Digital Therapeutics in China: A Comprehensive Review

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Submitted to: Journal of Medical Internet Research
on: January 09, 2025

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Abstract

Background: Digital therapeutics (DTx), software-driven interventions offering personalized, evidence-based treatments, are transforming global healthcare. China’s unique combination of widespread technological adoption, a large population base, and supportive government policies has positioned it as a potential global leader in DTx. Despite significant progress, gaps remain in areas such as clinical trials, product development, regulatory framework standardization, and reimbursement support within the Chinese healthcare system.

Objective: This study aims to comprehensively investigate the DTx landscape in China, identifying key factors contributing to its progress and offering lessons for other countries to accelerate DTx adoption and development.

Methods: A systematic review and meta-analysis were conducted to evaluate the state of DTx in China. The analysis synthesized data from peer-reviewed articles, government policy documents, and industry reports to assess progress in clinical trials, regulatory practices, product development, and reimbursement strategies.

Results: Four key factors emerged as critical contributors to the rapid progress of DTx in China: (1) targeted indications and innovative technology components tailored to local needs; (2) standardized clinical trials ensuring evidence-based validation; (3) streamlined regulatory and approval processes fostering rapid innovation; and (4) diversified pricing and reimbursement models supporting adoption and scalability. These insights highlight China's strategic approach to DTx integration and its broader implications for healthcare transformation.

Conclusions: China’s experience in developing and adopting DTx provides valuable lessons for other nations aiming to leverage digital health innovations. By addressing existing challenges and drawing from China’s experience, global healthcare systems can accelerate DTx development, adoption, and integration to transform healthcare delivery and improve patient outcomes.

(JMIR Preprints 09/01/2025:70955)
DOI: https://doi.org/10.2196/preprints.70955

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Funding
This research was supported by Ministry of Education (171-BHZX), National Key R&D Program of China (2022YFC3603000,2022YFC2502800), National Natural Science Fund of China (82388101), Beijing Natural Science Foundation (IS23096), Shanghai Medical Innovation Development Fund (04152100324).

Acknowledgements
The funding body has no role in the design, methods, subject recruitment, data collections, analysis and preparation of paper.

Running title: DTx Global Scale-up

Authors contributions:
NJ: Conceptualization (lead); Data curation (supporting); Methodology (lead); Formal analysis (lead); Project administration (lead); Funding acquisition (lead); Writing - original draft (lead). XRY: Data curation (lead); Visualisation (lead); Writing - review & editing (equal). YXY: Validation (lead); Methodology (supporting). CCH: Writing - review & editing (equal); Validation (supporting); Visualisation (supporting). GQL: Writing - review & editing (equal). MPW: Writing - review & editing (equal). YCT: Writing - review & editing (equal). TYW: Supervision (supporting); Project administration (supporting). KQR: Supervision (lead); Formal analysis (supporting). All authors contributed to the article and approved the submitted version.

Abstract

Background

Digital therapeutics (DTx) are software-driven interventions that provide personalized, evidence-based treatments for various medical conditions. China's rapid technological adoption, large population, and supportive government policies position it as a potential global leader in DTx. However, challenges remain in clinical trial standardization, regulatory approval, product development, and reimbursement models. A comprehensive assessment of clinical evidence, commercialization trends, and regulatory frameworks is essential for understanding China's evolving DTx ecosystem and its global implications.

Objective

This study systematically reviews and analyzes the DTx landscape in China, focusing on clinical trials, commercial products, regulatory frameworks, and pricing and reimbursement models. The findings provide insights for countries aiming to develop, regulate, and integrate DTx solutions into healthcare systems.

Methods

This comprehensive review integrates multiple methodological approaches to examine different aspects of the DTx ecosystem in China. We conducted a systematic review and meta-analysis following PRISMA 2020 guidelines to evaluate DTx clinical trials, searching PubMed, Google Scholar, IEEE, Web of Science, and ScienceDirect until July 2024. Meta-analyses employed random-effects models, reporting results as standardized mean differences (SMD) and 95% confidence intervals (CI). For commercial products, a scoping review using the National Medical Products Administration (NMPA) database was performed. Regulatory policies were systematically identified through manual review of official government sources, while pricing and reimbursement models were analyzed through comprehensive assessment of public and private insurance policies, government initiatives, and commercial pathways.

Results

A total of 96 clinical trials on DTx in China were identified, with cognitive disorders (21.9%) and diabetes (21.1%) being the most frequently studied, followed by cardiovascular diseases (8.3%), sleeping disorders (6.3%), and smoking cessation (6.3%). Meta-analysis for diabetes DTx showed a trend toward improved HbA1c levels in digital intervention groups compared to controls (SMD = −0.96; 95% CI: −2.03 to 0.1) but did not reach statistical significance (I^2 = 97%). Meta-analysis for cognitive disorders showed significant improvement in global cognitive function in DTx-treated participants (SMD = 0.65; 95% CI: 0.37 to 0.94), despite notable heterogeneity (I^2 = 71.7%). The commercial landscape analysis identified 97 active DTx solutions, primarily targeting cognitive impairment (38 companies), ophthalmic diseases (30 companies), and respiratory diseases (5 companies). Regulatory review highlighted China's reliance on general medical device policies under the NMPA rather than DTx-specific regulations, with emerging regional innovation policies supporting industry growth. Pricing analysis revealed diverse reimbursement models, including value-based pricing, private insurance partnerships, and government-facilitated programs.

Conclusions

China has made substantial progress in DTx development but still faces challenges in clinical trial standardization, regulatory approval, and reimbursement. Key factors driving DTx adoption include targeted indications, standardized clinical trials, streamlined regulation, and diversified pricing models. China's experience provides valuable lessons for other countries with emerging digital health ecosystems as they develop DTx research, regulations, and integration strategies.

*Keywords*Digital therapeutics, DTx, China, Global experience

Introduction

Digital therapeutics (DTx) encompass evidence-based interventions delivered via software or digital platforms to prevent, manage, or treat medical conditions, particularly major chronic diseases [1]. In China, DTx are defined as “evidence-based therapeutic interventions driven by high-quality software programmes to treat, manage, or prevent a disease or disorder” [2]. These programmes interact with patients through information (e.g., text, images, videos) and physical factors (e.g., sound, light, electricity, magnetic fields)[3]. Unlike traditional pharmaceuticals, DTx leverage digital tools like mobile apps, wearables, and virtual reality to enhance health outcomes [4]. These interventions are patient-facing software applications, which target behavioural change, cognitive training, or symptom management[5]. They thus far were primarily developed for indications such as chronic and neuropsychiatric diseases. DTx are gaining prominence in global healthcare systems [3] and can complement or even replace conventional medical approaches beyond basic health monitoring[6]. Since they are software-driven, DTx potentially allow more precise monitoring and measurement of patient progress and treatment adherence compared to pharmaceuticals [7]. For instance, DTx tailor treatments to individual needs, considering patient history, preferences, and real-time data from wearables or apps [8]. By modifying behaviours (e.g., medication adherence, exercise routines) through interactive apps, reminders, and feedback loops, DTx effectively manage chronic conditions by monitoring symptoms, providing health information, and promoting self-care [1]. They also enable clinicians to collect real-time patient data remotely, streamlining subsequent office visits [9]. Ultimately, DTx have the potential to reduce healthcare costs by personalized interventions, enhancing treatment engagement, and improving overall health outcomes, promising to transform healthcare delivery.

China’s rapidly ageing population and escalating chronic disease burden (e.g., cardiovascular diseases, diabetes, hypertension, and mental health disorder) necessitate early intervention [10-14]. The healthcare system faces challenges in managing this growing demographic, creating an urgent need for innovative solutions. DTx offer a promising approach, and China’s rapid growth in this area provides valuable lessons and examples for the rest of the world. With the increasing healthcare awareness, the DTx market in China has witnessed significant growth and interest. China’s DTx have grown exponentially, outpacing most Western countries, especially in healthcare areas directly linked to e-commerce [15]. The China DTx market was around $0·5 billion USD in 2023 and is projected to reach $2·92 billion by 2030, with a compound annual growth rate of 28·7% [16]. The evidence-based DTx market in China is around $200-250 million, including hospital-facilitated B2B products, pharma/med tech collaboration products, and non-prescription-based B2C products [15]. The Chinese government recognizes digital health as a key growth frontier and has actively supported its development through policies that facilitate clinical implementation, regulation, and commercialisation. These efforts have attracted numerous enterprises, fostering the emergence of preliminary DTx industry clusters.

While comprehensive reviews of the DTx ecosystem exist in regions like the USA, Europe, and South Korea [7], a holistic analysis of China’s DTx landscape remains absent. This represents a significant research gap, as understanding China’s approach to DTx requires examining the interconnections between clinical evidence, commercialisation strategies, and regulatory frameworks. Previous studies have typically focused on isolated aspects of DTx development, failing to capture the complex interplay between these critical dimensions. Given the sector’s reliance on patient engagement, public trust, and regulatory navigation, an integrated assessment that examines these three dimensions together is essential not only for advancing China’s DTx ecosystem but also for providing valuable insights that could inform

global DTx development (Figure 1).

[Insert Figure 1 about Here]

To address these gaps, our study aims to conduct a comprehensive assessment of China's DTx landscape through the integrated analysis of clinical trials, commercial products, regulatory frameworks, and reimbursement models. This multidimensional approach allows us to identify the key barriers and potential facilitators for DTx adoption in China, providing actionable recommendations to inform DTx research, development, adoption and implementation in other countries. We document the trends and characteristics in key DTx domains in China, including intended indications, commercial products, clinical trials, regulatory frameworks, and reimbursement policies. Furthermore, we delved into the intricate interplay among research, development, clinical trials, and regulatory aspects, considering both established and emerging DTx solutions. Our analysis leads us to propose essential considerations for each DTx domain and advocate open dialogue to effectively position DTx as a standard medical practice worldwide.

Methods

Methodological Framework

Our study employed a multi-method approach to comprehensively evaluate China's DTx ecosystem. This integrated framework was necessary to capture the full spectrum from clinical evidence to market dynamics and policy environments. We combined systematic review and meta-analysis of clinical trials to assess treatment effectiveness, scoping review of commercial products to understand market trends, regulatory analysis through policy document review to examine governance frameworks, and pricing/reimbursement analysis to evaluate economic sustainability. This methodological integration enabled us to examine how these different domains interact and influence each other, providing a more holistic understanding than any single methodological approach could offer.

Clinical trials

To evaluate the advancement of DTx research and clinical trials in China, we conducted systematic review and meta-analysis of relevant literatures followed the 2020 PRISMA guidelines [17]. Literature research was performed across five databases (PubMed, Google Scholar, IEEE, Web of Science, and ScienceDirect) from their respective inception dates until July 2024. The search was limited to English language publications. The search strategy included terms such as 'Digital therapeutics OR DTx,' 'China,' 'Digital health OR Healthcare,' and 'Smartphone OR Application.' The detailed search strings for each database are provided in Supplementary Table S1 and S2.

Clinical trial studies were included if they met the following criteria: 1) DTx clinical trials conducted in China; 2) intervention-based studies; 3) utilized DTx-related technologies. Studies were excluded if they were: 1) non-research articles such as conference abstracts, editorials, or opinion papers; 2) case reports; 3) observational studies. Two researchers (CH and XY) independently screened the titles and abstracts of the retrieved articles, and full-text articles were reviewed for eligibility. Disagreements were resolved through discussion with a third researcher (NJ). The PRISMA flow diagram detailing the study selection process is provided in the Supplementary Figure S1.

For data extraction, a standardized form was developed to systematically collect information from each included study. The extracted data included publication year,

indication, geographic location (province), type of study design, type of clinical research study, etc. This structured approach enabled comprehensive analysis of trends and patterns in DTx clinical research across China. Details regarding meta-analysis of clinical trials, such as search strategies, selection criteria, and risk of bias, are listed in the appendix (Supplementary Figure S3-S4, Supplementary Table S3-S4). The meta-analyses study of clinical trials was registered at PROSPERO CRD42024615584 for cognitive disorder outcomes and CRD42024611857 for diabetes outcomes. This separation was necessary due to the distinct outcome measures and analytical approaches required for each condition. Meta-analyses were conducted using random-effects models due to expected heterogeneity between studies. The analyses were performed using R version 4.3.2 with the 'meta' package. Standardized mean differences (SMD) with 95% confidence intervals were calculated.

