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Opportunities and challenges of lifestyle intervention-based digital therapeutics in LDL-C management: a scoping review

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Abstract

Background: In recent decades, the prevalence of dyslipidemia, especially high low-density lipoprotein cholesterol (LDL-C), has risen sharply in China. Although lifestyle interventions are important, traditional face-to-face approaches have limitations. Digital Therapeutics (DTx) can provide an effective solution by delivering remote medical interventions to patients via software and hardware, thereby optimizing existing clinical treatment methods with enhanced convenience and accessibility.

Objectives: This study aims to explore the current evidence on the effect of lifestyle intervention-based Digital Therapeutics (LI-DTx) on high LDL-C, and to analyze their advantages and disadvantages.

Eligibility criteria: This scoping review examines clinical studies assessing the effects of DTx on LDL-C levels. Papers were included in the final analysis if there was evidence that DTx had effects on lowering LDL-C levels.

Sources of evidence: Papers that were published between January 2014 and December 2023 were included in the PubMed database.

Charting methods: Data extracted from the publications included country, year, study type, study population, sample size, study duration, intervention, and changes in LDL-C level.

Results: A total of 23 target literature were identified. Twenty-one studies confirmed that LI-DTx could optimize the LDL-C level through remote lifestyle interventions such as diet, exercise, medication, and health education, of which 14 studies reported a significant reduction in LDL-C level ($p < 0.05$). In the future, the development and design of DTx will need to improve intelligence, personalization, applicability, real-time performance, and data security; integrate with traditional healthcare systems; facilitate multidisciplinary collaboration in dyslipidemia management; and enhance long-term patient engagement with DTx platforms.

Conclusion: LI-DTx may offer a more effective and sustainable solution for LDL-C management, although several challenges remain. Further randomized controlled clinical trials are needed to provide scientific support for its efficacy and safety.

Keywords: applications, cognitive behavior therapy, digital therapeutics, LDL-C, lifestyle modification

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Introduction

Challenges of traditional lifestyle management for cardiovascular disease

Cardiovascular disease (CVD) is the leading cause of death in both developed and developing countries. In 2019, CVD was the cause of 46.74% and 44.26% of deaths in rural and urban areas, respectively.[1] Dyslipidemia is a major risk factor for CVD, leading to atherosclerosis and increased morbidity and mortality from coronary heart disease and ischemic stroke.[2] With economic development, the prevalence of dyslipidemia in Chinese adults is increasing.[3] The ESC guideline on dyslipidemia provides advice on improving health through lifestyle changes.[4] Eating plant foods rich in monounsaturated fats may benefit heart health and blood glucose regulation.[5,6] Regular aerobic exercise has a beneficial effect on lipid levels.[7] In patients with familial hypercholesterolemia, losing 1 kg of weight can lower LDL-C levels by about 0.8 mg/dL.[8] Lifestyle factors that affect LDL-C levels include diet, exercise, smoking, and alcohol consumption.[9] However, current lifestyle interventions are mainly delivered in the traditional face-to-face format with limited effectiveness. In China, traditional lifestyle interventions often face several challenges, including low patient adherence, limited access to healthcare facilities, and a lack of personalized interventions, making it difficult to achieve sustained behavior change. Research by Kelly et al.[7] shows that although dietary changes and regular physical activity can effectively improve lipid profiles, their impact is often undermined due to poor adherence and inadequate follow-up support. Digital Therapeutics (DTx) offer a transformative solution by using technology to provide remote, personalized, and real-time interventions. Smartphones and other mobile devices can be used to deliver healthcare and lifestyle interventions. DTx allow for feedback and tailored interventions at an individual level.[10] This heralds a new era of lifestyle intervention, potentially targeting patients who are no longer constrained by time and space. A systematic review of mobile health technologies to promote physical activity and reduce sedentary behavior in the workplace found that about two-thirds of the studies reported a significant impact on reducing weight and total cholesterol.[11]

The concept, characteristics, and clinical significance of DTx

DTx are digital health solutions that provide evidence-based, software-driven therapeutic interventions for the prevention and management of medical disorders or diseases.[12] DTx have the following characteristics[13]: (1) Software-driven. Software plays a central role in DTx, helping patients interact with healthcare services and making healthcare more accessible. (2) Evidence-based. DTx are grounded in evidence-based medicine and follow standards for clinical evidence throughout the product life cycle. (3) Disease-specific interventions. DTx can improve a patient's health or slow down the progression of a disease. Advanced internet and information technologies, such as artificial intelligence (AI), cloud computing, intelligent sensors, and wearable device technologies, have been integrated into digital therapy.[14–17] Through software that enables remote patient interventions, DTx help to relieve the heavy workload of healthcare professionals. Currently, DTx have been used in various areas of diseases, including cardiovascular, metabolic, respiratory, oncological, psychosomatic, and ophthalmic conditions.[18–23] The United States, Japan, Germany, and other countries have approved several DTx products, including Parallel™ (for IBS), Somryst® (for insomnia), Smartinhaler™ (for COPD), CureApp SC® (for smoking cessation), CureApp HT® (for hypertension), Zanadio® (for obesity), Rehappy® (for stroke), and ESYSTA® (for diabetes).[24–26] While the commercial future of DTx remains uncertain, their clinical value is undoubtedly positive.

