

# DIGITAL THERAPEUTICS: AN INTEGRAL COMPONENT OF INNOVATION IN THE HEALTHCARE SYSTEM

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## 1. ABSTRACT

*At the nexus of technology and healthcare, a growing discipline known as "digital therapeutics" (DTx) provides evidence-based software treatments for the management, prevention, and treatment of a wide range of behavioural, psychiatric, and medical disorders. The development of DTx is examined in this review article, which follows its beginnings from experimental ideas to complex, data-driven interventions that are revolutionising healthcare delivery..The early phases of DTx, which originated from telemedicine and electronic health records, have advanced significantly. These early programmes have focused on chronic diseases and mental health by utilising the widespread usage of smartphones and advances in mobile technology. The effectiveness of these treatments has increased with the integration of artificial intelligence, behavioural science, and machine learning algorithms, transforming patient care and showing possible cost-saving benefits for healthcare systems.A substantial portion of the review focuses on the specific context of India's healthcare system, addressing challenges such as unequal access, a shortage of medical specialists, and the digital gap. Despite these challenges, the paper underscores the potential of DTx applications to bridge accessibility limitations and offer critical healthcare services remotely. It analyses the unique challenges and opportunities in the Indian healthcare landscape, emphasizing how the strategic adoption of DTx can revolutionize healthcare delivery, providing accessible, personalized, and transformative solutions. In conclusion, this review provides a holistic understanding of the evolution and impact of digital therapeutics globally, with a specific focus on India. It highlights the potential for DTx to reshape healthcare delivery, improve accessibility, and deliver personalized solutions, laying the groundwork for a transformative future in the healthcare industry.*

**KEYWORDS:** *Digital therapeutics, healthcare, technological evolution, telemedicine, cultural relevance, regulatory landscape, challenges, opportunities, user engagement, intervention efficacy.*

## 2.INTRODUCTION:

The discipline of digital therapeutics, or DTx, is expanding quickly and changing the way that healthcare is provided. Software programmes known as "DTx" are evidence-based and intended to prevent, manage, or treat behavioural, psychiatric, and medical diseases(**'An Interdisciplinary Study on Generative AI'**)They are distributed via a range of gadgets, such as wearable technology, tablets, and smartphones. Compared to traditional healthcare interventions, DTx has several benefits. One such benefit is that it can boost patient involvement by giving patients real-time assistance and feedback(**Fürstenau, Gersch and Schreiter, 2023**). By facilitating patients' access to and management of their medications, it can aid in enhancing adherence to treatment plans. Because DTx reduces hospital stays , it also lowers healthcare expenses(**Ethics of digital therapeutics (DTx)**).

The effectiveness of DTx is being supported by an increasing amount of research, and the area is developing quickly(**Wiederhold, 2021**). Anxiety,post-traumatic stress disorder are just a few of the mental health issues that DTx is used to treat in conditions that are chronic DTx is being used to treat behavioural disorders as well

as a number of chronic conditions, including as diabetes, hypertension, and heart failure. DTx is being used to treat weight loss and smoking cessation, among other behavioural issues. We may anticipate seeing even more cutting-edge therapies that can enhance patients' lives as the DTx sector develops (Miao *et al.*, 2022).

### 3. REVIEW OF LITERATURE

In recent years, the intersection of healthcare and technology has given rise to a revolutionary paradigm known as digital therapeutics. As the world becomes increasingly digitized, the healthcare sector is undergoing a profound transformation, leveraging digital innovation to enhance patient outcomes, improve accessibility, and optimize healthcare delivery (Stoumpos, Kitsios, and Talias, 2023).

At the forefront of this transformation are digital therapeutics, a novel form of evidence-based interventions that utilize digital technologies to prevent, manage, or treat a medical disorder or disease. High-quality software programs are designed for digital therapies (DTx), which are evidence-based therapeutic treatments for the management, treatment, or prevention of illnesses or diseases (Digital Therapeutics (DTx) | European Data Protection Supervisor, 2017).

