Cover Sheet

Title: mHealth for Patient Self-Management of Opioid Use Disorder

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BACKGROUND

Drug overdose is the leading cause of accidental death in the US, with opioids being the most common drug. Opioid addiction is driving this epidemic, with 20,101 overdose deaths related to prescription pain relievers, and 12,990 overdose deaths related to heroin in 2015.[1] In 2014, an estimated 1.9 million people had an opioid use disorder related to prescription pain relievers and an estimated 586,000 had an opioid use disorder related to heroin use.[2] The economic impact of illicit prescription opioid abuse alone is estimated to be $53-72 billion,[3-5] placing significant demands on our health care system and burdening society as a whole.

In previous work, we developed KIOS, an innovative software platform derived from nonlinear control theory. KIOS tracks multiple interacting symptoms to map patient trajectories and deliver evidence-based intervention strategies responsive to the specific needs of individuals. Accessible via computer or mobile devices, KIOS provides patients real time advice and reinforcement of lifestyle interventions to improve self-management. KIOS also can provide between-visit reporting to clinicians via downloadable reports or direct online monitoring.

By processing patient-entered assessment data in real-time via mobile devices, KIOS can provide early interventions for patients who exhibit elevated risk. KIOS provides responsive advice to patients to reinforce healthy practices, fostering self-management and adherence to treatment plans. KIOS is able to identify subtle changes in individual behavior when they first occur making it is possible to provide early warnings and intervention advice to guide the patient's trajectory. These early interventions reduce risk factors, prevent worsening of severity, and ultimately decrease resource utilization.

STUDY PROTOCOL

This study consists of a beta test of the KIOS software. Participants in the beta test (n=20) will be invited to participate by Community Medical Services, an opioid treatment clinic located in San Antonio, TX.

Beta Test. Twenty individuals in recovery from opioid use disorder will be recruited from the community to participate in a beta test. Study participants must meet the following inclusion criteria: (1) male or female outpatients 18 years of age or older; (2) currently enrolled in an opioid treatment program and receiving medication assisted treatment for OUD; (3) currently stable in OUD outpatient treatment for 4 weeks or longer; and (4) ability to access KIOS-OUD via computer, smartphone, or tablet. Participants will be excluded if they (1) are unwilling or unable to comply with study requirements; (2) have an unmanaged major psychiatric illness (e.g., schizophrenia, major depressive disorder, bipolar disorder) or suicidality.

Participants will be enrolled in a 4-week single group pre-post evaluation of the intervention. The primary outcome will be user satisfaction as measured by use, usability and utility. Secondary outcomes include self-reported opioid use, depressive symptoms (as measured by the PHQ-9),[6] and Quality of Life (as measured by WHOQOL-BREF).

Due to COVID-19, the beta test will be conducted primarily online and via telephone, including the consent process. All participants will attend an online orientation on Zoom to learn how to access and use KIOS, and participate in a training session. Prior to the online orientation but after consent has been obtained, participants will be asked to complete baseline PHQ-9 and WHOQOL surveys which will be converted to an electronic version and completed online. After the four-week evaluation phase, participants will complete a second round of surveys and participate in a final online debriefing session via Zoom. This approach permits social distancing while enabling users to be adequately trained while also evaluating KIOS-OUD within their typical environment rather than in a lab setting.

Use. Study participants will be asked to complete KIOS assessments online at least three times per week, but no more than once daily. KIOS may still be accessed by participants as many times as desired to review advice and graphs. All logins and assessments will be recorded on the KIOS server to tabulate frequency of use.

Usability. Evaluated at the end of the 4-week trial, the Systems Usability Scale-Modified (SUS),[7,8] a single-factor, 10-item self-report scale will be used to evaluate participants' subjective experience using KIOS. The SUS will be converted to an electronic version and completed online. Participants will rate a set of statements related to their experience in the study. For example, "I needed to learn a lot of things before I could get going with this program." Items will be evaluated using a 5 point Likert-type scale (1 = strongly disagree; 5 = strongly agree). Higher scores out of 0 - 100 indicate greater usability. Generally, systems in early development may expect to have a rating of 30, while more mature systems should rate between 60 - 80. The SUS has demonstrated good reliability ($\alpha = 0.91$) and validity.

Utility. After the 4-week trial, study participants will complete an additional questionnaire focusing on health metrics specific to KIOS. This survey will include questions regarding: (1) the content, appropriateness and relevance of the advice; (2) enhancement of self-management skills; (3) self-awareness and (4) overall satisfaction with health. Open ended questions will be asked to solicit suggestions, criticisms and comments. This survey will be completed online as well.