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DIGITAL TECHNOLOGIES FOR COMPREHENSIVENESS IN THE TREATMENT OF HYPERTENSION IN THE BRAZILIAN UNIFIED HEALTH SYSTEM: NON-RANDOMIZED CLINICAL TRIAL

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ABSTRACT

Comprehensive treatment is one of the guidelines of the Unified Health System for the treatment of arterial hypertension, and digital technologies are potentially useful resources to provide it. The objective of this study was to evaluate the effects of m-Health on the health conditions of patients with hypertension treated in the Unified Health System. In a trial involving 63 participants over 12 weeks, the m-Health app's effects were compared to conventional monitoring methods. The results showed that while the m-Health group experienced a significant drop in systolic blood pressure, there was no notable improvement in treatment adherence or eating habits. Additionally, user feedback indicated that the app had a neutral effect and required modifications to better cater to users, emphasizing the need for m-Health solutions to be tailored for underserved, low-income, and less-educated populations.

Keywords: Hypertension; Consumer Health Informatics; Primary Health Care; Brazil.

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INTRODUCTION

Arterial Hypertension (AH) is a global public health issue, with an unsatisfactory rate of control. AH is associated with several complications, making it the leading cause of death globally (BARROSO et al., 2021). In Brazil, AH entails a high economic and social cost, since it affects approximately 30% of adults. In 2018, AH was responsible for 59% of the direct cost of the Unified Health System (SUS), especially due to the great impact on mortality and early retirements (NILSON *et al.*, 2021).

Research indicates that self-care among hypertensive patients is associated with blood pressure control and, consequently, can prevent complications (DEBON *et al.*, 2019). However, many factors may interfere with greater self-management of the health conditions of this population, such as promoting the effectiveness of a more comprehensive treatment. Comprehensive treatment is one of the SUS guidelines, which includes health promotion and prevention actions (COMES *et al.*, 2016). The creation of new care strategies that provide comprehensiveness is necessary to outline treatment plans. Additionally, greater support is recommended for the improvement of physical, human, and technological structures to increase engagement in AH care (TOLAZZI; GRENDENE; VINHOLES, 2022).

Studies have shown that digital technologies are a potentially useful intervention strategy for blood pressure management (LI *et al*., 2020). Health promotion through the use of technologies can offer more integrated and humanized care, especially in primary health care (DEBON *et al.*, 2019). Among emerging technologies, the use of mobile health applications (m-Health) might be an effective strategy to strengthen non-pharmacological approaches to AH, motivate behavior changes and encourage users to achieve goals (DEBON *et al*., 2019; VOLPI *et al.*, 2021). The m-Health applications enable communication between professionals (physicians, nutritionists, psychologists, and others) and patients, through mobile devices with internet access (VEIGA *et al.*, 2017), which favors the development of comprehensive treatment. Furthermore, the use of m-Health brings positive results when associated with strategies focused on improving dietary habits, adherence to medication intake, and support for the regular practice of physical activity (JUNG; CHO, 2022), which are three options for coping with the disease, described in the guide to the prevention and control of arterial hypertension in local health systems (MINISTÉRIO DA SAÚDE DO BRASIL, 2016).

The functionalities available in these applications are varied. Therefore, there is a need to analyze and discover which ones are really capable of contributing to behavior change and self-management of the disease (SUDHIR, 2017). Studies also need to assess the multiple outcomes related to the main factors of comprehensive care in the treatment of hypertension, investigate whether medication reminders are well accepted by patients and if they may help to control BP (YU *et al.*, 2020).

While the World Health Organization (WHO) recognizes the innovative role of digital technologies in health, it reinforces the need to evaluate their effects, as the adoption of technologies requires behavior change and transition to new practices (WORLD HEALTH ORGANIZATION, 2019). Thus, stronger evidence from well-designed and implemented studies is needed (MINISTÉRIO DA SAÚDE DO BRASIL, 2020), mainly from thorough studies focused on public health in Brazil.

