science, engineering and health studies

Research Article

Science, Engineering and Health Studies
https://li01.tci-thaijo.org/index.php/sehs
ISSN (Online): 2630-0087

Developing a volume control innovation for elderly with congestive heart failure

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***Received**: 19 January 2024*
***Revised**: 10 June 2024*
***Accepted**: 13 June 2024*
***Published**: 26 December 2024*

***Citation**:*
Kitisri, C., Nokham, R., Boonprasert, P., Chaiwong, P., Konartorn, D., and Phetcharat, K. (2024). Developing a volume control innovation for elderly with congestive heart failure. Science, Engineering and Health Studies, 18, 24050025.

ABSTRACT

Maintaining effective volume balance through monitoring and control is crucial for preventing volume overload in patients with congestive heart failure (CHF). The purpose of the study was to develop and test a volume control innovation for elderly with CHF. The study applied the design thinking model to create this innovation. Research instruments included a questionnaire to assess the structure and function of volume control system, as well as a checklist for accuracy testing. These instruments were evaluated by experts and yielded an index of item objective congruence value ranging from 0.67 to 1.00. The questionnaire assessing user satisfaction, also evaluated by experts, showed a content validity index of 1.00. The study sample included 26 participants: 21 elderly individuals with CHF and 5 healthcare professionals. The volume control innovation consists of a sensor-based device that measures volume intake and output, along with web applications for both elderly users and healthcare professionals. Results showed that all accuracy tests—including alert when volume intake reached a specified limit, measurement of volume intake and output, automatically calculation of appropriate daily water intake, display of user information on a web application, and storage and recording of user data—achieved 100% accuracy. Elderly participants with CHF reported high satisfaction with the innovation, and healthcare professionals also expressed high satisfaction. The study recommends future research to explore the effectiveness of fluid self-management in elderly individuals with CHF.

Keywords: volume control; innovation; elderly; congestive heart failure

1. INTRODUCTION

Congestive heart failure (CHF) is a late-stage clinical syndrome associated with various heart diseases. It leads to inadequate cardiac output, resulting in symptoms such as breathlessness, fatigue, limb swelling, engorged neck veins, and pulmonary edema (McDonagh et al., 2021). CHF is a major global health concern, particularly in Thailand, where it poses substantial public health challenges and results in high healthcare costs. Despite advances in treatment, mortality rates remain elevated, especially among elderly patients experiencing acute heart failure exacerbations (Buakhamsri et al., 2019). Current treatment typically involves medication management and promoting patient self-care, with the caveat that treatment effectiveness relies on patient adherence to recommendations and consistent medication use. Failure to follow these recommendations or take medication regularly may undermine treatment effectiveness, potentially leading to severe and frequent complications, such as fluid overload (Jaarsma et al., 2021).

Fluid overload occurs when the body rapidly accumulates excess extracellular fluid due to excessive intake of water or sodium, disrupting the regulation of water balance. The increased extracellular fluid places additional strain on the heart, making it work harder than usual. As a result, the heart becomes less able to manage CHF effectively, potentially leading to life-threatening exacerbations and increased mortality if left untreated (Jaarsma et al., 2021; McDonagh et al., 2021). A review of the literature reveals that recurrent hospitalizations often stem from patients' inability to manage their self-care behaviors, particularly in regulating fluid balance. Maintaining a proper equilibrium between fluid intake and output is crucial, as excessive fluid intake in CHF patients can lead to fluid overload (Simpson and McIntosh, 2021). Therefore, it is essential for CHF patients to monitor and control their fluid balance. This involves tracking urine output and accounting for involuntary fluid losses, such as sweating, respiration, and bowel movements (insensible loss). The European Heart Association recommends that CHF patients limit their water intake based on the severity of their CHF symptoms (McDonagh et al., 2021). Patients are also advised to keep a daily record of their fluid intake and output, measuring and recording the amount of water consumed and the volume of urine produced each time. Maintaining a written record helps calculate the daily fluid balance, prevent volume overload and determining appropriate daily fluid intake (Lin et al., 2020).

