

RESEARCH ARTICLE (ORIGINAL) 

## Theoretical usability of an innovative device for post-infarction rehabilitation: Observational study with rehabilitation nurses

*Usabilidade teórica de um dispositivo inovador de reabilitação para doentes pós-enfarte: Estudo observacional com enfermeiros de reabilitação*

*Usabilidad teórica de un dispositivo innovador para la rehabilitación posinfarto: Estudio observacional con enfermeros de rehabilitación*

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**Abstract**

**Background:** Cardiac rehabilitation programs are essential for recovering and maintaining functional capacity in patients with acute myocardial infarction. Current programs have high dropout rates and require more motivational features.

**Objectives:** To assess and compare the usability of two prototypes of an innovative rehabilitation device for post-infarction patients.

**Methodology:** This is a quantitative observational study using a 5-point Likert-type scale with 16 nurse specialists in rehabilitation, selected through snowball sampling.

**Results:** The quantitative analysis showed a three-dimensional assessment of the prototypes with mean scores of 4, indicating usability and intention to use. Both prototypes were considered useful, functional, and easy to learn and use, with few differences reported on the three dimensions. The ease of learning was more consensual in the Alpha prototype.

**Conclusion:** The two developed prototypes present high usability scores and are very similar, demonstrating great potential for effectiveness in the intended context.

**Keywords:** rehabilitation nursing; myocardial infarction; cardiac rehabilitation; technological development and innovation projects; user-centered design

**Resumo**

**Enquadramento:** Os programas de reabilitação cardíaca são fundamentais para a recuperação e manutenção da capacidade funcional em pessoas vítimas de enfarte agudo do miocárdio. Os programas atuais evidenciam taxas de abandono elevadas e requerem mais elementos geradores de motivação nos utilizadores.

**Objetivos:** Avaliar e comparar a usabilidade de dois protótipos de um dispositivo de reabilitação inovador para doentes pós enfarte agudo do miocárdio.

**Metodologia:** Estudo observacional quantitativo, utilizando uma escala do tipo *Likert* de 5 pontos numa amostra de 16 enfermeiros especialistas em reabilitação, selecionados através da técnica de amostragem “bola de neve”.

**Resultados:** A análise quantitativa revelou uma avaliação tridimensional dos protótipos com uma pontuação média de 4 valores, indicando usabilidade e intenção de uso. Ambos os protótipos foram considerados úteis, funcionais e fáceis de aprender e utilizar, observando-se poucas diferenças nas três dimensões. A facilidade de aprendizagem revelou-se mais consensual no protótipo Alfa.

**Conclusão:** Os dois protótipos desenvolvidos alcançaram pontuações de usabilidade elevadas e são muito semelhantes, apresentando um forte potencial de eficácia no contexto desejado.

**Palavras-chave:** enfermagem em reabilitação; infarto do miocárdio; reabilitação cardíaca; projetos de desenvolvimento tecnológico e inovação; design centrado no usuário

**Resumen**

**Marco contextual:** Los programas de rehabilitación cardíaca son esenciales para la recuperación y el mantenimiento de la capacidad funcional de los pacientes que han sufrido un infarto agudo de miocardio. Los programas actuales tienen altas tasas de abandono y requieren más características de motivación.

**Objetivos:** El estudio pretende cuantificar y comparar la usabilidad de dos prototipos de un dispositivo innovador para la rehabilitación de pacientes que han sufrido un infarto.

**Metodología:** Se realizó un estudio cuantitativo observacional con enfermeros especialistas en rehabilitación, para lo cual se aplicó una escala tipo Likert de 5 puntos. Se reunieron 16 participantes con un método de muestreo por bola de nieve.

**Resultados:** El análisis cuantitativo mostró una evaluación tridimensional de los prototipos con una puntuación media de 4, lo que denota la facilidad de uso y la intención de uso. Ambos prototipos se consideraron útiles, funcionales y fáciles de aprender y utilizar, con pocas diferencias en las tres dimensiones. La facilidad de aprendizaje se consensuó más en el prototipo Alfa.

**Conclusión:** Ambos prototipos desarrollados presentan altos valores de usabilidad y son muy similares, con gran potencial para ser efectivos en el contexto deseado.

