RESEARCH

DEVELOPMENT AND ANALYSIS OF VALIDITY EVIDENCE OF A PROTOTYPE MOBILE APPLICATION FOR PEOPLE USING ORAL ANTICOAGULANTS

DESENVOLVIMENTO E ANÁLISE DE EVIDÊNCIAS DE VALIDADE DO PROTÓTIPO DE APLICATIVO MÓVEL PARA PESSOAS QUE UTILIZAM ANTICOAGULANTE ORAL

DESARROLLO Y ANÁLISIS DE EVIDENCIA DE VALIDEZ DEL PROTOTIPO DE APLICACIÓN MÓVIL PARA PERSONAS QUE USAN ANTICOAGULANTES ORALES

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ABSTRACT

Objective: the aim of this study was to develop and analyze the evidence of validity of a prototype application to assist in health education and self-care for patients using oral anticoagulants. **Method:** this is a methodological study based on Contextualized Instructional Design. The contents were validated between February and April 2021 by eight specialists in the areas of health and technology (including two doctors, a biomedical doctor, three nurses, a nutritionist and a systems analyst). Data was collected in a virtual environment using the Health Education Content Validity Instrument and the Content Validity Index calculation. The experts were encouraged to identify weaknesses and propose suggestions for improvement. **Results:** the prototype included the creation of 83 screens, covering topics such as diet (with an emphasis on the relationship between food composition and vitamin K intake), drug interaction, alerts and other functionalities. The mean experience of the experts who evaluated the screens was 19.75 years. The prototype's total content validity index reached 0.929, while the instrument's index for evidence of validity was 0.972; Cronbach's alpha showed a result of 0.943. **Conclusion:** the prototype showed evidence of validity as assessed by the experts, including functionalities that could improve care for patients taking oral anticoagulants.

Keywords: Educational Technology; Mobile Applications; Anticoagulants; Self-Management.

RESUMO

Objetivo: o objetivo deste estudo foi desenvolver e analisar as evidências de validade de um protótipo de aplicativo para auxiliar na educação em saúde e no autocuidado de pacientes que utilizam anticoagulantes orais. Método: trata-se de um estudo metodológico fundamentado no Design Instrucional Contextualizado. Os conteúdos foram validados no período de fevereiro a abril de 2021 por oito especialistas nas áreas de saúde e tecnologia (incluindo dois médicos, uma biomédica, três enfermeiras, uma nutricionista e um analista de sistemas). Os dados foram coletados em um ambiente virtual, utilizando o Instrumento de Validade de Conteúdo Educativo em Saúde e o cálculo do Índice de Validade de Conteúdo. Os especialistas foram incentivados a identificar fragilidades e propor sugestões de melhorias. Resultados: o protótipo incluiu a elaboração de 83 telas, abordando tópicos como dieta (com ênfase na relação da composição do prato com a ingestão de vitamina K), interação medicamentosa, alertas e outras funcionalidades. A média de experiência dos especialistas que avaliaram as telas foi de 19,75 anos. O índice de validade de conteúdo total do protótipo alcançou 0,929, enquanto o índice do instrumento para a evidência de validade foi de 0,972; o Alfa de Cronbach apresentou um resultado de 0,943. Conclusão: o protótipo demonstrou evidências de validade conforme avaliado pelos especialistas, incluindo funcionalidades que podem aprimorar o cuidado com pacientes em uso de anticoagulantes orais.

Palavras-chave: Aplicativos Móveis; Anticoagulantes; Autogestão; Tecnologia Educacional.