Commercial products

To understand the development trends and characteristics of commercial DTx products in China, we conducted a scoping review and searched for commercial products mentioned in the National Medical Products Administration (NMPA) product library without any specific time restrictions in order to capture all relevant products until July 2024 [18]. We limited the category to domestic medical devices (registration) and used the search terms: "software," "digital therapeutics," and "system." Products were excluded based on their scope of application or intended use. The flowchart for search process related to DTx products is presented in Supplementary Figure S2.

For the data extraction process, we systematically collected information on each eligible product, including the release year, indication, province, type of clinical research study, and regulatory classification. The same two researchers independently reviewed product documentation to ensure accuracy and comprehensiveness of the extracted data. This systematic approach allowed us to identify patterns in product development, geographic distribution of DTx companies, and evolving trends in the commercial landscape. The synthesis of this data provided insights into the maturation of the DTx market in China and how it compares with global developments.

Regulations

DTx regulations were examined in China to understand their impact on clinical trials, product development, and market adoption. We conducted a systematic document analysis using a thematic framework approach. The analysis covered three key regulatory domains: premarket approval pathways, technical review guidelines, and post-market surveillance requirement. We browsed websites of relevant government institutions, including the State Council of the P.R.C, the National Development and Reform Commission, the Ministry of Science and Technology of the P.R.C, the National Medical Products Administration, and the State Administration for Market Regulation. The inclusion criterion was whether the regulations were relevant to DTx and effective until July 2024. The same pair of two researchers independently analyzed the texts using a structured coding framework to identify policy hierarchies, regulatory requirements, and implementation timelines. The coded information was then synthesized into thematic maps illustrating the national and regional policy framework and the classification-based regulatory pathways for DTx products. This methodical approach allowed us to comprehensively document China's evolving DTx regulatory ecosystem, including both national directives and regional innovation policies.

Pricing and reimbursement

To analyze DTx pricing and reimbursement models in China, we conducted a

comprehensive review of public and private insurance policies, government initiatives, and commercial pathways. We examined official documents from healthcare authorities, insurance companies, and regional pilot programs. For regulatory documents, rather than using electronic database searches, we conducted a comprehensive manual review of all available policy documents on official government websites from the current to July 2024. The review focused on four key aspects: pricing mechanisms, public health insurance coverage, private insurance integration, and alternative financing models. Information was collected from government websites, insurance company reports, and publicly available policy documents up to July 2024.

Results

Clinical trials of digital therapeutics in China

A total of 3,548 literature records related to DTx in China were identified. After screening the full text based on the inclusion criteria, 96 clinical studies were included in the review (see Supplementary Figure S1 for the PRISMA flow diagram). Of the 96 included studies, 68 (70.8%) were registered - 27 on ClinicalTrials.gov and 41 on the Chinese Clinical Trial Registry website. The remaining studies were included based on published articles. These studies were included to ensure a comprehensive analysis of all relevant clinical research on DTx in China, regardless of their registration status.

[Insert Figure 2 about Here]

Figure 2a shows a Sankey diagram analysing clinical trials presented through published research papers. This diagram shows the relationship between publication year, indication, province, type of study design, type of clinical research study, etc. It indicates that the types of indications have been diversifying over the years, illustrating that companies are prioritizing clinical trials more proactively. In addition, most clinical trials were conducted using randomised controlled trials (RCTs). For study design, parallel design had the highest proportion. For primary endpoint, treatment was the most common outcome, followed by diagnosis.

21 out of 96 clinical trials (21·9%) were related to cognitive disorders, followed by diabetes (20 trials, 21·1%), cardiovascular diseases (8 trials, 8·3%), sleeping disorders (6 trials, 6·3%), and smoking cessation (6 trials, 6·3%). Neuropsychiatric and chronic diseases account for the majority of indications. However, it has been shown that the scope of DTx is expanding with indications for diseases as follows. Neurodegenerative diseases such as mild cognitive impairment and Parkinson’s disease, cancer diseases such as gynecologic cancer related pain management, chronic disease such as chronic kidney disease, liver disease, respiratory conditions, and hypertension, neurological diseases such as autism spectrum disorders, depression and anxiety, and sleep disorders.

For geographic distribution, Beijing conducted the most with 18 publications (18·8%), followed by Shanghai with ten (11·5%), Guangdong with seven (10·4%), Hong Kong SAR with seven (9·4%), Taiwan with seven (7·3%), Fujian with six (7·3%), Sichuan with six (6·3%), and Jiangsu with four (5·2%). Clinical research was conducted by various institutions, and all with collaboration with universities and affiliated hospitals.

Risk of bias assessment using the Cochrane Risk of Bias 2 (RoB 2) for RCT revealed varying quality across the included studies. For cognitive disorders/dysfunction studies (Supplementary Figure S4-A), three studies demonstrated overall low risk of bias [19-21], while five studies showed some concerns[22-26], and two studies presented high risk of

bias. Relative frequent sources of bias were in the randomization process (D1) and deviations from intended interventions (D2). For diabetes studies (Supplementary Figure S4-B), five studies demonstrated overall low risk of bias[27-31], while six studies showed some concerns or high risk of bias[32-37]. Across both indications, measurement of outcomes (D4) and selection of reported results (D5) showed better methodological quality. These findings highlight the need for more rigorous trial design standards specific to digital interventions, particularly regarding randomization procedures and intervention implementation.

Due to the heterogeneity of study outcomes, we only chose DTx for diabetes and cognitive disorders for meta-analyses. For diabetes, 11 studies (1,283 participants) were included in the meta-analysis on HbA_{1c}. Of the included studies in the meta-analysis, three DTx interventions were assessed as high risk of bias, and five as low. The meta-analysis showed a trend towards improvement in HbA_{1c} levels among participants in the DTx intervention group compared to the control group (SMD = −0·96; 95% CI: −2·03 to 0·11, Figure 3a), approaching but not reaching statistical significance. This effect size suggests potential clinical relevance, as a reduction of approximately 1% in HbA_{1c} is generally considered meaningful for diabetes management. However, substantial heterogeneity was observed across studies (τ^2 = 3·23, df=10, p <.001, I^2 =97%). For cognitive disorders, ten studies (866 participants) were included in the meta-analysis on global cognitive function measured by Montreal Cognitive Assessment (MoCA) and Mini-Mental State Examination (MMSE). This meta-analysis showed a significant improvement in global cognitive function among participants in the DTx intervention group compared to the control group (SMD = 0·65, 95% CI: 0·37 to 0·94, Figure 3b). The heterogeneity between the studies was statistically significant and considerable in magnitude (τ^2 = 0·15, df=9, p<.001, I^2 =71.7%). Three studies were rated as low risk of bias, and two studies may face high risk of bias.

[Insert Figure 3 about Here]

Commercialisation of digital therapeutics

A systematic search of DTx-related commercial products in China revealed that DTx initially focused on a limited range of conditions reliant on behavioural interventions, such as addiction and mental health. Recent DTx launches cover diverse indications, including diabetes, hypertension, respiratory diseases, hepatic conditions, sleep disorders, and ADHD. Cognitive impairment was the most active field, with 38 companies involved, followed by ophthalmic diseases (30 companies) and respiratory diseases (five companies). Together, these three fields involved over 73 companies, totaling 97 and accounting for more than half of the DTx market. See supplementary Figure S2 for search process details.

A representative example of commercialised DTx is Six Brain™ (BrainAu, Hunan, China), which is the first NMPA-cleared DTx for computerized cognitive training in older adults. Six Brain™ offers prescription behavioural medicine, providing multidomain, adaptive cognitive training to enhance global cognitive function, executive function, and brain functional connectivity [38]. Another NMPA-cleared DTx is BBRT™ (BestCovered, Shanghai, China). BBRT combines cognitive-behavioural therapy with a multidomain intervention, including diet, exercise, cognitive training, vascular risk monitoring, and professional online counseling services. It aims to prevent cognitive decline in at-risk older individuals. Additionally, the Shukang™ app (Shangyi, Sichuan, China), serves as a DTx for cardiac rehabilitation. The app offers domiciliary, mobile application-guided, and tele-monitored programmes to improve physical fitness, adherence, and health beliefs among patients who have undergone ablation for atrial fibrillation [39]. DTx differs from traditional medications as they deliver treatment through applications on computers or smartphones.

While the underlying technologies are similar across indications, treatment outcomes depend on content and application methods (Table 1). Companies customise content for specific indications on their platforms, collaborating with research institutions like universities and hospitals to expand DTx to various conditions through existing or new partnerships.

Table 1. Primary intervention mechanisms of Commercialised DTx: A Comprehensive Overview

Diseases	Indications	Intervention Mechanism of DTx	Mode of delivery	Unique DTx Benefits
Psychiatric/ Mental disorders	ADHD, Depression, Insomnia, Addiction, Anorexia Nervosa, Substance Abuse	Cognitive Behavioural Therapy, Behavioral Activation	Smartphone applications, web-based platforms, VR therapy, wearable devices	Boosting therapy effectiveness and patient outcomes with software-hardware integration.
Neurological diseases	AD, PD, Multiple Sclerosis, Epilepsy, Migraine	Cognitive Behavioural Therapy, Biofeedback Therapy, Relaxation Therapy	Smartphone apps, web-based platforms, VR therapy, wearable motion sensors, biofeedback devices	
Endocrine and Metabolic Diseases	Diabetes, Metabolic Syndrome	Exercise and Nutrition Therapy	Smartphone apps, wearable devices, connected glucose monitors, AI-driven analytics, web-based platforms, telemedicine integration	Enhancing patient self-management with long-term health tracking
Cancer	Cancer Complications	Pharmacokinetic Precision Medication, Disease Course Management	Smartphone apps, web-based platforms, remote patient monitoring, AI-driven analytics	Leveraging AI and big data to analyze in vitro drug data, personalizing treatments by understanding individual drug responses and optimizing patient outcomes
Respiratory diseases	Chronic Obstructive Pulmonary Disease, Asthma	Pharmacokinetic Precision Medication Monitoring	Smartphone apps, wearable devices, web-based platforms, inhaler sensors, VR-based rehabilitation	
Cardiovascular diseases	Heart Failure, Hypertension	Pharmacokinetic Precision Medication Monitoring, Disease Course Management	Smartphone apps, wearable devices, remote monitoring platforms, connected BP cuffs, telemedicine integration	
Ophthalmic diseases	Myopia, Amblyopia, Strabismus	Interfering with synapses in the central neural circuit of vision	VR headsets, eye-tracking screen devices, specialized digital visual simulation tools	Boosting brain plasticity and visual performance with focused, non-invasive stimulation of the visual cortex, resulting in enhanced binocular vision

Musculoskeletal diseases	Musculoskeletal Pain, Osteoarthritis	Exercise Therapy	Smartphone apps, wearable motion sensors, camera-based tracking, VR-based rehabilitation, digital physical therapy platform	Enhancing the therapeutic experience for both providers and recipients

Figure 2b shows a Sankey diagram of commercialised DTx products in China with release year, indication, province, type of clinical research study, and regulatory classification. The number of commercial products released has an increasing trend from 2018 to 2023. A total of 97 products received NMPA clearance from 2018 to the first half of 2024. Many of these products initially released were related to neurological diseases, ophthalmic diseases, psychiatric diseases, and endocrine diseases. Products released after 2022 were observed to be related to respiratory diseases, probably due to COVID-19. Most DTx emphasise treatment and rehabilitation, highlighting the benefits of DTx in enhancing adherence and improving patient experience. Among the approved DTx products in China, the majority are registered as Class II medical devices. There is only one DTx product classified as Class III, designed for medication dosage calculation.

Regulation of digital therapeutics

At present, there is no specific regulation or issued guidance principles for DTx products in China. The regulation and registration of similar products follow the relevant policies and procedures for medical device software approval (Figure 4a). The regulation and registration policy framework for DTx is guided by national policies [40-43] and specific procedures set forth by the NMPA [44-49]. These regulations cover various aspects of DTx development and deployment, including registration, classification, clinical evaluation, production, distribution, and software review. Additionally, to foster innovation and growth in the DTx industry, several provinces have implemented their own innovative policy frameworks and incentives, demonstrating a varied regulatory landscape across the country.

