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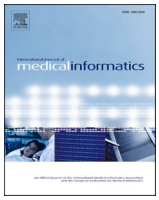

# Self-management in heart failure using mHealth: A content validation

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ABSTRACT

*Aim:* To describe the development of a mobile health application –mICardiApp- designed by a multidisciplinary professional team and patients with heart failure and to evaluate its content validity.
*Methods:* Critical reviews of the literature, semi-structured interviews with patients, and user stories guided the development of the content of the mobile application. These contents were refined and validated through a modified Delphi process. An expert panel of healthcare and social care professionals together with patients and academics evaluated the content through two content validity indicators, relevance, and adequacy, and provided narrative feedback. The content validity of the app and each screen was determined by calculating the Content Validity Index (CVI). Similarly, the Adequacy Index (AI) was analyzed.
*Results:* The developed app is composed by 8 topics: (1) available resources, (2) cardiac rehabilitation, (3) control of signs and symptoms, (4) emotional support, (5) learning and having fun, (6) medication, (7) nutrition, and (8) physical activity. The results demonstrated high CVI of the screens and the full app. 57 of the 59 screens in the app reached an excellent CVI $\geq$ 0.70 for both relevance and adequacy, except for 2 screens. The CVI Average Method of the app was 0.851.
*Conclusions:* mICardiApp is presented as an application to improve health literacy and self-management of patients with multimorbidity and heart failure, with proven validation.

## 1. Introduction

According to the World Health Organisation (WHO), non-communicable diseases (NCDs) are responsible for 41 million deaths each year (accounting for 71% of deaths worldwide). Cardiovascular diseases account for the majority of NCD deaths (17.9 million each year) [1]. The percentage of the population in Spain with at least one chronic problem is 34%, a percentage that reaches 77.6% among people aged 65 and over [2].

Heart failure (HF) is a chronic disease associated with the presence of comorbidities - more than 85% of HF patients have 2 or more comorbidities- [3], and with a high mortality rate [4], which has a great impact on the patient's quality of life [5] and, if not properly prevented and treated, HF can lead to significant losses in the autonomy of sufferers and their primary carers [6]. HF consumes a high number of socio-health and economic resources, due to the appearance of complications and the increase in healthcare demand and hospitalizations [7]. For these reasons, care should be multidisciplinary, evidence-based, and patient-centered, according to the burden needed to manage daily routines [8,9]. This also implies the involvement of professionals, patients, and caregivers in assessing the readability of the intervention program content [10].

Traditionally, information, advice, and care provided to patients with HF were given through printed materials, which do not seem to be effective for long-term patient engagement in self-care [11]. Nowadays, mobile devices have shown great promise for increasing the quality of self-care, therapeutic adherence, and guidelines provided to HF patients [12].

Among the main contributions of mHealth applications, patients highlight better access to health professionals, cost reduction, and better

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self-management of their health [13]. This self-management is a highly effective factor for improving overall health and encompasses measures such as patient education and monitoring of their processes, setting healthy goals, self-motivation, shared decision-making between patients and professionals, planning and recording specific behaviors, managing stress, and emotional regulation [14–20]. Furthermore, the use of mHealth [21] is particularly relevant at times when health monitoring is of vital importance, such as in the COVID-19 pandemic when mobility and access to the healthcare system were restricted [22].

In addition, the incorporation of Digital Technologies according to models and principles of health literacy (HL), helps to promote active participation in the decision-making processes about any activity related to health [23,24].

Throughout this amazing development, we cannot forget that patient acceptance is a key success factor in the implementation of mHealth-based interventions [15]. The design of the application, and the inclusion of content with acceptable clarity and relevance, are essential for its use and acceptance [25]. Similarly, several socio-demographic aspects of the user (age, cultural context…) should be taken into account [26–28].

However, there is controversy about the use of apps, as some studies have found no significant difference between patients who did and did not use these apps [9]. Perhaps this controversy may be due to the lack of readability of the content or the incomplete addressing of all aspects influencing the physical, psychological, and social spheres, which may influence HF patients. For this reason, apps should be created in which different professionals (physical exercise specialists, health professionals, psychologists…) and users participate in order to provide a more comprehensive approach.

User stories used in agile development methodologies and the Technology Acceptance Model (TAM) are recommended as theoretical models to establish user acceptance goals. A user story describes functionality that will be valuable to either a user. It is a semi-structured natural language description from the user's perspective on the required software system's functionality [29]. Thus, user stories help the stakeholders to share an understanding of the expected system goals and functions [30,31]. The TAM was designed to model user acceptance of information systems or technologies. It explains that the willingness to use and actual use of new technologies is determined by the user's perceived usefulness and ease of use [32,33].

In addition to the above-mentioned characteristics, evidence highlights that a health app focused on chronic patients should include the following aspects in its design: health information [14,34], goal planning that increases motivation and adherence to the app [35], a registration system [36], feedbacks [37], programming reminders or alarms [38], communication with health professionals [39], a space for the caregiver [27], and social networking [40].

