Assessing the Feasibility of a Novel Preventive Mobile Health App among Informal Caregivers of Outpatients at Risk of Developing Pressure Ulcers: A Quasi-Experimental Study

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Abstract

Pressure ulcers (PUs) are a major health concern. In today's tech era, mobile health applications (mHealth apps) offer real-time data, efficient scheduling, and automation, leading to cost-effective care and improved patient satisfaction. This study aimed to assess the feasibility of a novel preventive mobile health application targeted at informal caregivers of outpatients at risk of developing pressure ulcers. In this quasi-experimental study, 23 Informal Caregivers (ICs) were assigned to the intervention group, and 22 to the control group (n = 45). Feasibility was assessed by considering app utility, ease of use, knowledge gaps in prevention, PU rates, and ICs' self-efficacy. Data was collected at baseline, 2 months, and 4 months, and analyzed using descriptive statistics and inferential analysis. Group disparity in improvement: Prevention knowledge (p = 0.040) and patient support efficacy (p = 0.049). Control experienced no shift; Intervention (mHealth app) showed progress. Initial app acceptance was low but grew after 4 months (p = 0.010). After 4 months, perceived usefulness was linked to support efficacy (r = 0.40, p = 0.05), despite steady ease of use perception. This investigation proposes that the innovative preventative mHealth app has the potential to be viable and is well-received among ICs caring for outpatients at risk of developing PUs. In addition, the temporal fluctuations in metrics between the groups suggest that this application could serve as an advantageous instrument in aiding the efforts of ICs in PU prevention.

Impact Statement

Our study offers pioneering insights into the behavioral impact of a preventive mobile health app focused on pressure ulcers among informal caregivers. By filling a gap in existing research, our findings serve as a foundational resource for healthcare providers and policy-makers interested in leveraging technology to improve health outcomes. Specifically, the work has the potential to enhance the quality of care delivered by informal caregivers, thereby improving patient well-being on a broader scale.

Introduction

Pressure Ulcers (PUs) entail a significant global challenge that health systems must address. In particular, the estimated prevalence of PUs in Cyprus is 8.79% (Zakou, Basilopoulos & Gouni, 2015), which is comparable to the European rate of 10.8% (NPUAP/EPUAP/PPPIA, 2014). The consequences of PUs can be severe including prolonged hospital stays, readmissions and increased mortality rates (Chan et al., 2012). Furthermore, PUs are estimated to consume up to 4% of the annual health care budget in Europe (Posnett et al., 2009). According to a study by Moore et al. (2019), the majority of PUs are preventable with the right interventions; therefore, the prevention and management of PUs is a crucial health care priority requiring continued research and attention.

Mobile technology, through the use of mobile health applications (mHealth apps), has empowered users to manage, monitor, and detect diseases (West, 2012), resulting in an increasing acceptance and development of mHealth apps in the global market over the last decade (Global QYResearch, 2019). According to Grossman, Zak, and Zelinski (2018), many mHealth apps offer features that have been proven to reduce workload, thereby increasing the well-being of informal caregivers. The term "Informal Caregiver" (IC) in the current study, defines an unpaid individual (such as a spouse, partner, family member, acquaintance, or neighbour) who provide assistance to dependent individuals (Schulz and Tompkins, 2010). In most countries, care for the elderly is provided by ICs (WHO 2012), whereas in the United States, the most frequent reasons for requiring care from ICs are related primarily to aging, followed by cases of dementia, and thirdly, to situations requiring surgical procedures or the presence of incisions or PUs (NAC & AARP Public Policy Institute, 2015). Moreover, the home environment is deemed as the preferred place for care for individuals with PUs for most of the time (Garca et al., 2019; Sultana & Zecovic, 2017), with the IC assuming a significant role in the care of PUs (Artico et al., 2017). As prevention is the most important quality measure in care (Engels et al., 2016) and ICs are unable to detect early indications of a PU timely at home (Khan et al., 2017), evidence-based research on interventions that can support ICs in such matters is therefore necessary. However, there is a significant research gap in both national and international literature, as only one study has been found which examined such an intervention in the specific population (McKeown et al., 2022). A similar example is the research conducted by Friesen, Hamel, and McLeod (2013), which, despite involving ICs in the use of a mHealth application centered on PU, involved nurses as its investigated population. On the other hand, the case of Piette et al. (2015), whose population concerned ICs, dealt with the mHealth app on supporting patients with heart failure instead of PUs.
This study examines the hypothesis that the novel preventative mHealth app will be feasible and effective in preventing PUs among ICs of at-risk outpatients. A quasi-experimental, parallel-group design with an equal allocation ratio of 1:1 between the intervention and control groups was used to test the hypothesis. Following a thorough literature review and expert consultations at various levels, comprehensive information about the study's objectives has been gathered, examined, and synthesized to facilitate its successful implementation. The specific information has been carefully tailored to ensure its suitability for the intended purpose of the study.