RESUMEN

Objetivo: el objetivo de este estudio fue desarrollar y analizar la evidencia de validez de un prototipo de aplicación para ayudar en la educación en salud y el autocuidado de pacientes que utilizan anticoagulantes orales. Método: se trata de un estudio metodológico basado en el Diseño Instruccional Contextualizado. Los contenidos fueron validados de febrero a abril de 2021 por ocho expertos en las áreas de salud y tecnología (entre ellos dos médicos, un médico biomédico, tres enfermeros, un nutricionista y un analista de sistemas). Los datos fueron recolectados en ambiente virtual, utilizando el Instrumento de Validez de Contenido Educativo en Salud y calculando el Índice de Validez de Contenido. Se alentó a los expertos a identificar debilidades y proponer sugerencias para mejorar. Resultados: el prototipo incluyó la creación de 83 pantallas, abarcando temas como dieta (con énfasis en la relación entre la composición del plato y la ingesta de vitamina K), interacciones medicamentosas, alertas y otras funcionalidades. La experiencia media de los expertos que evaluaron las pantallas fue de 19,75 años. El índice de validez de contenido total del prototipo alcanzó 0,929, mientras que el índice de evidencia de validez del instrumento fue de 0,972; El Alfa de Cronbach arrojó un resultado de 0,943. Conclusión: el prototipo demostró evidencia de validez según la evaluación de expertos, incluidas características que pueden mejorar la atención a los pacientes que usan anticoagulantes orales.

Palabras clave: Tecnología Educacional; Aplicaciones Móviles; Anticoagulantes; Automanejo.

INTRODUCTION

Cardiovascular diseases (CVDs) are the leading cause of mortality among chronic non-communicable diseases both in Brazil and globally[1]. In 2019, there were 18.6 million deaths and 393 million cases of age-standardized disability (ASD), according to the Global Burden of Disease study. Currently, CVDs represent the biggest cause of death, lost years of life and years lived with disability, mainly affecting males around the world[1].

Among CVDs, oral anticoagulants (OACs) have played a crucial role in the prevention and treatment of thrombogenic events[2]. In the Brazilian context, in relation to the profile of patients being treated with OACs, the main indications for this therapy include valve prosthesis, venous thromboembolism and atrial fibrillation. These conditions represent a significant risk of thrombotic complications, making the use of anticoagulants an essential therapeutic approach to minimize cardiovascular risk[2].

Although the emergence of new anticoagulants has been observed in recent years, warfarin still stands out as the most widely used agent in Brazil[3]. Several factors explain this preference: their recommendation for some specific pathologies, the high cost of direct-acting anticoagulants and their exclusivity as a therapeutic option made available by the Unified Health System (Sistema Único de Saúde, SUS)[3].

Warfarin is a medication that acts as a vitamin K antagonist, interfering with blood coagulation. Its therapeutic use requires strict control by means of the prothrombin time, reflected in the International Normalized Ratio (INR)[4]. The target INR value varies according to the clinical indication, usually between 2 and 3[4]. Deviations from these values can lead to risks of thrombosis or hemorrhage[4]. The administration of this medication requires frequent monitoring through laboratory tests and control of variables such as drug and food interactions[4].

In this context, poor adherence to the necessary care can expose patients to high risks[4]. It is therefore essential to strengthen the knowledge and empowerment of these individuals by health professionals, given that lifestyle changes resulting from this treatment can affect patients' quality of life. This alters dietary dynamics, increases the frequency of tests and appointments for monitoring and adjusting medication dosage, and increases vigilance in relation to warning signs and symptoms. Thus, the use of health technologies becomes important to help and encourage self-care and self-management, since digital tools can provide secure information quickly for patients and their caregivers, as well as serving as a record so that their habits and doubts can be presented to health professionals at the appropriate time[5,6].

Thus, the growing inclusion of technology in everyday life has promoted the introduction of mobile health (mHealth) interventions, such as apps, aimed at supporting patients and health professionals in the management of diseases[7]. In this scenario, telehealth is emerging as a tool capable of promoting and enabling self-management, encompassing a wide range of activities and potential treatments[8].

Consequently, the internet presents an alternative way of carrying out secondary prevention interventions, overcoming travel barriers, offering useful information, with easier access for the user, favoring the adoption of healthy behaviors, encouraging adherence to treatment and promoting health education for chronic diseases[9,10]. This approach, aided by smartphones, tablets and other mobile devices, can have a positive impact on healthcare and preventive services, contributing to better patient outcomes[11].

Thus, despite the spread of digital health resources and the growing use of mobile devices in Brazil and around the world, telehealth strategies in the country still lack structure, especially in relation to applications that support the care of patients with CVDs. This gap is evident after a search for mobile applications in the Google® Play Store and Apple® Store, where no resources were identified for the self-management of individuals taking oral anticoagulants.

