The eHealtHeart Mobile Application for Managing Cardiac Toxicity in Patients with Breast Cancer: Preliminary Results From the CARDIOCARE Multicenter Study

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Abstract

Background: Breast cancer treatments can cause cardiotoxicity, particularly among elderly patients with comorbidities and frailty. This dual burden poses complex clinical challenges, including increased risk of cardiac complications, reduced resilience,

and reduced quality of life. To address these issues effectively, there is a growing need for continuous, patient-centered monitoring and integrated psycho-emotional support that goes beyond conventional care, empowering patients and enabling proactive, personalized interventions.

Objective: This study aimed to design, develop and evaluate a mobile application, the eHealtHeart, intended to support elderly women with breast cancer by enabling continuous cardiovascular monitoring and providing behavioral and psycho-emotional interventions.

Methods: The eHealtHeart mobile application was developed through a user-centered, multi-phase process involving active input from elderly patients and healthcare professionals. The application integrates physiological data collected via a smartwatch and a chest-strap (which monitors heart rate and heart rate variability) into 6 interactive digital modules addressing: (i) mobility & vitality, (ii) psychology & wellbeing, (iii) cognitive stimulation, (iv) education, (v) geriatric assessments and (vi) smart recommendations. A total of 79 women (mean age 67 ± 7 years) used the eHealtHeart mobile application over a six-month period, after which they completed three evaluation instruments: (1) the System Usability Scale (SUS), (2) a Technology-Acceptance-Model (TAM) questionnaire assessing Perceived Usefulness [PU], Perceived Ease-of-Use [PEU], Intention-to-Use [IU], Attitude-toward-Use [ATU]), and (3) a custom survey evaluating functionality, reliability and data security.

Results: The mean SUS score was 69.05 ± 15.84, with 61 out of 79 participants (77%) scoring above the established 68-point benchmark for good usability. TAM results were favorable across all constructs: Perceived Usefulness (PU) = 3.72?±?0.92; Perceived Ease of Use (PEU) = 3.35?±?1.05; Intention to Use (IU) = 3.35?±?1.05; and Attitude Toward Use (ATU) = 3.84?± 0.83, all rated on a 1–5 Likert scale. Functionality was rated highest for ease of use (3.96 ± 0.92) and system performance (3.21 ± 0.71); while reliability accuracy was also strong (3.94 ± 0.98), indicating no major technical limitations. Participants reported high perceived data security (4.26 ± 0.94). Digital literacy was strongly associated with usability, with a significant correlation between SUS scores and the Digital Literacy Index ($r = 0.78$, $p < 0.001$). Open-ended user feedback highlighted the value of biofeedback features, cognitive training games and personalized recommendations, although some users reported occasional data synchronization delays. These findings represent an interim analysis of 79 participants who completed the intervention while the CARDIOCARE randomized controlled trial is still ongoing.

Conclusions: The eHealtHeart mobile application demonstrated good usability and high levels of acceptance among breast cancer patients at risk of cardiotoxicity, including those with limited digital literacy. Its user-centered design, integrating cardiovascular monitoring with behavioral and psycho-emotional interventions offers a novel approach to addressing the complex care needs in geriatric oncology. These interim findings support the feasibility and acceptability of the proposed intervention and highlight its potential for broader implementation in routine care. Future iterations may incorporate artificial intelligence to enable personalized, adaptive support and further enhance clinical impact. Clinical Trial: ClinicalTrials.gov NCT06334445

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Trial Registration: ClinicalTrials.gov NCT06334445
Keywords: Healthcare; Cardiotoxicity; Breast neoplasms; eHealth; Palliative Care; mHealth; Geriatric; Wearable electronic device; Quality of life; Frailty;

Introduction

Breast cancer is a disease that primarily affects women and is caused by the uncontrolled growth of abnormal cells in breast tissue [1]. This type of cancer typically begins in the epithelial layer of the ducts or lobules within the glandular tissue of the breast[2]. Currently, breast cancer is the most frequently diagnosed malignancy in women worldwide[3]. The median age at diagnosis is over 60 years, indicating a correlation between age and the development of this condition[4]. Even though breast cancer deaths in Europe have been declining for over 20 years, projections from Santucci show an increase from ~85,000 in 2020 to ~91,000 in 2025 [5][6]. Advances in breast cancer treatment have contributed to considerable improvements in patient outcomes, including reduced morbidity and mortality. Commonly used therapeutic options across different breast cancer subtypes include neoadjuvant and adjuvant chemotherapy, targeted and hormone therapies, radiation therapy and surgical treatment [7].

Despite these advances, several of the above therapies are associated with cardiotoxic effects. Cytotoxic chemotherapeutic agents, in particular, are designed to eliminate cancer cells but can also induce adverse cardiovascular events, even in women with no pre-existing cardiovascular disease or cardiovascular risk factors. While many patients survive their initial cancer diagnosis, they are significantly more likely to develop cardiovascular disease [8],[9]. Consequently, monitoring these patients during their breast cancer treatment is crucial since it enables healthcare professionals (HCPs) to track treatment response and make the necessary adjustments to improve clinical outcomes. Furthermore, patients who are aware that their health is continuously monitored throughout their treatment feel more confident and supported [10]. For these reasons, consistent follow-up is crucial and should be prioritized to improve treatment outcomes and patient quality of care. The intersection of breast cancer treatment and cardiovascular health presents a significant clinical challenge, highlighting the need for monitoring systems that support treatment decisions and improve patients' quality of life (QoL).

This paper outlines the co-design and co-development process of the eHealtHeart application, which is part of the CARDIOCARE project [11], an interdisciplinary approach for the management of the elderly multimorbid patient with breast cancer . The study aims to provide patients with the ability to actively participate in their care process and improve their psychological and physical condition. CARDIOCARE aims to empower patients to engage in their health management by providing an individualized care plan based on the monitoring of their health status using a wearable sensor, a smartwatch and a mobile device. Specifically, the CARDIOCARE ecosystem digital tools consist of the eHealtHeart mobile application, the HCP platform and the administrator panel. These tools offer a unique user experience to patients and HCPs. The primary aim of the eHealtHeart mobile application is to provide an integrated monitoring system that enhances the clinical management of patients with breast cancer by enabling real-time tracking of cardiovascular parameters. This innovative approach not only seeks to improve patient outcomes but also aims to assist healthcare providers in making informed treatment decisions related to patients' QoL and risk of cardiotoxicity, guided by the Artificial Intelligence-based prediction tools developed within the project.

The primary users of the eHealtHeart mobile application are elderly women, diagnosed with breast cancer. This patient population has been the focus of intense research since cardiotoxicity frequently affects them, reducing life expectancy and QoL significantly [12] . Recent reviews confirm that among breast cancer survivors, especially older women, cardiovascular disease is now the leading

non-cancer cause of death, largely as a consequence of chemotherapy and radiation therapy [13][14]. Adding further complexity to the management and care of this population, 50%-60% of the newly diagnosed breast cancer patients are older than 65 years of age [15]. Beyond the elevated risk of treatment-related cardiotoxicity, many older patients also face frailty, multimorbidity and polypharmacy, reduced mobility, cognitive changes, and variable digital literacy. Psychological distress and social isolation are common and can undermine adherence. The app was therefore designed to pair continuous cardiovascular monitoring with practical education, psycho-emotional support, and simple prompts that facilitate day-to-day self-management.

The design and implementation of the CARDIOCARE intervention solution was based on a user-centered co-design and co-development process, heavily informed by valuable input from the different end-users. The CARDIOCARE concept is primarily driven by "use case" scenarios developed iteratively with the involvement of all stakeholders, including patients, family members and HCPs. Special attention was given to factors like technology acceptance and potential barriers, such as digital literacy since the targeted population is over 60 years old.

While several digital health interventions have been developed for cancer [16][17][18] or cardiovascular care [19][20], they often target younger populations, focus on single domains, or lack formal evaluation through randomized trials. To address this gap, we developed and evaluated the eHealtHeart mobile application specifically designed for elderly female patients with breast cancer at risk of cardiotoxicity. To our knowledge, this is the first multicenter RCT to assess such multilayered intervention in this population.

Related Work

The eHealtHeart mobile application was developed to support the overall health and QoL of elderly patients following breast cancer treatment, with a particular focus on those at risk of therapy-induced cardiotoxicity. To inform its development, we conducted an in-depth analysis of existing mobile health (mHealth) applications, identifying current capabilities, limitations, and unmet needs that eHealtHeart seeks to address. A total of 9 mobile applications were identified as relevant comparators. Of these, 4 primarily address physical activity and vital signs monitoring, two focus on improving psychological well-being and QoL, and 2 incorporate electrocardiographic (ECG) data collection and analysis.

(i) MyFitnessPal promotes healthy lifestyle behaviors by tracking physical activity and dietary intake, while employing gamification strategies to encourage adherence [21]. (ii) Cardiogram connects to smartwatches and provides continuous insights into heart function, sleep quality, and stress levels [22]. (iii) Elite HRV is designed to track heart rate variability (HRV), stress levels, and general wellness, primarily for fitness users [23]. (iv) Fitbit offers a user-friendly interface to monitor daily activity, including step count, distance, calories burned, floors climbed, and active minutes [24]. (v) MindShift focuses on anxiety management, guiding users in relaxation techniques, cognitive restructuring, and engagement in healthy activities [25]. Happify delivers psychological support through evidence-based activities intended to enhance mood and emotional resilience [26].

In terms of cardiovascular data captured via ECG signals: (i) The ECG EKG Recorder for Polar H10 allows the users to record and see the ECG, heart rate (HR), and the R-R interval (RR) [27]. (ii) the Qardio integrates ECG, blood pressure, and HR monitoring via proprietary devices (QardioArm, QardioBase 2, QardioCore) [28]. (iii) the Kardia by Alivecor enables quick ECG recordings (30 seconds) and provides heart rhythm, HR, and blood pressure data via KardiaMobile or KardiaBand devices [29]. While existing health applications offer valuable features, such as fitness tracking, stress management, or ECG monitoring, most are limited to a single domain, target younger or general populations, and are rarely evaluated in randomized controlled trials. While existing health applications offer valuable features such as fitness tracking, stress management, or ECG monitoring, most are limited to a single domain, target younger or general populations, and are rarely evaluated

in randomized controlled trials [16-19]. The eHealtHeart mobile application was developed to fill this gap by delivering a comprehensive, clinically tailored solution for elderly patients with breast cancer at risk of treatment-induced cardiovascular complications. It integrates physical activity tracking, HRV analysis, psychological support, and lifestyle monitoring within a single, user-centered platform. Notable features include gamified fitness elements and evidence-based tools to support mental and emotional well-being. This holistic and multidimensional approach enables continuous health surveillance and individualized care, setting the eHealtHeart app apart from general-purpose mHealth apps that lack integration across clinical domains and disease-specific personalization. The eHealtHeart app represents a novel, specialized digital health tool designed to meet the complex needs of a high-risk oncological population. A comparison of the features of the reviewed applications is presented in Table 1.

Table 1: Overview of Health and Wellness Mobile Applications

App Name	Description	Main Features
MyFitnessPal [21]	An application that promotes a healthy lifestyle by monitoring physical exercise and diet. It uses gamification to encourage exercise adherence.	• Diet tracking • Exercise monitoring • Gamification
Cardiogram [22]	Connected to a smartwatch, this mobile application provides information about heart functionality (including heart rate, heart rate variability, and rhythm irregularity alerts), sleep patterns, and stress levels.	• Heart functionality monitoring • Sleep tracking • Stress monitoring
Elite HRV [23]	A wellness and fitness mobile application designed to monitor HRV, stress, and overall well-being, including daily readiness and recovery status based on HRV trends.	• HRV tracking • Stress monitoring • Well-being tracking
Fitbit Tracker [24]	A mobile application with a friendly interface that tracks daily activities and provides information on steps, distance, calories burned, floors climbed, and active minutes.	• Activity tracking (steps, distance, calories burned) • Floors climbed • Active minutes
MindShift [25]	Focuses on anxiety management by guiding users to relax, develop new ways of thinking, and engage in beneficial activities through cognitive-behavioral therapy (CBT) techniques, guided meditations, breathing exercises, and goal-setting tools.	• Anxiety management • Relaxation techniques Cognitive-behavioral strategies

Happify [26]	Helps empower users to control their level of happiness and enhance psychological well-being through evidence-based activities, interactive games, mindfulness exercises, and guided reflections based on positive psychology principles.	• Happiness tracking • Psychological well-being • Positive psychology activities
ECG Recorder for Polar H10 [27]	A user-friendly mobile application that allows users to record and view the ECG, HR and the R-R interval RR.	• ECG recording • HR monitoring • R-R interval tracking
Qardio [28]	Provides measurements such as blood pressure and HR data.	• Blood pressure monitoring • HR tracking
Kardia by Alivecor [29]	Records the individual's ECG in 30 seconds and checks heart rhythm, blood pressure, and HR. Requires KardiaMobile or KardiaBand device.	• ECG recording • Heart rhythm monitoring • Blood pressure tracking
eHealtHeart	A comprehensive mobile application specifically tailored for breast cancer patients at risk for cardiotoxicity. Combines fitness, gamification, wellness, and psychological support in a holistic approach.	• Comprehensive health monitoring • Fitness tracking • Psychology & Wellbeing • HR monitoring • Cognitive Stimulation • Gamification • Nutrition Assessment • Hand Grip Strength Dynamometer • Patient-Reported Outcome Measures (PROMS) and Patient-Reported Experience Measures (PREMs) • Vision Assessment • Hearing Assessment • Incontinence management • Education and Training • Smart recommendations • Specialized for breast cancer patients

Unlike many health apps that focus on specific aspects of wellness, the eHealtHeart mobile application incorporates comprehensive monitoring tools specifically tailored for patients with breast cancer who are at risk of cardiotoxicity. It combines unique features such as fitness, gamification, wellness and psychological support, offering a holistic approach that monitors HRV, physical activity and psychological well-being. The eHealtHeart stands out by delivering a truly comprehensive and tailored solution that directly addresses the unique and intricate needs of its users, distinguishing itself from other mobile applications that often focus on broader, more generalized audiences with less specialized approaches.

Methods

The eHealtHeart mobile app was designed as part of the broader CARDIOCARE intervention, with the goal of supporting older patients with breast cancer by combining several tools for health tracking and self-management in app. It brings together wearable sensors, patient-reported outcomes, and a feedback system that updates in real time. In practice, the app is linked to a Garmin smartwatch to monitor physical activity and sleep on an ongoing basis, a Polar H10 chest strap to record HR and HRV, and also a simple hand grip dynamometer, which helps assess muscular strength and serves as a rough proxy for physical frailty.

The design is modular with each component capturing different physiological signals considered relevant for tracking the patient's condition during treatment. The app also includes features to support psychological wellbeing and track QoL using interactive questionnaires that patients fill in at specific time points, following the CARDIOCARE trial protocol. All information, from both sensors and self-assessments, is securely sent to a backend system that clinicians can access. This setup makes it possible to tailor treatment more precisely and intervene earlier when needed, although we must admit that coordinating all these data streams has proven to be complex.

Design Phase

The design phase of the eHealtHeart mobile application, adopted a multi-center interdisciplinary approach. This approach was used to evaluate the efficacy of eHealth behavioral capacity, health outcomes and QoL for the management of the elderly multimorbid patient with breast cancer. The primary objective was to develop a detailed understanding of the patient through direct interaction and engagement, while ensuring that the software architecture was designed to meet the needs of the end users [25]. Each user group possesses distinct needs, interests, and demands and the software architecture was designed focused on effectively addressing those.