**Methods**

**Study setting**

The study was conducted in the Republic of Cyprus, and data collection took place between October 2021 and December 2022. The study sample consisted of ICs who provide care or support to patients at risk of developing PUs in a community setting.

**Eligibility criteria**

The participation requirements for this study are as follows: The primary adult IC (as defined by Schulz and Tompkins (2010)) must provide care or support to an outpatient at risk of developing PUs. The level of risk for PUs is determined by their score on the Braden scale (they are considered to be at moderate to severe risk if their score is 18 or less). The IC must be between the ages of 18 and 74 years old and express an interest in participating in the study. Furthermore, the IC should speak Greek, to ensure that they can comprehend the intervention instructions and be able to complete the questionnaire. Participants must also own an Android or iOS mobile device to access the study mHealth app. Finally, it is required that the patient being cared for by the IC should not have been bedridden for more than 4 months at the time of recruitment.

**Intervention group**

In a previous study by Polychronis et al. (2022), an mHealth app was introduced to enhance care quality through integrated clinical support. Built on the Behavioral Intervention Technology Model (Crutzen, 2014), the app has three core features. Firstly, it provides a customizable position change reminder, ensuring timely patient mobilization, with alerts that only stop upon user confirmation. Secondly, it educates on prevalent PU development points, offering both written guidelines for ICs and multimedia content for proper patient repositioning; essential PU areas are distinctly marked on a body sketch for focused interventions. Please refer to Figure 1 for a visual representation of the mHealth app. Lastly, the app includes a PU risk assessment tool based on the Braden scale (Bergstrom et al., 1987), advising on the need for specific support surfaces such as air mattresses. This app represents a synergy of research and technology aimed at refining care practices.

**Control group**

The information booklet administered to the control group consists of the printed version of the bibliographic content of the mHealth app. Additionally, a diary is available that can be used as a reminder method for the patient's repositioning, while the Braden scale is also explained in printed form, allowing the IC to apply it manually and assess the need for support surfaces.

**Outcome measures**

The definitive version of the questionnaire is presented in the form of an electronic questionnaire that is self-administered. The questionnaire is comprised of 52 questions and utilizes three scales (FCAT®, TAM, and BRADEN Scale) that have been extensively used in previous research and have demonstrated good psychometric properties. A specific scale was also developed for this study. The scales were implemented after consulting experts in the field to ensure that they were appropriate for determining whether survey administration is feasible to the population under investigation.