The objective of this study was to evaluate the effects of m-Health on the health conditions of patients with hypertension treated in the public health network in Passo Fundo, a city in the north of the southern Brazilian state of Rio Grande do Sul.

METHODS

Study design

This is a study applied to technological innovation with software development and analysis of its effects through a controlled, non-randomized, non-blind, prospective, and monocentric clinical trial. The study included 63 participants, patients with hypertension registered in the SUS, who attended a primary health care center in the city of Passo Fundo, RS, Brazil. Recruitment was carried out at the health care center and also by telephone.

Ethics approval

The research was approved by the local research ethics committee of the University of Passo Fundo, under opinion number 1.890.882. The study was registered in the Brazilian Registry of Clinical Trials (ReBEC), under the number RBR-2rkkgn. A detailed description of the methods can be found in the study protocol by De Marchi et al. (DE MARCHI *et al.*, 2020).

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Participants and sampling

For sample calculation, we used Epi Info version 6.0 software (sample size/2 proportions). We considered an estimate of 40% proportion difference between groups, a 95% confidence interval, and 80% statistical power (beta). The calculation resulted in at least 28 individuals for each group.

The 63 participants were evaluated before and after 12 weeks of intervention, using specific instruments. Participants were divided into two groups: the Intervention Group (IG), which used the Monitora PA application to support the treatment of hypertension, and the Control Group (CG), which did not use the application. All participants signed an informed consent form.

The sample size was based on the estimated effects detailed in the study protocol by De Marchi *et al*. (2020). The inclusion criteria required the participant to be over 18 years old, cognitively preserved, as evidenced by the Mini-Mental State Examination (MMSE) (BRUCKI *et al*., 2003), and undergoing treatment for hypertension. To be part of the experimental group, the participant needed to own a smartphone with the Android operating system, version 7.0 or higher, have some experience with the use of mobile devices, have internet at home, and be willing to measure BP at local health care centers. Illiterate participants and those undergoing chemotherapy treatment were excluded.

The allocation of participants was determined based on the eligibility criteria. The first group recruited was the CG. Then, during IG recruitment, if the participant met all eligibility criteria but owned a smartphone that was not compatible with the application, that participant was included in the CG. Data were collected during three phases: pre-intervention, intervention, and post-intervention.

Measurements

The primary outcome considered was the reduction and stabilization of blood pressure. Secondary outcomes included treatment adherence, eating habits, and user experience with the app. At baseline, sociodemographic data were collected from all participants, including gender, age, education level, income, comorbidities, health status, and medication use. The adherence to treatment was measured using the Martín-Bayarre-Grau (MBG) questionnaire (ALFONSO; BAYARRE VEA; GRAU ÁBALO, 2008; MATTA; LUIZA; AZEREDO, 2013). This questionnaire determines the level of adherence according to the operational definition of therapeutic adherence formulated by the WHO; it was developed and validated by Alfonso et al. (ALFONSO; BAYARRE VEA; GRAU ÁBALO, 2008) and adapted to Brazilian Portuguese by Matta *et al*. (MATTA; LUIZA; AZEREDO, 2013). The MBG includes information about the patient's medication, doctor appointments, treatment, diet, and exercise. It consists of 12 statements that must be answered on a five-point Likert scale (never, rarely, occasionally, very frequently, always). A higher score means greater adherence. Participants were classified as "adherent" if they scored 38 to 48 points, "partially adherent" if they scored 18 to 37 points, and "non-adherent" if they scored 0 to 17 points (ALFONSO; BAYARRE VEA; GRAU ÁBALO, 2008).

Participants' diets were evaluated using the Dietary Guidelines for the Brazilian population (GABE; JAIME, 2020), which are classified into three categories: 0 to 30 points indicating a need for improvement in eating habits, 31 to 41 points indicating good eating habits but with room for improvement, and above 42 points indicating excellent, which means the participant has healthy eating habits.

