INTEGRATING DIGITAL APPROACHES IN SUD TREATMENT

Resource Guide

This resource guide includes clinical practice guidance, checklists, key takeaways, and other resources and references on integrating digital approaches for the treatment of substance use disorders.



Resource Guide Description

This resource guide contains an overview of the latest digital approaches available for the treatment of substance use disorders (SUDs).

Designed for prescribing clinicians, the evidence supporting the efficacy of digital interventions for SUDs is examined and practical strategies are explored for integrating these approaches into clinical practice as an adjunct to other evidence-based treatment approaches.

Faculty



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Dr. San Bartolome serves patients with SUDs through FQHCs and is the former National Medical Director for Substance Use Disorders at Molina Healthcare and currently serves as CEO of Thru Health, a telehealth behavioral health organization.



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Dr. Barman is an expert in Digital Therapeutics for substance use disorders and serves on committees for the American Society of Addiction Medicine (ASAM) and the American Academy of Addiction Psychiatry (AAAP).

Key Topics



Evolution of Digital Approaches and Key Terminology



Summary of Digital Solutions for SUD Treatment



Best Practices for Integrating Digital Approaches

Learning Objectives

Define basic terminology related to digital approaches in SUD.

Explore the landscape of digital approaches for SUD treatment.

Evaluate digital tools that are evidence-based and differentiate the quality of various tools.

Identify patient characteristics that make use of digital approaches appropriate.

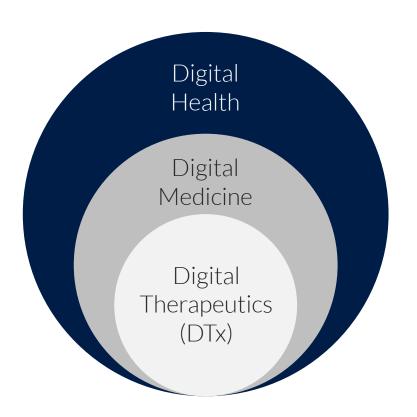
Examine best practices for implementing digital tools in your practices to supplement the current evidence-based treatments.

Definitions Matter

Digital Health encompasses:

mobile health, health information technology, wearable devices, telehealth/telemedicine, and personalized medicine.

- Engages consumers for wellness and health-related purposes.
- Collects health data.
- Does not require clinical evidence.
- Does not meet the regulatory definition of a medical device.
- Does not require regulatory oversight.



Digital Medicine is a subset of Digital Health.

It utilizes evidence-based software and/or hardware products to measure human health.

- Requires clinical evidence.
- Regulatory oversight requirements vary.
- Products classified as medical devices require regulatory approval.
- Products used as a tool for developing other drugs, devices, or medical products require regulatory acceptance by the appropriate review division.

Digital Therapeutics is a subset

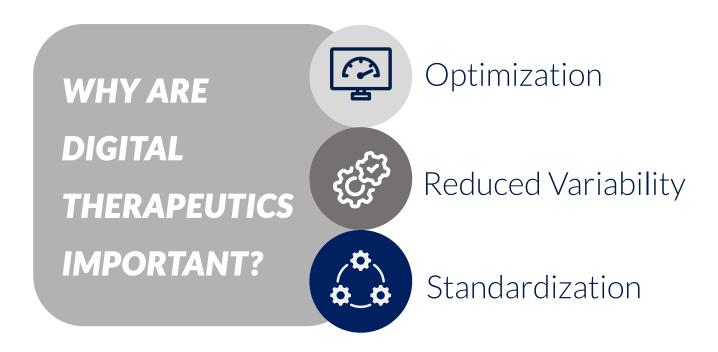
of Digital Health and Digital Medicine.

It utilizes evidence-based, clinically evaluated software to directly deliver medical interventions for treating, managing, and preventing a wide range of diseases and disorders.

- Deliver evidence-based therapeutic interventions to prevent, manage, or treat diseases.
- Require clinical evidence and data on real-world outcomes.
- All Digital Therapeutics products must undergo review and obtain clearance or certification from regulatory bodies.
- Regulatory clearance ensures support for product claims regarding risk, efficacy, and intended use.

