**FACILITIES AND OTHER RESOURCES**

1. Risks to Human Subjects

1. Human Subjects Involvement, Characteristics and Design

Human Subjects Involvement: This Human Subjects Research meets the definition of a clinical trial, and thus requires the inclusion of human subjects. The purpose this study is to measure the effectiveness of Contingency Management (as delivered by the DynamiCare Rewards system) for [PURPOSE OF STUDY] among [PATIENT POPULATION].

1. Sources of Materials

DynamiCare Rewards is a HIPAA-compliant platform designed for use in healthcare settings. It protects patient information with encryption in-transit and at-rest, and limits visibility of patient data to only those with authorized access. In this study, data will be collected on [PATIENT BEHAVIORS]; these data are automatically uploaded to the DynamiCare HIPAA-compliant server. Only staff working on the research project at the various sites (i.e. DynamiCare Health, [SITES]) will have access to participant data. All personal data collected will be used for research purposes only, including determination of study eligibility and to characterize the sample. All records and data will be kept strictly confidential and will only be released outside of the research staff with the written consent of the participant. Participants will be assigned a unique identifying code at the time of study enrollment to help ensure confidentiality. Data will be maintained through the use of these identifiers and no patient names will be used for data purposes. Names that are linked to identifiers will be stored in password-protected, encrypted electronic databases.

1. Potential Risks

This is a low risk study, as the proposed intervention is a mobile application which does not provide any diagnosis or treatment for any disease. Three potential risks can be cited; protections are discussed below. One risk is that of mild stress when performing self-administered saliva or breath testing. Since participants have the potential to earn money for abstinence, they may become distressed if they believe that the equipment is not performing accurately. A second risk is use of the debit card for contra-therapeutic purposes, in particular purchase of alcohol or cigarettes, although the card is configured to block most of these transactions. A final potential risk is that participant confidentiality could be breached, in regard to patient health information, during transmission of electronic data including patient names or exercise adherence. Participants can decline to be in the study, or leave the study early, if they have any concerns, and as an alternative to study participation they can continue in usual care.

2. Adequacy of Protection Against Risks

1. Informed Consent

Eligible persons will be provided a copy of the IRB-approved informed consent form to review. Only study staff who have completed IRB training and are IRB-approved to sign study consent for this project (e.g., consent designee) will conduct the consenting procedure. Participants will be invited to discuss any questions or concerns with a study staff member who is authorized to witness the informed consent and will be provided as much time as they need to make an informed decision about study participation. Importantly, participants will be informed that neither study participation, voluntary withdrawal from the study, or discharge from the study will have any impact on any past, present nor future medical treatment they may receive at any participating treatment facility. All participants will be provided with a copy of their signed informed consent form to keep and will be encouraged to contact study staff with any questions that may arise at any time during the study. The original, signed informed consent form will be kept with the participant’s research chart. Individuals who are unable (for any reason) to provide voluntary informed consent will not be enrolled.

1. Protections Against Study-Specific Risk
2. Risk Associated with a Breach of Confidentiality

To protect confidentiality, all research participants will be assigned unique participant identification codes that will be used on all study-related forms and online websites. Documents that include the participants’ full names (e.g., signed informed consent forms) will be stored in password-protected, encrypted electronic databases. Confidential information will never be shared with anyone outside of the research program without the explicit written permission of the research participant. Only selected designated staff members will be approved to share confidential information after explicit written permission is obtained from the participant and the participant will be able to revoke written permission at any time. In accordance with IRB requirements, all research staff will be formally trained in these procedures. No identifying participant information will be used in written reports, manuscripts and/or conference presentations. Even though the final dataset will be stripped of identifiers prior to release for sharing, we believe that there remains the possibility of deductive disclosure of subjects with unusual characteristics. Thus, we will make the data and associated documentation available to users only under a data-sharing agreement that provides for: (1) a commitment to using the data only for research purposes and not to identify any individual participant; (2) a commitment to securing the data using appropriate computer technology; and (3) a commitment to destroying or returning the data after analyses are completed.