Since the patients are a sensitive group consisted of elderly patients, special emphasis was put on the collection and analysis of the requirements of the users and their expectations from the eHealtHeart mobile application. The user needs collection strategy within CARDIOCARE project, involved organizing several focus groups, questionnaires and interviews to collect input from users. The collection of user needs aimed to define a set of specifications which were utilized as a basis for the mobile application design and implementation. Use cases were created and presented to end users to identify requirements and potential restrictions. The use cases were refined accordingly to meet and fulfill the needs of both groups of end users. An additional set of questionnaires has been designed to collect data on usability and functionality expectations. The questionnaires were answered by 43 patients with breast cancer, while dedicated interviews were also held. Several focus groups have been organized with HCPs, in which the different aspects of the eHealtHeart mobile application were defined, examined and evaluated and a preliminary definition of the main characteristics and modules was prepared. In these focus groups the mockups of the mobile application were presented, and the HCPs were encouraged to express their opinions on potential improvements and concerns. The methodological approach followed in the design phase of the eHealtHeart mobile application is presented in Figure 1.

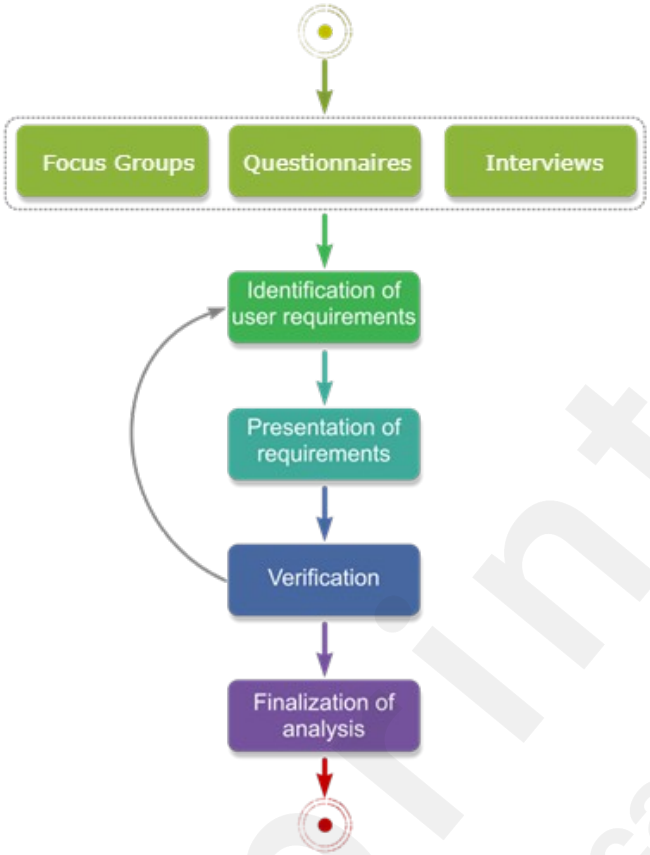

Figure 1: Design phase workflow

The design and development of the eHealtHeart mobile application were the result of close, iterative collaboration between technical developers and clinical experts across the CARDIOCARE consortium. This interdisciplinary partnership enabled a dynamic co-development process, ensuring that each functional feature was clinically relevant, technically feasible, and aligned with real-world medical workflows. Continuous feedback loops between software engineers, HCPs, and end-user representatives allowed for agile refinement of the application's modules, enhancing usability while maintaining adherence to clinical protocols. Recognizing the cultural and linguistic diversity of the study population, the application was developed with multilingual support from the outset. Initially created in English, the interface and content were professionally translated and culturally adapted into 4 additional languages, Greek, Italian, Slovenian, and Swedish, to support the multicenter clinical trial conducted in Greece, Cyprus, Italy, Slovenia, and Sweden. This localization process was critical not only for patient comprehension and engagement but also for facilitating seamless integration into site-specific clinical environments and improving the fidelity of patient-reported data.

The eHealtHeart Module Availability

The eHealtHeart mobile application comprises 6 core modules and 19 submodules, each designed to address specific clinical and psychosocial aspects of care for elderly patients with breast cancer. Module accessibility is customized based on study group allocation: participants in the control group are granted access to a subset of the application's features, while those in the intervention group have full access to all modules and functionalities. Figure 2 displays the available modules, with the control group having access to the modules depicted within the left rectangle, and the intervention group within the right rectangle. Moreover, the intervention group can access both the modules assigned to the control group and those specifically designed for the intervention group. The "Mobility and Vitality" and the "Psychology and Wellbeing" modules which are available for both

patient groups, monitor patients' physical activity using sensors and a hard grip dynamometer and help patients to express their feelings, as well as completing patient reported outcomes (PROs). The "Cognitive and Stimulation" module aims to improve cognitive simulation through gamification. The "Education and Training" module provides educational material tailored for patients with breast cancer. The "Geriatric Syndromes Assessment" module manages geriatric syndromes such as incontinence and fall detection. The "Vision and Hearing" module includes tests to assess patients' vision and hearing. Finally, a recommendations feature is available for both groups, which collects data and provides personalized advice to patients. In addition, both groups have access to a personalized recommendation engine, which aggregates data collected from sensors and user inputs to generate adaptive, patient-specific guidance for self-management and behavior modification. This modular and tiered architecture ensures that the intervention remains adaptable to patient needs, ethically appropriate within a clinical trial framework, and scalable for future implementations across diverse clinical settings.

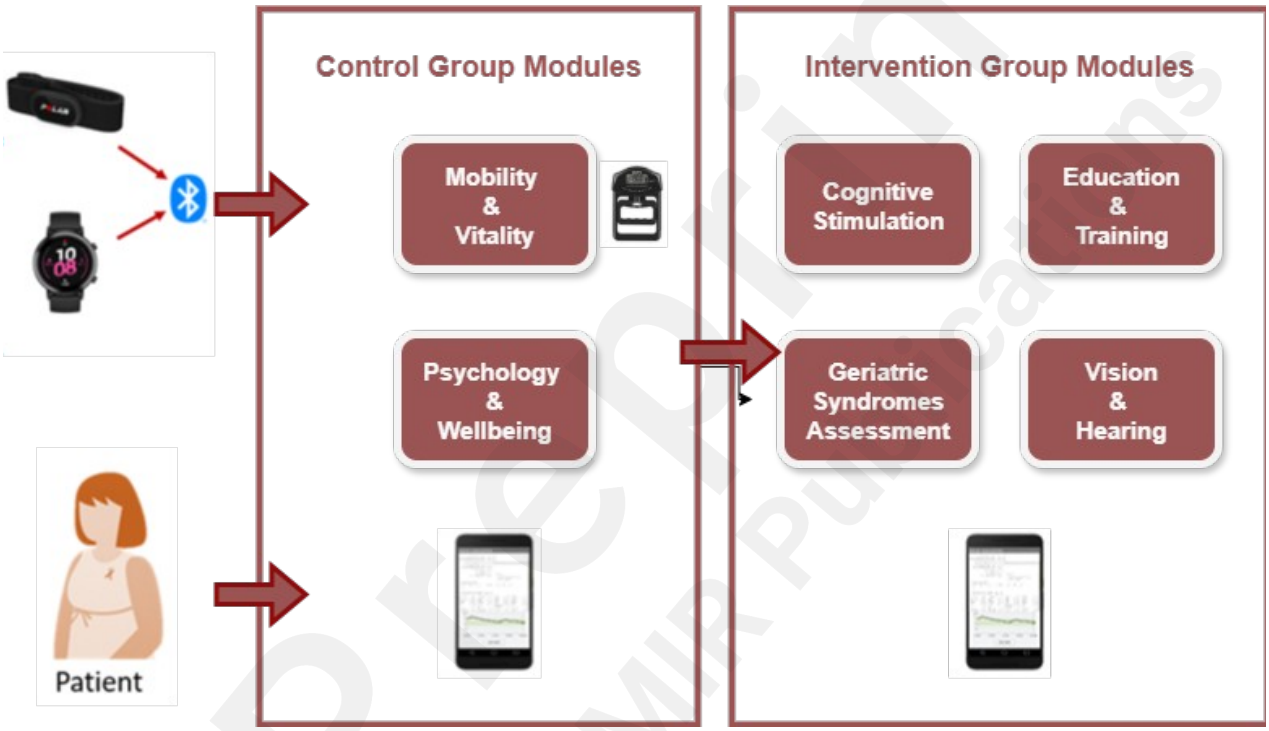

Figure 2: eHealtHeart Available Modules

Development Phase

The methodology adopted to identify end user needs was based on an agile, user-centered design approach. The development phase followed numerous iterations and software advancements. The architecture of the eHealtHeart application is a combination of robust components and practices focused on the creation of a healthcare application on managing patients with breast cancer who are at risk for developing cardiotoxicity. The approach followed a module-based development to allow iterative improvements and revisions based on users' feedback. The integrated modules are tailored to support both patients and HCPs focusing on PROs, data management and comprehensive analytical tools. There are four distinct layers in the system's architecture:

1. The Data Tier layer, which is the foundation of efficient data handling, transformation and serving mechanisms.

2. The Modules Tier layer, which is the technological modules, including electronic PROs accessible, Sensors and Internet of Things (IoT) modules, alongside self-management and psycho-emotional evaluation tools. The modules available in the application are divided based on the intervention group and the focus group.

3. The Interaction Tier layer, which features innovative user interfaces specifically designed to align with the needs and preferences of end-users.

4. The Backend and Security Tier layer, which is responsible for user privacy and data integrity, and follows strict security protocols. The tiers and their interactions are shown in Figure 3.

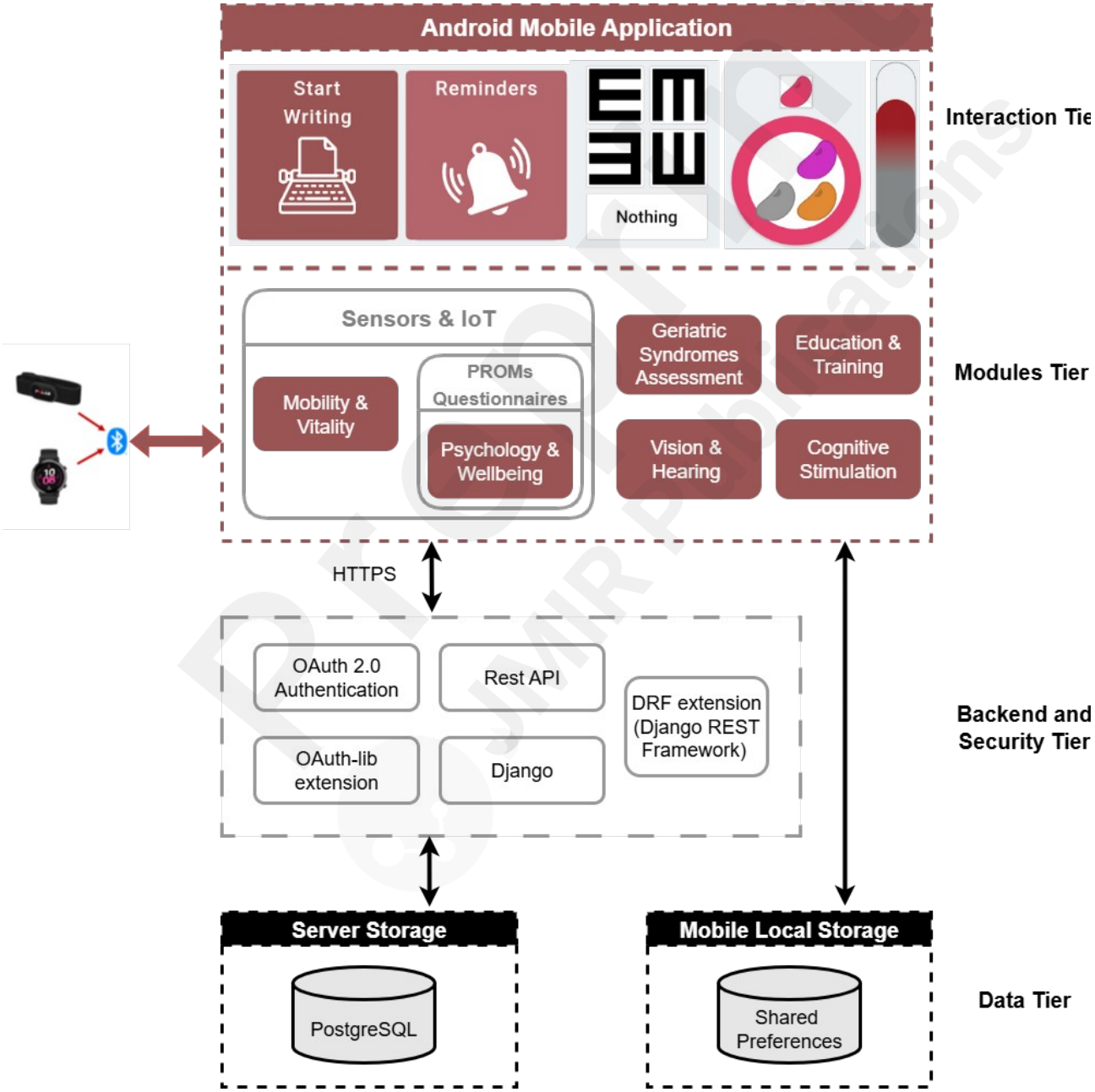

Figure 3: eHealtHeart Mobile Application Tiers

The process of creating, storing and sharing personal data while complying with data security regulations requires a comprehensive set of functions provided by well-designed interconnected

components. To address this challenge, CARDIOCARE has designed a flexible architecture with multiple components. These components are combined to create an innovative solution with an improved user interface, allowing patients and healthcare professionals to fully benefit from its features and resources.

The eHealtHeart application integrates a smartwatch and a HR sensor to enable continuous tracking of HR, physical activity, and sleep quality. These smart devices provide valuable insights and improve health monitoring of the patients. Data from these devices is transmitted to the system's Data Tier, where it is processed and stored in line with established security protocols. These wearables provide real-time monitoring of patients cardiovascular and health condition and are part of "Mobility & Vitality" and "Psychology & Wellbeing" modules.

The eHealtHeart was built to be user-friendly. It combined questionnaires, timely alerts, and gamification so patients can navigate the application without difficulties. The "Privacy by Design" [26] supported by the European Commission's General Data Protection Regulation (GDPR), has emphasized the integration of data protection measures into products and services right from their inception. The eHealtHeart mobile application embraces the principles of "Privacy by Design," incorporating them not only into technical solutions but also into organizational procedures and business models, thus ensuring a comprehensive approach to privacy and security.

Iterative Validation and Refinement

During the development process, software validation is important in order to confirm that the application covers functional requirements and user needs. This phase included usability testing with actual users, patients and HCPs, to help refine the application's features and overall design. To better understand patient experiences, interviews were also carried out at the end of each user's interaction with the mobile application, providing insights that supported further development.

A clear description of the concept and aim of the eHealtHeart mobile application was provided at the start of each interview to inform the patients of the overall objective of the mobile application. Patients interacted with the mobile application and offered real-time feedback which provided the opportunity to observe their engagement and ease of use. The patients were encouraged to express their initial reaction and concerns and the validators were discouraged from intervening or provide guidance. Moreover, focus groups were conducted with the HCPs to discuss patients' comments, reactions and worries.