However, currently available apps are not suitable for use by older adults with heart failure, and there is a need for mobile health apps to refine their development process so that the needs and capabilities of users are identified during the design phase to ensure the app's usability [41]. Studies advise that end users should be involved with the design of an app to better understand their needs to ensure the uptake and usability of an intervention. Additionally, methodology based on content validation testing by clinical and research experts has been used successfully to support the development of mHealth interventions [16,42–46]. The concept of content validity originates in the area of instrument development. Content validity is assessed with regard to a particular purpose or aim of assessment, and a particular targeted population [47]. Quantitative and qualitative indicators derived from expert review of a content validity can be useful in identifying missteps and honing content during the development phase of an mhealth intervention [47]. According to Kassam-Adams et al. [48] the content validity of a mHealth intervention is defined as the extent to which its component intervention activities are relevant to the underlying construct and likely to be effective in achieving a particular intervention purpose in a specific intended population.

Finally, to alleviate the deficiencies identified in the scientific literature, the present study aims to describe the development of a mobile health application –mICardiApp- designed by a multidisciplinary team (professionals from different disciplines such as Nursing, Medicine, Physical education, Psychology, Physiotherapy, Nutrition, and Informatics Engineering) and patients with HF, and to evaluate its content validity.

## 2. Methods

This study belongs to the project "Development and Effectiveness of a Mobile Health Intervention in Improving Health Literacy and Self-management of Patients with Multimorbidity and Heart Failure: Protocol for a Randomized Controlled Trial" (Trial Registration: ClinicalTrials.gov NCT04725526) [49].

A prospective method through a modified Delphi study was conducted for the development and validation of the content of the app. The modified Delphi technique offers advantages such as improving the response rate and reducing the effects of bias due to panel experts' interaction by assuring anonymity [50]. To accomplish this, an expert panel is commonly selected.

Previously, a three phases study was conducted: In the first phase, six integrative reviews were conducted in order to identify intervention proposals to promote the autonomy/self-management of the patient with multi-morbidity and HF. Secondly, a qualitative methodology based on Van Manen's hermeneutic phenomenology [51] through semi-structured interviews, and finally (third phase), user stories [29] were used to incorporate their opinions and needs into the contents of the app. Thus, the content design was driven by the information obtained in these preliminary phases. The importance of this research design for the development of a mHealth App focused on people with comorbidities has been demonstrated [52].

A mock-up of the app was made using the Pencil v.3.1.0 software, to create a first draft of the interface and its navigation. The first version underwent a pilot evaluation by the research team to establish that the contents were valid and to improve the final instrument. After that, all the content was validated by an expert panel in the field using the modified Delphi method. Following Escobar and Cuervo's method [53], in the consensus round, each of the screens were measured: a) Relevance: A screen will be relevant if "it is essential or important to include"; b) Adequacy: A screen will be adequate if "it means content setting". Both, relevance and adequacy were measured with a 4-point Likert scale, where 1 means "Not relevant/adequate"; 2 = relevant/adequate; 3 = Fairly relevant/adequate; 4 = Totally relevant/adequate.

### 2.1. Sample/Participants

A convenience sampling method was used for forming an expert panel. The sampling strategy aimed to ensure that participants met the following inclusion criteria: (1) health care provider with experience (>5 years) in the care of patients with multimorbidity or HF; (2) professors and researchers with experience in research projects in the thematic areas addressed (HL, intervention programs, or patients with multimorbidity); (3) other professionals with experience in research, assistance, or care of patients with multimorbidity (social workers, psychologists, communication professionals); (4) computer engineers with experience in the design of health apps; (5) representatives of patients organizations with chronic diseases; and (6) patients with multimorbidity and HF. They were invited to join the panel via email, where the purpose of the study was explained, and informed consent for their participation was requested. The optimal size for a Delphi group is estimated to be between 6 and 30 participants [54]. Considering the attrition rate, we tried to tend to the maximum number of experts recommended who were different from those researchers involved in the project. Finally, 30 experts were contacted by email, and 20 agreed to

take part.

### 2.2. Data collection

Data collection was developed between April and May 2022. To facilitate the participation of experts, a web-based platform (Google Forms) was deemed appropriate as it is cost-effective and efficient [55]. The online survey consisted of twelve sections (https://docs.google.com/forms/d/e/1FAIpQLScm5tsswrR0P3_go7UxiXFCobZR0dnGlFbZ95amBbgGym2e3Q/viewform). The first section contained a description of the study, the informed consent, and the survey instructions, including a clear definition for each choice category of the ranking scale. The second section collected sociodemographic data, and the rest of the sections contained items to assess the relevance and adequacy of each screen of the app. Finally, a free-text section within each topic was available for experts to provide feedback and comments. Experts were asked to rate the relevance (a screen will be relevant if "it is essential or important to include") and adequacy (it means content setting) of both the screen and the app by using a Likert scale ranging from 1 to 4 (1 = no relevance/adequacy and 4 = high relevance/adequacy). To facilitate the evaluation process, at the beginning of each section a video was presented with the navigation through the different screens included in it.