**Palabras clave:** enfermería de rehabilitación; infarto de miocardio; rehabilitación cardíaca; proyectos de desarrollo tecnológico e innovación; diseño centrado en el usuario

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Received: 08.09.21

Accepted: 26.04.22



**How to cite this article:** Bernardes, R. A., Parreira, P., Sousa, L., & Cruz, A. G. (2022). Theoretical usability of an innovative device for post-infarction rehabilitation: Observational study with rehabilitation nurses. *Revista de Enfermagem Referência*, 6(1), e21108. <https://doi.org/10.12707/RV21108>



## Introduction

Cardiac rehabilitation (CR) is an essential multidisciplinary intervention for recovering patients that suffer acute cardiac events, such as myocardial infarction (Anderson et al., 2016). However, conventional rehabilitation programs can be restrictive and demanding, and the lack of customized intervention programs and ergonomic devices increases the dropout rates (Mikkelsen et al., 2014). Developing innovative technologies and assistive devices is current practice, and nurses' inclusion in this process is crucial for achieving effective solutions (Castner et al., 2016).

This study aims to assess and compare the usability of two prototypes of an innovative device for rehabilitating post-infarction patients. Moreover, it intends to improve the *Ablefit* prototypes, assessing their usability from the rehabilitation nurses' point of view, developing them into efficient and safe assistive devices, and responding to the challenges posed by current research in this area.

## Background

The European Society of Cardiology (Thygesen et al., 2019) has recently defined acute myocardial infarction (AMI) as myocardial cell death due to prolonged ischemia, resulting in insufficient oxygen supply to the muscles. AMI and concurrent physiological changes cause patients to feel fatigued, have dyspnea, and lose muscular strength, thus limiting their activities of daily living (ADL; Lopes et al., 2018). Including these patients in CR programs is recommended, as these are complex multidisciplinary interventions with specific benefits for post-AMI patients (Michelsen et al., 2020). Physical exercise is one of CR's core components and interventions, and, according to Price et al. (2020), it should be indicated for pathologies such as stable *angina pectoris* or AMI.

In this context, using interventions assisted by medical devices has shown significant results in recovering motor function (Phyo et al., 2016). For bedridden patients with reduced muscular strength, as in the first phase of CR programs, some "conventional" programs (such as progressive walking or transfer and resistance training) can be too demanding, as observed by Resurrección et al. (2019), who reported high dropout rates. Thus, it is crucial to investigate and study more effective and motivating patient interventions. Using technology in a rehabilitation program has been demonstrated to be highly beneficial due to its potential attractiveness and efficiency. Nurses play a vital role in developing new devices, particularly in concept design and prototype development (Castner et al., 2016), due to their expertise and proximity to real-life problems.

The Health Sciences Research Unit: Nursing (UICISA: E) of the Nursing School of Coimbra (ESENfC) and the *Instituto Superior de Engenharia de Coimbra* (ISEC - Coimbra Institute of Engineering) have developed the *Ablefit* device. The device has an approved national patent for limb rehabilitation in bedridden patients. Alpha

and Beta prototypes were developed for the *Ablefit* device. The Alpha prototype includes a cycloergometer for lower limbs. The Beta prototype does not present this feature but has several elastic bands with progressive resistance and a real-time biofeedback system. The first is multi-modal, being easy to assemble and transport, allowing the mobilization of upper and lower limbs with a single elastic band, hardly variable in resistance. The second has several elastic bands with different resistance levels and is interfaced with a computer, which measures other exercise parameters, such as time and intensity.

This study aims to assess and compare the usability of both prototypes for the rehabilitation of post-infarction patients. According to the International Organization for Standardization (ISO, 2018), usability can be defined as the effectiveness, efficiency, and satisfaction with which specified users achieve specified goals in specific contexts. In this sense, this study used the Technology Acceptance Model (TAM) as a conceptual framework and focused on the intended dimensions of usability. This model seeks to explain and predict users' intention to use a given technology based on perceived usability and ease of use (Sagnier et al., 2020).

## Research questions

What are the usability and ergonomics of the Alpha and Beta prototypes of the *Ablefit* device for post-AMI patients? How can the prototypes be compared?

## Methodology

A quantitative observational study was conducted with rehabilitation nurses working in Portugal. The nurses were selected using the exponential snowball sampling method. The inclusion criteria were to be a nurse with at least a postgraduate specialization degree in rehabilitation nursing (nurse specialist in rehabilitation nursing) and at least three years of clinical experience as a nurse (not necessarily as a nurse specialist in rehabilitation nursing). General care nurses and professionals with previous contact with the device under study (either theoretical, by knowing the underlying concept, or practical, by having experimented with it) were excluded.