The user experience in the intervention group was assessed using the User Experience Questionnaire (UEQ) (LAUGWITZ; HELD; SCHREPP, 2008) after the intervention. The UEQ is a validated instrument composed of 26 items with a seven-point semantic differential rating scale. The items are related to six user experience scales: attractiveness, perspicuity, efficiency, dependability, stimulation, and novelty. The scores generated by the UEQ range from -3.0 to 3.0, based on answers in seven semantic differential points. A result less than -0.8 indicates a negative user experience, a result between -0.8 and 0.8 indicates a neutral user experience, and a result greater than 0.8 indicates a positive user experience.

The IG also answered the acceptance questionnaire, based on the technology acceptance model (TAM), proposed by Davis *et al.* (DAVIS; BAGOZZI; WARSHAW, 1989). his questionnaire has three categories: perceived usefulness (determining the degree to which a person believes that using technology can improve performance and productivity), ease of use (determining the degree to which a person believes that using digital technology will be easy to learn and interact with), and external variables (providing insight into what influences perceived usefulness and ease of use). The usability evaluation questionnaire corresponds to the System Usability Scale (SUS), created by Brooke

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(BROOKE, 1996) which is related to ease of use and effort of use.

During the study, medications were managed by the participant's primary care physician, and we did not interfere with their medical treatment. However, we did provide a section within the app where participants could record their medications and dosages, and this information was available for the physician to view. Although the app did not allow for direct medication control or adjustments, the physicians were able to use the information in the app to assist with hypertension management.

Data collection

For data collection, local healthcare protocols for COVID-19 were followed. The pre- and post-intervention interviews were conducted at the healthcare center or the participants' homes. The interviews lasted one hour and included guidance on the research objectives and application of the questionnaires. In the pre-intervention, IG participants were registered on the digital platform and received instructions regarding the application's functionalities. In addition, participants received an online guide for the app, with tutorials and extra information that could help them during the intervention. Both groups were instructed to measure BP at the healthcare center throughout the study, and therefore, the BP values were collected by the researchers in this way.

During the intervention period, the IG participants used the Monitora PA application for 12 weeks. All data registered by the user in the application were used in the analysis of the results. IG participants were also instructed to answer the dietary questionnaire once a month through the tab available in the application. To alert participants, a recurrence of reminders was scheduled on the day the app was installed on each participant's smartphone. Additionally, participants received daily reminders to take their medication. Every six days, they received reminders to practice physical activity, and every 28 days, they received a reminder to measure their blood pressure. In addition, monthly messages were sent to the IG via the app to gather users' feedback and check if they were able to follow nutritional guidelines (care with chewing, tips for reducing sodium, increasing water consumption, and eating natural foods), and recommendations on the importance of physical activity.

In the post-intervention, both groups received printed healthcare instructions, encouraging control of sodium consumption, the practice of physical activity, proper use of medication, and other recommendations. The IG was instructed to continue using the Monitora PA app if they wanted to, while the CG received a link to the app and a brief explanation about it if they wanted to test it.

Digital resources for the intervention

The Monitora PA application is a health app that has been registered with the National Institute of Industrial Property (INPI) under the number BR512021000928-2. It provides users with a range of features to help monitor and manage their health. Users can access their latest measurements regarding physical activity, heart rate, waist circumference, body fat, mood, lipids (HDL, LDL, total cholesterol, triglycerides), weight, eating practices, BP, sleep, reminders, BMI, and chat. The app also includes gamification elements to improve users' motivation, as well as reminders and notifications about their health. Users can also communicate with health professionals through the app.

The functional structure of the application is divided into five modules, distributed between the Mobile App Monitora PA (Figure 1) and the Web App Monitora PA (Figure 2). The Web App includes a module for integration and monitoring of hypertensive patients, management of the platform's basic settings, the configuration of risk analysis based on functional guidelines, gamification settings, ana a module for researchers

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Figure 1. Monitora PA Mobile App.