Objectives of this study

Current evidence suggests that lifestyle intervention-based Digital Therapeutics (LI-DTx) can effectively reduce LDL-C levels, though studies vary in intervention types and outcomes. This scoping review aims to examine and summarize the existing evidence on the effects of LI-DTx on LDL-C levels. It also seeks to identify potential limitations or real-world barriers to the adoption of LI-DTx, especially in populations with lower technological access.

Methods

This study was conducted and reported in accordance with the PRISMA statement (Supplemental Material).[27] A comprehensive literature search of the PubMed database was conducted to include studies published from January 2014 to December 2023.

Search strategy: Keywords "digital, remote, internet, smartphone, mobile, app, mHealth, eHealth, self-management," "LDL-C, low-density lipoprotein cholesterol," and "lifestyle, diet, physical activity, exercise, smoking, drinking, alcohol" were used. Articles related to the effect of LI-DTx on LDL-C levels were collected and analyzed. English language studies published from 2014 to 2023 were included in this review.

Eligibility criteria: All studies assessing the effects of DTx on LDL-C were included. Included studies were published in English-language peer-reviewed journals that assessed the effectiveness of DTx interventions in modulating LDL-C as one of the primary or secondary outcomes and used mobile apps (Android or iOS) or web-based mobile apps, digital sensors, AI devices, etc., as interventions or as part of interventions.

Selection process: Studies were screened at several stages using inclusion and exclusion criteria. First, all titles and abstracts were screened to remove irrelevant studies. Then, full-text copies of all potentially relevant articles were obtained. The full text of the paper was also obtained if the abstract was insufficient to determine eligibility. Next, full-text articles were screened and excluded if they did not meet the inclusion criteria. Two authors independently screened and evaluated all titles, abstracts, and full texts. Disagreements between the two authors were resolved through discussion, and consensus was reached.

Data collection process: Data extraction was performed independently by two authors using a data extraction form. Information about the source, experimental design, and results of each of the selected studies was extracted.

Results

Search results

The initial literature search yielded 406 relevant articles published between 2014 and 2023. After screening titles and abstracts, 363 articles were excluded for failing to meet inclusion criteria. Full-text reviews were conducted for the remaining 43 articles, of which 20 were excluded for various reasons: nonclinical studies (6), no DTx interventions (2), no assessment of DTx efficacy (2), and no LDL-C in outcomes (10). This process resulted in a final inclusion of 23 articles for the review. The detailed literature screening process is presented in Figure 1.

The 23 included studies[28–50] consisted of 14 randomized controlled trials (RCTs), 5 single-arm studies, and 4 non-RCTs (Table 1). Fourteen studies[28–41] reported a significant reduction in LDL-C levels ($p < 0.05$), 7 studies[42–48] showed a reduction that was not statistically significant ($p > 0.05$), and 2 studies[49,50] reported no reduction. The aforementioned studies were published in English-language, peer-reviewed academic journals. These publications assessed the effectiveness of DTx interventions in lowering LDL-C. The interventions included software in the form of mobile applications or mobile-responsive web applications, as well as hardware, such as digital sensors or AI devices.

Proven effect of LI-DTx on LDL-C

For better understanding, the 21 studies with positive results were categorized into three main intervention types: single intervention, multifaceted interventions, and comprehensive interventions.

Effect of single LI-DTx on LDL-C

Effect of dietary-related LI-DTx on LDL-C. A digital nutrition platform called *Foodsmart*[28] was used to provide personalized dietary recommendations to patients with dyslipidemia. Foodsmart promotes healthy eating habits through nutrition education, personalized recipe suggestions, and integrated food ordering services. Results showed improvements in participants' lipid levels, with HDL-C increasing by 38.5%, total cholesterol decreasing by 6.8%, cholesterol ratio decreasing by 20.9%, LDL-C decreasing by 12.9%, N-HDL-C decreasing by 7.8%, and triglycerides decreasing by 10.8%.[28]

Effect of exercise-related LI-DTx on LDL-C. In an 8-week follow-up study of a virtual Internet-based physical activity motivation program for road maintenance workers, highly educated workers showed significant reductions in total cholesterol and LDL-C.[29] In a real-world study,[30] 258 referred veterans received a digital health intervention consisting of telecardiac rehabilitation, a 3-month structured home exercise program, multi-component counseling, a commercial smartphone app, and a wearable activity tracker. There was a significant improvement in LDL-C at 3 months ($p < 0.01$).

