Usability evaluation of connected health devices in home monitoring: Toward devices adapted to the characteristics of informal caregivers

Claire Cardon (claire.cardon99@outlook.fr)
University of Picardie Jules Verne
Cécile I. Bernard
University of Picardie Jules Verne
Noémie Chaniaud
Institut Polytechnique de Bordeaux
Emilie Loup-Escande
University of Picardie Jules Verne

Research Article

Keywords: Informal caregivers, Blood pressure monitor, Connected medical device, Home medical device, M-health, Usability as-sessment.

Posted Date: December 6th, 2022

DOI: https://doi.org/10.21203/rs.3.rs-2333296/v1

Abstract

While an increasing number of Informal CareGivers (ICGs) are assisting their dependent loved ones with the daily living tasks and medical care, they are rarely considered in the medical devices design process. The objective of this study is to identify the characteristics of ICGs impacting the use of the iHealth® Sense BP7 medical device, namely a connected wrist blood pressure monitor. For this purpose, user tests were conducted with 29 potential or actual ICGs. First, the participants filled out a socio-demographic questionnaire and then handled the blood pressure monitor. Finally, they completed the System Usability Scale questionnaire. The results revealed an impact of technophilia and age on usability dimensions. To conclude, the consideration of the ICG population in the design process of connected medical devices is discussed, particularly the age and level of technophilia.

Introduction

The aging of the population coupled with the increase in chronic, cardiovascular and neurodegenerative diseases will change the health needs in the coming years [1, 2]. In addition, advances in medical technology and the policy of home care are contributing to a growing number of dependent people remaining at home. These people may be dependent due to old age, illness, or disability and all require the help of a relative or professional to carry out daily activities and medical care.

The term *Informal CareGiver* (ICG) has become increasingly important in societal debates in recent years. This is anyone who provides assistance to a dependent relative due to age, illness or disability [3, 4]. In 2019, France has recorded approximately eleven million ICGs and this number is still increasing [5]. Unlike professional caregivers (nurses, orderlies, etc.), ICGs do not have any training in home care. Moreover, because of a system of voluntary assistance to a loved one, ICGs have much more varied profiles than professional caregivers. Indeed, many different situations can arise, such as a child helping a parent or, conversely, a parent helping a child, an elderly or even a young spouse, a friend, a neighbor, etc. The possible situations are as numerous as there are profiles. Thus, ICGs can be men, women; minors, adults; young people, elderly people; people in school, working or retired; of any socio-professional category; of any level of education and any social background.

This increase in the number of ICGs is occurring in parallel with the development of technology and, in particular, the development of eHealth. This term, which appeared in 1999, is defined by Mitchell as "the combined use of the Internet and Information Technology for clinical, educational and administrative purposes, both locally and remotely" [6, p.9]. The prefix "e" stands for "electronic," but the current perception of eHealth is much more restrictive. According to Eysenbach [7], eHealth represents improved health services for both patients and caregivers in technical terms, but also a mindset and a way of thinking to improve care. The field of eHealth encompasses other concepts such as mHealth defined by the WHO as "medical and public health practices that rely on mobile devices such as cell phones, patient monitoring systems, personal digital assistants and other wireless devices" [8, p. 6].

However, medical devices in mHealth still have many limitations such as usability [9] or data security [10]. Similarly, design processes do not always consider ICGs, who are often the final users of these devices. Indeed, according to Ehmen and al. [11], problems with the use of medical devices occur when a product is used by people outside the initial target user group. However, to the best of our knowledge, there are currently few studies reporting on the specific needs and demands of ICGs. As a result, ICGs generally must use medical devices that have been designed for patient or professional use. This can lead to misuse and errors that can result in more or less serious consequences.

Ergonomic evaluation through testing with potential users upon the design process is a way to reduce the risk of errors during future use in a real context. The usability measured during ergonomic evaluations is multidimensional and influenced by the context of use integrating the characteristics of the users [12–15].