### 2.3. Data analysis

A uni-bivariate descriptive analysis was performed to determine the sample distribution for each of the variables studied. The characterization variables were summarised using descriptive statistics, expressing qualitative variables in terms of frequency and percentages, and quantitative variables in terms of mean and standard deviation (SD).

To identify convergence in respondent input between iterations, mean and standard deviation were calculated. The standard deviation has been considered an effective approach to present information regarding the experts' collective judgment [56].

For the content validity of the sections included in the app, the approach advocated by Lynn was used [57]. The content validity index (CVI) was calculated [58] both at the individual screen level (I-CVI) and the average of the content validation index of all the screens.

I-CVI was computed as the number of experts giving a rating of 3 or 4 "relevance" for each screen divided by the total number of experts. The content validity index of all the screens was calculated in two methods, one was the Content Validity Index Universal Agreement Method (CVI-au), and the second, was the Content Validity Index Universal Average Method (CVI-p). CVI-au was calculated by adding all screens that achieve a relevance rating of 3 or 4 by the experts divided by the total number of screens, while CVI-p was calculated by taking the sum of the I-CVIs divided by the total number of screens [58]. The adequacy Index (AI) was computed as the number of experts giving a rating of 3 or 4 "adequacy" for each screen divided by the total number of experts.

Taking into account the size of the expert panel and according to the bibliography consulted, the relevance/adequacy of the screens were considered good if the CVI and AI were greater than or equal to 0.70; if the value was below 0.70 the screen was eliminated [59,60]. Those screens that did not reach these scores were reviewed and reformulated based on the feedback collected until a final version was agreed upon. The acceptable standard of the Content Validity Index Universal Average Method ranged from 0.8 to 0.9 [58]. The resulting prototype was sent to a developer to create the mHealth tool under an agile approach.

A data matrix was created and data were processed statistically using SPSS, version 22 (IBM). Statistical significance was set at 95% ($\alpha$ = 0.05).


**Fig. 1.** Content sections included in the app.

### 2.4. Ethical considerations

The study was conducted in accordance with the Declaration of Helsinki [61], and approval was obtained from the Cádiz Research Ethics Committee (protocol date, 31 May 2019). The informed consent was included in the first section of the online survey.

## 3. Results

### 3.1. mICardiApp

The final version of mICardiApp was developed based on integrative reviews, a qualitative methodology based on interviews with patients, and user stories.

The application is structured with a first screen leading to a registration form. After that, the app shows profile and emergency buttons, and nine main sections (Fig. 1): Cardiac Rehabilitation and Physical Activity, Nutrition, Medication, Emotional support, Signs and Symptoms, Resources, Learn and have fun, Goals, and Alerts.

Table 1 shows a summary of the main contents created following the properties that a health app focused on chronic patients should include

**Table 1**
Main contents included in mICardiApp.

| Properties | Section | Content |
|---|---|---|
| *Health information* | Content transversal. All sections | In general, it is intended to offer information and resources to the patient considering the main recommended actions to improve the health outcomes of them. In order to facilitate the usability the information provided is presented by text, images and videos. |
| | Cardiac Rehabilitation and Physical Activity | Information on physical activity recommended for the patient based on the stage of their disease, recommendations on physical activity and sedentary lifestyle, and information on cardiac rehabilitation exercises. |
| | Nutrition | Information on recommended food for this type of disease, recipes and dietary advice in general, allowed foods, and tips on drinking fluids. |
| | Medication | Information on drug interactions and drug-food interactions. |
| | Emotional support | Information on how our emotions influence the evolution of the disease, relaxation strategies and emotional control. |
| | Signs and Symptoms | Information on the main warning signs and symptoms and how to act when they appear. |
| | Resources | Information on the socio-sanitary resources available for these patients, patient associations, and measures to eradicate toxic habits -smoking-. |
| | Learn and have fun | Gamification strategy to strengthen the information and knowledge acquired. |
| *Goal planning that increases motivation and adherence to the app* | All sections | The application consists of a section of objectives. Depending on the weekly record made by the patient (depending on each of the main areas to be evaluated: physical activity, nutrition, fluid control, emotions…), challenges will appear to be met in that week. The patient and the health provider will agree on the health goals. |
| *Registration system* | All sections | The patient initially registers in the application and creates their user profile. Once registered, there are a series of daily records necessary for the evaluation of self-care (daily physical activity, daily alarm signs and symptoms, emotional state, daily fluid consumption…). |
| *Feedbacks* | | Every time the user registers content in the application, the system gives feedback on their evolution in the form of evolution graphs and/or motivational messages. |
| *Programming reminders or alarms* | Cardiac Rehabilitation and Physical Activity Nutrition Medication Emotional support | A lot of attention was paid to the functionality to create interactive reminders, that is, There is an alarm system built into the app to remind you of physical activity and medication taking. Similarly, pop-ups appear randomly reminding us of the importance of mental health for good emotional management of the disease. |
| *Communication with health professionals:* | Signs and Symptoms | The application has a section where the user can write down the main doubts that arise for a future appointment with the health professional. In the same way, the most important records that have been noted down daily can be generated in the form of a pdf report for delivery and/or sending to the healthcare professional. |
| *Space for the caregiver* | Main menu | On the homepage of the application registration, the user can enter the data of their main caregiver so that they can register and access the application. |
| *Social network* | Main menu. User profile. | In the user's profile, they can indicate if they want to share their contact with other users to generate a group of contacts who want to share their experiences through social networks. The application does not incorporate social networks directly because there are already applications designed for this purpose. |