**INTRODUCTION TO APPLICATION**

Background/Significance

Contingency Management (CM) is a highly effective, evidence-based methodology for improving substance use disorder 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). Over 100 RCT’s (Prendergast, 2006; Davis, 2016) and 7 meta-analyses (Ainscough, 2017; Davis, 2016; Benishek, 2014; Dutra, 2008; Griffith, 2000; Lussier, 2006; Prendergast, 2006) demonstrate its effectiveness. Nevertheless, CM is used consistently by less than 10% of treatment programs (Herbeck, 2008). Practical barriers to adoption include lack of funds, the frequent drug testing required, lack of training for staff, and difficulty of managing the rewards on an individual basis (Carroll, 2014). Therefore, an automated version of CM which does not require staff effort would have significant advantages in overcoming these practical barriers. Traditionally, CM has been implemented without any computerization, using:

* Pre-determined schedules of when patients need to show up for treatment or take drug tests.
* Manual tracking of patient abstinence (via in-person supervised drug tests) or treatment attendance (as recorded by treatment providers)
* Manual (pen-and-paper) calculation of the rewards due to each patient according to personalized reward schedules that may include complex features such as escalating incentives and resets.
* Manual distribution of rewards/prizes

There have been attempts to automate CM, most of which were successful in improving patient outcomes. However, all computerized implementations of CM have still required staff involvement for many of its processes. The prior art of CM programs that have automated some of these steps includes:

* Campbell et al describe a computerized system called TES which automated the calculation of rewards due to each patient, but still required manual drug testing and distribution of rewards: “Research staff entered target behaviors into the computer and oversaw prize distribution” (Campbell et al, 2014). Over 12 weeks, the intervention reduced dropouts by 28% and increased abstinence 62%.
* Reynolds et al describe a computer program called motiv8, which innovated by using a webcam on a personal computer to enable patients to record a video of their drug tests (using a carbon monoxide detector) from home, obviating the need for manual, in-person drug tests. However, the software still required a pre-set schedule for drug tests (twice per day with an 8-hour interval in between) and manual prize distribution: “A designated staff member placed on-line orders for participants to pre-approved stores” (Reynolds, 2015). The intervention nearly cut breath CO levels in half for the treatment group relative to the controls.
* For our endeavor, the most relevant previous study is Alessi and Petry’s randomized controlled trial of a CM procedure using basic feature phones (flip phones) to record selfie videos of breathalyzer tests (Alessi & Petry, 2013). Dr. Petry is a leading expert in CM research, and serves as an advisor to DynamiCare. In the study, the participants were recruited based on a desire to reduce alcohol consumption, but were not in or seeking treatment. The researchers manually texted participants to request breathalyzer tests, which participants performed using the phone’s built-in video recording and sending features (no custom software was developed). Participants were randomized either to incentives contingent on abstinence, or rewards for submitting tests regardless of the results. In addition to being well-received by patients, the incentive procedure cut the number of drinking days in half -- 21.8 days in the control group versus 10.8 in the CM group, while also reducing number of drinks per drinking day. The technology in the study was limited to simple flip phones (i.e., not smartphones as in the proposed study), and therefore all request messages, video submissions, and reward notifications had to be submitted manually via texting, with rewards distributed only at the end of the study by mailed checks. It is also important to note that their study did not include patients currently in treatment as ours does; they write, “whether similar results would be observed in patients trying to quit or reduce their drinking is an important empirical question.”

DynamiCare Platform Description

The DynamiCare Health digital platform for monitoring and rewarding recovery from addictions is based on a very effective, evidence-based, and often overlooked behavioral intervention: contingency management. Contingency management (CM) uses rewards to incentivize patients to stay sober and stay in treatment (more detail in the Proof of Concept section). DynamiCare Health has fully automated this behavioral intervention by using smartphone-based random substance tests, treatment attendance tracking, and appropriate rewards. The following provides an overview of DynamiCare’s underlying technology and clinical approaches.

