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SIM2PeD– Intelligent monitoring system for prevention of diabetic foot

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Diabetes is an endocrine chronic disease that causes high blood sugar level, produced by retardation in, or deficiency of, glucose metabolism in the body of the individual with the disease. Neuropathies and/or angiopathies are complications of diabetes that result in changes in the lower limbs which subsequently evolve for the diabetic foot. Diabetic foot represents one of the most devastating complications of diabetes and can lead to ulcerations, amputations and even death. Based on these, the aim of this work was to develop an Intelligent System for Monitoring the Prevention of Diabetic Foot (SIM2PeD), allowing personalized care from each individual routine. The work consists of a platform integrated with a mobile device to capture individuals' data, entitled Mobile SIM2PeD, and a web device for monitoring the medical patient, titled Web SIM2PeD. Individuals receive alerts regarding care according to their location and activity directly from their smartphones. After capturing, the information is passed to the expert system (Intelligent module) that generates recommendations from the answers. The developed system presents a model of alerts as the best architecture, to the detriment of the pictogram model. The data captured show that slight displacements in frequency caused large variations of answers delivered to the application. The various experiments conducted made the system performed to be specified, and suitable for the remote monitoring of self-care activities in patients with diabetic foot.

Key words: Intelligent module, diabetes, application, diabetic foot.

INTRODUCTION

Diabetes (formerly known as diabetes mellitus) is a chronic and endocrine disease that causes high blood sugar level produced by retardation in, or deficiency of, glucose metabolism due to the lack or poor absorption of insulin, hormone produced by the pancreas, which has the function of breaking down glucose molecules and

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turning them into energy for cells (Andersen, 2012; Cubas et al., 2013).

Neuropathy and/or angiopathy (ischemia) are common complications associated with diabetes. These complications result in biomechanical changes of the lower limbs in diabetic patients. Changes in the patients' feet include loss of sensitivity, reduced strength, motor control change, reduced static joint amplitude of movement, limited mobility of joints, decreased fat pads and soft tissue thickening (Castro and Costa, 2013; Giacomozzi et al., 2005; Oliveira et al., 2014; Weiss and Coyne, 1997).

The lesions usually arise from trauma and often become complicated with gangrene and infection, caused by faults in the healing process which can result in amputation when an early and proper treatment is not applied (Formosa et al., 2013). When untreated, besides the possibility of deformation or amputation, the worst is that, a serious systemic infection can lead to death. At the same time, about 7 to 10% of diabetic patients will develop trophic lesions on their feet. Patients who develop a foot ulcer have a probability of up to 8% of suffering an amputation in the first year, and up to five years after amputation, 45 to 55% of these patients die (Dabiri et al., 2008; Giacomozzi et al., 2005). Diabetic foot is an ulceration, infection or destruction of the deep tissues and is associated with neuropathies. The foot is one of the first parts of the body to be affected by diabetes mellitus (Nunes et al., 2016; Cubas et al., 2013).

The formation of lesions on the diabetic foot in diabetic patients can be attributed to various socio-cultural practices, such as: walking barefoot, using inappropriate tools for diabetic foot care, inappropriate shoes and insufficient education and socioeconomic conditions. The main risk factors identified were: age, diagnosis time of DM, low schooling, overweight and obesity, inadequate diet, physical inactivity, poor metabolic control, lack of specific feet care and hypertension (Costa, 2013).

Literature review revealed several possible prophylaxis models to be adopted in injuries associated with the diabetic foot, which can prevent amputations and save resources (Andersen, 2012; Pedrosa et al., 2004). In addition, Damasceno and Galvão (2002) showed that up to 85% of amputations could be prevented with early discovery, appropriate clinical guidelines and rapid intervention in ulcers.

To help achieve this objective, a comprehensive understanding of all the risk factors that may contribute to the rate of ulceration and amputation is necessary. Assistive Technology (AT) sector contributes to improving the functional abilities of people affected by light or severe damage and thus provide a minimally dignified and autonomous life to the patient (Damasceno and Galvão, 2002). Several possible prophylaxis models could be adopted in injuries associated with the diabetic foot, which can prevent amputations.

Texier et al. (2013) also claims that a multidisciplinary management that focuses on education, regular checkups of the foot and biomechanical assessments along with other care, should be adopted. It should be noted that each individual is different and the peculiarities influence significantly, the quality of life of the person. In this way, the authors looked for works in literature related to the identification of the individual's behavior and how technologies may modify this behavior.

In addition to efforts to treat diabetic foot ulcers with the aid of *telecare* or *m-health* (Boell et al., 2014; Clemensen et al., 2005, 2008; Wrobel and Najafi, 2010), monitoring state of health of diabetic feet (Boell et al., 2014; Chammas et al., 2013; Mueller et al., 1989; Prompers et al., 2008; Wang et al., 2014) and education of health professionals on the problem (Snyder and Hanft, 2009), in accordance with the facts, represent other useful means to aid diabetic foot.

Larsen (2006) proposes a computational model based on trained ontologies that can shape the development of an automated software tool with the purpose of providing specific reminders of each patient, guidelines and action in preventing the development of diabetic foot in diabetic patients. The tool was intended for patients who would manage the disease and health professionals and can share knowledge more effectively. This study focuses on the development of the ontological tool.

Based on these assumptions, and to provide the patient a multidisciplinary tool that focuses on education, guiding regular checkups and primary care, the proposal presented in this article is to prevent diabetic foot problems in a population of patients.