User characteristics can be classified according to factors such as physical, sensory, psychological and social [12]. Among these four types of factors, the social factors relate to socio-demographic characteristics and are the most investigated in the literature [16–20]. Age is the most studied user characteristic in the search for influencing factors. Georgsson and Staggers [19] showed better overall usability, while Chaniaud and al. [17] and Liang and al. [21] showed no relationship between age and satisfaction. Conversely, Czaja and al. [18] showed no link between age and usability. Technophilia, defined as previous experience in using technology, is also often investigated. Georgsson and Staggers [19] showed better usability in terms of effectiveness, efficiency and satisfaction for the most technophile subjects, while Czaja and al. [18] only showed an effect of technophilia on effectiveness. The level of education is also a variable that has been investigated many times in the scientific literature, but, to the best of our knowledge, no experiment seems to have demonstrated its influence on usability [17, 19–22].

Therefore, the objective of this study is to evaluate the usability of a connected medical device to determine the impact of ICG characteristics. Our hypotheses were as follows:

- Hypothesis 1: Age would have an impact on usability.
- Hypothesis 2: Technophilia would have an impact on usability.
- Hypothesis 3: Education level would have no impact on usability.

Methods

Population

Twenty-nine potential or actual ICGs, including 17 women and 12 men with a mean age of 37.03 years (SD = 19.3; Min = 21; Max = 79) participated in this study. Inclusion criteria were: being over 18 years old and native-speaker in French. All participants signed an informed consent form.

Procedures and materials

The study was conducted in March 2022 and includes three steps. Participants were received one after the other. The first step was to complete a socio-demographic questionnaire collecting the following information: age, gender, highest level of education obtained, technophilia (via a 5-point Likert scale), comfort with technology, and current role or not as an ICG.

The second step was the manipulation of the iHealth® Sense BP7 wireless wrist blood pressure monitor (Fig. 1). This was used in combination with an Apple smartphone, model iPhone XR. Participants were asked to record the blood pressure and heart rate of another person in the experimental room, considered dependent, on a slate. The person voluntarily participated in the study after signing a consent form, specifying that no medical data would be stored or shared. To perform the task, participants were provided with a procedure sheet based on the instructions provided and showing the steps of the manipulation. This step was filmed for further analysis.

The third step concerned the completion of the System Usability Scale, adapted to eHealth and translated in French [23–25].

Usability Measurement

Usability was measured according to the criteria defined by the 2018 ISO 9241-11 standard [12] i.e., by assessing effectiveness, efficiency, and satisfaction. *Effectiveness*[1] was assessed by the final success on the task (i.e., picking up the correct numbers). It was also measured by the number of manipulation errors. Based on Chaniaud and al. [17], five types of errors were referenced on the same medical device in which an additional error was added: (1) the participant puts the monitor on the wrong hand; (2) the palm of the hand is not turned up; (3) the monitor is not placed in the right direction; (4) the Bluetooth connection is not established; (5) the measurement is not done in full; (6) the monitor is not turned off. *Efficiency*[2] was measured by the total time to complete the task and the number of returns to the procedure sheet. *Satisfaction*[3] was assessed by the score on the SUS questionnaire.

Analytical methods

The videos were viewed using the VLC media player and manually analysed to obtain the effectiveness measure (i.e., number of errors) and efficiency measures (i.e., total time and returns to procedure sheet). The quantitative data were then analysed using IBM SPSS version 28.0 software. Descriptive statistics, chi-square tests, ANOVAs, and Student's t tests for independent samples were performed when the conditions of homoscedasticity were met. In the opposite case, nonparametric tests were used such as chi-square with Yates correction, Kruskal-Wallis test and Mann-Whitney test.

[1] Effectiveness is defined by ISO 9241-11 as “accuracy and completeness with which users achieve specified goals” [12, p. 3]

[2] Efficiency is defined by ISO 9241-11 as “resources used in relation to the results achieved” [12, p. 3]

[3] Satisfaction is defined by ISO 9241-11 as “extent to which the user’s physical, cognitive and emotional responses that result from the use of a system, product or service meet the user’s needs and

expectations" [12, p. 3]

Results

Population characteristics

Participants were characterized by age (young/old), level of technophilia (low/high), and education (level 1/2/3) according to Table 1.

