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Review Article

Role and Effectiveness of Digital Therapeutics in the Non-Pharmacological Management of Irritable Bowel Syndrome in India and Abroad

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Abstract

Irritable Bowel Syndrome (IBS) is a gastrointestinal disorder characterized by abdominal pain, bloating, and changes in bowel habits, including diarrhoea, constipation, or both. It affects millions worldwide and can significantly reduce quality of life. The estimated prevalence of IBS in India is 4-8%. [5] Although pharmacological and non-pharmacological treatments exist, many patients do not achieve sufficient symptom relief, highlighting the need for complementary or alternative approaches. Digital therapeutics (DTx) are software-driven, evidence-based interventions designed to prevent, manage, or treat medical disorders. They are particularly well-suited for chronic conditions like IBS, where behavioural, psychological, and lifestyle factors play a significant role. This review compared studies and clinical trials from the past five years to analyze the effectiveness of DTx interventions in IBS management. The characteristics of DTx included cognitive behavioural therapy (CBT), dietary modification, gut-directed hypnotherapy, virtual education, and real-time symptom tracking. The future of DTx in IBS lies in delivering personalized and multimodal therapies. It has the great potential to revolutionize IBS management in India by providing accessible, personalized, and cost-effective solutions. However, DTx adoption for IBS management faces a few challenges that include limited digital literacy, and cultural stigma around bowel health. Overcoming these challenges with the advancements in AI, wearable devices, and immersive technologies can enhance engagement and outcomes. At the same time, broader clinical validation can drive scalable, cost-effective, and holistic management.

Keywords: Irritable Bowel Syndrome; Diet; Cognitive Behavioural Therapy; Digital Therapeutics; Gastrointestinal Disorder

Introduction

Irritable Bowel Syndrome (IBS) is a complex and chronic Disorder of Gut Brain Axis (DGBI) characterized by abdominal pain, bloating, urgency, the sensation of incomplete evacuation, and altered bowel habits, all occurring without identifiable biochemical abnormalities. The condition is associated with physical suffering, psychological comorbidities, social disability, and economic non-productivity affecting professional and daily activities, all of which contribute to a reduced quality of life (QoL) [1].

The pathophysiology of IBS appears to be multifactorial, involving motility disorders, genetic factors, immune responses, visceral hypersensitivity, brain-gut dysregulation, and altered intestinal

microbiota [2]. Although the exact etiology of IBS remains undetermined mainly, potential mechanisms involved in gut dysfunction, visceral sensation, and symptom generation seem to contribute significantly to the disease [3]. The primary risk factors to consider include female sex, age under 50 years, and a history of previous gastrointestinal infections [4].

Management of the disease typically aims to alleviate symptoms and enhance QoL, incorporating both nonpharmacologic and pharmacologic therapies. Non-pharmacological options include physical activity, gut-brain axis tracking, dietary modifications such as low fermentable oligosaccharides, disaccharides, monosaccharides and polyols (FODMAP), soluble fibres, personalized meal plans, elimination diet as well as cognitive behavioural therapy (CBT) [5]. The Low FODMAP diet, which has gained significant traction globally, is still not widely practiced in India due to a lack of awareness among healthcare professionals and patients. Pharmacologic treatment options consist of antidepressants, antispasmodics, and newer gastrointestinal agents [2].

Patients are encouraged to reduce the intake of spicy, oily and high FODMAP foods which are the common triggers for IBS symptoms in the Indian population. Indian culture has a long history of using traditional medicine systems like Ayurveda and Yoga to manage health conditions, including IBS. These are frequently used in conjunction with modern medicine. The use and potential of DHIs in improving patient outcomes and being a part of practical multimodal strategies for management in IBS [6].

Self-management through digital technology is an emerging field that has significantly transformed healthcare delivery. [7] Digital therapeutics (DTx) is valued for its ability to place individuals at the centre of care, address personal challenges, enhance health literacy, and facilitate informed decision-making about medical conditions and treatment options [8]. These have emerged as valuable resources that empower patients to self-manage symptoms and comorbidities through mobile applications and web-based programs. These provide access to clinical and actionable content, enhancing disease-related knowledge and improving health outcomes of DTx in IBS management [9,10].

