Application Prospects of Domestic and International Hypertension Digital Therapeutics Products and Implications for China (Postprint)

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Date: 2025-10-29T17:04:31+00:00

Abstract

Hypertension is characterized by unclear etiology, prolonged disease course, and inability to be completely cured, with its prevalence ranking first among metabolic diseases. To alleviate the disease burden on patients, hypertension health management has been incorporated into the National Basic Public Health Service Program since 2009; however, the follow-up rate among hypertensive patients remains far below expected levels. Digital therapeutics deliver evidence-based therapeutic interventions through high-quality software programs to prevent, manage, or treat hypertension, which holds significant importance for enhancing the frequency of physician-patient communication and improving health resource utilization efficiency. This study reviews hypertension digital therapeutics products from the International Digital Therapeutics Alliance product repository and those with published randomized controlled trial results in current literature databases, exploring the future application prospects of hypertension digital therapeutics products in China. This article suggests that China should draw upon the experience of international hypertension digital therapeutics products in health management, leverage the social environment to improve acceptance of the digital therapeutics concept among both physicians and patients, establish regulatory systems aligned with product characteristics from a policy perspective, enhance enterprise research and development capabilities, and promote the development of digital therapeutics products in the field of hypertension health management.

Full Text

Preamble

Prospects for the Application of Digital Therapy Products for Hypertension at Home and Abroad and the Implications for China

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Abstract: Hypertension is characterized by unclear etiology, prolonged disease duration, and incurability, ranking highest in prevalence among metabolic disorders. To alleviate patient burden, hypertension health management (HHM) was incorporated into the National Essential Public Health Services Program (NEPHSP) in 2009. However, patient follow-up rates remain substantially below expected levels. Digital therapeutics (DTx) deliver evidence-based therapeutic interventions through high-quality software programs to prevent, manage, or treat hypertension. This approach significantly enhances clinician-patient communication frequency and optimizes healthcare resource utilization efficiency. This study examines hypertension DTx products within the Digital Therapeutics Alliance (DTA) product library and published randomized controlled trials (RCTs) to explore application prospects in China. Findings indicate that China should draw on international DTx experiences for HHM, leverage socio-environmental factors to enhance stakeholder acceptance of DTx concepts, establish regulatory frameworks aligned with product characteristics, strengthen enterprise research and development capabilities, and accelerate DTx advancement in hypertension management.

Keywords: Hypertension; Digital therapeutics; Chronic disease management; Review

Introduction

Elevated blood pressure (BP) represents a primary risk factor for cardiovascular disease mortality, including cardiac death, coronary heart disease, heart failure, and ischemic and hemorrhagic stroke [1]. According to the Global Burden of Diseases, Injuries, and Risk Factors Study (GBD), metabolic disease mortality demonstrated a steady upward trend globally from 2000 to 2019, with hypertension ranking as the fourth leading cause. In 2019, hypertension caused 1.1 million deaths worldwide, and approximately 256.7 million Chinese adults aged 30–79 suffer from hypertension [2-3], imposing substantial burdens on families and the healthcare system. High sodium and low potassium diets, obesity, low physical activity, and smoking constitute important risk factors for hypertension in Chinese populations [4]. However, pharmacological treatment alone cannot directly identify and intervene upon these risk factors. Data from the Chinese Center for Disease Control and Prevention (CDC) indicate that blood pressure control rates among Chinese adults with hypertension remain only 9.7%–16.8%. Consequently, regular follow-up and continuous lifestyle intervention combined

with medication guidance constitute essential processes in hypertension management, yet these require substantial human and material resources.

In China, primary healthcare institutions serve as the main arena for chronic disease management. Hypertension health management was incorporated into the National Essential Public Health Services Program in 2009, with primary care institutions and general practitioners providing one free annual physical examination and four health follow-ups annually to patients with primary hypertension within their jurisdiction. However, limited general practitioner resources result in follow-up rates far below record-keeping rates. While approximately 60% of districts and counties achieve chronic disease record-keeping rates exceeding 60% (some reaching 100%), 82.5% of districts and counties report hypertension follow-up rates of merely 20%–60% [5]. Projections indicate that by 2030, China will have only five general practitioners per 10,000 population on average [6]. Therefore, identifying safe and effective long-term hypertension management tools to facilitate sustained, high-frequency communication between physicians and patients holds significant importance for improving blood pressure and risk factor control levels while enhancing healthcare system resource utilization efficiency.