[Insert Figure 4 about Here]

Classification

In China, DTx products must be registered with the NMPA or local counterparts based on their classification (Figure 4b). Most DTx products are classified as Class II medical devices, which offer more development flexibility but are subject to stricter regulations than Class I devices, though less stringent than Class III [49].The DTx products are generally classified as Software as Medical Device (SaMD) under existing categories, although these may not fully capture the specifics of DTx. General software regulations, encompassing technical review and classification, are applicable; however, the guidelines specific to DTx remain comparatively lenient.

When compared to the U.S., both China and the U.S. adopt a risk-based classification system for DTx, categorizing products into Class I, II, and III based on intended use and risk level. In the U.S., DTx is regulated by the FDA's Center for Devices and Radiological Health (CDRH) under the Mobile Medical Applications (MMA) framework. Class I devices are subject to general controls, Class II devices typically require 510(k) clearance, and Class III devices, which pose the highest risk, undergo Premarket Approval (PMA) [50]. In contrast, China's NMPA follows a similar tiered classification approach, but regulatory pathways and enforcement mechanisms differ. Key differences include regulatory oversight, where China's approach remains more prescriptive, approval pathways, which rely on pre-existing classification rules rather than de novo pathways, and post-market surveillance, where China enforces stricter compliance measures to ensure long-term safety and efficacy.

Clinical evaluation

According to the ‘Measures for the Registration and Filing Management of Medical Devices’ (SAMR Decree No·47) [43], clinical evaluation is typically required for medical device registration to confirm safety and effectiveness, unless specific exemptions apply. For DTx products, the ‘Catalogue of Medical Devices Exempt from Clinical Trials’ (Notice No·71 of the National Medical Products Administration in 2021) [51] allows exemptions for certain Class II software, such as trace analysis and clinical management software. However, determining whether a product qualifies for exemption should involve a thorough algorithmic assessment and expert consultation. Clinical evaluation can be conducted through either clinical trials or by analysing existing literature and data from similar devices.

Security and data governance

DTx in China handle extensive personal data from medical services like disease prevention and treatment. Regulations require companies to disclose data processing rules, implement robust security measures, address vulnerabilities promptly, and conduct regular risk assessments with reports to authorities. In 2022, the NMPA updated the ‘Guiding Principles for Technical Review of Medical Device Network Security Registration [52]’, requiring Class II and III medical devices with network connectivity to ensure security throughout their life cycle, from design to maintenance. These measures safeguard data, ensure device effectiveness, and support the growth of the DTx industry. In the same year, the NMPA Medical Device Technical Review Centre spearheaded the establishment of a ‘Digital Therapeutics Working Group’ within the AI Medical Device Innovation Cooperation Platform [53] to advance the exploration of AI regulatory frameworks in DTx.

Pricing and reimbursement of digital therapeutics

Pricing

In China, there is no well-defined framework for determining the prices of digital health apps. Additionally, there is no centralised committee responsible for setting national-level prices for these solutions. Instead, pricing negotiations occur at the hospital level, where each hospital collaborates with digital health manufacturers to reach agreements. Pricing mechanisms were found to be at different stages of development across China. For instance, Hainan deploys on a fee-for-service basis and determines the price of DTx in the context of the health care process in which they are deployed [54], and it is transiting to a value-based pricing system [54].

When comparing globally, reimbursement models differ significantly across countries (Table 2). In the U.S., DTx reimbursement is primarily private insurer-driven, with some products covered under Medicare/Medicaid through CPT codes and value-based agreements [50]. Europe has structured models, such as Germany’s DiGA, which provides temporary fast-track reimbursement, and France’s PECAN system, which offers conditional reimbursement [55-57]. Canada and Australia rely on provincial or mixed public-private funding, with decentralized reimbursement decisions [58, 59]. China’s reimbursement framework remains underdeveloped, with limited national coverage but growing private insurer involvement and pilot programs exploring new funding mechanisms. Despite these differences, similarities in risk-based classification and expanding payer coverage suggest potential for global harmonization. International collaboration on DTx value assessment, health economic evaluations, and regulatory alignment could support broader adoption. Models like DiGA have influenced other regions, and a structured framework could

accelerate DTx reimbursement in China. A standardized evaluation system would facilitate market integration, improve accessibility, enhance global DTx adoption, and drive innovation in digital healthcare solutions.

Table 2. DTx Pricing model across different regions

Region	Reimbursement Model	Coverage Approach	Challenges	Potential for Harmonization
United States	Private insurers, Medicare/Medicaid coverage, CPT codes for some DTx	Case-by-case evaluation by private insurers, emerging value-based pricing	Lack of standardization across payers, slow adoption of prescription DTx	Standardizing payer criteria, wider Medicare adoption
Europe	National frameworks in some countries (e.g., Germany's DiGA, France's PECAN), others rely on regional/national health services	Temporary reimbursement while gathering evidence (Germany), conditional models in France	Varying national policies, not all countries have structured reimbursement	DiGA-style frameworks could expand to other EU countries
Canada	Provincial-level assessments, limited national coordination, employer-based insurance	Fragmented provincial funding, some employer and private coverage	No national framework, digital health products evaluated on a case-by-case basis	Adoption of a unified evaluation system across provinces
Australia	Mixed public-private model, some Medicare support for digital health, private insurer involvement	Medicare covers some telehealth services; private insurers fund digital health	No centralized DTx policy, slow public adoption	National DTx reimbursement framework development
China	Limited national coverage, pilot reimbursement programs, growing role of private insurers	Primarily out-of-pocket or private insurance, limited government funding	Government insurance yet to cover DTx, regulatory pathways still evolving	Potential for structured reimbursement similar to Europe’s DiGA model

Eligibility and mechanism of reimbursement through public health insurance

China does not have a specific reimbursement process for DTx, nor established criteria for assessment. In digitally advanced areas, reimbursement decisions for DTx are driven locally by hospital groups. For example, Shanghai is integrating DTx into its comprehensive medical insurance as a tool for screening and disease management [60], while Hainan is encouraging the inclusion of DTx in medical service specifications and fee structures [61]. Two reimbursement archetypes could be derived: either reimburse the digital health solution itself or reimburse the clinical pathway that the digital health solution is a part of.

Financing DTx through private health insurance

We found an array of DTx solutions in China that are financed through private health insurance. This involves insurance providing payment and management for medical care, while medical services guide and interact with insurance. Constructing a closed loop for “preventive medicine” benefits both insurance and DTx by creating a positive incentive cycle. Insurance companies are increasingly using DTx to collect patient data and develop more targeted products. For example, ZhongAn Insurance launched a cognitive protection insurance product that includes BBRT therapy [62], Miao Health introduced a product that incorporates DTx for hypertension management [6], and Huzhibao offers comprehensive coverage for Alzheimer’s disease (AD) management, including eye movement screening, mild cognitive impairment (MCI) blood biomarker testing, DTx intervention services, and medication reimbursement [60]. By integrating these services, DTx tools can provide comprehensive care for insurance beneficiaries, spanning from early detection and prevention to treatment, rehabilitation, and long-term management.

Financing DTx outside health insurance

Examples of DTx financing independent of health insurance is prevalent in China, primarily focusing on public health and civil affairs. The dominant commercial pathway involves government-facilitated access for end users, following models such as business-to-government-to-consumer (B2G2C) or business-to-hospital-to-consumer (B2H2C). For instance, Amity Brain Health, in collaboration with tertiary hospitals in Fujian Province and Shenzhen City, has launched a pilot programme for cognitive prevention and treatment, aiming to build a multi-layered service system. This initiative aligns with government goals of improving healthcare accessibility and efficiency by addressing challenges such as limited screening, delayed diagnosis, and high treatment costs. Through rapid screening, remote consultations, and home-based digital exercises, it provides comprehensive disease management, supporting the government’s efforts to enhance public health and reduce the burden of cognitive disorders [63] .

Discussion

Our study offers a comprehensive exploration of the DTx ecosystem in China. We summarise the following key lessons: (1) targeted indications and technology components; (2) standardised clinical trials; (3) streamlined regulation and approval process; and (4) diversified pricing and reimbursement models. These insights offer valuable lessons for other countries, particularly low- and middle-income nations that are looking to leverage DTx to improve healthcare outcomes and enhance population health.

Key Insight 1. Targeted indications and technology components

Our analysis revealed strategic patterns in China's DTx indication selection and technology deployment. Initially, DTx in China development primarily targeted chronic diseases like diabetes, cardiovascular conditions, and chronic pain; ophthalmic diseases such as myopia, amblyopia, strabismus, asthenopia, and post-operative rehabilitation; sleep disorders like insomnia; mental health challenges encompassing depression, anxiety, ADHD, and mild cognitive impairment; and substance abuse including smoking cessation. While these areas remain core to DTx applications, recent research indicates a growing trend towards more specialised DTx solutions tailored to specific disease subpopulations and clinical needs[1]. DTx is being used in a growing number of medical fields, including oncology, neurology, gynecology, urology, gastroenterology, orthopedics, pulmonology, immunology, otolaryngology, and infectious diseases. It also extends to various conditions like Parkinson's disease, hepatitis B, and multiple sclerosis. A common trend of these emerging DTx domains in China is evident: DTx tend to be prioritised in areas where they can directly implement cognitive-behavioural interventions or serve as complementary tools for medical professionals supporting doctors' treatment and follow-up management. This aligns with the prediction that DTx would be preferentially adopted in fields with high demands and a potential for cognitive-behavioural therapeutic approaches [64]. Supplementary Table S2 presents a classification of DTx products based on their therapeutic indications, including both commercially available and investigational treatments.

The technology deployment for DTx in China shows distinctive characteristics shaped by the country's digital infrastructure. The near-universal smartphone penetration and advanced mobile payment ecosystems have enabled a mobile-first DTx strategy, enabling real-time patient monitoring, personalized feedback, and improved adherence. This enhances cognitive-behavioral interventions and disease management, optimizing outcomes through remote monitoring and AI-powered decision support [50, 65]. This approach has facilitated rapid scaling and accessibility of DTx solutions across diverse geographic regions and socioeconomic groups, offering valuable lessons for other large countries with significant urban-rural divides.

A fundamental aspect of DTx is content, which manifests in diverse forms such as virtual reality, gaming elements, online monitoring, and interactive assessments. The therapeutic efficacy of a DTx is significantly influenced by the nature and design of its content. To optimise patient engagement and treatment outcomes, content development necessitates careful consideration of factors including target condition, patient demographics, and cultural context. Evolving societal values, cultural norms, and customs can also alter patient perceptions of digital content over time, thereby impacting the effectiveness of DTx. While this dynamic is difficult to standardise, it underscores the inherently changing nature of DTx efficacy. Clinician expertise has traditionally driven content creation, however, the integration of artificial intelligence into treatment content is a burgeoning trend that warrants close attention [66, 67]. Furthermore, there is a growing emphasis on the development of human-computer interaction and neurofeedback technologies to enhance the effectiveness [53]. China's experience in this area demonstrates the critical importance of cultural adaptation in content development - a lesson particularly relevant for other countries with strong cultural traditions and diverse populations seeking to develop locally appropriate DTx solutions.

The efficacy of DTx is contingent upon users' digital literacy and cognitive capabilities. Strong digital skills in using smartphones and computers are associated with enhanced content comprehension, engagement, and ultimately, therapeutic outcomes. However, the digital divide, particularly pronounced in China's urban-rural divide, poses a

significant challenge, potentially exacerbating existing health disparities. While direct evidence linking these factors to DTx outcomes in China is scarce, research on digital media suggests that age, education, and income impact user acceptance and engagement with digital content [68, 69]. Given the parallels between DTx and other digital platforms, it is reasonable to infer that similar factors likely influence DTx effectiveness.

China's experience in addressing this digital divide offers important lessons on designing inclusive DTx solutions. Equitable design principles that consider the specific needs of different regions have been essential to mitigate these disparities in the Chinese context. Patient engagement, influenced by sociocultural and demographic factors, is critical to DTx success [7], and China's approaches to enhancing accessibility across diverse geographic regions and socioeconomic groups provide valuable insights. Countries with similar demographic and geographic diversity can learn from these strategies for tailoring interventions to diverse populations, maximizing the benefits of DTx while minimizing the risk of widening existing health inequities.