Despite strong evidence supporting the effectiveness of fluid management in preventing volume overload and reducing hospital readmissions, many patients continue to struggle with fluid management (Michelsen et al., 2022; Woods et al., 2018). Elderly individuals with CHF should be supported in developing the skills to monitor their daily water intake and maintain records of both water consumption and regular urine output. Using visual aids to represent different container types can help patients estimate and record these quantities (Stickel et al., 2019). Based on previous experiences, paper documentation is the most commonly used method for recording fluid intake. Although widely recommended, this method has limitations in terms of accuracy, potentially due to measurement errors, estimation inaccuracies, data loss, or unclear and inconsistent documentation—issues that are particularly prevalent among elderly patients (Simpson and McIntosh, 2021; Stickel et al., 2019).

The research team has developed an innovative volume control device to address the significant issue of fluid management among elderly individuals with CHF. This innovation is designed to help patients maintain an appropriate daily water intake while enabling self-assessment to prevent and manage volume overload. It was developed using the design thinking model, a well-regarded approach for fostering creative and innovative product development. Design thinking also play a key role in advancing innovative healthcare services by providing nurses with a structured approach to developing clinical problem-solving strategies and healthcare systems that effectively meet patients' needs. The process includes five steps: 1) empathize; 2) define; 3) ideate; 4) prototype; and 5) test (Gwangwava, 2021; Roberts et al., 2016). The volume control innovation includes a water volume meter with sensor technology, along with two web applications—one for elderly patients with CHF and another for healthcare professionals, Each component works together through the Internet of Things (IoT).

Following prototype development, rigorous testing by qualified individuals evaluated the system's operational efficiency, structural design, and technology safety. The innovation's accuracy has been assessed, with a user satisfaction assessment planned as the next step. Nurses, in particular, can play a vital role in promoting patient self-management and in the development of innovations like this one. Such innovation help patients monitor and manage their symptoms more easily and accurately, enabling elderly individuals to better care for themself and control their conditions (Cohen et al., 2021; Feijen et al., 2021; Tongdee and Boongchieng, 2017). As a result, the research team recognized the importance of this issue and developed this volume control innovation to incorporate technology in promoting volume balance monitoring and control for elderly individuals with CHF.

2. MATERIALS AND METHODS

This study utilized research and development (R&D) efforts aimed at creating and testing a volume control innovation for the elderly individuals with CHF. It is based on the design thinking model developed by Stanford d.school, which includes the stages of empathizing, defining, ideating, prototyping, and testing (Gwangwava, 2021; Roberts et al., 2016).

2.1 The empathize stage

The empathize stage involves a concerted effort to thoroughly understand the users' needs. The researcher presented an initial prototype that earned a bronze medal at the Thailand New Gen Inventors Award (I-New Gen Award 2020), organized by the National Research Council of Thailand. The prototype was presented to 10 users (3 elderly individuals with CHF, 3 caregivers, and 4 healthcare professionals). Following this, the researchers conducted interviews with all users to better understand their problems and summarize their requirements. Details are shown in Table 1.

2.2 The define stage

The define stage involved deriving insights from the interviews and a literature review, followed by the identification of the problem to guide further development based on existing equipment. Using the user needs and requirements gathered in the empathize stage, the researchers defined a list of key functions for the innovation as follows: 1) automatically calculate the optimal amount of drinking water per day; 2) use sensor technology to measure the volume of intake and output in real time; 3) save data automatically to cloud storage; 4) alert user when volume intake reaches a set limit, automatically analyze the severity of volume overload and provide recommendations based on the severity; 5) allow healthcare professionals to view patient information and provide real-time feedback.

Table 1. Problems and requirements from users for the development of an innovation

Details of an initial prototype	Problems and requirements from users for the development of an innovation
1. Automatically calculate the appropriate daily water intake.	Maintain this function.
2. Measures daily volume intake and output by the user.	Manually measuring volume intake and output may lead to errors. Therefore, users required a function that automatically measure the amount of volume intake and output.
3. Alerts when volume intake reaches a specified limit.	Maintain this function.
4. Process the body's volume balance and display indicators showing whether the balance is within the desired range over the course of one week.	Maintain this function. In addition, users need a function to self-monitor signs and symptoms of volume overload. The system should display the severity of volume overload on the screen, allowing user to better manage their condition. Healthcare professionals should be able to access patient data remotely and provide recommendations as needed.
5. Records and stores data on an SD card	Cloud storage should replace the SD card for recording and storage patient data, ensuring greater security and accessibility.

