Review Article

Digital Therapeutics: A New Dimension to Diabetes Mellitus Management

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Abstract: Digital therapeutics (DTx) play a transformative role in diabetes management by leveraging technology to provide personalized, data-driven medical interventions. These tools enhance self-management by offering continuous monitoring and real-time feedback on glucose levels, diet, and physical activity. This personalized approach helps patients adhere to treatment plans and make informed lifestyle changes, leading to improved clinical outcomes such as reduced HbA1c levels and better overall diabetes control. The importance of DTx lies in their ability to make diabetes care more accessible and convenient. Mobile apps and telemedicine platforms enable patients to receive support and guidance from anywhere, reducing the need for frequent in-person visits. Additionally, DTx often include behavioral support features like reminders, educational content, and motivational tools, which are crucial for maintaining healthy habits and managing stress. Currently, the dynamics of DTx in diabetes are rapidly evolving, with increasing integration of artificial intelligence and machine learning to further personalize and optimize care. As the adoption of these technologies grows, they hold the potential to significantly improve patient outcomes and revolutionize diabetes management on a global scale. This article will focus on the benefits of novel digital therapeutics for prevention and management of type II diabetes that are currently available in the market.

Keywords: Digital Therapeutics, Digital Health, Software as a Medical Device (SaMD), Healthcare Digitization, Technology in Healthcare

1. Introduction

The landscape of healthcare is becoming increasingly digital, with concepts such as personalised and precision medicine taking the lead. The integration of health and digital technology has resulted in the development of Digital Health, a broad category of digital health technologies aimed at improving human health and well-being, enhancing the quality and safety of care, expanding access to treatment, improving the efficiency of health services, and lowering overall health-care costs.

Digital therapeutics (DTx) defined by the Digital Therapeutics Alliance as "evidence-based therapeutic interventions driven by high-quality software programs to prevent, manage, or treat a medical disorder or disease" [1] have emerged as a new therapeutic modality for the prevention, management, or treatment of chronic, behaviour-modifiable disease. To prevent, manage, and/or treat a medical problem, these software-driven medical interventions combine pharmacologic and non-pharmacologic techniques with/without expert supervision. However, many companies follow four primary methods for validation. These include FDA (Food and Drug Administration) approval or clearance for use, registered clinical trials, observational studies or clinical trials, and retrospective studies.

The benefits of digital medicines align with market demand, therefore the market for digital therapeutics is growing worldwide, with an emphasis on advanced medical markets [2]. It is a relatively new discipline that uses digital implements like mobile devices, apps, sensors, the Internet of Things, and others to spur behavioural changes in patients. Mostly, DTx systems draw upon the evidence-based principles of behavioral or psychological intervention protocols known as "cognitive behavioral therapy" (CBT) [2]. It uses evidence-based techniques to change problematic behaviors and unhelpful cognitive distortions, and to improve emotional regulation and coping skills to solve the current problems [3]. Patients, physicians, and payers benefit from digital therapeutics because they provide sophisticated and accessible tools for addressing a wide range of diseases with high-quality, safe, and effective data-driven interventions.

According to the latest data from the International Diabetes Federation (IDF), the global prevalence of diabetes has reached 10.5% of the adult population (ages 20-79), which translates to approximately 537 million adults living with diabetes. Alarmingly, nearly half of these individuals are unaware that they have the condition. Projections indicate that by 2045, the number of adults with diabetes will rise to 783 million, or about 1 in 8 adults [4]. By leveraging technology, DTx provide scalable and effective solutions to manage diabetes, ultimately improving patient outcomes and quality of life.

This article will focus on the benefits of novel digital therapeutics for prevention and management of type II diabetes that are currently available in the market.

2. Materials and Methods

Comprehensive, structured literature searches were conducted in PubMed, Google Scholarand print media using key words digital therapeutics, digital health, Software as a MedicalDevice (SaMD), healthcare digitization and technology in healthcare.

Subsequently, the relevant papers and data published from 2010 to 2024 were fully reviewed,and their findings were noted.