Initially, the questionnaire consists of eleven sociodemographic questions concerning the ICs (such as gender, age, marital status, relationship with the patient, educational background, etc.) and five questions addressing the patient profile (gender, age,
quantity of PUs/Non-Blanchable Erythema present today). Inclusion of the aforementioned questions in the questionnaire ensures that the study results can be analysed with re concerning demographic factors and patient characteristics that may influence the outcomes. The quantity of PUs and Non-Blanchable Erythema (NBE) is used for comparison purposes between the baseline measurement and the quantity reported by the ICs during the follow-up phase. Specifically, a PU is a type of injury that occurs in the skin and/or underlying tissue, typically as a result of prolonged pressure. This particular pressure, may be caused by immobility or a medical device that applies pressure to the skin (often over a bony prominence). In some cases, pressure combined with shear can also lead to the development of a PU. NBE therefore, is an indication of the initial stages of tissue damage that can lead to a Stage 1 PU (NPUAP/EPUAP/PPPIA, 2014).

Subsequently, during the admission and exclusion criteria process, ICs utilize the Braden Scale to assess the patient's risk of developing PUs. The results obtained from the Braden Scale are then used to classify the patient into one of two risk categories for the development of PUs: Mild to Moderate Risk (13-18) and High to Severe Risk (12-6). The two risk categories are determined by the cumulative score across six sub-scales of the Braden Scale (sensory perception, moisture, activity, mobility, nutrition, friction, and shear). The sub-scales are rated on a scale of 1 to 4, with the lowest score indicating a higher risk in each case (Bergstrom et al., 1987).

Acceptance of the mHealth app was assessed using the Technology Acceptance Model (TAM), which was developed by Davis (1989) to explain and predict users' acceptance of technology. The Perceived Ease of Use and Perceived Utility of the technology are the two sub-scales examined by the questionnaire. Perceived Utility is defined as "the degree to which an individual believes that using a particular technology system will enhance their job performance," while Perceived Ease of Use is defined as "the degree to which an individual believes that using a particular technology system requires little effort." The scores can range from 0 to 100, with higher values indicating more utility and ease of use.

The Family Caregiver Activation in Transitions (FCAT) scale developed by Coleman et al. (2015) was employed to examine the level of organizational and supportive effectiveness of IC in providing care to their patients. In particular, the FCAT comprises of ten (10) Likert scale questions, with six (6) response options, aimed at determining the IC's level of organizational and supportive effectiveness in carrying out various general caregiving tasks related to medication management, medical appointments, care plans, and awareness of how to access medical information. The FCAT score ranges from six (6) to sixty (60), with higher scores indicating higher levels of organization and effectiveness of patient support.

The Knowledge Levels regarding Preventative Measures (KLRPM) of PUs were assessed using a scale specifically developed for this study. A limitation of the existing measurement tools is identified in the literature, as researchers mainly use self-developed scales to assess the knowledge of ICs regarding PU prevention. The scale was developed based on a similar questionnaire from the relevant literature (Tan et al., 2018) and through consultation with experts. It consists of ten (10) questions that examine three (3) specific areas of PU prevention knowledge: 1) reducing pressure, 2) reducing shear and friction forces, and 3) managing skin surface moisture. The scale ranges from 0 to 10 units, with higher values indicating higher KLRPM.

**Pilot study**

Pilot research was deemed necessary to evaluate the appropriateness, relevance, and practicability of the mHealth app as well as the validity and reliability of the final Greek questionnaire.

**Reliability and validity of the questionnaire**

After following all necessary steps (forward translation, synthesis, backward translation, expert review) to ensure that the translated questionnaire is culturally appropriate and that it accurately measures the intended constructs in the target population, a pilot test was conducted. Through contact with ICs receiving home health care services between September 2021 and October 2021, a convenient sampling of participants was made. The inclusion criteria for the pilot phase, which involved 15 participants, were identical to the admission criteria outlined in the relevant preceding chapter. Results of the pilot test indicate an overall acceptable level of reliability among the foreign-language scales that were adopted for this study, suggesting that the translated questionnaire consistently measures the same constructs as the original versions. Specifically, Cronbach's alpha internal consistency for the FCAT
scale was 0.90, indicating excellent reliability, whilst the internal consistency for the TAM subscales of perceived utility and perceived ease of use were 0.75 and 0.73, respectively, indicating acceptable reliability. For the Braden scale, Cronbach's alpha internal consistency was 0.7, indicating acceptable reliability as well (Tavakol & Dennick, 2011). As far as the specially designed scale for assessing KLRPM is concerned, internal consistency reliability was found to be acceptable (Cronbach's alpha = 0.78), whilst content validity was assessed through experts' opinions (Almanasreh et al., 2019). Construct validity was tested using correlation analysis, and the results demonstrated significant correlations, indicating acceptable construct validity (Strauss & Smith, 2009).

