

Use of wellness applications for patients with venous disorders: a literature review and the emerging role of the European quality label (CEN-ISO/TS 82304-2)

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Abstract:

Introduction: Venous disorders including chronic venous insufficiency (CVI) and varicose veins substantially impair patients' quality of life. Digital health tools—especially wellness applications—offer emerging opportunities for self-management, lifestyle modification, and continuous monitoring. However, concerns remain regarding their clinical validity, data protection, usability, and the absence of standardized quality assessment.

Aim: To review the literature on wellness applications relevant to patients with venous diseases and to evaluate the potential role of the European health app quality label CEN-ISO/TS 82304-2 in improving trust, acceptance, and recommendation rates among healthcare professionals.

Methods: A narrative review of contemporary studies on mobile health (mHealth) and wellness apps for venous disorders, physical activity promotion, and chronic disease prevention was performed. Additional emphasis was placed on empirical research assessing the impact of standardized quality labelling on professional recommendation behavior.

Results: Wellness apps demonstrate promising benefits in promoting physical activity, improving adherence to preventive behaviors, and supporting monitoring of key parameters such as hydration, blood pressure, sleep quality, and mobility. Studies on mHealth for venous leg ulcers show feasible patient engagement despite technological limitations. Research on app quality assessment reveals that many commercially available applications lack scientific validation, medical involvement, and quality assurance mechanisms. Importantly, a European experimental vignette study showed that the CEN-ISO/TS 82304-2 quality label significantly increases healthcare professionals' willingness to recommend wellness apps to patients, irrespective of patient socioeconomic status or app category.

Conclusions: Wellness apps can complement clinical management of venous disorders, but their integration into practice requires robust quality evaluation frameworks. The adoption of the European quality label appears to enhance professional trust and could contribute to safer and broader clinical use. Future research should investigate long-term patient outcomes and the implementation of certified apps in vascular practices.

Keywords: wellness apps; venous disorders; chronic venous insufficiency; mobile health; CEN-ISO/TS 82304-2; quality label; self-management; e-Health.

INTRODUCTION

Chronic venous disease (CVD), including varicose veins and chronic venous insufficiency (CVI), represent one of the most common vascular conditions globally, affecting millions of individuals and contributing to significant morbidity, reduced mobility, and impaired quality of life. Their high prevalence—exacerbated by aging, sedentary lifestyles, and obesity—necessitates innovative strategies for prevention and self-man-

agement¹⁻³. This highly prevalent condition is characterized by venous hypertension arising from valvular incompetence, venous reflux, obstruction, and impaired calf muscle pump function, leading to microcirculatory inflammation and progressive tissue damage. Epidemiological studies demonstrate that CVD affects up to one-third of adults, with symptoms ranging from pain and edema to skin changes and venous ulceration, contributing substantially to reduced mobility and diminished quality of life. Modern evaluation relies on CEAP classification and duplex ultrasonography, which together provide a structured assessment of disease severity and underlying mechanisms, forming the basis for individualized management strategies including lifestyle modification, compression therapy, and procedural interventions⁴⁻¹⁰.

Physical inactivity is recognized by the World Health Organization as a major global public health problem, contributing substantially to the rising burden of noncommunicable diseases worldwide. In its Global Action Plan for the Prevention and Control of NCDs 2013-2020, the WHO emphasizes

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that increasing physical activity through accessible, population-level interventions is essential for reducing cardiovascular and metabolic disease risk—an approach directly relevant to patients with chronic venous disorders, who often benefit from enhanced mobility and structured lifestyle support¹¹⁻¹².

Digital health tools, and specifically wellness applications, have evolved rapidly over the last decade, becoming increasingly sophisticated in their ability to support personalized health management. These applications commonly integrate features such as guided physical activity programs, diet and hydration monitoring, sleep quality assessment, and continuous biometric tracking through connected wearables. By leveraging real-time data, behavior-change techniques, and automated feedback loops, wellness apps can deliver tailored recommendations that encourage healthier routines and sustained lifestyle modification. For patients with venous disorders, these capabilities are particularly relevant. Regular movement and structured activity reminders can help stimulate the calf muscle pump, a key driver of venous return, while tracking step counts and mobility patterns enables early identification of prolonged sedentary periods that contribute to venous stasis. Hydration and blood pressure monitoring may support maintenance of optimal blood rheology and vascular function, and sleep analytics can identify patterns associated with leg heaviness or nocturnal edema. Moreover, longitudinal biometric data—such as daily step trends, limb temperature, or changes in swelling—can assist in the early detection of deteriorating symptoms, prompting timely clinical evaluation. Collectively, digital wellness tools offer a promising adjunct to conventional venous disease management, helping patients adhere to preventive strategies and enabling clinicians to monitor functional progress between visits¹³⁻²⁰.