Effect of multifaceted LI-DTx on LDL-C. Multifaceted lifestyle interventions refer to interventions from two or more lifestyle aspects.

Effect of LI-DTx containing diet and exercise on LDL-C. Several studies have demonstrated positive outcomes from DTx strategies integrating

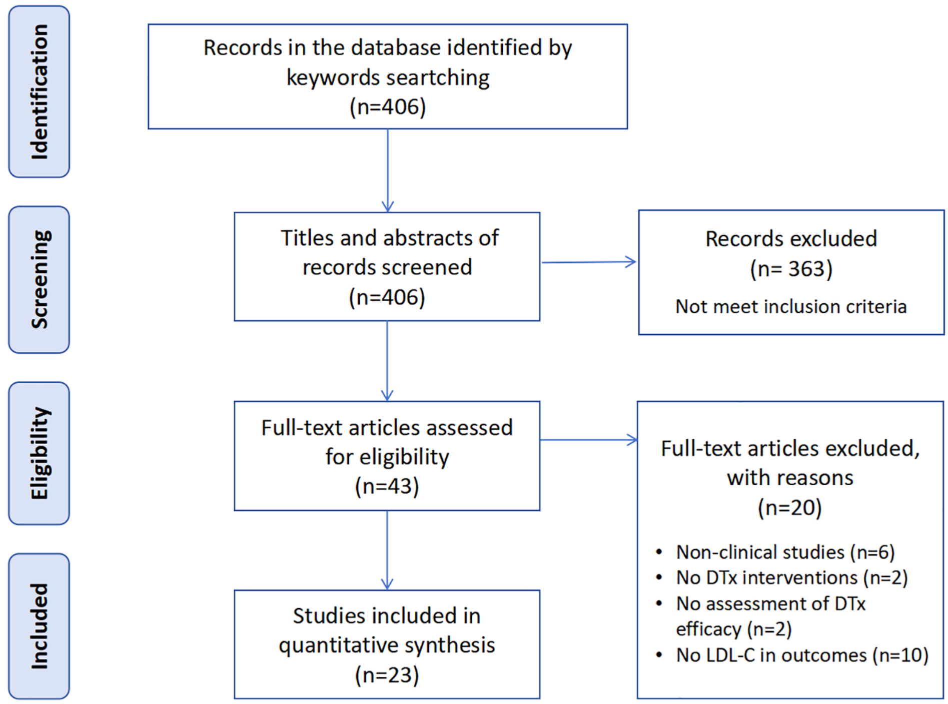

Figure 1. Flow diagram of literature screening.

diet, exercise, and other lifestyle modifications. A smartphone application based on Japanese health guidance reduced LDL-C levels in HIV-positive men.[31] A 12-week digital cardiac rehabilitation program helped patients achieve guideline-recommended lifestyle, medical, and treatment targets.[32] A 9-month Dutch digital health program significantly reduced cholesterol levels, with 61% of participants showing improvements in LDL-C.[33] For high-risk cardiovascular patients, a digital intervention led to reduced ASCVD scores and LDL-C levels over a year.[34] In South Korea, a diet and exercise tracking program significantly reduced LDL-C in 15 weeks.[35] The D'LITE trial reported substantial improvements in LDL-C after 6 months of self-monitored diet and physical activity.[36] In addition, five other studies[42–46] showed a trend toward lower LDL-C with LI-DTx containing diet & exercise ($p > 0.05$).

Effect of LI-DTx containing education and medication on LDL-C. Studies have shown that DTx based on education, medication, and other lifestyle interventions can achieve desirable outcomes. A study[37] using mobile-based cognitive behavioral therapy (CBT) for the management of atherosclerotic cardiovascular disease (ASCVD) showed significant reductions in LDL-C. Patients with coronary heart disease who used a self-management app were significantly more likely to achieve LDL-C <1.8 mmol/L at 12 months compared with standard care.[38] A mobile intervention for patients with acute coronary syndrome also helped more than 70% of participants achieve guideline-recommended LDL-C levels after hospital discharge.[39]

Effect of comprehensive LI-DTx on LDL-C. Trials of comprehensive interventions that include diet, exercise, education, medication, and key indicators monitoring have shown promising results. A Chinese study using the SMART-CR/SP system on WeChat for patients with coronary heart disease showed significant improvements in lipid profiles and high user satisfaction.[40] Another web-based T2DM management study showed that a self-management program combining diet, exercise, medication adherence, and health education significantly improved LDL-C and reduced body weight compared with usual care.[41] Besides, two other studies[47,48] showed a trend toward lower LDL-C with comprehensive LI-DTx ($p > 0.05$).

Table 1. Studies on the effect of LI-DTx on LDL-C level.