Key Insight 2. Standardised clinical trials

The predominant study design in our DTx research analysis was RCT, accounting for over 80% of included studies (81.2%, 78 of 96). This reflects China's commitment to rigorous clinical validation of digital interventions, which sets an important precedent for other countries developing their DTx evaluation frameworks. However, challenges persist particularly in establishing suitable control groups for multi-centre trials. Among the clinical research investigated in this study, only 21 multi-centre clinical research were found. Moreover, the software nature of DTx complicates the creation of effective placebos, hindering the maintenance of blind conditions. Consequently, a tailored RCT framework is essential to address the unique characteristics of DTx. China's experience highlights the need for adaptations to conventional clinical trial methodologies when evaluating digital interventions - a challenge faced globally. Due to the heterogeneity in outcomes, exposure, quantity, and quality of studies, meta-analysis was often infeasible or insignificant for many indications in our study. This underscores the field's relative novelty and the urgent need for standardized methodologies and reporting guidelines.

While RCTs are essential for establishing treatment efficacy, real-world data is crucial for evaluating how interventions perform in practical settings. China's approach to resolving these methodological challenges, including the emerging emphasis on real-world evidence to complement RCTs, offers valuable insights for other countries grappling with similar issues in DTx evaluation. Post-market surveillance by both industry and academia is necessary to monitor the ongoing safety and effectiveness of approved DTx. The evolution of China's clinical trial standards for DTx could serve as a reference point for countries developing their own evaluation frameworks, particularly those with limited experience in digital health assessment. By emphasising evidence-based advantages, DTx may foster increased user acceptance and compliance in China. Subsequent to successful clinical trials, the industry should prioritise product dissemination, accelerate clinical integration, and expand community outreach. Thus, DTx may surmount adoption barriers and realise its full potential in improving patient outcomes and transforming healthcare delivery.

Key Insight 3. Streamlined regulation and approval process

Although the NMPA has not yet issued clear guidelines specifically for DTx, approvals and registrations are increasing, and the potential for long-term growth is substantial. The regulatory landscape in China demonstrates a pragmatic approach that balances innovation with safety considerations. Unlike the US (e.g., De Novo, 501(k), 501(k)exemption) [70] and EU (e.g. DiGAs in Germany) [55, 56], China lacks a dedicated

DTx regulatory pathway. This approach differs notably from the more structured frameworks seen in these regions, offering an alternative model that may be more appropriate for countries with developing regulatory infrastructures.

Establishing an industry association to define DTx and distinguish them from other health management software is crucial for industry alignment. A unified conceptual framework can guide the creation of a comprehensive classification and definition system, clear approval standards, expedited reviews, and a streamlined approval process to assist companies in navigating product registration and entering the market more rapidly.

The regionalised innovation in regulatory approaches seen across different Chinese provinces provides a unique experiment in regulatory flexibility. To accelerate industry growth, local governments are increasingly competing to implement innovative incentives and create priority approval channels for DTx products [71]. This decentralized approach to regulation could be particularly instructive for other large countries with diverse regional healthcare needs and capabilities. With government leadership, local authorities can actively foster industry development, implement supportive policies, and create priority approval channels to expedite the registration and approval of DTx products.

China's experience suggests that countries can make significant progress in DTx adoption even without fully developed DTx-specific regulatory pathways, provided there is sufficient flexibility within existing medical device regulation frameworks. This insight is especially valuable for countries that may lack the resources to develop comprehensive new regulatory frameworks specifically for digital health. Additionally, regulators in China carefully observe the DTx industry. If the use of new technologies such as artificial intelligence increases, it will be necessary to develop standards for safety and efficacy verification [45, 66, 72].

Key Insight 4. Diversified pricing and reimbursement models

China has pioneered innovative approaches to DTx reimbursement, with local governments taking the lead in shaping pricing and coverage strategies. These regional efforts reflect the complexity of navigating the fragmented reimbursement landscape while addressing challenges such as user acquisition, policy disparities, and cost-effectiveness evaluations. Local initiatives have leveraged direct-to-consumer sales, insurance-based coverage, and government funding to create tailored models that align with regional healthcare priorities [5].

The diversity of reimbursement models observed across different Chinese regions - from direct integration into public health insurance in Shanghai [60] to value-based approaches in Hainan [61] - offers a natural experiment in financing strategies that other countries can learn from. These varied approaches demonstrate that reimbursement pathways can be adapted to local healthcare financing systems and priorities, rather than requiring a one-size-fits-all approach. A value-based approach, focusing on clinical outcomes and cost-effectiveness, underpins these efforts. Health economic and outcomes research have been instrumental in quantifying the impact of DTx, such as reductions in hospitalisations and medication reliance, providing a solid basis for outcomes-based contracts and customised pricing strategies.

China's experience with private insurance integration is particularly instructive for countries with mixed public-private healthcare systems. The creation of "closed loops" linking preventive medicine, treatment, and insurance reimbursement provides innovative models for sustainable DTx financing that extends beyond traditional fee-for-service approaches. By aligning incentives and fostering collaboration among government agencies, insurers, and healthcare providers, these local programs have driven significant innovation in reimbursement strategies [57].

The B2G2C and B2H2C models developed in China offer alternative commercialisation pathways that could be especially relevant for countries where direct-to-consumer digital health markets are underdeveloped. Notably, local governments have introduced targeted policies, including pilot programs and dedicated reimbursement codes, to streamline DTx integration into their healthcare systems. This reimbursement for DTx is integrated into the remuneration of broader healthcare processes, aligning more effectively with diagnosis-related group (DRG) payment models for healthcare.

These intermediate models leverage existing healthcare delivery and financing structures to accelerate DTx adoption without requiring radical system changes. By leading in this area, local governments exemplify how regional initiatives can maximise DTx potential, establish models for nationwide adoption, and enhance healthcare delivery through efficient and cost-effective resource allocation across China.

Limitations

Our analysis faced several key constraints. Firstly, we relied solely on publicly available information, which precluded consideration of cutting-edge research in development, planned clinical trials, and emerging regulations from governments and institutions. Additionally, our focus on published studies, clinical trials, and commercially available products meant we inevitably overlooked insights that might have been gleaned from failures. Finally, the limited amount of real-world evidence for each product restricted our ability to incorporate existing literature on verifying effectiveness in practical settings. Nonetheless, the significance of real-world evidence for DTx cannot be overstated, particularly in the context of health technology assessments that inform reimbursement decisions.

DTx hold great promises for chronic, ophthalmic, psychiatric, and neurological conditions that have traditionally been difficult to manage with conventional methods. Consequently, demand for DTx is expected to rise significantly. However, to move beyond the introductory phase and become a mainstay in healthcare, DTx must address several challenges. Key among these is the need for robust verification through real-world evidence. Strengthening the integration of research, development, clinical trials, and regulatory frameworks is vital to overcoming this challenge. Additionally, addressing patient engagement barriers and streamlining regulatory processes will be crucial for widespread adoption. The infrastructure and adaptability of DTx within clinical settings must also be carefully considered to ensure stable integration.

China’s experience in advancing DTx provides valuable lessons for other countries. The country’s rapid adoption of digital health solutions, along with its evolving regulatory environment and healthcare infrastructure, offers insights into how DTx can be scaled effectively. Global stakeholders can draw on these lessons to streamline their own DTx research, development, and implementation, facilitating a faster and more efficient integration of these therapies into healthcare systems worldwide.

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Figure 1. DTx Ecosystem in China: Overview

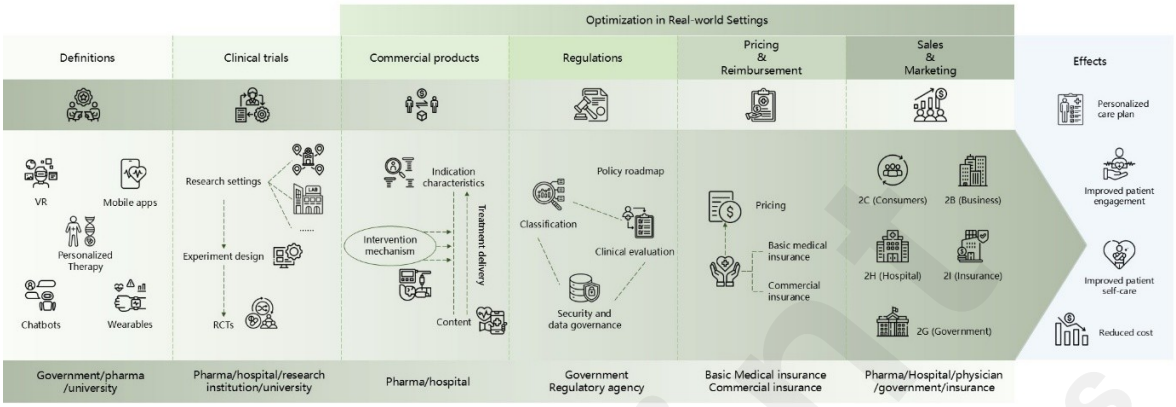
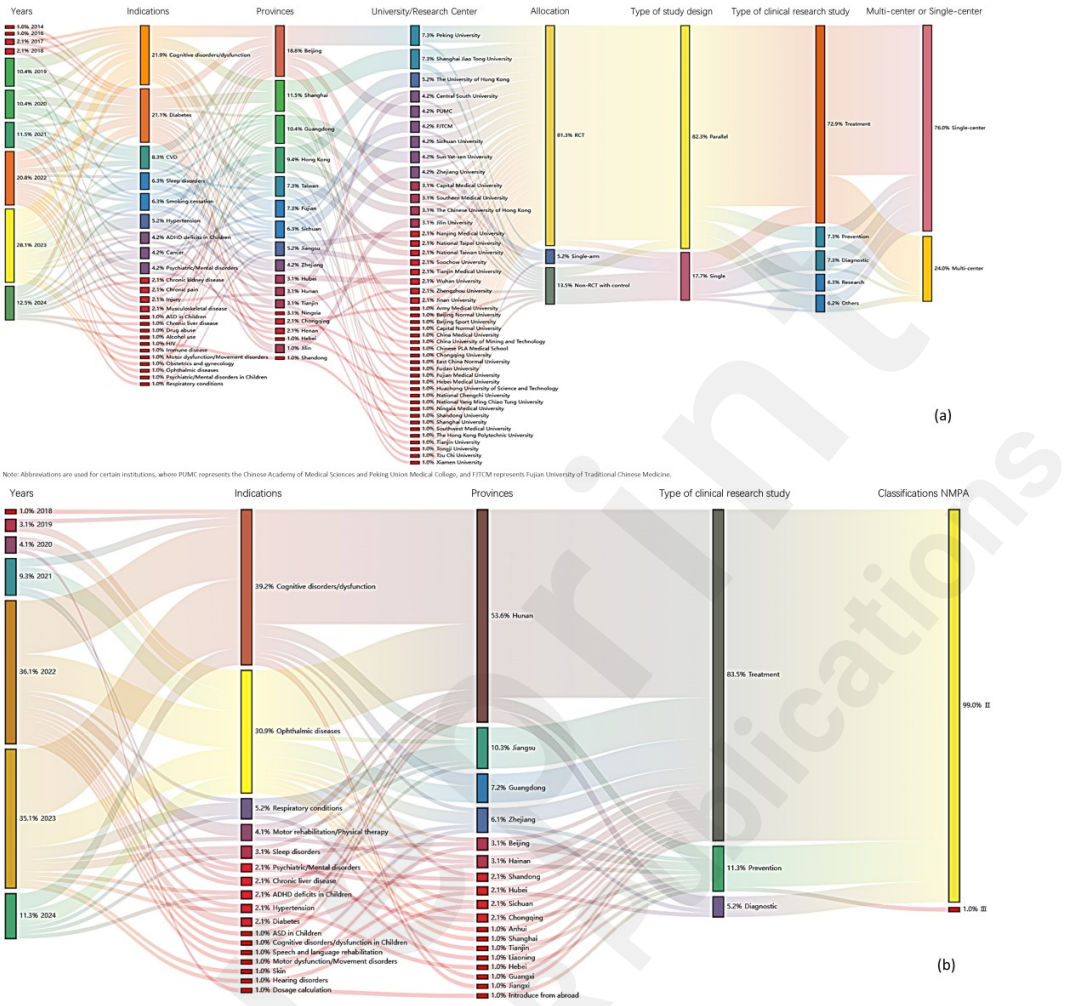