To our knowledge, no recent review has identified and summarized the effectiveness of DTx in IBS, especially in the Indian context. This narrative review aims to address this knowledge gap by identifying and categorizing types of DTx use in IBS management, evaluating their effectiveness, exploring plausible mechanisms through which it works, and discussing integration and its application in clinical practice.

Digital therapeutics: an overview

Definition and scope

With the rapid advancement of medical technologies, the digital age has introduced a new category of therapies known as DTx. According to the Digital Therapeutics Alliance, DTx are evidence-based therapeutic interventions primarily driven by software, aimed at preventing, managing, or treating medical disorders or diseases [11]. In simpler terms, DTx refers to patient-facing software applications that assist individuals in self-managing their symptoms, ultimately enhancing their QoL and clinical outcomes. The development of DTx has the potential to significantly improve the customization of health services, as these solutions are designed to meet the specific needs of patients. Recognized as one of the most innovative sectors in digital health, the DTx ecosystem has experienced substantial progress over the past two years. It has proven to be a valuable resource for patients, enabling them to self-manage their symptoms and comorbidities through mobile applications and web-based programs.

Mechanism of digital therapeutics work

Digital health interventions (DHIs) provide evidence-based medical treatments through software programs designed to treat, manage, or prevent specific medical conditions. These incorporate digital technologies such as mobile applications, sensors, and algorithms to develop personalized treatment plans. Unlike general health applications, DTx is subject to rigorous testing through randomized controlled trials (RCTs) to establish their effectiveness, safety, and reliability and often require regulatory approval [12].

Key components of how DTx operates in IBS include behavioural interventions like CBT, stress management, and gut-directed hypnotherapy; symptom monitoring and personalized diet planning; and IBS education. DTx offers an integrated approach to enhance treatment adherence, support lifestyle changes, and enable continuous monitoring for individuals with IBS [13]. The design and functionality of DHIs typically fall into one or more categories, including symptom tracking, patient and community-based resources, telemedicine, and connectivity to digital and wearable devices [14]. The mechanism by which DTx works is shown in figure 1.

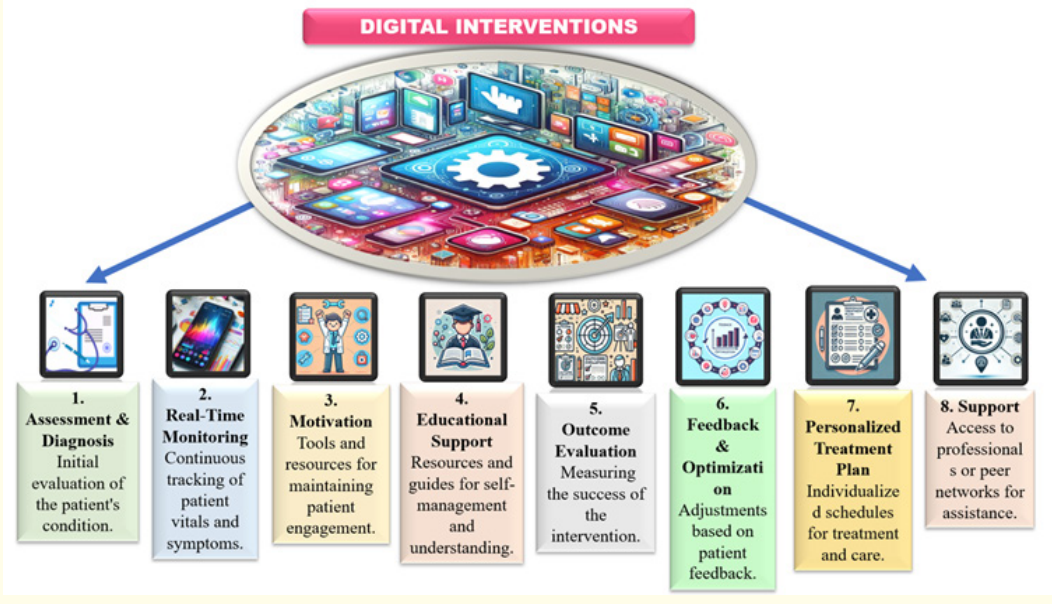

Figure 1: Mechanism of Digital Therapeutics.

Source: Adapted from Kim., et al. 2024 [15]; Phan., et al. 2023 [13]; Dang., et al. 2020 [16].