Author (year)	Study type	Patients/ population	Country	Sample	Duration	LI-DTx intervention details		Change of LDL-C level		
				Total (intervention group: control group)	Intervention or follow-up	Main aspects	Digital platforms	Mean difference/ relative change	Percentage of change	*p* Value
Emily A Hu et al. (2021)	Longitudinal study[28]	Dyslipidemia	United States	653 (353: 300)	16.9 months	Dietary recommendation	Web / iOS / Android operating system	−20.6 mg/dL	−12.90%	$p_{overtime} < 0.01$
Skogstad M et al. (2016)	Longitudinal study[29]	Road workers	Norway	121 (121 : 0)	8 weeks	Physical activity motivation	Virtual internet	−0.52 mmol/L	−16.25%	$p_{overtime} = 0.035$
Arash Harzand et al. (2023)	Clinical trial[30]	Adults aged 21 years or older referred to cardiac rehabilitation	United States	258 (258 : 0)	3 months	Home exercise program	Commercial smartphone app, wearable activity tracker	−11 mg/dL	−13.58%	$p_{overtime} < 0.01$
Maki Aomori et al. (2023)	RCT[31]	Men living with HIV who have dyslipidemia	Japan	38 (19: 19)	6 months	Diet and physical activity interventions	Smartphone application	−14.11 mg/dL	−9.79%	$p_{group} = 0.042$
Gibson I et al. (2023)	Observational study[32]	Patients (88%) with coronary heart disease)	Ireland	77 (77 : 0)	12 weeks	Healthy eating, physical activity, health education, stress management	Digital program	−0.76 mmol/L	−32.62%	$p_{overtime} < 0.001$
José Castela Forte et al. (2022)	Observational study[34]	General population	Netherlands	348 (104: 244)	9 months	Nutrition, physical activity, and other health behaviors	Health application	−0.39 mmol/L	−8.88%	$p_{overtime} = 0.04$
Tekkeşin Aİ et al. (2021)	Pragmatic RCT[34]	Patients with high cardiovascular risk	Turkey	483 (242: 241)	12 months	Enter daily data regarding their diet, blood pressure, weight and step count, motivational messages toward a healthy lifestyle	Application compatible with smartphones	−15.5 mg/dL	−11.48%	$p_{group} = 0.001$
Toro-Ramos T et al. (2017)	Preliminary Study[35]	Overweight or obese adults	Korea	159 (104: 55)	15 weeks	Food and exercise logging, education, and coaching	Smartphone app	−21.0 mg/dL	−16.75%	$p_{overtime} < 0.001$
Lim SL et al. (2022)	RCT[36]	Adults with prediabetes and BMI ⩾ 23 kg/m^2	Singapore	148 (72 : 76)	6 months	Self-monitor their weight, diet, physical activity, and blood glucose levels	Mobile app	−0.31 mmol/L	−9.90%	$p_{overtime} < 0.05$
DuanBin Li et al. (2023)	RCT[37]	Patients with atherosclerotic cardiovascular disease	China	300 (150: 150)	6 months	Health education, exercise interventions, adherence to medicine	WeChat Mini app	No data	−10.03%	$p_{group} = 0.02$

(Continued)

Table 1. (Continued)

Author (year)	Study type	Patients/ population	Country	Sample	Duration	LI-DTx intervention details		Change of LDL-C level		
				Total (intervention group: control group)	Intervention or follow-up	Main aspects	Digital platforms	Mean difference/ relative change	Percentage of change	*p* Value
Yuxi Li et al. (2022)	RCT[38]	Patients with coronary heart disease	China	300 (148: 152)	12 months	Self-management, medication, lifestyle intervention, health education	Mobile app	−0.22 mmol/L	−9.13%	$p_{group} = 0.001$
Sonia Ruiz-Bustillo et al. (2022)	Single-center study[39]	Patients discharged after a hospitalization for an acute ischemic heart disease event	Spain	497 (497 : 0)	12 months	Health education; physical activity, control of anxiety, and adherence to medicine	Mobile devices	−31 mg/dL	−26.91%	$p_{group} < 0.001$
Dorje T et al. (2019)	Parallel-group, single-blind, RCT[40]	Patients with coronary heart disease who had received percutaneous coronary interventions	China	312 (156: 156)	12 months	Health education, medication adherence, physical activity, healthy eating, smoking cessation, blood pressure, and heart rate monitoring	WeChat	−0.20 mmol/L	−10.00%	$p_{group} = 0.016$
Xia SF et al. (2022)	Non-blinded RCT[41]	Patients with type 2 diabetes	China	156 (78: 78)	6 months	Self-monitoring, healthy eating, active physical exercise, increasing medication compliance, health education, blood glucose monitoring	Web-based software, WeChat	−0.42 mmol/L	−16.80%	$p_{group} = 0.006$
Sato M et al. (2023)	Single-arm trial[42]	Patients with nonalcoholic steatohepatitis	Japan	19 (19 : 0)	48 weeks	Health education, diet and exercise lifestyle modifications, home weight monitoring, digital diary, medical advice	Smartphone application	−6.0 mg/dL	−4.78%	$p_{overtime} = 0.14$
Yoshimi Fukuoka et al. (2015)	RCT[43]	Overweight adults	United States	61 (30 : 31)	5 months	Home-based exercise program, self-monitoring of weight, activity, and caloric intake	Mobile app	−8.1 mg/dL	−6.64%	$p_{overtime} = 0.36$
Kayo Waki et al. (2014)	Non-blinded RCT[44]	Type 2 diabetes patients	Japan	54 (27: 27)	3 months	Diet and exercise monitoring, evaluation, communication	Smartphone–based Self-management Support System	−1.4 mg/dL	−1.21%	$p_{overtime} = 0.43$

