

Mindset-SUD: A Mobile Dialectical Behavioral Therapy Tool for SUD

Substance use disorder (SUD) often follows trauma and stress, which precede many mental health disorders. For example, most people suffering from bipolar disorder (BPD) have SUD [1]. Dialectical Behavioral Therapy (DBT) has outperformed other therapies in treating BPD and SUD [2,3]. Innovations in ecological assessments have increased the validity of stress and addiction measures [4]. DBT is poised for mobile assessments because it uses paper-and-pencil DBT journals. These daily journals increase patient's self-awareness through by helping them track urges and substance use. A therapist evaluates journals and helps learn skills to fight the urge to use substances. We propose a startup that leverages mobile technology to facilitate delivery of DBT for BPD with SUD. The proposed technology improves three critical aspects of DBT: 1) DBT journal delivery and analysis, 2) DBT skill practice and 3) emotional awareness. DBT therapists will have a new tool help their clients understand personalized associations between emotions, physiology and substance use behaviors.

A mobile application called "Mindset-SUD" will accomplish this by 1) delivering easy-to-use DBT journal to patients and analyzing results for therapists, 2) providing in-application exercises that promote DBT skills and 3) quantifying physiological trends related to a patient's substance use. These three improvements alone will help deliver DBT treatments to those in need according to DBT experts like Ryan Lindsay MSW and Ass Dean for Social Work at the Brown School of Public Health. The Mindset-SUD app allows therapists and researchers to study the neuropsychology of SUD by collecting subjective survey data alongside objective physiological data.

To collect physiological data Mindset-SUD connects to wearable heart rate monitors. When the SUD patient logs an urge to use, Mindset-SUD records autonomic state via heart rate and heart rate variability. We have classified differences between stress, rest, exercise and meditation using five minute periods of heart rate data. If stress triggers a patient to use, automated stress detection can promote preventative behaviors. Thus, Mindset-SUD is a biometric tool that uses both physiological and behavioral patterns to improve care (Figure 1). In summary, Mindset is enterprise software that supports DBT therapists in treating BPD/SUD with digital tools. It leverages mobile innovations and data science to understand the personalized neuropsychology of SUD so it can be better treated.

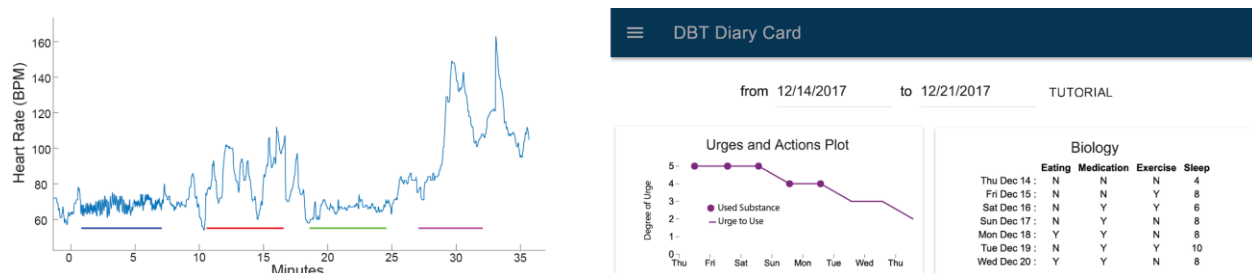


Figure 1: Demonstration of Mindset-SUD capabilities. A) Wearable heart rate monitors can discriminate periods of meditation (blue), stress (red), rest (green) and exercise (purple). Physiological measurements help researchers understand the neuropsychology of SUD. B) The "Therapist Portal" obviates relationships between biology (e.g. sleep) and substance use, helping therapist address neuropsychological patterns with cilents in-session.

Background of Founders

Co-founders Elizabeth Russell B.S. and Ravi Chacko Ph.D. are both biomedical engineers with previous scientific and startup experience. Elizabeth won Washington University in St. Louis's Discovery award for the most promising entrepreneur. Subsequently, she and Ravi placed 3rd in the Biomedical Engineering Society's Biodesign Competition in 2013. The two then founded DataDog Health to develop digital mental health tools. They won Demo Day for the Sling Health Incubator, a national student-run biotech incubator which Ravi co-founded. The team were accepted into the Launch Incubator in San Francisco and the Prosper Women's Entrepreneurship Accelerator in St. Louis. Recently, the team won the JAZ Tank competition at Jefferson University in Philadelphia.