**Validity of the App**

The results of the mHealth app validation are presented in a previous study (Polychronis et al., 2022). The validation process for the mHealth app consists of two phases. In the first phase, the content validity was evaluated by nine (9) experts, and in the second phase, the face validity was assessed by fifteen (15) ICs.

In summary, the results regarding the content validity of the mHealth app were evaluated by the participating experts in the study. The experts rated the content as superior, while the technological validity was deemed adequate (Doak et al., 1994). Notwithstanding, the findings of the analyses and the voluntary feedback provided by the participants were duly considered. As a result, in some instances, the mHealth app data was subjected to review through consultations with the research team. For instance, the input of wound specialists indicated that incorporating additional summaries or reviews into the mHealth app could be beneficial. Concerning the face validity, the IC participants deemed the clarity validity to be acceptable. Moreover, the participants expressed a strong inclination to accept the mHealth app on both scales of ease of use and utility.

**Participant allocation and follow-up**

The sample size was attained through organized private and philanthropic organizations that provide home health care services. These responsible parties approached potential participants, distributing a pamphlet that briefly explains the objectives of the study. If interested, the prospective participant could copy the electronic link (or scan the QR code) listed in the informational brochure and, after being fully informed via the link, proceed voluntarily to the online application for study participation. Specifically, the candidate was required to complete a brief questionnaire to ensure that he or she met all the study’s inclusion criteria. After completing the application for meeting the inclusion criteria, the IC was randomly assigned to either the intervention or control group (based on odd or even numbers, depending on the order of entry into the study). A link directing the participants to complete the first questionnaire was subsequently sent via email or telephone. Immediately following the completion of the first questionnaire, distribution group-specific instructions were provided for the download and installation of the mHealth app or the information booklet in Portable Document Format (PDF). To confirm the ICs’ receipt of the study interventions, additional communication interventions were conducted with them.

Each participant needed 4 months to fulfill the requirements of the program. Specifically, each group underwent three measurements over the course of 4 months. The first measurement was taken before the intervention (baseline), the second 2 months after the intervention (time 2), and the third, 4 months after the intervention (time 3). The same evaluations were conducted in both groups, except for the TAM scale, which was completely omitted from the control group, which received only traditional interventions from the health care System of Cyprus and an information booklet provided by the study.

**Sample size calculation**

The power analysis for the current study was carried out for a design with three levels of comparisons over time (analysis of variance for repeated measures) and two levels of comparisons between two groups (intervention and control). Both comparisons between two groups at the same time point and comparisons between three-time points within the same group were subjected to power analyses. To achieve 90% power with an effect size of 0.40 for the comparison between groups in this design, 95% power with an effect size of 0.25 for the comparison between two-time points, and 95% power with an effect size of 0.25 for controlling the interaction term, 46 participants (23 in each group) are needed.
Statistical analysis

The Kolmogorov-Smirnov test was used to examine the normality of the distributions of quantitative variables. The mean and Standard Deviation (SD) were used to describe those with a normal distribution, whereas the median and interquartile range were used to describe those not following a normal distribution. Categorical variables were characterized using absolute frequencies (N) and relative frequencies (%). When necessary, Pearson's chi-square test or Fisher's exact test were used to compare proportions.