Therefore, this study aims to develop and analyze evidence of content validity of an application prototype that assists in health education and, consequently, in the self-monitoring of patients taking oral anticoagulants.

METHOD

Type of study

Methodological study of development and evidence of validity based on Contextualized Instructional Design (CID), a model that incorporates the phases of analysis, development, implementation and evaluation, highlighting human activity as the central element of the method[12]. The core of this methodology lies in contextualizing the content, ensuring a meaningful integration between theory and practice[12]. The process stages are intrinsically interlinked, with the implementation phase being progressive and carried out simultaneously with the other stages[12]. This study was guided by the approach recommended by the Guideline for Reporting for Intervention Development Studies (GUIDED) tool, which

provides guidelines and criteria for reporting intervention development studies[13].

Study setting

The study was carried out in the context of a research group at a public university in São Paulo, whose university hospital is a reference in specialized cardiology care. Technological resources and a non-immersive virtual environment were used to develop and validate the prototype.

Study participants and eligibility criteria

The phase of identifying evidence of the content and screen validity was based on the formation of an evaluation committee made up of eight judges from the areas of health and technology, as recommended by Lynn, who suggests a number of between five and ten judges[14]. The sample was selected by convenience, and the invitation was sent by e-mail, along with the Informed Consent Form, to professionals with academic degrees, specialists or with at least one year's clinical experience in the areas of cardiology, anticoagulation or technology. After acceptance, the judges received a video showing how the prototype worked and questionnaires to characterize the specialists, for general evaluation, as covered by the Instrument for the Validation of Educational Content in Health (Instrumento de Validação de Conteúdo Educativo em Saúde, IVCES)[15], and for individual evaluation of the items, with a space available for comments and suggestions on each screen of the prototype, as recommended in the literature[16].

The inclusion criteria for participation were as follows: the health professionals selected had to be 18 years old or over and have more than one year's professional experience; information science professionals had to be 18 years old or over and have more than one year's professional experience.

The exclusion criteria were: incomplete answers from the judges.

Study protocol

The proposal to develop the application consists of creating two complementary platforms: one aimed at the professionals involved in anticoagulation management, who are responsible for setting up individualized care and parameters for each patient; and the other, which aims to support patient self-monitoring, allowing access to information on treatment, alarms and tools that provide self-management of health.

The app prototype's content was developed based on an integrative literature review carried out by the authors for this purpose, in order to address the needs and care related to the use of this drug. Thus, in the app's interface for patients, the items available are: nutrition, medication, agenda, performance, mood and guidance.

In the application aimed at professionals, the following items were covered: nutrition, medications, agenda, performance, patient information and registration of information about the INR. The selection of items covered was made by the authors based on the nursing care provided in clinical practice to monitor individuals taking oral anticoagulants.

Data Collection

Data collection took place between February and April 2021 and strictly followed the established criteria for analyzing evidence of validity. The instrument and the screens were evaluated using a reduced Likert scale, where zero corresponds to "do not agree" and two to "totally agree", following the original model of the validated instrument chosen (IVCES). The scores "zero - do not agree" and "one - partially agree" were considered unsatisfactory and had to be accompanied by the justification for this assessment, allowing the prototype to be adjusted according to the experts' suggestions[15].

Data analysis and processing

The data was extracted and stored in an Excel® spreadsheet. For the content analysis, the CVI was calculated and, in order to analyze the prototype's internal consistency, Cronbach's Alpha was calculated for the screens validated by the judges. The judges' suggestions for improvements were taken into account for the final version of the prototype. SPSS Statistics software, version 26.0 (IBM Corp., Armonk, NY, USA) was used for the statistical analysis. The cut-off point for interpreting the data was a CVI above 78% for validations with six or more judges[17].

Ethical aspects

The study was approved by the Human Research Ethics Committee of a public university in São Paulo on March 6, 2019, in accordance with Resolution 466/2012 of the National Health Council. All participants signed the Free and Informed Consent Form in two copies.

RESULTS

The "VivaCor ACO" application prototype was made up of 83 screens, offering use to healthcare professionals,

who had to configure the standards and values established for the patient, in addition to the version intended for patient use. In view of this, the following menus were addressed, as shown in Figure 1.