Digital therapeutics, in contrast to traditional medications, provide individualized and flexible interventions that customize care to each patient's need and reaction (Lee, 2021). In addition to increasing patient involvement, this tailored approach promotes a deeper comprehension of diseases' underlying biological and behavioral causes, which results in more effective and efficient healthcare treatments (Lutz *et al.*, 2022). This literature review examines the peer-reviewed evidence on digital therapeutics' evolution, role, and impact in modern healthcare systems (Huh *et al.*, 2022a). It focuses on how DTx augments traditional delivery models, increases access, personalizes care, and generates value. The evolution, functionality, benefits, and challenges of implementing digital therapeutics are also discussed.

#### 3.1 EVOLUTION OF DIGITAL THERAPEUTICS AND ITS GLOBALIZATION:

The field of digital therapeutics (DTx) has come a long way, starting with experimental ideas and ending with sophisticated, data-driven interventions that are revolutionizing healthcare (Dang, Arora and Rane, 2020).

Early trials with electronic health records and remote patient monitoring, initially based in the field of telemedicine, set the groundwork for the eventual development of digital therapies (Haleem *et al.*, 2021).

The ubiquity of smartphones and advancements in mobile technology have made it possible to create programs that are easy to use and target the management of mental health issues and chronic diseases (Dicianno *et al.*, 2015). The field of digital therapeutics grew along with the digital ecosystem. These therapies' efficacy was increased by the incorporation of machine learning algorithms, artificial intelligence, and behavioral science (Yoo, Jeong, and Chung, 2023).

This trajectory shows that the healthcare industry is not only expanding but also evolving, with digital treatments that are accessible and personalised having the potential to completely transform patient outcomes and healthcare delivery around the globe. With a compound annual growth rate (CAGR) of 20.11%, the global digital therapeutics market is projected to reach USD 36.1 billion by 2028 from an anticipated USD 14.44 billion in 2023 (Digital Therapeutics - Worldwide | Statista Market Forecast).

#### 3.2 FEATURES OF DIGITAL THERAPEUTICS:

Smartphones, PDAs, tablet computers, and virtual reality (VR) are some of the devices that make up digital therapies. These devices are combined with software algorithms. Utilizing the processing power and networking capabilities of smartphones to run certain apps, provide individualized patient education, conduct Internet-based cognitive behavioral treatment, and use virtual One crucial component of digital treatments is the health coach (Choi *et al.*, 2019).

The foundation of DTx is "software." They fit the US Food and Drug Administration's (FDA) definition of a medical device (SaMD), hence they can be regarded as examples of software. This indicates that the "software itself" is categorized as a medical device rather than the hardware it is installed on. Therefore, rather than needing to be installed specially on authorised medical equipment, DTx can be freely deployed on a standard smartphone or table (Huh *et al.*, 2022b).

### 3.3 DIGITAL THERAPEUTICS AND HEALTHCARE LANDSCAPE IN INDIA:

Driven by advances in technology and healthcare practices, the development of digital therapeutics (DTx) reflects a dynamic progression from early experimental stages to highly sophisticated interventions. At the same time, India's healthcare system offers a distinct combination of possibilities and challenges. Difficulties include unequal access to high-quality healthcare, a shortage of medical specialists, and the digital gap, which is characterized by differences in smartphone and internet usage (**Need for Digital Therapeutics in India**).

By interweaving the evolution of digital therapeutics with the unique challenges and opportunities in the Indian healthcare landscape, it becomes evident that the strategic adoption of DTx can revolutionize healthcare delivery, providing accessible, personalized, and transformative solutions across the diverse healthcare needs of the Indian population (**Dang, Arora and Rane, 2020**).