Overall usability

Twenty-four participants were in a successful situation *versus* five participants in a failed situation. Successful participants on the measurement task made an average of 0.46 errors (i.e. effectiveness; SD = 0.51). They completed the task in an average of 293 seconds (i.e. efficiency; SD = 136) and returned to the procedure sheet an average of 16.5 times (i.e. efficiency; SD = 4.23). Participants who successfully completed the task assigned a mean SUS score of 81.04 (on 100), whereas participants who failed assigned a mean score of 58.5 (i.e. satisfaction).

Effects of user characteristics: age, technophilia and education level

Age had a significant effect on manipulation time (*efficiency*: U = 14, $p < .01$) and the number of returns to the procedure sheet (*efficiency*: t (22) = -2,40, $p = .025$). However, age showed no significant impact on success rate (*effectiveness*: $\chi^2(1) = 1{,}25$, $p = .541$), number of errors (*effectiveness*: $U = 48$; $p = .272$), and SUS questionnaire score (*satisfaction*: $U = 46{,}5$; $p = .294$).

Technophilia had a significant impact on the success rate (*effectiveness*: $\chi^2(1) = 5{,}44$, $p = .02$). In contrast, technophilia had no significant effect on the number of errors (*effectiveness*: $U = 38$; $p = .893$); handling time (*efficiency*: $U = 30$; $p = .462$); number of returns to the procedure sheet (*efficiency*: $U = 34$; $p = .668$); and SUS questionnaire score (*satisfaction*: $U = 29{,}5$; $p = .435$).

In contrast, education level had no impact on either effectiveness (*success rate*: $\chi^2(2) = 3{,}61$, $p = .164$; *number of errors*: $\chi^2(2) = 0{,}089$, $p = .957$), efficiency (*handling time*: $\chi^2(2) = 0{,}332$; $p = .847$; *number of returns to procedure sheet*: $F(2{,}21) = 0{,}607$; $p = .554$), and satisfaction (*SUS score*: $\chi^2(2) = 1{,}91$; $p = .384$).

Discussion

Effects of user characteristics on usability

The goal of this study was to understand what influences ICGs' usability of connected medical devices to improve their experience.

The first hypothesis expected that effectiveness, efficiency, and satisfaction of the blood pressure monitor would be better for younger people than for older people. This hypothesis was partially validated. The results show that the younger the participants are, the less time they take to complete the task and the less time they return to the procedure sheet. Thus, younger people are more efficient than older people to use the device. However, no relationship was found between age and usability in terms of effectiveness and satisfaction. The results concerning effectiveness are in agreement with Czaja and al. [18]. The lack of relationship between age and satisfaction is consistent with the results obtained by Liang and al. [21] and by Chaniaud [26]. However, these results are at odds with Georgsson and Staggers [19] which were only obtained from a sample of 10 participants and therefore have low external validity. The efficiency results are consistent with previous research [19, 22, 26–28] We believe that younger people were quicker to manipulate the blood pressure monitor because of their ease of use of the iPhone, unlike older people. In contrast, we do not observe an effect of age on effectiveness because older people took longer to manipulate the device (less efficient), which reduced their rate of handling errors.

The second hypothesis argued that technophile individuals would be more effective, efficient, and satisfied than non-technophile individuals. The results partially confirm this hypothesis, as no effect of technophilia on efficiency and satisfaction was observed, which is in disagreement with the results obtained by Georgsson and Staggers [19]. However, the results showed a partial relationship between task success and technophilia, i.e., with effectiveness. This result is consistent with Czaja and al. [18]. Nevertheless, this link was not confirmed by the second measure of effectiveness since there was no significant relationship between the number of errors made and technophilia. This finding can be explained by the fact that the measurements were performed on participants in a successful situation. Some of the errors made were blocking for some participants, resulting in their failure. As some of the participants in failure were not able to complete the task, the total number of errors could not be counted and compared to the participants in success situation [26]. As a result, excluding failing participants in the total error measure decreased observable differences.

The third hypothesis predicted a lack of relationship between education level and effectiveness, efficiency, and satisfaction. This hypothesis was validated, as no significant relationship was shown between education level and usability in terms of effectiveness, efficiency, and satisfaction. The results obtained are in agreement with previous work [18, 19, 21, 22, 26]. According to Chaniaud and al. [17], the skill variable with the greatest effect on usability is health literacy, which is not dependent on education level. Indeed, the results show that health literacy influences effectiveness, efficiency and satisfaction.