A total of 18 health and technology professionals were invited to take part in the study for the validation stage. The electronic response collection form remained accessible for a period of 56 days, resulting in 11 evaluations. However, three of these evaluations were considered invalid, as they did not meet the inclusion criteria established for the study. Therefore, eight judges took part in the study.

Among the judges, three were nurses (including a technology specialist), a nutritionist, a biomedical doctor, two doctors and a systems analyst. This population of evaluators had different education levels, including: one undergraduate, two specialists, two masters and three doctors in their respective fields. The mean time these professionals had been working was 19.75 years, with two years being the shortest and 33 the longest.

The CVI was calculated, expressing the ratio between the number of responses from judges who received the maximum score and the total number of responses for the item. This calculation was carried out for both the application screens and the IVCES. The CVI resulting from the application screens was 92.92%, while the value obtained from applying the selected Instrument was 97.22%.

When detailing the results of the CVI by domain, it can be seen that in the version of the application intended for professionals, the "Agenda" and "Medications" menus showed the highest agreement among the judges, with a respective CVI of 97.91% and 92.04%. The "LogIn" and "General Menu" menus had a lower CVI of 87.5%, while the "Nutrition" menu reached 83.33%. In the version of the app aimed at patients, the best CVIs were observed in the "Agenda" and "Orientations" menus, both with 100% agreement. The "Mood", "LogIn" and "General Menu" menus had 84.37% and 83.33%, respectively.

The educational content validation index was evaluated by the judges, screen by screen, and its raw result was correlated with the CVI. The analysis by category showed a CVI of 100% in the three IVCES domains. Table 1 shows the results of this correlation. To complement the statistical analysis, Cronbach's Alpha for the validated screens was calculated, revealing a remarkable internal consistency of the complete mobile app prototype, with a result of 0.943.

The judges were asked to comment on the screens that indicated modifications, and the consolidated results of these evaluations are shown in Figure 2.

The final version of the application's main prototype screens, not yet available for use or offered on download platforms, includes all the changes suggested by the judges, as illustrated in Figures 3 and 4.

Figure 1 - Representation of the "VivaCor ACO" application prototype menus: patients and professionals.
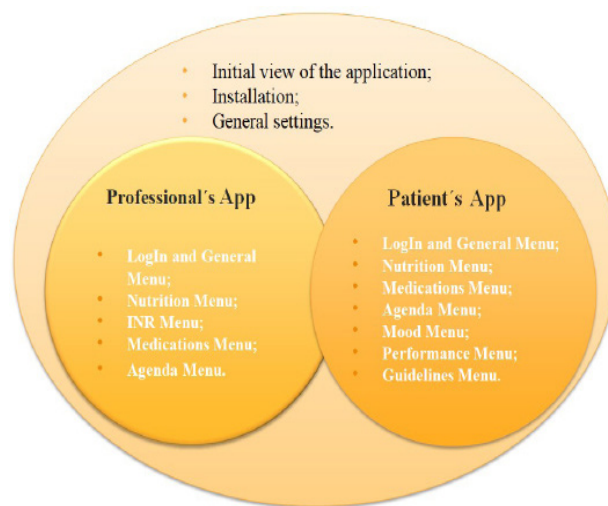

Table 1 - Correlation between the IVCES and CVI domains. São Paulo, SP, Brazil, 2023

Domínios do IVCES	IVC
Objective: purposes, goals or aims	100%
Structure / Presentation: organization, structure	96.25%
Relevance: significance, impact, motivation	95.83%

Figure 2 - Judges' suggestions according to evaluation area.

Domínio	Sugestão do avaliador
Initial overview, presentation and installation	Logo optimization
Log in and General Menu of the application for professionals	Differentiate the functions of the application for professionals and patients Present more options for access and log-in Present the list of patients that the professional sees
Patient App Nutrition Menu	Add more visual indications of foods with low, medium and high amounts of vitamin K
Patient App Agenda Menu	Differentiating consultations with a cardiologist from consultations with other professionals
Patient app Guidelines Menu	Increase the font size of texts