The feedback and insights from these resulted in significant technical improvement which focused on optimizing the user interface and error handling. The validation phase was conducted to evaluate the mobile application, ensuring its usability in the clinical practice. In the validation phase, significant technical issues were addressed based on the received feedback and were integrated in the final version of the mobile application. Our goal was to create a refined application based on real user feedback which fulfills the user needs, design specifications and predefined requirements.

Pilot for Adults

The eHealtHeart mobile application is to meet the specific needs of elderly patients with breast cancer, with emphasis on ease of use, personalized health tracking, and psycho-emotional support. The clinical evaluation of the application was embedded within the CARDIOCARE randomized controlled trial, whose study protocol was collaboratively developed by representatives from all participating clinical sites and key consortium partners. This inclusive, multidisciplinary approach ensured that the protocol reflected both scientific rigor and patient-centered care principles. The clinical centers participating in the CARDIOCARE clinical trials are:

- The Karolinska University Hospital (KSBC), Sweden.
- The Bank of Cyprus Oncology Centre (BOCOC), Cyprus.
- The European Institute of Oncology (IEO), Italy.

- The Institute of Oncology Ljubljana (IOL), Slovenia.
- The National and Kapodistrian University of Athens (NKUA), Greece.
- The University of Ioannina (UOI), Greece.

These centers were selected based on their recognized expertise in breast cancer care, as well as their proven capacity to conduct complex, multicenter clinical trials, ensuring high standards in patient recruitment, monitoring, and data integrity.
The recruitment period is set to twelve months and ethical approval for the study was obtained from ethical committees in each country involved, ensuring compliance with local regulations. During enrollment, patients are randomly assigned to either intervention or control group. Participants, then, use the eHealtHeart mobile application according to their group allocation, with access to specific modules as defined in the study protocol.
To be eligible for inclusion in the study, each patient must fulfill any of the criteria below:

- Women ≥ 60 years with a diagnosis of early/locoregional breast cancer who will undergo neoadjuvant and/or adjuvant treatment with regimens including anthracyclines and/or taxanes and/or endocrine therapies +/- CDK 4/6 inhibitors.
- Women ≥ 60 years with a diagnosis of HER2-positive early/locoregional breast cancer who will undergo neoadjuvant and/or adjuvant treatment with anti-HER2 therapy (trastuzumab or trastuzumab and pertuzumab).
- Women ≥ 60 years with HER2-positive metastatic breast cancer who will undergo first-line therapy with anti-HER2 therapy (trastuzumab or trastuzumab and pertuzumab +/- chemotherapy).
- Women with age ≥ 60 years before starting the aforementioned treatment for breast cancer.
- Women eligible ≥ 60 years who will undergo first-line therapy in the metastatic setting with any type of treatment (chemotherapy, immunotherapy, biological agents).
-

Furthermore, patients can be included in the study if they:

- are willing and able to comply with scheduled visits, laboratory tests, and other trial procedures,
- are able to understand provided information and can provide written informed consent.
- are affiliated to a social security system.
- have a life expectancy of at least 12 months.

Exclusion criteria:

- Age < 60 years.
- Diagnosed with severe psychiatric or neurological disorders that might impair their ability to give informed consent.

In line with the clinical study protocol, patients are informed regarding the study and provide written consent prior to participation. After randomization, patients in each arm actively contribute data over a period of 6 months, as part of the main usage phase. Patient data are anonymized and securely stored to ensure confidentiality, following GDPR guidelines. Recruitment is underway across all clinical centers (KSBC, UOI, NKUA, BOCOC, IOL, and IEO) and 617 patients have been enrolled in the clinical study so far.

Proposed Digital Intervention Model

The CARDIOCARE System Architecture

The architecture of the CARDIOCARE system consists of multiple components and their interactions as shown in Figure 4. The system's final architecture is a result of multiple software development cycles influenced by end-user interactions. It consists of the mobile application, the healthcare professional platform and the administration tool which are available as web applications.

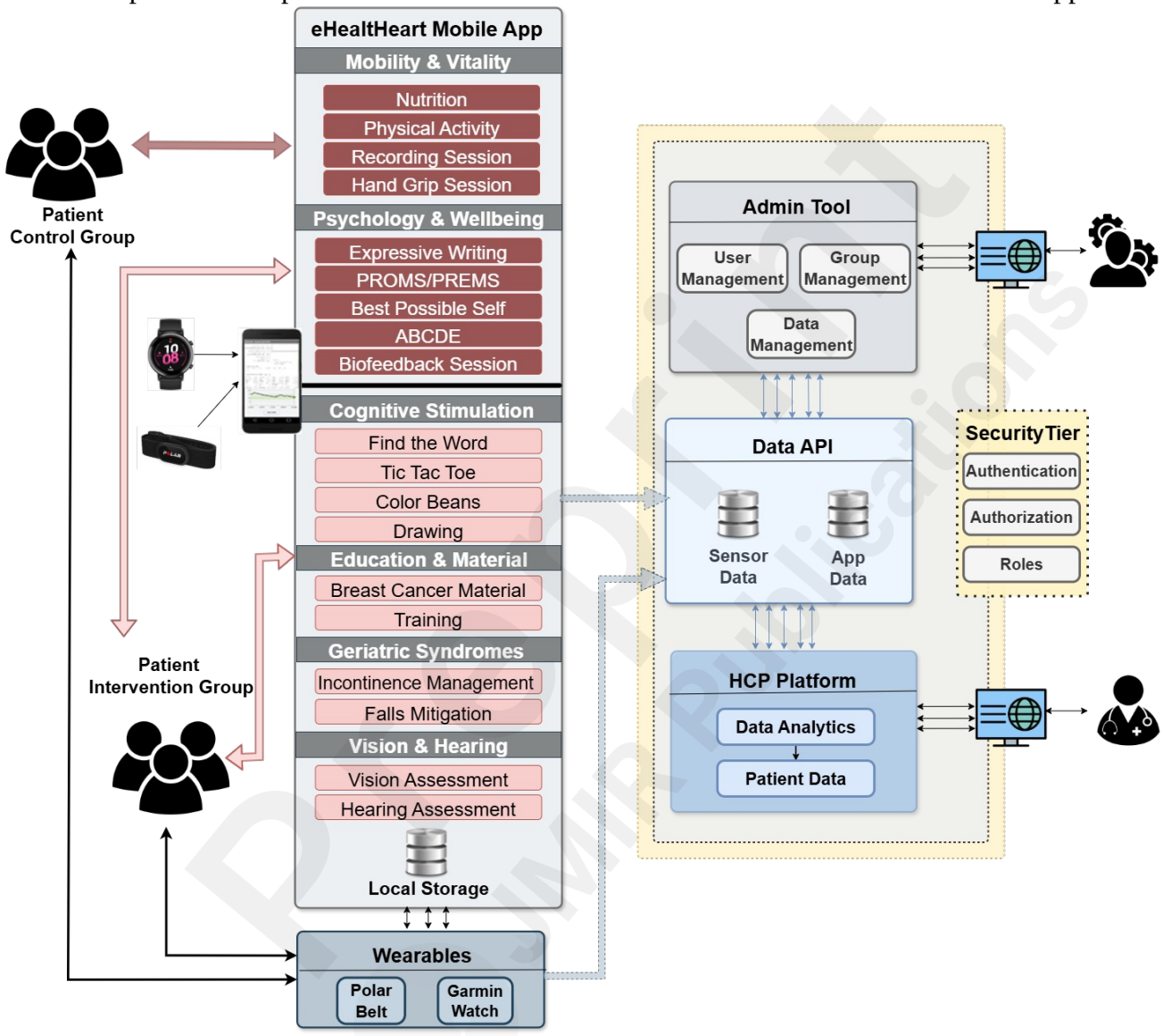

Figure 4: CARDIOCARE System Architecture

The eHealtHeart Mobile Application

The eHealtHeart Mobile Application was developed as part of the CARDIOCARE project to assist with overall assessment of the patients. The application's UI/UX is designed based on best practices for elderly users and focuses on women over the age of 60 [30][31], particularly on aspects such as accessibility and usability for users facing physical challenges (impaired eyesight, deterioration in haptic feedback, reduced hearing) and experiential challenges (unfamiliarity with modern technologies, limited understanding of processes, non-intuitive controls)[32][33]. Gamification and touchscreen interactions were similarly designed following the aforementioned design patterns [34]. These efforts ensured that the eHealtHeart mobile application remains accessible and user-friendly

for its target users.

The data collected through the application, are made available to the HCPs in order to assess the patients cognitive, mental and physical status through the web platform. Through the modules of the mobile application the patient is provided with various tools. The available modules are:

Mobility & Vitality module consists of 4 submodules: nutrition, physical activity, cardio recording session and hand grip session. It provides patients with tools that monitor physical activity and sleep quality through smartwatches, assess dietary habits through detailed questionnaires, and monitor cardiovascular health by performing electrocardiograms using a HR sensor. Additionally, a hand grip dynamometer measures physical strength, providing critical data on the patient's physical endurance. Examples of the mobility and vitality module are shown in Figure 5.

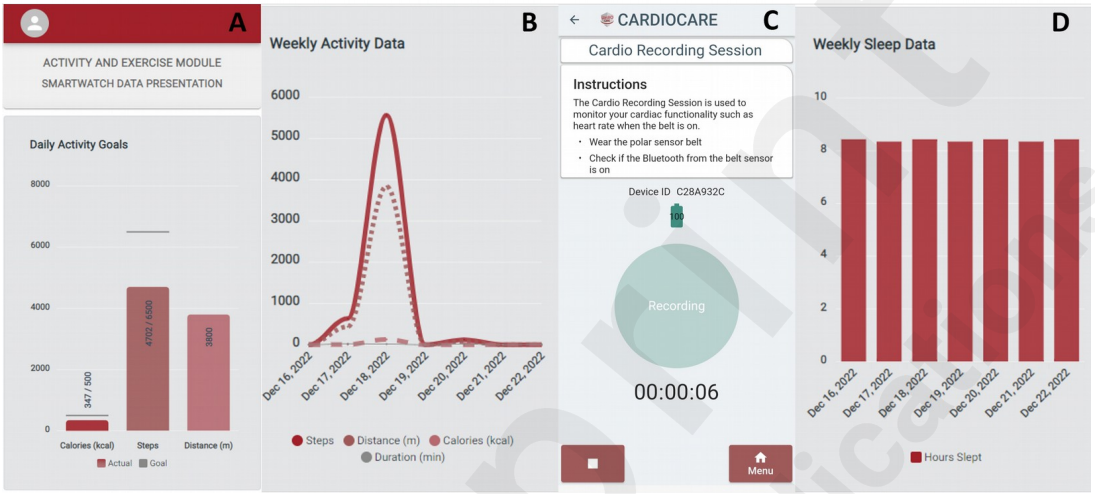

Figure 5: A) Activity Goals B) Activity Data C) Cardio Recording Session D) Sleep Data

Cognitive Stimulation module consists of 4 submodules and engages patients with games such as “Find the Word”, “Tic Tac Toe”, “Color Beans” and “Drawing”. The gamification provides mental stimulation but also tracks the cognitive agility and responsiveness, crucial elements in assessing overall brain health. Examples of cognitive stimulation module are shown in Figure 6.

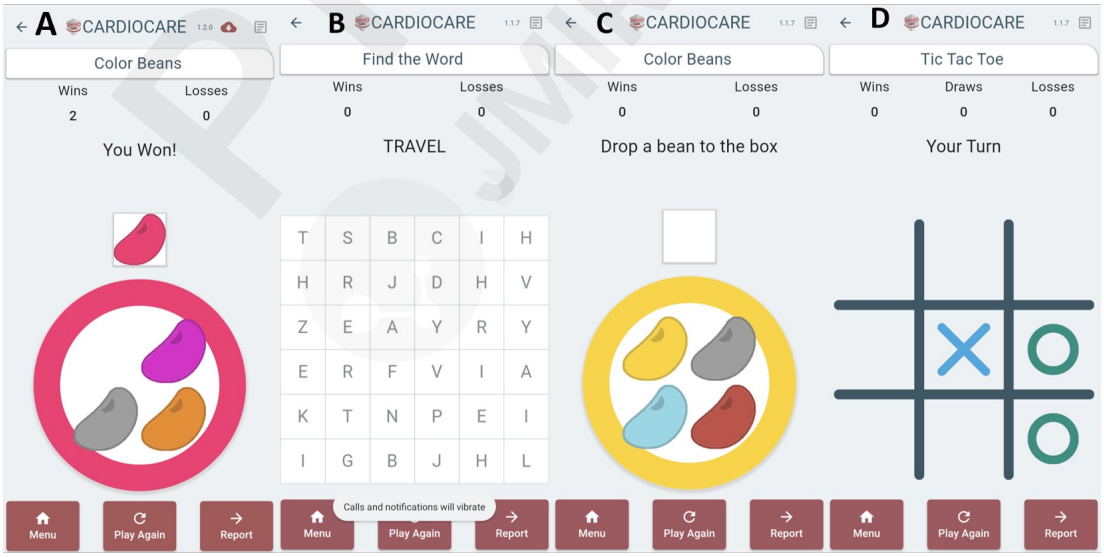

Figure 6: A) Drawing B) Find the Word C) Color Beans D) Tic Tac Toe

Education & Training module consists of 2 submodules: breast cancer material and training, and provides patients with important information regarding breast cancer and related health issues. Moreover, specifically designed interactive videos are available to help patients improve their

strength and balance which are important for preventing falls and promoting independence. Examples of the available modules are shown in Figure 7.

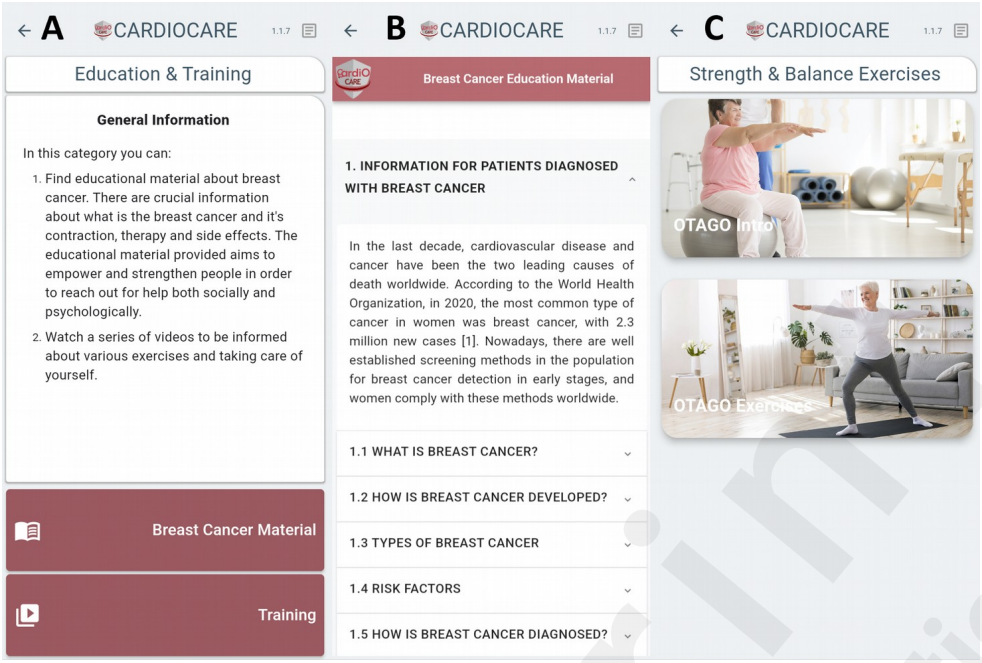

Figure 7: A) Submodules B) Breast Cancer Material C) Training

Geriatric Syndromes Assessment module consists of 2 submodules: incontinence management and fall mitigation, and provides the patient with tools to manage geriatric syndromes such as incontinence and fall detection. Data of these assessments are shown on the HCP platform, so clinicians can spot early functional decline or safety risks and tailor care accordingly, by adjusting therapy intensity, reviewing fall-risk medications, initiating continence support or arranging targeted referrals. Patients can log their urine events, perform pelvic exercises[35] or enable prompted voiding[36]. Prompted voiding is a process to help the patient void normally by tracking and reminding toilet. Additionally, reminders for toilet use and pelvic floor exercises are available. Finally, patients can enable the fall detection service for fall tracking. Examples of the module are presented in Figure 8.