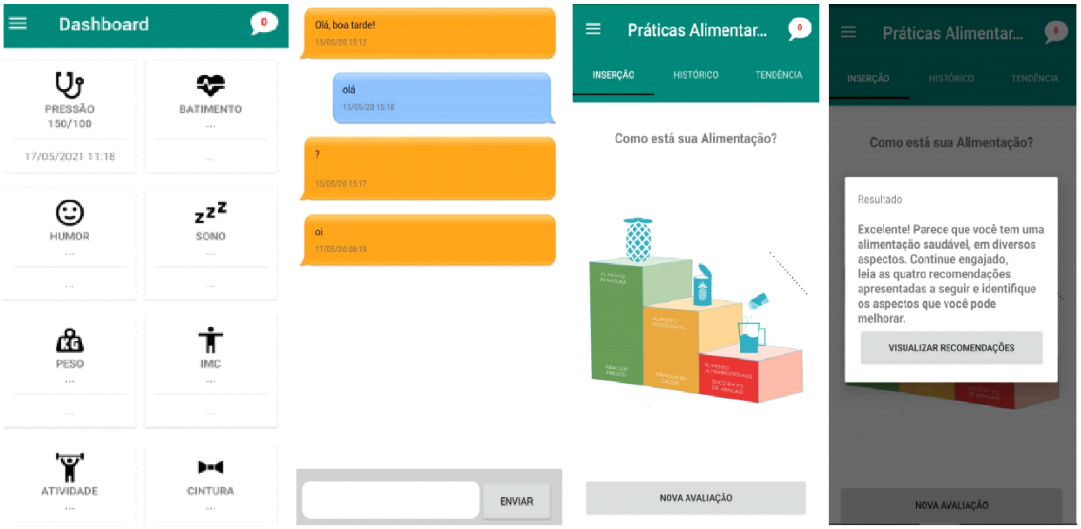
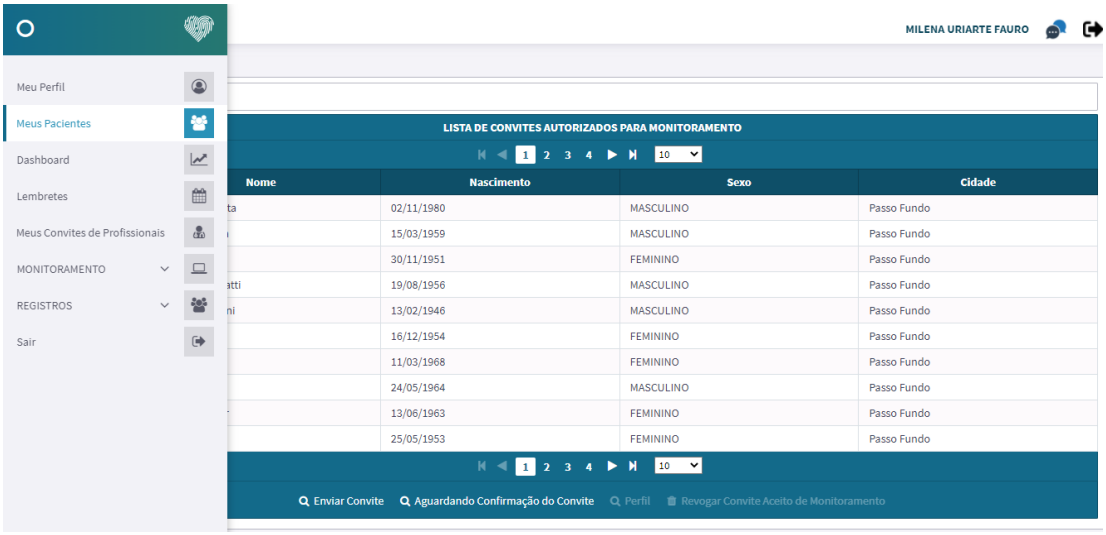


Figure 2. Monitora PA Web App.



Statistical analysis

The results were analyzed using the Statistical Package for the Social Sciences (SPSS, version 24). The significance level was set at 5%. Since the variables were not normally distributed according to the Kolmogorov-Smirnov tests, the Wilcoxon test (paired) or the Mann-Whitney test (independent) was used to compare the means. The independent t-test was applied for variables with normal distribution. Therefore, the Wilcoxon test was used to compare pre- and post-intervention values and to compare diastolic and systolic blood pressure measurements between pre- and post-intervention groups. The Mann-Whitney test was also applied to compare medication adherence in the control and intervention groups after the intervention, and the independent t-test was used to compare medication adherence between the control and intervention groups in the pre-intervention period.