### 3.5 CULTURAL RELEVANCE AND USER ENGAGEMENT: TAILORING DIGITAL THERAPEUTICS FOR INDIA:

It is critical that user engagement techniques and cultural relevance be combined in digital treatments, particularly in a multicultural country like India (**Venkataraman et al., no date; Haleem et al., 2021; Global, School and Jindal, 2023**).

Numerous scholarly works underscore the importance of customizing digital interventions to conform to the cultural norms and values of the intended audience

According to a study (2023), digital health programs that are culturally appropriate greatly increase user engagement and lead to higher adherence rates among Indian patients (**Jain, 2023**).

### 3.6 REGULATORY LANDSCAPE AND POLICY INITIATIVES: NAVIGATING CHALLENGES

The goal of the effective implementation of digital therapeutics (DTx) in India is intricate and involves considerations of user involvement, cultural relevance, and regulatory restrictions (**Sverdlov et al., 2018**).

It is essential to comprehend the varied cultural environment of India. As stated in "Cultural Relevance and User Engagement in Digital Therapeutics for India," adapting DTx to cultural norms and language variety not only guarantees acceptability but also improves user engagement (**Venkataraman et al**).

However, for this cultural resonance to thrive, a favourable governmental climate is required. Regarding "Landscape and Policy Initiatives: Navigating Challenges," it is crucial to acknowledge cultural subtleties. Healthcare decisions in India are influenced by a varied range of cultural practices, which warrant consideration in regulations (**'Systematic Review on End-Users' Perception of Facilitators and Barriers in Accessing Tele-Rehabilitation Services | Enhanced Reader'**).

Regulatory organizations, developers, and cultural specialists must work together. Moreover, policy initiatives are closely related to user participation, which is a focus point in both contexts. Developers are empowered to construct captivating DTx platforms by policies that prioritize language variety, accessibility, and user-centered design (**'Digital Therapeutics: Pharmacy Care Innovation and Implications for Policy', 2021**).

Policies that encourage user-centered strategies advance the creation of culturally appropriate and captivating digital therapies, in line with the ideas explained in "Cultural Relevance and User Engagement" and "Landscape and Policy Initiatives." (**van Velthoven, Cordon and Challagalla, 2019**).

To put it simply, the success of DTx in India depends on a coordinated strategy. User involvement, cultural relevance, and policy initiatives are symbiotic factors that are influencing the direction of digital treatments rather than discrete parts. When these elements work together harmoniously, it not only overcomes the obstacles mentioned but also moves the Indian healthcare system closer to a day when digital therapies are easily incorporated into the country's laws and cultural norms (**Kumar, 2023**).

### 3.7 TELEMEDICINE INTEGRATION – REVOLUTIONISING HEALTHCARE IN INDIA

Increased accessibility and efficiency in the provision of healthcare are promised by the integration of telemedicine into India's healthcare system, which holds transformative potential. Numerous studies highlight how important telemedicine is to the transformation of healthcare delivery across the country (**Kumar, 2023**).