For this purpose, the aim of this study is to present a Monitoring Intelligent System for the prevention of diabetic foot (SIM2PeD) which enables a personalized care with the diabetic foot for diabetic patients. The SIM2PeD seeks to raise the user awareness regarding diabetic foot care and supports, through an intelligent module, and medical decision making regarding the prevention of the appearance of ulcers. The mobile SIM2PeD (system mobile module) is also equipped with an intelligent system based on location and is prepared to receive alerts from another intelligent component that performs inferences in web SIM2PeD (system web module, use of health professionals).

MATERIALS AND METHODS

Treatment of diabetic patients requires a change in routine and lifestyle, making treatment adherence a challenge for professionals and health services (Mueller et al., 1989). Treatment adherence is much more than simply complying with health professional's determinations because, if understood this way, it is assumed that the patient does not have the awareness of the problem and is completely excluded from his health self-control.

Due to the importance of diabetic patients' foot care and the difficulty these patients face in carrying out this care, the need for a system that is based on daily routine is recommended and foot care of these patients and to monitor the realization or not of such care is primary. Care monitoring is necessary to assist and support

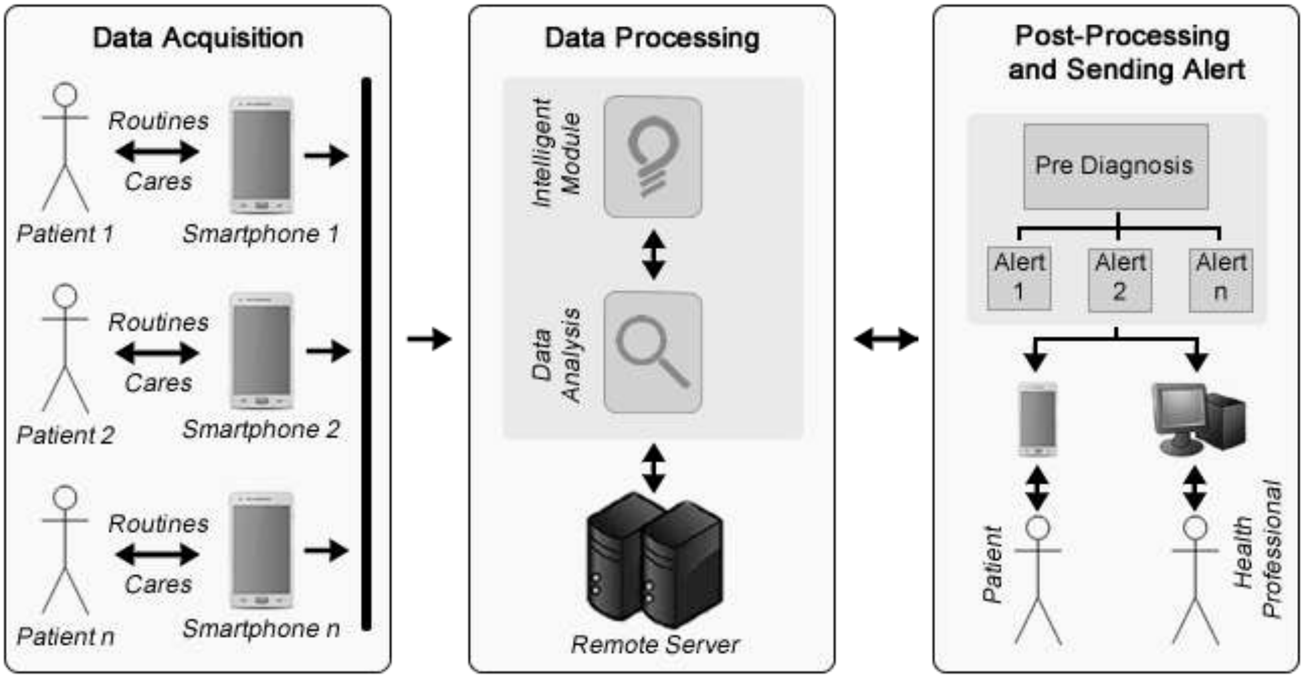

Figure 1. Overview of model of SIM2PeD with the system components.

medical decision in order to avoid complications in the lower limbs of these patients.

So, to recommend and accompany such care, the SIM2PeD (mobile and web) which is an autonomous system, adaptable to the user's routine was developed. This system aims to guide diabetic patients or caregivers based on reminders on foot care, exploring an educational approach aiming at the change of habit through the following features: feedback from user responses to feet care; remote monitoring of tips viewing; and foot care that you will be suggested to incorporate a statistical analysis on the patient's interest with their feet health. However, it should be noted that the process of self-care is very subjective because it depends on the intention and personal interest of the subject (Damasceno and Galvão, 2002). And it is in this direction that the authors intend to work with Light Assistive Technology with the goal of modifying the behavior of the subject in relation to the diabetic foot self-care.

System overview

SIM2PeD is an educational system of habit change for foot care in diabetic patients. To ensure the architectural requirements, the system consists of two main components: the mobile SIM2PeD and the web SIM2PeD. Thus, Figure 1 presents an overview of the proposed system that send data stored in mobile SIM2PeD via an internet connection to the web, to be processed, recognized and correlate patterns of patient's responses for the caregiver team through the web SIM2PeD.

The flowchart represents the main stages in the process of data acquisition and information availability to the medical staff and patients.