**Table 2**
Sample socio-demographic profile.

| Gender | N | % |
|---|---|---|
| Female | 10 | 50 |
| Male | 10 | 50 |
| **Educational Level** | | |
| Without studies | 0 | 0 |
| Primary education | 0 | 0 |
| Secondary education (Baccalaureate, high school…) | 1 | 5 |
| Bachelor's degree | 11 | 55 |
| Master's degree | 4 | 20 |
| Doctorate | 4 | 20 |
| **Profile** | | |
| Health care provider | 11 | 55 |
| Professor or researcher | 4 | 20 |
| User/patient | 3 | 15 |
| Other professionals (psychologist, social worker, …) | 2 | 10 |
| **Professional Experience (health care providers)** | | |
| < 5 years | 0 | 0 |
| 5–10 years | 2 | 18.18 |
| 10–20 years | 1 | 9.09 |
| > 20 years | 8 | 72.72 |
| **Health care provider with experience (>5 years) in the care of patients with multimorbidity or HF** | | |
| Yes | 11 | 100 |
| No | 0 | 0 |
| **Patients with multimorbidity and HF: years of disease evolution** | | |
| < 5 years | 0 | 0 |
| 5–10 years | 1 | 33.33 |
| 10–20 years | 2 | 66.66 |
| > 20 years | 0 | 0 |
| **Professor and researchers with experience in research projects in the thematic areas addressed (HL; intervention programs, or patients with multimorbidity);** | | |
| Yes | 2 | 50 |
| No | 2 | 50 |

in its design (described in the introduction section).

### 3.2. Panel of experts

A convenience sample of 30 professionals who met the selection criteria was contacted to form the panel of experts, and 20 of them indicated a willingness to participate (66.66% response rate). Participants were 50% female (n = 10), and the average age was 49.95 years old (SD = 11.655) (age range 28 to 70). Table 2 shows the socio-demographic data profile of the sample experts.

