

REVIEW



Digital therapeutics: metamorphosis of healthcare

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ABSTRACT

We live in an era of innovation, transformation, and digitalization, where the pharmaceutical and healthcare industries are experiencing significant growth. Digital therapeutics is a groundbreaking fusion of pharmaceuticals, treatments, and digitalization that has revolutionized patient care by combining software, wearable technology, and medications. Integrating social media platforms, smart gadgets, and applications into our daily lives has led to the development of new implications and applications in therapeutics. Digital therapeutics has blessed patients with chronic diseases and practitioners alike. It has helped overcome the challenges of non-compliance and non-adherence that used to cause therapeutic failure. Digital therapeutics has contributed substantially to treating diseases such as diabetes, hypertension, dementia, Parkinson's, and many more.

KEY WORDS

Digitalization; Digital therapeutics; Medications; Chronic; Therapeutics; Non-Compliance

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Introduction

The Digital Therapeutics Alliance (DTA) defines dtx as "delivering evidence-based therapeutic interventions to patients that are driven by software to prevent, manage, or treat a medical disorder or disease" [1]. They may be used alone or with medicines, devices, or other treatments to enhance patient care and health outcomes. Innovative technology combines industry-leading standards for design, clinical assistance, usability, and data security in dtx solutions [1]. Regulators examine and approve these products to verify that the products' risk, efficacy, and intended use claims are accurate. Dtx contains therapeutic acts used to treat, manage, or prevent a disease or a medical condition and is backed by evidence. Examples include digital sensors, wearable technology, particularly virtual reality (VR), and artificial intelligence (AI) devices [1]. This review examines digital therapeutics - an emerging field that has amalgamated technology, software, and medicine to transform patient care. Our focus lies on defining digital therapeutics as a field and exploring its application to managing chronic diseases and mental health while overcoming regulatory hurdles. This current review sheds light on the patient-centric nature of dtx while acknowledging ongoing research to overcome obstacles and meet future challenges. Digital therapeutics promise to enhance patient outcomes, reduce healthcare costs, and reshape healthcare delivery in this digital era.

Implications

The growing presence of digital therapeutics (DTx) in the healthcare landscape reshapes patient care and how healthcare is delivered. As healthcare transitions towards value-based care, breaks down traditional silos between settings, and emphasizes data-driven collaboration, DTx is emerging as a powerful tool [2]. These digital health technologies, including apps, software programs, and sensors, empower patients to adhere to treatments, set and achieve care goals, and avoid costly hospital visits [3]. Simultaneously, DTx equips healthcare practitioners with tools to ensure optimal patient outcomes, streamline costs, and closely monitor patient progress through data analysis and sharing. In this era of digital healthcare, patients are

taking more control over their treatment decisions, making digital health solutions, including DTx, essential for meeting the needs of today's empowered patients. DTx represents a category of evidence-based, software-driven therapeutic interventions that revolutionize the prevention and management of various medical disorders and diseases [4]. In this context, the implications of DTx span multiple healthcare domains, promising to enhance cognitive rehabilitation, mental health treatment, medication adherence, and much more. DTx is poised to transform patient care and reshape the healthcare landscape by harnessing innovative technologies.

DTx is ushering in a new era of healthcare, offering a wide array of applications that benefit patients, healthcare providers, and payers. Like pharmaceuticals, the effectiveness of DTx-based products in preventing, managing, or treating diseases must be scientifically established. These therapies can stand alone or complement other forms of treatment, providing a versatile approach to healthcare. This section discusses some of the latest developments in DTx and their holistic impact on healthcare consumers [5].

Cognitive enhancement

Cogmed's Therapeutic Training for Working Memory offers individuals suffering from cognitive deficits due to stroke, brain injuries, and neurological diseases the opportunity to enhance working memory through specialized training sessions designed to increase working memory recall [5].

Constant therapy for speech and language

Constant Therapy is an iPad program that assists individuals who suffer from speech, language, and cognitive deficits due to neurological conditions by offering tailored rehabilitation [6].