For the purposes of this system, the following requirements inherent in architecture were defined (Figure 2). The alerts process on foot care and therefore data acquisition process of the responses on the implementation of these cares must follow health professional temporal rules, which we call user's routines.

Data acquisition

After setting mobile SIM2PeD and web SIM2PeD, data was acquired regarding answers and the user answered YES or NO to that care realization.

The proposed system will show a screen with tips about the diabetic foot care, in which the subject must select YES if he followed the tip or NO if he did no (Figure 3). With the answers obtained, the system will generate suggestions based on the patient routine and will show them as in Figure 3b.

Data processing

After the answers are submitted by the mobile SIM2PeD, the intelligent module is able to find patterns in statistical data from users' responses and alert professionals and diabetic users about feet health. In this environment, the professional accompanies the performance of the care realized by the diabetic user through graphs that show the number of cares that should be carried out, the number of cares conducted by the individual and the percentage among them. The environment illustrated in Figure 4 presents the graph for the last 30 days of the application use. The graphs (Figure 5) can display the periods of the last 30 days, last 7 days and the complete history of the diabetic user.

The environment of the web SIM2PeD has also another intelligent component which was implemented based on a Rule-based Expert System, a computational system that use rules to provide diagnoses or recommendations in order to decide a course of action in a particular situation or to solve a specific problem. This component aims to correlate usage statistics based on the last report and the diabetic user's history, generate alerts with levels that draws attention to care and submit to the mobile SIM2PeD. The usage summary report and suggest the intelligent web SIM2PeD component.

In mobile SIM2PeD, intelligence is accomplished through

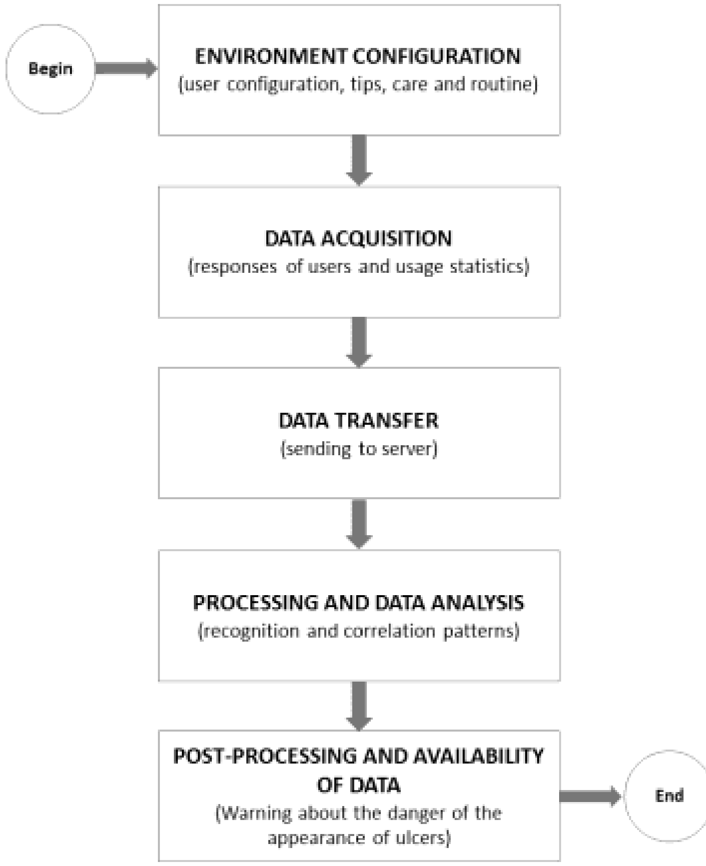

Figure 2. Flowchart of system activities implementation.

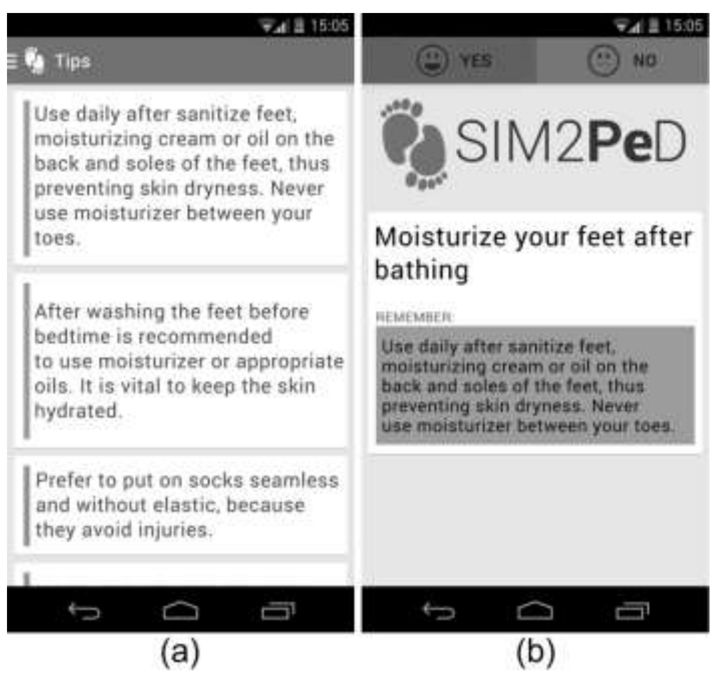

Figure 3. Screens captured from the system developed. (a) The screen of foot care tips; (b) the screen of suggestion of care based on patient's routine.