Figure 3 - Main screens of the prototype of the "Viva-Cor ACO" professional's application.
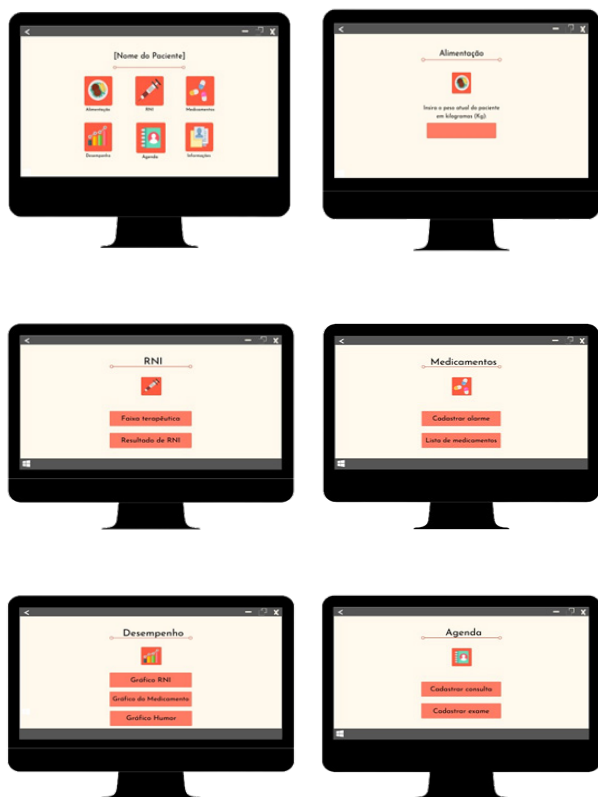
Mains screens of professional´s application:

Figure 4 - Main screens of the prototype "VivaCor ACO" patient application.

Main screens of the patients application:

DISCUSSION

This study focused on the development and content validation of the "VivaCor ACO" prototype, presenting positive results that corroborate its application as a health self-management tool. Healthcare apps are becoming increasingly common among chronic patients and represent an innovative engagement tool capable of stimulating patient interest and motivation[18].

In this context, a systematic review carried out in 2023, involving the analysis of 25 articles on the use of telemedicine in the management of oral anticoagulant therapy, showed that although technological interventions did not have a significant impact on the final outcome of thromboembolic events compared to traditional interventions, there was an improvement in the time within the therapeutic range with the use of telemedicine compared to conventional care[19]. It is important to note that many of the studies in this review had some methodological bias, and the follow-up period was mostly short, which possibly influenced the clinical results observed.

In addition, the authors pointed to regional issues as possible determinants of the results found, since the studies were carried out in areas with a high quality of oral anticoagulation management. Thus, mobile technology could be especially effective in regions lacking this type of care[19]. Therefore, developing and validating an application aimed at self-monitoring patients on OAC therapy is extremely important, considering the complexity of the anticoagulation regimen.

In this study's quantitative analysis, 92.92% of the CVI of the screens evaluated and 0.943 for Cronbach's alpha were obtained. These results are high for both indicators, as recommended by the literature. In validations with six or more evaluators, a CVI of 78% or more is expected. The value obtained for Cronbach's Alpha points to robust internal consistency, suggesting possible redundancy in the material analyzed[17].

However, it is expected that the screens evaluated will have similar content, since they are intended for a specific clinical situation. The choice of IVCES as part of the evaluation tool came from the need to develop reliable and accurate strategies that promote health education, meeting the requirements of individuals taking warfarin.

The tool has previously been used to validate Brazilian technological resources aimed at health[16]. It should be noted that the content design process was carefully planned to adapt the form of expression and the language used, bringing scientific language closer to everyday language, in order to make it easier for users to understand the content and contribute to the effectiveness of the tool.

Reflecting on the importance of developing apps for the self-care of patients taking OACs, a literature review discussed educational mHealth strategies in the management of oral anticoagulation. Analyzing 12 studies, the review highlighted the importance of creating apps that encourage not only self-management, but also adherence to treatment, including decision-making tools supported by indicators[20]. Functionalities such as setting alarms, describing medication, scheduling medical appointments and consulting medical performance and guidelines are considered essential for improving patient adherence to treatment.