Elizabeth hails from a software development background, from working on mobile EMR with Epic to developing mobile apps for research and other biomedical startups. Ravi's Ph.D. research on brain computer interfaces to improve stroke symptoms helped him develop an understanding of human subject research and data science. Previously, Ravi developed tools to understand the relationship between autonomic measures (e.g. heart rate) and decision making at the NIMH. Elizabeth and Ravi used their combined skills to develop an app that detected and relieved moments of stress using wearable heart rate monitors. They applied this technology to improve PTSD symptoms in veterans through an iOS and Android app called Mindset. An independently run study demonstrated that Mindset reduced standard measures of depression after one-month of use. They are currently engaged with PTSD researchers in a study involving veterans to test Mindset's influence on PTSD symptoms.

Tony Buchanan, Ph.D., is the director of the Cognitive Neuroscience of Stress Lab at Saint Louis University. Dr. Buchanan serves as Principal Investigator on several foundation- and NIH-funded grants. His lab focuses on understanding the cognitive and biological mechanisms underlying stress and addiction, including SUD.

The team has demonstrated an ability to create products that improve mental health and are looking for ways to commercialize the technology. Through a collaboration with DBT expert Ryan Lindsay MSW and SUD expert Tony Buchanan PhD, they believe the best route for commercialization is to use Mindset in conjunction with therapists to treat clients with BPD and SUD.

Tool Description

Sarah has BPD and is a recovering alcoholic. She is referred to a therapist named Peter who uses the Mindset-SUD app to quantify Sarah's urges, emotions, and behaviors. The app helps Sarah learn DBT skills and improves Peter's ability to deliver and track therapy. The steps to use the Mindset-SUD are as follows. 1) A DBT therapist sends his client the Mindset-SUD app, connecting their accounts, 2) The client fills out a daily DBT journal and connects a wearable in the app, 3) the therapist tracks the client's physiology, urges, and behaviors and addresses associations between them in session, 4) the therapist uses the app to teach his client DBT skills and demonstrate their effectiveness. We will demonstrate these steps below.

On Sarah's first appointment, Peter sends a link to the Mindset-SUD mobile application directly to Sarah's phone. She downloads it and securely links her account with Peter's account. Peter wants to address factors that precipitate Sarah's urges and actions related to alcohol use. He directs Sarah to fill out a daily DBT journal in the Mindset-SUD app. This journal tracks whether Sarah drank and quantifies her urges on a scale from 1 to 5. It also tracks Sarah's emotions and behaviors (e.g. hours of sleep). Before their weekly session, Peter looks for associations between Sarah's urges, emotions and behaviors. These associations become the subject of that day's session. Peter introduces DBT skills like mindfulness meditation to address difficult emotions and challenge urges to drink. Guided meditations and exercises are built into the Mindset-SUD app.

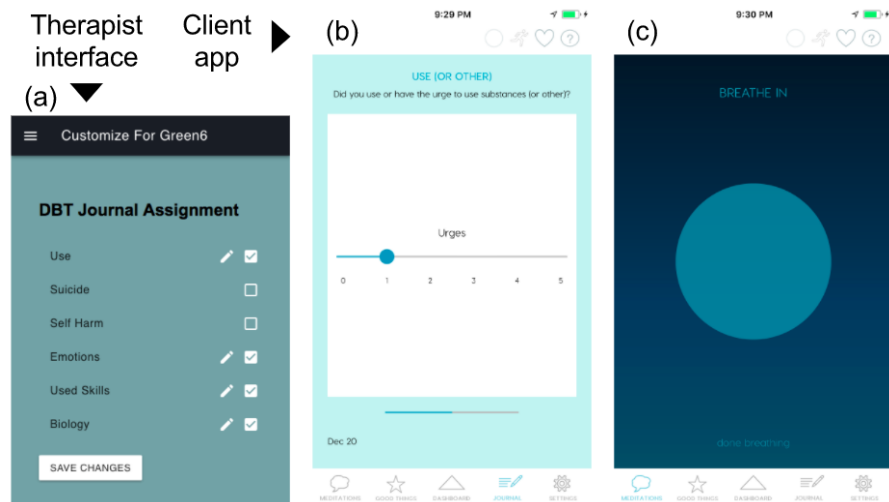


Figure 2: (a) Therapist assigns journal exercises (b) Client completes the assigned journal in the mobile app (c) Client does a timed breathing exercise in the mobile app