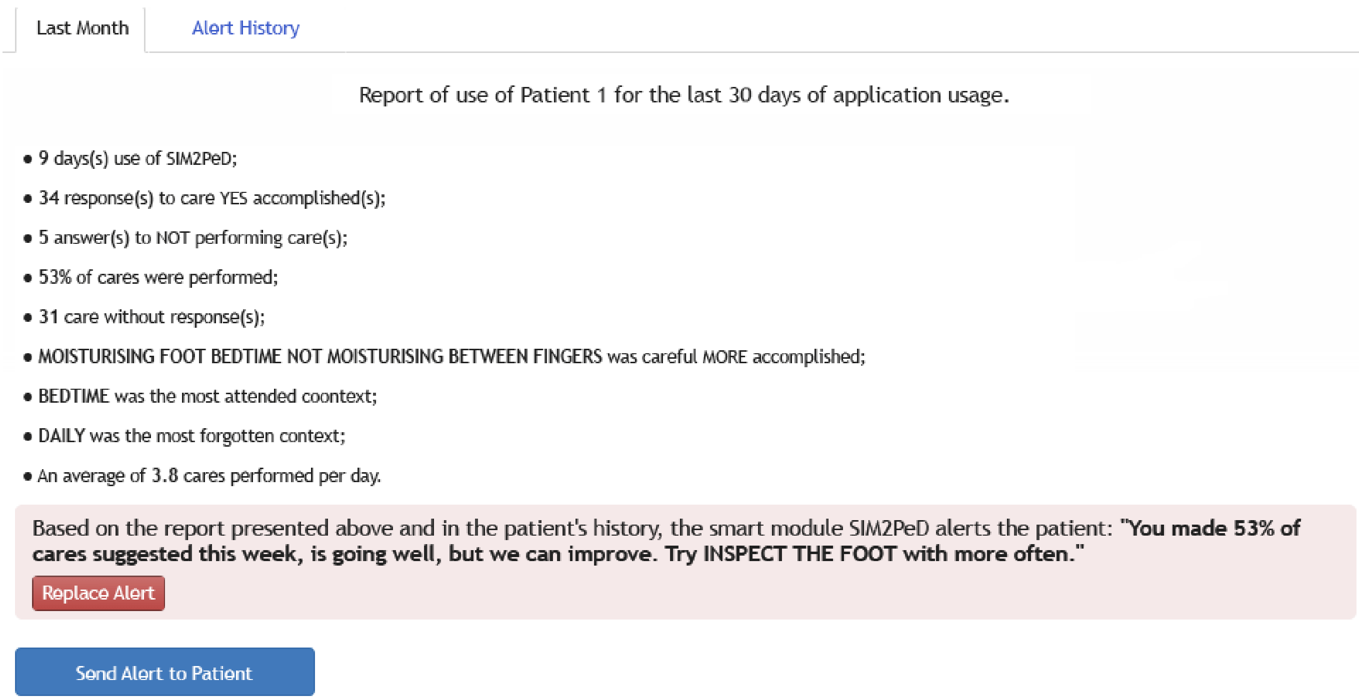

Figure 4. SIM2PeD application usage summary report by a diabetic user within the last 30 days and suggestion of alert generated by the SIM2PeD intelligent module.

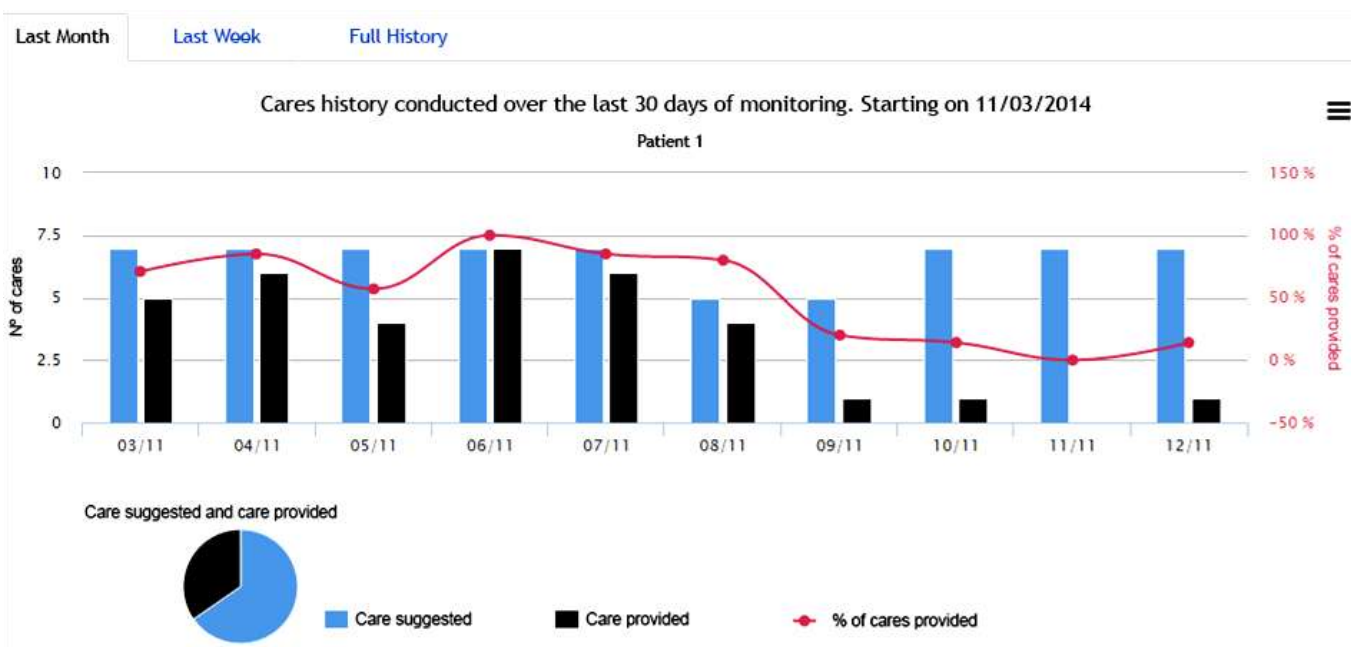

Figure 5. SIM2PeD application usage graphic report by a diabetic user. The number of care to be realized, the number of care performed and their percentages.