SOURCE: <u>HTTPS://WWW.NCBI.NLM.NIH.GOV/PMC/ARTICLES/PMC7380804</u>

Introduction to Digital Therapeutics in SUD



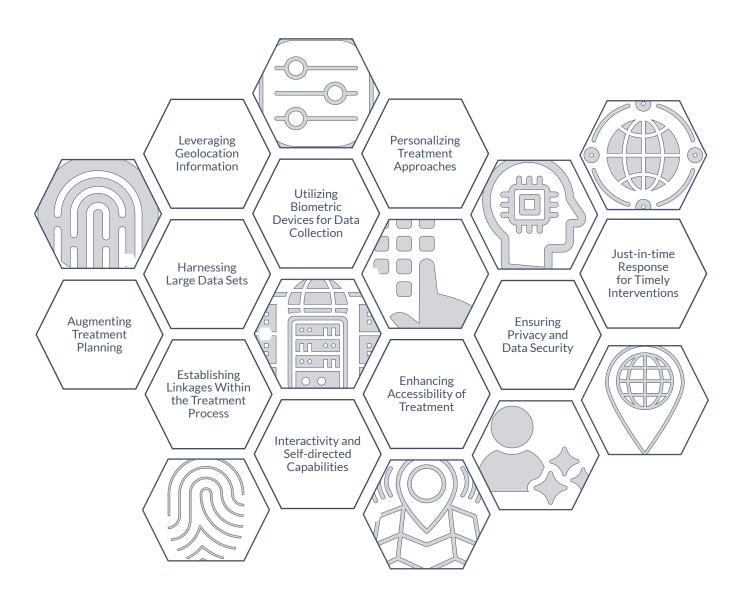
Potential Benefits of Digital Therapeutics for Patients with SUD

- Limited access to specialty SUD treatments with fidelity
- Elimination of geographic barriers to treatment access
- Ability to be used alongside other available treatments
- Self-paced nature of digital therapeutics
- Cost-effectiveness
- Improved engagement, overcoming challenges posed by stigmatization
- Empowerment of patients to actively participate in their care
- Personalization opportunities

SOURCE: DIGITAL THERAPEUTICS ALLIANCE

AI in SUD Treatment

Artificial Intelligence (AI) has emerged as a transformative force in various fields, including healthcare. Al combines computer science with robust datasets to enable problem solving. It refers to algorithms that have the ability to mimic human intelligence, taking over tasks and making decisions. In the context of SUD assessment and treatment, AI offers tremendous potential to enhance patient care and outcomes.



Legal and Ethical Considerations in AI

Responsibility

It is important to define clear responsibilities for the development, deployment, and outcomes of AI systems in SUD treatment. This includes establishing accountability among developers, operators, and users to ensure responsible and ethical use of AI technologies.

Informed Consent

Respecting the privacy of individuals seeking SUD treatment by obtaining informed consent is crucial when collecting and utilizing personal data for Aldriven interventions. Ensuring individuals understand and consent to the use of their data is essential for maintaining trust and ethical practice.

Privacy and Surveillance

Safeguarding patient privacy and minimizing unnecessary surveillance are key considerations in AI-enabled SUD treatment. Protecting personal information and implementing robust privacy measures are critical to uphold confidentiality and maintain patient trust in the use of AI systems.

Algorithmic Bias and Fairness

Al systems used in SUD treatment must be designed to avoid biases that could perpetuate inequities or discriminate against certain populations. Ensuring fairness and mitigating algorithmic biases is essential to provide equitable treatment and avoid potential harm to vulnerable groups.

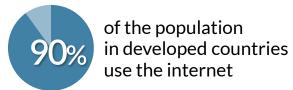
Safety and Transparency

Prioritizing the safety of patients and promoting transparency in AI systems are vital in SUD treatment. AI technologies should be developed with safety measures in place to minimize risks. Providing explanations and insights into the decision-making process can enhance transparency and accountability.