After several weeks, Peter sees that stress frequently precedes Sarah's alcohol use urges. He shows Sarah she can connect her wearable heart rate watch to Mindset-SUD. The app helps her recognize stress the moment it occurs. He shows Sarah her heart rate reducing and oscillating when she engages with an in-app mindfulness exercise.

The app intermittently detects a rapid increase in heart rate alongside a decrease in heart rate variability, a pattern indicative of increased stress. The Mindset-SUD app automatically notifies Sarah of heightened stress and directs her to a breathing exercise. This feedback helps her reduce her stress level in minutes and subsequently reduce her urge to use.

The Mindset-SUD app increases Sarah's engagement in her DBT therapy and the improving trends encourage her continued treatment. Eight months later, her urges to use have decreased and her positive behaviors (e.g. mindfulness exercises) have increased.

Sarah can now control her physical stress with breathing. She understands and predicts her urges to use before they happen. Peter is connected to her between-appointment experience through Mindset-SUD. Peter finds that clients who engage with the technology are less likely to prematurely drop out of therapy. He also finds it easier to predict which clients are deteriorating.

Commercial Strategy for Mindset-SUD

The target audience for our product are DBT therapists treating patients with BPD and SUD. A primary market analysis conducted by the founding team asked the question whether our software was most appropriate for corporate wellness, institutional wellness, employee assistance programs (EAP), or clinical settings. We found after 93 calls that there was more receptivity to our software in clinical settings.

Next, we asked whether our target purchaser, the clinic, was willing to pay for our software. In a phone survey of 18 clinics in Missouri, an entry price of \$14 / therapist / month was the average expected cost for our tool. At the sample average of 18 therapists / clinic, each clinic would bring in just over \$3,000 / year. Many therapists cited opportunities for added value, so a premium tier could increase the attractiveness. Other clinics, such as the integrative medicine center, Palm Health, desired to contract white labelling the software solution to enhance their branding. Thus we conservatively calculate our base market size as \$3000 times the 15,000 of SUD clinics [5] = 45 million.

Emerging mobile mental health technologies confirm our assessment of the market opportunity. Pear Therapeutics recently became the first company to achieve FDA approval for a prescription-only adjunct for SUD patients [6]. While market penetration is low, startups with strong research / academic relationships and a regional growth strategy will prevail.

Our growth strategy is to concurrently validate in an academic setting and in commercial clinics. Our advisor, Ryan Lindsay's clinic, St. Louis Center for Family Development, specializes in DBT and serves SUD clients. A successful pilot story with the Center can then be disseminated to Ryan's engaged listserv of DBT specialists across Missouri. Revenue from deployment in Missouri companies will fuel online marketing and automation for Mindset-SUD expansion across the country.

References

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<https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm576087.htm>

Mental Health App Marketing Respondants

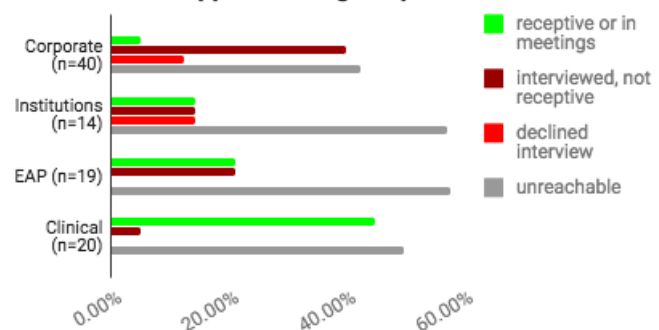


Figure 3: Primary market research showing that clinical personnel are the most likely to be receptive to a mental health app, with nearly 50% of cold calls resulting in follow-up interest.