classification of the diabetic user environments (home, work and leisure) and from this classification, care is given according to the location of that user.

Experimental part

This experiment was approval by the Research Ethics Committee of

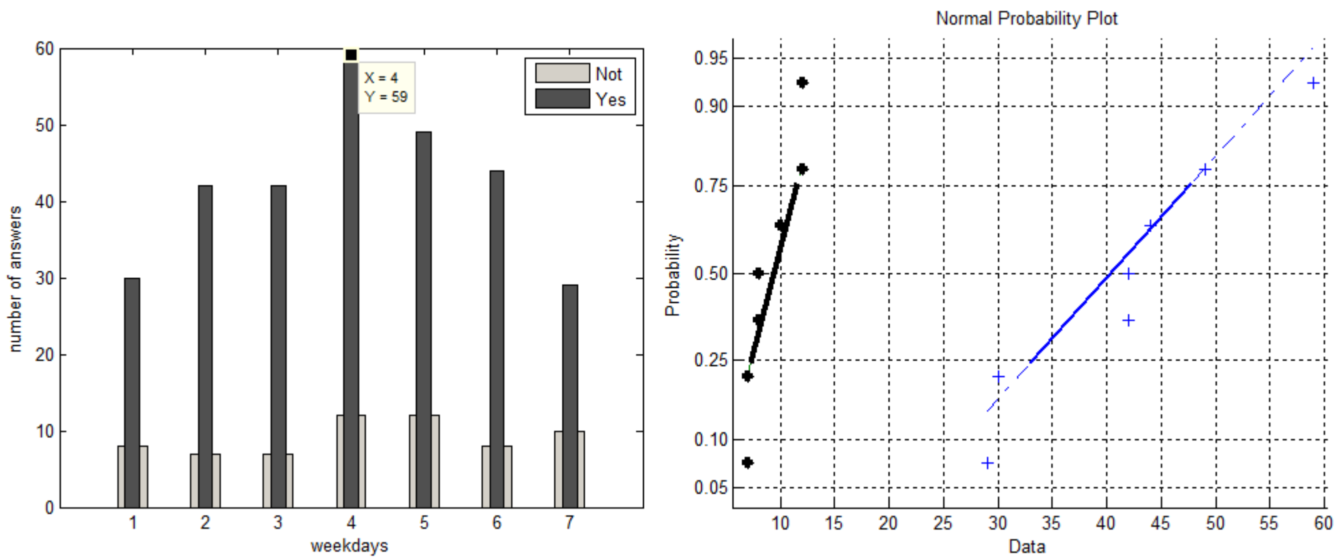

Figure 6. Graphs showing the correlation of positive responses (yes) and negative responses (no) to the days of the week - being 1 (Sunday) and 7 (Saturday).

the University of Estado do Rio Grande do Norte under opinion number 761.229. Data were obtained from experiments performed with two groups of subjects. The first group was composed of 1 male (40 years old) and 2 female (45 and 60 years old) diabetic subjects that have diabetes diagnostic time quite heterogeneous. The male was diagnosed with type II diabetes a log time ago. The women were diagnosed with type I diabetes 3 and 20 years ago, respectively. Individuals of this group do not have neuropathies, it is worth mentioning that the history of neuropathies in these individuals was not taken into consideration.

The second group was composed by individuals who do not have been diagnosis diabetes. This group was formed by 11 male and 5 female students, health professionals, physiotherapists, masters of Health Technology Program and professors. Individuals have varying ages with an average of 25 years.

The test with both groups was conducted over a period of two weeks, one with each group. All tests were carried out at the University of Brasilia (UnB), Brasilia, Brazil on November 2015.
The 14 patients had a previous training on how to use the system by means of recorded videos. Then, the possibility to use the system quickly and easily was presented to diabetic users, especially due to the objectivity of the application options. In every interface, the layout of the application was developed for a quick and easy interaction, containing large buttons and with contrasting colors.

Data analysis

Development of the investigation process focused on providing answers to the main hypothesis of this study, by means of the Ansari-Bradley test: can technology promote education through reminders, change the habit of the subjects with respect to the feet care and therefore reduce the number of occurrences of diabetic foot?

RESULTS AND DISCUSSION

Care alerts were based, as stated earlier, on contexts or situations based on the diabetic user's weekly routine. The necessary settings for the user's weekly routine were made by health professionals based on a conversation related to the activities performed by each patient. On the basis of the care routines, sequentially notifications are presented on the main screen of the user's smartphone. This strategy provided a customized system for each user thus avoiding a generic system that can cause the user's disinterest in the application.

The experiment in a real environment, presented favorable points to the system as regards its operation. Also, the tests revealed that the diabetic patients with more advanced ages (45 and 60 years old) had difficulty in remaining vigilant to care suggested by the application.