The paired t-test was used to compare the TAM scale measurements between the two-time points and the Wilcoxon signed-rank test was utilized in order to compare the frequency of mHealth app usage between the time points. In addition, the incidence rates of PUs and NBEs were compared between the measurements using the McNemar test. To compare quantitative variables between the two groups, the Student's t-test was applied. Repeated measures analysis of variance (ANOVA) was used to examine differences in the FCAT and KLRPM scales between groups and over time. The possible degree of change in the scales over time between the two groups was also estimated using the method described above. To control for Type I error resulting from multiple comparisons, the Bonferroni correction was applied, and the significance level was set to 0.05/k (k = a number of comparisons). The variation in the incidence rate of PUs and NBEs over the course of the follow-up period was analyzed using linear mixed models, from which dependency coefficients ($\beta$) and their standard errors (SE) were derived. Due to the asymmetry of their distributions, logarithmic transformations were used for this analysis. The correlation between the FCAT, TAM, and KLRPM scales and the incidence rate of PUs and NBEs was also evaluated using mixed linear models. The Pearson correlation coefficient ($r$) was utilized to investigate the relationship between the scales over time. The questionnaires' internal consistency was evaluated using Cronbach's alpha coefficient. Two-tailed significance levels were applied, and the level of statistical significance was set at 0.05. For the analysis, the statistical software package SPSS 26.0 was utilized.

Results

Participant withdrawal was recorded at a rate of 15.1%, resulting in a decrease in the final number of participants, nonetheless, this is a common occurrence in research studies. During power analysis, the reduction in the final sample size was accounted for, to ensure the generalizability of the results. The final sample consisted of 45 ICs (native Greek speakers), with 23 (51.1%) in the intervention group and 22 (48.9%) in the control group. The majority of ICs in both groups were female, with 68.2% in the control group and 87.0% in the intervention group. In the control group, the average age of ICs was 40.3 years (SD = 10.6 years), whilst in the intervention group, the average age was 37.1 years (SD = 9.9 years). The majority of ICs in the control group (31.8%) were unmarried, while 43.5% of ICs in the intervention group were cohabiting. In addition, the majority of IC patients in both groups were male. The majority of ICs in both groups had been caring for their patients for three to four months.

The ICs in the intervention group had a significantly higher level of education ($p=0.013$) and they spent less time caring for their patients in comparison to the ICs in the control group ($p=0.047$). Moreover, their marital status ($p=0.036$) and the relationship they had with the patient ($p=0.046$) differed significantly between the two groups. Specifically, a higher percentage of the ICs in the intervention group were cohabiting with the patient and a lower percentage consisted of patient offspring.

The scores on the Braden scale (risk levels of developing PUs) were found to be significantly different between the two groups, with the control group scoring higher risk levels.

Acceptance of the App

The scores from the 'perceived utility' and 'perceived ease of use' subscales of the TAM for the intervention group of ICs at both 2 and 4 months serve as indicators of mHealth app acceptance. These subscales' internal consistency was 0.79 and 0.70, respectively, indicating acceptable reliability. At 4 months of follow-up, the "perceived utility" subscale score increased significantly, indicating an increase in levels ($p = 0.010$). In contrast, the "perceived ease of use" subscale score did not change significantly between 2 and 4 months. Regarding the frequency of app usage by ICs in the intervention group at 2 months, 41.7% of ICs in the intervention group utilized the app daily. At 4 months, the frequency of use decreased significantly, with 39.1% of ICs in the intervention group using it infrequently.
Occurrence of Pressure Ulcers