Before signing the informed consent forms, the individuals considered eligible for this study received all the necessary information on the study's objective, the procedures inherent to the investigation, and the voluntary nature of participation.

The Portuguese version of the System Usability Scale (SUS; Martins et al., 2015), originally developed by John Brooke in 1996, was used to assess usability. The SUS evaluates three essential components of usability – efficiency, effectiveness, and satisfaction – while also allowing a subjective (qualitative) assessment. This instrument was selected because participants find it easy to complete, can be used in small samples with reliable results, and has construct validity, effectively differentiating between

systems with perceived usability and systems without perceived usability.

Initially, the instrument was designed exclusively to assess perceived ease of use. Nevertheless, some authors (Martins et al., 2015) have considered it a global measure of usability, which can be divided into two subscales: usability (items 1, 2, 3, 5, 6, 7, 8, 9) and learning (items 4 and 10). The SUS was validated for the Portuguese population in 2015 by Martins et al. (2015) in a study with 32 participants, resulting in 10 items considered equivalent to the original SUS. Due to the percentage of agreement (76.67%) among the participants about the usability/non-usability of the system under study, the authors concluded that the Portuguese version of the SUS can draw this distinction effectively.

The instrument consists of ten questions, scored from 1 to 5 on a Likert scale, ranging from *totally disagree* to *totally agree*. The items are as follows: 1 – “I think that I would like to use this system frequently”; 2 – “I found the system unnecessarily complex”; 3 – “I thought the system was easy to use”; 4 – “I think that I would need the support of a technical person to be able to use this system”; 5 – “I found the various functions in this system were well integrated”; 6 – “I thought there was too much inconsistency in this system”; 7 – “I would imagine that most people would learn to use this system very quickly”; 8 – “I found the system very cumbersome to use”; 9 – “I felt very confident using the system”; 10 – “I needed to learn a lot of things before I could get going with this system.”

Due to the Covid-19 Pandemic context, the questionnaires were completed without participants practicing on the prototypes. Thus, it was necessary to adapt the Portuguese version of the instrument, namely items 9 and 10, which were rewritten as 9 – “I would feel very confident using this system” and 10 – “I would have to learn a lot before I could get going with this system.” In this sense, and taking into account the mentioned subscales, it was considered that applying the scale in the described context would allow assessing the device’s usability and learning potential.

Sociodemographic data were collected using a questionnaire built by the research team and inserted in *Google Forms*, together with the SUS.

Before contacting the participants, the research team recorded two videos demonstrating each prototype’s operation. These videos were merged into a single 6-minute video with an overall demonstration of each prototype and embedded audio explanations.

Participants were invited to be part of the investigation via email, which included the informed consent form. Participants were recruited between May and June 2020. After receiving the positive response to the invitation and the signed informed consent form, the research team sent an individual email with a *Doodle* for participants to choose one of three *ZOOM* sessions to be held in July 2020. Each session began by briefly presenting the agenda to the participants, followed by the video demonstrating each prototype’s operation. Next, the *Google Forms* link was sent via *ZOOM* chat. Each session had a mean du-

ration of one hour.

Strategies in care of withdrawal of participants consisted of collecting the reasons for opting-out, regardless of the phase of the study and information collected, which was eliminated from the database, to which only the principal investigator had access.

Responsible for this study’s ethical evaluation, the Ethical Committee of the UICISA: E gave it a favorable opinion (P671-05/2020).

Statistical analysis and data treatment were performed using the *Statistical Package for the Social Sciences* (SPSS) software, version 25, and descriptive and inferential statistics (Student’s *t*-Test). The independent samples *t*-test was performed to assess differences between the mean values of the prototypes’ scores. Differences between means whose *p-value* was less than or equal to 0.05 were considered statistically significant.

An exploratory factor analysis (EFA) was conducted to explore the dimensions of the participants’ scores. Since some items were inverted, and to ensure a higher score corresponds to a more positive assessment, the negative items were inverted (2, 4, 6, 8, 10). To analyze the extent to which data shows a normal distribution, the Kolmogorov-Smirnov (KG) and Shapiro-Wilk (SW) normality tests were performed.