*Substance Use Testing:*

One of DynamiCare’s major innovations is to enable patients to conduct self-administered substance tests through the app. Patients receive a breathalyzer and/or a box of instant saliva test cups from their treatment program when they sign up for the app. In both test types, patients receive random alerts for substance testing, asking them to complete a test in the next 90-120 minutes. Patients must use the app to record a selfie video of themselves as they breathe into the breathalyzer or perform the saliva test. DynamiCare staff watch each video to verify the patient’s identity and ensure that they performed the test correctly without cheating. The breathalyzer (BACTrack Mobile Pro from KHN Solutions) is a small Bluetooth-connected device which transmits BAC results directly to the app, and the test only takes ~30 seconds to perform. The saliva tests used are instant, disposable 12-panel immunoassay cups (SalivaConfirm from Confirm Biosciences) which change color to indicate positive/negative results. This color change can be seen by DynamiCare reviewers in the selfie video, and the whole process usually takes 5- 10 minutes. The saliva cups test for most common drugs of abuse and distinguish between multiple opioids: morphine/heroin, oxycodone, buprenorphine, and methadone, so they can be used to ensure medication adherence in addition to detecting illicit use. At each stage of the testing process, patients receive on-screen step-by-step prompts for self-administering their substance test. Once a substance test is complete and reviewed by DynamiCare, both the patient and provider receive alerts announcing the results. Patients who test negative are given monetary rewards through the app.

DynamiCare’s self-administered tests offer some major advantages over current urine testing systems. The only downsides are: that patients must have a smartphone with a data plan; they must keep the pocket-sized breathalyzer and saliva cups near them throughout the day to be able to respond to random test requests; and that instant immunoassay saliva cups are not as accurate as LC/MS lab-based urine testing, which may require confirmation for contested positives (similar to instant urine cups). The first major benefit is convenience -- patients do not have to take time out of their day to show up for an in-person urine test, and this enables remote monitoring for rural populations. These tests are also clinically more valid because they are

harder to cheat than most urine tests, provide the opportunity for true random testing (rather than testing only when patients are scheduled for weekly appointments), and they bring the patient more dignity and autonomy than witnessed urine tests. Furthermore, the cost of DynamiCare saliva tests ($15) is less than half of what major lab companies charge for in-person urine tests.

*Treatment Attendance Tracking:*

Patients will receive reminder alerts for upcoming appointments, including but not limited to AA/NA meetings, therapy and medical appointments, and exercise routines. GPS tracking technology enables the patient to be checked-in at the right time, place, and duration of their appointment, to increase their accountability. The check-in system is fully automated and provides real-time updates for the patient and the provider. Completion of appointments earns the patient rewards.

*Surveys:*

Surveys can be administered through the app to assess patient progress in treatment, risk of relapse, and other pertinent study metrics. Patients receive push notifications on their smartphone alerting then to new surveys which they complete within the app. Patients receive rewards upon completion of the survey.

*Monetary Rewards:*

Funding patient rewards can come from a few different channels; payers, employers, providers, and crowdfunding from patient support networks.

In order for any technological innovation addressing the opioid epidemic to be scalable and sustainable, a reliable funding source is needed, which means healthcare payers need to be on board. As DynamiCare becomes more established and builds a strong evidence base for its effectiveness, it will become a channel through which payers can easily and reliably fund contingency management, and bring it to hundreds of thousands of patients. Payers recognize the immediately discernible cost savings of keeping patients out the hospital by utilizing outpatient providers and the DynamiCare platform. DynamiCare is already partnering with multiple payers on launching pilots. Patients with SUD cost $4,400 on average in excess claims costs for a commercial payer (Milliman, 2014). Research has demonstrated that contingency management is able to achieve similar effect sizes as Medication Assisted Treatment (MAT), which has been demonstrated to produce net cost savings to payers of ~$3,500 over a 6-month period (Baser, 2011-alcohol, Baser, 2011-opioids). DynamiCare, including the cost of incentives, would only cost payers $750 over a 6-month period. This is much more cost-effective and scalable than existing treatments, although it can be added on to existing treatments for stronger, longer-lasting effects. DynamiCare has developed a process for applying for an HHS OIG Advisory option to allow us to use incentive payments for Medicaid populations.