Types of digital therapeutics interventions

DTx can be categorized based on their application and functionality. These therapies utilize digital tools, including mobile devices, applications, sensors, virtual reality, and the Internet of Things (IoT), to facilitate patient behavioural and diet changes. The primary distinction between DTx and wellness applications is their focus. DTx applications are specifically designed to address disease conditions, particularly major chronic illnesses such as diabetes, cardiovascular issues including hypertension, and pulmonary diseases like chronic obstructive pulmonary disease (COPD) [16].

Digital therapeutics in IBS

Despite the increasing research interest in the relationship between DHIs and gastrointestinal (GI) health, recent reviews extensively addressed the various DTx products globally, for their specific impacts on IBS symptoms and mental wellness outcomes [5,17,18]. Given the diverse symptoms and varying treatment preferences among patients, with country specific demographics, managing IBS is a complex process that should be personalized whenever possible.

DTx for treating IBS primarily focuses on behavioural therapy, which addresses the brain-gut axis; pain, and triggers; and self-management, which empowers patients with the knowledge and strategies to manage their condition [6]. A summary of widely used digital healthcare apps for managing IBS is provided in the table [19,20]. (Table 1).

Digital health intervention	Application	Platform	Diagnostic ability	Physiological management	Medical management	Regulatory approval
Cognitive Behavioural Therapy [CBT]-Based Apps	MAhana IBS	App and Website	Prescription-only digital therapeutic tool	Focuses on symptom management, particularly abdominal pain associated with IBS	Complementary tool	US FDA, CE mark-[Europe]; UKCA mark [UK]
	Zemedy	App and Website	Support symptom management	Alleviates symptoms related to IBS, such as abdominal pain, bloating, and discomfort, by improving users' mental well-being and providing coping strategies	Complementary tool	None
	Regulora	App and Website	Support symptom management	Alleviates IBS symptoms, particularly abdominal pain, through a structured hypnotherapy program.	Therapeutic regimen to manage IBS symptoms	US FDA
	Nerva	App and Website	Support symptom management	Focuses on reducing abdominal pain through a combination of gut-directed hypnotherapy and other behavioural interventions	Therapeutic treatment for IBS	None
	The calm gut	Website	Support symptom management	Manage IBS symptoms through gut-directed hypnotherapy, mindfulness, and CBT	Complementary tool	None
	CaraCare	App and Website	Support symptom management	Offers personalized symptom tracking, dietary guidance, and therapeutic interventions such as CBT and stress management	Complementary tool	DiGA [Germany]
Dietary modification and symptom monitoring	Bowelle	App and Website	Support symptom management	Tracks various factors such as mood, food intake, stress levels, and bowel movements	Symptom management tool	None
	MyHealthyGut	App and Website	Support symptom management	Provides therapeutic meal plans, symptom tracking, and educational resources to support digestive health	Self-management tool	None
	MySymptomTrack	App	Symptom tracking and identifying potential triggers	Logs food intake, symptoms, medications, and other factors that might influence their health	Self-management tool	None
	myIBS	App and Website	Symptom tracking and educational resources	Tracks symptoms, dietary intake, stress levels, and other health factors	Self-management tool	None
	FODMAP apps [eg. Monash University FODMAP app, Low FODMAP A-Z, Fast FODMAP]	App	Support symptom management	Identifies and manages foods that may trigger IBS symptoms.	Self-management tool	None
	IBS coach	App	Support symptom management	Offers dietary modifications and lifestyle changes	Self-management tool	None

Wellness	HealthTap	Website	Through partnerships with diagnostic service providers	Offers virtual healthcare support, including consultations, symptom assessments, and access to health information	AI-powered symptom assessment tool	None
	Heathifyme #	App and Website	Through partnerships with diagnostic service providers	Offers personalized fitness and nutrition plans, leveraging AI and health diagnostics tools	AI-assisted self-management tool	None
Nutrition and holistic management	DailyBloom IBS #	App and Website	Support symptom management	Offers personalized diet plans, wellness support, and symptom tracking	personalized care and symptom tracking	None
	IBS Relief #	App and Website	Support symptom management	Provides symptom management through personalized dietary recommendations, symptom tracking, and educational resources	Personalized care and symptom tracking	None

Table 1: Digital Therapy Platforms for IBS Management.