2.1. Digital therapeutics market size & growth opportunities

The 2024's breakout funding in digital therapeutics is evidence of an unprecedented mandate for change, across all aspects of healthcare. Investments in digital therapeutics companies in the United States have grown as digital health funding continues to break records during 2024's blockbuster year, with the three highest-funded quarters ever [5]. Due to the increasing prevalence of diabetes, the diabetes application segment dominated the market in 2024.

The global digital therapeutics market size is estimated to grow from USD 2.83 billion in2024 to USD 19.76 billion by 2035, representing a CAGR of 19.32% during the forecast period 2024-2035 [6] (See Figure 1).

Global Digital Therapeutics Market
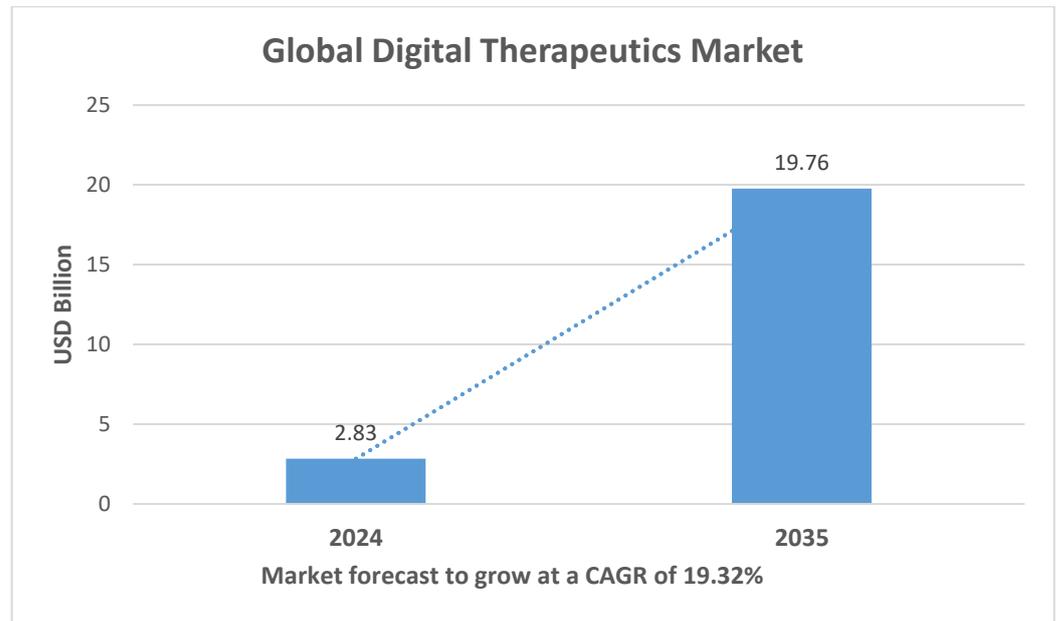
Figure 1. Global Digital Therapeutics Market

Furthermore, the market is expected to increase due to the cost-effectiveness of digital health technology for providers and patients, as well as rising demand for integrated healthcare systems and patient-centric care.

2.2. Potential benefits of Digital therapeutics in Diabetes

Digital therapeutics in diabetes offer a range of benefits aimed at improving disease management and patient outcomes. Here are some key aspects:

1. **Personalized Treatment:** Digital therapeutics provide tailored interventions based on individual patient data, which can include glucose levels, diet, physical activity, and medication adherence [7].
2. **Enhanced Self-Management:** These tools empower patients to take control of their diabetes management through continuous monitoring and feedback. This can lead to better adherence to treatment plans and lifestyle changes [8].
3. **Improved Clinical Outcomes:** Studies have shown that digital therapeutics can help reduce HbA1c levels, improve physical activity, and enhance overall diabetes knowledge [9].
4. **Accessibility and Convenience:** Digital platforms, including mobile apps and telemedicine, make it easier for patients to access care and support from anywhere, reducing the need for frequent in-person visits [10].
5. **Behavioral Support:** Many digital therapeutics include features like reminders, educational content, and motivational support to help patients maintain healthy behaviors and manage stress [7].