Individuals in a patient’s support network (such as family members) can support them in their recovery through the use of the DynamiCare Crowdfunding platform. The funds contributed by the patient’s support network will be pooled with funds from other channels (e.g. payer contributions) and paid out as the patient completes reward-based tasks.

*DynamiCare Smart Debit Card*

Patients receive their rewards on a smart debit card which blocks spending at liquor stores, bars, casinos, and cash withdrawals. Money is automatically added to the card upon completion of recovery tasks. Providers can receive alerts when patients engage in risky spending behavior, such as trying to use the card at a blocked vendor.

*DynamiCare Analytics:*

DynamiCare Analytics is the back-end dashboard where providers can track and manage their patients using the DynamiCare app. Providers can set substance testing schedules, adjust frequency of random tests, and view test results. They can decide which appointments to track and reward, and see attendance records. It serves as a recovery scorecard, tracking patients’ progress in recovery, and also as a control panel for adjusting parameters in patients’ treatment.

Advantages/Innovation:

* No effort for the provider after patient sign-up: With our model, care providers do not need to administer drug tests, calculate reward schedules, or distribute rewards to patients. No computerized CM program to date has completely eliminated provider effort from the process. By eliminating the need for provider training in CM techniques and the burden of program administration, our system overcomes a significant challenge to CM adoption discussed in the scientific literature.
* Outcomes tracking: There is a severe lack of outcomes data in the world of alcohol use disorder treatment programs; many programs do not know what happens to patients after leaving treatment or have biased, self-reported data. DynamiCare can collect objective, verified breathalyzer and saliva test data for months post-discharge, which programs can use to measure and improve performance. This could bring much-needed accountability to the field.
* Predictive drug testing: More abundant data, combined with advances in machine learning, have enabled powerful predictive analytics to be applied in healthcare. Although there has not been much published on the use of predictive analytics for addiction, it has become quite advanced in other areas, such as predicting risk of suicide based on textual analysis of health record clinical notes (Poulin 2014). By using our predictive analytics from the data generated by our DynamiCare Rewards system (spending patterns, drug test results) and other sources, we don’t need frequent, explicitly specified testing schedules for CM as other programs have mandated. DynamiCare’s smart testing can improve on the yield of random drug testing, by predicting the times when a patient is most likely to use and sending real-time prompts for users to take drug tests then. This allows for less frequent testing (e.g. twice per week instead of twice per day) and lowers the cost (because of fewer video verifications and less usage/depreciation of drug testing equipment).
* Crowdfunding: Family and friends, who often provide financial assistance to a loved one with no way to ensure the funds are used appropriately, can be unwittingly drawn into either denying their loved one or enabling them. DynamiCare has designed a financial management model that benefits families with knowing that their funds serve a therapeutic function, that the smart debit card blocks spending on drugs and alcohol, and that DynamiCare Analytics is monitoring the patient and will alert the family and/or caregivers when the patient is at-risk.
* Furthermore, a recent study showed that 87% of parents of opioid-addicted children would be willing to pay $200/week for an incentive based program such as DynamiCare (Baltimore Research). This indicates that patients, programs, and families are already willing to put substantial resources to work for the purpose of recovery, which we believe could be redirected through the DynamiCare crowdfunding and CM platform as an additional therapeutic benefit. Lack of funding for incentives has been a significant barrier to CM adoption, and could be solved for a large subset of patients by easily enabling them to raise their own funds.
* Payers: DynamiCare already has a pilot contract with its first commercial payer to commit to funding 50:50 matching incentive funds with families, up to $50 per patient per month. Multiple other insurers and employers are actively contracting and/or in discussions to follow suit.