(Continued)

Table 1. (Continued)

Author (year)	Study type	Patients/ population	Country	Sample	Duration	LI-DTx intervention details		Change of LDL-C level		
				Total (intervention group: control group)	Intervention or follow-up	Main aspects	Digital platforms	Mean difference/ relative change	Percentage of change	*p* Value
Bae JW et al. (2021)	RCT[45]	Coronary heart disease patients	Korea	727 (377: 350)	6 months	A healthy diet, physical activity, smoking cessation, and cardiovascular health	Website and messaging program	−3.6 mg/dL	−3.25%	$p_{group} = 0.12$
Soo Lim et al. (2016)	RCT[46]	Type 2 diabetes patients	Korea	100 (50: 50)	6 months	Diet and exercise counseling, nutrition and exercise education	Mobile phones and websites, clinical decision support system	−7.5 mg/dL	−8.72%	$p_{overtime} = 0.081$
Vivien Xi Wu et al. (2022)	Pilot study[47]	Older adults with chronic diseases	Singapore	12 (8 : 4)	8 weeks	Health education, healthy diet, lifestyle modification, medication adherence, exercise	Mobile app	−4.81 mg/dL	−4.63%	$p_{overtime} = 0.25$
Zhou W et al. (2016)	Non-blinded RCT[48]	Type 2 diabetes patients	China	100 (50: 50)	3 months	Knowledge, diet, exercise, medications, blood glucose monitoring, communication	Smartphone–based diabetes management application	−0.08 mmol/L	−3.31%	$p_{overtime} > 0.05$
Papandreou P, et al. (2021)	RCT[49]	Breast cancer patients	Greece	44 (22: 22)	3 months	Diet plans, physical activity guidelines	Data aggregation tools based on computer technology	+0.6 mg/dL	+0.53%	$p_{overtime} = 0.936$
Gonzalez-Sanchez J (2019)	RCT[50]	Healthy subjects without cardiovascular disease	Spain	833 (415: 418)	12 months	Diet, physical activity	Smartphone app	+3.62 mg/dL	+2.92%	$p_{group} = 0.055$

$p_{overtime}$, Comparison before and after the intervention in one group; p_{group}, comparison between different groups.

This demonstrates the feasibility and value of using a novel method for effective self-management.

These findings demonstrated that the efficacy of different LI-DTx interventions in reducing LDL-C levels varied significantly. Among the intervention types, LI-DTx containing education & medication exhibited the most substantial average LDL-C reduction percentage at 15.35%, followed by exercise intervention alone at 14.92%, and the diet intervention alone achieved a reduction of 12.90%. The comprehensive LI-DTx approach resulted in an average reduction of 10.48%. LI-DTx containing diet and exercise resulted in a reduction of 10.37%.

Potential impact of other LI-DTx on LDL-C

A healthy lifestyle is first recommended in lipid-lowering therapy. In addition to a sensible diet, moderate increases in physical activity and weight control, smoking cessation, and alcohol control are recommended.[3] Clinical trials have shown that current DTx products have favorable intervention effects for smoking cessation and alcohol control. Consequently, LI-DTx that control tobacco and alcohol may have an additional effect in regulating LDL-C.

Potential impact of smoking-related LI-DTx on LDL-C. Smokers had significantly higher levels of TC, TG, LDL-C, VLDL-C, TC:HDL ratio, and HDL-C compared to non-smokers[51,52] In a study using the Clickotine smoking cessation app, 51.5% of participants reported 7-day abstinence and 29.9% reported 30-day abstinence after 8 weeks.[53] Although changes in LDL-C were not measured in the study, we hypothesize that smoking-related LI-DTx may have a potential impact on the regulation of LDL-C levels. Further studies are needed to confirm this speculation.

Potential impact of drinking-related LI-DTx on LDL-C. High-risk drinking is associated with an increased risk of hypertriglyceridemia and hyper-LDL-C in both sexes, and hypercholesterolemia in men.[54] An open-label study evaluated the SWiPE app and found it feasible and effective in reducing alcohol consumption and craving in adults with hazardous drinking habits.[55] Although changes in LDL-C were not measured, it is hypothesized that alcohol-related LI-DTx may potentially regulate LDL-C levels and warrants further research.