Limitation and perspectives

The results presented above must be discussed regarding the limitations of this study. Firstly, as the analyses were based on the comparison of socio-demographic categories, the sub-groups compared were very heterogeneous, with most technophiles (72.41%), most young people (62.07%) and a most women (58.62%). This distribution made it difficult to carry out parametric statistical tests and therefore reduced the power of the results. Thus, further studies with more homogeneous subgroups would be necessary to confirm or refute these results. Secondly, according to ISO 9241-11 [12], no single measure of effectiveness, efficiency, or satisfaction is sufficient to represent usability. Therefore, in this study, two measures of efficiency and two measures of effectiveness were conducted. However, there are many possible measures for each criterion, and it would be interesting to use others in the future (e.g., degree of completion and quality of performance for effectiveness; workload and learning time for efficiency) to compare the results and obtain a global approach to each criterion. Regarding satisfaction, the SUS questionnaire used only considers pragmatic attributes, i.e., those related to the product itself. Thus, it could be interesting to look at the user experience of the ICG, to collect his or her feelings about using the device. Indeed, the user experience is often linked to the direct user of medical devices, i.e., patients, but little to the user experience of ICGs and, therefore, indirect users [29]. A third limitation is the coding of the videos. In fact, this was only done by one person, but in a future study, it could be the subject of an inter-judge measurement to increase the reliability of the data. Finally, a limitation of the analysis of the results lies in the subgroups constructed to analyze the impact of socio-demographic characteristics. Indeed, each characteristic was divided into 2 subgroups (3 for the level of education) because of the small size of the sample. Thus, this division may seem reductive (e.g., young/old), but was necessary to perform statistical analyses. In a future study with a larger population, it would be interesting to have more subgroups for each socio-demographic characteristic so that they are more representative of the population. Also, other user characteristics can be investigated, such as health literacy. Further studies are therefore needed to confirm the results obtained and deepen them.

Conclusion

With the aging of the population and the policy of home care, the use of ICGs is increasingly significant. They come to the aid of dependent persons to carry out the tasks of daily life, including medical acts.

During the study, we have observed the heterogeneity of ICGs' profiles. To adapt to each of them, it is necessary to broaden the potential users of connected medical devices in health to include ICGs upstream from the design stage. This population must be considered as being composed of users who may be inexperienced and with varied profiles. This makes it possible to consider their needs and requirements in the same way as those of patients or healthcare professionals.

This study provides empirical insight into the effects of ICG characteristics on the usability of the iHealth Sense BP7 blood pressure monitor. Based on the results, it is important to consider the user's age as well as their level of technophilia to optimize the usability with the connected medical device for patient home in order to limit handling errors and ensure correct patient monitoring.

Declarations

Ethical Approval This study complied with the principles set out in the Declaration of Helsinki of 1964 and its subsequent amendments. Before the experiment, the participants signed a consent form, and the questionnaire was validated by the research ethics committee of the university Picardie Jules Verne. The participants did not receive any financial compensation for their participation, and they agreed to voluntarily participate in the study. The anonymity, confidentiality, and secure storage of the data were guaranteed to the participants and respected.

Authors' Contributions Claire Cardon contributed to the conceptualization, systematic review of articles, methodology development, formal analysis, and original writing. Cécile Bernard participated in the conceptualization, methodology and correction. Noémie Chaniaud, specialized in the design and evaluation of connected medical devices, participated in the correction. Emilie Loup-Escande, head of the Smart Angel project, contributed to the external supervision and correction. All authors read and approved the final manuscript.

Fundings Not applicable.

Conflicts of interest The authors declare that they have no conflict of interest.

Acknowledgements

This publication is part of the Smart Angel project, which is financially supported by the European Regional Development Fund (ERDF), Evolucare and the Programme d'Investissements d'Avenir (PIA).