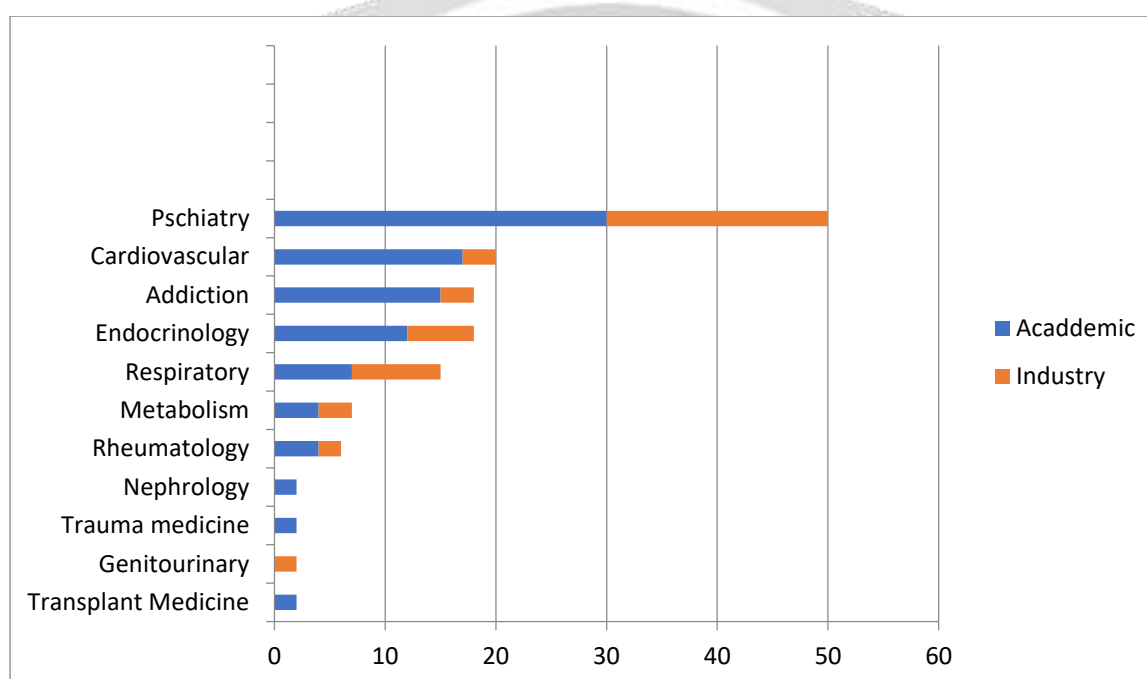
Second, Improved Primary Healthcare: Telemedicine has a significant influence on primary healthcare. Research shows that teleconsultations are a useful tool for managing chronic conditions since they allow for

ongoing observation and prompt action (**Beheshti et al., 2022**). This pre-emptive strategy lowers hospital stays and helps in optimization.

In India, there is still a digital divide despite improvements. People living in rural areas have difficulties because of poor internet availability (**Saeed and Masters, 2021**). According to research by Bali. S (2018), the adoption of telemedicine is impeded in places with inadequate connectivity, emphasizing the necessity of infrastructural development (Bali and Bali, 2018). In addition, Quality of Care and Ethical Issues: It is crucial to guarantee the calibre of telemedicine services. According to a study by insufficient physical inspections during virtual consultations may lead to misdiagnosis. Strict regulation is also required for ethical considerations including patient privacy and data security (**Solimini et al., 2021**).

India has witnessed policy actions in response. To address quality problems and standardize telemedicine practices, the Ministry of Health and Family Welfare of the Government of India launched the National Telemedicine Service (NTMS) (e-Health & Telemedicine | Ministry of Health and Family Welfare | GOI). Although a positive move, there are still implementation and awareness issues that need to be addressed

### 3.8 PAST ANALYSIS AND FUTURE TRENDS IN DIGITAL THERAPEUTICS:



In line with developments observed in clinical trials during the previous 10 years, there has been a focus on developing treatments for cardiovascular disease (CVD), including hypertension, hyperlipidaemia, and acute coronary syndrome (ACS). Instead, it deviates from the pattern of the previous ten years by emphasising the development of DTx treatments for gastrointestinal disorders such GERD, IBD, and irritable bowel syndrome. (**Wu et al., 2023**)

This implies that DTx businesses are trying to broaden the scope of their pipelines by introducing additional indications where there is currently a need that is not being met, such as chronic kidney disease (CKD) for which there has been evidence of DTx's potential to enhance health outcomes. (Evidera)

However, because over 95% of people between the ages of 16 and 34 own a smartphone<sup>13</sup>, and many of them also own tablet computers and/or gaming consoles, DTx offers a unique opportunity to engage with this group in order to enhance health outcomes. (Choi et al., 2019)