With the continuous growth in global smartphone users [7], digital therapeutics (DTx) delivered via mobile devices demonstrate substantial potential as a complementary strategy for optimizing chronic disease management. Domestic and international hypertension DTx products primarily target patients' daily lives, aiming to correct erroneous dietary habits, lifestyles, and harmful behaviors while improving medication and treatment regimen adherence, thereby optimizing patient care processes and health outcomes [8]. This approach aligns seamlessly with the philosophy of long-term hypertension health management. Foreign chronic disease management DTx products have obtained medical device registration through authoritative agencies, with some even incorporated into national medical insurance or commercial insurance systems, enabling patient access at minimal cost. However, China' s hypertension DTx products remain in the preliminary exploration stage, with most offering single-functionality, weak competitiveness, and unstable efficacy. Related research has only progressed through small-scale pilot studies. Therefore, this study aims to systematically review hypertension DTx products in the Digital Therapeutics Alliance (DTA) Product Library [Product Library-Digital Therapeutics Alliance (DTA) (dtxalliance.org)] and those currently in clinical trial stages domestically and internationally, exploring future application prospects for hypertension DTx in China.

1. Application Status of Hypertension Health Management DTx Products

In 2019, the International Digital Therapeutics Alliance (DTA) defined DTx as evidence-based medical interventions driven by high-quality software to prevent, treat, or manage medical symptoms and diseases [9]. In China' s *Digital Therapeutics Industry Development White Paper*, DTx is defined as software-driven, evidence-based intervention protocols for treating, managing, or preventing dis-

ease. These products influence patients through information (e.g., text, images, video on applications), physical factors (e.g., sound, light, electrical current, magnetic fields, and their combinations), and pharmaceuticals to optimize patient care and health outcomes. Synthesizing these authoritative definitions, this study analyzes products that are evidence-based, utilize APPs or internet platforms as carriers, and primarily function to promote hypertension health management.

The DTA product library includes products that have undergone clinical trials, received approval from health authorities, and been launched for use. Additionally, the WHO' s 2019 *Global Strategy on Digital Health (2020-2025)* [10] emphasized the priority of digital health strategies in development. Driven by policy support and industry prospects, hypertension health management DTx products have generated numerous clinical studies demonstrating positive effects [11]. Therefore, this study searched Web of Science, PubMed, Cochrane, Embase, and CNKI databases to summarize existing RCT evidence for current DTx products. As shown in Table 2 , 14 DTx products were included in the research scope. These products in clinical trial stages primarily originate from Europe and the United States, controlling blood pressure and managing hypertension risk factors through long-term blood pressure monitoring and early warning, medication monitoring, health education, and personalized dietary and exercise interventions.

2. Functions and Effects of Hypertension DTx Products

2.1 Mode of Action

Through systematic review of current hypertension DTx products and their functions, we identified a concentrated blood pressure management model involving three components: patients, physicians, and virtual platforms, which collaboratively intervene in hypertension risk factors to ultimately control blood pressure within ideal ranges and slow or prevent hypertension complications. On the patient side, bidirectional interactive communication occurs between patients and the APP. Patients upload their physiological indicators and medication information to the user interface. Using this data, the products generate personalized health education and daily lifestyle guidance. Simultaneously, products provide blood pressure monitoring and early warning services to help patients control blood pressure. On the physician side, doctors can directly monitor patients' blood pressure fluctuations, medication status, physiological characteristics, and other indicators over time, adjusting medical orders promptly based on algorithmic evidence-based results. Additionally, DTx serves as a multifunctional consultation platform between doctors and patients. Patients can leave messages to inquire about medical advice regarding condition changes, enabling online follow-up consultations that save costs for both parties. During emergencies, products can help patients call ambulances and transmit patients' medical history and current illness information to receiving hospitals to facilitate medical care. Since product functions vary considerably, intervention effects on vari-

ous indicators also demonstrate significant differences in clinical trials (Figure 1 [Figure 1: see original paper]).