Indian applications.

Global perspective on digital therapeutics for IBS

Prevalence, classification, and impact of IBS worldwide

Epidemiological data indicate significant variation in the prevalence of IBS. A recent review reported a global pooled prevalence of 9.2% (95% CI 7.6% to 10.8%) based on the Rome III criteria [21] and 3.8% (95% CI 3.1% to 4.5%) according to the Rome IV criteria [22,23]. The review highlighted a range of prevalence from as low as 0.4% in India and Ghana in one multinational study [24] to as high as 29.2% in Croatia [23,25]. In contrast, other studies have reported prevalence rates between 4.2% and 7.5% [24,26-28]. The availability of medications in India differs significantly from that in other regions [29], and the working conditions of physicians also vary [30], both of which contribute to the variability of IBS prevalence within the Indian population [24,28,30]. This wide variation may also reflect the complex nature of IBS and the challenges associated with its diagnosis.

IBS is typically classified into four subtypes based on the predominant stool pattern: IBS with constipation (IBS-C), IBS with diarrhea (IBS-D), IBS with mixed bowel habits (IBS-M), and IBS unclassified (IBS-U), which is utilized when the stool pattern does not fit the other categories [31]. The global pooled prevalence is highest for IBS-M at 3.7% (95% CI 2.6% to 4.9%), followed by IBS-D at 3.1% (95% CI 2.6% to 3.8%), IBS-C at 2.3% (95% CI 1.7% to 3.1%), and IBS-U at 1.5% (95% CI 1.0% to 2.0%). Additionally, the prevalence of IBS varies by sex, with a pooled prevalence of 12.0% (95% CI 9.3% to 15.0%) in women compared to 8.6% (95% CI 6.3% to 11.2%) in men [23]. The overall variation in IBS prevalence may be attributed to diagnostic challenges, as symptom reporting can be influenced by cultural beliefs, education, genetics, ethnicity, environmental factors, and dietary differences across geographical areas [23]. Furthermore, IBS symptoms may fluctuate over time [32] and can resemble those of other disorders, such as celiac disease, bile acid diarrhea, microscopic colitis, and diverticulosis [33], thereby complicating the diagnosis further.

Current interventions

The currently available treatment options, both pharmacological and non-pharmacological, help in the management of IBS. Categories of Pharmacological interventions are described in Table 2 (a) [2,34].

Pharmacological Class of Drugs	Examples
First-line Antidiarrheals [IBS-D]	Oral Rehydration Therapy [ORT]; Loperamide
Laxatives [IBS-D]	Methylcellulose; Psyllium
Antispasmodics	Hyoscine Butylbromide; Dicyclomine
Antidepressants [TCAs and SSRIs] Second-line new agents	Amitriptyline; Duloxetine
Guanylate cyclase-C [GC-C] agonists [IBS-C]	Linaclotide [IBS-C]
Antibiotics [IBS-D]	Rifaximin

Table 2(a): Current Pharmacological Interventions Used in the Treatment of IBS.

Non-pharmacological treatments for IBS focus on symptom management and improving QoL through lifestyle modifications, dietary changes, and psychological therapies. These interventions are frequently tailored to meet the specific symptom profiles and triggers of each individual. Close collaboration with healthcare providers, including dietitians and therapists, can enhance treatment outcomes. A summary of commonly utilized non-pharmacological treatment options for IBS is presented in the table (Table-2(b)).