However, challenges persist: many apps lack scientific rigor, clinical involvement, long-term validation, or appropriate data protection frameworks²¹⁻²⁵. Recognizing these challenges, the

European Committee for Standardization (CEN) and the International Organization for Standardization (ISO) introduced the CEN-ISO/TS 82304-2 Technical Specification, a comprehensive framework designed to evaluate the quality, safety, reliability, and usability of health and wellness applications. This specification establishes a standardized, evidence-based scoring system and a consumer-facing quality label, enabling both clinicians and patients to quickly assess whether an app meets essential criteria for clinical robustness, data protection, and user experience. By defining transparent benchmarks across domains such as healthy and safe functioning, data security, ease of use, and technical robustness, the CEN-ISO/TS 82304-2 label aims to strengthen trust in digital health tools, facilitate professional recommendation, and support safer integration of wellness apps into routine clinical practice—including in fields such as phlebology, where digital self-management tools are becoming increasingly relevant.²⁶⁻²⁹

This short review synthesizes current knowledge on wellness applications relevant to venous disease management and examines the potential impact of the new European quality label on their acceptance by healthcare professionals.

METHODS

A narrative literature review was conducted using evidence from: a) studies on wellness applications, wearable technology, and lifestyle monitoring^{13-15,19,20}, b) clinical research on mHealth interventions for venous leg ulcers^{9,16}, c) technology-assisted leg health monitoring¹⁷, d) reviews on mobile apps for varicose vein prevention and self-care¹⁸, e) research on barriers to health app recommendation and the impact of CEN-ISO/TS 82304-2²⁹. Full-text data, figures, and tables from the uploaded documents were integrated. The aim was descriptive synthesis rather than meta-analysis. A summary of evidence gathered is shown in Table 1.

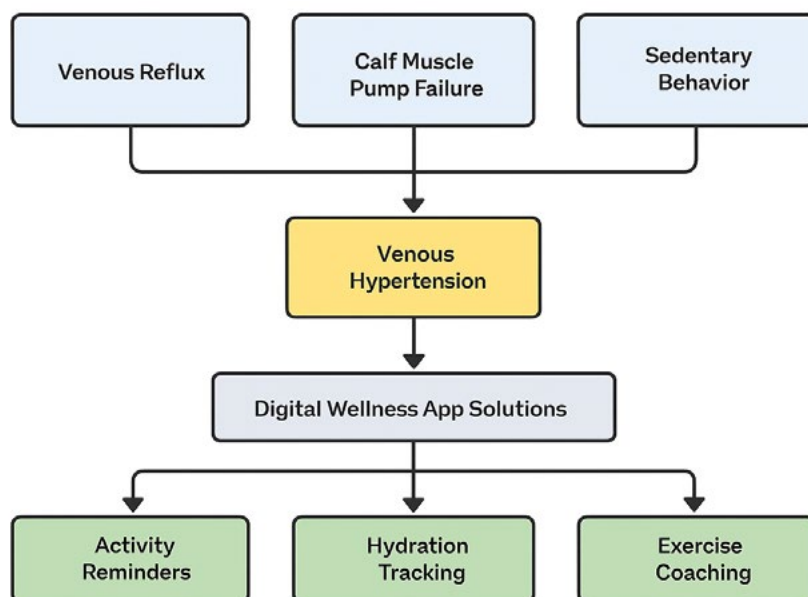


Figure 1. Pathophysiology of venous hypertension & opportunities for mHealth intervention