Improved medication adherence

BETACONNECT stands out for its automated injection tracking feature, enabling more objective assessments of medication adherence, an integral element for successful treatments [7].

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Mental health support

Freemira, which has received FDA endorsement, has shown significant benefits in reducing panic attacks and treating post-traumatic stress disorder (PTSD), underscoring its value as a digital therapeutic in mental health treatment [4-6].

NightWare™ for nightmare management

NightWare™ is classified as a Class II device with low risk and uses biosensors inside of a smartwatch to detect and prevent nightmares by vibrating their arm to interrupt them, offering a novel approach to treating sleep disorders [5-7].

Attention enhancement with endeavor Rx(r)

Children with ADHD can extend their attention spans through EndeavorRx(r), a video game-based digital therapeutic program that encourages them to multitask while maintaining selective concentration and attention regulation [4-6].

Substance use disorder treatment

ReSET™ and ReSET-OTM, developed by Pear Therapeutics, are FDA-approved DTx for treating substance use disorders, underscoring their promise as interventions in addiction treatment [6,7].

Accessible therapeutic content

Digital delivery allows users to easily access therapeutic exercises through mobile phones at their convenience, giving them access to therapeutic exercises through personal mobile devices at any time and place [4-8].

Redefining healthcare with technology

Cloud and mobile technologies have revolutionized healthcare, opening the way for new therapeutic interventions in disease prevention and management. DTx provide safer, cost-effective therapies that benefit patients and providers [7,8].

Artificial intelligence

Artificial intelligence and digital biomarkers play a pivotal role in DTx, distinguishing them from traditional therapies. They allow practical monitoring and treatment of patient symptoms efficiently while, freeing healthcare professionals for more compassionate interactions that tackle sensitive personal matters [7]. DTx hold tremendous promise across various healthcare domains, from cognitive rehabilitation and mental health treatment to medication adherence and beyond. Integrating innovative technologies promises to enhance patient care and change the healthcare landscape.

Applications

DTx offers patients, healthcare providers, and payers easy-to-use, data-driven therapies to treat various illnesses. Like pharmaceuticals, the efficacy of DTx-based products used for disease prevention, management, or treatment should be scientifically established before being given to patients. DTx may be administered alone or combined with other forms of treatment as necessary. Mobile device use harms the audiovisual and central nervous systems (CNS). It may cause slumped posture that strains the musculoskeletal system, irritability or mishaps when driving, necessitating further clinical studies and driver training monitoring for safety purposes [6,7]. To combat these problems further, additional clinical research must be performed alongside driver testing monitoring [7,8].

People with cognitive impairments can improve their working memory skills with Pearson Education Inc.'s Cogmed Working Memory Training platform in Stockholm, Sweden. The program includes verbal and visual working memory activities to assess patients' recall abilities. After receiving Cogmed training at home, stroke patients saw their working memory and attention improve and reported fewer cognitive difficulties post-training [8,10]. Attaining effective management of hypertension requires maintaining an ongoing bidirectional relationship between physicians and patients and lifestyle modifications before any evidence of hypertension is discovered; lifestyle modification could prevent its onset and its negative side effects, such as cardiovascular disease. Therefore, in addition to digital therapies designed specifically to manage hypertension, research into developing DBM tools that prevent lifestyle-related disorders, including early hypertension, is also crucial [9].

Digital therapies have shown the ability to enhance patient outcomes, reduce healthcare costs, and boost patient happiness. Although DTx is still in its infancy in urology, it may provide patients with more options when treating various urological disorders. Before DTx for urinary disease can be integrated into clinical practice guidelines, more clinical evidence must be accumulated to give doctors confidence in the accuracy of sensor-collected data. This may require training medical virtualists. Furthermore, any discomfort caused by wearable technology must be minimized to increase patient compliance [10]. CureApp SCTM DTx for nicotine dependence is a therapeutic system that offers intervention and support for psychological dependence to quit smoking in addition to traditional 12-week smoking cessation plans in Japan. The system consists of a mobile carbon monoxide (CO) tester gadget with Bluetooth connectivity, web-based medical software, and a smartphone therapy app; each user receives customized behavioral treatment materials from therapeutic software to quit [11].