2.3 The ideation stage

The ideation stage focused on drafting a conceptual framework for the volume control innovation. Once all the functional requirements identified in the define stage were established, the next step was to develop a proof-of-concept by proposing a framework for the volume control innovation. This framework consists of two main components (Figure 1).

2.3.1 A component for the elderly with CHF

This component for elderly individuals with CHF includes a device that measures volume intake and output in real time and sends the data to cloud storage. It also feature a web application that automatically calculates the appropriate daily water intake, displays alerts when volume intake reaches a specified limit, tracks daily intake and output data, allows self-monitoring of signs and symptoms of volume overload, displaying the severity of overload, and provides recommendations.

2.3.2 A component for healthcare professionals

This component consists of a web application that allows healthcare professional to view patient information and provide recommendations to patients.

The two components operate in conjunction with cloud services via the internet. The cloud service includes an application programming interface (API), web service, and a database that facilitate communication, data processing, and data storage.

Subsequently, the researchers consulted with three experts—one in computer software engineering and two in senior and elderly care. This consultation was aimed at gathering feedback and insights on the conceptual framework. Based on the experts' recommendations, adjustments and revisions were made to improve the framework.

2.4 The prototype stage

The prototype stage involved the design and development of the volume control innovation based on the draft, as follows:

2.4.1 A component for the elderly with CHF

2.4.1.1 A device for measuring the volume intake and output

A device for measuring the volume intake and output is shown in Figure 2. Inside a device, a load cell weight sensor is used to measure the amount of volume intake and output. The sensor sends this data to a cloud service via the internet, where it is recorded and displayed on a web application for real-time tracking.