Similarly, the volunteers at the beginning of the process had a number of negative responses ("NO") far lesser than the care suggestions that appear in greater number at the beginning of the device use. Figure 6 shows the normal distribution for the behavior of the positive and negative response and the natural difficulty of care which is beyond the graph generated.

It is observed that the normal function does not match the theoretical normal distribution which shows the actual distribution of the variables "YES" and "NO" and are these also different from normal. This behavior contradicts the option of this study that people need the actions derived from health or health care, when they meet the requirements of emerging self-care.

During the experiment, care suggested a direct correlation with the routine and voluntary environment. The difficulty in getting this interaction system and with the daily routine is perceived though the analyses of NO that a specific care received. So, getting the best strategies to achieve without too much difficulty, this correlation is another important step of this study.

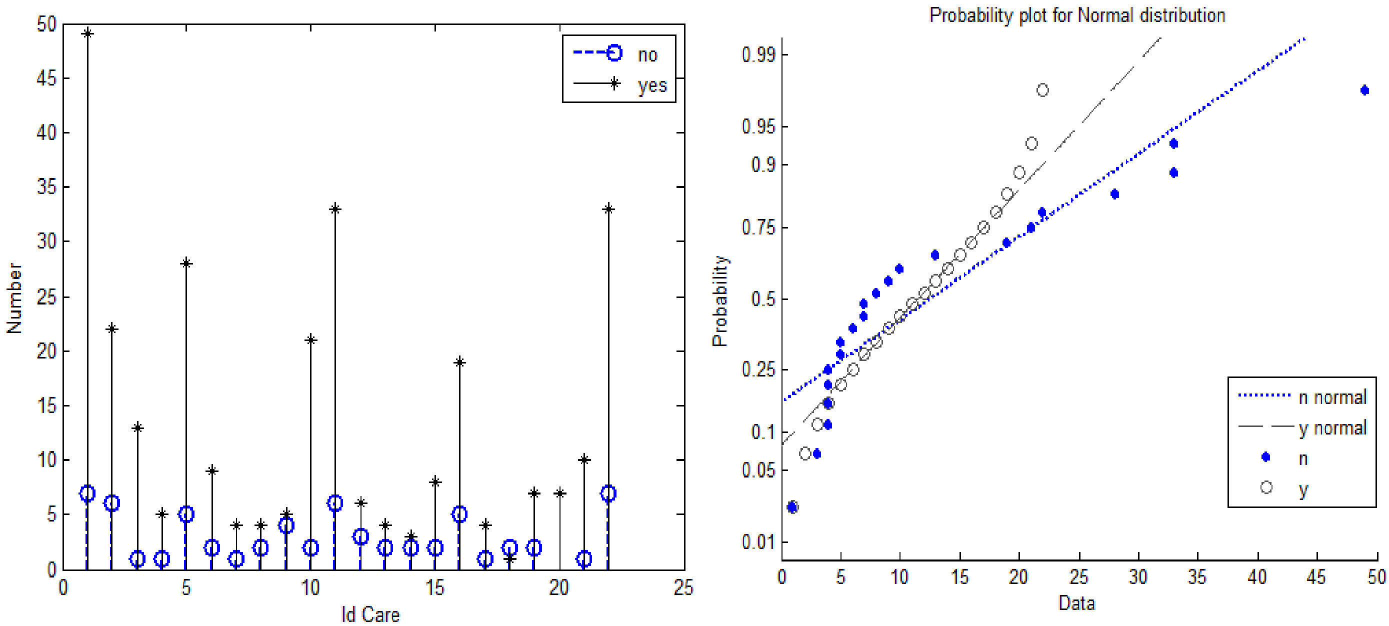

Figure 7. Chart showing the positive and negative responses, which directs perception of the user's self-care. The development of the self-care individual is feasible, fact suggested by the normal curve of positive conditions ("YES").

In Figure 7, it is observed that the group that participates in the DD has the ability of self-care, that is, the individual can satisfy their own needs through ongoing regulatory care, identify, define and implementing the activities deemed necessary.

Tests running are a fundamental procedure that should be performed continuously throughout the development process of any product of engineering applied to medicine. The more critical the system, greater efforts should be devoted to their achievement. The basic requirements for developing test program are the needs or system requirements, as well as all specifications in terms of basic functionality, working and operation conditions, safety and reliability. Testing means to subject the system to situations that show its weaknesses, its answers features and fault conditions, is to verify that the system meets all its specifications and requirements and is also a mechanism for detecting errors and deviations from a given expected behavior. These validation tests and verification have fundamentally distinct purposes, as observed in the previous analyses, the user's relation with the answers "YES" and "NO". Through verification, it is determined whether the product meets design specifications. In contrast, validation consists of determining whether such specifications meet diabetic user's needs. It is observed in Figure 8 that the user implemented the care routines what does not correlate with the change of behavior expected by the authors. However, it should be noted that the concepts of testing, verification and validation are subject to the development methodology used, and the definitions given here are those relevant to the proposal, which does not refute the hypothesis discussed.

Figure 9 presents the analysis of the data obtained from users to care "YES" or "NO" by means of an Xbar graph of matrix A measurements which are the numbers of answers. Each column of A is considered a subset of measurements (number of answers) to the same over time. The graph represents the average of the subgroups in order of time, a central line (CL) with the average of the means, and the upper and lower control limits (UCL and LCL) in three standard deviations from the centerline. The standard error is the estimated standard deviation of the process divided by the square root of the subgroup size. Out of control measures are marked as violations and taken with a red circle.