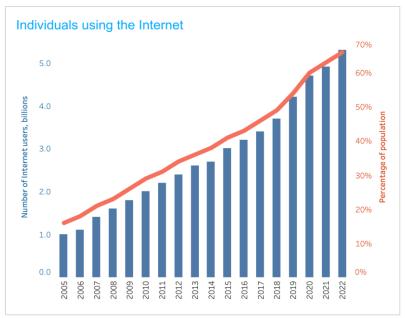
Integrating Digital Approaches For SUD Treatment Into Practice

Adoption of Internet & Mobile Technologies Has Skyrocketed









SOURCE: INTERNATIONAL TELECOMMUNICATION UNION

Summary of Solutions for SUD



What can we do about healthcare's "5000-hour problem"?

Each year, patients typically spend only a few hours a year in front of a clinician, but what happens during the remaining 5000+ waking hours of their year? Digital solutions may be able to provide more data on those 5000 hours and allow clinicians to extend the duration and impact of their treatment interventions.

SUD is intertwined with daily activities and life, making technology valuable in:

- Logging substance use in real-time
- Providing a return to use prevention plan at one's fingertips
- Observing actions and influencing choices in the moment

Technology addresses limited access and stigma associated with traditional treatment modalities.

SOURCE: DOI: 10.1056/NEJMP1203869

Summary of Digital Solutions for SUD

Digital Therapeutics Tools, Programs and Services

A brief summary of a range of digital therapeutic tools, programs, and services.

Provider/ Product	Platform	Use Case	Cost
RESET/RESET-O	Арр	Community Reinforcement Approach (CRA)	Product not available as of June 2023
Dynamicare Health	Арр	 Personalized coaching Self-paced lessons, at-home tests, and online recovery support meetings Financial rewards for recovery behaviors 	\$30-60 per week
Chess Health	Smartphone apps	Support in treatment and recovery, referral, and prevention	Information not available
CBT4CBT	Web-based	 Cognitive Behavioral Therapy Narrated videos with strategy modeling 	\$100 per license

While inclusion does not indicate endorsement, the tools and programs above are subjects of ongoing clinical research to evaluate the clinical efficacy of the treatment and programs associated with them. The development of a solid evidence basis for the use of digital therapeutic tools in SUD treatment is still emergent.

Considerations for Implementing DTx

- Development costs for DTx are high.
- Challenges exist in obtaining payment for DTx.
- Adoption of DTx can be challenging.
- Further research is needed for successful implementation and dissemination.
- There are limited options in the current DTx landscape for SUDs.

Mobile Applications



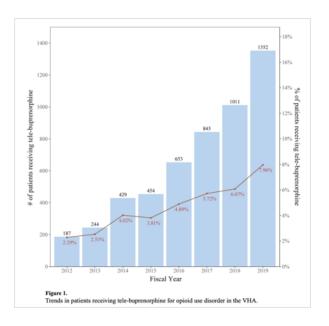
10,000+ mental health apps available for mobile devices!

However,

- · Their quality varies.
- May have low utility in practice.
- Retention was only about 3% in the 15-30 day range.
- · Limited reliable research available.
- Only 2% supported by original research.

Telemedicine

- The pandemic increased telehealth visits.
- Telehealth is not recommended as a replacement for conventional treatment.
- DEA extended COVID-19 telemedicine flexibilities for controlled medication prescription, with the potential reestablishment of Ryan Haight Act restrictions. For more info, visit <u>SAMHSA.GOV</u>.
- Best practices for video telehealth can be found through the American Telemedicine Association and American Psychiatric Association.



Social Media



- exposure to peer posts discussing the negative consequences of using substances and positive experiences with treatment/recovery can increase treatment-seeking intentions, while posts that are pro-use may reduce this intention.
- A study of TikTok, a popular video platform, showed a high level of interaction with videos discussing recovery, recovery milestones, and return to use in SUD.

Chatbots

Chatbots are AI-powered tools that engage in conversations with users, offering personalized support and enhancing engagement in DTx for SUD treatment. They hold promise for comprehensive treatment platforms and raise ethical concerns regarding data privacy, security, and informed consent.

Safeguarding patient information and complying with regulations are crucial in addressing these considerations.