References

1. Institut national de la statistique et des études économiques, Ed., *Tableaux de l'économie française. Edition 2020*. Paris: Insee, 2020.
2. INPES, 'Prospective santé 2030 - prévention 2010, rapport final', p. 52, Nov. 2010.
3. D. Saint-Charles and J.-C. Martin, 'De la perspective d'« aidant naturel » à celle de « proche-soignant »: un passage nécessaire', Santé Ment. Au Qué., vol. 26, no. 2, pp. 227–244, 2001, doi: 10.7202/014533ar.
4. J.-P. Lavoie, J. Pepin, S. Lauzon, and P. Tousignant, 'Les modèles de relation entre les services formels et les aidantes naturelles. Une analyse des politiques de soutien à domicile du Québec', p. 94, Jun. 1998.
5. 'Stratégie de mobilisation et de soutien en faveur des aidants', *Gouvernement.fr*, Oct. 23, 2019. https://www.gouvernement.fr/sites/default/files/document/document/2019/10/dossier_de_presse_relatif_a_la_strategie_de_mobilisation_et_de_soutien_en_faveur_des_aidants_-_23.10.2019.pdf (accessed Jun. 03, 2022).
6. J. Mitchell, *From telehealth to e-health: the unstoppable rise of e-health*. Canberra: Department of Communications, Information Technology and the Arts, 1999.
7. G. Eysenbach, 'What is e-health?', *J. Med. Internet Res.*, vol. 3, no. 2, p. e20, Jun. 2001, doi: 10.2196/jmir.3.2.e20.

8. World Health Organization, ‘mHealth: new horizons for health through mobile technologies: second global survey on eHealth’, vol. 3, 2011, Accessed: Dec. 28, 2021. [Online]. Available: https://apps.who.int/iris/handle/10665/44607
9. I. Ten Haken, S. Ben Allouch, and W. H. van Harten, ‘The use of advanced medical technologies at home: a systematic review of the literature’, BMC Public Health, vol. 18, no. 1, p. 284, Feb. 2018, doi: 10.1186/s12889-018-5123-4.
10. P. Simon, ‘Bénéfices et risques des objets connectés en télémédecine et santé mobile’, *Eur. Res. Telemed. Rech. Eur. En Télémédecine*, vol. 6, no. 2, pp. 47–57, Jul. 2017, doi: 10.1016/j.eurtel.2017.05.002.
11. H. Ehmen, M. Haesner, I. Steinke, M. Dorn, M. Gövercin, and E. Steinhagen-Thiessen, ‘Comparison of four different mobile devices for measuring heart rate and ECG with respect to aspects of usability and acceptance by older people’, Appl. Ergon., vol. 43, no. 3, pp. 582–587, May 2012, doi: 10.1016/j.apergo.2011.09.003.
12. ISO 9241-11, ‘Ergonomie de l’interaction homme-système - Partie 11: Utilisabilité - Définitions et concepts’. 2018. Accessed: Oct. 27, 2021. [Online]. Available: https://viewerbdc.afnor.org/pdf/viewer/4BPcp2SEwjM1
13. M. C. Trivedi and M. Akheela Khanum, ‘Role Of Context In Usability Evaluations: A Review’, *Adv. Comput. Int. J.*, vol. 3, no. 2, pp. 69–78, Mar. 2012, doi: 10.5121/acij.2012.3208.
14. B. Pavard and L. Karsenty, ‘Différents niveaux d’analyse du contexte dans l’étude ergonomique du travail collectif’, *Réseaux*, vol. 15, no. 85, pp. 73–99, 1997, doi: 10.3406/reso.1997.3136.
15. B. Shackel, ‘Usability – Context, framework, definition, design and evaluation’, in *Human factor for Informatics Usability*, 1991, pp. 21–37. Accessed: Dec. 07, 2021. [Online]. Available: https://doi.org/10.1016/j.intcom.2009.04.007
16. ISO 20282-1, ‘Facilité d’emploi des produits quotidiens - Partie 1: exigences de conception pour le contexte d’utilisation et pour les caractéristiques de l’utilisateur’. 2006. Accessed: Oct. 27, 2021. [Online]. Available: https://viewerbdc.afnor.org/pdf/viewer/vJmahrHOX8k1
17. N. Chaniaud, O. Megalakaki, S. Capo, and E. Loup-Escande, ‘Effects of User Characteristics on the Usability of a Home-Connected Medical Device (Smart Angel) for Ambulatory Monitoring: Usability Study’, *JMIR Hum. Factors*, vol. 8, no. 1, p. e24846, Mar. 2021, doi: 10.2196/24846.
18. S. J. Czaja *et al.*, ‘Factors influencing use of an e-health website in a community sample of older adults’, *J. Am. Med. Inform. Assoc.*, vol. 20, no. 2, pp. 277–284, Mar. 2013, doi: 10.1136/amiajnl-2012-000876.
19. M. Georgsson and N. Staggers, ‘Quantifying usability: an evaluation of a diabetes mHealth system on effectiveness, efficiency, and satisfaction metrics with associated user characteristics’, J. Am. Med. Inform. Assoc., vol. 23, no. 1, pp. 5–11, Jan. 2016, doi: 10.1093/jamia/ocv099.
20. M. G. Morris and V. Venkatesh, ‘Age Differences in Technology Adoption Decisions: Implications for a Changing Work Force’, Pers. Psychol., vol. 53, no. 2, pp. 375–403, 2000, doi: 10.1111/j.1744-6570.2000.tb00206.x.