## Results

Three focus groups were carried out with a total of 16 nurses, of which 68.8% (11) were male and 31.3% (5) female, with a mean age of 31.38 years ( $SD = 7.63$ ). Regarding education, besides being nurse specialists in rehabilitation nursing, 25% (4) of the participants had a postgraduate degree, 31.3% (5) a master’s degree, 18.8% (3) a doctoral degree, and 6.3% (1) a post-doctoral degree. A total of 3 (18.75%) missed answers were registered regarding this sociodemographic topic, probably due to an error in the questionnaire used to collect data, but without prejudice to the study’s results. Most participants, 75% (12), worked in public hospital institutions, and the remaining 25% (4) were in the higher education area, namely in nursing schools. Participants from public hospitals worked in different units/services, namely intensive care, gastroenterology, pediatrics, medical oncology, internal medicine, physical rehabilitation and medicine, and cardiothoracic surgery. Of the 16 nurses, 25% (4) were in their current workplace for 5 years or less, 12.5% (2) between 6 and 10 years, 37.5% (6) between 11 and 20 years, and 25% (4) for more than 20 years. Considering the length of professional experience as nurses, 56.3% (9) worked for more than 20 years. As nurse specialists in rehabilitation, 37.5% (6) had a length of professional experience between 11 and 20 years.

The SUS theoretical dimensions of usability were analyzed, and the values presented as Mean (M) + Standard Deviation (SD).

Considering the questions regarding the Alpha Prototype (Table 1), items Q2 – “I found the system unnecessarily complex” ( $M = 1.88 \pm 0.96$ ), Q6 – “I thought there was

too much inconsistency in this system” ( $M = 1.94 + 0.68$ ) and Q8 – “I found the system very cumbersome to use” ( $M = 1.44 + 0.63$ ) presented lower mean scores. On the other hand, items Q3 – “I thought the system was easy to use” ( $M = 4.31 + 1.01$ ) and Q7 – “I would imagine that most people would learn to use this system very quickly” ( $M = 4.50 + 0.52$ ) presented high mean

scores. Item Q7 – “I would imagine that most people would learn to use this system very quickly” had a low level of variability ( $M = 4.50 + 0.52$ ), while items Q3 – “I thought the system was easy to use” ( $M = 4.31 + 1.01$ ) and Q4 – “I think that I would need the support of a technical person to be able to use this system” ( $M = 1.69 + 1.08$ ) showed higher levels of variability.

**Table 1**

*Minimum, maximum, mean, and standard deviation values of the SUS theoretical dimensions for the Alpha Prototype*

Dimensions	Items	Min	Max	M	SD
Usability	Q1 – I think that I would like to use this system frequently	2	5	3.94	0.85
	Q2 – I found the system unnecessarily complex	1	4	1.88	0.96
	Q3 – I thought the system was easy to use	2	5	4.31	1.01
	Q5 – I found the various functions in this system were well-integrated	2	5	3.88	0.81
	Q6 – I thought there was too much inconsistency in this system	1	3	1.94	0.68
	Q7 – I would imagine that most people would learn to use this system very quickly	4	5	4.50	0.52
	Q8 – I found the system very cumbersome to use	1	3	1.44	0.63
	Q9 – I would feel very confident using this system	3	5	4.25	0.68
	Learning	Q4 – I think that I would need the support of a technical person to be able to use this system	1.00	4.00	1.69
Q10 – I would have to learn a lot before I could get going with this system		1.00	4.00	1.94	0.93

*Note.* M = Mean; SD = Standard deviation; Min = Minimum; Max = Maximum.

Analyzing the answers to the questions on the Beta Prototype (Table 2), items Q2 – “I found the system unnecessarily complex” ( $M = 1.81 \pm 0.83$ ), Q6 – “I thought there was too much inconsistency in this system” ( $M = 1.81 \pm 0.75$ ) and Q8 – “I found the system very cumbersome to use” ( $M = 1.56 \pm 0.73$ ) had lower mean scores, while items Q3 – “I thought the system was easy to use” ( $M = 4.38 \pm 0.81$ ) and Q7 – “I would imagine that most people would learn to use this sys-

tem very quickly” ( $M = 4.50 \pm 0.52$ ) presented higher mean scores.