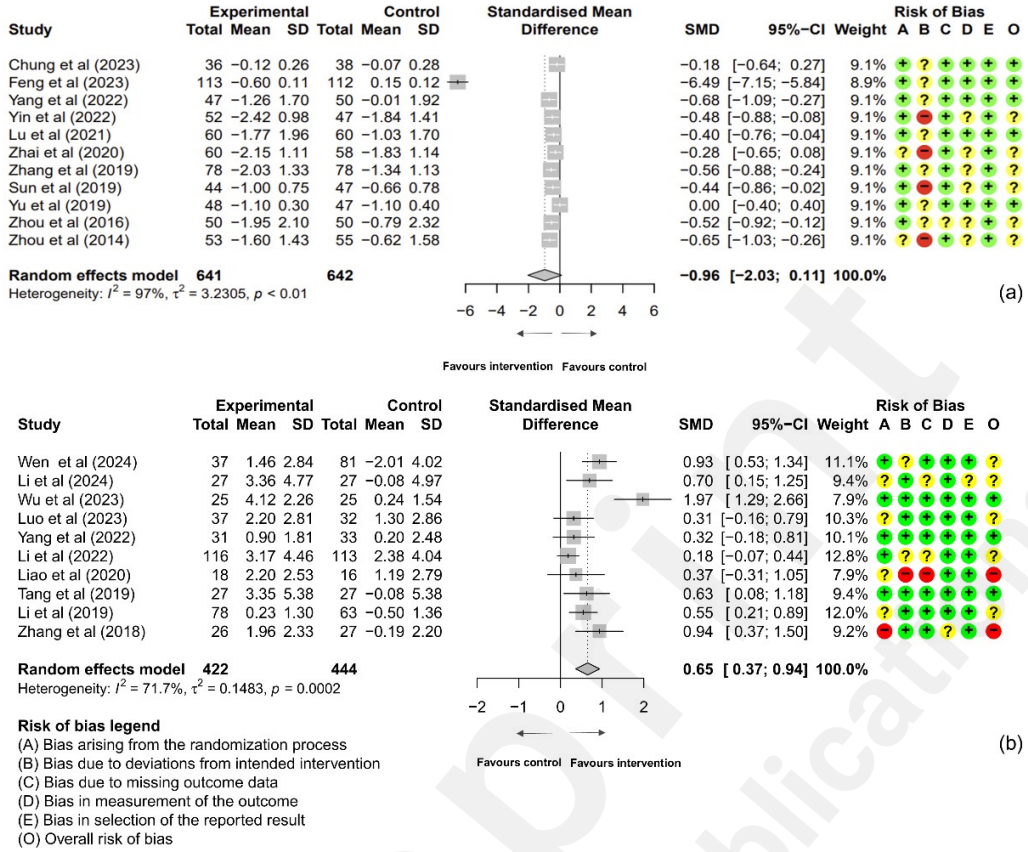
Figure 2. Sankey diagrams



Notes: (a) A Sankey diagram was utilized to analyse trends in indication, institution, province, trial type, intervention, and major outcomes for clinical trials. Between 2014 and 2024, a total of 96 clinical trials related to digital therapeutics were identified. The clinical trials were conducted by a variety of institutions, including pharmaceutical companies, hospitals, research institutes, medical consortia, universities, and corporations. These trials were carried out in China, employing interventions such as parallel, single, crossover, and factorial designs, with primary objectives that included treatment, research, prevention, and diagnosis.

(b) A Sankey diagrams were employed to analyse trends in the types of indications, registered provinces, primary endpoint, and class types for commercial digital therapeutic devices (N=97). The investigation focused on products listed on the NMPA websites. Commercial digital therapeutics are primarily launched for indications related to neurology, psychiatry, ophthalmic diseases, chronic diseases, respiratory conditions, with additional products available for hearing disorders, skin conditions, and sleep disorders. The primary objectives include treatment, prevention, and diagnosis.

Figure 3. Meta-analysis for DTx interventions for diabetes and global cognitive function



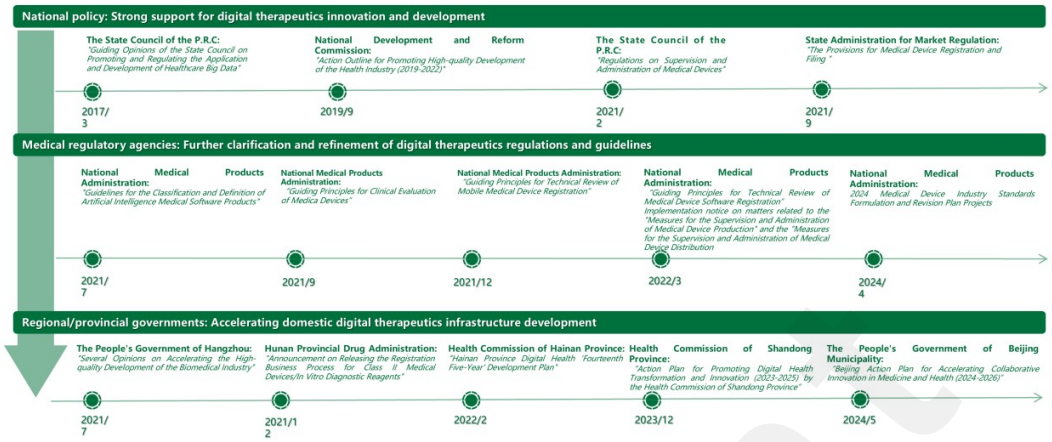
Notes: (a) Forest plot of mean difference in HbA1c (expressed as percentage) between the DTx intervention and the usual care group in Chinese patients with T2DM. The meta-analysis showed a trend towards improvement in HbA1c levels among participants in the DTx intervention group compared to the control group, approaching but not reaching statistical significance. The data from 11 RCTs (involving 1,283 participants) present substantial heterogeneity.

(b) Forest plot of mean difference in global cognitive function (measured by Montreal Cognitive Assessment, MoCA, and Mini-Mental State Examination, MMSE) between the DTx intervention and the usual care group in Chinese patients with cognitive impairment. A statistically significant greater increase in global cognitive function scores is seen in the DTx intervention group compared with the control group. The data from 10 RCTs (involving 866 participants) present substantial heterogeneity.

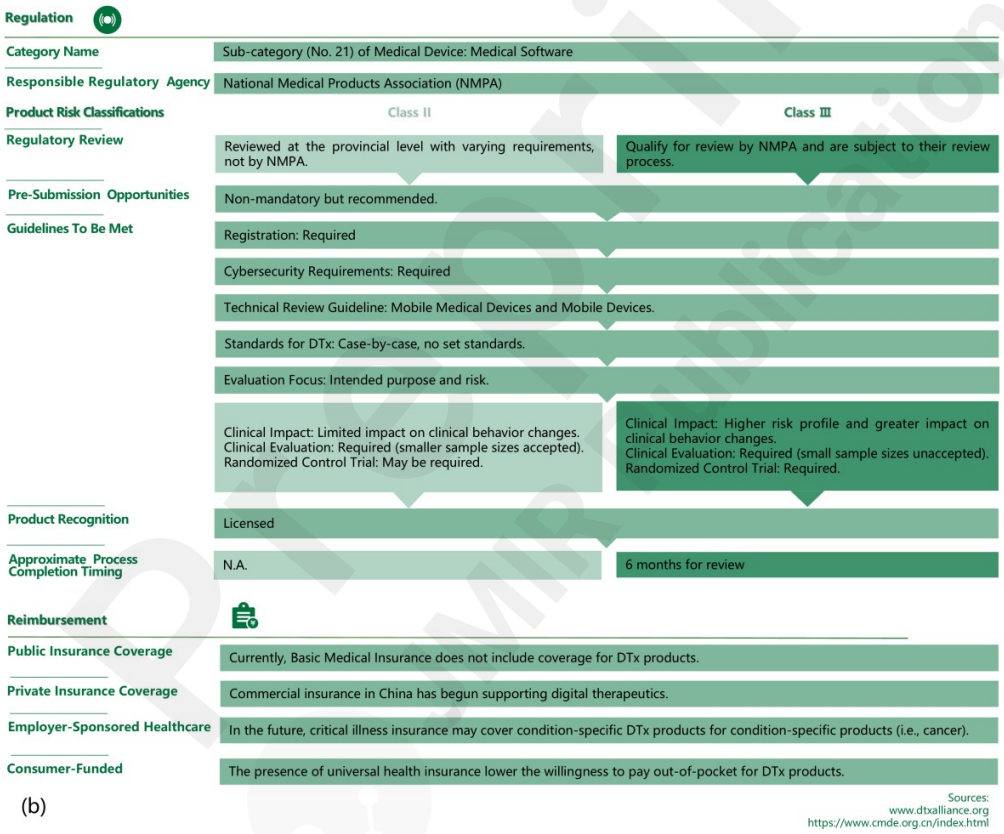
The size of the squares indicates the weight of the evidence from each of the studies; studies with CI (horizontal line) crossing zero (vertical line) are inconclusive; powerful studies (those with more participants) have narrower CIs; the diamonds represent the summary effect sizes in the overall sample, with the width of the diamond indicating the 95% CI.

HbA_{1c}=glycated haemoglobin A1c. T2DM=Type 2 Diabetes Mellitus. CI=Confidence interval. RCT=Randomized Controlled Trial. RoB 2 tool=Revised Cochrane Risk-of-Bias Tool for Randomized Trials.

Figure 4. DTx Policy Development in China: (a) DTx Innovation Development Policy Map; (b) Regulation and reimbursement framework of DTx in China



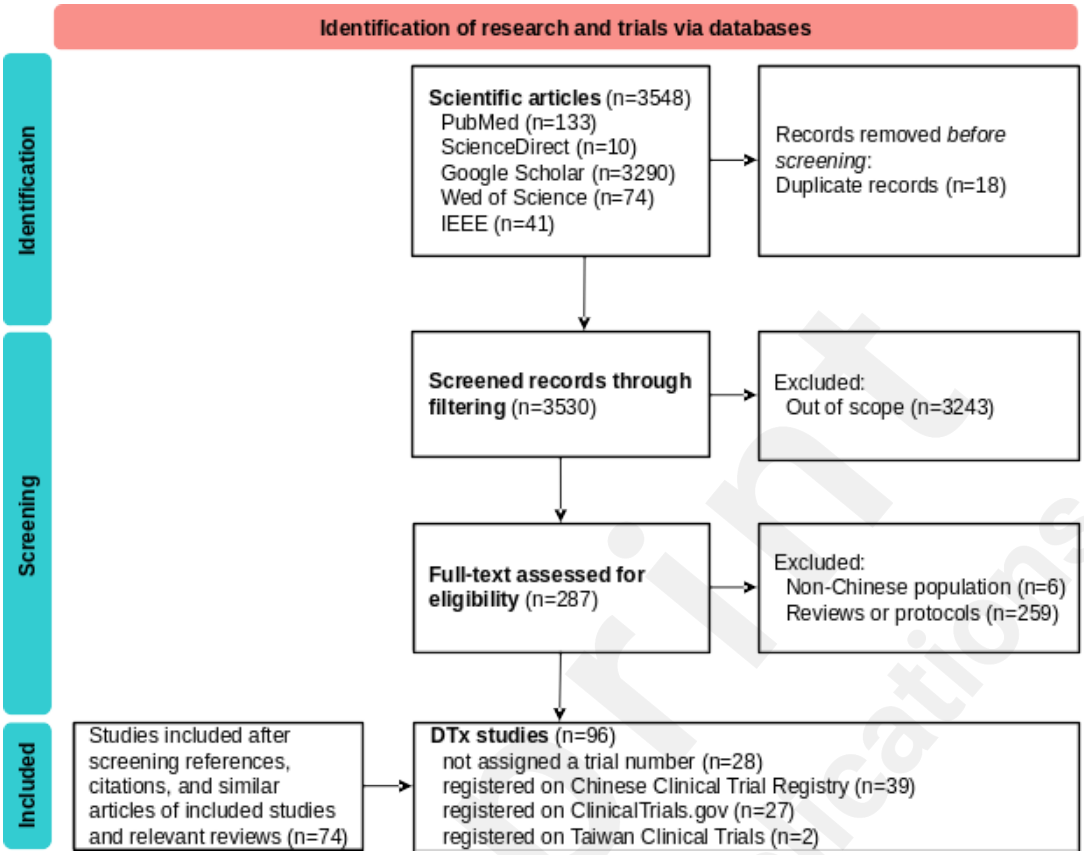
(a)



(b)

Supplementary appendix

Supplementary Figure S1. Flowchart for search process related to clinical research and trials of DTx