Discussion

The main points of this paper have been summarized in Table 2, which provides a comprehensive overview of what was already known on the subject and the new contributions of this study.

Interpretation of the present study results

This review found that 14 included studies reported significant reductions in LDL-C levels ($p < 0.05$) and 7 studies showed trends toward reductions, supporting the positive role of LI-DTx interventions in reducing LDL-C levels. Based on the available evidence, DTx may achieve effective management of LDL-C through multiple aspects of lifestyle interventions, including diet control, exercise, health education, medication compliance, monitoring of key indicators, and possibly smoking cessation and alcohol restriction (Figure 2).

In addition, the 21 studies with positive outcomes included in Table 1 were of different study types, involved diverse populations, and used various interventions of different duration, resulting in considerable variation in LDL-C reduction. This suggests that future research should focus on identifying which patient populations benefit the most and how to optimize the intervention methods and duration for maximum effectiveness.

For the seven studies that reported improvements in LDL-C levels but without significance, several factors may have contributed to these nonsignificant findings: (1) Small sample size: $N_{total} = 19$,[42] $N_{total} = 12$,[47] $N_{total} = 61$,[43] $N_{total} = 54$.[44] (2) Insufficient intervention duration: 8 weeks.[42] (3) Study design flaws: Nurses provided medication and education to patients in both groups, which may have narrowed the gap.[45] (4) Normal baseline LDL-C levels: 86.0 mg/dl and 83.8 mg/dL,[46] 2.48 mmol/L and 2.42 mmol/L.[48] These findings indicate that larger sample sizes and longer interventions are often needed to capture the full effect of LI-DTx on lipid levels and that populations with elevated baseline LDL-C may benefit more from LI-DTx interventions.

Only two studies did not report a reduction in LDL-C levels. The CDSS study[49] found no significant change in LDL-C in the intervention group after 3 months of following dietary plans and physical activity guidelines (113.9 ± 27.8 mg/dL to 114.5 ± 39.7 mg/dL; $p = 0.936$), while the control group showed a significant increase

Table 2. Summary points.

What was already known on the topic?	Changing unhealthy lifestyles can help optimize LDL-C levels.
	DTx have been widely used for chronic disease management and lifestyle intervention in various populations.
	LI-DTx offer advantages over traditional lifestyle interventions in terms of accessibility, convenience, and individualized support.
What this study added to our knowledge?	Different populations have generally shown favorable treatment outcomes after treatment with LI-DTx, including reductions in LDL-C levels, which provides evidence of the efficacy of LI-DTx in the management of LDL-C.
	In low-resource primary care settings, IL-DTx hold promise as an effective therapeutic approach to managing LDL-C.
	Future directions for DTx development: Advancing intelligent algorithms, personalized interventions, multidisciplinary integration, real-time data monitoring, and robust security protocols to optimize clinical utility and patient adherence.

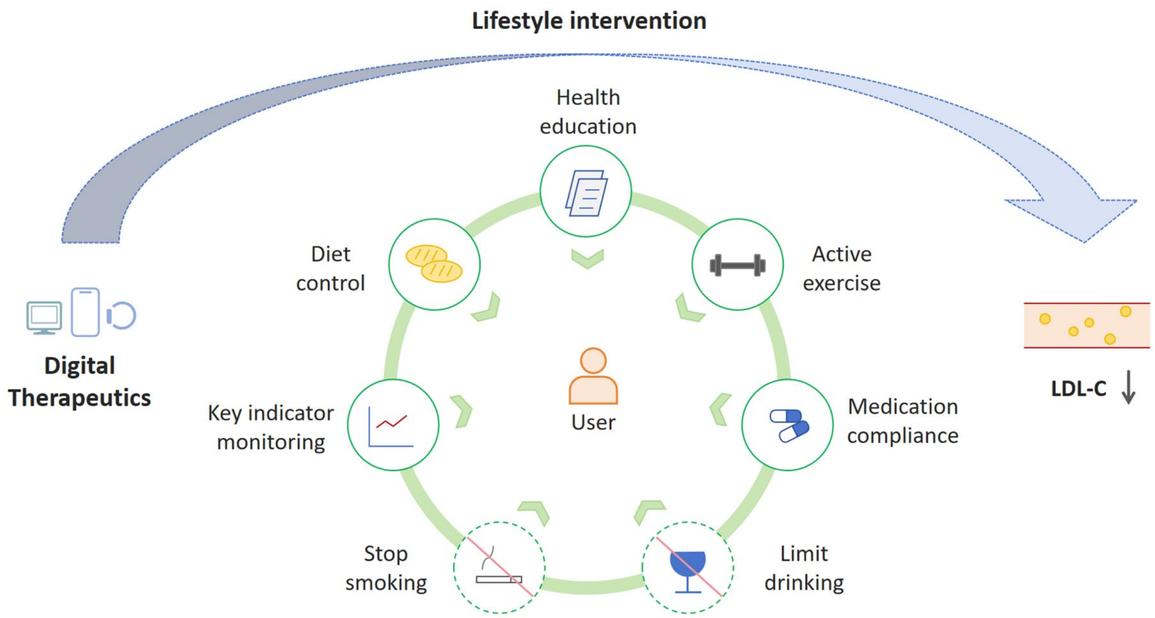

Figure 2. DTx promote lifestyle changes that affect LDL-C levels.