The prevalence of PUs did not differ significantly between the two groups at any time measurement, nor did the rate of change in the number of PUs over time ($\beta = -0.06$, $SE = 0.04$, $p = 0.105$) in either group. NBE prevalence also did not differ significantly between the two groups at any time measurement. The rate of change in the number of NBEs over time, however, differed significantly between the two groups ($\beta = 0.09$, $SE = 0.11$, $p = 0.024$). In the control group, the number of NBEs at 4 months tended to be greater than at 2 months ($\beta = 0.20$, $SE = 0.12$, $p = 0.082$) and was significantly greater than at baseline ($\beta = 0.22$, $SE = 0.12$, $p = 0.050$) over time. In contrast, the number of NBEs in the intervention group tended to decrease at 2 months compared to baseline ($\beta = -0.07$, $SE = 0.04$, $p = 0.078$), whereas the number of NBEs at 4 months did not significantly differ from either baseline or 2 months. Table 1 illustrates the variations in the incidence of non-blanchable erythema across diverse groups.

Preparation and Confidence

The FCAT scale scores represent the preparation and confidence levels of ICs. The Cronbach's alpha coefficient of reliability was 0.78, indicating acceptable questionnaire reliability.

There were no statistically significant differences between the two groups at any time measurement. The levels of organizational and effective care did not change significantly in the control group during the monitoring period. On the contrary, the initial score in the intervention group was significantly lower compared to both the 2-month and 4-month measurements.

The interaction effect between the two groups varied significantly. In the intervention group, an increase was observed, while the control group experienced no significant change.

Knowledge of Prevention Measures

The KLRPM scale scores, with a Cronbach's alpha coefficient of 0.73, indicated that the questionnaire's reliability was acceptable. In addition, at baseline and after 2 months, there were no significant differences recorded between the two groups. At 4 months, however, the KLRPM score in the intervention group was found to be significantly higher than in the control group. Additionally, the intervention group's knowledge score increased significantly over time across all measurements. In the control group, the knowledge score only increased after 4 months and was significantly different from both the initial and 2-month assessments. The interaction effect between the two groups was significant, as the increase observed in the intervention group over time was significantly greater than in the control group. Figure 2 depicts the change in scale score by group.

The changes in KLRPM scores according to the demographic data of the intervention group's ICs are provided in Table 2. The study's findings show a significant increase in KLRPM scores at 4 months compared to both the initial value and at 2 months for all participants, regardless of their demographic data. Regarding demographic differences, ICs with a postgraduate diploma presented significantly higher scores at 4 months compared to those with a diploma or degree. In addition, ICs who reported having 1-3 members in the household had significantly higher scores at 4 months compared to ICs with 3-5 members in the household. Furthermore, the study revealed that ICs who cared for their patients for 3 months had significantly higher scores at 2 months compared to ICs who cared for their patients for only 1 month.

To examine the relationship between the TAM, FCAT, and KLRPM and the PUs incidence rates, mixed linear models were used, with the PUs incidence rates serving as the independent variable and the TAM, FCAT, and KLRPM serving as the dependent variables. The dependency coefficients for the PU incidence rates are derived from the mixed linear models. The PU incidence rates were significantly associated with the FCAT score in the control group. Specifically, the level of organization and effectiveness in patient support decreased as the number of PUs a patient had increased ($\beta = -0.84$, $SE = 0.33$, $p = 0.011$). In the intervention group, there was a significant relationship between the PU incidence rates and the perceived utility scale. Specifically, the perceived utility of the application was greater according to the ICs of the intervention group as the number of PUs on a patient increased ($\beta = 4.94$, $SE = 1.49$, $p = 0.001$).
The Pearson correlation coefficients between the TAM, FCAT, and KLRPM scales at the 4-month follow-up per group are illustrated in Table 3. At 4 months, there was no correlation between the FCAT and KLRPM scales in the control group whilst in the intervention group at 4 months, higher levels of organization and effectiveness were significantly associated with greater perceived ease of use ($r = 0.40$, $p = 0.05$).

**Discussion**

The purpose of this study is to evaluate the feasibility of a novel preventative mHealth app among ICs of patients at risk of developing PUs within the community setting. Comparisons were made between participants who received instructions to use the mHealth app and those who received a relevant informational booklet in terms of a) knowledge level of prevention measures, b) PU incidence rates, and c) organization and effectiveness of patient support. Additional dimensions related to the acceptance of the mHealth app (perceived utility and ease of use) are also investigated. All scales utilized in the study's questionnaire exhibited an adequate level of internal consistency.