Overall, digital therapeutics offer a promising adjunct to traditional diabetes care, providing scalable and effective solutions to improve patient outcomes and quality of life (8). Table 1 summarizes the DTx currently available in market.

Table 1. Details of digital therapeutics currently available in the market

Wellthy Care	Hypertension + Diabetes	Lifestyle management and modification programme that is designed to help manage diabetes better. Patient can make better diet and lifestyle choices through instant feedback, expert coaching and diabetes related expert-verified content.
Twin health	Hypertension + Diabetes	This program gives a dynamic digital representation of patient's unique metabolism, built from thousands of data points gathered daily from non-invasive wearable sensors and self-reported preferences.
Fitterfly's Diabefly	Diabetes	Its cutting-edge technology uses Ambulatory Glucose Monitoring (AGM) with flash technology to track & record 1300+ blood sugar levels. Correlating these readings with patient's diet & lifestyle it enables to understand the exact causes of blood sugar fluctuations. Based on these insights an expert Diabefly Coach gives personalised recommendations on diet, exercise, sleep & stress.
Sugar Beat	Diabetes	Available as skin patch for Continuous Glucose Monitoring (CGM) The mobile app allows other manual inputs such as food, medicine, and exercise, to help users observe how all those factors are impacting their glucose levels.
OrpyxSl SensoryIn-soles	Diabetic footulcer	This comes with a pair of custom-made insoles, a digital display that is set up and ready to use out of the box, a charger, and the instruction manual. Orpyx® SI sensory insoles provide real-time feedback, enabling you to take immediate action when sustained high pressure is detected. High pressure can cause skin damage on the soles of the feet, which if left untreated could lead to foot ulcers, infections and, at worst case scenario, amputations.
Livongo	Diabetes	It provides real-time tips and insights after every check. If patient's reading is out of range, a Livongo expert coach will reach out. Patient can also contact a coach directly from platform for more guidance and support.
Tandem Diabetes Care	Diabetes	Tandem Diabetes Care builds the right products to craft a connected care experience that is positively different, while helping to make diabetes management easier.
Breath WellBeing	Diabetes	The company claims to have a clinically proven digital programme, which uses a personalised approach to help people with the disease reduce their blood sugar, lose weight, and eventually stop medication.
Welldoc	Diabetes	Empower people everywhere to self-manage their chronic conditions. Enable health ecosystems to optimize interventions, clinical decisions and population health.
Tidepool Uploader	Diabetes	Tidepool uploader is a universal uploader app that allows one to retrieve data over 50 supported devices, including every brand if insulin pump and continuous glucose monitor (CGM) on the US market and a wide variety of blood glucose meters and diabetes apps.
Insulia	Diabetes	Available via mobile app or web portal, Insulia is a prescription-only medical device that recommends basal insulin doses for adults with type 2 diabetes based on the treatment plan created by the healthcare provider.
dNav by Hygieia	Diabetes	Revolutionary technology for patients who inject insulin. Like the closed loop system for patients using a pump, d-Nav Technology seamlessly takes a glucose reading and calculates the next dose of insulin appropriate for the patient. The patient need only inject the recommended dose. Information regarding patient's glucose readings and insulin recommendations are always available to healthcare practitioner via dedicated provider portal.
Better Therapeu-tics	Diabetes, Hypertension, Hyperlipidemia, MASH/MASLD,CKD	Representing a new treatment modality for cardiometabolic diseases, this prescription digital therapeutics give intense behavioural treatment together with assistance from a remote multi-disciplinary care team.

MayaMD	Diabetes, CKD,Hypertension,Chronic diseases	Maya is a complete patient engagement platform which makes appropriate recommendation based on the patient's condition that is continuously tracked via its AI and ML based technology. Remote patient monitoring is a feature that helps in chronic daily care management of diseases including diabetes.
Ultrahu-manCy-borg	MetabolicFitness	It is a continuous Metabolic fitness tracker that helps to optimize lifestyle. It consists of a continuous glucose monitor (CGM) wearable device in the form of a non- invasive patch to track glucose levels and enable the patient to make healthier lifestyle choices throughout the day.
Dario	Cardiometabolic	Dario's evidence-based, personalized approach takes the guesswork out of managing diabetes. A pocket-sized smart meter and unlimited test strips allow for quick testing anytime, anywhere – no batteries required. Access to certified coaches and educational content provide the right support at the right time.
HelloBet-terDiabe-tes	Diabetes	Offers online course designed to reduce depressive symptoms and emotional burdens associated with diabetes.