(115.6 ± 35.9 mg/dL to 127.6 ± 37.7 mg/dL; P= 0.037). This suggests that although the intervention did not reduce LDL-C, it may have prevented further increases, which is still beneficial. In the EVIDENT II study,[50] LDL-C in the control group decreased by 3.62 mg/dL (p = 0.055) at 12 months compared with the intervention group, which promoted a Mediterranean diet and increased physical activity. The difference in medication use between the groups may have influenced the results. The control group showed a significant increase in lipid-lowering medication (p < 0.05), while the intervention group did not (p > 0.05). The increased use of lipid-lowering medications in the control group may have contributed to the reduction in LDL-C levels.

Practical implications and real-world implementation

In clinical practice, LI-DTx may be particularly valuable for patients who have difficulty adhering to traditional face-to-face interventions, providing a flexible and scalable solution for managing dyslipidemia. Several practical strategies can be used to implement digital therapeutics in the lipid-lowering field. First, integrating DTx into existing clinical workflows can facilitate real-time monitoring and personalized patient management. Second, patient education and engagement are critical—introducing user-friendly platforms with tailored feedback and support can improve adherence to lifestyle changes such as diet and exercise. Third, developing reimbursement models and demonstrating cost-effectiveness will be important to encourage the adoption of DTx by healthcare systems and payers. Finally, partnerships between healthcare providers, technology developers, and policymakers can help establish clear guidelines and data privacy standards.

Proven efficacy of digital therapeutics in diseases

In addition to dyslipidemia, DTx has been successfully implemented in diabetes, hypertension, and mental health management, demonstrating its feasibility and efficacy. A phase III RCT[56] evaluated the efficacy and safety of DTx with CBT in improving glycemic control in adults with T2DM. Results from another RCT[57] showed that patients with T2DM had significantly greater reductions in HbA1c after 90 days of using the DTx application compared with the control group. These successful applications suggest that similar strategies could be used to manage dyslipidemia. Best practices from these areas, such as incorporating CBT for behavior change and using wearable devices for continuous monitoring, may help to develop more comprehensive DTx solutions for LDL-C management.

Potential limitations and real-world barriers to LI-DTx adoption

Despite its promising potential, the widespread adoption of LI-DTx faces several challenges. First, data privacy is a critical concern, as LI-DTx involves the collection and storage of sensitive patient information. Ensuring robust cybersecurity measures, complying with data protection regulations, and maintaining patient trust are essential to mitigate risks of breaches or unauthorized access.[58] Second, adherence is also a challenge, as patient engagement with digital tools often wanes over time. Strategies such as gamification, personalized feedback, and behavioral nudges are needed to sustain long-term use and maximize therapeutic benefits.[59] Finally, cost barriers limit accessibility, particularly for low-income populations who may lack the financial resources for devices or internet access. Developing affordable and scalable solutions, such as subsidized programs or simpler technologies, is crucial for equitable implementation.[60]

Recommendations for future clinical applications of DTx in LDL-C management

LI-DTx has the potential to become an effective therapeutic approach for managing LDL-C. However, the implementation of DTx is hindered by several factors, including product design, sustainability of interventions, personalized advice, professionalism of intervention content, alignment with service goals, patient compliance, accuracy of data collection, and cost considerations. Here are some recommendations for future clinical applications of DTx in LDL-C management.

Enhancing intelligent design of DTx for LDL-C management. Current DTx products often use standardized modules and artificial coaching for lifestyle changes. Advanced AI technologies should be incorporated to dynamically adapt content and optimize databases. DTx should incorporate multiple modules, including health knowledge, dietary guidance, exercise prescription, medication reminders, sleep management, psychological guidance, counseling services, and real-time assessment.

Sustainability of LI-DTx in long-term LDL-C management. While the current evidence demonstrates the short-term efficacy of LI-DTx in reducing LDL-C levels, lipid management is fundamentally a long-term process. The sustainability of these interventions over years, rather than months, remains a critical area for further investigation. Challenges such as patient adherence, technological fatigue, and behavioral maintenance must be addressed to ensure long-term success. Strategies such as personalized and adaptive interventions, integration with routine healthcare, and periodic re-engagement campaigns may improve the sustainability of LI-DTx. Future research should prioritize long-term follow-up studies to assess the durability of LDL-C reduction and the impact of LI-DTx on cardiovascular outcomes over several years to ensure that these interventions can be effectively integrated into lipid management.

