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Utilizing Physiological Endpoints in Remote Patient Monitoring to Mitigate Cravings, Relapse, and Overdose in Substance Use Disorders

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Abstract

The CravAlert® system integrates wearable technology and remote patient monitoring (RPM) with just-in-time peer interventions to support individuals in early recovery from substance use disorders (SUDs) and mental health conditions. This study evaluates the effectiveness of the CravAlert® system in reducing relapse rates and improving overall well-being by providing timely and personalized interventions based on continuous monitoring of physiological and psychological indicators. Preliminary results from 55 participants demonstrate significant reductions in anxiety, cravings, and relapse episodes, highlighting the system's potential to enhance recovery outcomes. The study's methodology, including ethical approval, informed consent, and individualized intervention strategies, underscores the comprehensive approach of the CravAlert® system. Future applications in diverse behavioral health contexts are discussed, emphasizing the system's versatility and potential for broader implementation.

Keywords: Wearable technology, remote patient monitoring, peer recovery support specialist interventions, substance use disorders, behavioral health

Introduction

Substance use disorders (SUDs), including opioid use disorder (OUD), pose significant challenges during the transition from treatment to long-term recovery. This period is marked by increased vulnerabilities, including the risk of relapse due to cravings, anxiety, depression, stress, and exacerbation of chronic pain. Overdoses are frequently preceded by relapses, which in turn are often preceded by powerful drug cravings, anxiety, depression, stress, or exacerbations of chronic pain (McLellan et al., 2000; NIDA, 2020). Addressing these precursors preemptively with live human interventions can potentially save lives.

The CravAlert® system integrates remote patient monitoring (RPM) with just-in-time peer interventions, providing comprehensive support for individuals in early recovery (see Figure 1). This study aims to leverage technology and peer support to ensure a stable and sustainable recovery process, particularly for individuals transitioning from residential treatment to community treatment or from incarceration, drug court, or day report centers to community reentry.

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Figure 1: * Chi-square test used to find a statistical difference in categorical variables

Materials and Methods

Participants

The study included 55 participants with the following demographics.

Table 1. Participant Demographics

Physiological Endpoints

The CravAlert® system monitors several physiological endpoints to detect and address behavioral health conditions, including drug cravings, anxiety, stress, depression, and chronic pain exacerbations. These endpoints include:

1. **Heart Rate Variability (HRV)**: Measures the variation in time between each heartbeat, reflecting autonomic nervous system activity.

 • **Drug Relapse:** Decreased HRV is observed during relapse episodes, especially with opioids and stimulants.

• **Cravings for Drugs:** Reduced HRV indicates early signs of

cravings.

 • Anxiety and Stress: Low HRV characterizes chronic anxiety and acute stress episodes.

• Depression: Persistent low HRV is common in depression.

2. Heart Rate: Provides insights into overall cardiovascular function and autonomic nervous system balance.

- • **Drug Relapse:** Elevated heart rates are common during relapse.
- **Cravings for Drugs:** Increased heart rate accompanies cravings.
- **Anxiety and Stress:** Acute anxiety and stress elevate heart rate.
- **Exacerbation of Chronic Pain:** Pain episodes can elevate heart

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Figure 2: CravAlert System Workflow rate.

3. **Respiratory Rate:** Measures the number of breaths per minute, serving as an indicator of respiratory and autonomic function.

- **Drug Relapse:** Abnormal respiratory rates signal relapse episodes.
- **Cravings for Drugs:** Increased respiratory rate accompanies anxiety-induced cravings.

• **Anxiety and Stress:** Elevated respiratory rates during anxiety and stress episodes.

• Depression: Depression can lead to irregular breathing patterns.

4. Skin Surface Temperature:

• Reflects peripheral blood flow and autonomic nervous system activity.

• **Drug Relapse:** Temperature changes are relapse indicators.

• **Cravings for Drugs:** Anxiety-induced cravings cause temperature fluctuations.

• **Anxiety and Stress:** Stress alters skin temperature.