Preliminary Studies

Dr. David Gastfriend and Eric Gastfriend presented preliminary findings from their work on DynamiCare Analytics in June 2016 at the College on Problems of Drug Dependence 20th

Annual Workgroup on Contingency Management (Gastfriend & Gastfriend, 2016). Proof-of- concept machine learning algorithms have been developed and back-tested on spending data from Next Step debit cards (1,400 users, 90,000 financial transactions) with data available from clinics where the cards were being used by patients as an intervention for financial monitoring and control. We found that we could predict approximately 70% of lapses/drop-outs with a 20% false positive rate. This is a prediction accuracy rate 3 times better than chance. For example, attempting to make purchases at blocked merchants was a strong predictor of relapse, as was compulsive spending behavior.

In 2017, DynamiCare’s pilot year, the platform has been implemented at four separate centers totaling 99 users managed by 12 counselors (Gastfriend & Gastfriend, 2018). Furthermore two randomized control trial studies have begun using these patients as well. A short description of key projects is below:

* Gosnold on Cape Cod is a suburban and rural recovery coaching program for young adults with opioid and stimulant use disorder. The DynamiCare integration is currently funded by a combination of families and grant funding.
  + Some Gosnold patients are participating in an NIAAA grant funded RCT. Eric Gastfriend serves as the principal investigator for this study.
* The Gavin Foundation is an urban recovery home program for all ages and substances. The integration is paid for by philanthropic funds.
* The University of Vermont (UVM) has integrated DynamiCare in a study for pregnant females seeking smoking cessation. Participants are in a remote setting and the study is funded by UVM.
  + This is the second RCT study integrating DynamiCare and is led by University of Vermont investigator Dr. Allison Kurti.

Across these programs, DynamiCare has tracked 795 appointments, 197 surveys, 364 saliva tests, and 566 breathalyzer tests. Engagement is high due to rewards and ease-of-use: 83% of breathalyzer tests are completed on-time when requested. In addition to these positive initial engagement metrics, we have recorded stories of particular patients who benefited from DynamiCare in ways that highlight the platform’s features:

* *Truth Telling:* A patient attended a substance abuse group therapy session despite being heavily intoxicated. Unfortunately, the patient was surprisingly adept at hiding his condition such that it was not recognized by the counselor leading the group. Fortunately, the patient complied with a DynamiCare breathalyzer request shortly before the therapy session started; his counselor saw the alert after the session ended and was able to reach out to the patient and, address the issue with him., The counselor called the insurance company and successfully used the DynamiCare data to extend and increased his number of approved sessions to provide ongoing support.
* *Under the Radar:* A patient was believed to be attending all of her AA meetings, and as far as her clinician could tell, she was doing very well in treatment. However, through the use of the DynamiCare treatment attendance tracker, we discovered she was going to her AA meetings, but only to sign in and leave a few minutes later. For months she had been “under the radar” until our technology gave the clinician a more complete picture of the patient she was treating and facilitated reengaging her in treatment. The clinician was able to see the impact of addressing the issue, because afterward the patient did start to consistently attend her AA meetings, as verified by DynamiCare.
* *Our Favorite – Helping Others*: While we were reviewing a patient’s saliva test selfie video, we saw that he was performing the test in front of his entire weekly outpatient group, as a live demo for them! He was talking about how easy it is to use and was teaching them how to use it, encouraging them to sign up! Patients encouraging others to join DynamiCare is among the best possible endorsements.

Project Narrative

In this proposal, we aim to: 1) promote an overlooked yet effective evidence-based methodology which consistently improves patient outcomes (CM); 2) overcome known barriers by building an automated solution (the DynamiCare platform) which offers benefits to patients, families, providers, and payers; 3) validate the feasibility, acceptability, and efficacy of the system through a pilot study and randomized controlled trial; and 4) disseminate the results to key industry players. With this grant, we believe we can build a rapidly scalable, sustainable business that makes the field of addiction treatment more effective, accountable, and accessible.

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