and alcohol) addiction recovery behavior using Contingency Management (CM). CM is shown as a highly effective, evidence-based methodology for improving substance use disorder (SUD) outcomes. It does so by activating the brain's reward and inhibitory systems through both positive and negative reinforcement using immediate, concrete incentives in a progressive reinforcement schedule. CM involves setting frequent (>1/week), objective goals (usually abstinence or participation in treatment), which patients can achieve to earn tangible rewards (such as cash or vouchers). The DynamiCare smart phone app (iOS/Android) uses CM to incentivize patients to attend scheduled appointments and to submit negative alcohol and drug tests as they are rewarded for these behaviors. The DynamiCare smart phone app will be used to see if treatment retention can be increased when this app is added to treatment as usual, as well as whether the percentage of scheduled appointments can be increased by using the app. In addition, we want to see if using the DynamiCare app can reduce substance use. The intentions of this project are to assess whether use of the smartphone app as an add-on to treatment as usual can increase treatment retention, increase the percentage of appointments that are kept, and whether substance use can be reduced.

NUMBER OF PEOPLE TAKING PART IN THE STUDY AND DURATION

If you agree to participate, you will be one of the about 100 subjects who will be participating in this research study locally. Your participation will last approximately for four months.

PROCEDURES FOR THE STUDY

If the patient is interested, information about study procedures and requirements will be provided for review as well as a video describing the DynamiCare Rewards program. If the patient remains

interested, a member of the research team will determine if inclusion and exclusion criteria are met. If eligibility criteria are met, research member will meet with the patient, review the eligibility criteria, answer any questions about the study, and obtain written Informed Consent. A baseline assessment will then be conducted with consented participants prior to any other study procedures.

After completing the Informed Consent process, participants will provide baseline demographic data and information on their recent substance use and severity. In addition, a urine sample will be collected at baseline and each study visit as indicated by the ASAM guidelines. Breathalyzers may be used when indicated for patients with Alcohol Use Disorder or when there is concern for problematic alcohol use.

Study procedures related to the DynamiCare Rewards intervention are conducted *via* smartphone and there are no visits related to the study intervention. Research visits including collection of a urine sample and medical exams. Participants assigned to the DynamiCare Rewards group will receive: 1) the app on their smartphone, 2) drug testing devices when indicated (pocket-sized breathalyzer), and a reloadable debit card for receiving the financial incentives (the PEX debit card). The app will periodically prompt the user to deliver a urine drug test or conduct a breathalyzer. The breathalyzers (BACTrack Mobile Pro) submit BAC results directly to the smartphone app via Bluetooth. When taking these tests, patients take selfie videos of themselves and these videos are loaded to DynamiCare's Analytic website where they are viewed by trained personnel to ensure that they are valid. Videos are kept for 7 days and then destroyed. GPS tracking also ensures that patients have attended their scheduled appointments. GPS is not used at any other times. All information is uploaded on the DynamiCare Analytic website where providers can see the status of patients. Information includes whether appointments have been attended, the status of all alcohol and drug testing, and incentives earned. Negative tests result in points which the patient can immediately transfer from a reserve account (where the patient's incentive funds are inaccessible), to the spendable PEX debit card. The amount of funds are available on a progressive variable reward schedule. The app provides reminders to patients for all therapy and drug/alcohol testing appointments. It also informs providers if appointments have been kept, and whether breathalyzer and oral saliva testing has been completed as well as the results of these rests. Both providers and patients can schedule appointments. Patients do this *via* the app; providers *via* the DynamiCare Analytic website.
The PEX card provides a convenient way to monitor and protect the patient from risky spending. The card will block cash withdrawals, and spending at identified liquor stores and bars. All substance testing devices and the debit card are existing, commercially available, valid and reliable products. At all times, the participant retains the right to choose whether to use, and when to use the devices and funds.