**Table 3**
Agreement rate of expert penalties and content validity index Delphi.

| | **Content validity indicators** | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | **Relevance** | | | | **Adequacy** | | | | **Interpretation** |
| Screens App | *CVI | Mean | (SD) | Expert agreement (n = 20) | *CVI | Mean | (SD) | Expert agreement (n = 20) | |
| Welcome | 0.90 | 3.55 | 0.68 | 18 | 0.90 | 3.40 | 0.68 | 18 | Excellent |
| Main menu | 0.85 | 3.40 | 0.75 | 17 | 0.85 | 3.20 | 0.83 | 17 | Acceptable |
| PA1. Assessment of physical activity | 0.80 | 3.30 | 0.80 | 16 | 0.80 | 3.25 | 0.78 | 16 | Acceptable |
| PA2. Training heart rate calculation | 0.80 | 3.35 | 1.04 | 16 | 0.85 | 3.40 | 0.88 | 17 | Acceptable |
| PA3. Step log | 0.95 | 3.45 | 0.60 | 19 | 0.95 | 3.40 | 0.59 | 19 | Excellent |
| PA4. Tips on physical activity | 0.95 | 3.65 | 0.58 | 19 | 0.95 | 3.60 | 0.59 | 19 | Excellent |
| P.A5. Tips to Avoid the Sedentary Lifestyle | 0.90 | 3.50 | 0.68 | 18 | 0.95 | 3.55 | 0.60 | 19 | Excellent |
| PA6. Physical inactivity alert | 0.80 | 3.20 | 0.76 | 16 | 0.85 | 3.25 | 0.71 | 17 | Acceptable |
| CR1. Vital signs | 0.80 | 3.35 | 0.81 | 16 | 0.80 | 3.25 | 0.78 | 16 | Acceptable |
| CR2. Difficulty breathing assessment | 0.85 | 3.50 | 0.76 | 17 | 0.85 | 3.40 | 0.75 | 17 | Acceptable |
| CR3. Breathing exercises | 0.80 | 3.30 | 0.80 | 16 | 0.85 | 3.30 | 0.73 | 17 | Acceptable |
| CR4.New respiratory assessment | 0.90 | 3.45 | 0.68 | 18 | 0.90 | 3.50 | 0.68 | 18 | Excellent |
| CR5. My respiratory distress records | 0.85 | 3.30 | 0.86 | 17 | 0.85 | 3.30 | 0.86 | 17 | Acceptable |
| N1. Initial registration | 1.00 | 3.65 | 0.48 | 20 | 0.90 | 3.55 | 0.68 | 18 | Excellent |
| N2. Initial record of physical activity | 0.95 | 3.50 | 0.60 | 19 | 0.90 | 3.45 | 0.68 | 18 | Excellent |
| N3. Initial record of fluid intake | 0.80 | 3.10 | 0.96 | 16 | 0.80 | 3.02 | 0.94 | 16 | Acceptable |
| N4. Reports | 0.90 | 3.40 | 0.68 | 18 | 0.95 | 3.45 | 0.60 | 19 | Excellent |
| N5. Fluid intake | 0.80 | 3.15 | 0.98 | 16 | 0.80 | 3.10 | 0.96 | 16 | Acceptable |
| N6. Menu | 0.90 | 3.35 | 0.81 | 18 | 0.90 | 3.35 | 0.81 | 18 | Excellent |
| N7. Presentation of the Menu | 0.90 | 3.25 | 0.78 | 18 | 0.90 | 3.30 | 0.80 | 18 | Excellent |
| N8. Recipes | 0.95 | 3.45 | 0.60 | 19 | 0.95 | 3.40 | 0.59 | 19 | Excellent |
| N9. Presentation of the recipes | 0.85 | 3.35 | 0.74 | 17 | 0.90 | 3.35 | 0.67 | 18 | Acceptable |
| N10. Food barcode scanner | 0.95 | 3.35 | 0.60 | 19 | 0.90 | 3.45 | 0.68 | 18 | Excellent |
| N11. Nutritional Recommendations | 0.95 | 3.65 | 0.58 | 19 | 0.95 | 3.60 | 0.59 | 19 | Excellent |
| M1. Treatment | 1.00 | 3.55 | 0.51 | 20 | 0.90 | 3.50 | 0.68 | 18 | Excellent |
| M2. Drugs information | 0.85 | 3.30 | 0.86 | 17 | 0.85 | 3.30 | 0.86 | 17 | Acceptable |
| M3. Add medicine | 1.00 | 3.60 | 0.50 | 20 | 0.95 | 3.50 | 0.60 | 19 | Excellent |
| M4. Dosage form | 0.85 | 3.30 | 0.73 | 17 | 0.85 | 3.25 | 0.71 | 17 | Acceptable |
| M5. Dosage | 0.90 | 3.40 | 0.82 | 18 | 0.85 | 3.30 | 0.86 | 17 | Excellent |
| M6. Take frequency | 0.95 | 3.55 | 0.75 | 19 | 0.90 | 3.40 | 0.82 | 18 | Excellent |
| M7. Timing medication | 0.95 | 3.55 | 0.75 | 19 | 0.90 | 3.35 | 0.81 | 18 | Excellent |
| M8. Stock Medication | 0.80 | 3.30 | 0.92 | 16 | 0.80 | 3.25 | 0.91 | 16 | Acceptable |
| M9. Alert | 0.95 | 3.65 | 0.58 | 19 | 0.90 | 3.45 | 0.68 | 18 | Excellent |
| M10. Storage | 0.75 | 3.25 | 0.96 | 15 | 0.75 | 3.20 | 0.95 | 15 | Acceptable |
| M11. Medication refill | 0.80 | 3.20 | 0.89 | 16 | 0.80 | 3.20 | 0.89 | 16 | Acceptable |
| ES1. How do you feel today? | 0.70 | 3.10 | 0.96 | 14 | **0.65** | 2.95 | 1.05 | 13 | Revised based on experts' suggestions and the contents were included in the initial evaluation screen |
| ES2. Power your emotions | 0.75 | 3.20 | 0.83 | 15 | 0.80 | 3.20 | 0.76 | 16 | Acceptable |
| ES3. Sharing your emotions | 0.70 | 3.10 | 0.96 | 14 | 0.75 | 3.10 | 0.78 | 15 | Acceptable |
| ES4. Feelings journal diary | **0.60** | 3.00 | 1.02 | 12 | 0.70 | 3.10 | 0.85 | 14 | **Screen delete** |
| ES5. Relaxation and breathing | 0.90 | 3.40 | 0.68 | 18 | 0.90 | 3.35 | 0.67 | 18 | Excellent |
| ES6. Think well and you will succeed | 0.70 | 3.10 | 0.85 | 14 | 0.70 | 3.05 | 0.82 | 14 | Acceptable |
| ES7. Proposals for the week | 0.80 | 3.20 | 0.89 | 16 | 0.80 | 3.15 | 0.87 | 16 | Acceptable |
| ES8. People in the same situation | 0.70 | 3.10 | 0.96 | 14 | 0.75 | 3.15 | 0.81 | 15 | Acceptable |
| ES9. Shared stories | 0.75 | 3.25 | 0.85 | 15 | 0.75 | 3.15 | 0.81 | 15 | Acceptable |
| ES10. Share your story | **0.60** | 2.95 | 0.99 | 12 | **0.65** | 3.00 | 0.85 | 13 | **Screen delete** |
| ES11. Organizations | 0.90 | 3.30 | 0.65 | 18 | 0.90 | 3.25 | 0.63 | 18 | Excellent |
| CSS1. Common signs and symptoms | 0.95 | 3.70 | 0.57 | 19 | 0.95 | 3.60 | 0.59 | 19 | Excellent |
| CSS2. Description of common signs and symptoms | 0.90 | 3.60 | 0.68 | 18 | 0.90 | 3.50 | 0.68 | 18 | Excellent |
| CSS3. My symptoms | 0.90 | 3.60 | 0.68 | 18 | 0.90 | 3.55 | 0.68 | 18 | Excellent |
| CSS4. My vital signs | 0.90 | 3.65 | 0.67 | 18 | 0.90 | 3.55 | 0.68 | 18 | Excellent |
| CSS5. Questions to ask at your next doctor appointment | 0.90 | 3.40 | 0.68 | 18 | 0.95 | 3.45 | 0.60 | 19 | Excellent |
| CSS6. What to do in an acute chest pain crisis | 0.95 | 3.75 | 0.55 | 19 | 0.95 | 3.65 | 0.58 | 19 | Excellent |
| R1. My referral primary care center | 0.80 | 3.30 | 0.92 | 16 | 0.80 | 3.25 | 0.91 | 16 | Acceptable |
| R2. My referral hospital | 0.80 | 3.25 | 0.91 | 16 | 0.80 | 3.20 | 0.89 | 16 | Acceptable |