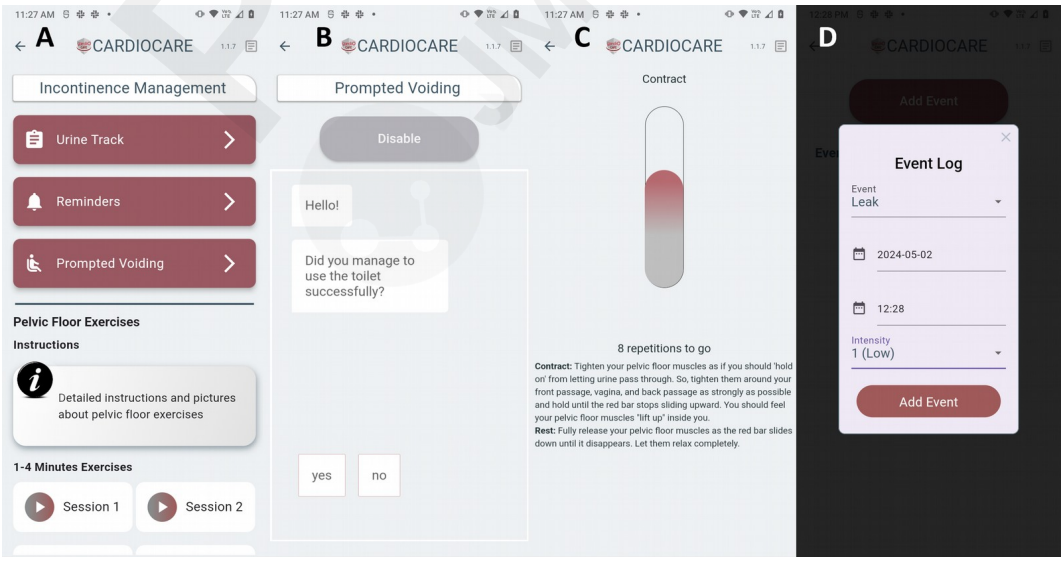

Figure 8: A) Incontinence Module B) Prompted Voiding C) Pelvic Floor Exercises D) Urine Event

Vision & Hearing module consists of 2 submodules: vision assessment and hearing assessment. It

includes specialized tests to evaluate the deterioration of vision and hearing which can impact the overall QoL. Vision assessment simulates the equivalent ophthalmological test and hearing assessment presents sounds using various frequencies and volumes in a digital form. Examples of hearing and vision tests are shown in Figure 9.

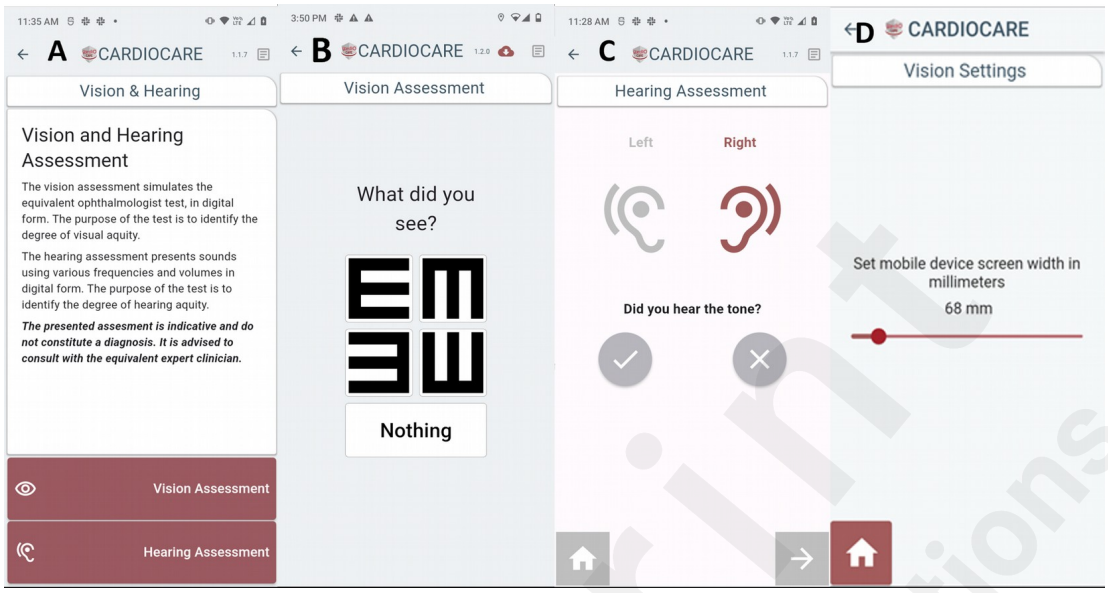

Figure 9: A) Submodules B) Vision Assessment C) Hearing Assessment D) Vision Assessment

Psychology & Wellbeing module consists of 5 submodules, Expressive Writing (EW)[37], PROMS, Best Possible Self (BPS)[38], ABCDE[39] and a biofeedback session. These help patients express their emotions and additionally complete monthly psychological questionnaires. Moreover, patients can reflect on past events and perform biofeedback sessions to monitor and improve their HR through breathing exercises, therefore reducing their stress or anxiety levels. The application uses sensors to facilitate these assessments such as the Polar H10 sensor which is a HR monitor chest strap that measures patients HR. Moreover, reminders for completing the expressive writing, best possible self and ABCDE modules are available.

The PROs available in the “Questionnaires” submodule are:

- European Organization for Research and Treatment of Cancer Quality of Life questionnaire (EORTC QLQ-C30) which assess general quality of life [40],
- EORTC QLQ-C30 for breast cancer (EORTC QLQ-BR23) which assesses cancer-specific quality of life[41],
- Life Orientation Test Revised which measures optimism (LOT-R) [42],
- Functional Assessment of Chronic Illness Therapy Fatigue Scale (FACIT-F) which assesses fatigue[43],
- Brief Resilience Scale (BRS) which measures resilience[44],
- Burden Scale for Family Caregivers (BSFC-s) which evaluates caregiver burden [45],
- The Four-Item Patient Health Questionnaire for Anxiety and Depression (PHQ-4) which screens for anxiety and depression[46],
- Emotion Regulation Questionnaire (ERQ) which assesses emotion regulation[47],
- Multidimensional Scale of Perceived Social Support (MSPSS) which measures perceived social support[48],
- Cancer Behavior Inventory short form (CBI-B) which assesses body image[49],
- Perceived Stress Scale (PSS) which measures perceived stress[50],
- Brief measure of positive and negative affect (PANAS) which assesses the positive and

negative effect[51],

- The Impact of Event Scale: Revised(IES-R) which measures post-traumatic stress symptoms[52],
- Self-Control and Self-Management Scale (SCMS) which measures adaptive self-regulatory coping skills and
- Satisfaction With Life Scale (SWLS) which measures life satisfaction[53].

Examples of “Psychology and Wellbeing” module are presented in Figure 10.

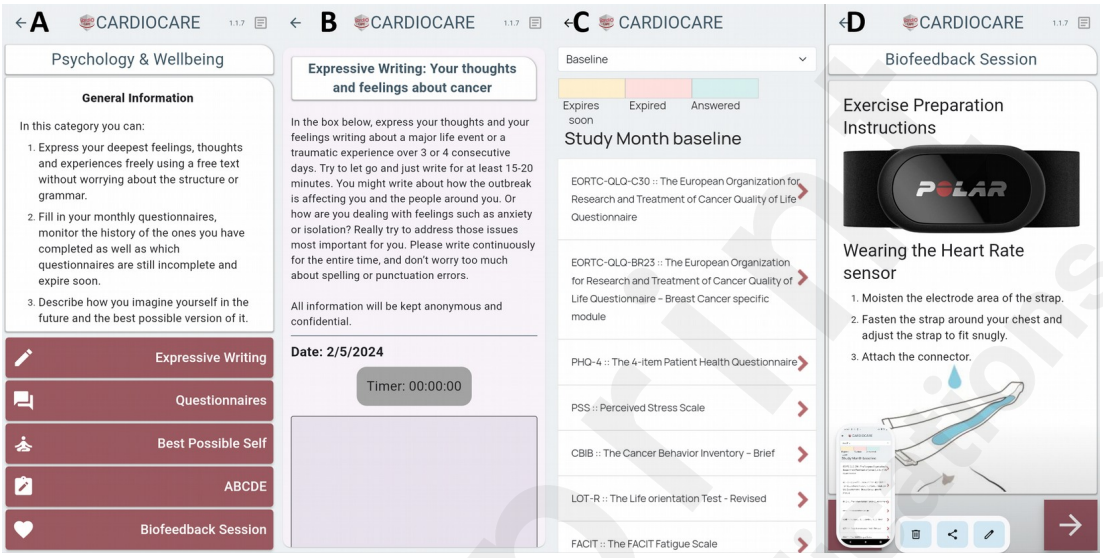

Figure 10:A) Submodules B) Expressive Writing C) Questionnaires D) Biofeedback Session

All modules and submodules have detailed descriptions and instructions at their initial pages. Moreover, a recommendation feature is available for both patient groups which collects data from wearables and questionnaires, and provides personalized advice through smart suggestions like a personal health guide. The goal of this functionality is to help patients improve their QoL by suggesting actions like breathing exercises to reduce stress, mobility exercises for strength, reminders to complete questionnaires and read the in-app educational material. Finally, the app uses a scoring system based on cognitive and psychological assessments to recommend playing cognitive stimulation games. An example of a smart recommendation is shown in Figure 11.

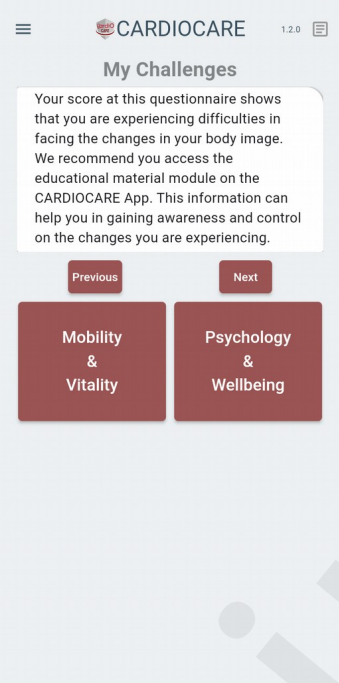

Figure 11: Smart Recommendation

Backend and Security

A centralized approach to manage data is followed in the mobile application deployment. All study-related data are stored in a single server, thereby simplifying data management and enhancing security. The centralized data management process eliminated the need for separate installations across various clinical sites and reduced the complexities arising from data transfer.

The infrastructure supporting CARDIOCARE, primarily comprises a database for storing CARDIOCARE data, an OAuth2.0-based authentication server, and essential software modules to facilitate their operations. Additionally, administrators are provided with a user interface for management and testing of available REST services. The administrator can utilize the platform to manage user groups which are divided in Patient, Administrator and Clinician. Part of the initial screen of the administration panel is shown in left part of Figure 12.

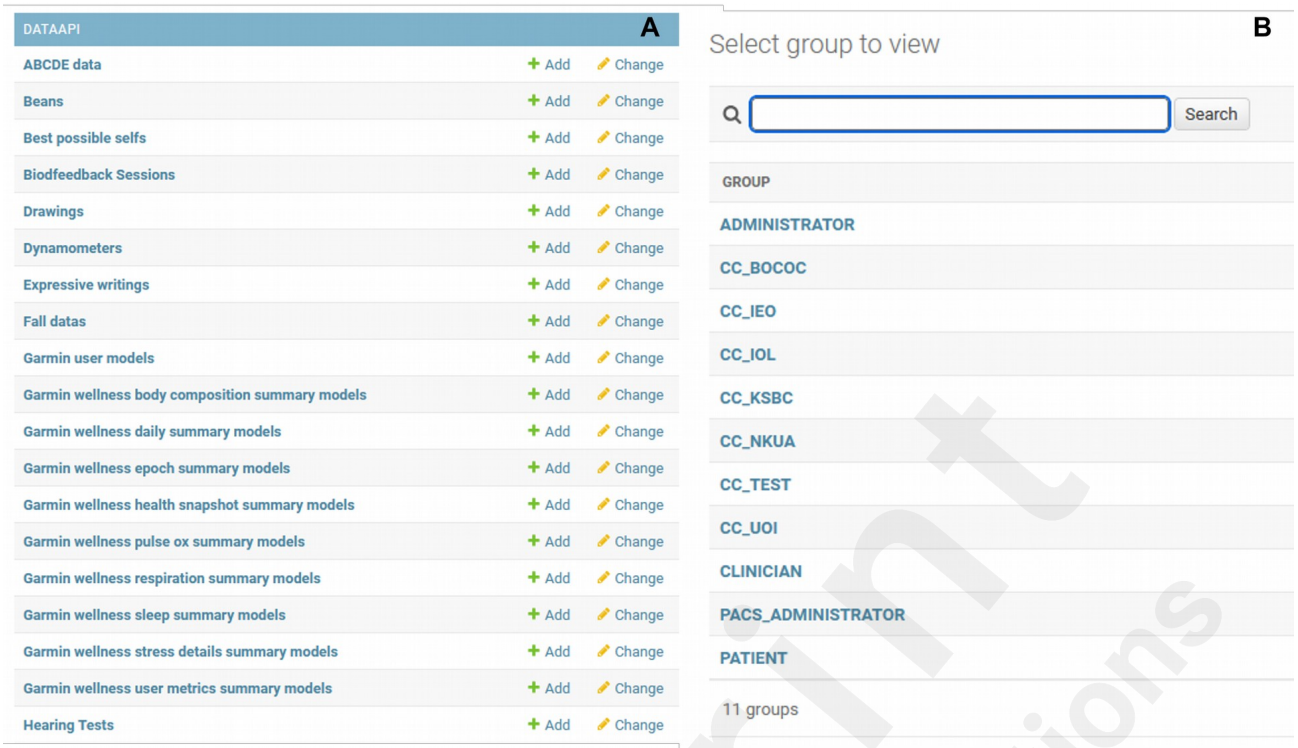

Figure 12: Administrator Panel A) Home screen B) Groups page

The administrator's user interface offers the following functionalities:

In the "Groups" section, administrators can view a list of group categories. Typically, no modifications are required in this section as it is preconfigured during the platform's initial installation. The available groups are created based on the clinical site and users' role. The groups' page is shown in right part of Figure 12.
In the "Users" section, administrators can access a list of existing users (displaying user account pseudonyms and minimal data) and add or modify their accounts as needed. The users' personal information is anonymized, ensuring that the administrator does not have access.
In the "Data API" section, the administrators supervise the endpoints utilized for the transmission of data from the mobile application. These endpoints include various functionalities such as managing questionnaires, hearing tests, pelvic floor exercises and processing polar data etc. The Data API facilitates the transfer of data between the mobile application and the backend system, enabling efficient data collection and analysis. The data transfer through the API is using OAuth 2.0 server which provides authentication and authorization. Administrators monitor the usage of these endpoints to ensure efficient data flow, essential for the application's operation. The system follows GDPR guidelines for data protection and patient data are anonymized in order to protect patient privacy and ensure compliance with ethical regulations.