POTENTIAL RISKS, SIDE EFFECTS, DISCOMFORTS, INCONVENIENCES

This device poses non-significant risk to participants and is exempt from IDE regulations [21 CFR 812.2(c)]. The study design will prevent or minimize potential risks or discomforts to the greatest extent possible *via* having patients use a passcode on their smartphones, use of a random code number for patient record identification rather than patient names, data encryption for all electronic transmissions, destruction of substance testing video selfies in the immediate timeframe following test validation, and use of HIPAA-compliant data storage servers.

POTENTIAL BENEFITS

A subject participating in the study may experience potential medical benefits, i.e., increased awareness and focus on achieving desired health goals, i.e., maintenance of abstinence from alcohol and/or drug use.

NEW INFORMATION

You will be informed in a timely manner if new information that may influence your willingness to continue participation in the study becomes available.

COMPENSATION TO YOU

If you complete all study requirements you will receive up to a total of up to $400 over the four months depending on testing frequency. Whenever a negative drug test is confirmed, the server will initiate a release of funds from the DynamiCare study reserve account to the patient's Next Step debit card.

COSTS TO YOU

Your standard care will be charged to your insurance company in the usual manner.

FINANCIAL INTEREST DISCLOSURE

The investigator and his group at BrightView may receive funding from the company makes the device (DynamiCare Health) to pay for the cost of doing this study.

VOLUNTARY PARTICIPATION/WITHDRAWAL

Your decision to participate is entirely voluntary. You may refuse to participate or withdraw from the study, at any time, without penalty or loss of benefits to which you are otherwise entitled. Your ongoing medical care will not be affected by your decision and your current and future relations with BrightView.

CONFIDENTIALITY AND AUTHORIZATION TO COLLECT, USE AND DISCLOSE YOUR MEDICAL INFORMATION

Efforts will be made to keep your personal information confidential. Your personal information may be disclosed if required by law. Your identity will be held in confidence in reports in which the study may be published.

Organizations that may inspect/or copy your research records for quality assurance and data analysis include groups such as the study investigator and his groups at Brightview, the DynamiCare Health, the U.S. Food and Drug Administration (FDA), and Sterling Institutional Review Board (IRB), who may need to access your medical and/or research records.

Your study information may be released to the groups listed above. If your study information is reviewed by these people, they may need to see your entire medical record; it is possible that your Social Security number may be included in the records reviewed. Because of this, it cannot be assured that your confidentiality will always be protected. It is possible that your information will be shared (re-disclosed) in a way that it would no longer be protected. However, this access to your records will be granted without violating your confidentiality to the extent permitted by applicable laws and regulations. By signing this form, you are authorizing this access to your records.

The results of the study, including your information, may also be presented at meetings or in articles written about the study (publications). If the results of the study (including your research or health information) are published, your identity will remain confidential.

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.

QUESTIONS

If you have questions, concerns or complaints about the research study, please contact Dr. Shawn Ryan (MD, MBA) at 513-834-7063 (or Dr. Samin Rezania (PhD) at 317-200-2805).

If you have questions regarding your rights as a research participant, or if you have questions, concerns, complaints about the research, would like information, or would like to offer input, you may contact the Sterling Institutional Review Board Regulatory Department, 6300 Powers Ferry Road, Suite 600-351, Atlanta, Georgia 30339 (mailing address) at telephone number 1-888-636-1062 (toll free)

PARTICIPANT STATEMENT AND AUTHORIZATION

I have read or have had read to me the Participant Informed Consent Form and Authorization to Use and Disclose Medical Information and I give my consent to participate in this study. I will receive a signed copy of this form to keep for my records and all my questions have been answered. I have not waived any of my legal rights by signing this document.

_____
Printed Name of Participant

_____ _____
Signature of Participant Date

_____
Printed Name of Person Explaining Consent

_____	_____
Signature of Person Explaining Consent	Date
_____	_____
Signature of Principal Investigator	Date