DTx is becoming a valuable tool for patients, healthcare providers, and payers, offering user-friendly, data-driven therapies for various conditions. Similar to pharmaceuticals, the efficacy of DTx-based products must be scientifically established for disease prevention, management, or treatment. These digital interventions can be used alone or with other treatments as needed. However, it is crucial to address the potential adverse effects of excessive mobile device use, such as musculoskeletal strain and distracted driving, through further clinical research and safety measures [12].

Digital Therapeutics in Healthcare

The DTx field is at the forefront of a transformative era in healthcare, offering novel solutions with the potential to augment patient care and reshape the management of medical conditions. DTx encompasses a spectrum of innovative interventions, including mobile health applications (mHealth) that extend personalized healthcare and cognitive-behavioural therapy (CBT). These interventions extend to cost-effective approaches for conditions like insomnia. DTx is progressively extending its influence and scope. In the below-mentioned section, we will discuss some of the latest examples of DTx in healthcare [13].

Integrating mobile health apps

Mobile health applications (mHealth) can supplement digital

treatments, providing remote access to healthcare providers such as physiotherapists. This extends personalized care, such as CBT. Sleepio, an online therapy program developed by Big Health that uses visual activities to aid people in overcoming insomnia, may provide a more cost-efficient and effective solution than traditional sleeping medications. Suggestive Therapeutics provides a doctor-authorized diet and lifestyle plan to enhance heart health. Their solution monitors heart rate, rhythm, and movement to support managing cardiovascular conditions more effectively [13].

Innovations in urology

DTx have quickly emerged as valuable additions to conventional urological treatments, but their implementation requires extensive clinical evidence and specialized virtualists to ensure accurate data collection and patient compliance.

Smoking cessation

The CureApp SCTM DTx for nicotine dependence provides psychological dependence treatment alongside standard 12-week smoking cessation plans. Utilizing mobile carbon monoxide (CO) testers, web-based medical software, and smartphone therapy apps, this solution offers personalized behavioral treatment plans to aid smoking cessation.

Cost-effective solutions

DTx have proven their cost-effectiveness, particularly for CBT applications. As CBT applications expand their clinical indications, more clinicians are turning to digital platforms as a bridge between traditional healthcare and digital platforms for patient treatment, affordability, and access [14]. Particularly beneficial are real-world data collection and analysis platforms facilitated through digital therapeutic applications, helping chronic mental and neurological conditions that cannot be properly managed with conventional medicine alone [15-17].

Patient-centric care

DTx fosters patient-centricity by offering tailored, engaging solutions for managing conditions such as weight loss, cancer, diabetes, and mental health [18]. Real-time monitoring and disease management improve outcomes, lower medical costs, and enhance quality of life. At the same time, DTx use real-time data for personalized insulin dose recommendations for managing diabetes [19].

Enhancing user/patient centricity

DTx takes an approach that emphasizes active patient participation in digital solution design and enhancement, with patient advocacy to ensure solutions are designed with user input, mitigating implementation challenges and increasing adoption rates [20].

Challenges in Implementation

Effective use of DTx requires extensive patient training and the development of specialized skills for data gathering, analysis, and equipment operation [21]. Overcoming language barriers among healthcare professionals is paramount for effectively deploying this medication. While historically focused on behavioral and chronic conditions, some producers are now offering it for acute conditions too, necessitating proactive regulatory evaluation and labeling processes [22].

Post-marketing studies

Post-marketing studies provide essential data on the real-world use of DTx in diverse populations, long-term safety,

and patient adherence to its use in multiple settings. Furthermore, these studies reevaluate its benefit-risk ratio while gathering insight into the widespread adoption of its usage [23].

In pursuing patient-centered care, DTx solutions are undergoing adaptive refinement to encompass a diverse spectrum of medical conditions, including but not limited to weight management, oncology, diabetes, and mental health disorders. These solutions incorporate real-time monitoring and data-driven methodologies to manage various medical conditions effectively [24]. However, the maturation of DTx presents notable challenges, encompassing issues related to implementation, specialized training prerequisites, and the imperative of regulatory scrutiny. These challenges assume particular salience when DTx applications expand into acute medical conditions [25].