Results and Evaluation

The CARDIOCARE clinical trial is still ongoing. The results presented here reflect a preliminary usability and acceptance evaluation based on 79 patients who have completed their six-month study period and the associated questionnaires. Full-scale evaluation will be conducted once data collection is complete across all clinical sites. To evaluate the usability, acceptability, and quality of the eHealtHeart mobile application, we used a structured questionnaire consisting of five sections:

1. **Background Information**: Collected participants' age, education, occupation status, experience with mobile applications (medical and non-medical), digital comfort, and self-perceived technology literacy.

2. **System Usability Scale (SUS)**: A standardized 10-item scale assessing perceived usability on a 0–100 scale. For SUS scores 68 is used as the benchmark for acceptable usability.

3. **Technology Acceptance Model (TAM)**: Included four constructs

    - **Perceived Usefulness (PU)** (5 items),
    - **Perceived Ease of Use (PEU)** (3 items),
    - **Intention to Use (IU)** (3 items), and
    - **Attitude Toward Use (ATU)** (4 items), each measured on a 5-point Likert scale (1 = Strongly disagree, 5 = Strongly agree).

4. **Application Functionality**: Users rated ease of use, performance, and feature quality using items inspired by the user version of the Mobile Application Rating Scale (uMARS).

5. **Application Reliability and Security**: Evaluated system stability, data accuracy, and perceived data security using Likert-type and binary (yes/no) responses.

These usability and acceptance measures were completed by patients only. However, healthcare professionals contributed during the design and iterative testing phases, offering feedback on clinical relevance, workflow integration, and the clarity of data presentation. Below we report the findings for each questionnaire in the exact order of administration. All statistics presented below are based on the responses of patients (n = 79).

Participant Profile

Participants were on average 67.9 (SD 5.6) years old (range 60–86). The majority were retired (53/79, 67%) and had completed high school (50/79, 63%) or held a higher education degree (Master's or above: 21/79, 27%). Most participants had prior experience in using general mobile applications (61/79, 77%), while 35 (44%) reported the use of medical apps. The average self-rated Digital Literacy Index was 3.22 (SD 1.01), and Tech Savviness was 3.06 (SD 1.03).

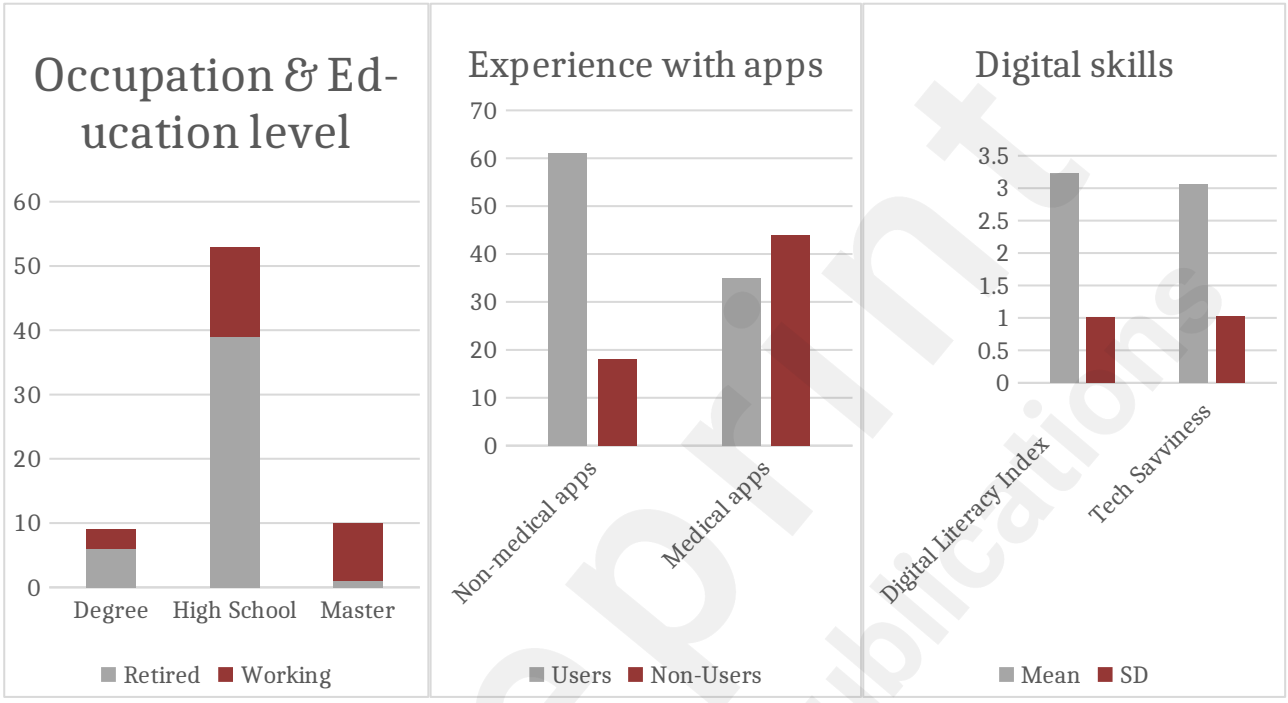

Figure 13: Participant characteristics including occupation status, educational level, experience with apps and digital skills.

System Usability Scale (SUS)

Using the 10-item System Usability Scale, the eHealtHeart mobile application received a mean SUS score of 69.1 (SD 15.8), slightly above the usability benchmark of 68. Participants with higher digital literacy rated the app significantly higher (mean 74.3 (SD 14.1)) than those with lower literacy (mean 60.1 (SD 15.2); $t_{84} = 3.54$; $P < .001$). An independent-samples t-test confirmed this difference between the high- and low-literacy groups, indicating that greater digital literacy was associated with significantly higher perceived usability. Results showed:

- **High literacy group**: SUS = 74.3 (SD 14.1)
- **Low literacy group**: SUS = 60.1 (SD 15.2)
- **$t(84) = 3.54$, $P < .001$**

This difference is statistically significant, indicating that higher digital literacy is associated with significantly higher perceived usability of the application.

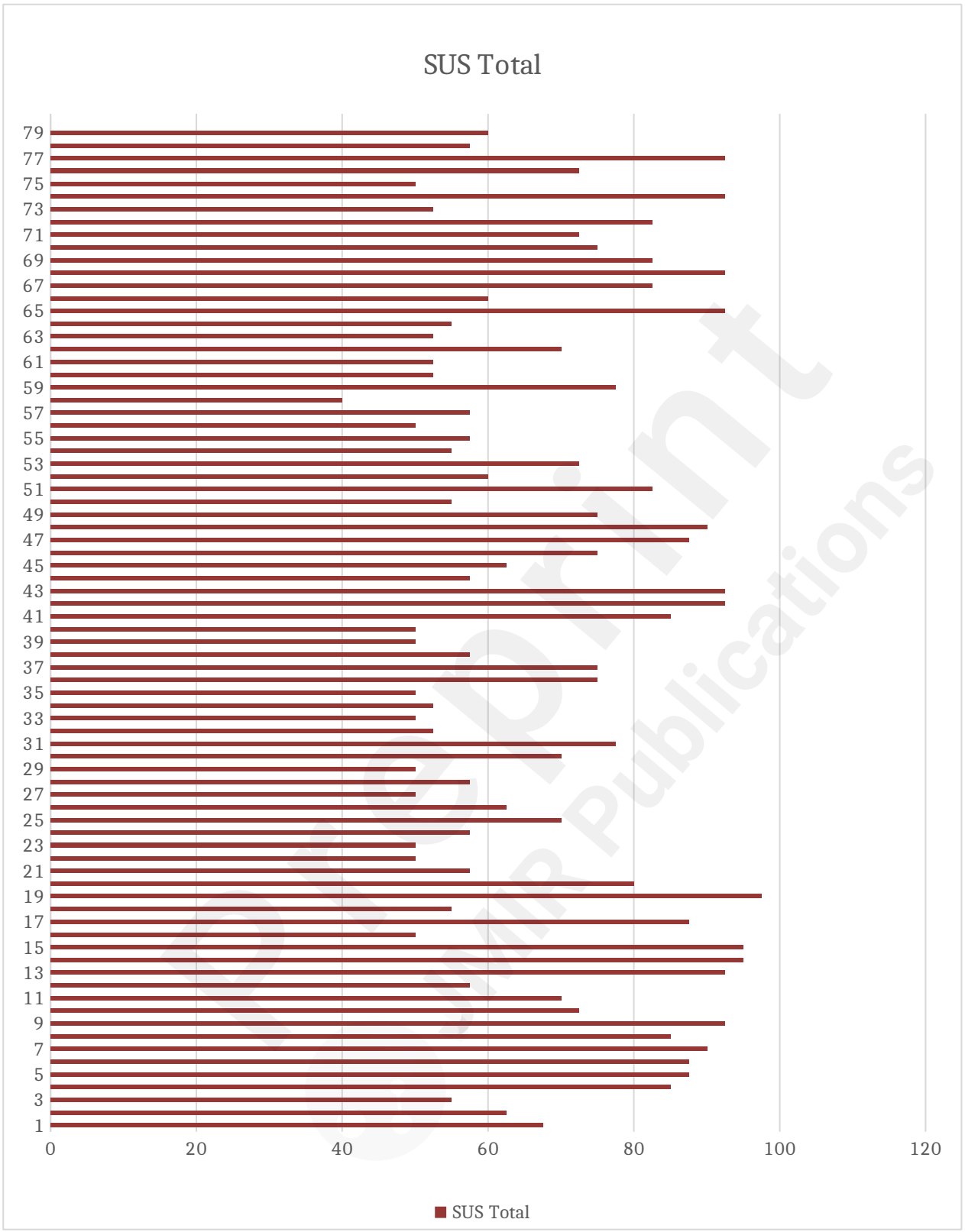

Figure *14*: SUS Total Per User

Technology Acceptance Model (TAM)

The TAM questionnaire was divided into 4 constructs: Perceived Usefulness (PU), Perceived Ease of Use (PEU), Behavioral Intention to Use (IU), and Attitude Toward Use (ATU). All four TAM

dimensions were above the neutral midpoint (3.0). Means and standard deviations are shown below:

Table 2: TAM results

Construct	Items	Mean (SD)
Perceived Usefulness (PU)	5	**3.72 (0.92)**
Perceived Ease-of-Use (PEU)	3	**3.35 (1.05)**
Intention to Use (IU)	3	**3.35 (1.05)**
Attitude Toward Use (ATU)	4	**3.84 (0.83)**
TAM composite Score	15	**3.57 (0.88)**

These results suggest that most users found that the application is useful, reasonably easy to handle and worth adopting. High digital literacy was associated with significantly higher TAM scores (3.79 (0.82)) compared to the low literacy group (3.19(0.82)), P = .001. An independent-samples t-test confirmed this difference in TAM total scores between the 2 groups:

- **High literacy group**: TAM = 3.79 (SD 0.82)
- **Low literacy group**: TAM = 3.19 (SD 0.82)
- **t(84)= 3.36**, ***P* = .001**

This statistically significant result further supports the role of digital literacy in shaping technology acceptance.

Functionality and Reliability Evaluation

Participants rated application features such as ease of use, intuitiveness, and system performance on a Likert scale (1–5). The average scores are presented in Table 3:

Table 3: Functionality and Reliability Results

Dimension	Mean (SD)
Functionality – Ease of Use	**3.96 (0.92)**
Functionality – Performance	**3.21 (0.71)**
Functionality – Features	**3.66 (0.96)**
Functionality Total	**3.61 (0.92)**
Reliability – Stability	**3.94 (0.98)**
Reliability – Accuracy	**3.94 (0.98)**
Overall Reliability	**3.94 (0.98)**

Additionally, only 7% of users reported experiencing data discrepancies, and the majority of patients felt confident that their data were securely stored and processed.

Links between digital skills and usability

These findings underscore the importance of digital literacy in shaping how older adults engage with mobile mHealth tools. Users with higher digital skills consistently reported better usability and

greater acceptance of the application. As shown in Table 4, digital literacy was significantly associated with both SUS and TAM scores, highlighting the value of tailoring support strategies to users' digital capabilities.

Table 4: SUS and TAM by Digital Literacy Group

Metric	**High Literacy Mean (SD)**	**Low Literacy Mean (SD)**	**t(df)**	***P* value**
SUS	74.3 (14.1)	60.1 (15.2)	3.54	< .001
TAM Composite	3.79 (0.82)	3.19 (0.82)	3.36	.001

Based on these results, the eHealtHeart mobile application was generally well received, showing high acceptance and usability even among patients with breast cancer and limited digital experience.

Discussion

Principal Results

This study presents preliminary findings from the ongoing CARDIOCARE randomized controlled trial evaluating the usability and acceptance of eHealtHeart mobile application for elderly patients with breast cancer at risk of cardiotoxicity. Designed with a user-centered approach, the application integrates modules that monitor cardiac function, psychological wellbeing, physical activity, and cognitive status. Beyond usability, the eHealtHeart app was designed with the intention of supporting early detection and timely management of cardiotoxicity in this vulnerable group. By tracking heart rate, heart rate variability, and other relevant parameters, the app enables continuous observation of potential warning signs. This information can be acted upon promptly by healthcare teams, potentially preventing further cardiac decline and improving long-term cardiovascular outcomes. While the app is not a diagnostic device, it is intended to shorten the time between emerging cardiotoxicity signals and clinical action, whether this translates into fewer cardiac events will be evaluated in the completed trial.

Results from 79 participants indicate good usability (mean SUS score of 73.2) and positive user perceptions, particularly regarding ease of use (PEU ≈ 3.9) and intention to continue using the app (IU ≈ 3.6). These early outcomes suggest that even older adults with limited digital experience can successfully engage with well-designed eHealth tools, especially when the interface is intuitive and tailored to their needs. Participants rated the application positively across several measures, including SUS, TAM, and basic reliability, suggesting its use as a helpful tool for supporting cardiotoxicity monitoring and encouraging patient involvement. Strong associations with digital skills underline the importance of short orientation sessions or micro-tutorials to help elderly and not experienced users. Some minor reliability concerns were brought up, primarily relating to sporadic data-sync difficulties. Resolving these issues could increase the app's inclusivity and maintain users' interest over time. The ability to support remote monitoring .proved especially valuable during reduced in-person care (e.g., COVID-19), sustaining breast/gynecologic oncology visits and, in cancer cohorts with COVID-19, reducing hospitalizations under remote-monitoring programs [54][55].

Although this interim evaluation was mainly concerned with usability and how well the application was received by users, the wider clinical significance of the eHealtHeart platform should not be underestimated. By monitoring both physiological and psychological parameters, digital tools like eHealtHeart may help detect complications earlier and support more timely interventions. Earlier identification of cardiotoxicity symptoms or emotional distress could help avoid unnecessary hospitalizations or interruptions in treatment. The inclusion of personalized suggestions and routine feedback could also improve adherence to both medication and lifestyle recommendations which is particularly valuable in patients' groups where motivation tends to reduce due to fatigue or other

factors. Future work will explore the possible links between engagement with the eHealtHeart mobile application and longer-term indicators like cardiac events, reported fatigue and overall quality of life.