Table 1. Summary of evidence from reviewed studies

Study	Target Population	Intervention Type	Outcomes Measured	Key Results	Limitations
<i>Laberiano et al. (18)</i> — Mobile application for the prevention and self-care of varicose veins	Adults at risk of varicose veins	Mobile app prototype	Usability, acceptability, educational content	Prototype found intuitive and useful for self-care education	Prototype only, no clinical outcomes
<i>Kelechi et al. (FOOTFIT) (16)</i> — VLU activity intervention	Adults with venous leg ulcers	Wearable accelerometer + app	Adherence, step counts, feasibility	>85% adherence; mobile coaching feasible for older patients	Tech challenges; small sample
<i>Sannino et al. (13-15)</i> — SmartHealth 2.0 wellness app	Adults 18–65	Comprehensive wellness app + wearables	MAI, TPA, TCI, PSQI, Wellness Index	Significant improvement in all wellness indices; high usability	Short-term, small cohort, self-reported data
<i>Nguyen M. (17)</i> — Wearable tech for venous health - Vein doctor report	Individuals with venous insufficiency	Wearable sensors (compression, hydration, BP, gait)	Leg-health monitoring potential	Wearables provide comprehensive monitoring	Commentary only; no clinical trials
<i>Higgins JP et al. (19)</i> — Smartphone Applications for Patients' Health and Fitness	General adult population using fitness/wellness apps	Fitness, activity tracking, nutrition, lifestyle & wearable-integrated apps	App functionality, health behavior support	Demonstrates rapid growth of wellness & wearable-based apps; categorizes app types relevant for lifestyle modification	Not venous-specific; narrative review
<i>Middelweerd et al. (20)</i> — Apps to Promote Physical Activity	Adults using PA apps	Physical activity apps categorized by BCTs (tracking, goals, feedback, reminders, social features)	Behavior-change techniques; functionality analysis	PA apps widely use BCTs like feedback, self-monitoring, goal setting; strength in promoting PA	Not clinical; no disease-specific data; no long-term outcomes
<i>Biliunaite et al. (29)</i> — CEN-ISO/TS 82304-2 Quality Label Study	European healthcare professionals	Vignette-based evaluation	Willingness to recommend; APEASE domains	Quality label significantly increases recommendation likelihood	Hypothetical scenarios; moderate sample

List of abbreviations:

MAI – Mediterranean Adequacy Index

TPA – Time spent per week on Physical Activity Index

TCI – Target Calorie Index

PSQI – Pittsburgh Sleep Quality Index

VLU – Venous Leg Ulcer

CVI – Chronic Venous Insufficiency

PA – Physical Activity

BCT – Behavior Change Technique

mHealth – Mobile Health

HCP – Healthcare Professional

EHR – Electronic Health Record

CEAP – Clinical, Etiological, Anatomical, Pathophysiological (classification of chronic venous disease)

ISO – International Organization for Standardization

CEN – European Committee for Standardization

QoL – Quality of Life

RCT – Randomized Controlled Trial

APEASE – Acceptability, Practicability, Effectiveness, Affordability, Side-effects, Equity (evaluation criteria)

RESULTS

Wellness apps for venous disease prevention and self-care

Several studies highlight the clinical relevance of mobile applications designed to improve lower-limb health and prevent venous stasis. Laberiano et al. describe the development of a mobile prototype for varicose vein prevention using *design thinking*. Patients valued educational content, exercise reminders, and monitoring tools. Wellness apps can encourage daily physical activity, improve adherence to compression therapy, and support early identification of symptoms (Figures 2,3). These findings align with the documented role of physical activity in reducing venous hypertension and improving microvascular perfusion¹⁸.

Wearable technologies supporting venous health

A wide range of wearable technologies now complement wellness apps. Fitness trackers monitor steps, heart rate, and activity levels—are promising key elements in venous return enhancement. Smart compression wearables adjust pressure dynamically, optimizing blood flow, smart hydration devices prevent dehydration, which can increase blood viscosity, whereas wearable blood pressure monitors, smart insoles, echocardiogram (ECG) devices, and sleep monitors provide additional data relevant to venous function (Figure 4). These technologies support a holistic wellness ecosystem, particularly valuable for patients with early venous symptoms or at high vascular risk¹⁷.