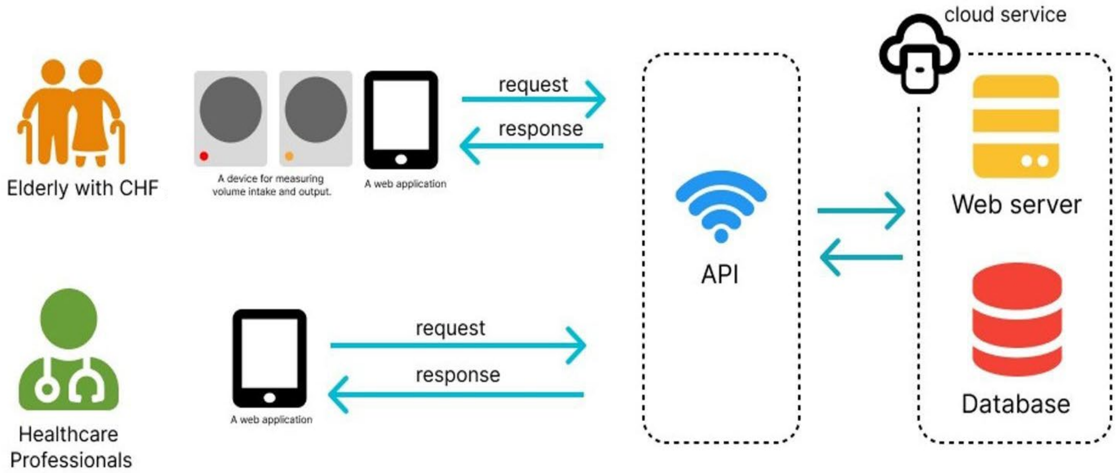

Figure 1. A conceptual framework for a volume control innovation

Figure 2. A device for measuring volume intake and output

2.4.1.2 A web application for the elderly with CHF

The main screen and its sections are shown in Figure 3. Section 1 displays the appropriate daily water intake, calculated based on urine output (volume output) and insensible fluid losses from the previous day. Section 2 displays an icon of a drinking bottle, representing daily water intake. Section 3 displays the severity of volume overload for each day. Section 4 displays daily volume intake and output data for the past week, based on measurement from the intake and output measuring devices. Section 5 displays a daily check button, allowing elderly users to input their weight data and self-assess signs and symptoms of volume overload every morning. These symptoms includes dyspnea, edema, orthopnea, and fatigue. Section 6 includes a chat box for receiving real-time recommendations from healthcare professionals. When healthcare professionals interact to provide additional recommendations, information will be displayed. In section 2, the water level in the bottle icon serves as a visual indicator of the user's progress. The water in the icon changes color to alert the elderly when their intake reaches a specified limit. It turns yellow and red when the user has consumed more than 50% and 80% of the recommended daily water intake, as shown in Figure 4. In section 3, there are four levels of severity: normal (blue), mild (green), moderate (yellow), and severe (red). Severity levels are determined based on signs and symptoms of volume overload. When a symbol is selected, a pop-up display provides recommendations based on the severity of volume overload (Figure 5).

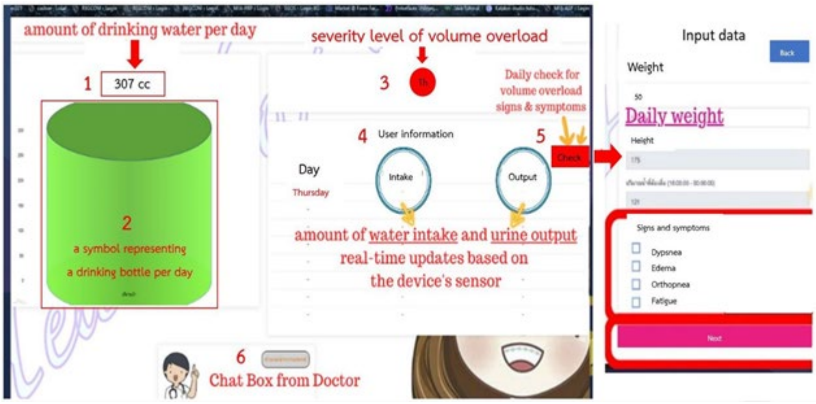

Figure 3. A web application for the elderly individuals with CHF

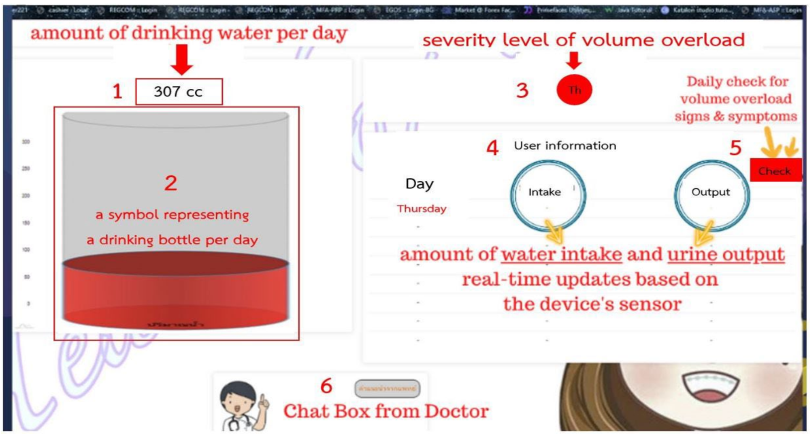

Figure 4. The water in the icon changes color to alert elderly users when their intake reaches a specified limit