Intervention	Type	Effect Observed	Reference
Dietary modification			
	Low FODMAP Diet	Reducing foods high in fermentable oligosaccharides, disaccharides, monosaccharides, and polyols alleviates IBS symptoms and improves QOL scores.	[35,36]
	High-Fiber Diet	Gradual increases in soluble fiber [e.g., psyllium] help regulate bowel movements and relieve constipation.	[37-39]
	Avoiding Trigger Foods	Common triggers include caffeine, alcohol, spicy foods, and fatty foods.	[39]
	Hydration	Maintaining adequate fluid intake alleviates symptoms of constipation	[39]
Lifestyle Changes			
	Regular Exercise	Moderate aerobic activity, such as walking or swimming, can improve gut motility and reduce stress.	[40,41]
	Stress Management	Reducing stress through yoga, mindfulness, or relaxation techniques may improve symptoms.	[42,43]
	Sleep Hygiene	Ensuring adequate and consistent sleep can support overall gut health.	[44]
Behavioural and Psychological Therapies			
	CBT	Effective in addressing the brain-gut interaction and reducing the severity of symptoms	[45]
	Gut-Directed Hypnotherapy	A specialized form of hypnotherapy focuses on calming the gut-brain axis.	[46]
	Mindfulness-Based Stress Reduction [MBSR]	Helps reduce stress and improve symptom perception.	[47]
		Certain probiotic strains [e.g., Bifidobacterium and Lactobacillus] may improve symptoms, although the effects vary by individual and strain.	[48,49]
Other Remedies and Therapies			
	Peppermint Oil	Shown to reduce abdominal pain and bloating in IBS due to its antispasmodic properties	[50]
	Chamomile or Ginger Tea	Soothes the digestive system.	[51]
	Acupuncture	It may provide relief for some patients, although evidence is mixed and may depend on individual response	[52]
	Probiotics	Certain probiotic strains [e.g., Bifidobacterium and Lactobacillus] may improve symptoms, although the effects vary by individual and strain	[48,49]

Table-2(b): Non-Pharmacological Interventions for IBS Management.

Role of digital therapeutics in managing IBS globally

DTx represents a promising and innovative approach to managing IBS, a condition that is challenging to treat due to its complex and often individualized symptoms. By leveraging digital platforms such as mobile applications, health monitoring tools, wearable devices, and virtual CBT programs, DTx can effectively address key aspects of IBS management, including symptom tracking, patient education, stress management, and behaviour modification. As the field continues to evolve, DTx has demonstrated the potential to significantly enhance the QoL for patients with IBS by addressing not only the symptoms but also the underlying psychological, behavioural, and lifestyle factors that contribute to the condition.

Digital therapeutics for IBS in India

Adoption and effectiveness of digital therapeutics in India

In India, where digital adoption is rapidly increasing, DTx holds promise for addressing gaps in healthcare delivery, especially for chronic and lifestyle-related diseases. DTx solutions like mobile apps and AI-driven platforms have shown success in helping patients monitor blood sugar, adhere to medication, and improve lifestyle choices. Studies indicate improved glycemic control and reduced HbA1c levels in users [53,54,55]. Apps also offer cognitive behavioural therapy (CBT), mindfulness exercises, and personalized mental health support. They address the stigma associated with in-person treatment and improve access to mental health care. Online platforms focus on weight loss, exercise adherence, and dietary modifications, improving heart health outcomes. DTx bridges the gap for rural and semi-urban populations by providing healthcare solutions via smartphones which is critical in India, where access to quality healthcare is often limited outside urban centers. The rise of teleconsultation services, especially during and after the COVID-19 pandemic, has increased the adoption of DTx as part of a hybrid healthcare model [56,57].

DTx services are expected to reduce healthcare costs while providing additional value for insurers, enabling them to tailor products to better meet patients' needs. However, DTx remains limited in India, with only a few companies planning to invest in this area. Indian pharmaceutical company aims to streamline the management of cardiovascular disorders through a combination of prescription drugs and AI-driven digital therapies [16]. The app focuses on holistic management by incorporating dietary guidance, symptom tracking, and stress management techniques [58].

Challenges and opportunities for digital therapeutics in India

DTx holds immense potential to revolutionize healthcare delivery in India, but several barriers hinder its widespread adoption. The Digital Health Mission and Ayushman Bharat Digital Mission (ABDM) are steps toward standardization. Data privacy is another important concern. India's Personal Data Protection Bill has been built to ensure trust among Indian users. Addressing these challenges requires a multi-faceted approach. Below are the key limitations associated with DTx in managing IBS [13,37,44,59-62] (Table 3).

Effectiveness of digital therapeutics in managing IBS

Review of studies on effectiveness of DTx

Data were retrieved from the past 10 years, using three electronic databases: PubMed, Cochrane library and CINAHL. The search strategy used a combination of keywords (e.g. "digital", "IBS," "app-based," "web-based," "CBT," "brain-gut hypnotherapy," and "diet") utilizing the "OR" and "AND" Boolean operators to broaden and narrow the search results. Full-text articles selected for in-depth analysis encompassed clinical trials, observational studies, systematic reviews, and meta-analyses: Eligible populations comprised adults diagnosed with IBS and DTx interventions specifically designed for the management of IBS. A full-text review was subsequently conducted, utilizing exclusion criteria to eliminate studies involving non-IBS patients, paediatric patients, caregivers of IBS patients, or adult patients where the IBS diagnosis was not the primary focus of the study.