Digital Peer Support



- Cochrane Review (2020) demonstrated that Twelve Step Facilitation (TSF) was more effective than other established treatments, such as CBT, in increasing abstinence.
- Completing certain elements of TSF, such as finding a sponsor, disclosure, and picking up on cues, may be more challenging via video platforms.
- Challenges exist around access to technology and privacy, particularly for groups that value anonymity.

Wearables and Tracking

- Concerns of consistency and accuracy.
- Passively collects real-time data.
- Aids in return to use prevention and intervention.
- Detects overdose risk.
- Rae Health, an SUD behavioral modification wearable, can assist with trend identification and costs \$1,000 per year, which includes the device.



Virtual Reality



- Used for exposure therapy.
- Mixed results in a 2021 systemic review of studies with some positive, null, and negative outcomes.
- Further research is necessary before widespread clinical use.

Patient Characteristics Checklist

When integrating digital therapeutics in patient care, providers should evaluate patient readiness in these areas:



Motivation and Readiness

Patient demonstrates willingness and commitment to engage in digital interventions for substance use disorder treatment.





Personal Preferences

Patient prefers or shows interest in digital approaches as a complement or supplement to traditional in-person treatment.





Technological Literacy

Patient possesses basic technology skills and is comfortable navigating digital platforms and applications.





Availability and Accessibility

Patient has regular access to reliable internet connection and appropriate technology devices, with privacy and confidentiality measures in place.





Self-Monitoring and Self-Management

Patient is willing to track and monitor substance use patterns, engage in self-reflection, and utilize digital resources for coping and return to use prevention.





Social Support

Patient has access to a supportive network and expresses a desire to connect with others through digital platforms for encouragement and assistance.





Clinical Considerations

Patient's substance use disorder is at an appropriate level for digital interventions (e.g., mild or moderate), and their physical and mental health conditions do not hinder effective engagement with digital tools. A digital tool would aid in determining the next steps.



Provider Characteristics Checklist

Providers seeking to integrate digital therapeutics in treatment should have or build competencies in these areas:



Technological Proficiency

Physicians utilizing digital approaches should be comfortable and proficient in using technology, including electronic medical records, telehealth platforms, mobile applications, and virtual communication tools. They should have the ability to navigate and leverage these digital tools effectively to support patient care.





Openness to Innovation

Physicians should be open-minded and receptive to adopting innovative digital approaches in their practice. They should be willing to explore new technologies, stay updated with advancements in digital health, and embrace evidence-based digital interventions for substance use disorders.





Strong Communication Skills

Effective communication is crucial when using digital approaches for substance use disorder treatment. Physicians should possess excellent verbal and written communication skills to engage with patients remotely, convey empathy, and deliver clear instructions through digital channels.





Adaptable and Flexible

Digital approaches to substance use disorder treatment may vary in form and delivery. Physicians should be adaptable and flexible to accommodate different digital interventions and platforms, tailoring their approach to the specific needs and preferences of each patient. They should be comfortable adjusting their treatment plans based on patient feedback and technological advancements.





Data Literacy

Digital approaches generate vast amounts of patient data, including treatment outcomes, adherence, and engagement metrics. Physicians should be comfortable analyzing and interpreting this data to inform their clinical decision-making and identify areas for improvement. They should understand how to protect patient privacy and adhere to data security protocols.





Continuous Learning

Digital health is a rapidly evolving field. Physicians should have a commitment to lifelong learning and staying updated with emerging research, guidelines, and technologies related to substance use disorder treatment. They should actively seek professional development opportunities and engage in peer collaboration to enhance their digital practice.



Ethics, Safety, and Data Privacy



Ensure adherence to ethical guidelines and industry standards for digital health interventions.



Comply with regulatory requirements and appropriate FDA guidance for the use of digital health solutions.



Safeguard patient privacy and protect personal health information through secure data handling practices.

Industry Core Principles of Digital Therapeutics

From the Digital Therapeutics Alliance

- Prevent, manage, or treat a medical disorder or disease.
- Produce a medical intervention that is driven by software.
- Incorporate design, manufacture, and quality best practices
- Engage end users in product development and usability processes
- Incorporate patient privacy and security protections
- Apply product deployment, management, and maintenance best practices.