Through the variability of the process of saying "YES", it is possible to identify unusual changes in strategic points on the use of the device at that time. This chart also shows changes in decrease in the average of "YES". This system also indicates evidence of a change in the average of "YES". In this way, it is necessary to carry out a more comprehensive analysis with the user through the process, in order to identify possible factors that caused this change. The possible causes identified for this variation were as follows: i) actions taken from the suggested tips which reduced variability process and ii) spatial dispersion-(person out of routine).

The decision to test the null hypothesis– the patient changed behavior was applied on the answers "YES" and "NO". The result is 0 h, if the test rejects the null hypothesis on the basis of a 1% significance level. It

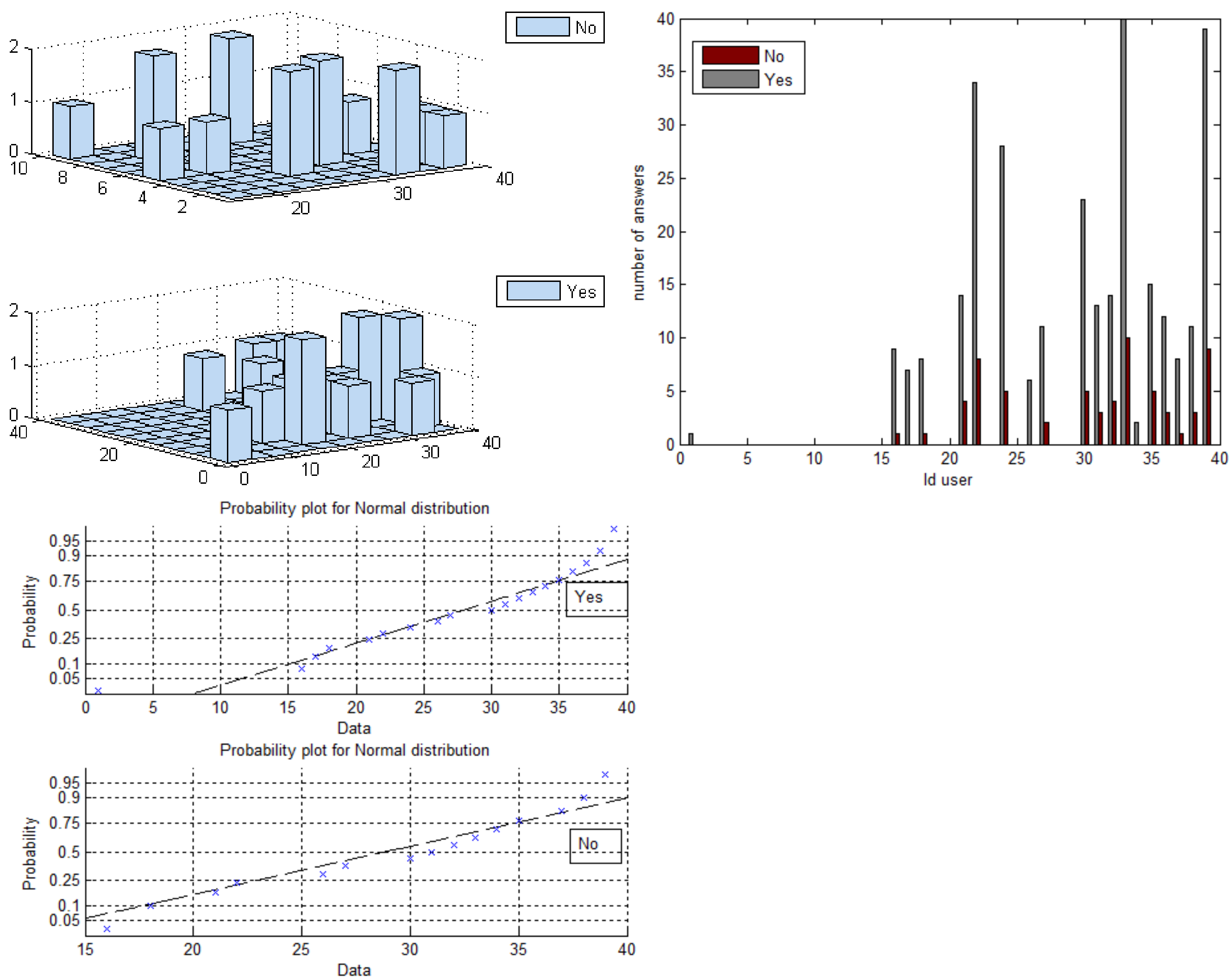

Figure 8. Bi variant distribution of data via histogram with matrix elements to a grid of 10 for 10 equally spaced data. Each column of data (1 and 2) corresponds to a dimension and distribution of data obtained, which shows concentration of Yes responses.