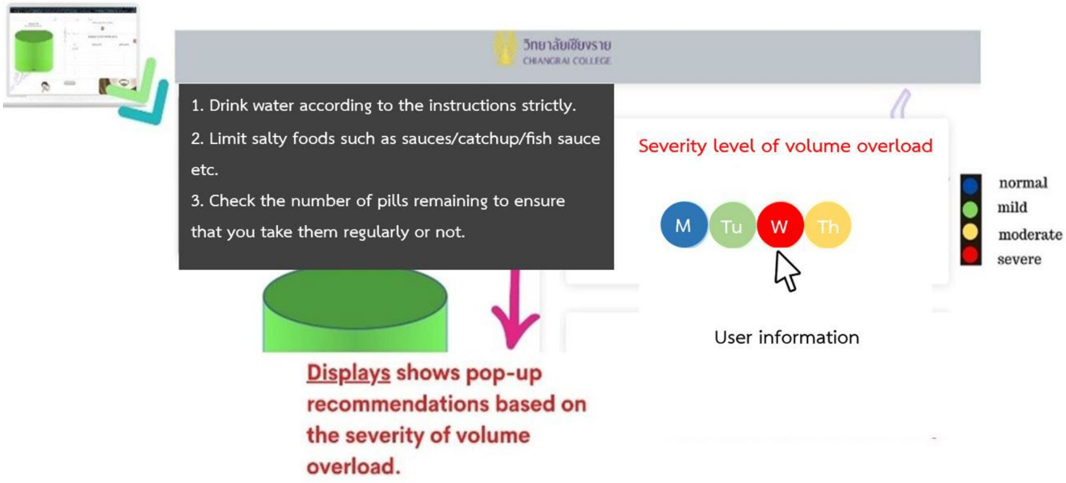

Figure 5. The display shows pop-up recommendations based on the severity of volume overload

Usage steps for the elderly with CHF:

1. Connect a device for measuring volume intake and output to the internet. Once the connection is successful, the device will display the message "Connect OK" and will be ready to measure volume intake and output.

2. Open a web application on a device, such as a mobile phone or tablet and log in using your username and password. The main page will be displayed after a successful login.

3. First, press the check button to input weight data in the morning, immediately after waking up, and assess signs and symptoms of volume overload.

4. Next, begin measuring the volume of intake and output.

- To Measure volume intake, place the glass of water on the intake device and press the button to save.
- After drinking, place the glass on the intake device and press the button to save.
- To measure volume output, place the urine container on the output device and press the button to save.

5. Volume intake and output data will be displayed on the web instantly.

2.4.2 A section for healthcare professionals

This section includes a web application designed for healthcare professionals to view patient information and providing recommendations.

Usage steps:

1. Open a web application on a device, such as a mobile phone or tablet.

2. Log in by entering your username and password. The main page will appear after a successful login. The main page displays a list of all users and their severity level of volume overload (Figure 6).

3. Select the patient whose information you wish to view information. The next page will display details about the patient's body weight, signs and symptoms of volume overload, and daily volume intake and output. Healthcare professionals can also provide immediate recommendations to the patient via the chat box (Figure 7).