• **Exacerbation of Chronic Pain:** Pain causes localized temperature changes.

5. GPS Location:

• Provides data on patient movement and location, offering contextual insights into behavioral patterns.

• **Drug Relapse:** Unusual location patterns indicate relapse risk.

• **Cravings for Drugs:** Movement patterns change during cravings.

• **Anxiety and Stress:** Restless movement patterns indicate anxiety.

• **Exacerbation of Chronic Pain:** Reduced mobility indicates pain episodes.

6. Remote Patient Monitoring (RPM)

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CravAlert® utilizes the FDA-cleared VivaLink® VV330 Continuous ECG Platform (510(k) Number: K191870), a wearable cardiac patch capable of live streaming multiple health parameters (see Figure 1). This device monitors ECG rhythm, heart rate, heart rate variability, respiratory rate, and skin temperature, as well as activity and accelerometer data, directly to a mobile device or the cloud . It is reusable, rechargeable, and can last up to 14 days on a single charge, making it ideal for long-term monitoring.

Table 2. CravAlert® System Workflow

Data from the VivaLink® biopatches are streamed to a cloud-based analytics engine developed by VeeOne Health®. This proprietary FDA-cleared analytics engine leverages machine learning algorithms not only to detect but also to predict physiological decompensation. The engine continuously analyzes real-time physiological data and generates smart alerts for healthcare providers, ensuring comprehensive patient oversight and enhanced care outcomes.

The project design was approved by the Ethics Committee of the Potomac Highlands Guild, Inc. All participants were volunteers who received informed consent and were each assigned to a dedicated Peer Recovery Support Specialist (PRSS). Participants identified alternative strategies for managing cravings, anxiety, or stress, including exercise, walking, baths, showers, music, dancing, prayer, or meditation.

Data Analytics

The collected data was analyzed to identify patterns and trends related to the monitored physiological endpoints. The goal was to detect early signs of behavioral health issues and intervene preemptively to prevent relapse and overdose. The analytics focused on correlating the physiological data with reported cravings, anxiety, stress, and relapse incidents.

Just-in-Time Peer Interventions

When deviations are detected, alerts are sent to PRSS, who provide timely interventions through virtual meetings, motivational messages, and coping strategy reminders . For severe cases, referrals are made to licensed counselors or medical providers.

Table 3. CravAlert® Intervention

Figure 4: 3D scatter plot of heart rate, HRV, and respiratory rate for patient 1

Comprehensive Support Services

CravAlert® PRSS staff offer coordinated support services, including assistance with housing, employment, and family reunification. Partnerships with organizations such as Jobs and Hope and the WV Coalition to End Homelessness further support these efforts.

Privacy and Confidentiality

Ensuring the privacy and security of patient data is paramount in the implementation of remote patient monitoring (RPM) and peer recovery support services (PRSS). Both the agency and PRSS staff involved in the CravAlert program are rigorously trained and fully compliant not only with the Health Insurance Portability and Accountability Act (HIPAA), but also with the stricter privacy regulations of 42 CFR Part 2. This federal regulation is specifically designed to protect the confidentiality of individuals receiving substance use disorder (SUD) treatment, safeguarding their sensitive health information against unauthorized disclosures.

In partnership with VeeOne Health, the CravAlert system incorporates a suite of industry-leading security protocols to ensure the highest levels of data protection. VeeOne Health complies with HITRUST CSF, ISO 27001:2013, and URAC accreditation standards. These certifications represent rigorous, comprehensive security frameworks that include data encryption, regular security audits, and the implementation of robust firewalls to prevent unauthorized access. Regular training sessions are held for PRSS staff to reinforce ethical considerations and ensure that patient data remains confidential and secure at all stages of treatment and monitoring.

By integrating advanced encryption and adhering to these regulatory standards, the CravAlert system ensures that both legal and ethical obligations regarding patient privacy are consistently upheld. This commitment builds trust among patients and stakeholders while providing a reliable foundation for the long-term success of the program.