Regarding the variability of answers, item Q7 – “I would imagine that most people would learn to use this system very quickly” ( $M = 4.50 \pm 0.52$ ) presented a low level, whereas items Q1 – “I think that I would like to use this system frequently” ( $M = 4.13 \pm 0.96$ ) and Q10 – “I would have to learn a lot before I could get going with this system” ( $M = 2.06 \pm 1.06$ ) presented high levels.



**Table 2***Minimum, maximum, mean, and standard deviation values of the SUS theoretical dimensions for the Beta Prototype*

Dimensions	Items	Min	Max	M	SD
Usability	Q1 – I think that I would like to use this system frequently	2	5	4.13	0.96
	Q2 – I found the system unnecessarily complex	1	4	1.81	0.83
	Q3 – I thought the system was easy to use	3	5	4.38	0.81
	Q5 – I found the various functions in this system were well-integrated	2	5	3.88	0.89
	Q6 – I thought there was too much inconsistency in this system	1	3	1.81	0.75
	Q7 – I would imagine that most people would learn to use this system very quickly	4	5	4.50	0.52
	Q8 – I found the system very cumbersome to use	1	3	1.56	0.73
	Q9 – I would feel very confident using this system	3	5	4.25	0.77
	Learning	Q4 – I think that I would need the support of a technical person to be able to use this system	1	4	1.63
Q10 – I would have to learn a lot before I could get going with this system		1	5	2.06	1.06

Note. M = Mean; SD = Standard-Deviation; Min = Minimum; Max = Maximum.

Cronbach's Alpha was determined to assess the internal consistency of the SUS theoretical dimensions, scoring 0.85 for the "Usability" dimension and 0.18 for the "Learning" dimension. Considering that the second dimension did not present acceptable values, an EFA and a Principal Components Analysis were

conducted (Table 3).

The matrix generated by the EFA revealed three interpretable dimensions with factorial loadings greater than 0.56, different from the SUS theoretical dimensions.

Cronbach's Alpha was also determined, revealing adequate values of internal consistency.

**Table 3***Mean, standard deviation, communalities, and factorial loadings of the SUS dimensions*

Items	D1	D2	D3	h <sup>2</sup>	M	SD
Q10 (i) I would have to learn a lot before I could get going with this system.	<b>0.91</b>			0.84	4.00	0.98
Q5 - I found the various functions in this system were well integrated.	<b>0.79</b>			0.66	3.88	0.83
Q6 (i) - I thought there was too much inconsistency in this system.	<b>0.71</b>	0.35		0.63	4.13	0.71
Q4 (i) - I think that I would need the support of a technical person to be able to use this system.		<b>0.93</b>		0.87	4.34	1.00
Q1 - I think that I would like to use this system frequently.	0.42	<b>0.65</b>	0.38	0.74	4.03	0.90
Q8 (i) - I found the system very cumbersome to use.	0.43	<b>0.64</b>		0.63	4.50	0.67
Q9 - I would feel very confident using this system.	0.53	<b>0.62</b>		0.70	4.25	0.72
Q3 - I thought the system was easy to use.	0.47	<b>0.57</b>	0.47	0.76	4.34	0.90
Q7 - I would imagine that most people would learn to use this system very quickly.			<b>0.96</b>	0.92	4.50	0.51
Q2 (i) - I found the system unnecessarily complex.		0.48	<b>0.67</b>	0.68	4.16	0.88

Note. Rotation method = Varimax with Kaiser Normalization; (i) = inverted items; D1 = Dimension 1; D2 = Dimension 2; D3 = Dimension 3; h<sup>2</sup> = Communalities; M: Mean; SD = Standard-Deviation

Dimension 1 (D1) "Functionality and Learning" consists of three items (Q5, Q6, and Q10), Dimension 2 (D2) "Intentionality and Ease of Use" includes five items (Q1, Q3, Q4, Q8, and Q9), and Dimension 3 (D3) "Complex-

ity and Learning" comprehends two items (Q2 and Q7). Regarding internal consistency, D1 and D2 were considered adequate (Cronbach's Alpha > 0.70). D3 was deemed acceptable despite having a value of 0.63. According to

Taber (2018), in dimensions with two items, an internal consistency value greater than 0.60 is considered acceptable.

Thus, the three new dimensions were considered interpretable, with adequate internal consistency values.

With a value of  $SW(32) = 0.94$  ( $p = 0.07$ ), the data were considered to have a normal distribution. The independent samples *t*-test is presented in Table 4.