(*continued on next page*)

**Table 3** (*continued*)

| Screens App | Content validity indicators | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | Relevance | | | | Adequacy | | | | Interpretation |
| | *CVI | Mean | (SD) | Expert agreement (n = 20) | *CVI | Mean | (SD) | Expert agreement (n = 20) | |
| R3. Organisations | 0.90 | 3.20 | 0.61 | 18 | 0.90 | 3.15 | 0.58 | 18 | Excellent |
| R4. Caregiver Resources | 0.85 | 3.35 | 0.74 | 17 | 0.85 | 3.30 | 0.73 | 17 | Acceptable |
| LHF1. Knowledge game | 0.80 | 3.20 | 0.89 | 16 | 0.85 | 3.25 | 0.71 | 17 | Acceptable |
| LHF2. Add questions to the Knowledge game. | 0.80 | 3.10 | 0.85 | 16 | 0.85 | 3.15 | 0.67 | 17 | Acceptable |
| LHF3. Challenges | 0.80 | 3.20 | 0.89 | 16 | 0.85 | 3.25 | 0.71 | 17 | Acceptable |

P.A.: Physical Activity; C.R.: Cardiac Rehabilitation; N.: Nutrition; M.: Medication; E.S.: Emotional Support; C.S.S.: Control of Signs and Symptoms; R.: Resources; L.H.F.: Learn and Having Fun.
*Content Validity Index (CVI) = (the number of experts rating an item ≥ 3) / (the total number of experts), CVI ≥ 0.70 is acceptable.

**Table 4**
Agreement rate of expert penalties and content validity index Delphi.

| | |
|---|---|
| Number of screens with a relevance rating of 3 or 4/Total number of screens | CVI-au |
| 57/59 | 0.97 |
| Average of the CVI-i of all the screens | CVI-p |
| 50.25/59 | 0.851 |

Content Validity Index Universal Agreement Method (CVI-au); Content Validity Index Universal Average Method (CVI-p).

### 3.3. Content validity result

Table 3 shows the CVI of each screen. 57 screens were evaluated by the expert panel and most of them showed acceptable I-CVI as to relevance and adequacy. The calculated I-CVI values for 57 screens ranged between 0.6 and 1.00. Screens whose I-CVI was<0.70 were eliminated (three emotional support screens).

Table 4 shows the CVI Universal Agreement Method (CVI-au) and the CVI Average Method (CVI-p). The CVI-au provides the degree of agreement that exists among the experts to classify the screens as "quite and totally appropriate". The CVI-p indicates the content validation index average of all the screens.

In the second round of consultation, the second-version content and responses indicated that 100% of respondents agreed with the content improvements. After a review with the developer to speed up and facilitate the navigation through the app, Table 5 shows the final version compared with the initial prototype.

## 4. Discussion

The advancement of technology has been a driving force in providing remote health care, and smartphones have contributed to the development of mHealth, supporting health education and promotion [38,62]. This study aimed to describe the development of an app -mICardiApp- designed by a multidisciplinary team, and to evaluate its content validity.

One of the most frequently discussed issues of using a health app is the reliability and accuracy of the information it contains [63] since it has to be used in the long term by both patients and professionals. Concerning this, a Delphi technique was used to validate the content of mICardiApp which was based on exhaustive bibliographic reviews, the opinion and needs of the target population, and their user stories. This design is consistent with the approaches that consider that user stories could promote shared understanding of a newly proposed digital tool among diverse clinical and non-clinical stakeholders resolving a common challenge [30], and with those that declare that the collaboration of professional experts in the design and development improves the information quality [64].