Studies with IBS symptom and QoL as outcome measures were selected and compared. This review provides a recent and comprehensive summary and evaluation of studies investigating the self-management of IBS. Unlike previous reviews, this is the first to collectively examine and assess IBS symptom severity, psychological factors, patient education, and adherence, while also exploring potential correlations between DTx characteristics and effectiveness outcomes. A comparison of the features and outcomes of DTx interventions over traditional non-pharmacological treatment options for IBS is presented in the tables (Table 3).

Limitation	Challenge	Example	Potential solution
Accessibility and digital divide [63,64]	Many patients with IBS, especially those in rural or underserved areas, may have limited access to smartphones, tablets, or reliable internet, which are necessary for the effective use of DTx.	Apps like Regulora and Nerva require devices with stable internet access for set-up and session downloads.	Develop offline-capable applications or streamlined interfaces.
	Older adults, a significant demographic for IBS, may have low digital literacy, making app navigation difficult.		Provide access through public health programs or subsidized devices.
Adherence and engagement challenges [65,66]	IBS management often requires sustained behaviour change, such as maintaining dietary logs, practicing relaxation techniques, or completing therapy sessions. Many patients struggle to stay engaged over time.	Apps like Zemedy and Mahāna IBS provide structured CBT programs but may see drop-offs in adherence as users lose interest.	Incorporate gamification, reminders, and rewards to improve adherence.
	Lack of personalization in some DTx solutions may reduce their appeal and perceived relevance to individual users.		Use AI to tailor interventions to the user's symptoms and lifestyle.
Limited clinical evidence for long-term outcomes [67]	Many IBS-focused DTx solutions have demonstrated short-term benefits [e.g., symptom reduction, and quality-of-life improvements], but long-term efficacy and safety data are limited.	Nerva and Mahāna IBS have shown efficacy in clinical trials, but their effectiveness across diverse patient populations and settings needs further validation.	Conduct larger, long-term randomized controlled trials [RCTs] with diverse populations.
	Real-world evidence [RWE] studies are lacking for many widely used apps.		Generate RWE through post-market surveillance and patient-reported outcomes.
Lack of integration into clinical practice [13]	Many DTx tools operate independently and are not integrated with EHRs or routine clinical workflows.	Some gastroenterologists may not be familiar with DTx solutions like Regulora or are hesitant to prescribe them due to limited clinical training or integration issues.	Develop API integrations with EHRs to allow seamless sharing of patient data.
	This limits clinicians' ability to monitor patients' progress or provide tailored recommendations based on app data.		Train clinicians on the use of IBS-specific DTx tools and their evidence base.
Variability in reimbursement and coverage [68]	Reimbursement policies for DTx are inconsistent across regions, leading to out-of-pocket costs for many patients.	Mahāna IBS is covered by some U.S. insurers but remains inaccessible to patients in countries without established DTx reimbursement frameworks	Policy reforms should include DTx under public and private insurance plans.
	This financial barrier may deter adoption, particularly among low-income patients.		Provide freemium models with basic features free and premium features at a cost.
Psychological and behavioural barriers [69]	Some IBS patients may not perceive DTx solutions as effective compared to traditional treatments like medications or in-person therapy.	Patients using Zemedy or Nerva may drop out if they feel that app-based therapy doesn't address their emotional needs or preferences.	Combine DTx tools with human support, such as teleconsultations with therapists or dietitians.
	Behavioural therapies delivered digitally may feel impersonal or lack the emotional connection provided by in-person therapists.		Offer hybrid care models that include both digital and face-to-face interactions.