For the assessment of medication adherence by the GBM test pre- and post-intervention, Fisher's Exact test was applied in both the control and intervention groups. The same test was used to compare demographic and socioeconomic characteristics, in addition to the chi-

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square and t-test. A significance level of 5% was considered for all analyses.

RESULTS

Out of the 64 participants who enrolled in the study, 37 completed it, with 18 in the control group and 19 in the intervention group. Participants were lost due to a lack of interest. Enrollment and follow-up occurred between May and August 2021. Figure 3 presents the Consort flowchart of the study, and Table 1 shows the participants' demographic characteristics. The mean age and standard deviation of participants in the control group were 60.3 ± 15.3 years, and in the intervention group, they were 60.0 ± 8.3 years. There were no statistically significant differences between the control and intervention groups regarding any of the baseline demographic variables.

Figure 3. Consort study flowchart.

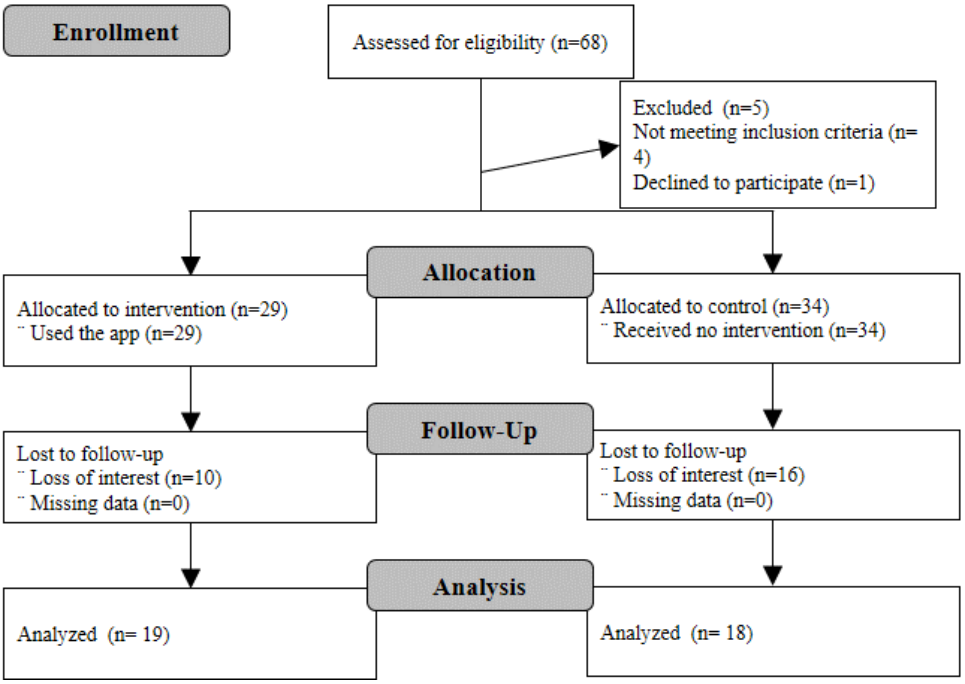

Table 1. Baseline demographic characteristics of participants from a sample of hypertensive patients treated in primary health care in Passo Fundo, RS, 2021 (n=37).