2.2 Effects

2.2.1 Blood Pressure Control The most important clinical outcome in hypertension management is blood pressure control, including systolic blood pressure (SBP), diastolic blood pressure (DBP), and blood pressure control rates. Blood pressure measurements are influenced by the measurement environment; therefore, product application scenarios primarily occur in patients' homes. Some products connect smartphone APPs with home smart blood pressure monitors, which accurately transmit measured blood pressure values to the APP to evaluate patients' blood pressure improvement effects.

The Dario product [25] combines a blood pressure monitoring system with an APP, enabling 71% of hypertensive patients to achieve average SBP reductions of 8.1 mmHg and DBP reductions of 6.0 mmHg, with 38% of patients experiencing disease alleviation and decreased disease classification. DTx products demonstrate superiority in blood pressure control. In the PIA APP development study [17], 62.6% of patients in the intervention group (PIA APP) achieved target blood pressure range compared to only 44.6% in the usual care group ($P<0.001$). In the "Yan Fu" APP clinical trial [21], the intervention group demonstrated higher blood pressure control rates than the control group ($P=0.011$).

2.2.2 Waist Circumference, Body Mass Index, and Weight Research indicates that obesity is an independent risk factor for hypertension, with obese individuals exhibiting significantly higher hypertension risk than non-obese individuals [26]. To reduce disease risk, DTx products monitor users' obesity indicators and provide regular personalized health guidance to help users maintain healthy lifestyles and enhance confidence in weight management. Welldoc user storage information shows [27] that among 106 individuals, 68% achieved an average 6% weight reduction within six months. In a clinical study [13], the "TELEM+TELEMEV" intervention group demonstrated higher adherence to lifestyle changes compared to the usual care group, resulting in total body fat reduction of 4.05 kg, trunk segment fat reduction of 1.69 kg, and abdominal circumference reduction of 4.36 cm. In a digital therapy intervention experiment conducted in Chinese communities [14], the between-group mean difference in BMI at 12 weeks was 0.92 kg/m^2 ($P=0.023$). Simultaneously, the intervention group' s waist circumference was significantly lower than the control group, with between-group differences of 3.30 cm at 6 weeks ($P=0.04$) and 3.86 cm at 12 weeks ($P=0.014$), both statistically significant.

2.2.3 Mental Health Research demonstrates significant bidirectional associations between hypertension and depression [28-29]. On one hand, hypertensive patients are more susceptible to depressive symptoms due to disease burden,

treatment side effects, and health concerns. On the other hand, chronic psychological stress, anxiety, and depression activate the sympathetic nervous system and hypothalamic-pituitary-adrenal axis, leading to increased heart rate, vasoconstriction, and salt sensitivity, thereby affecting blood pressure regulation and even inducing or exacerbating hypertension. To help patients maintain positive attitudes during lengthy treatment processes, many DTx products aim to regulate patients' negative emotions and build confidence in their medications and the DTx itself. The Dario product clinical trial [25] indicated that after six months of use, patients' depressive symptoms decreased by 48% and anxiety symptoms by 59%. The HPCP coaching program [12], still in clinical trial stage, divided hypertensive patients into two groups (one using the mini-program for health management, the other conducting self-monitoring). The study systematically measured confidence changes in both groups at baseline and six months post-intervention across multiple dimensions using a 5-point scale [ranging from 1 (no confidence) to 5 (very confident)], including using blood pressure monitoring devices, controlling blood pressure, understanding when medication changes are needed, and implementing non-pharmacological blood pressure control behaviors. Results showed statistically significant differences in mean confidence change scores for blood pressure control between the two groups ($P<0.001$).