Limitations

The insights and results are still preliminary since only 79 patients have completed the evaluation process. The lack of statistical power cannot yet address clinical endpoints. Finally, while usability and user perception were assessed, clinical outcomes (e.g., reduced cardiotoxic events or improved Qol) have not yet been evaluated and will be addressed in the final analysis.

Comparison with Prior Work

Most cancer-focused applications emphasize on a single aspect of care such as physical activity, symptom tracking or medication reminders. While a few cardiology applications monitor heart-related metrics, they often ignore the psycho-social burden associated with cancer therapy. The eHealtHeart mobile application tries to create a holistic approach for the elderly cancer patients that is usually omitted of the digital-health research. Early usability scores and feedback suggest that this tailored approach can overcome common difficulties faced in this population. To our knowledge, this is the first randomized controlled trial to evaluate a mobile application that combines QoL monitoring, psycho-emotional support, cognitive stimulation, educational content, and geriatric assessment tools specifically designed for elderly patients with breast cancer. While previous studies have focused on individual components, such as physical activity, psychological interventions, or heart monitoring, none of them have integrated all these domains into a single, user-centered platform evaluated in a multicenter RCT setting.

This multidimensional, patient- centered approach targets the gap in digital health for older, frail patients, aligning with care principles that emphasize personalized prevention and patient empowerment.

Conclusions

The eHealtHeart mobile application represents a novel, patient-centered approach to managing the complex health needs of elderly patients with breast cancer at risk of cardiotoxicity. Its design and early results show that such technologies can be both usable and acceptable among older adults**,** an often-overlooked group in digital health innovation.

Although these findings are preliminary, they support the feasibility of the use of mobile tools to promote real-time monitoring and more personalized care. The application's multilayered approach, which includes physical, cognitive and psycho-emotional modules, aligns well with modern oncology's shift towards a more holistic and integrated patient-oriented care.

Future work will focus on completing the full clinical trial, evaluating clinical impact and exploring integration with machine learning models to enhance predictive capabilities. Broader validation across populations and care settings will also be essential for establishing the app's generalizability and long-term effectiveness. As digital health continues to evolve, the development and improvement of tools, like the eHealtHeart app, could result in a more inclusive, technology-supported cancer care.

Acknowledgements

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Conflicts of Interest

None declared

Abbreviations

CARDIOCARE: Cardiac Toxicity Prevention in Breast Cancer Patients Through mHealth Interventions
GDPR: General Data Protection Regulation
HCP: Health Care Professional
IU: Intention to Use
mHealth: Mobile Health
PEU: Perceived Ease of Use
PU: Perceived Usefulness
QoL: Quality of Life
RCT: Randomized Controlled Trial
SUS: System Usability Scale
TAM: Technology Acceptance Model
AI: artificial intelligence

Appendix A

Consortium investigators will be listed in the final version of the manuscript.

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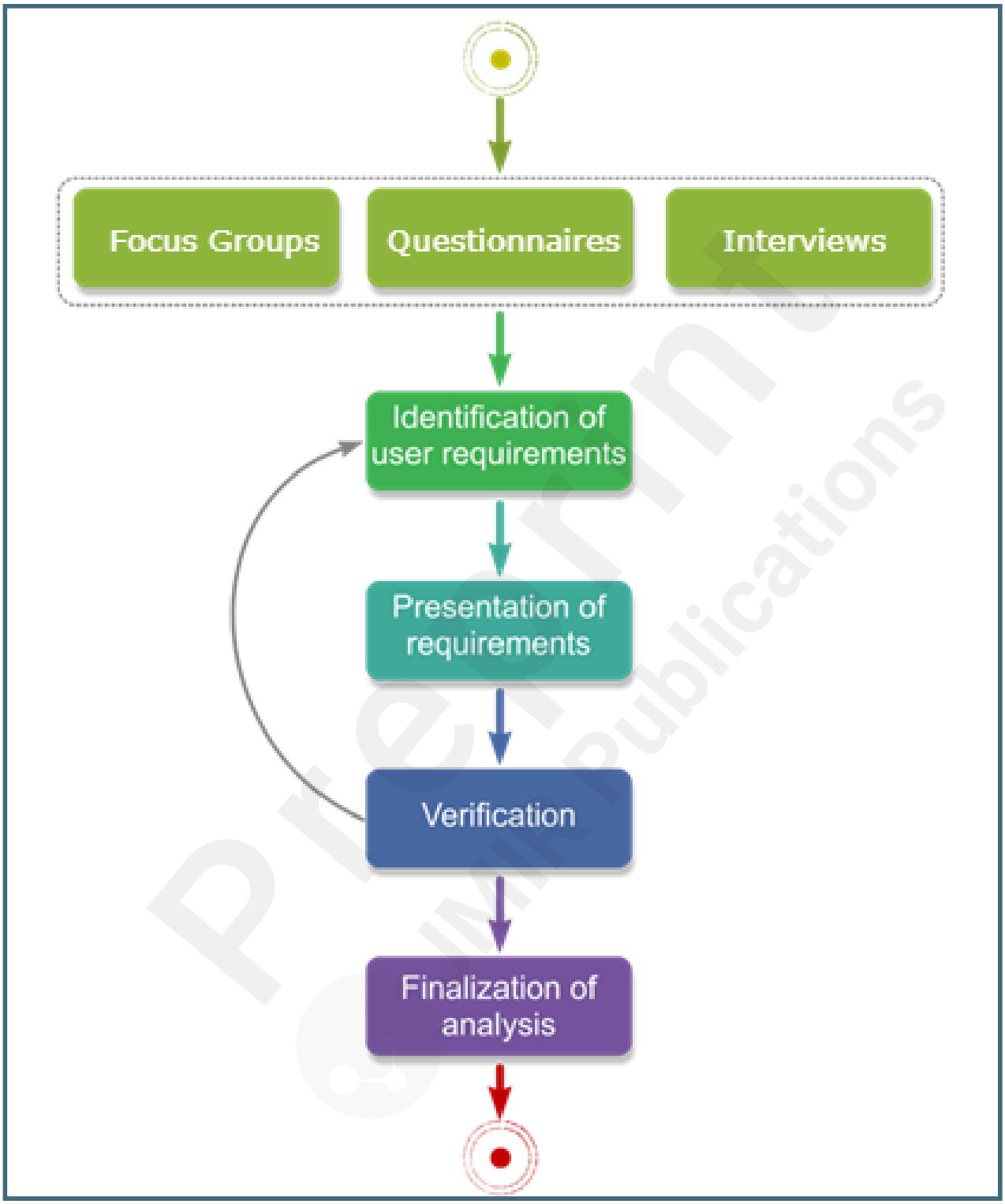
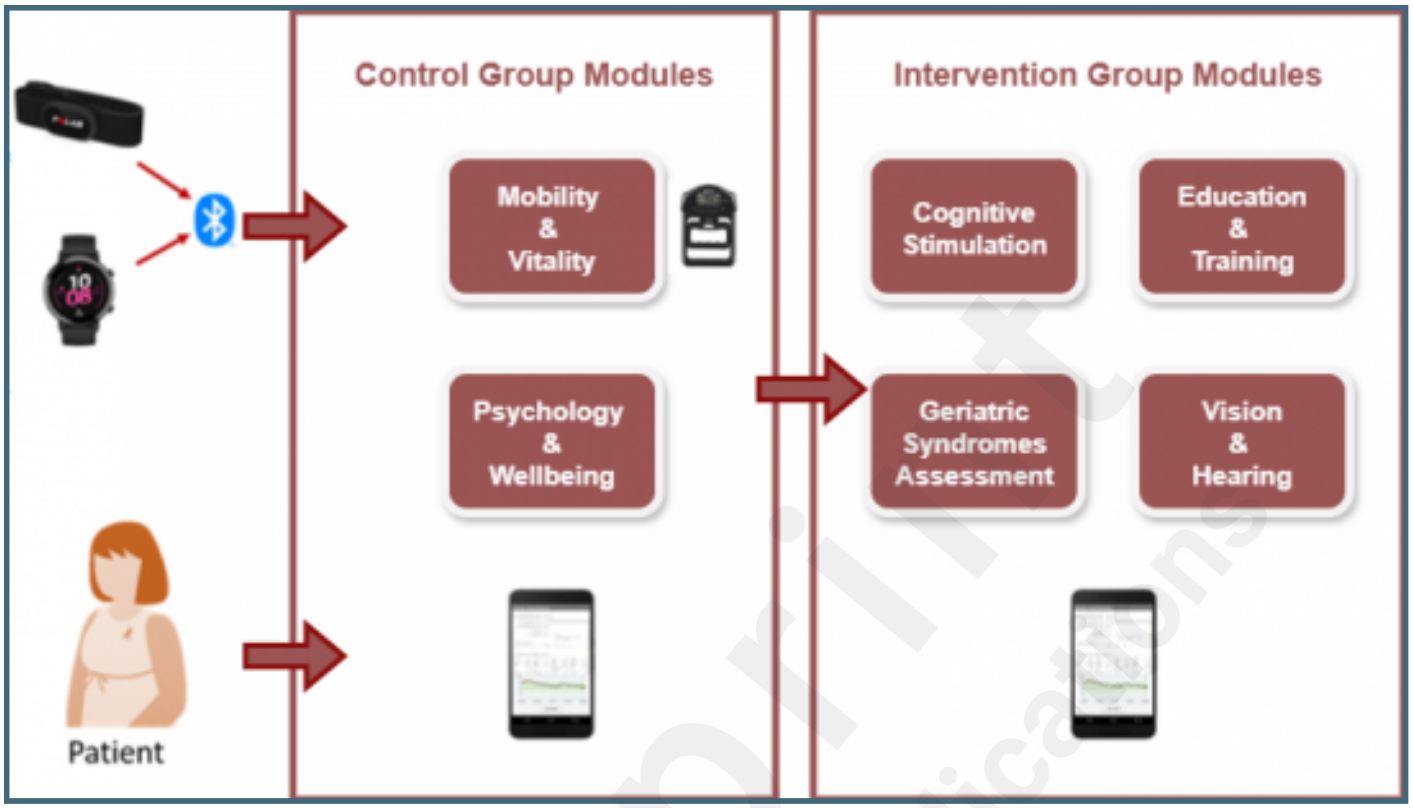
Supplementary Files

Figures

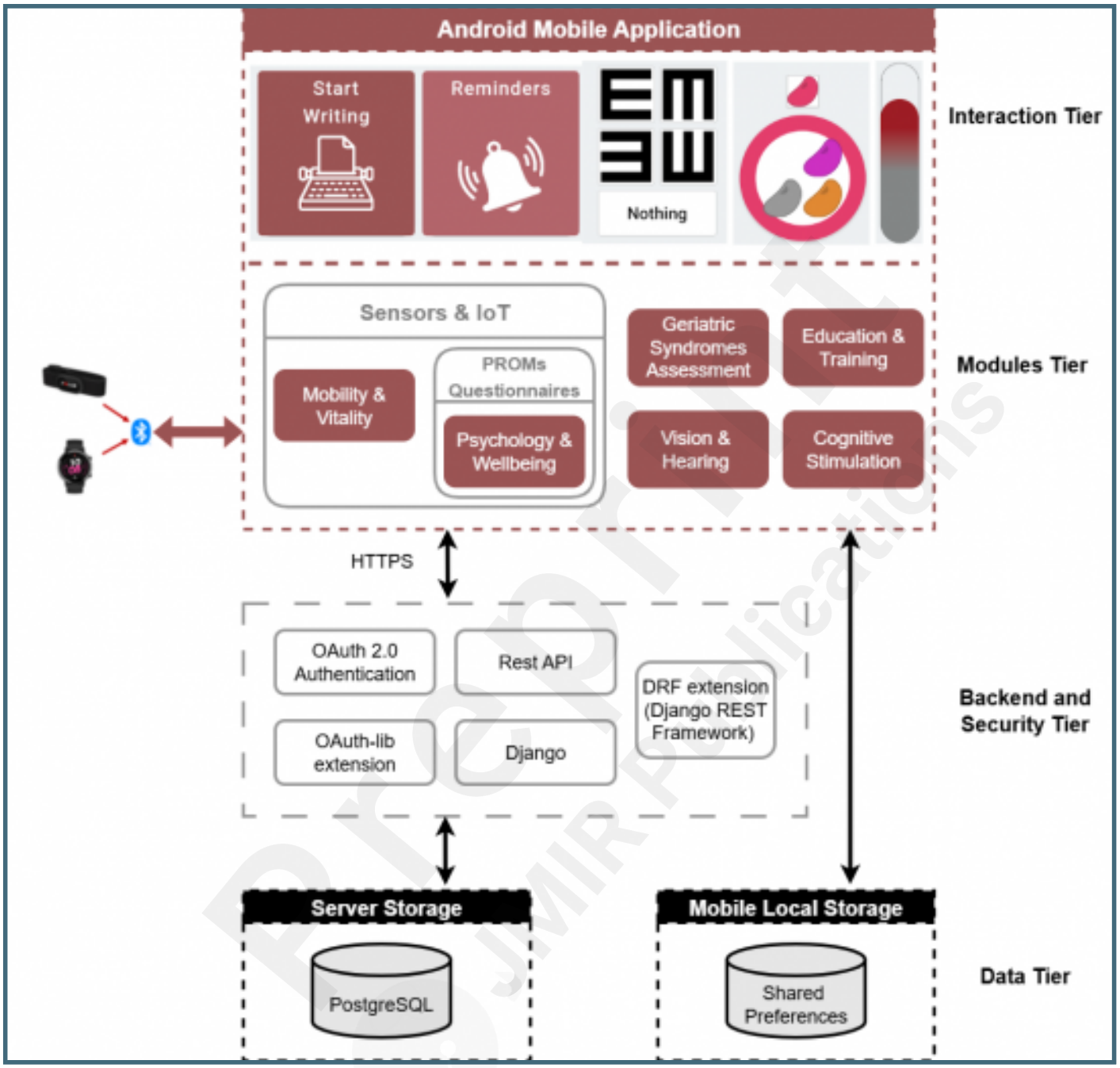
Design phase workflow.