Variable	Categories	Control Group		Intervention Group		p-value
		N	%	n	%	
Gender	Male	9	50	6	31,6	0,254*
	Female	9	50	13	68,4	
Categorized age	Adults	6	33,3	9	47,4	0,385*
	Seniors	12	66,7	10	52,6	
Marital status	Single	4	22,2	4	22,1	0,931*
	With partner	14	77,8	15	78,9	
Education	0 to 5 years of study	7	43,8	10	52,6	0,600*
	6 to 18 years of study	9	56,3	9	47,4	
Brazilian economic classification	Class A	0	0	2	10,5	0,395**
	Class B	4	22,2	4	21,1	
	Class C	13	72,2	13	68,4	
	Class D and E	1	5,6	0	0	

* Fisher's Exact Test
**Chi-square test

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Table 2 presents the results of the tests of differences in adherence to hypertension treatment between and within groups. No significant difference was found between the control and intervention groups. Before the intervention, most participants in the control group were partially or not adherent to pharmacotherapy (66.7%), while in the intervention group, the highest proportion were participants who adhered to pharmacotherapy (78.9%; p=0.006). In the control group, there was no significant difference in adherence proportions between before and after the intervention (p=0.688). However, in the intervention group, there was a higher proportion of participants who were partially or not adherent after the intervention (p=0.012).

Table 2. Comparison of the change in adherence to hypertension treatment inter-groups and intra-groups from a sample of hypertensive patients treated in primary health care in Passo Fundo, RS, 2021 (n=37).

Time	Variable	Control Group	Intervention Group	p* for intergroup comparison
		n (%)	n (%)	
Baseline	Adherents	6 (33.3)	15 (78.9)	0,006
	Partially or non-adherents	12 (66.6)	4 (21.1)	
Post-intervention	Adherents	8 (44.4)	6 (31.6)	0,320
	Partially or non-adherents	10 (55.6)	13 (68.4)	
	p** for intragroup comparison	0,688	0,012	

* Comparison of adherence between groups (intergroup) baseline and post-intervention using Fisher's exact test.
** Comparison of adherence in each group (intragroup) baseline and post-intervention using McNemar's test.

When analyzing the participants' eating habits through the Dietary Guidelines for the Brazilian population questionnaire, there was no significant difference between the means in the pre-intervention (p=0.219) and post-intervention (p=0.506) between the groups. There was also no difference between the means in the control group (p=0.174) and the intervention group (p=0.457), before and after the intervention (Table 3).

Table 3. Comparison between the means of intragroup and intergroup eating habits from a sample of hypertensive patients treated in primary health care in Passo Fundo, RS, 2021 (n=37).

Variables	Control Group n=18		Intervention Group n=19		p* for intergroup comparison
	Mean	SD	Mean	SD	
Baseline eating habits	42,00	8,15	45,58	9,19	0,219
Post-intervention eating habits	44,22	9,91	46,37	9,46	0,506
p** for intragroup comparison	0,174		0,457		

*T Independent t-test (intergroup comparison).
**Paired sample t-test of baseline and post-intervention eating habits.

Table 4 shows the comparison between the means of systolic and diastolic blood pressure before and after the intervention. There was a significant reduction in systolic blood pressure in the intervention group from 142.11 to 130.53 mmHg (p=0.026). The reduction in diastolic blood pressure from 87.37 to 83.95 mmHg was not significant (p=0.125). In the control group, there was no significant difference between the means.

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Table 4. Comparison of intragroup diastolic and systolic blood pressure from a sample of hypertensive patients treated in primary health care in Passo Fundo, RS, 2021 (n=37).

Blood Pressure	Measurement	Mean	SD	p *
Intervention n=19	baseline systolic BP	142.11	22.50	0.026
	post-intervention systolic BP	130.53	21.72	
	baseline diastolic BP	87.37	10.98	0.125
	post-intervention diastolic BP	83.95	5.91	
Control n=18	baseline systolic BP	133.33	8.40	0.523
	post-intervention systolic BP	132.22	16.99	
	baseline diastolic BP	78.89	10.79	0.162
	post-intervention diastolic BP	85.83	15.65	

*Wilcoxon test

Regarding the means of the categories assessed with the UEQ in the intervention group, the results showed that users had a neutral experience with the app. The attractiveness aspect had a mean of -0.37±0.70; perspicuity was 0.29±0.59; efficiency was -0.12±0.83; dependability was 0.01±0.49; stimulation was -0.04±0.36; and, the novelty was -0.28±0.63.