Although there is evidence that indicates that from 11 experts, a CVI of 0.6 can be assumed [65], we defined the value 0.7 to eliminate the screens showing lower scores. All the selected screens were considered relevant and appropriate, except for three screens related to the expression of emotions. This may be explained by a non-prioritization of the benefits of emotional expression for health management (the field of specialty and expertise of the experts might have played a role at that point), and the consideration of the negative influence of maladaptive models. Moreover, looking carefully at the three sections eliminated, we identify that all of them required active and regular participation of the user; that is: ("proposals for the week", "feelings diary" and "share your story"). Although those three sections were initially included to foster patient engagement with the application, it seems that they were seen as an unnecessary burden of self-monitoring in addition to the burden of using the app itself. Thus, by eliminating them, while we softened the burden of using the application, engagement with the app could potentially be promoted. In the same vein, to boost user motivation and ensure this engagement happens, we included a persuasive technique [66]. It was a trigger pop-up the user received daily once the application is installed and the user profile is set. Although the pop-up led directly to the Emotional regulation section, actually it resulted in a reminder for the user to use the whole app, and thus to engage him in a better self-manage of the health condition [67].

Regarding the application as a whole, although the CVI-p presents a value of 0.85, somewhat below the recommendation of Polit and Beck who suggest values equal to or greater than 0.90 (and CVI-i below 0.78). This may be due to our decision to include the final version indicators with a CVI-i below 0.70.

Experts' suggestions led to an improved version of the app. We can identify three types of changes, with clearly different levels of importance for clinical professionals and patients. Some of them are technical and include access and navigation aspects, including the legal requirements that were not considered in the first design. Other changes were related to simplifying, clarifying, and ordering the material, such as merging information into one section or connecting information between sections. A third group of changes was related to the elimination of content, which focused only on the psychosocial aspects, as mentioned above.

Validity and engagement are also promoted in mICardiApp by being designed based on TAM 3 theory [33], which takes into account individual differences, system characteristics, social influence, and facilitating conditions, which are determinants of perceived usefulness and perceived ease of use. According to the evidence, health information, goal planning, registration system, reminders, communication with health professionals, social network, and a space for the caregiver, have been taken into account in the design of mICardiApp.

**Table 5**
Comparison of the content menu between the initial and the final version of the app.

| Initial version | Final version | Change motivation |
|---|---|---|
| **Welcome** | 1. Login<br>2. Registration<br>3. General Assessment | |
| | 4. Profile | To facilitate the navigation. Direct Access to the user's profile. |
| | 5. Legal Warning | Legal requirements. |
| | 6. Cookies Policy | Legal requirements. |
| **Main Menu** | **Main Menu** | |
| | 1. Goals | To facilitate the navigation. New subsection that includes all the goals. |
| | 2. Alerts | To facilitate the navigation. Direct Access to the user's alarms. |
| **Cardiac Rehabilitation (CR)** | **Cardiac Rehabilitation (CR)** | |
| CR1. Vital signs | CR1. Vital signs | |
| CR2. Difficulty breathing assessment | CR2. Difficulty breathing assessment<br>CR3. MRC Scale<br>CR4. Borg Scale<br>CR5. Borg Scale decisions | To facilitate the user's registration the difficulty breathing assessment was divided in different scales. |
| CR3. Breathing exercises | CR6. Breathing exercises | |
| CR4. New respiratory assessment | CR7. New respiratory assessment | |
| CR5. My respiratory distress records | CR8. My respiratory distress records | |
| **Physical Activity (PA)** | **Physical Activity (PA)** | |
| PA1. Assessment of physical activity | PA1. Assessment of physical activity | |
| PA2. Training heart rate calculation | PA2. Training heart rate calculation | |
| PA3. Step log | PA3. Step log | |
| PA4. Tips on physical activity | PA4. Tips on physical activity | |
| PA5. Tips to Avoid the Sedentary Lifestyle | PA5. Tips to Avoid the Sedentary Lifestyle | |
| PA6. Physical inactivity alert | PA6. Physical inactivity alert | |
| **Nutrition (N)** | **Nutrition (N)** | |
| N1. Initial registration | – | To facilitate the navigation and not to repeat contents, they are moved to Physical activity and Medication sections. |
| N2. Initial registration: physical activity and medication | – | |
| N3. Initial record of fluid intake | N1. Initial record of fluid intake | |
| N4. Reports | N2. Reports | |
| N5. Fluid intake | N3. Fluid intake | |
| N6. Menu | | To facilitate the navigation and not to repeat screens, these contents are moved to the Recipes subsection. |
| N7. Presentation of the Menu | | |
| N8. Recipes | N4. Recipes | |
| N9. Presentation of the recipes | N5. Recipes Menu<br>N6. Individual recipes | |
| N10. Food barcode scanner | | Due to technical problems, this section could not be developed. |
| N11. Nutritional Recommendations | N7. Nutritional Recommendations | |
| **Medication (M)** | **Medication (M)** | |
| M1. Treatment | M1. Treatment | |
| M2. Drugs information | M2. Main interface Treatment | |
| M3. Add medicine | M3. Add medicine | These contents are merged in one screen. |
| M4. Dosage form | | |
| M5. Dosage | | |
| M6. Take Frequency | M4. Take Frequency | |
| M7. Timing medication | M5. Treatment start time | |
| M8. Stock Medication | M6. Stock Medication | |
| M9. Alert | M7. Alert | |
| M10. Storage | M8. Storage | |
| M11. Medication refill | M9. Medication refill | |
| **Emotional Support (ES)** | **Emotional Support (ES)** | |
| ES1. How do you feel today? | – | To facilitate the user's registration, this evaluation was included in the General assessment section. |
| ES2. Power your emotions | ES1. Power your emotions | |
| ES3. Sharing your emotions | ES2. Share your emotions | |
| ES4. Feelings journal diary | – | Deleted based on experts' evaluation. |
| ES5. Relaxation and breathing | ES3. Relaxation and breathing | |
| ES6. Think well and you will succeed | ES4. Think positive | |
| ES7. Proposals for the week | – | Deleted based on qualitative experts' suggestions |
| ES8. People in the same situation | ES5. People in the same situation | |
| ES9. Shared stories | ES6. Shared stories | |
| ES10. Share your story | – | Deleted based on experts' evaluation. |
| ES11. Organisations | ES7. Organisations | |
| **Control of signs and symptoms (CSS)** | **Control of signs and symptoms (CSS)** | |
| CSS1. Common signs and symptoms | CSS1. Common signs and symptoms | |
| CSS2. Description of common signs and symptoms | CSS2. Description of common signs and symptoms | |
| CSS3. My symptoms | CSS3. Initial Signs and symptoms<br>CSS4. My symptoms<br>CSS5. Symptoms registration | To clarify and order the information. |
| CSS4. My vital signs | CSS6. My vital signs<br>CSS7. Vital signs registration | To clarify and order the information. |
| CSS5. Questions to ask at your next doctor appointment | CSS8. Questions to ask at your next doctor appointment | |
| CSS6. What to do in an acute chest pain crisis? | CSS9. What to do in an acute chest pain crisis? | |
| **Resources (R)** | **Resources (R)** | |
| R1. My referral primary care center | – | Due to technical problems, this section could not be developed. |
| R2. My referral hospital | – | |
| R3. Organisations | R1. Organisations | Screen shared with emotional support. |
| R4. Caregiver Resources | – | Contents are included in the Organisations section. |
| **Learn and Have Fun (LHF)** | **Learn and Have Fun (LHF)** | |
| LHF1. Knowledge game | LHF1. Knowledge game | |
| LHF2. Add questions to the knowledge game. | LHF2. Add questions to the knowledge game. | |
| LHF3. Goals | LHF3. Goals | |
| TOTAL: 59 screens | TOTAL: 54 screens | |