The results of this research contribute significantly to the ongoing discussions in the academic literature about the efficacy of different instructional methods in promoting preventive behaviors related to PUs. In the conclusion drawn from our study, we found that ICs who were directed to utilize the mHealth app displayed considerably higher levels of knowledge regarding preventive measures compared to their counterparts who were given an informational booklet. While there were no notable differences between the two groups observed at the 2-month interval, at the 4-month mark of utilizing the mHealth app, the intervention group demonstrated a significant increase in their KLRPM scores. Previous studies (Piette et al., 2015; Changizi & Kaveh, 2017) which highlighted the potential of mHealth apps to foster health behaviors, including preventive behaviors, have corroborated this data. Our findings are also in line with the conclusions drawn by McKeown et al. (2022), who investigated a similar mHealth app within the same demographic. Specifically, after 2 and 6 weeks of follow-up, they concluded that the participants' knowledge base had increased and they confirmed the application's information's quality as being beneficial.

The utilization of mHealth apps can provide ICs with a practical resource for acquiring and incorporating preventive behaviors into their caregiving routines. As suggested by Guessi Margarido et al. (2022), this may be due to the user-friendly and interactive nature of such mHealth apps. This study's application was designed to provide ICs with step-by-step instructions, reminders and feedback regarding the risk of PU development. This could enhance their engagement and motivation to engage in preventive behaviors. In contrast, even though the instructional booklet contains pertinent information, it may have been less engaging and lacked interactive elements that could have enhanced ICs' learning and adherence to preventive behaviors. This suggests that the mode of instruction can play a significant role in promoting behavior change, and mHealth apps may offer significant benefits in this regard. In their study, Ghahramani and Wang (2021) analyzed the factors that influence ICs' intent to integrate mHealth applications into routine duties. Important determinants included ICs' app-use skills, the app's ability to meet their needs, ICs' control over responsibilities, and care recipient decisions. These factors predicted the likelihood that ICs would adopt mHealth apps for caregiving. Therefore, future interventions must take into account the preferences and characteristics of the target population to optimize their effectiveness. Features such as educational level and family size should not be overlooked, given both the findings of the present study and results from similar research (Piette et al., 2015; Garfield et al., 2016). For instance, in the current study, the knowledge scores regarding preventive measures among ICs with postgraduate degrees were found to be significantly higher compared to those with diplomas or degrees over a 4-month observation period. Similarly, at the 4-month follow-up mark, ICs with 1-3 household members had significantly higher scores compared to ICs with 3-5 members.

The results of the current study also indicate that the use of a PU prevention mHealth app can lead to higher levels of organization and effectiveness in patient support compared to ICs who receive traditional instruction booklets. The degree of change in the levels of organization and effectiveness of patient support on the FCAT scale significantly differed between the two groups, as there was an increase in the intervention group while there was no significant change in the control group. With reference to the control group, it appears that the levels of organization and effectiveness in patient support were negatively affected by the number of NBEs. Specifically, as the number of NBEs increased, the level of organization and effectiveness decreased ($\beta = -0.84$, $SE = 0.33$, $p = 0.011$). All of the preceding highlights therefore, the significance of considering these factors when designing and implementing efficient mHealth interventions.
Our findings indicate that the ICs’ acceptance of the mHealth app was relatively low. Additionally, a similar study using the TAM scale for evaluating health technologies (Chiu et al., 2020) also reached the same conclusion regarding low acceptance. On the contrary, McKeown et al.’s (2022) study revealed that the ICs discovered high levels of app usability and acceptance. At 4 months, however, the score on the “perceived utility” subscale of the TAM scale increased significantly, indicating an increase in perceived utility. In contrast, the "perceived ease of use" subscale score did not significantly change over time. Nonetheless, after 4 months of monitoring, it was discovered that the levels of organization and effectiveness of patient support positively influenced the perceived ease of use ($r = 0.40, p = 0.05$).