The popularity of DTx applications in a variety of industries has increased dramatically since the epidemic began. The current review's goal is to investigate the characteristics and advancements of different DTx uses in various treatment modalities and their prospects in the post-COVID period. (**Dang, Dang and Rane, 2021**)



The expected market trends provide a compelling framework for the rapidly evolving field of digital therapies, which has progressed from experimental stages to sophisticated treatments powered by data. The market for digital therapeutics, which is expected to grow to \$2.65 billion in the US in 2023, is crucial to this development (*Digital Therapeutics - Worldwide / Statista Market Forecast, no date*)

#### 4. METHODOLOGY:-

The entire foundation of the study is secondary data and material that was gathered from various journals. The search for articles was done online by using the search words 'Digital therapeutics, Healthcare innovation, Wearable devices, Data-driven healthcare, Remote patient monitoring' in the title Elsevier, Research gate, Academia.

#### 5. ANALYSIS:-

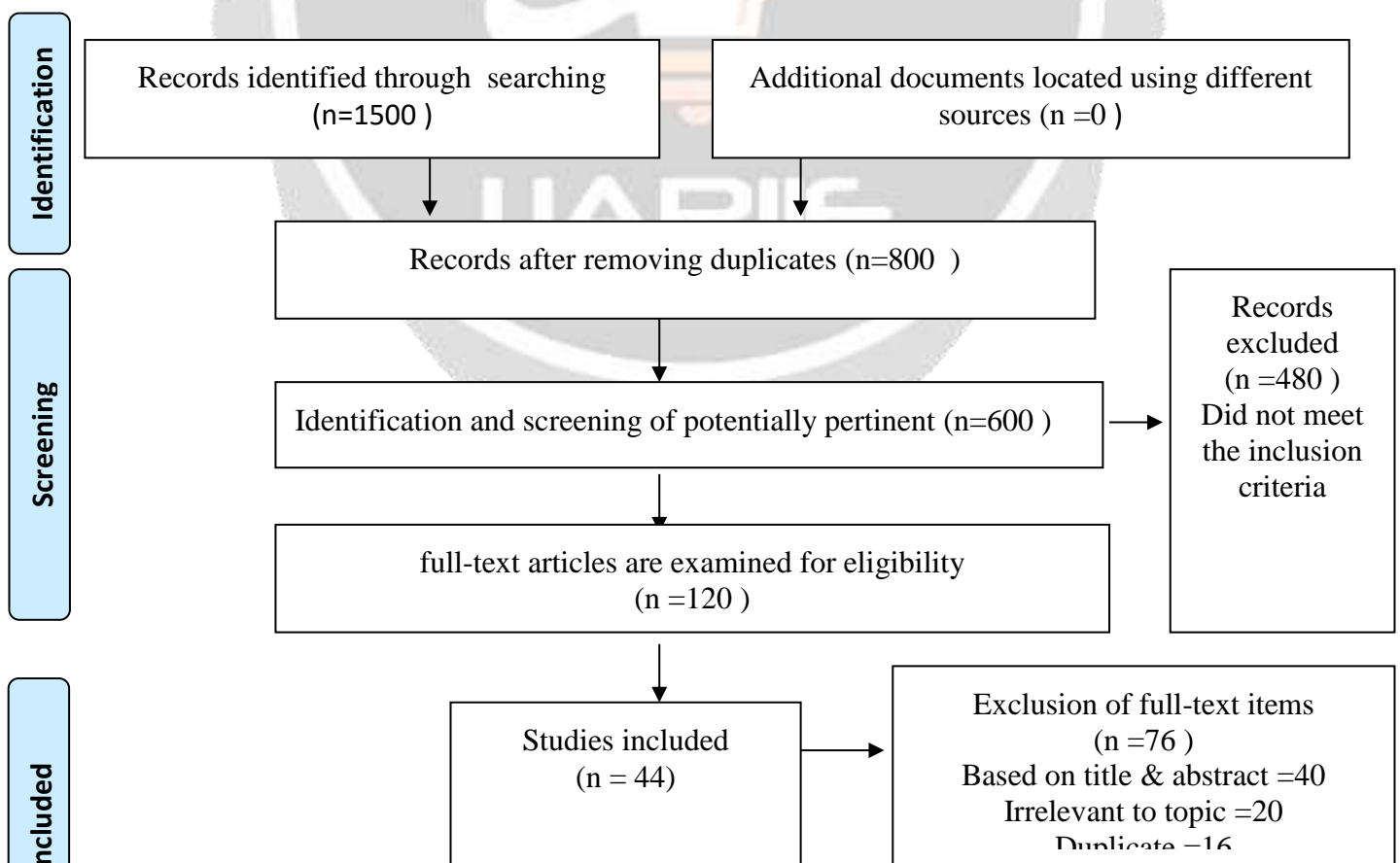
The (prisma) approach is the one utilized. the aims, year of publication, amount of citations, and recommendations for additional research were all taken into consideration as all publications that had made it through the selection process were examined and summarised.