3. Discussion

DTxs have shown to enhance clinical outcomes in T2DM patients in cohort studies. Over the course of a 3-month research [11], a mobile medical app named FareWell (now changed to Better Therapeutics) that gave intense behavioural treatment together with assistance from a remote multidisciplinary care team showed mean HbA1c reduction of 0.8%. Greater glycemic control was observed with increasing app engagement.

Digital therapeutic applications (DTx) like Blue Star, Diabeo System, Livongo Diabetes Program, and Tidepool, use web-based applications/cloud platforms to provide evidence based, personalized, rapid point of care management of chronic, behavior-modifiable conditions like diabetes mellitus (DM). It has significantly improved patient compliance, therapeutic success and economic outcomes in DM management by enabling active patient engagement, lifestyle change, comprehensive medical care, and periodic monitoring of glycemic status [12].

Regulated digital therapeutics are those that have been approved by the FDA and follow a prescription model similar to medical technology and pharmaceuticals. Software algorithms that administer insulin are one example in diabetes. Some examples of insulin dosage algorithms have been [13] certified by the FDA and are commercially accessible - Tandem, Voluntis, Hygieia, and Welldoc. Livongo's effort to combine remote monitoring and coaching with blood glucose monitoring is an excellent example of digital therapeutics that complement devices and pharmaceuticals. Onduo and Welldoc's work are two further examples which are working globally to reduce the disease burden. While in the Indian market, Mumbai based Fitterfly is a leading digital therapeutics company that provides a 360-degree holistic care and support to patients to help manage their diabetes.

In a recent study of 109 participants in the Fitterfly Diabetes CGM program, there was significant reduction in the mean HbA1c levels, weight, and BMI of the participants, emphasizing a high level of engagement with the program [14].

Another tool named MayaMD.AI [15] has features of recording vitals and care program through which remote patient monitoring is possible. This application consists of a customized and evidence-based medicine curated 'Care Program' (See Figure 2) for wide range of lifestyle diseases like Hypertension, Diabetes, CKD and CHF etc. The symptom checker is intended to assist patients in deciphering their medical symptoms and provide them with reliable information to help them maintain their health. For instance, to have a look at the blood glucose levels in case of diabetes along with timely vital check, right diet consumption and exercises in order to maintain healthy lifestyle.

The Connect with Care team feature consists of a team of expert professional doctors further aiding in pharmaceutical intervention along with lifestyle intervention.

It has a dedicated medical records section designed to help patients to store and access their health information making them track their own progress or health journey. It also increases portability of clinical information including the better interaction between patient and health service provide. Patients can even take their medical records to a new provider for second opinions. One can very easily use the application for doing daily wellness check in order to track progress and motivate themselves. The medication and refilling section provide system generated alerts in order to remind the user in case of medicine stock refilling ahead in time to keep patient constantly motivated towards the healthy goals.

Figure 2. A(left) depicts the Care Program of MayaMD app while B (right) depicts graphical representation of vitals like blood glucose level used for blood glucose monitoring.

The MayaMD.AI app presently allows customers to make simple digital payments and view their health insurance coverage information, ensuring that the buyer-seller service is transparent about treatment costs. It not only provides therapy but educates the patient about diabetes making patient self-aware, conscious controller of their own health. Medication increases control attributions while decreasing behavior management stability. As a result, medication and behavior therapy combined with a focus on overall comprehensive disease management are recommended to promote compliance.

3.1. Benefits and barriers of digital therapeutics

Digital therapeutics in diabetes prevention and management can have profound benefits in the overall health of the patient. It can help improve medication and dietary adherence, thereby helping in weight loss, better glycemic control and lower medication requirement. Increased app usage has been linked to better diabetes management, including

increased diabetes awareness and diabetes self-management behaviors like blood glucose monitoring and insulin administration [16, 17].