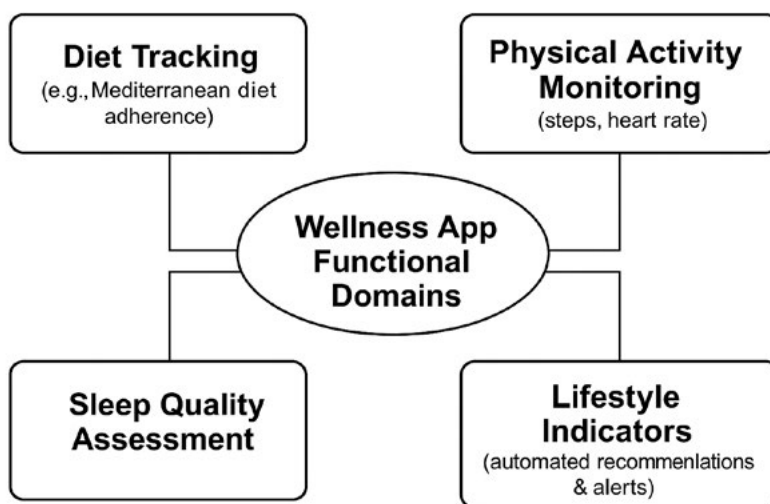


Figure 2. Wellness app functional domains relevant to venous disease

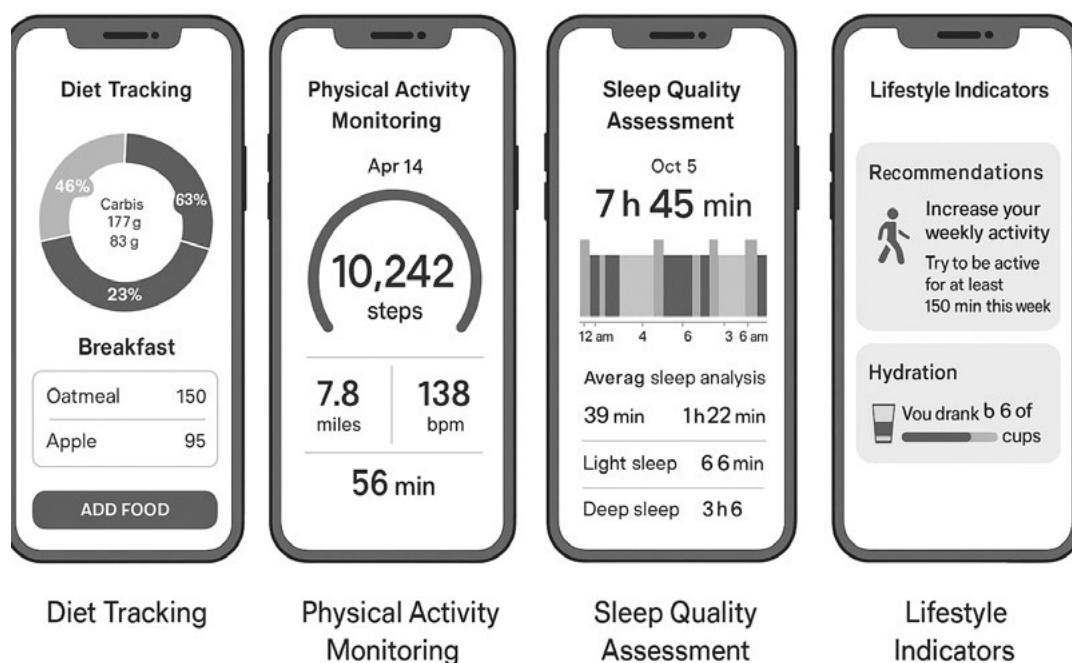


Figure 3. Examples of wellness app interfaces



Figure 4. Wearable ecosystem supporting venous health

mHealth Applications for venous leg ulcers (VLU)

Evidence from the randomized controlled trial FOOTFIT shows high adherence (>85%) to short daily conditioning exercises tracked via an accelerometer-linked mobile app. Patients reported usability challenges with older technology, yet overall engagement was positive. The intervention demonstrates that mHealth can feasibly assist VLU patients, many of whom are elderly or have limited mobility. This underscores the importance of usability, interface quality, and updated sensor integration¹⁶.

Evidence-based wellness app development

The *Wellness app* studied by Sannino et al. integrates diet tracking and mediterranean diet adherence scoring (MAI), physical activity monitoring (steps, distance, heart rate), sleep quality assessment (PSQI), automated personalized recommendations and behavior change techniques (n=9) embedded into the app design. Pilot studies demonstrated significant improvements in wellness indices and high user satisfaction¹³⁻¹⁵.