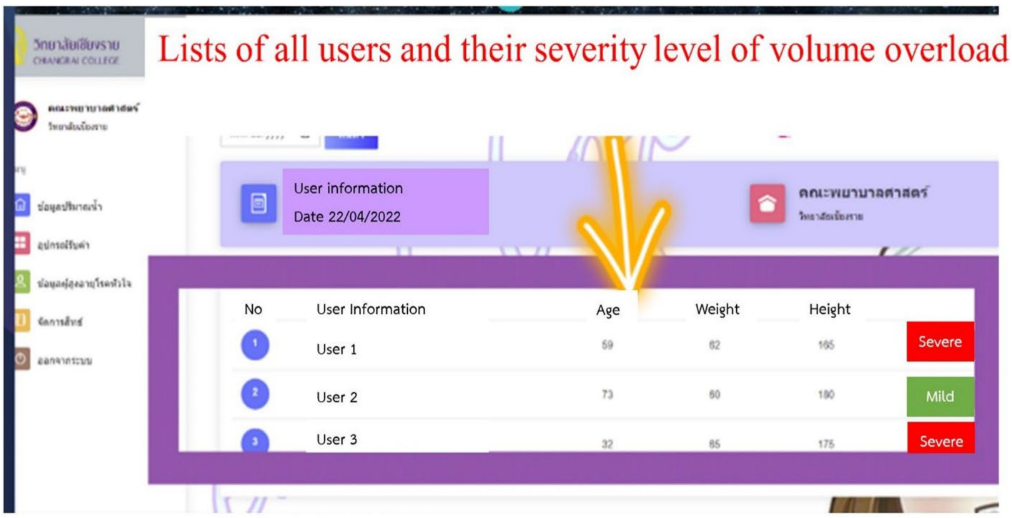

Figure 6. The main page of a web application for healthcare professionals

Figure 7. The page displays information of each patient

The web application for the elderly with CHF and healthcare professionals was developed by a software programmer using the Bootstrap framework, Embedded JavaScript templates (EJS), Hypertext Markup Language 5 (HTML5), JavaScript, NodeJS, jQuery, and Cascading Style Sheet (CSS) as coding languages. For layout design, image assets of images for the user interface were created using the Figma interface tool online. Coding, editing, and debugging were conducted using the Visual Studio Code Integrated Development Environment (IDE). XAMPP's Apache Web Server was used as the server, and My Structured Query Language (MySQL) was employed as the system for managing relational databases. The JavaScript Object Notation (JSON) format was used to transfer data between module through an API service on a cloud service on a cloud platform.

Subsequently, the prototype of the innovation was evaluated for content validity index (CVI) by three experts (one expert in computer software engineering and two experts in senior and elderly care) using a questionnaire assessing the structure and function of volume control innovation. The evaluation focused on the quality and suitability of the innovation in terms of operational efficiency, structural design, and technological safety. The expert evaluation results were used to calculate the CVI, which yielded a value of 0.83. Following the expert evaluations, the innovation prototype was tested with a small group consisting of 5 elderly individuals with CHF and 5 healthcare professionals. Feedback from both experts and users emphasized the need for larger font sizes and clearer language in the web application to better accommodate elderly users. Users also recommended using distinct color buttons for the volume intake and output devices. Based on this feedback, the researchers made improvements to the prototype based before testing it with a large sample.

2.5 The test stage

2.5.1 Accuracy testing

The researcher developed five volume control innovation prototypes and tested their accuracy in several key areas: alerting when the volume intake reaches a specified limit, measuring volume intake and output, automatically calculating the appropriate daily water intake, displaying user information on a web application, and storing and recording user data. The accuracy of each task was assessed by recording the number of correct operations on a checklist during one week of continuous testing. All prototypes were required to achieve an accuracy level of 95% or higher. If the accuracy fell below 95%, the innovation was revised and improved before further implementation.

2.5.2 Usability testing

The researcher tested the five volume control innovation prototypes with 26 participants (21 elderly individuals with CHF and 5 healthcare professionals). Following the testing, user satisfaction was evaluated based on several factors, including convenience, ease of use, the usefulness of automatically calculating the optimal daily water intake, the usefulness of controlling volume intake and output, the usefulness of recording daily volume intake and output, the safety of use, ease of storage and cleaning, suitability for daily life use, and its ability to promote self-care in volume control and prevent volume overload.

2.6 Participants

The target population consisted of individuals aged 60 and older who have been diagnosed with CHF, as well as healthcare professionals working at the Chiang Rai Medical Center for Heart Disease, Faculty of Medicine, Mae Fah Luang University, Thailand. Data were collected from September 2020 to December 2021.

Purposive sampling was used to recruit 26 participants, comprising 5 healthcare professionals from the Heart Center, Mae Fah Luang University Hospital, and 21 elderly individuals with CHF from the same facility. The inclusion criteria were as follows: 1) proficiency in the Thai language, 2) ability to read and write, 3) no cognitive impairment, 4) independence in daily activities, and 5) access to devices capable of connecting to the internet.

2.7 Instruments

1. The questionnaire for the structure and function of volume control innovation was developed by the researcher. This questionnaire was used with experts

and small-scale experimental groups. It consists of 13 items: 5 items related to the structure and function of the innovation, 7 items related its design, and 1 item concerning its safety. Responses were based on a Likert scale. The index of item objective congruence (IOC) for this questionnaire ranges from 0.67 to 1.00.

2. The checklist for accuracy testing of the volume control innovation was also created by researchers. This checklist assess accuracy in 5 areas: 1) alerting when volume intake reaches a specified limit, 2) measuring volume intake and output, 3) automatically calculating the appropriate daily water intake, 4) displaying user information on a web application, and 5) storing and recording user data. The IOC for this checklist ranges from 0.67 to 1.00.
3. The questionnaire for user satisfaction is a 9-item questionnaire developed by researchers. It was used to assess user satisfaction in term of convenience, ease of use, the usefulness of automatically calculating the optimal daily water intake, controlling volume intake and output, recording daily volume intake and output, safety, ease of storage and cleaning, suitable for daily life, and promoting self-care in volume control and preventing volume overload. All items were answered on a four-point scale with satisfaction levels classified as high, moderate, or low. This CVI for this questionnaire is 1.00.