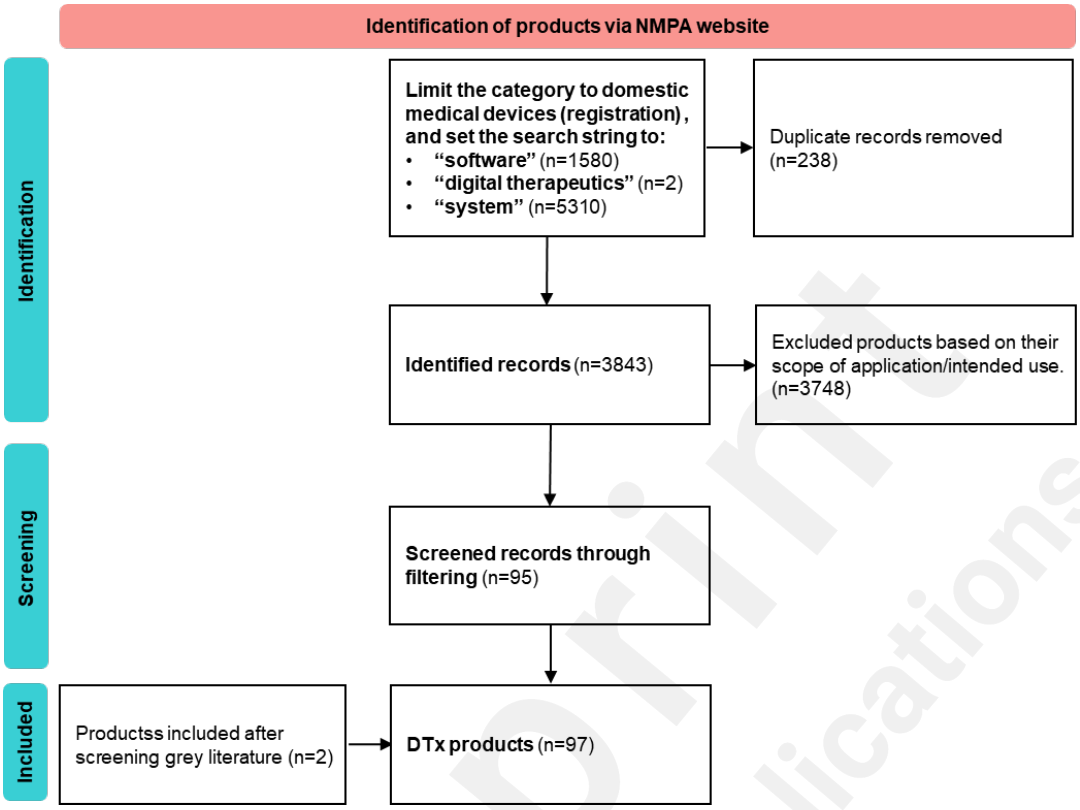


Chinese Clinical Trial Registry. https://www.chictr.org.cn/searchproj.html.

ClinicalTrials.gov. https://clinicaltrials.gov/

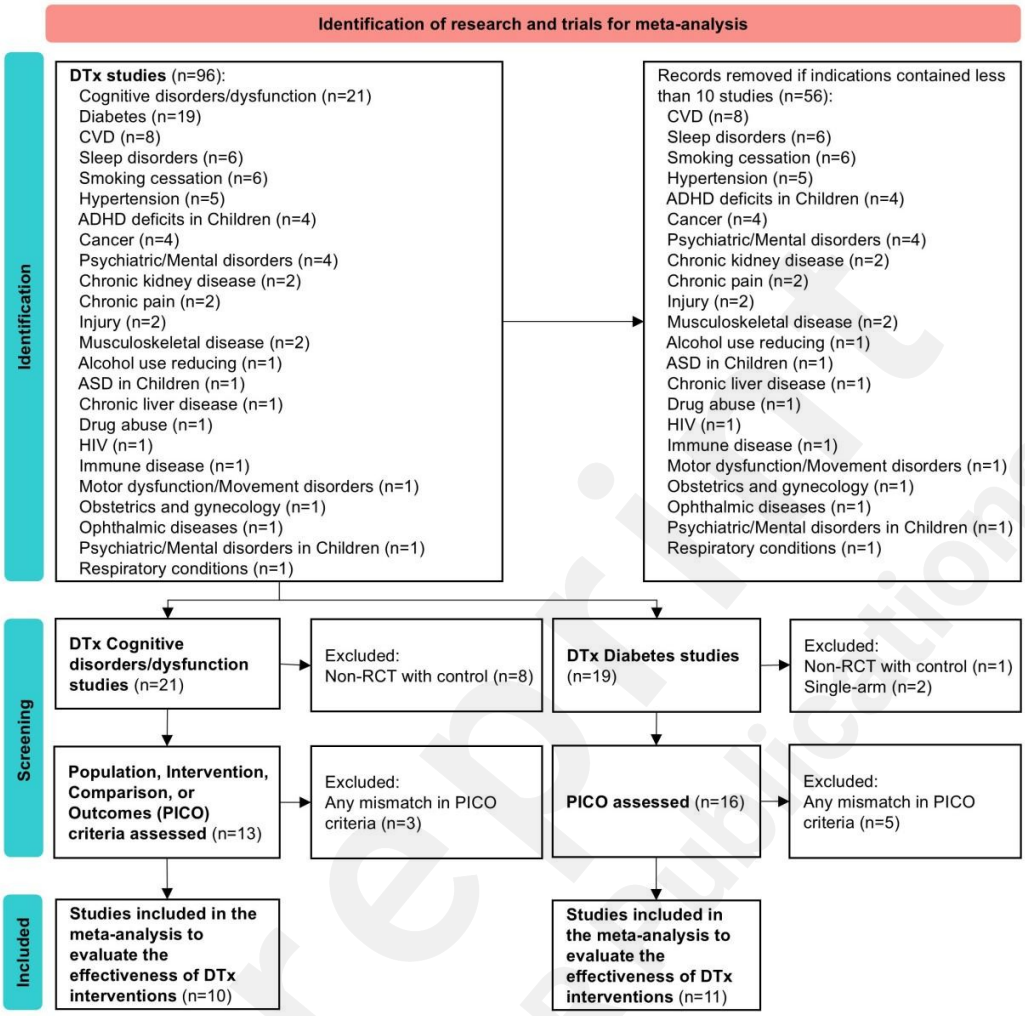
Taiwan China Clinical Trial. https://www.taiwanclinicaltrials.tw/ctc

Supplementary Figure S2. Flowchart for search process related to DTx products in China



NMPA website: https://www.nmpa.gov.cn/datasearch/home-index.html?itemId=ff80808183cad7500183cb66fe690285#category=ylqx

Supplementary Figure S3. Flowchart for selection process for two meta analyses of DTx Intervention



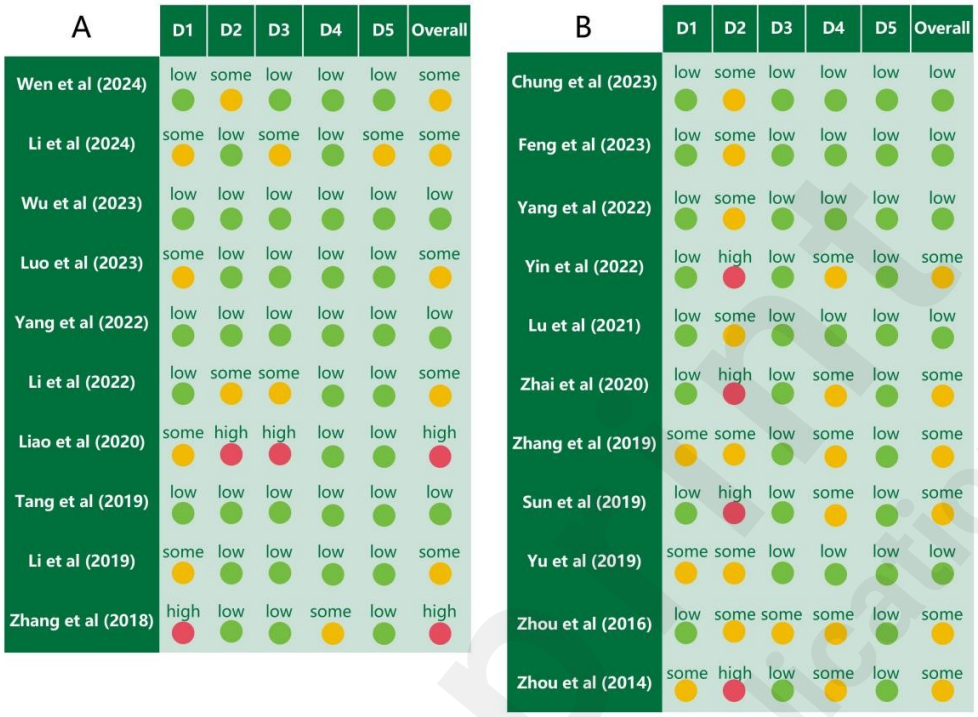
Note:

For meta-analysis of diabetes studies, studies were selected according to the following criteria: Population (P): Adults diagnosed with type 2 diabetes mellitus, particularly those with poor glycemic control (HbA1c ≥7%), regardless of disease duration; Intervention (I): Digital therapeutic interventions, including but not limited to smartphone-based applications, WeChat-based interventions, and web-based telemedicine systems; Comparison (C): Standard care or usual care, encompassing regular face-to-face clinical visits, traditional diabetes education, routine blood glucose monitoring, and standard lifestyle advice; Outcomes (O): Change in HbA1c levels (%). Only full-text peer-reviewed randomized controlled trials published in English were considered for inclusion.

For meta-analysis of cognitive disorders/dysfunction studies, studies were selected according to the following criteria: Population (P): Adults with a confirmed diagnosis of mild cognitive impairment (MCI) or vascular cognitive impairment (VCI) by a medical physician or based on accepted classifications/criteria, excluding those with psychiatric issues, significant medical comorbidities, or conditions affecting cognitive test performance; Intervention (I): Any digital health intervention, including but not limited to smartphone-delivered interventions, PC-delivered interventions, tablet-delivered interventions, digital assistants, media players, and video game consoles; Comparison (C): Active control groups receiving conventional education or usual care; Outcomes (O): Change in global cognitive ability measured via standardized neuropsychological tests such as MMSE and MoCA. Only full-text peer-reviewed randomized controlled trials published in English were considered for inclusion.

Both meta-analyses were registered at PROSPERO: CRD42024611857 (for diabetes) and CRD42024615584 (for cognitive disorders/dysfunction).

Supplementary Figure S4. The risk of bias analysis by using the Rob-2: adherence by RCT study (detailed judgments for each domain). A. Meta-analysis of cognitive disorders/dysfunction studies; B. Meta-analysis of diabetes studies.



Note: D1: Bias arising from the randomization process. D2: Bias due to deviations from intended intervention. D3: Bias due to missing outcome data. D4: Bias in measurement of the outcome. D5: Bias in selection of the reported result.

Appendix. Methods for Meta-analyses

Search strategies and selection criteria

In this systematic review and meta-analysis, we searched PubMed, Embase, Web of Science, IEEE, and Science Direct for publication from database inception up to June 30, 2024, limiting our search to Chinese and English literature. Detailed information of the selection process for meta-analyses and the search terms for each database are provided in the Supplementary appendix. Reference lists of relevant systematic reviews and meta-analyses identified from the database search were screened for potentially eligible studies. Pertinent literature was manually added. Two investigators (XY and NJ) independently screened the titles and abstracts of papers identified from the database search. Papers deemed eligible by both investigators underwent full-text review for final inclusion. Any disagreements throughout the screening process were resolved through discussion, with persistent disagreements adjudicated by a third independent investigator (CH). We used Endnote 20 (Clarivate Analytics, Philadelphia, PA, USA) for study storage and screening, and Microsoft Excel (Microsoft, Redmond, WA, USA) for data extraction and organization.

The inclusion criteria and search strategies were based on population, intervention, comparison, and outcomes (PICO) framework. Studies were eligible for inclusion if they included clinical trials investigating digital therapeutic (DTx) interventions conducted in China. The intervention could involve digital health applications, smartphone-based therapeutic solutions, or other DTx technologies designed for healthcare delivery. Eligible studies had to be randomized controlled trials (RCT) that had a controlled group that received usual care or conventional care. Studies were excluded if they were non-research articles (such as conference abstracts, editorials, or viewpoints papers), case reports, or observational studies.