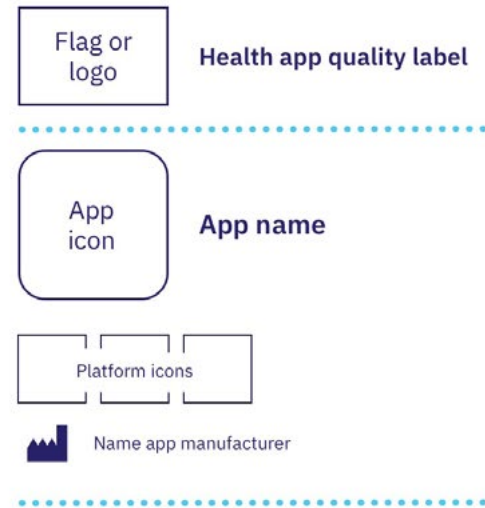
Lack of scientific validation in commercial apps

Consistent across multiple analyses is the finding that most available wellness apps lack medical involvement. Standardized effectiveness data are rare and only few apps undergo long-term or heterogeneous population testing, while data privacy and security features vary widely. This validates the need for systematic quality assessment frameworks.

The European quality label (CEN-ISO/TS 82304-2)

The recent vignette-based study by Biliunaite et al. provides the strongest evidence to date that the presence of the label (Figure 5) significantly increases healthcare professionals' willingness to recommend apps. This effect is stable across app type (prevention, self-management, clinical support) and

patient socioeconomic status (Figure 6). The label improves perceived acceptability, trust, and professional confidence. Given that healthcare professionals act as gatekeepers for digital tools, this quality label may substantially influence clinical transmission into practice^{28,29}. The European label's key features are shown in detail in Table 2.



Benefit of the app
 With this app [intended users] can [intended use] / With this app [x in 10] [intended users] [health effect] [if use]
 ⚠ Check [here] when app requires approval from a health professional before use

Healthy and safe					
	B			A	
Easy to use					
	E	D	C	B	A
Secure data					
	C			B	A
Robust build					
	A				
↓					
Overall health app quality score					
C			B	A	
<input checked="" type="checkbox"/>	App checked on [date]				

CEN-ISO/TS 82304-2:2021

Figure 5. The European quality label (CEN-ISO/TS 82304-2) (available at: <https://label2enable.eu/results>)

Table 2. Structure and scoring domains of the CEN-ISO/TS 82304-2 quality label

Category	Weight (%)	Criteria (Summary)	Examples Relevant to Vascular / Wellness Apps
Healthy & Safe	50%	<ul style="list-style-type: none"> Clinical safety assurance Risk management and hazard mitigation Evidence supporting claimed benefits Clear contraindications Appropriate onboarding and safety warnings 	<ul style="list-style-type: none"> App provides evidence-based recommendations for improving venous return (e.g., activity promotion, calf-pump exercises) Includes warnings for patients with acute DVT or severe edema Provides safe-use guidance for compression wearables Includes validated algorithms for monitoring steps or mobility in CVI patients
Easy to Use	15%	<ul style="list-style-type: none"> Usability testing Accessibility compliance Clear navigation and language Minimal cognitive burden 	<ul style="list-style-type: none"> Simple interface for logging symptoms (leg heaviness, swelling) Clear icons for hydration, sleep, or activity tracking Large-text mode for older adults with venous disease Quick-start tutorials for first-time users (common in CVI management apps)
Secure Data	25%	<ul style="list-style-type: none"> GDPR compliance Encryption of data at rest & in transit Transparent data-processing policies User control over data sharing and deletion 	<ul style="list-style-type: none"> Secure transmission of heart rate, BP, step count, gait metrics Clear permission settings for sharing data with vascular specialists Data-minimization for sensitive health metrics (e.g., ulcer photos, inflammation readings) Automatic anonymization for research use
Robust Build	10%	<ul style="list-style-type: none"> App performance, uptime, and stability Interoperability with devices or EHRs Responsiveness and bug-free operation Long-term maintenance and updates 	<ul style="list-style-type: none"> Reliable pairing with smart compression devices Stable syncing with wearables (step counters, hydration sensors, smart insoles) Works offline for patients with poor connectivity Regular updates incorporating new venous-care guidelines