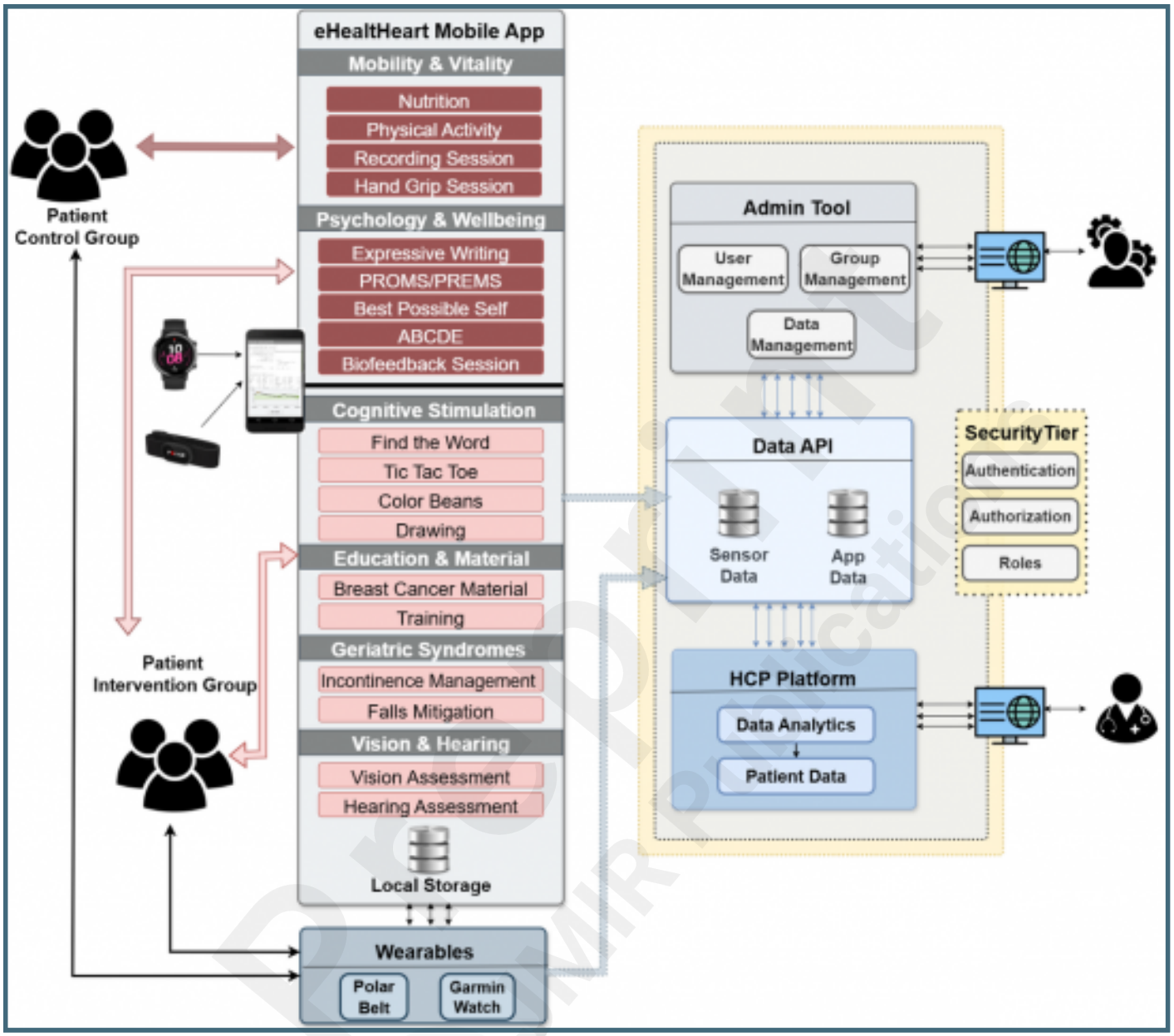
eHealtHeart Available Modules.



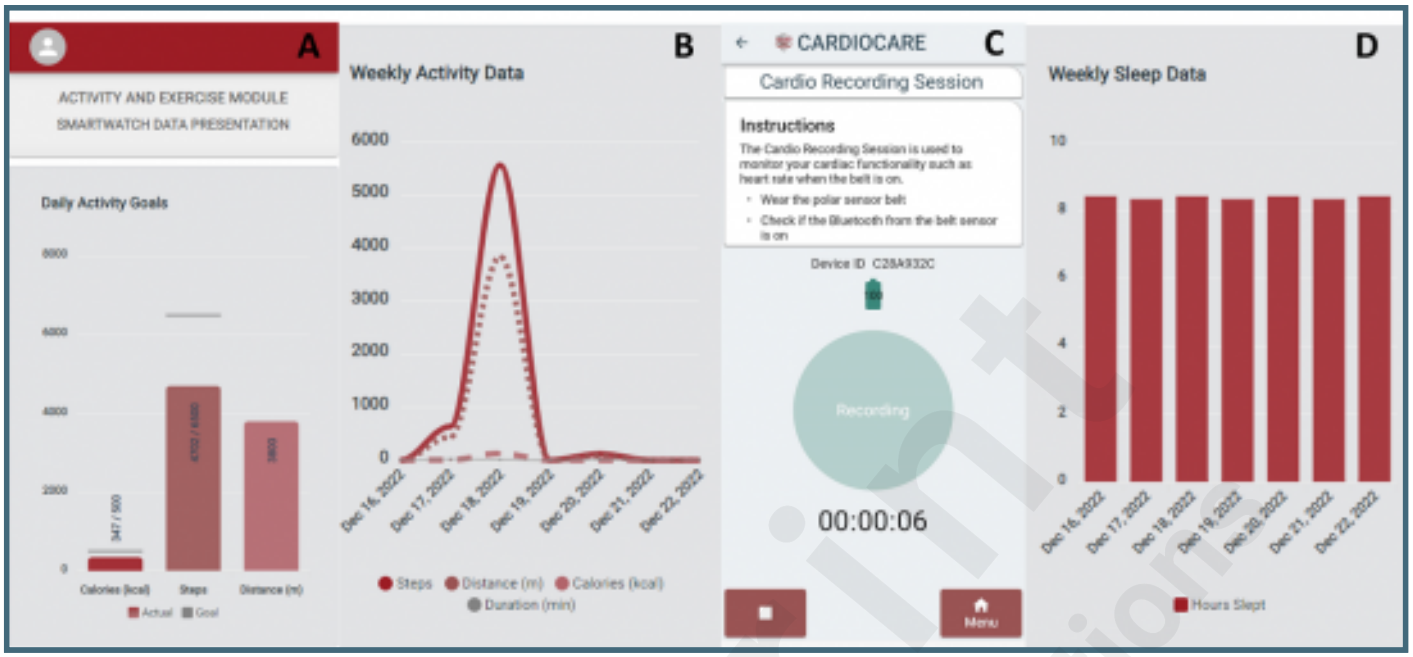
eHealtHeart Mobile Application Tiers.



CARDIOCARE System Architecture.

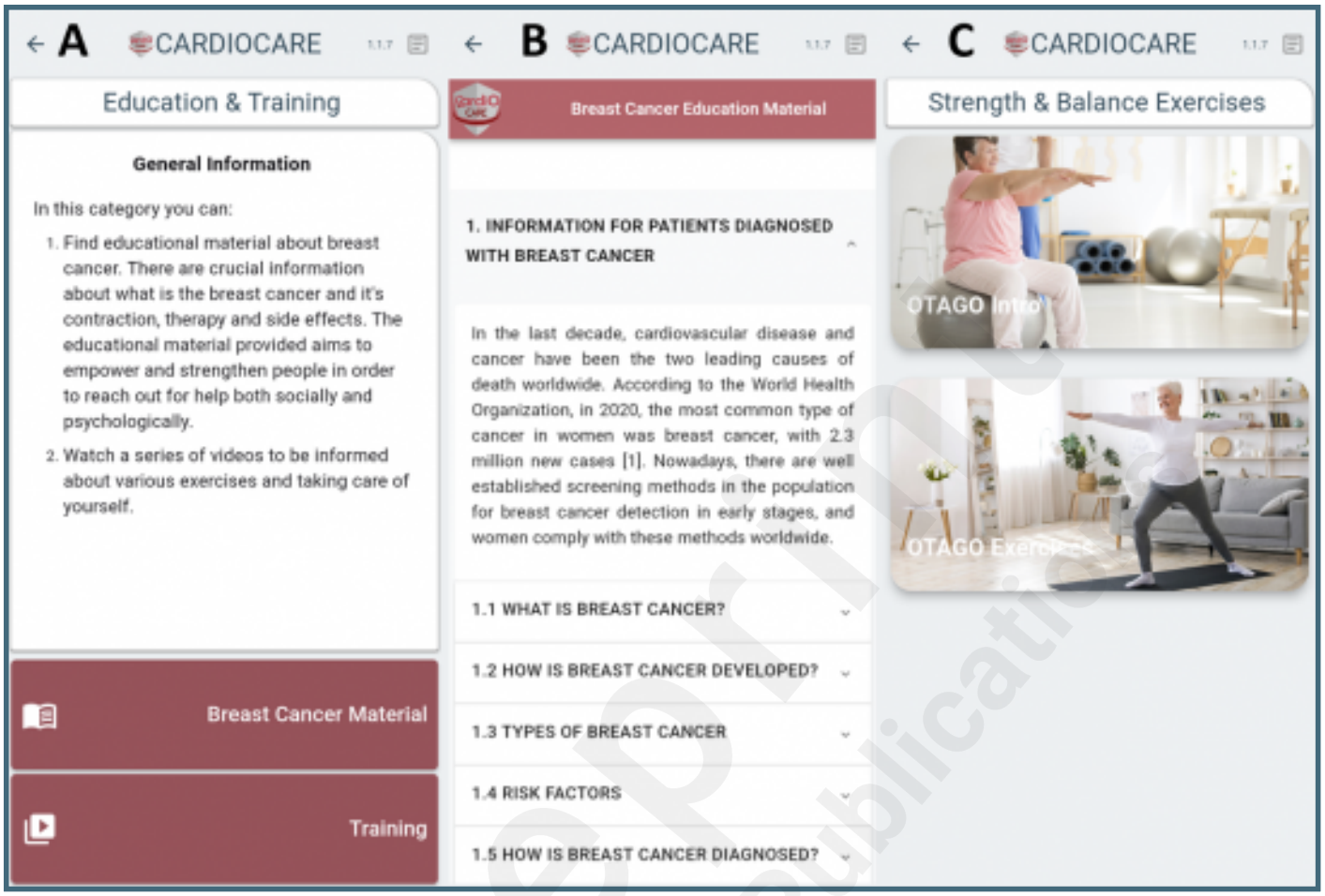


A) Activity Goals B) Activity Data C) Cardio Recording Session D) Sleep Data.

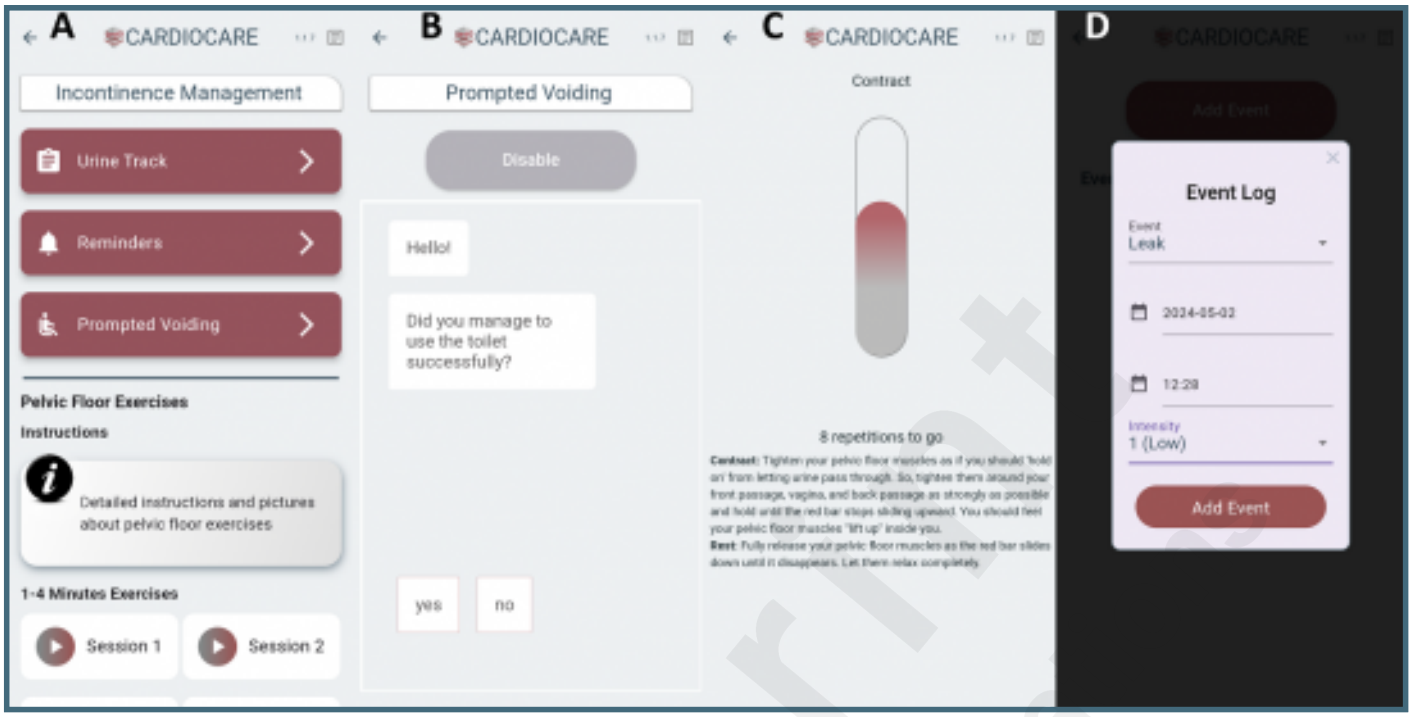


A) Drawing B) Find the Word C) Color Beans D) Tic Tac Toe.

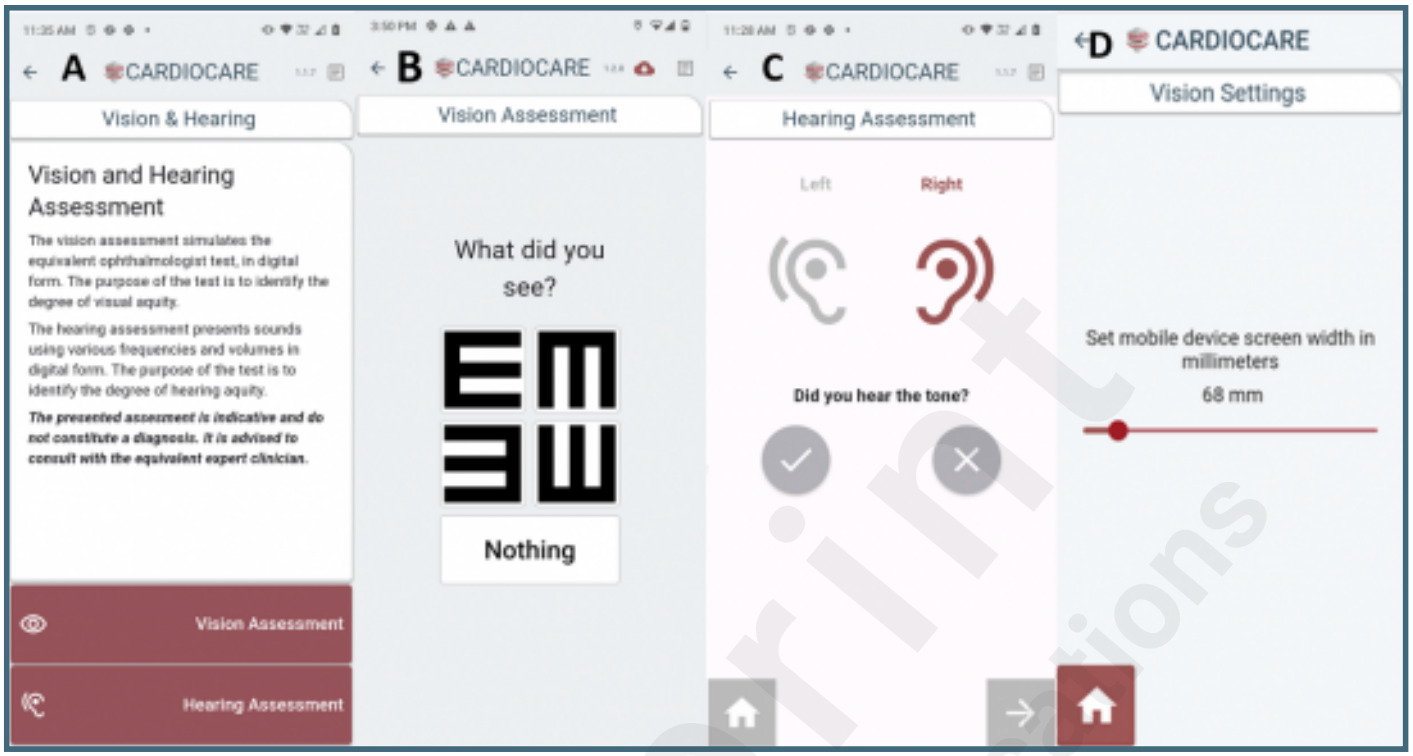
A) Submodules B) Breast Cancer Material C) Training.