Expanding personalization of DTx for LDL-C management. Lifestyle-influenced LDL-C is highly heterogeneity among patients. The guidelines[4] recommend a diet rich in whole grains, vegetables, fruit, and fish while minimizing saturated fat intake. For busy young people who often choose high-fat fast food,[61] DTx should offer convenient meal plans. Setting personal goals and self-monitoring can help to keep healthy eating habits. Exercise daily can improve lipid profiles.[62] DTx exercise regimen needs to be individualized based on personal preferences, concomitant diseases, and physical tolerance.

Integration with traditional healthcare systems. The integration of DTx with traditional healthcare systems is enhancing care delivery by making it more connected, intelligent, and patient-centered. Key aspects include: (A) Data sharing: Seamless communication with electronic health records provides healthcare providers real-time access to patient data from mobile applications and wearables, improving treatment decisions. (B) Decision support: AI-powered systems assist physicians in making accurate diagnoses and timely care decisions.[12] (C) Chronic care: DTx enable continuous monitoring and personalized support, empowering patients to manage conditions like diabetes and hypertension at home.[13]

Emphasizing multidisciplinary dyslipidemia teams in DTx. Dyslipidemia often coexists with other diseases and requires multidisciplinary involvement and different treatments.[63–69] Teams of experts in endocrinology, nutrition, exercise physiology, and psychology can provide better solutions for individual patients. Holistic care helps create comprehensive and targeted solutions for individual patients and achieve desired outcomes.[66] Therefore, it is necessary to involve a multidisciplinary team in the development and design of DTx products.

Expanding the applicability for the dyslipidemia population. The prevalence of dyslipidemia is higher in the elderly (76%) compared to younger individuals (41%),[67] and older adults often have lower acceptance of digital devices,[68] requiring the involvement of family members in the development of DTx.[69] Gender differences also affect healthcare accessibility through DTx,[70,71] as men prefer gaming while women favor social networking.[72] Low-income populations may lack internet access and necessary devices, limiting the use of DTx. Simpler and more convenient programs or devices may improve accessibility.[60]

Improving the stickiness of dyslipidemia users. The long treatment process and repeated training in DTx may reduce patient compliance and lead to high dropout rates. To increase engagement, online interactions and incentives are recommended. A virtual health manager could provide daily coaching and simple dialogues, while real healthcare providers, such as specialists and nutritionists, can add credibility to the system. Also, personalized plans and rewards can help people stick to their treatment plan for long-term success.[59,73–75]

Tracking real-time data in DTx. Real-time data monitoring, tailored feedback, and timely adjustment of interventions can improve the effectiveness and safety of DTx. While physical activity tracking is widely used,[76,77] dietary monitoring remains a challenge.[78] Current dietary quantification methods include food weight records, food tables, and food frequency questionnaires.[79–82] Vision-based measurement systems, which use mobile cameras to capture images of food, show promise for dietary tracking.[83]

Enhancing data security in DTx. Data security is critical for DTx due to the large amounts of sensitive data involved. Unauthorized access or breaches can lead to information leakage and misuse, threatening patient privacy.[58] To mitigate these risks, regulatory authorities should oversee DTx processes throughout the product life cycle. Establishing a dedicated security infrastructure and enhancing privacy protections for healthcare providers, patients, and insurers are essential steps to ensure data security and compliance.

Limitations of the scoping review process

While the present scoping review provides valuable insights into the potential of LI-DTx in managing LDL-C, there are some limitations in the scoping review process. First, the literature search was restricted to English-language publications from the PubMed database, which may have limited the scope of the study and excluded literature available in other databases. Second, variations in study design, population characteristics, intervention methods, duration, and outcome measures among the included studies make it difficult to directly compare the effectiveness of different LI-DTx interventions.

Conclusion

This review highlights the potential of LI-DTx for LDL-C management through their positive impact on lifestyle factors. Compared to traditional interventions, LI-DTx offer advantages such as increased accessibility, convenience, and personalized support. Clinical studies have demonstrated that LI-DTx can promote healthy outcomes, including regulation of LDL-C levels. Future studies should focus on identifying patient demographics most likely to benefit from LI-DTx, such as those at increased cardiovascular risk or with limited access to traditional care. In summary, LI-DTx will provide an innovative and feasible alternative for the management of LDL-C.

Declarations

Ethics approval and consent to participate

According to Ethical Guidelines for Epidemiological Research issued by the Office of Medical Ethics Expert Committee, China National Health Commission, ethics approval and informed consent did not apply to this study.

Consent for publication

Not applicable.

Author contributions

Jia Tang: Conceptualization; Project administration; Writing – original draft.

Tiantian Song: Data curation; Methodology; Writing – original draft.

Ming Kuang: Formal analysis; Resources; Writing – review & editing.

Hongying Liu: Investigation; Supervision; Writing – review & editing.

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Supplemental material

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