List of abbreviations:

- ISO – International Organization for Standardization
- CEN – European Committee for Standardization
- GDPR – General Data Protection Regulation
- BP – Blood Pressure
- CVI – Chronic Venous Insufficiency
- EHR – Electronic Health Record
- DVT – Deep Vein Thrombosis

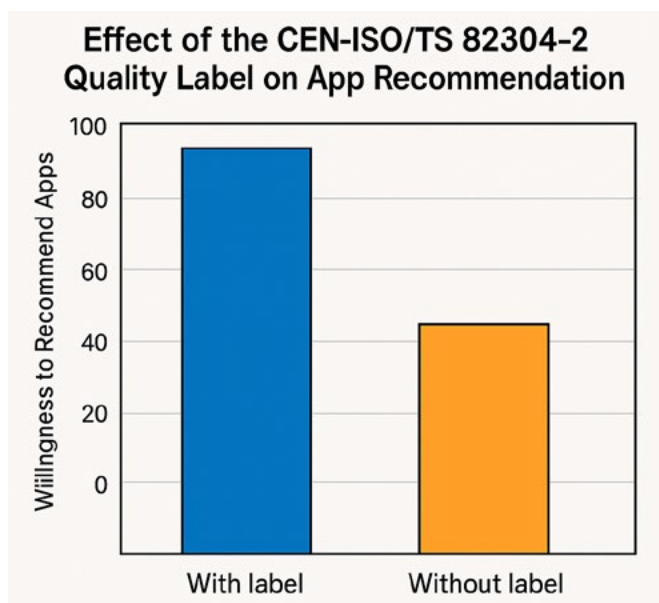


Figure 6. Effect of the CEN-ISO/TS 82304-2 quality label on app recommendation

DISCUSSION

Wellness apps represent a promising adjunct in the prevention and self-management of venous disorders, offering digital support that can complement traditional clinical care. Their potential benefits extend across several dimensions of venous health: (a) encouraging regular mobility and reducing sedentary behavior, thereby stimulating the calf muscle pump and improving venous return; (b) supporting adherence to compression therapy through reminders, tracking tools, and education on correct use; (c) enhancing patient education and autonomy by providing accessible information on risk factors, symptom monitoring, and lifestyle modification; (d) enabling real-time data collection—such as step counts, hydration levels, sleep quality, or limb temperature—which may facilitate early detection of deteriorating symptoms like edema, increasing pain, or reduced mobility; and (e) integrating wearable technology to provide comprehensive, continuous physiological monitoring relevant to venous function. Despite these advantages, several challenges limit widespread adoption. Usability issues—particularly among older adults or those with limited digital literacy—can hinder engagement, while the lack of clinical validation raises concerns about the reliability and accuracy of app-generated recommendations. Long-term adherence remains difficult to achieve, and variability in data security practices across commercially available apps intro-

duces significant privacy and safety risks. This heterogeneity in app quality underscores the need for structured oversight.

The CEN-ISO/TS 82304-2 quality label helps address these gaps by providing a standardized, transparent mechanism for evaluating the safety, reliability, usability, and data protection practices of health and wellness applications. Evidence demonstrates that the presence of this quality label increases healthcare professionals’ willingness to recommend digital tools—an essential step toward integrating certified wellness apps into vascular clinical pathways and improving patient trust. Future directions should include longitudinal clinical trials assessing the impact of certified wellness apps on venous disease progression, recurrence, and patient-reported outcomes; integration of app-based monitoring into European vascular care pathways; the creation of venous disease-specific quality criteria within the ISO framework (e.g., compression adherence, ulcer photography quality, mobility metrics); and the strengthening of multidisciplinary collaboration among vascular surgeons, digital health specialists, behavioral scientists, and patient organizations to ensure real-world feasibility and adoption (Figure 7).