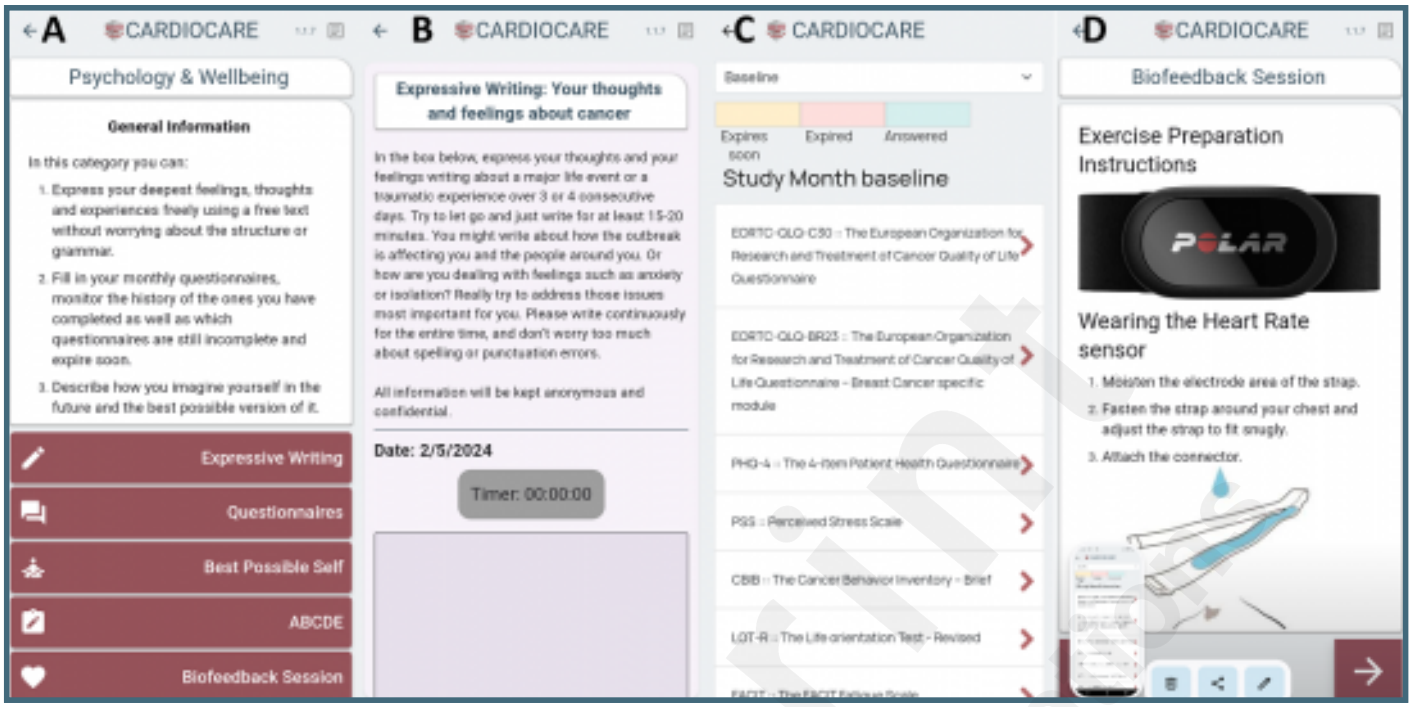
A) Incontinence Module B) Prompted Voiding C) Pelvic Floor Exercises D) Urine Event.



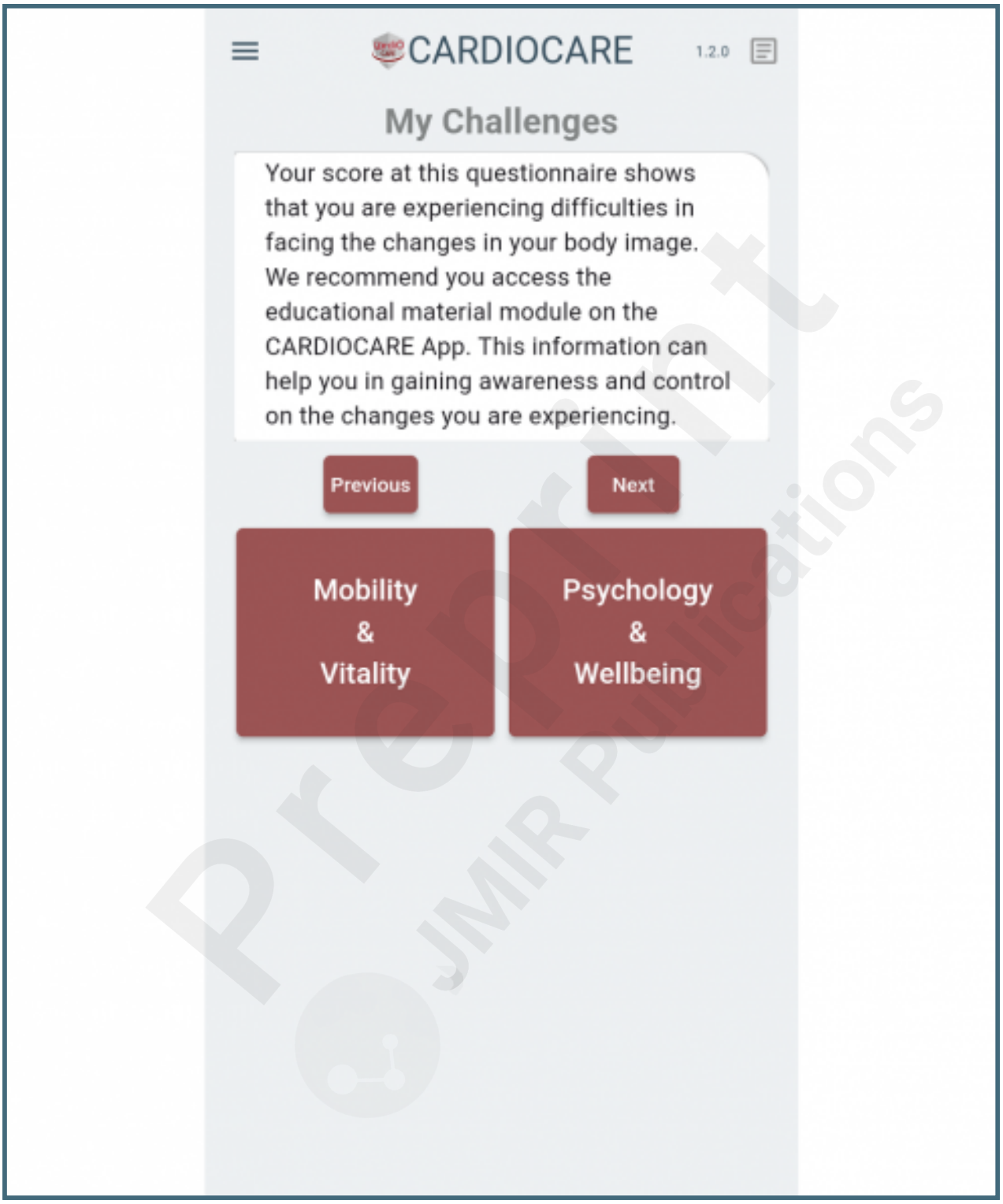
A) Submodules B) Vision Assessment C) Hearing Assessment D) Vision Assessment.



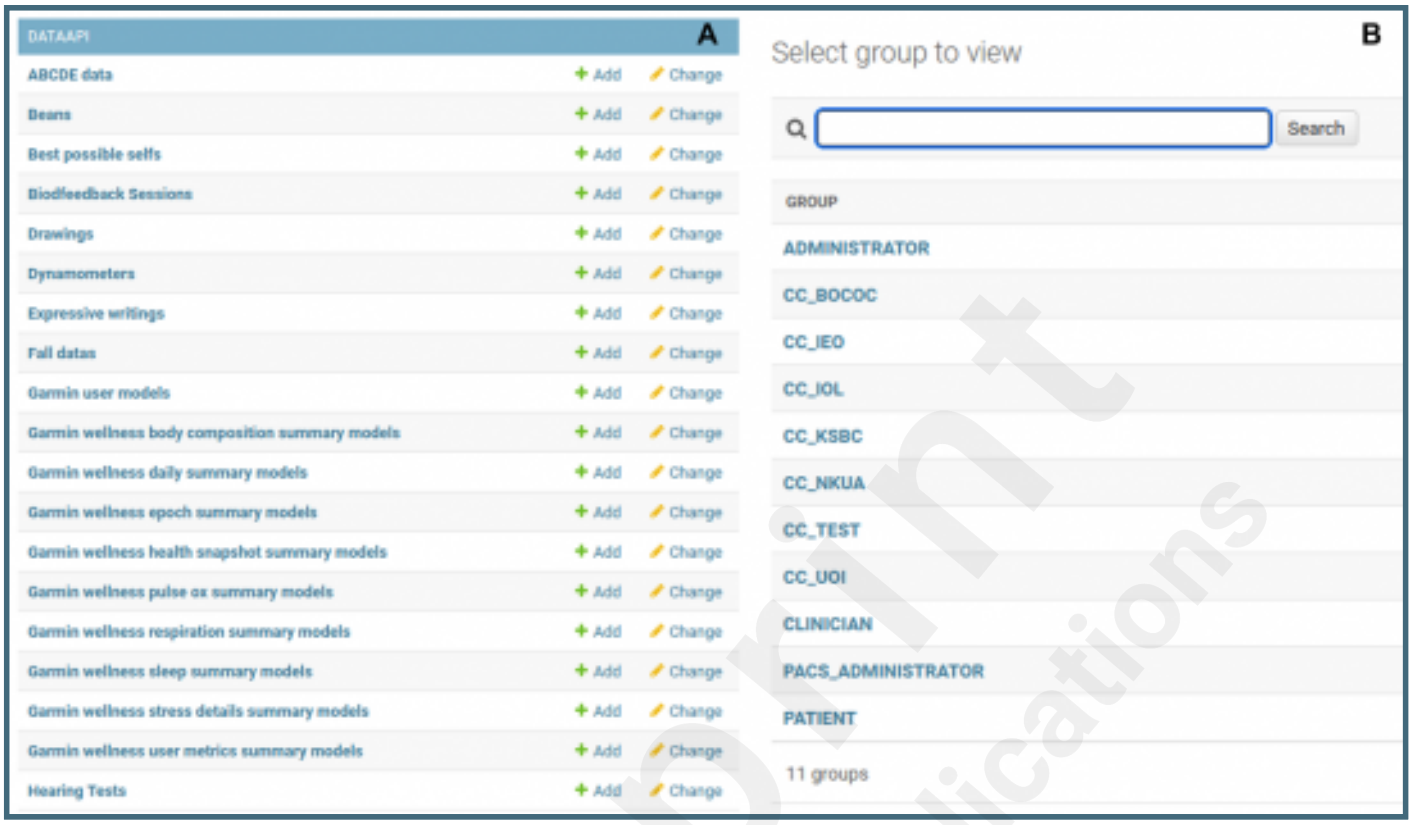
A) Submodules B) Expressive Writing C) Questionnaires D) Biofeedback Session.



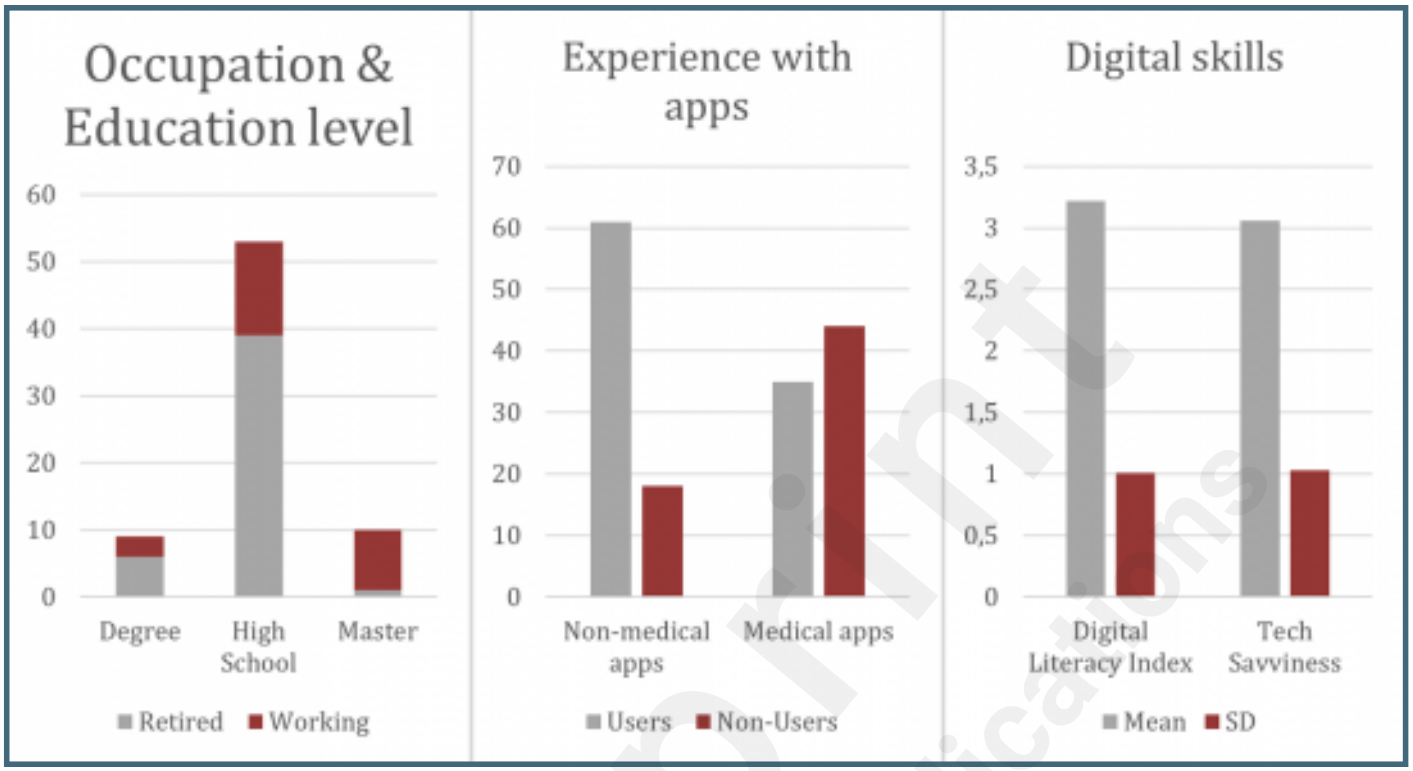
Smart Recommendation.



Administrator Panel A) Home screen B) Groups page.



Participant characteristics including occupation status, educational level, experience with apps and digital skills.



SUS Total Per User.