Despite the benefits, there is still scope of work pertaining to the quality of clinical data andreal-world evidence, as well as adapting digital therapeutics' business model to meet the demands of payers, providers, and health systems. The benefits and limits [18] of digital therapeutics is well summarized in Figure 3.
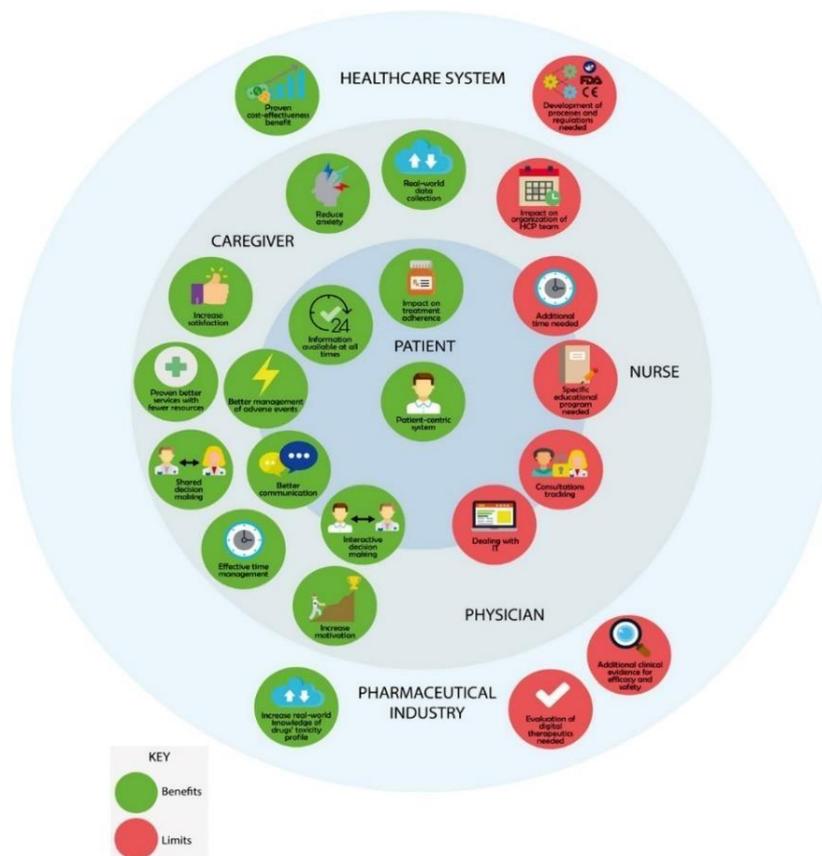
Figure 3. Benefits and limitations of digital solutions in the healthcare system. FDA US Food and Drug Administration, HCP healthcare professional, IT information technology; Source: (Aapro et al., 2020) Adapted from Digital health for optimal supportive care in oncology: benefits, limits, and future perspectives. *Supportive Care in Cancer*, *28*(10), 4589–4612. https://doi.org/10.1007/s00520-020-05539-1

There are several benefits that have a significant influence on all stakeholders (patients, physicians, caregivers, nurses, healthcare system, pharmaceutical firm), with limitations linked to technological problems, regulatory restraints, prices, and practice adjustments [19]. Although many medications and medical devices have undergone several validation and stability testing throughout time, the hurdles to approval for DTx are thought to be very low when compared to traditional drugs and medical devices [20]. Moreover, as technology gathers additional data, the proof will need to be updated on a frequent basis.

4. Conclusion

In a short span of time, digital therapeutics has become an integral part of healthcare systems. With chronic lifestyle diseases like diabetes on the rise, technology support would be required in effective management especially in monitoring. This technology would partly empower the patient to take charge of their health. While DTx cannot take

the place of healthcare providers (HCPs), it will support the HCPs in decision making and treatment planning, thereby making their work easier and organized. Considering some aspects of healthcare may never be completely replaced by technology, it is probable that DTx will be used in conjunction with other treatments to enhance patient results.

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