CONCLUSIONS

The expanding digital ecosystem of wellness applications and wearable technologies has created new possibilities for supporting patients with venous disorders, yet their meaningful clinical integration depends on the availability of trustworthy, clinically sound tools. The CEN-ISO/TS 82304-2 quality label provides a structured mechanism to distinguish reliable applications from the broader digital market, offering a foundation for safer and more consistent adoption in vascular practice. Moving forward, coordinated efforts across clinical, technological, and regulatory domains are essential to translate these digital innovations into measurable improvements in venous care. Robust clinical trials, implementation studies, and targeted quality frameworks will be critical to ensure that certified digital tools can be effectively embedded within everyday phlebology workflows (Table 3) and deliver sustained value to patients and clinicians alike.

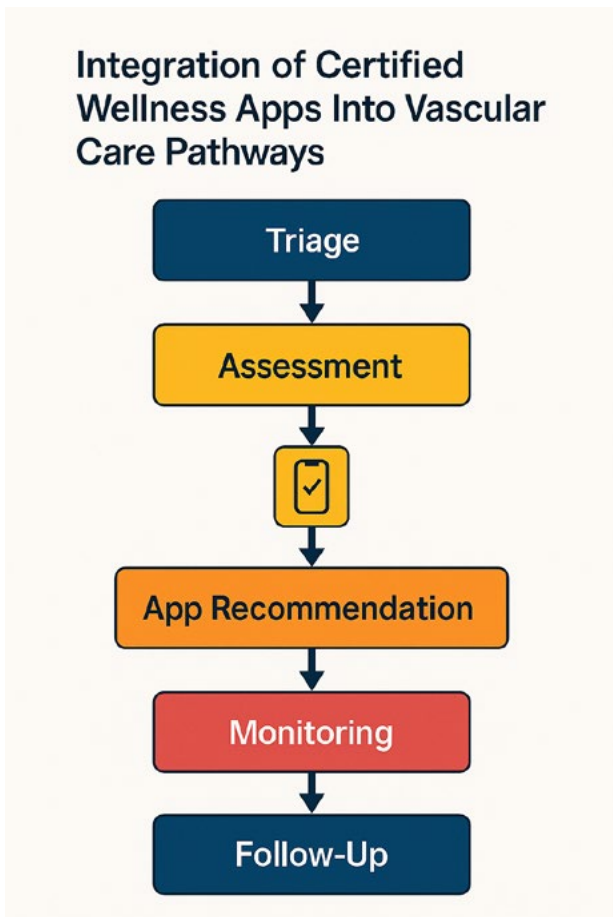


Figure 7. Proposed integration of certified wellness apps into vascular practice

Table 3. Gaps in current evidence and priorities for future research

Research Gap	Current Evidence	Future Research Priority
Lack of long-term clinical outcomes	Studies focus on short-term usability; few measure venous disease progression.	Longitudinal trials assessing CEAP changes, ulcer recurrence, edema, and QoL.
No venous-specific app certification	ISO 82304-2 is general; no criteria tailored to venous care needs.	Develop vascular-focused certification standards (compression, ulcer care, calf pump metrics).
Poor integration with clinical systems (EHRs)	Apps operate independently; data not shared with vascular clinics.	Build interoperable systems allowing automatic data transfer into EHRs.
Unknown effect on ulcer healing or recurrence	FOOTFIT improves activity but does not study wound outcomes.	Test digital ulcer monitoring tools in RCTs to evaluate healing/recurrence.
Usability issues in older or low-literacy patients	Older VLU patients report tech difficulties; training is often needed.	Co-design apps with elderly patients; simplify interfaces; add voice or auto-sync features.
Wearable metrics lack validation for venous physiology	Devices measure steps, hydration, pressure—but are rarely validated in venous patients.	Validate venous-specific wearable metrics (edema, calf pump surrogates, compression pressure).
Limited real-world evidence on ISO quality label impact	Vignette study shows increased willingness to recommend—but only in scenarios.	Conduct implementation trials in vascular practices to measure adoption and outcomes.
Data security concerns for sensitive venous data	Apps vary widely in privacy standards; ulcer photos and symptom logs may be insecure.	Develop venous-care-specific GDPR protocols; perform security testing.

List of abbreviations:

- CVD – Chronic Venous Disease
- CVI – Chronic Venous Insufficiency
- VLU – Venous Leg Ulcer
- EHR – Electronic Health Record
- RCT – Randomized Controlled Trial
- QoL – Quality of Life
- GDPR – General Data Protection Regulation
- ISO – International Organization for Standardization
- CEN – European Committee for Standardization

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