This systematic review and meta-analysis is registered at PROSPERO (CRD42024611857 for diabetes and CRD42024615584 for cognitive disorders/dysfunction) followed the PRISMA guidelines.

Outcomes

The primary outcome of interest was change in HbA1c levels (%) for diabetes, and change in global cognitive ability for cognitive disorders/dysfunction. HbA1c level was measured via biochemical analyzer. Global cognitive function was measured via standardized neuropsychological tests such as Mini-Mental State Examination (MMSE) and Montreal Cognitive Assessment (MoCA).

Data analysis

Study characteristics including study design, population characteristics, intervention characteristics, intervention period, comparison, and outcome measurements. The data was independently extracted and verified by the same two investigators, with disputes resolved as previously described. To calculate effect size, information regarding the sample size and mean (SD) of outcome measure at baseline and post-intervention were collected for individual study. For results not presented as mean (SD), validated methods were used to convert them to the desired format.

Risk of bias was assessed using the Cochrane Risk of Bias 2 (RoB 2) for RCT, which classifies studies into three categories, which are low risk of bias, some

concerns, or high risk of bias. The same investigator team independently assessed risk of bias following the previously described resolution process.

The meta-analysis was performed using R (Version 4.3.2), with the “meta” package. A random-effects model was used to calculate the standardized mean differences (SMD) using mean changes from baseline to post-intervention timepoint, the SD at the post-intervention timepoint, and sample size. Positive effect sizes indicated a positive effect of enhancing cognitive function or reducing HbA1c.

To examine heterogeneity beyond sampling error, Higgins I^2 statistic and Cochran Q statistic (where $p < 0.05$ indicates heterogeneity) were used. I^2 values with 95% confidence intervals (95% CI) were categorized as low (25%), moderate (50%), and high (75%) heterogeneity.

Supplementary Table S1. Search strategies related to clinical research and trials of DTx

Databases	Search Strings
PubMed	(Digital therapeutics OR DTx) AND (digital health OR healthcare OR telemedicine OR telerehabilitation OR mHealth OR eHealth OR Wearable OR Mobile OR Remote OR Smart OR Intelligent OR Wireless OR SaMD OR "smartphone application" OR "smartphone apps" OR WeChat OR "online platform")) AND (China OR Chinese OR "Hong Kong" OR Macau OR Taiwan OR Taipei) NOT (Review[Publication Type] OR Meta-Analysis[Publication Type] OR Systematic Review[Publication Type])) AND (clinicaltrial[Filter] OR randomizedcontrolledtrial[Filter])
Web of Science	TS=("Digital therapeutics" OR DTx) AND TS=("digital health" OR healthcare OR telemedicine OR telerehabilitation OR mHealth OR eHealth OR Wearable OR Mobile OR Remote OR Smart OR Intelligent OR Wireless OR SaMD OR "smartphone application" OR "smartphone apps" OR WeChat OR "online platform") AND CU=(China OR Chinese OR "Hong Kong" OR Macau OR Taiwan OR Taipei) AND DT=(Article OR Clinical Trial) NOT DT=(Review OR "Systematic Review" OR "Meta-Analysis")
IEEE	(("Digital therapeutics" OR DTx) AND ("digital health" OR healthcare OR telemedicine OR telerehabilitation OR mHealth OR eHealth OR Wearable OR Mobile OR Remote OR Smart OR Intelligent OR Wireless OR SaMD OR "smartphone application" OR "smartphone apps" OR WeChat OR "online platform") AND (China OR Chinese OR "Hong Kong" OR Macau OR Taiwan OR Taipei)) NOT ("Review" OR "Survey" OR "Systematic Review" OR "Meta-Analysis"))
Science Direct	Find articles with these terms: ("Digital therapeutics" OR DTx) AND (China OR Chinese OR "Hong Kong" OR Macau OR Taiwan) Title, abstract or author-specified keywords: ("digital health" OR healthcare OR telemedicine OR mHealth OR "smartphone application") Title: NOT (Review OR "Meta-Analysis") Article type: Research articles
Google Scholar	("Digital therapeutics" OR DTx) AND ("digital health" OR healthcare OR telemedicine OR telerehabilitation OR mHealth OR eHealth OR

	Wearable OR Mobile OR Remote OR Smart OR Intelligent OR Wireless OR SaMD OR “smartphone application” OR “smartphone apps” OR WeChat OR “online platform”) AND (China OR Chinese OR “Hong Kong” OR Macau OR Taiwan OR Taipei) -Review -“Systematic Review” -“Meta-Analysis”

Supplementary Table S2. Major indications of DTx

Category	Indications
Chronic Diseases	Diabetes, Chronic kidney disease, Chronic liver disease, Cardiovascular diseases (CVD), Hypertension, Respiratory conditions, Chronic pain
Psychiatric/Mental Health	Psychiatric/Mental disorders (adults), Psychiatric/Mental disorders in Children, ADHD in Children, ASD in Children
Cognitive and Neurological	Cognitive disorders/dysfunction (adults), Cognitive disorders/dysfunction in Children, Cranial nerve disorders
Substance Use and Addiction	Drug abuse, Smoking cessation, Alcohol use
Sleep Disorders	Insomnia, Sleep Apnea, Hypersomnia
Cancer	All kinds of cancer and malignant tumors
Musculoskeletal and Motor	Musculoskeletal disease, Motor dysfunction/Movement disorders (including swallowing disorders)
Obstetrics and Gynecology	Obstetrics and gynecology
Infectious Diseases	HIV
Sensory Systems	Ophthalmic diseases, Hearing disorders
Pediatrics	ADHD in Children, ASD in Children, Cognitive disorders/dysfunction in Children, Psychiatric/Mental disorders in Children
Rehabilitation	Motor rehabilitation/Physical therapy, Speech and language rehabilitation
Lifestyle and Prevention	Healthy lifestyle promotion, Vaccination, Dosage calculation
Other Specific Conditions	Urinary incontinence, Skin conditions, Malnutrition, Injury

Supplementary Table S3. Characteristics of the included studies in the meta-analysis of diabetes studies

Study	Province	Study design	Population	Clinical setting	Intervention	Comparison	Duration	Follow up	Primary outcome	Second outcome
Chung et al [1] (2023)	Taiwan	Open-label, parallel, prospective RCT.	Adults (≥20 years) diagnosed with prediabetes: HbA1c: 5.7%-6.4% or Fasting plasma glucose: 100-125 mg/dL. Those with cardiopulmonary disease, cancer, other major diseases, or recent use of certain medications were excluded.	Health examination center and outpatient clinics at a teaching hospital in northern Taiwan.	Received usual care plus standard mobile health app. The app included modules for health diary, health education, milestone tracking, and chatroom features.	Received usual care only (15-20 minutes of health education by physicians).	12 weeks	1 month	Blood glucose control including Fasting Plasma Glucose (FPG) and Glycated Hemoglobin A1c (HbA_{1c}), Body constitution, Body energy, Health-related quality of life (HRQOL).	BMI, Dietary behavior. Physical activity.
Feng et al [2] (2023)	Shanghai	Open-label, parallel, prospective RCT.	Adults (18-79 years) diagnosed with T2DM (HbA1c ≥7%) for ≥6 months. Those who had other serious illnesses, were pregnant or planning pregnancy, were unable to complete follow-up, were unwilling to provide consent, were currently in another	Two community health service centers in Jiading District, Shanghai.	eHealth family-based intervention via WeChat platform plus usual care. Patients had a family member who could use WeChat and lived with or visited them weekly.	Received usual care only (standard community health center management).	12 months	Follow-up assessment at end of intervention (12 months).	HbA_{1c} level	Self-care activities (diet, exercise, blood sugar testing, foot care, smoking), Risk perception (risk knowledge, personal control, worry, optimism bias, personal

			study, or had used hypoglycemic agents, β-blockers, thiazide diuretics, nicotinic acid, or steroids within the past 3 months were excluded.						risk), Family support (supportive and non-supportive behaviors)
Yang et al [3] (2022)	Chongqing	Open-label, parallel, prospective RCT.	Adults (40-60 years) diagnosed with T2DM (HbA1c: 6.5%-7.5%) and specific blood pressure ranges within past 3 months. Those who had other serious illnesses, eating disorders, psychological disorders, were pregnant/planning pregnancy, were smokers/ alcoholics, or participating in other trials were included.	Xinqiao Hospital and Yuzhou road community health service center in Jiulongpo district, Chongqing.	Mobile phone-based telemedicine management via WeChat including: daily uploads of meals, weight, glucose, blood pressure, medications, automated feedback on dietary choices, monthly 40-minute phone consultations, educational content on diet and exercise.	Received routine outpatient care with standard dietary advice and exercise recommendation.	12 months	Clinical examinations at baseline and 12 months.	Blood glucose measurement (FPG and HbA_{1c}), Body composition parameters, Blood pressure, Quality of life (SF-36), Weight, BMI, waist circumference.	Lipid profiles (TG, TCH, LDL-c, HDL-c), Total treatment costs for 1 month
Yin et al [4] (2022)	Jiangsu	Open-label, parallel, prospective RCT.	Adults (18-55 years) diagnosed with T2DM (HbA1c: 7%-10%) for >6 months. Those who had serious cardiovascular disease, pregnancy,	Outpatient endocrine Clinic at the First People's Hospital of	Hospital's telemedicine app for blood glucose monitoring offered: custom-tailored dietary	Received conventional outpatient clinic appointments and usual	Initial 21-day home isolation period and 6-month	Assessments at baseline, 22 days (after isolation), 3 months, and 6 months.	Blood glucose control (FPG and HbA_{1c}), SDS (Self-Rating Depression Scale) scores.	Body composition parameters, Blood pressure, Lipid profiles, BMI, Waist-to-

			obesity surgery history, COVID-19 infection, or other major comorbidities were excluded.	Xuzhou, Jiangsu	recommendations, exercise guidance, weekly medical advice and monitoring.	care.	interventi on period.			hip ratio.
Lu et al [5] (2021)	Tianjin	Open-label, parallel, prospective RCT.	Adults (18-75 years) diagnosed with T2DM (HbA1c: 7%-10%) who were on medication adjustment. Those who were pregnant or breastfeeding, had deafness or mental disabilities that could interfere with proper follow-up care, or were diagnosed with serious conditions were excluded.	Inpatient department of Integrated Traditional Chinese and Western at one Tianjin Hospital.	WeChat-based medication consultation and guidance. Medication alarm clock and instruction services. Regular online follow-up. Blood glucose data transmission via Bluetooth.	Standard care per hospital procedures: Outpatient visits every 2 weeks, Self blood glucose monitoring at home.	6 months	The intervention group had weekly follow-ups in month one, bi-weekly in months 2-3, and monthly thereafter, while the control group attended bi-weekly clinic visits. Both completed a 6-month follow-up.	Change in HbA_{1c} level and in proportion of patients achieving HbA1c <7%.	FPG, Daily medication cost, Number of medication types, Hypoglycemic events.
Zhai et al [6] (2020)	Tianjin	Open-label, parallel, prospective RCT.	Adults (18-60 years) diagnosed with T2DM for ≥3 months. Those who had serious complications, cognitive impairment, type 1 diabetes, pregnancy, malignancy, or were	Community Health Service Center of Zhangjiawo Town, Xiqing District,	Diabetes management app "YuTangYiHu" with connected glucometer for blood glucose monitoring, giving diet advice and medication guidance. Patients received	Received conventional diabetic treatment only.	6 months	Assessments at baseline, 3 months, and 6 months.	HbA_{1c} level	Diabetes Self-Efficacy Scale (DSES) scores measuring: Self-efficiency on diet, Regular exercise, Medication,

			participating in other studies were included.	Tianjin.	online instruction from education nurse.				Blood glucose monitoring, Foot care, Prevention and management of high/low blood glucose.
Zhang et al [7] (2019)	Shanghai	Open-label, parallel, prospective RCT.	Adults (18-65 years) diagnosed with poorly controlled diabetes for ≥6 months, HbA1c ≥8% within 3 months before enrollment. Those who were insulin pump users, pregnant or planning pregnancy during the study period, excessive drinkers or drug users, those who used drugs affecting blood sugar in the previous 3 months, patients receiving treatment for psychotic conditions, those with severe complications or systemic diseases,	The outpatient clinic of Shanghai Jiao Tong University Affiliated Sixth People's Hospital, Department of Endocrinology and Metabolism, Shanghai.	Self-management app (Welltang app) provided: Educational content about diabetes management, Self-management tools for recording blood glucose, diet, exercise, medication, and weight, Patient community features, Communication channel with clinicians.	Received usual care without app installation. Patients learned diabetes knowledge through self-learning and adopted lifestyle changes voluntarily.	6 months	Assessments at baseline, 3 months, and 6 months.	HbA_{1c} level	FPG, Body weight, Lipid levels (triglycerides, HDL-c, LDL-c), Blood glucose test rate, Frequency of app usage, Guiding time.