Considering D1, participants attributed mean values higher than the scale's midpoint to the Alpha ( $M = 4 \pm 0.64$ ) and Beta prototypes ( $M = 4 \pm 0.79$ ), indicating

functionality and ease of learning.

They gave D2 mean values higher than D1, with  $M = 4.3 \pm 0.73$  for the Alpha prototype and  $M = 4.3 \pm 0.67$  for the Beta prototype, demonstrating the ease of use and intention to use frequently and confidently.

D3 presented high mean values ( $M = 4.3 \pm 0.68$ ) for the Alpha prototype and  $M = 4.3 \pm 0.57$  for the Beta prototype, indicating speed and ease of learning but also some degree of complexity.

The *t*-test was evaluated for differences in means to assess statistically significant differences.

**Table 4**

*Mean, standard deviation, and significance level in the Student's t-test of the empirical dimensions of Alpha and Beta Prototypes and KS and SW normality tests*

Empirical Dimensions	Prototype	N	M	SD	SEM	Sig (2-tailed)
D1 «Functionality and Learning»	Alpha	16	4.000	0.644	0.161	1.00
	Beta	16	4.000	0.788	0.197	
D2 «Intentionality and Ease of Use»	Alpha	16	4.275	0.726	0.181	0.88
	Beta	16	4.312	0.665	0.166	
D3 «Complexity and Learning»	Alpha	16	4.312	0.680	0.170	0.89
	Beta	16	4.343	0.569	0.142	

  

Kolmogorov-Smirnov <sup>a</sup>			Shapiro-Wilk	
Df	p	Statistics	Df	p
32	0.021	0.938	32	0.067

Note. M = Mean; SD = Standard Deviation; SEM = Standard Error of the Mean; a. Lilliefors Correction; Df = degrees of freedom; p = significance.

The Student's *t*-test demonstrated that the differences observed between the means of D1, D2 and D3 of the two prototypes were not statistically significant: D1  $t(30) = 0.00$  ( $p = 2.00$ ); D2  $t(30) = -0.15$  ( $p = 0.88$ ); and D3  $t(29.10) = -0.14$  ( $p = 0.89$ ), which allows accepting the null hypothesis ( $H_0$ ).

Thus, it is possible to conclude that participants' usability assessment was similar and highly positive for both prototypes.

## Discussion

Physical exercise is a core component of health professionals' interventions. In Cardiac Rehabilitation Programs (CRP), the developed assistive technology acts as a catalyst and a supplement to professional practice. In this sense, the American Heart Association recommends CR after cardiovascular disease, primarily to reduce the risk of relapses (Thomas et al., 2018). According to Claes et al. (2017), CR based on physical exercise favors recovery following an episode of cardiovascular disease, with a 15% to 31% reduction in associated mortality. Within this context, the research team developed the *Ablefit* device and invited a group of experts to assess its usability.

Applying the SUS allowed assessing the usability of the two prototypes (Alpha and Beta), bearing in mind this instrument's theoretical dimensions: "Usability and Learning".

Concerning the Alpha prototype, although there is consensus regarding the speed of learning (Q7: "I would imagine that most people would learn to use this system very quickly";  $M = 4.50 \pm 0.52$ ), the results also show that from the user's point of view the device's functions may be somewhat complex (Q3: "I thought the system was easy to use";  $M = 4.31 \pm 1.01$  and Q4: "I think that I would need the support of a technical person to be able to use this system";  $M = 1.69 \pm 1.08$ ).

Regarding the Beta prototype, it is interesting to observe the same answer variability of the Alpha prototype in item Q7 ( $M = 4.50 \pm 0.52$ ). It is also possible to identify a lower level of answer variability in items Q3 ( $M = 4.38 \pm 0.81$ ) and Q4 ( $M = 1.63 \pm 0.96$ ), which indicates a greater consensus among participants about the simplicity and ease of use of the Beta prototype, when compared to the Alpha.

The significant evolution in the theoretical scale from one prototype to the other is a significantly positive aspect of the medical device development process. It prevents design errors, which can limit the user's performance (either a health professional or a patient) and decrease

its effectiveness (Ribeiro et al., 2018).