- Publish trial results inclusive of clinically-meaningful outcomes in peer-reviewed journals.
- Be reviewed and cleared or certified by regulatory bodies as required to support product claims of risk, efficacy, and intended use.
- Make claims appropriate to clinical evaluation and regulatory status.
- Collect, analyze, and apply real world evidence and/or product performance data.

SOURCE: DIGITAL THERAPEUTICS ALLIANCE

Barriers and Considerations

The successful implementation of digital approaches in SUD treatment faces various barriers and considerations.

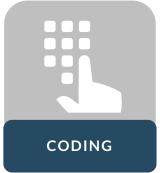






Overcoming these challenges is crucial for the effective integration of digital interventions into SUD treatment practices.







Additional Resources



AMERICAN SOCIETY FOR ADDICTION MEDICINE

SUPPORTING ACCESS
TO TELEHEALTH FOR
ADDICTION SERVICES

https://www.asam.org/quality-care/ clinical-recommendations/covid/supportingaccess-to-telehealth-for-addiction-services



TELEMEDICINE ASSOCIATION



AMERICAN PSYCHIATRIC ASSOCIATION

BEST PRACTICES IN VIDEOCONFERENCING-BASED TELEMENTAL HEALTH

Published online:14 Nov 2018 https://doi.org/10.1089/tmj.2018.0237



Additional Resources

Part One: Evolution of Digital Approaches and Key Terminology

- Center for Devices and Radiological Health. (n.d.). What is Digital Health? U.S. Food and Drug Administration. Retrieved February 25, 2023, from https://www.fda.gov/medical-devices/digital-health-center-excellence/what-digital-health
- Dang A, Arora D, Rane P. Role of digital therapeutics and the changing future of healthcare. J Family Med Prim Care. 2020;9(5):2207-2213. Published 2020 May 31. doi:10.4103/jfmpc.jfmpc_105_20
- Brezing CA, Brixner DI. The Rise of Prescription Digital Therapeutics in Behavioral Health. Adv Ther. 2022 Dec;39(12):5301-5306. doi: 10.1007/s12325-022-02320-0. Epub 2022 Oct 15. PMID: 36242730; PMCID: PMC9569000.
- Digital Therapeutics Alliance. (2022, September 16). What is a DTX? Digital Therapeutics Alliance: What is a DTx? Retrieved February 24, 2023, from https://dtxalliance.org/understanding-dtx/what-is-a-dtx/#understand
- Naik N, Hameed BMZ, Shetty DK, Swain D, Shah M, Paul R, Aggarwal K, Ibrahim S, Patil V, Smriti K, Shetty S, Rai BP, Chlosta P, Somani BK. Legal and Ethical Consideration in Artificial Intelligence in Healthcare: Who Takes Responsibility? Front Surg. 2022 Mar 14;9:862322. doi: 10.3389/fsurg.2022.862322. PMID: 35360424; PMCID: PMC8963864.

Part Two: Summary of Digital Solutions for SUD Treatment

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- Timakum T, Xie Q, Song M. Analysis of E-mental health research: mapping the relationship between information technology and mental healthcare. BMC Psychiatry. 2022 Jan 25;22(1):57. doi: 10.1186/s12888-022-03713-9. PMID: 35078432; PMCID: PMC8787445.
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- Lougheed T. How "digital therapeutics" differ from traditional health and wellness apps. CMAJ Can Med Assoc J. 2019 Oct 28;191(43):E1200–1.
- Capito SM. S.3791 117th Congress (2021-2022): Access to Prescription Digital Therapeutics Act of 2022 [Internet]. 2022. Available from: http://www.congress.gov/

Part Three: Integrating Digital Approaches for SUD Treatment Into Practice

Digital Therapeutics Alliance Digital Therapeutics Definition and Core Principles
 Version: November 2019 Accessed date July 13, 2023 https://dtxalliance.org/wp-content/uploads/2021/01/DTA DTx-Definition-and-Core-Principles.pdf