2.8 Data Collection

A total of 26 participants (21 elderly individuals with CHF and 5 healthcare professionals) attended group sessions to receive training on how to use the volume control innovation. They were then provided with login IDs and passwords to ensure data security while using the web application. Participants used the volume control innovation for one week. The researcher followed up on any issues by telephone or video call every Monday, Wednesday, and Friday. At the end of the week, an evaluation was conducted to assess user satisfaction with utilizing the prototype of the volume control innovation for the elderly with CHF.

2.9 Data analysis

The accuracy testing and user satisfaction scores for the volume control innovation among elderly individuals with CHF were analyzed using descriptive statistics, including average and standard deviation.

2.10 Ethical consideration

The study was approved by the Human Research Ethics Committee from Chiang Rai Provincial Public Health Office (approval number 85/2563).

3. RESULTS

3.1 Accuracy testing results of the prototype

The accuracy of each task was assessed by recording the number of correct operations on a checklist during one week of continuous testing. The results are presented as percentages in Table 2.

3.2 Usability testing results

After receiving training and demonstrations on how to use the volume control innovation, the 21 elderly individuals with CHF and 5 healthcare professionals participated in usability testing. The data on user satisfaction with the volume control innovation is shown in Table 3.

Table 2. Accuracy testing results of the prototype

The testing items	Percentage of accuracy testing
1. Alerting when the volume intake reaches a specified limit	100%
2. Measuring volume intake and output	100%
3. Automatically calculate the appropriate daily water intake	100%
4. Displaying user information on a web application	100%
5. Storing and recording user data	100%

Table 3. User satisfaction with the volume control innovation

Evaluation items	Elderly individuals with CHF (n = 21)		Satisfaction Level	Healthcare professionals (n = 5)		Satisfaction Level
	Mean	SD		Mean	SD	
1. Convenience	2.95	0.86	Moderate	2.60	0.66	Moderate
2. Ease of use	3.00	0.95	High	2.60	0.66	Moderate
3. Usefulness of automatically calculating the optimal daily water intake	3.67	0.58	High	3.60	0.60	High
4. Usefulness of controlling volume intake and output	3.43	0.87	High	3.40	0.60	High
5. Usefulness of recording daily volume intake and output	3.48	0.75	High	3.40	0.60	High
6. Safety of use	3.52	0.60	High	2.80	0.60	High
7. Ease of storage and cleaning	3.48	0.68	High	3.00	0.61	High
8. Suitable for daily life use	3.14	0.73	High	3.20	0.63	High
9. Ability to promote self-care in volume control and prevent volume overload.	3.33	0.91	High	3.80	0.67	High
Overall satisfaction	3.33	0.77	High	3.16	0.62	High

4. DISCUSSION

Overall, satisfaction was high following the implementation of the volume control innovation. This success may be attributed to the innovation's development using the design thinking model (Gwangwava, 2021; Roberts et al., 2016), which emphasize a deep understanding of the users for whom products or services are designed. It encourages empathy and observation of the target user (Srinivas, 2021). The issue of hospital readmission among heart failure patients often arises when they are unable to manage their self-care regimen effectively. Volume control is a critical skill for preventing volume overload, which can lead to higher readmission rates. Furthermore, the lack of immediate guidance when an issue arises reduces the patient's ability to manage their condition independently. To address this challenge, the volume control innovation was developed after a thorough analysis of the needs and problems faced by both patients and healthcare professionals—the primary users. In response to heart failure patients' difficulty in maintaining fluid balance at home, a wearable device could be created to continuously monitors and alert patient when their fluid levels are unbalance. By incorporating ongoing feedback from both patients and healthcare providers throughout the design process, the final product will be user-friendly and tailored to meet the specific needs of heart failure patients.