21. J. Liang *et al.*, ‘Usability Study of Mainstream Wearable Fitness Devices: Feature Analysis and System Usability Scale Evaluation’, *JMIR MHealth UHealth*, vol. 6, no. 11, p. e11066, Nov. 2018, doi: 10.2196/11066.
22. R. Van der Vaart *et al.*, ‘The Role of Age, Education, and Digital Health Literacy in the Usability of Internet-Based Cognitive Behavioral Therapy for Chronic Pain: Mixed Methods Study’, *JMIR Form. Res.*, vol. 3, no. 4, p. e12883, Nov. 2019, doi: 10.2196/12883.
23. J. Brooke, ‘SUS: A “Quick and Dirty” Usability Scale’, in *Usability Evaluation In Industry*, CRC Press, 1996.
24. J. R. Lewis and J. Sauro, ‘The Factor Structure of the System Usability Scale’, in *Human Centered Design*, vol. 5619, M. Kurosu, Ed. Berlin, Heidelberg: Springer Berlin Heidelberg, 2009, pp. 94–103. doi: 10.1007/978-3-642-02806-9_12.
25. G. Gronier and A. Baudet, ‘Psychometric Evaluation of the F-SUS: Creation and Validation of the French Version of the System Usability Scale’, *Int. J. Human–Computer Interact.*, vol. 37, no. 16, pp. 1571–1582, Oct. 2021, doi: 10.1080/10447318.2021.1898828.
26. N. Chaniaud, ‘L’évaluation ergonomique de dispositifs connectés en santé pour le domicile patient dans le cadre de la chirurgie ambulatoire: Vers un modèle de l’utilisabilité adapté à la e-santé’, Université de Picardie Jules Verne, 2020.
27. A. L. Mykityshyn, A. D. Fisk, and W. A. Rogers, ‘Learning to Use a Home Medical Device: Mediating Age-Related Differences with Training’, *Hum. Factors J. Hum. Factors Ergon. Soc.*, vol. 44, no. 3, pp. 354–364, Sep. 2002, doi: 10.1518/0018720024497727.
28. A. Sonderegger, S. Schmutz, and J. Sauer, ‘The influence of age in usability testing’, Appl. Ergon., vol. 52, pp. 291–300, Jan. 2016, doi: 10.1016/j.apergo.2015.06.012.
29. S. Fleury and N. Chaniaud (Accepted), ‘Multi-user centered design: acceptance, user experience, user research and user testing’, *Theor. Issues Ergon. Sci.*.

Tables

Table 1 Population characteristics by age, education level and technophilia

Variable (N = 29)	**Modalities**	**n (%)**
Age	Young (≤ 45 years)	18 (62,07)
	Old (≥ 46 years)	11 (37,93)
Education level	Level 1 (None, GCSE, NVQ Level 1,2)	4 (13,79)
	Level 2 (A Level, BTEC National Diploma, BTEC Higher National Diploma, Diploma of Higher Education)	19 (65,52)
	Level 3 (Master’s degree and more)	6 (20,69)
Technophilia	Low	8 (27,59)
	High	21 (72,41)

Figures

Figure 1

iHealth® Sense BP7 blood pressure monitor used in this study