2.2.4 Dietary Habits Unhealthy dietary habits constitute another important risk factor for hypertensive patients. During conventional diagnosis and treatment, physicians cannot directly quantify and analyze patient dietary habits. However, DTx products can better assist, record, and analyze patients' daily nutritional intake while transmitting data to the physician interface, enabling doctors to provide personalized counseling based on patient conditions to help maintain healthy dietary habits. Numerous studies investigating salt intake across different regions in China have confirmed that excessive salt consumption represents an important cause of elevated population blood pressure and hypertension [30-32]. In the CureApp product clinical trial [33], compared with the control group, the digital therapy group' s salt intake (based on salt checklists) decreased significantly. At 12 and 24 weeks, between-group differences (95%CI) were -2.9 points (-3.7 to -2.2), $P<0.001$ and -2.7 points (95%CI=-3.6 to -1.9), $P<0.001$, respectively. Beyond salt intake, other nutritional intake indicators also changed due to digital therapy intervention. The "Blood Pressure Management Application" clinical trial [12] demonstrated that compared with the control group, the intervention group increased consumption of dairy products, fruits, and vegetables. Additionally, intervention group participants better adhered to low-fat, low-salt dietary plans, with plan adherence measured by the 14-item Hill-Bone scale increasing by 1.7 points (95%CI=1.30-2.10) and 1.5 points (95%CI=1.16-1.90), respectively.

2.2.5 Medication Adherence (MA) According to surveys, China' s hypertension diagnosis rate is 51.5%, while treatment control rate is only 15.9% [16], indicating substantial room for improvement. Since most patients with

primary hypertension require long-term medication, poor medication adherence represents an important factor preventing patients from achieving blood pressure reduction goals. Methods for assessing medication adherence changes are diverse, primarily including: clinical decision-based assessments, standardized scale assessments, and medication record-based assessments.

In the HOME BP clinical trial [16], participants using digital intervention were more likely to adjust their antihypertensive medication categories and dosages in a timely manner during the study period. The SMASH clinical trial [15] designed a medication adherence scoring mechanism (doses taken within 3 hours of the designated time received full points, doses taken within 3-6 hours received 0.5 points, doses taken after 6 hours received 0 points). After patients returned the DTx products, researchers assessed adherence changes post-return using the Morisky Medication Adherence Scale self-report. Results showed SMASH group patients maintained monthly average MA values of 0.89-0.95. After returning the products, patients maintained good medication adherence with stable blood pressure.

3. Prospects and Recommendations for China

Both DTA product library hypertension health management products and currently developing DTx products typically provide users with accessible formats such as Apps or websites. Clinical data have proven that applying DTx on top of conventional pharmacological treatment yields superior blood pressure reduction effects compared to conventional medication alone. Beyond significant blood pressure reduction effects, DTx products address health risk factors to help patients develop good daily habits and positive life attitudes, resulting in improvements in salt intake, BMI, mental health levels, medication adherence, and other outcome targets. Through product iteration, domestic and international hypertension health management DTx products have gradually exhibited the following characteristics:

Clear functional positioning with gradually diversifying forms. Hypertension health management DTx products do not replace existing pharmacological treatment but rather accelerate patient recovery as adjunctive therapy. Considering hypertension disease characteristics, DTx products cleverly integrate information technology with wearable devices to ensure data accuracy, improve patient medication adherence to enhance drug efficacy, and even provide new options for patients unable to take medications. Foreign DTx products exhibit relatively diverse forms. In Germany, for example, the Digital Healthcare Act classifies DTx products into detailed categories, including standalone software use and combination use with drugs or medical devices. Although domestic DTx product types and quantities have not yet reached foreign levels, continuous integration with internet technology has gradually enriched domestic DTx product functions, awaiting discovery of scientific DTx product management methods.