In the current context, a review carried out in 2022, which contemplated the analysis of 32 articles in areas such as the management of vitamin K antagonist therapy, educational apps for patients, solutions to increase adherence to therapy and treatment decision support, highlighted the lack of apps focused on the management of the diet of patients who need to restrict vitamin K due to the use of ACOs[21]. Thus, there is a clear need to develop apps that emphasize the importance of proper nutrition as part of self-care for those being treated with OACs. This demand highlights the continued urgency of innovations that specifically address nutritional care, promoting a holistic vision for patients.

In addition, the authors highlight the importance of constantly updating the information in the app and including spaces dedicated to both patients and health professionals[21]. In this sense, the prototype developed by this study is in line with the needs identified, since it has been content validated and has resulted in the creation of two applications: one for patients and one for healthcare professionals. This strategy aims to offer complete guidance, ranging from care with food and medication interactions to the provision of performance charts and self-monitoring tools. Thus, the prototype aims to be a comprehensive and up-to-date solution, meeting the needs of both patients and the healthcare team in charge of managing oral anticoagulation.

In relation to advances in mobile applications in health, a specific study was carried out to develop an application that would serve as an educational reference for users of removable partial dentures[22]. The methodology adopted began with a survey of the target audience's needs and the development of an initial application version[22].

The content validation phase was supported by four health specialists, while usability was assessed by a technology specialist, followed by a pilot test and a satisfaction questionnaire completed by patients and students[22].

In the end, the application was well evaluated and the suggestions for adjustments made by the participants were incorporated[22]. This validation process reinforces the approach used in this study, which prioritizes the applicability of the application for both professionals and patients, showing the importance of the content validation stage for the success of mHealth tools.

Apps produced in Brazil follow a similar development process. One example is the prototype of an app aimed at supporting health professionals in the context of breastfeeding. During its development, specialists from different health areas were selected to guide and evaluate the tool, using free comments and filling in a specific questionnaire. The responses were considered positive when they reached a 70% consensus among the participants. The evaluation of the prototype was generally positive, despite some differences[23].

Similarly, another national app, aimed at the self-care of adolescents with Type 1 Diabetes Mellitus, followed a similar methodology[24]. The process began with a literature review and analysis of similar apps on the market[24]. Subsequently, the app was defined and prototyped, followed by validation with the help of both content and technical experts, who used specific tools for this purpose[24]. The CVI was calculated, considering satisfactory responses to be those above 78%, and the overall CVI achieved was 96%[24].

Another application, the MASS App, developed by the University of California, was created for anticoagulation management purposes and has characteristics comparable to the prototype mentioned. Its aim is to increase knowledge, improve adherence and promote more suitable emotional conditions for older people using warfarin[25]. Common points include health education, alerts, dietary guidelines, medication monitoring and INR values, and showed good results after a 3-month intervention with patients[25]. Despite the similarities, important cultural and organizational differences between the two applications should be highlighted.

It is also important to point out that the small number of judges was seen as a limitation, although it was within the range recommended by the reference literature. The association of a reduced scale with a moderate number of responses limited the acceptance of scores of 1 or 0. However, even with this limitation, the prototype achieved significant levels of agreement and approval among the target audience.

An additional aspect refers to the advantages of using a previously validated questionnaire, which makes it possible to assess content in areas such as objectives,

structure/presentation and relevance. However, the use of a reduced Likert scale in IVCES imposed restrictions on the evaluation of the application's interfaces. This standardization limited the evaluators' responses to a narrower spectrum, resulting in a certain rigidity in the CVI calculations, where only "2 - Completely agree" responses were considered satisfactory. Although this restriction is a limiting factor, it highlights the need to consider future adjustments to improve the sensitivity of the scale and offer a more detailed evaluation of the application interfaces.

CONCLUSION

The app prototype was developed with 83 screens, including features such as an agenda, alarms, general guidance, mood tracking, nutrition guide, information storage and performance monitoring, with the aim of supporting the self-care of individuals who use oral anticoagulants and the professionals who assist them. The content was validated by experts in the fields of health and technology, with high agreement rates.

The next phase of this study will focus on evaluating the acceptability and usability of the app by patients. This is in line with the Individual-Centered Design approach, which emphasizes the importance of gradual, collaborative construction throughout the validation stages. This approach seeks to adapt the vocabulary used and explore the potential and limitations of the prototype in interaction with the target audience, fostering the continuous evolution of the final product.

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