Data privacy and security concerns [70]	DTx apps collect sensitive health data, including symptom logs and mental health information.	Apps like CaraCare and Monash FODMAP handle extensive dietary and symptom-tracking data, requiring stringent data security measures.	Apps should comply with regulations like the Digital Personal Data Protection Act, 2023 [DPDP Act]
	Patients may hesitate to use these apps due to fears of data breaches or misuse.		Use transparent privacy policies and strong encryption to build user trust.
Overreliance on self-management [71]	DTx solutions often require high levels of self-motivation, such as completing daily exercises or logging food and symptoms	Users of apps like Bowelle and MyHealthyGut may abandon the app if they find self-tracking overwhelming or unhelpful.	Provide optional human coaching or peer support groups.
	Patients with severe IBS or mental health comorbidities may struggle to manage their condition independently.		Automate tracking features [e.g., using wearables] to reduce patient burden.
One-size-fits-all approach [72]	IBS is a highly individualized condition with varying triggers, symptoms, and responses to treatment. Generic DTx solutions may not meet the needs of all patients.	Diet-focused apps like *Monash FODMAP* may not address non-dietary factors like stress or gut-brain axis dysfunction	Integrate multimodal approaches combining diet, mindfulness, and CBT
	Comorbid conditions like anxiety or depression may require additional interventions.		Use machine learning to personalize interventions based on user data.
Limited support for complex or severe cases [73]	Patients with severe IBS or overlapping gastrointestinal conditions [e.g. Inflammatory bowel disease [IBD] may need more intensive interventions than DTx can provide.	Apps like *Nerva* focus on gut-focused hypnotherapy but may not adequately address severe or refractory IBS cases	Position DTx as a complementary tool rather than a standalone solution for complex cases.
			Severe cases should be referred to specialists for additional care.

Table 3: Challenges and Appropriate Solutions for Digital Therapeutics in the Management of IBS.

This review provides a recent and comprehensive summary and evaluation of studies investigating the self-management of IBS. Unlike previous reviews, this is the first to collectively examine and assess IBS symptom severity, psychological factors, patient education, and adherence, while also exploring potential correlations between DTx characteristics and effectiveness outcomes.

Similar to this review, other systematic reviews and meta-analyses involving IBS patients have found significant improvements in both IBS symptoms and QoL [5,82-84]. Previous review indicated that several psychological therapies are effective for IBS; however, none were found to be superior to the others. Among these therapies, CBT and gut-directed hypnotherapy had the most substantial evidence base and demonstrated the greatest long-term efficacy [60].

DTx, like traditional medical treatments, depends on the interaction between the treatment and the patient's mindset. Consequently, the placebo effect can significantly influence outcomes in various ways, including belief in the benefits of the intervention, increased user engagement, and app-generated positive reinforcement [85].

Future of digital therapeutics

DTx are a new form of interventions that deliver treatments to patients through evidence-based software. The future of DTx is

promising, with technology, healthcare systems, and regulatory frameworks converging to transform how medical conditions are managed. DTx is set to redefine healthcare altogether. (Figure 2) The current trends and advancements, shaping the trajectory of DTx are summarised below.

Figure 2: Future of Digital Therapeutics.

Source: Dang., et al. 2020 [16]; Kukreja., et al. 2023 [86]; Yeung., et al. 2023 [87]; Valeria blogpost 2020 [88]; Digital therapeutics alliance 2017 [11]; Salvatore., et al. 2022 [89].

- **Expansion:** While DTx has achieved notable advancements in managing conditions such as diabetes, mental health, and chronic pain, its potential for future development lies in addressing a broader spectrum of more complex health challenges:
- **Neurological disorders:** Alzheimer's, Parkinson's disease, epilepsy, and rehabilitation following a stroke [90].
- **Cardiovascular health:** Hypertension, heart failure, and the prevention of cardiovascular events [91].
- **Oncology:** Providing supportive care during cancer treatment, tracking symptoms, and offering survivorship care [92].
- **Autoimmune and rare Diseases:** Developing innovative approaches to address the needs of underserved patient populations [92].

Enhanced personalization

- **Adaptive interventions:** AI-driven algorithms will enable real-time, personalized treatment adjustments based on individual patient behaviour and outcomes [62].
- **Predictive analytics:** Machine learning will aid in forecasting disease progression and recommending preventive measures [93].