As a result, elderly individuals with CHF typically report high levels of satisfaction, with the convenience of automatically calculating the optimal daily water intake ranking as the top benefit. This feature addresses the common concern of determining how much water they should drink each day, which is a major strength of the innovation. Following this, satisfaction with the safety of use, the usefulness of recording daily volume intake and output, ease of storage and cleaning, and the usefulness of controlling volume intake and output were also highlighted. Other positive factors included promoting self-care in volume control, preventing volume overload, suitability for daily life, and overall ease of use. Similar to previous studies on mHealth and automated digital devices, most participants expressed satisfaction with the device's ease of use (Lefler et al., 2018). This aligns with feedback from interviews with elderly participants, who reported that feeling of having a "personal nurse" helped improved communication between patients, caregivers, and healthcare professionals. Through innovative design and development, the technology can automatically determine the elderly's daily water consumption. A symbol indicates the total water volume and triggers an alarm when the water level near a specified limit, allowing user to adjust their water intake accordingly. This system provides an overview of the daily water intake and output, raising awareness among the elderly about their ability to control their drinking water and offering tailored guidance based on individual circumstances.

The innovation simplifies fluid self-management for elderly individual with CHF by monitoring volume status, assessing their condition and symptoms, and helping them maintain a balanced fluid management approach. Ultimately, fluid self-management behavior is the responsibility of the heart failure patient, leading to improved patient outcomes and quality of life (Apiromrat, 2017; Promwong and Meenongwah, 2019). However, some elderly participants reported moderate satisfaction with the innovation's convenience. Specifically, they found the urine collection process inconvenient as it does not allow for direct collection. Therefore, further refinement of this aspect of the innovation is needed.

For healthcare professionals, the design provides a platform for interaction with patients. The collected data is sent to a web application for processing, and results are displayed on a device equipped with a web browser, aiding in data analysis. This allows healthcare professionals to assess and monitor volume overload symptoms in their patients while offering advice through innovation. As a result, healthcare professionals expressed high satisfaction with the innovation's ability to promote self-care in volume control to prevent volume overload. The ability to automatically calculate the optimal daily water intake, monitor volume intake and output, and record daily volume intake and output were all key factors contributing to the high satisfaction levels among both healthcare professionals and elderly individuals with CHF.

In the 21st century, advancements in digital technologies have significantly impacted patient care, including in area such as communication technology, artificial intelligence, and the Internet of Things. Consequently, nurses and healthcare professionals must adapt to using digital technology for care and management (Cheevakasemsook, 2021). Previous studies on the use of applications to promote self-care among heart failure patients have shown increased awareness, self-monitoring, and empowerment (Heiney et al., 2020; Luštrek et al., 2021; Choi et al., 2023). However, during training to use the innovation, both elderly participants with CHF and healthcare professionals suggested simplifying that the installation process or providing an automatic connection when the device is first set up, making the innovation more user-friendly. Furthermore, healthcare professionals expressed concerned about using complex technology with the elderly. In case where the internet connection is unstable or devices malfunction, those living alone may struggle to solve the issues independently. As a result, healthcare professionals reported moderate ease of use and safety when using the innovation. A literature review indicates that technological access and internet connectivity remain significant challenges for older individuals, making it difficult for health team to plan, develop, and implement technology-based solutions for the elderly based on the concept of lifelong learning (Wilson et al., 2021). Therefore, the elderly require social support during the training period to learn alongside others, and training guidelines should include solutions for any problems that arise.

5. CONCLUSION

The study focused on developing and testing a volume control innovation specifically for elderly patients with CHF. Researchers employed a design thinking approach to create a sensor-based device with web applications that accurately monitor and regulate fluid intake and output. This innovation has also introduced a new process for healthcare professionals to monitor, assess, and communicate with the elderly CHF patients. As a result, the innovation supports self-care for CHF patient through volume control and provides a communication channel with healthcare provider via a chatbox.

ACKNOWLEDGMENT

This research was supported by the Research Fund of the Ministry of Higher Education, Science, Research, and Innovation (MHESI). The authors would like to acknowledge the Faculty of Nursing, Chiang Rai College and the Faculty of Computer and Information Technology at Chiang Rai Rajabhat University for their support of this study.

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