Despite the scores obtained in the theoretical dimensions, the internal consistency of the “Learning” dimension was not acceptable (Cronbach’s alpha 0.18). Nevertheless, the EFA performed revealed three empirical dimensions: D1 – “Functionality and Learning”; D2 – “Intentionality and Ease of Use”; and D3 – “Complexity and Learning,” with internal consistency values (Cronbach’s Alpha of 0.78; 0.87 and 0.64, respectively) considered adequate. When analyzing the mean scores of the empirical dimensions, it is possible to determine that participants’ appraisals are significantly favorable for both prototypes. Regarding D1, the mean score for both Alpha and Beta prototypes was 4.00 ( $p = 1.00$ ), indicating that participants considered the prototypes’ functionality and their learning as simple and easy. The mean scores for D2 were higher than 4.00 ( $p = 0.88$ ), showing that nurses would use the devices frequently and without difficulty. D3 had the best mean scores ( $M > 4.00$ ;  $p = 0.89$ ), demonstrating that all participants strongly agreed about the prototypes’ simplicity and ease of learning. The health professionals’ appraisals regarding the three dimensions were significantly positive and did not present statistically significant differences between the two prototypes.

Thus, it is possible to conclude that no prototype is better than the other, and the most notable differences between them lie in their properties and distinct characteristics. The fact that all dimensions have in common the learning factor demonstrates the device’s need to be quick and easy to learn. Govindarajulu et al. (2017) point out that medical devices usually require specific training and, often, learning curves can be long. Thus, developing an easy-to-use prototype allowing health professionals and patients to learn quickly is more efficient and increases user motivation.

In this sense, the TAM conceptual model, which guided *Ablefit’s* usability studies, signals the significance of a device’s perceived usefulness (PU) and perceived ease of use (PEOU), underlying the importance of devices’ ease of learning and simplicity of use (Ho et al., 2019). Thus, the studies developed allowed meeting these assumptions and reinforcing *Ablefit’s* usability.

Although confidence is the major influencing factor in adherence to mHealth services, followed by PU and PEOU (Son et al., 2020), this study’s participants focused more on the device’s ease of learning and simplicity.

According to the theoretical model He et al. (2018) developed, perceived ease improves end users’ beliefs about a device’s ability to perform the intended task. Therefore, it is urgent to create simple and intuitive devices from the user’s point of view.

It is possible to conclude that all participants focused on the concept of learning, which coincides with the assumptions of the SUS. Nevertheless, when analyzing the results, it is interesting to note that the participants divided the dimension “Usability” described in the theoretical scale into three broad concepts: functionality, intentionality, and complexity, following the ISO’s definitions previously presented. Thus, the major dimensions considered in analyzing the device’s usability – “Functionality and

Learning”, “Intentionality and Learning”, and “Complexity and Learning” – demonstrated being significantly consistent with the theory and allowed achieving the objectives proposed at the beginning of this research.

However, this study presents some limitations. The small number of cardiac nurses in the sample may have impoverished or decreased the variety of suggestions for improving the prototypes. Implementing this study during the Covid-19 Pandemic prevented nurses from practicing on the prototypes in a practical simulation scenario. This may have contributed to a poorer perception of the devices’ advantages or disadvantages. Moreover, the SUS is typically used after participants had the opportunity to experiment with the systems under evaluation but before any discussion.

This study benefited from the possibility of successfully comparing two functional prototypes of the same device, which, in turn, will allow for a better understanding of how this device works and how it can be improved.

## Conclusion

Cardiac pathologies, namely AMI, constitute a significant cause of mortality, particularly in the long term and in the absence of safe and effective interventions.

Applying innovative devices to CRP in a structured and planned way allows for more effective interventions. It is within this context that the present study was developed. Both prototypes in the study appear to be safe and easy to use, and their functions seem quick to learn. The prototypes demonstrate significant potential to be effective in the contexts for which they were developed. Both show high functional and intentional potentials and learnability, complying with the usability score considered acceptable for a developed system.

This study contributes to developing a new device that will help increase cardiac patients’ motivation and participation levels in CRP as well as their functional recovery and performance of ADL.

Future research must define the best safety criteria and functional assessment parameters, thus allowing health professionals and patients to work towards improving the quality of care and producing favorable health outcomes. After the initial concept and prototyping phases, further studies should advance to the verification and validation phase of the medical device development process, consisting of experimental studies to assess effectiveness and safety among post-AMI patients.

## Author contributions

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## Acknowledgments

Health Sciences Research Unit: Nursing (UICISA: E),  
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