Regardless of measurement time, the rate of change in the number of PUs was found to be similar in both groups. Nonetheless, the number of NBEs was found to differ between the two groups, with a significant decrease in the intervention group. These findings should be interpreted with caution however, because this difference was only observed in the 2-month relationship compared to the initial number (baseline). For instance, the fact that at 2 months, the majority of ICs in the intervention group were using the mHealth app daily, whereas, at 4 months, the usage frequency decreased significantly, with 2/5 ICs using it infrequently, could potentially influence the results. Additionally, since there are significant differences between the two groups on the Braden scale, with the control group having a higher risk level, the risk of PU development may have an impact on the results. According to Aloe et al. (2017), quasi-experimental studies may be susceptible to exogenous (external) factors that are beyond the control of the researchers. The same researchers also note that the absence of sample stratification may result in heterogeneity among comparison groups. The majority of ICs in the control group were unmarried (35%), whereas the majority of ICs in the intervention group were cohabiting (43.5%), with significant differences in marital status between the groups (higher percentage of cohabitation in the intervention group). There was also a significant difference in the IC’s relationship with the patient between the groups, as the control group consisted primarily of the patient’s offspring. Despite the fact that the intervention group’s ICs had a significantly higher educational level and provided care for their patients for a shorter duration than the control group’s ICs, there are similarities in certain IC characteristics between the groups. During their inclusion in the study, the majority of ICs in both groups provided home care for their patients for a period of 3 to 4 months, with a slightly younger median age in the intervention group (37.1 years) compared to the control group (40.3). WHO (2012) reports that the majority of ICs in the majority of countries are female.

Regarding the acceptance of technology by ICs, our findings highlight several obstacles and restrictions. For instance, age appears to be a significant factor, as those younger than 33 reported a greater perceived utility of the mHealth app ($P = 0.003$). Younger age groups frequently develop a high level of technological knowledge and skills as a result of their continuous exposure to technology (Czaja et al., 2006). This may present a challenge to older ICs that have not kept up with technological advancements. Other determinants identified included the presence of a health care professional within the patient’s family, ICs historical engagement with PU management as well as the number of PUs the patient was dealing with. For example, among intervention group ICs, the perceived utility of the mHealth app tended to increase with the number of PUs ($\beta = 4.94, SE = 1.49, p = 0.001$). Ultimately, providing additional training to ICs, especially those with limited tech skills, is crucial for increasing acceptance and effective use of mHealth apps. This has implications for policy, which may need to mandate basic training, and for practice, as healthcare organizations should consider specialized training programs for these individuals.

**Conclusion**

The present study validates the utilization of the specific mHealth app by ICs in the community as a preventive measure against PUs. The mHealth apps could be a promising tool for encouraging ICs to engage in preventive behaviours, with potential implications for improving patient health and ICs’ well-being. The study has important implications for health care professionals and policymakers involved in IC support programs, as mHealth apps can improve ICs’ knowledge, skills, and motivation to participate in preventive behaviours. Further research is needed however, to investigate the long-term effects of mHealth apps on ICs’ preventive behaviours and to determine the optimal design and characteristics of such interventions for different populations.

**Abbreviations**

Informal Caregiver (IC)

Knowledge Levels regarding Preventative Measures (KLRPM)
Mobile Health app (mHealth app)
Non-Blanchable Erythema (NBE)
Pressure Ulcer (PU)
Technology Acceptance Model (TAM)
The Family Caregiver Activation in Transitions (FCAT)

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**Tables**

Tables 1-3 are not available with this version

**Figures**

Figure 1

Image of the APP.
Figure 2

Change of KLRPM score between Groups.