Regulatory and reimbursement aspects

Integrating DTx into the healthcare landscape presents a host of regulatory and reimbursement complexities that must be navigated to ensure their effective adoption and utilization. As healthcare systems worldwide grapple with the transformative potential of DTx, several critical aspects come to the forefront [26]. These aspects encompass the challenges of seamlessly integrating DTx data into patients' longitudinal health records. These diverse regulatory models govern their usage, the imperative of safeguarding user privacy through innovative techniques like Federated Learning (FL), and the need for DTx to balance safety, efficiency, and cost-effectiveness while upholding trust and transparency. In this context, this section discusses the complexities of these regulatory and reimbursement dimensions, shedding light on the multifaceted landscape surrounding the incorporation of DTx within healthcare settings [27].

Data integration challenges

Nations and regions around the globe continue to face difficulties with integrating DTx data into patients' longitudinal health records, with outcomes depending on factors like data type, usage by healthcare organizations, and interchange characteristics that vary greatly, resulting in different levels of interoperability across Electronic Health Records (EHR) functionalities across nations [28].

Diverse regulatory models

Digital Therapy is governed by established models for overseeing medications and medical devices. Each of these models varies based on where it is implemented; nations or regions often opt for their own versions, each offering its own set of strengths and weaknesses. Europe and the UK, for instance, offer self-certification (Class I CE mark), while MDR will introduce stricter regulations regarding digital medicines functioning as software applications. Embracing regulatory harmonization could bring many advantages [29].

Federated learning to protect user privacy

Federated Learning (FL) is an innovative algorithm designed to protect the privacy of individual user information. Instead of collecting it centrally, FL begins with creating an initial global model by a central server; devices involved in the learning process receive model weights, which they incorporate into their data sets before sending revised weights back to the server for compilation – thus keeping sensitive records secure as its access or verification cannot take place through central servers [27-29].

Safe, efficient, and cost-effective DTx

When employed wisely, DTx offers safe, efficient, and cost-effective treatment solutions. However, trust and transparency must be preserved throughout its development and deployment processes; adherence to FDA guidelines and best practices must also be implemented to help keep patients trustful while limiting potential harm. Insufficient regulation and reimbursement also present an obstacle; eliminating barriers is key to expanding its usage in clinical practice settings [27-29].

Integrating DTx into healthcare systems is a transformative journey fraught with regulatory and reimbursement complexities. The challenges of seamlessly integrating DTx data into patient records, navigating diverse regulatory models, and safeguarding user privacy through Federated Learning implicate the need for a holistic approach. While DTx holds great promise as an efficient, cost-effective treatment method, adhering to regulatory guidelines and overcoming reimbursement obstacles are critical elements in its successful application. Harmonization will streamline these innovations. As healthcare evolves, harnessing its full potential will require taking into account multiple dimensions such as these to unlock its full potential for patient care improvement and improved healthcare outcomes [30,31].

Conclusions

DTx, defined as evidence-based software interventions designed to treat medical conditions, has the potential to revolutionize patient care and disease management. From cognitive enhancement and mental health support services to substance use disorder treatments, DTx provides an agile yet patient-centric solution. Although DTx holds immense promise, it also presents several obstacles - from regulatory diversity and data integration complexities to safeguarding user privacy - that must be overcome to reach its true potential. Tackling these hurdles effectively is vital to unlocking its full potential. As healthcare moves toward value-based care and data-driven collaboration, DTx is an invaluable asset for patients to manage their healthcare delivery and empower themselves as healthcare providers. By taking advantage of innovative technologies and adhering to regulatory standards, DTx can produce improved patient outcomes, lower healthcare costs, and reshape healthcare delivery in today's digital era. Indeed, their continued development will undoubtedly shape healthcare in the years to come.

Disclosure Statement

No potential conflict of interest was reported by the authors.

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