The results of the SUS questionnaire obtained aa mean score of 45.97 (SD=13.34), showing the design and usability of the app could be improved, as the study population had an average score below the cutoff point of 63.

Considering the items of the TAM questionnaire, the item "perceived usefulness," which covered questions about the importance of the application for patient care and engagement, obtained the highest score (21.0 ± 7.99). The results showed that participants rated the app as important for healthcare. On the other hand, the "attitude towards" subgroup, which concerned the question "It would be better to use the app instead of using the monitoring method that I currently use," received the lowest score (1.56 ± 1.20), showing that participants were not willing to exchange the traditional method of monitoring blood pressure for the method with digital technology. The "external variables" subgroup, which had two questions about the need for training to use the application and the researcher's level of knowledge about the application, obtained a neutral score (8.56 ± 2.64). The score for the item "ease of use" (14.59 ± 5.94) was medium/high. The item "demonstrated results" obtained a neutral score (6.18 ± 3.36).

Regarding engagement measurements, participants scored high on usability perception (14.5 ± 5.8), aesthetics (13.0 ± 2.6), and dependability (12.3 ± 3.9). However, the application was not able to provide a satisfactory result for the categories of engagement (5.7 ± 3.3), focus and attention (6.0 ± 0.1), and novelty (4.3 ± 2.9).

DISCUSSION

Mobile health applications can enhance care quality and blood pressure control (LI *et al*., 2020). In our study, only systolic blood pressure reduced in the intervention group. This might be due to the short intervention time and limited participants. Other factors, such as participants' motivation to adopt healthier behaviors, could have influenced this outcome. Santiago *et al.* (2021) emphasizes the importance of longer interventions for better patient adherence.

The groups in our study were demographically and socioeconomically homogeneous. Unlike other studies, our participants were already adhering to their AH treatment. Volpi *et al*. (2021) showed varied adherence levels before interventions, which might explain our unchanged blood pressure values. Our participants had excellent eating habits from the outset, possibly due to increased health awareness.

Most participants were older adults, less familiar with technology, which might have affected the intervention's impact. The elderly's limited exposure to technology, as noted by (HE; MORALES; GUTHRIE, 2020), underscores the need for more inclusive research. Our participants' lower education levels, compared to Volpi et al. (VOLPI *et al*., 2021), might have contributed to their app usage difficulties. Many faced challenges with the app, suggesting a need for more user-friendly designs for the elderly (LIU *et al*., 2021).

Despite these challenges, many participants would recommend the app, finding its reminders beneficial. Effective m-Health interventions often involve health professionals for better adherence (DEBON *et al.*, 2019). Active professional monitoring enhances trust and outcomes in m-Health interventions (POMEY *et al.*, 2021). However, more research is required to optimize these technologies for long-term use.

LIMITATIONS

The study faced several limitations. The pandemic affected data collection and participant return rates after the 12-week intervention due to fears or health issues related to the pandemic. Participants' low education and income levels might have impacted their adherence to the Monitora PA app. Both the intervention and control groups were on hypertension medications, which could have influenced the results. Even though the study tried to maintain consistent medication use, changes in medication or dosage might have happened. The study also didn't control for the specific type or dosage of medications used, potentially affecting outcomes.

CONCLUSION

The results of this study suggest that the use of mobile health applications to manage hypertension in older adults and elderly patients needs further improvement. While the intervention group had a reduction in systolic blood pressure, the lack of significant changes in other measurements, such as adherence and eating habits, indicate that the intervention may not have been entirely effective in improving patients' overall health outcomes. The findings suggest that older adults and elderly populations may have different needs and limitations when it comes to using technology and m-Health solutions, which should be taken into account when designing interventions.

Despite the neutral user experience metrics, the study adds to the growing body of evidence that emphasizes the need to investigate new approaches and strategies to improve the effectiveness and long-term sustainability of m-Health solutions. This study also contributes to the literature on hypertension management in older adults and highlights the importance of personalized and active monitoring to improve adherence to treatment and promote better health outcomes.

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