			patients who experienced cardio- or cerebrovascular events in the previous 6 months, individuals with severe hearing or visual impairment were excluded.							
Sun et al [8] (2019)		Open-label, parallel, prospective RCT.	Adults (65 years) with T2DM (HbA1c: 7%-10%), without illiteracy, abnormal liver and kidney function, severe diabetic complications, use of insulin pumps, and participation in other clinical trials.	Department of Endocrinology of one affiliated hospital in Jilin.	mHealth management system with glucometer data transmission via bluetooth. Medical team review and advice every 2 weeks via messaging/phone. Diet management software for daily dietary records.	Standard care through conventional outpatient clinic appointments. Regular self-monitoring without additional tracking.	6 months	Regular outpatient clinic visits at 3-month intervals. Physical examinations and blood tests at baseline, 3 months, and 6 months.	HbA_{1c} level	Postprandial blood glucose levels, Blood biochemical indices, Patient compliance (frequency of uploading blood glucose data), Patient satisfaction (7-point questionnaire).
Yu et al [9] (2019)	Shanghai	Open-label, parallel, prospective RCT.	Adults (35-65 years) with T2DM (No HbA_{1c} limitation defined), without severe liver/kidney diseases,	The outpatient department at one Shanghai	Mobile phone application (MPA) “Diabetes-Carer” app offered diabetes education, self-	No MPA or self-monitoring of blood glucose.	24 weeks	Assessments at baseline, week 12, and week 24.	Change in HbA_{1c} level and in proportion of patients achieving HbA1c <7%.	FPG and 1,5-anhydroglucitol levels.

			insulin pump use, pregnancy, mental illness, visual impairment, or inability to access web.	hospital.	management, patient community, and real-time communication with clinicians.				
Zhou et al [10] (2016)	Zhejiang	Open-label, parallel, prospective RCT.	Adults (18-74 years) diagnosed with diabetes (No HbA_{1c} limitation defined), without severe complications.	The outpatient department of endocrinology at the one affiliated hospital in Zhejiang.	Smartphone-based Welltang diabetes management app offer: Knowledge database on diet, exercise, medicine guidelines; Self-management tools for blood glucose, diet tracking; Communication with clinicians; Standard care.	Received usual standard care only.	3 months	Assessments at baseline and 3 months.	HbA_{1c} level	Blood glucose (fasting and 2h post-breakfast), LDL cholesterol, Weight, Blood pressure, Hypoglycemic events, Patient satisfaction with app use, Diabetes knowledge, Self-care behaviors.
Zhou et al [11] (2014)	Guangdong	Open-label, parallel, prospective RCT.		The outpatient department at one affiliated hospital in	A telemedicine system to upload patients' blood glucose and other metabolic information at home at least every	Received traditional face-to-face visits without any specific telemedicine	3 months	Follow-up assessment at end of intervention (3 months).	HbA_{1c} level	FBG, incidence of hypoglycemia, and achievement of HbA1c target <7%.

	Guangzhou, Guangdong.	2 weeks. The researchers then provided appropriate advice based on their key behaviors.	intervention.

Supplementary Table S4. Characteristics of the included studies in the meta-analysis of cognitive disorders/dysfunction studies

Study	Province	Study design	Population	Clinical setting	Intervention	Comparison	Duration	Follow up	Primary outcome	Second outcome
Wen et al [12] (2024)	Jilin	Open-label, parallel, prospective RCT.	Urban adults (≥45 years) residents diagnosed with Mild Cognitive Impairment (MCI) per 2018 Chinese Guidelines, financially able to afford cognitive training, without prior systematic cognitive training in past year, without severe physical diseases or mental disorders, without long-term psychotropic drug use, without severe anxiety (HAMA ≥14) or depression (HAMD ≥17).	Outpatient of memory clinic of a grade-A hospital in Changchun, Jilin.	Standard nursing care. Home-based occupational therapy (OT). Computer-assisted cognitive training (CCT).	Standard nursing care only (including paper-pencil cognitive training).	12 weeks	3 months	Cognitive function measured by Mini-Mental State Examination (MMSE) and Montreal Cognitive Assessment (MoCA).	Anxiety (HAMA scale), Depression (HAMD scale), Activities of daily living (ADL scale).
Li et al [13] (2024)	Beijing	Open-label, parallel, prospective RCT.	Patients with Vascular Cognitive Impairment No Dementia (VCIND), diagnosed with cognitive impairment without dementia and small vessel ischemia.	Department of Neurology and Department of Radiology	CCT including: Processing speed, attention, perception, Long-term and working memory, Calculation,	Fixed cognitive training focused only on: Processing speed, Attention, Fixed primary	7 weeks	Follow-up at Baseline, week 7 (post-intervention) and month 6 (follow-up).	Changes in functional connectivity (FC) of brain networks assessed by fMRI.	Cognitive performance measured by: MoCA for global cognition, Trail Making Test B-A (TMT B-A) for

				at Xuanwu Hospital in Beijing.	executive control, reasoning, Problem-solving, 30-minute daily sessions with adaptive difficulty levels.	difficulty level throughout.				executive function, Boston Naming Test (BNT) for linguistic function.
Wu et al [14] (2023)	Fujian	Single-blind, parallel, prospective RCT.	MCI right-handed patients (50-85 years) with MoCA scores ≤25 points, being at stage 2-3 on Global Deterioration Scale, without contraindications for MRI.	Rehabilitation departments from three hospitals affiliated with Fujian Traditional Chinese Medicine University.	24 one-hour CCT sessions over 8 weeks. Three sessions per week using FDA approved Cognitive Assessment and Rehabilitation Training Machine. Multi-domain training (attention, memory, processing speed etc.).	Standard care only. Instructed to refrain from cognitive training.	8 weeks	Post-intervention assessment within 1 week after completion and 3 month follow-up.	Global cognitive function measured by MoCA.	Processing speed (DSST), Cognitive flexibility (Stroop), Episodic memory (CAVLT), Nonverbal memory (Rey CFT), Brain functional connectivity changes measured by MRI.
Luo et al [15] (2023)	Fujian	Single-blind, parallel, prospective RCT.	MCI right-handed Patients (>60 years) who were diagnosed with MCI by Peterson's criteria, with MMSE score ≥17 for illiterate, >20 for 1-6 years education, >24 for ≥7 years	Memory Clinic of Fujian Provincial Hospital and Community	60-minute remote expressive arts program (rEAP) sessions delivered via electronic devices with WeChat platform.	Health education sessions twice weekly for 12 weeks delivered by geriatric nurses. Focus on	12 weeks	Post-intervention assessment within 2 weeks after completion.	Global cognitive function measured by MoCA.	DSST, Stroop, Memory function (AVLT), Executive function (Shape Trail Test) Language proficiency (VFT,

			education.	Health Service Center of Gulou District, Fuzhou	Two sessions per week for 12 weeks. Included visual art creation and storytelling activities.	cognitive health maintenance and prevention strategies.			BNT), Brain functional connectivity measured by fMRI.
Yang et al [16] (2022)	Guangdong	Open-label, parallel, prospective RCT.	Community-dwelling adults (aged ≥65 years) diagnosed with MCI, with over 95% lived with spouse or children.	Two large regional communities in Guangzhou.	Dietary guidance (face-to-face meetings every 3-4 weeks). Physical training (progressive muscle strength and aerobic exercise). 60-90 min CCT weekly sessions. Management and monitoring of metabolic indicators and vascular risk factors.	Usual care including three 45-min health education classes during the 6-month period covering epidemiology, etiology, clinical manifestations, prognosis of MCI, and recommendations for social activities.	6 months	Data collected at baseline, 1 month, 3 months, and 6 months.	Global cognitive function measured by MoCA. Comprehensive physical capacity (Short Physical Performance Battery and Timed Up and Go test). Depression (15-item Geriatric Depression Scale). Quality of Life in Alzheimer's Disease scale).	Not explicitly specified.
Li et al [17] (2022)	Hong Kong	Open-label, parallel, prospective	Community-dwelling adults with MCI who were diagnosed according to	Community centers of three non	BRAVE program with three components:	Usual care including social and leisure	8 weeks	Assessments at baseline, immediately	Cognitive function measured by	HRQoL measured by SF-36. Participant

		RCT.	National Institute on Aging-Alzheimer's Association criteria.	governmental organizations in Hong Kong.	Mobile application providing brain health info and exercise videos Peer volunteer training program Group-based multicomponent exercise intervention (3 sessions/week for 8 weeks) Group format (8-10 participants per group) with peer volunteer support	activities. No structured exercise or cognitive training activities.		post-intervention, and 3 months post-intervention.	Alzheimer's Disease, Assessment Scale-Cognitive subscale (ADAS-Cog), Colour Trails Test (CTT), Digit Span Forward and Backward tests.	satisfaction survey. Program engagement metrics (app logins, video views).
Liao et al [18] (2020)	Taiwan	Single-blind, parallel, prospective RCT.	Community-dwelling adults (aged ≥65 years) diagnosed with MCI, with MMSE score ≥24 and MoCA score <26.	Communities and day care centers in Taipei.	VR-based physical and cognitive training. Using VIVE system with VR glasses and motion controllers IADL-based functional tasks in VR (shopping, food	Combined physical and cognitive training. Resistance exercises, aerobic exercise, balance	12 weeks	Assessed at baseline and post-intervention. No additional follow-up after intervention completion.	MoCA, Executive function (EXIT-25). Verbal memory (CVVLT). Brain activation measured by NIRS during cognitive tasks.	Not explicitly specified.

					preparation, etc.).	exercises. Simultaneous cognitive training during physical exercises.			Instrumental activities of daily living (IADL).	
Tang et al [19] (2019)	Beijing	Open-label, parallel, prospective RCT.	Patients with subcortical VCIND.	Three medical centers in Beijing.	Multidomain, adaptive CCT including processing speed, attention, orientation, memory, calculation, etc.	Waitlist control receiving usual care.	7 weeks	Follow-up at baseline, immediately post-intervention, and 3 months post-intervention.	Global cognitive function measured by MoCA. Executive function measured by TMT B-A.	Brain functional connectivity changes. Brain structural changes. Quality of life.
Li et al [20] (2019)		Open-label, parallel, prospective RCT.	MCI patients diagnosed based on CDR score=0.5 and medial temporal lobe atrophy, with Chinese Han descent with >6 years of education. Screening included MMSE, anxiety and depression scales.	Memory clinics in Shanghai.	CCT program with 8 tasks: Visual working memory, 30-second memory, Episodic memory, Speed of calculation, Visual search, Alertness, Mental rotation, Image re-arrangement.	Received only observation and follow-up.	6 months	Follow-up in initial 6-month intervention period. Additional 12-month follow-up period after intervention (total 18 months).	Changes in MMSE scores.	Neuropsychological tests including Addenbrooke's cognitive examination-revised (ACER), Auditory verbal learning test, Shape trail test, Complex figure test Symbol digit substitution test,

Zhang et al [21] (2018)	Jilin	Open-label, parallel, prospective non-RCT with control.	Elderly MCI patients (aged ≥60 years) diagnosed based on Petersen's criteria, with preserved general intellectual functioning (MMSE), memory impairment on MoCA-BJ, intact daily living activities, and were willing to participate.	Long-term care facilities in Changchun.	MESSAGE communication strategy combined with group reminiscence therapy (GRT). Used multimedia elements including electronic albums, videos, and music.	Receiving no intervention.	12 weeks	Assessments at Baseline, 6 weeks, and 12 weeks (end of intervention).	Cognitive function measured by MMSE and MoCA-BJ. Quality of life measured by Chinese (mainland) version of SF-36.	Stroop Color-Word Test. fMRI measures of brain activity. Individual cognitive domains from MoCA-BJ including: Visuospatial/executive function, Naming, Attention, Language, Abstract thinking, Delayed memory, Orientation.

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Supplementary Files

Figures

DTx Ecosystem in China: Overview.