Empowering primary healthcare institutions to enhance service capacity through diverse application scenarios. Hypertension health management DTx products apply to multiple scenarios including clinical care, daily life, and work-study settings, enabling patients to monitor their blood pressure status anytime. Among the trials retrieved in this study, over 64% of hypertension health management DTx product trials recruited participants from primary healthcare institutions and achieved positive primary outcomes, demonstrating that most DTx products primarily target populations seeking basic public health services, indicating good application prospects in primary hypertension health management.

Multi-pronged promotion of product application to reduce user economic burden. Foreign hypertension DTx products developed earlier, particularly in the United States and Europe, forming relatively mature markets. Multiple countries have introduced relevant policies supporting DTx inclusion in medical insurance systems, promoting widespread DTx application. In 2020, the National Medical Products Administration approved the first DTx product, marking formal DTx application in China. Although no Chinese DTx products for hypertension management have been included in medical insurance, DTx demonstrates tremendous development potential in China as relevant policies gradually improve and market demand increases.

Improving stakeholder acceptance of DTx. From a social environment perspective, China should strengthen health education for chronic disease patients while simultaneously providing specialized information training for general practitioners, enabling both parties to understand DTx superiority in directly intervening upon risk factors. Additionally, most DTx products are paid services, and existing basic medical insurance has not yet covered DTx products, causing most patients to be unwilling to pay for DTx products. Therefore, commercial medical insurance and other channels should promptly address payment issues.

Improving policy and regulatory support to innovate DTx product supervision systems. Regarding government regulation, China' s existing medical device supervision mechanism is not suitable for DTx products, necessitating creation of regulatory systems aligned with product characteristics. In the United States, the Food and Drug Administration (FDA) oversees DTx approval. In Europe, national drug and medical device regulatory agencies typically handle DTx product approval, such as Germany' s Federal Institute for Drugs and Medical Devices (BfArM). China should draw on these countries' experiences, clarify relevant departments responsible for DTx product approval, and develop specific management measures including product definitions, classification standards, review processes, and clinical trial requirements. DTx products differ from traditional medical devices, mostly employing clinically low-risk technologies; traditional regulatory approval may delay innovation and promotion of products offering significant patient benefits. Of course, DTx products often store substantial amounts of personal patient information, making data security and patient privacy protection critical issues for regulators to address.

Enhancing enterprise innovation and R&D capabilities for DTx products. In Europe and the United States, governments support DTx technological innovation through multiple approaches, particularly for small and medium-sized enterprises. Regarding enterprise R&D, the Chinese government could provide partial tax incentives to encourage enterprise investment and R&D in the DTx field, thereby reducing enterprise burdens. Enterprises should actively seek venture capital and research institution partnerships, standardize data collection and management processes, and strengthen clinical data accumulation targeting hypertensive populations. Simultaneously, enterprises should emphasize primary hypertension management as a development pathway, broaden their commercial sales and operation models, and actively develop innovative DTx products.

4. Conclusion

Cutting-edge domestic and international hypertension health management DTx products utilize algorithms to help patients improve quality of life and facilitate long-term, high-frequency communication between doctors and patients, thereby reducing physician workload and demonstrating excellent prospects in primary hypertension health management. However, compared with foreign hypertension health management DTx products, China' s relevant products have developed more slowly, with most clinical trial studies including too few participants to be representative. Although some products have begun development, they primarily target high-income groups and have not achieved large-scale application at the primary care level. China should learn from cutting-edge hypertension health management DTx product experiences and take more actions to improve this situation.

Author Contributions: Jiao Xitong conceived the research idea, responsible for research design and implementation, and drafted the manuscript. Jiao Xitong, Liu Lu, and Guo Jiayue collected and organized data, performed statistical analysis, and created figures and tables. Liu Lu and You Lili revised the manuscript. You Lili was responsible for quality control and review, overall responsibility for the article, and supervision.

Conflicts of Interest: None declared.

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Appendix 1 American Heart Association Life' s Simple 7: Definitions of Poor, Intermediate, and Ideal Cardiovascular Health for Each Component/Metric

(Received: 2024-10-15; Revised: 2025-08-08)

(This article was edited by Cui Sha)

Note: Figure translations are in progress. See original paper for figures.