#### 6. INCLUSION & EXCLUSION CRITERIA

The be included in the current study, studies have to meet some criteria

- (a) Studies have included some kind of selection criteria (Digital therapeutics, Healthcare). These criteria limited the number of studies (b) Accordingly excluded the studies in which based on irrelevant information there is no proper Title, Abstract & Review

##### 6.1 PRISMA Flow Diagram



## 6.2 FINAL DATA SET :

The research database search resulted in all keywords search results obtained 1500 research articles. After scanning the title, there was the same article in two different databases. The results after deducting the duplicates are 800 articles. A total of 600 articles were screened. 480 Articles excluded that they not meet the inclusion criteria.

Articles accessed for eligibility are 120 articles. A Total number of 76 articles excluded based on title and abstract (40) Irrelevant to topic (20) Duplicate (16).

The final data set consists of 44 articles.

The oldest included study was published in the year 2010 and the most recent study was conducted on 2023.

The Entire process is shown in figure.

## 7. DISCUSSION:

By empowering people, improving patient outcomes, and making healthcare resources more efficient, DTx can open the door to a healthier and more accessible future for everybody. A new chapter in the history of healthcare has begun with the introduction of digital therapeutics (DTx), which present a hopeful future in which technology empowers patients, improves patient outcomes, and streamlines healthcare delivery DTx, or digital health interventions, is the umbrella term for a wide variety of evidence-based software programmes that use digital technologies—like wearables, smartphones, and virtual reality—to offer therapeutic interventions. These cutting-edge treatments address a broad range of illnesses, including mental health issues like anxiety and depression as well as chronic ailments like diabetes and hypertension.

## 8. CONCLUSION:

Digital therapeutics (DTx) has emerged as a revolutionary force in the Indian healthcare landscape, offering a plethora of benefits that enhance patient outcomes, improve accessibility, and optimize healthcare delivery. By leveraging cutting-edge software applications, DTx provides evidence-based therapeutic interventions for a wide spectrum of medical conditions, empowering patients to take an active role in their well-being. The evolution of DTx has been marked by continuous innovation and advancements, driven by the ubiquity of smartphones, the rise of mobile technology, and the integration of artificial intelligence and machine learning. These advancements have paved the way for more personalized, effective, and data-driven therapeutic solutions. DTx has great potential to help India with its problems with the digital divide, a lack of medical expertise, and unequal access to healthcare. DTx can bridge the divide between urban and rural healthcare institutions by offering healthcare interventions remotely using web-based platforms and mobile applications, giving underserved areas much-needed help.

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Evidera (no date b) *EVIDENCE FORUM SPRING 2020 Digital Technologies Topics include • • Leveraging Decentralized RWE Data Collection Strategies • • Simulation to Patch a Broken Trial • • Adopting eCOAs for Use in Clinical Trials • • FDA's Emergency Use Authorization • • And Much More!*

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