### 4.1. Strengths

An advantage of the Delphi method is that participants remain anonymous to each other during the study [13]. This allows participants to express their honest opinions without social pressure, and without being influenced by the identities of other experts, thus ensuring objectivity in their decision-making process [16]. Every effort was made to ensure the methodological rigor of this modified Delphi study, by

including opinions from experts with extensive experience in their field. In addition, the high response rate of experts is a valuable strength that decreases the possibility of selection bias and consensus reached by the expert panel.

Likewise, another strength is the inclusion of patients in the process. This approach has been identified in the literature as an important gap in the piloting and validation of the health apps that have been fixed in this study.

### 4.2. Limitations

This study investigated content validity, which is one aspect of validity; future investigation into the usability and clinical validation of the developed app will be carried out.

Although, it was observed that some experts left a few questions unanswered, Hyrkäs et al. [68] state that 10 would provide a reliable estimate of the content validity. Anyway, in future studies, it would be recommended to configure the questions as mandatory answers to ensure that no questions remain unanswered.

## 5. Conclusions

mICardiApp an app to improve HL and self-management of patients with multimorbidity and HF, designed by a panel of professionals from different disciplines and patients, has been validated by a diverse set of experts. This, together with the fact that the content has been developed from both an exhaustive literature review of mHealth interventions for HF patients, and previous qualitative research to define patients' needs and preferences, make for an application with proven validation.

## 6. Summary table

***What was already known on the topic?***

•Heart failure (HF) is a chronic disease associated with the presence of multimorbidity and high mortality rate, which has a great impact on a patient's quality of life.

•Apps have shown great promise for increasing the quality of self-care and adherence to HF patients.

•To provide a more comprehensive approach, different professionals and users should participate in the design and creation of apps.

***What did this study add to our knowledge?***

A multiphase design based on an exhaustive bibliographic review, the opinion and needs of this population segment, and the Delphi technique have allowed the development of a valid app aimed at improving the life quality of patients with multimorbidity and HF.

### *CRediT authorship contribution statement*

**Martina Fernández-Gutiérrez:** Conceptualization, Methodology, Data curation, Writing – original draft, Writing – review & editing. **Pilar Bas-Sarmiento:** Conceptualization, Methodology, Data curation, Writing – original draft, Writing – review & editing. **Antonio Jesús Marín-Paz:** Methodology, Data curation, Writing – original draft, Writing – review & editing. **Cristina Castro-Yuste:** Writing – original draft. **Eduardo Sánchez-Sánchez:** Writing – original draft. **Eulàlia Hernández-Encuentra:** Writing – original draft. **Maria Jesus Vinolo-Gil:** Writing – original draft. **Inés Carmona-Barrientos:** Writing – original draft. **Miriam Poza-Méndez:** Methodology, Data curation, Writing – original draft, Writing – review & editing.

### Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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