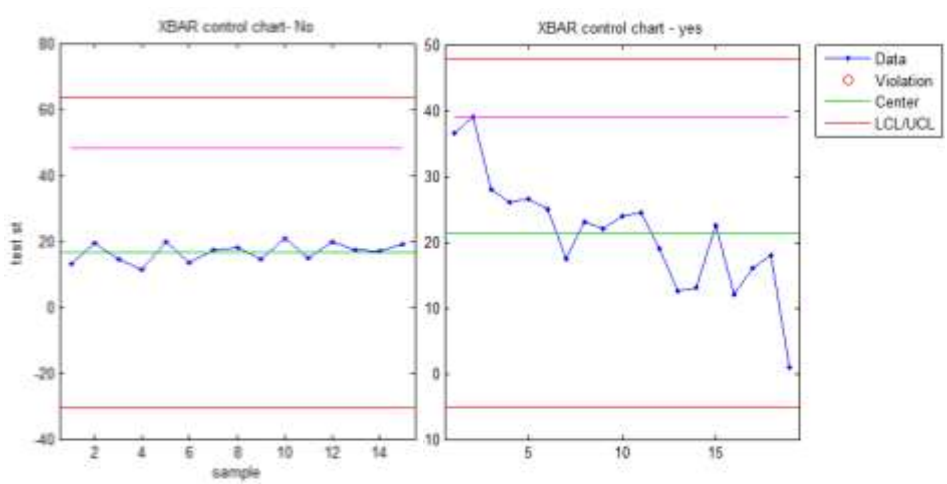

Figure 9. Diagnostic and monitoring phase of the Shewhart control chart for the behavior of users' responses.

should be noted that not rejecting the null hypothesis means that it has was not possible, through the data available, to demonstrate it is false.

Conclusion

The main objective of this study was to map the contribution a Light Assistive Technology System could provide to meet the demands of a patient with diabetes, identify key correlated metrics and propose specifications that fulfill these demands. In essence, the goal was to provide a methodology for the selection of a routine based on the requirements of specialists in the area, and only then, in the light of this choice, take conscious decisions to guide the patient. The proposed method identified the alerts model as the best architecture in detriment to the pictogram model that is widely used in portable devices that make use of Light AT. However, several comparative experimental studies such as the one directed by Texier et al. (2013), strengthen the results obtained here, showing that the alerts model has better performance than the pictogram in DM patients.

The method was also able to identify the metrics that influence Light TA system performance more. The results of the optimization experiments confirm that the efficiency is more sensitive to variations in the alerts frequency and the tips operation. The results of the captures show that small displacements in frequency cause large variations in the variability of response delivered to the application. The same effect is observed in the responses of the most commonly used ID scenarios and a higher number of YES responses where the difference in efficiency between the responses used have a difference in answers "YES" and "NO", led to a fall in performance and greater variability.

The tests conducted led to the conclusion that the system performed as specified and is suitable for the remote monitoring of self-care activities in patients with diabetes. It also has great potential for application in various treatments. In general, the major elements observed in SIM2PeD and that distinguishes from the others found on the market and in the literature are: i) the extreme ease of operation, without the intense and common use of menus and submenus to the realization of the ultimate goal of the application; ii) a system fully adaptable to the user's routine; iii) remote monitoring of care carried out with users; iv) remote monitoring of the user’s interest on the tips presented and; v) an application setting suitable for the page layout, to facilitate the use by patients with some types of visual impairment.

The mobile SIM2PeD was developed for smartphones with Android operating system with a version higher than the 2.3.3. Based on this premise, a limitation to the use of the mobile SIM2PeD is the possibility to install it only in Android devices, thus excluding, devices with operating systems that do not work based on this system. The web SIM2PeD, for use by health professionals, was developed based on web platforms and works in any browser of any device with internet access, excluding therefore other limitations.

One of the difficulties in the development of the study was to find users to test the technology. Some could not do it due incompatibility of the mobile device, while others declined the opportunity. Another difficulty was observed in older people. Individuals in this age group tend not to use the device as expected and revoke some questions about care. As noted by the authors, this phenomenon is due to the fact that these users do not have the smartphone as a personal item or forget about it several hours during the day.

It should be noted that all the analyses and conclusions provided in this study are entirely based on responses of two groups of diabetics and non-diabetics individuals that simulated the behavior, since the results were not validated in diabetics only. It should also be noted that, despite the proposed model incorporating the primary needs raised by specialists, it does not take into account the loss of responses by superposition of alerts and by spatial dispersion-(person out the routine), nor the effects of the tips between the alerts, which can result in efficiency falls.

In this way, the approach of this work has undergone some changes over the course of its development. Primarily, the idea was to use SIM2PeD to avoid probable ulcerations; however, proposed specifications had to be validated to confirm whether they met the needs of the system, not requiring a comprehensive modeling of the mechanisms of loss, dispersion and tips together with the participants involved. But the range of possibilities for the control factors and the extent of its levels, made the specification process hard and efficient. The Light TA is a relatively new area and features numerous exploitable aspects. Following the line of this work, future efforts in the development of computational models that encompass space dispersion losses and changes in behavior would improve considerably the robustness of specifications raised through optimization experiments.

As future work, it is expected that the SIM2PeD is added to a system that monitors not only the feet health of the diabetic users but the entire health of the individual. Other intelligent techniques and data correlations are also suggested as experiments for future works. To improve the SIM2PeD mobile and interaction with its users is suggested to integrate the application platforms of multimedia materials to enable a more appropriate statement of foot care realization, as well as the possibility of free text in which the diabetic user can insert points that are considered important at that moment. The implementation of a conversation channel between the diabetic user and the healthcare professional directly on the platform is also suggested with the aim of enhancing the user’s experience. Further studies are recommended to test the effectiveness on the diabetic foot. Finally, the system presented should be applied in other real-world scenarios (different diseases) in order to analyze and compare the behavior of individuals related to the use of the presented system.

Conflict of interests

The authors have not declared any conflict of interests.

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