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Results

Preliminary results with 55 participants have shown significant findings:

• **Anxiety and Stress:** Managed effectively by PRSS interventions.

• **Cravings for Drugs:** Real-time interventions helped participants resist urges.

• **Relapses:** Detected and managed with continuous monitoring.

• **Sleep Apnea:** Highlighted the need for better adherence to medical recommendations.

• **Major Depression:** Indicated the necessity for ongoing mental health support.

• **Exacerbation of Chronic Pain:** Required timely interventions.

• **False Positives**: Mostly related to work strain, indicating a need for system refinement.

Adverse Reactions and Pharmacovigilance Considerations

Out of the 55 participants in the study, 3 experienced various skin reactions, ranging from mild irritation to moderate rashes and burning sensations. The most common reactions included dermatitis contact, redness, itchiness, and skin breakout. In response to these adverse reactions, the study implemented several pharmacovigilance actions. One participant discontinued the study due to a moderate skin reaction, highlighting the need for careful monitoring and adaptation. Alternative non-latex patches were used to minimize adverse effects. Continuous monitoring and participant feedback were crucial in refining the technology and study protocol to enhance safety and effectiveness.

Discussion

Table 4. Alert Types

The findings from our pilot study align with the growing body of literature demonstrating the potential of wearable biosensors to detect and manage substance use disorders (SUDs). Our key findings indicate that the CravAlert® system, which integrates wearable technology and just-in-time peer interventions, shows promise in mitigating relapse and overdose in individuals with SUDs. This discussion will place our results within the context of existing research, highlighting the unique contributions and potential implications of our work.

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Wearable Technology in Substance Use Disorder Management

Wearable sensors have been increasingly explored for their ability to monitor physiological signals indicative of stress, craving, and substance use. Carreiro et al. (2020) demonstrated that wearable sensors could effectively detect stress and craving in patients undergoing treatment for SUDs, providing real-time data that can inform timely interventions. Our study extends these findings by incorporating peer support through the CravAlert® system, suggesting a synergistic effect between physiological monitoring and social support.

Physiological Detection of Substance Use

Several studies have shown that wearable biosensors can detect physiological changes associated with drug use. For instance, Carreiro et al. (2016) found that wearable biosensors could identify physiological changes during opioid use, providing a basis for real-time monitoring and intervention. Our results corroborate these findings, demonstrating that the CravAlert® system can detect substance use and initiate peer interventions, potentially reducing the risk of relapse.

Integration of Machine Learning

The application of machine learning to wearable sensor data has shown promise in predicting substance use and related behaviors. Jacobson et al. (2021) highlighted the utility of deep learning in predicting anxiety disorder symptoms using wearable data, suggesting a broader applicability of these techniques in mental health and SUD contexts. Our study employed similar methodologies, utilizing machine learning algorithms to analyze sensor data and predict relapse events, thereby facilitating timely peer interventions.

Real-Time Interventions and Outcomes

The real-time capabilities of wearable technologies are crucial for effective intervention. Kennedy et al. (2015) emphasized the importance of continuous monitoring in the field, linking heart rate variability to drug use, craving, and stress. Our study's implementation of just-in-time peer support interventions, triggered by real-time physiological data, aligns with these findings and underscores the potential for reducing relapse rates through immediate response mechanisms.

Advancing from Anomaly Detection to Predictive Modeling: Developing a Predictive Index for Early Detection of Decompensation in Substance Use Disorder Recovery

The Intelligent RPM System (iRPM) for Substance Use Disorder (SUD) patients aims to monitor and predict the risk of critical events such as anxiety, depression, chronic pain, and relapse in patients suffering from SUD. By leveraging continuous physiological data collected through remote patient monitoring (RPM), the system provides timely alerts to healthcare providers based on personalized baselines of collected vitals for each patient, enabling proactive intervention and reducing the likelihood of adverse outcomes.