Integration with emerging technologies

- **Wearables and Internet of Things (IoT) devices:** Facilitate seamless tracking of vital signs, including glucose levels, heart rate, and mobility [94].
- **Virtual reality (VR) and Augmented reality (AR):** Offer immersive therapeutic experiences for various conditions such as PTSD, phobias, and chronic pain. E.g. EaseVRx by Applied VR is specifically designed for pain management [95].
- **Digital biomarkers:** Enable non-invasive monitoring of health metrics, including sleep patterns, gait analysis, and voice biomarkers, to assess mental health. [96].

Integration into healthcare ecosystems

- **Hybrid models:** Integrating DTx with in-person care to establish comprehensive treatment plans [18].
- **EHR integration:** Ensuring seamless synchronization with EHR to enhance coordination between patients and healthcare providers [97].
- **Telehealth synergy:** Integrating DTx with telehealth services for effective remote monitoring and consultations [98].
- **Public health integration:** Governments are adopting solutions to combat chronic disease epidemics [99].

Preventive healthcare

DTx will progressively transition from a treatment-centred approach to a preventive model by identifying at-risk individuals and implementing early interventions aimed at reducing the onset of disease.

- **Lifestyle interventions:** Applications focused on nutrition, physical activity, and stress management [100-102].
- **Behavioural change models:** Tools designed to target smoking, obesity, and other modifiable risk factors [103,104].

Enhanced accessibility

- **Culturally adapted solutions:** Development of culturally tailored DTx tools for diverse populations [105].
- **Cost-effective options:** Creation of streamlined applications to address healthcare disparities in low-resource settings [105].
- **Multilingual and offline capabilities:** Enhancements to increase usability in underserved regions [105].

Regulatory innovations

- **Accelerated FDA approvals:** Regulatory agencies will implement frameworks, such as real-world evidence (RWE), to enhance the efficiency of the approval process [106].
- **Value-based reimbursement:** Insurers will provide reimbursement for DTx based on their clinical outcomes and cost-effectiveness [106].
- **Global standards:** An international initiative will be launched to harmonize regulations, thereby facilitating the cross-border deployment of therapies. [106]

Advanced data utilization

- **Real-time monitoring:** Continuous data collection enables early detection of warning signs and facilitates immediate interventions [107].
- **Population health insights:** Aggregated data helps identify public health trends and allows for customized large-scale interventions [107].
- **Privacy-first designs:** Enhanced encryption and strict compliance with General Data Protection Regulation (GDPR) in Europe, HIPAA stands for Health Insurance Portability and Accountability Act in United States and Personal Data Protection Bill (PDP Bill) in India, insure the safeguarding of patient data [107].

Collaboration

- **Companion diagnostics:** Integrating DTx with traditional medications enhances efficacy and improves adherence. e.g. Proteus Digital Health provides medication tracking solutions [108].
- **Clinical trial support:** Utilizing DTx to monitor patient adherence and gather real-time data during clinical trials [109].
- **Cross-sector innovation:** Partnerships among healthcare, academia, and technology sectors will drive the development of new solutions [110].
- **Patient input:** Incorporating patient feedback into the design and development of DTx for enhanced adoption [111].

Engagement strategies

- **Gamification:** Incorporating rewards, challenges, and leaderboards to enhance patient adherence [112].
- **Immersive storytelling:** Engaging patients through compelling narratives that resonate emotionally and cognitively [113].

Focus on wellbeing

- **AI-driven mental health tools:** Implementing chatbots, mood tracking, and CBT applications to address issues like depression, anxiety, and stress [114].
- **Workplace wellness programs:** Integrating DTx platforms into corporate health initiatives to support employee well-being [115].

Conclusion

DTx holds great potential to revolutionize healthcare in India by offering scalable, accessible, and personalized solutions for chronic disease management. However, their widespread adoption will depend on regulatory clarity, stakeholder collaboration, and continuous innovation to meet the needs of the diverse and enormous Indian IBS sufferers.

Although DTx for IBS is showing considerable promise globally, validated research methodologies are necessary to establish their efficacy in larger, more diverse populations and to assess their synergistic impact beyond existing standard of care. Future studies should focus on optimizing user engagement, identifying the most effective combinations of interventions, and assessing long-term outcomes. Furthermore, regulatory oversight and clinical validation will be essential to ensure that DTx platforms for IBS meet established safety and efficacy standards.

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Conflict of Interest

This educational project was supported by Dr. Reddy's Laboratories. In compliance withthe ICMJE uniform disclosure form, all authors declare the following

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