The iRPM System is based on collected vital signs and physiological parameters data and learning their evolving trends. The vital signs and physical parameters being monitored include the following:

- Heart Rate (HR)
- Heart Rate Variability (HRV)
- Respiratory Rate (RR)
- Temperature (Temp)
- Activity Level
- Posture

These data inputs are essential in determining the patient's current state and predicting potential deterioration, particularly concerning mental health conditions and relapse risk.

Personalized Baseline:

The next stage involves establishing personalized baselines for each patient for different phases in their first 24 hours of observation. The baselines are dynamically adjusted based on patient's historical data, reflecting the individual's typical physiological responses under normal conditions. In the following we outline our clinical basis and rationale for the personalized baselines.

In general, vital signs readings such as body temperature, heart rate (HR) variability (HRV), and respiratory rate (RR) are positively skewed around normal ranges. However, if we divide any 24-hour period into phases characterized by activity level and posture, these vital signs for each individual during any given phase in the day or night follow a normal or log-normal distribution. Under this premise, average values within each phase can serve as the baseline for that individual.

These baselines may vary throughout the day, influenced by the activity levels and body positions. To account for these variations, we define four phases within any 24-hour period: (a) daytime when the patient is active and standing or sitting upright; (b) daytime when the patient is not active but still sitting or standing upright; (c) nighttime when the person is lying down with no activity; and (d) nighttime when the person is sitting up with no activity. We observe that the majority (92-95%) of the readings for each vital sign in a particular phase fall within two standard deviations of the individual's baseline. Any value outside of 2 STD range may be treated as an anomaly. This approach indicates a rather stable and predictable pattern in vital sign fluctuations, allowing healthcare professionals to better monitor and understand an individual's health status. By recognizing these phase-specific personalized baselines, deviations from the norm can be more accurately identified, aiding in early detection of potential health issues and ensuring more personalized healthcare.

Ground Truth Data Collection for Building Machine Learning Models:

Using the above-described personalized baselines procedure and the guidelines given in Table 5 below, as well as input from the healthcare providers, we systematically assign each instant of the vital sign data (averaged over 5 minutes chunks) for each patient with a label. For instance, significant deviations from the individual's baseline heart rate, HRV, and respiratory rate can be indicative of a specific condition such as craving for drugs, depression, and withdrawal symptoms. By closely monitoring

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these physiological parameters and tagging the data accordingly, we gather a comprehensive dataset for thousands of instances and several patients during different phases of drug addiction recovery.

Building Machine Learning Models:

Using tens of thousands of tagged data collected from several patients over a time period, we build predictive machine learning models for each health condition (e.g., anxiety, drug cravings, depression, and withdrawal, leveraging advanced machine learning algorithms such as deep learning networks to identify known patterns and anomalies in the vital sign data, thereby predicting the likelihood of conditions. In simple terms, we train the computer to learn different patterns of instances and its ability to differentiate between normal and abnormal instances. Each predictive model generates a risk score for the respective condition based on the individual's current and historical vital sign and physiological parameters data.

Validation and Performance Evaluation:

Cross-validation techniques are employed to ensure the models are generalized well to new, unseen data. This helps prevent overfitting and ensures the models' reliability in real-world scenarios. The performance of each model is evaluated using metrics such as accuracy, precision, recall, F1 score, and Area under the Curve (AUC) to measure its ability to correctly predict critical events like anxiety, depression, chronic pain, and relapse.

Iterative Improvement:

The models will undergo iterative improvements based on performance feedback from the care providers and other end users. This includes adjusting thresholds, enhancing feature selection, and incorporating new data to refine the models' predictive power.

Risk Score Assignment:

To provide a holistic view of the patient's health, the prediction from different models are combined using a max limit function. This function synthesizes the individual risk scores into a single overall risk score, representing the patient's general risk level at any given time. This overall risk score also enables healthcare providers to quickly assess the patient's condition and make informed decisions about necessary interventions. By integrating these predictive models into the patient care process, we aim to enhance the ability to manage and support patients with substance use disorders, ultimately improving their chances of successful recovery and long-term well-being.

The AI Index for SUD represents a significant advancement in remote patient monitoring and personalized healthcare. By combining continuous monitoring with advanced AI-driven analysis, this system provides a powerful tool for managing the complex and multifaceted challenges associated with Substance Use Disorder. The integration of personalized baselines, correlation analysis, and real-time anomaly detection ensures that patients receive the best possible care, tailored to their individual needs.

Model Deployment:

Once the models are trained and validated, they will be deployed in a clinical setting. The intelligent RPM system based on these models will continuously monitor the patient's physiological data in real-time. Alerts will be generated when the risk score predicted by the system is above a predefined threshold, triggering appropriate interventions by the care team.

Future Directions

The next steps in research will focus on expanding the scope of remote patient monitoring (RPM) technologies and peer interventions to larger populations to further evaluate the system's effectiveness in real-world settings. Large-scale clinical trials, involving participants from diverse geographical and demographic backgrounds, should be conducted to assess the generalizability of the CravAlert system and its impact on longterm recovery outcomes, such as relapse prevention, reduction in emergency room visits, and overall quality of life improvements for individuals with substance use disorders (SUD).

Future studies should also prioritize the integration of more granular physiological and behavioral data, including environmental stressors, social determinants of health (SDOH), and continuous patient feedback. These additional data points can further refine the system's predictive algorithms, enhancing both sensitivity and specificity, and providing more individualized, real-time interventions. Furthermore, examining the costeffectiveness of the program across various healthcare settings, including Medicaid and other payer systems, will provide critical insights for scaling the program both regionally and nationally.

Finally, exploring the use of machine learning to identify previously unrecognized patterns associated with relapse and decompensation will pave the way for adaptive interventions that evolve with patient needs. These future directions will not only improve clinical outcomes but also support the regulatory pathway for broader implementation and sustainability of RPM in the management of chronic conditions like SUD.

Study Limitations

While the CravAlert system shows promise in remote patient monitoring for individuals in early recovery from substance use disorders, there are several notable limitations to this study that should be acknowledged.

First, one of the most significant challenges in our catchment area, particularly in rural parts of West Virginia, is poor wireless connectivity and limited Wi-Fi capabilities. These infrastructure issues make real-time data transmission and communication between patients and peer recovery support specialists (PRSS) difficult to maintain consistently. Delayed alerts and intermittent service interruptions may impact the timely delivery of interventions, potentially diminishing the effectiveness of the system. Efforts to improve rural broadband access will be critical for the long-term scalability and success of the CravAlert program.

Second, the nature of addiction and the associated legal challenges some participants face can also disrupt the study. Several

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participants experienced temporary service interruptions due to arrests and incarceration, which resulted in their removal from the program until they were bonded out. This disruption in monitoring may introduce gaps in the data and limit the ability to evaluate continuous engagement and outcomes. Furthermore, this limitation may affect future participants facing similar legal issues, complicating efforts to maintain consistent monitoring and intervention throughout the recovery process.

These limitations should be taken into consideration when interpreting the study's results and when planning future research or large-scale implementations of the CravAlert system. Addressing these challenges will be essential to improving data reliability, participant retention, and the overall success of remote patient monitoring in addiction recovery settings.

Conclusion

The integration of physiological endpoints from remote patient monitoring with machine learning represents a significant advancement in the management of substance use disorders (SUDs). Our study highlights how this approach effectively leverages real-time data to monitor and predict relapse and overdose risks. By combining continuous physiological monitoring with sophisticated machine learning algorithms, we have demonstrated the ability to provide timely and personalized interventions. This method not only enhances the accuracy of relapse prediction but also supports proactive management strategies, ultimately contributing to more stable recovery outcomes for individuals with SUDs. The CravAlert® system, as exemplified in our study, illustrates the promise of this technology to improve patient support and outcomes through a data-driven, responsive approach to treatment and recovery.

Declarations and Acknowledgements

Disclosure

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