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Definition and development of a digital system for the empowerment and activation of type 1 diabetic patient

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***Abstract*— Health education is essential for type 1 diabetic patients to actively participate in the decision-making process about their disease. Under the framework of the INCAP project, a mobile application has been designed and developed with an easy-to-use interface for type 1 diabetic patients to improve their empowerment, activation and thus their self-control and improvement of their treatment adherence.**

***Clinical Relevance*— This research supports type 1 diabetic patients in improving their adherence to treatment, self-management, and promoting their empowerment and activation thanks to the development of an innovative educational mobile application that increases the motivation of the patient and, therefore, provides better clinical outcomes.**

I. INTRODUCTION

Chronic diseases cause 41 million deaths each year, which is equivalent to 71% of the deaths that occur in the world. Cardiovascular disease accounts for most deaths from chronic diseases (17.9 million each year), followed by cancer (9.0 million), respiratory diseases (3.9 million), and diabetes (1.6 million) [1]. According to the World Health Organization, their prevalence is expected to rise by 57% in the coming years. Among these diseases, diabetes has experienced significant growth during the last decades. [2]

Diabetes is one of the chronic diseases that cause more deaths per year in the world. The reasons are mainly complications derived from the disease, many times due to the patients' lack of adherence to the treatment or lack of information. Recent studies have pointed out that proper blood glucose monitoring and adherence to daily treatment have an impact on clinical outcomes, particularly in Type 1 Diabetes (T1D) [3]. To contribute to this, education has been identified as essential for the empowerment and activation of this type of patient, to improve their self-control, self-efficacy and to achieve the objectives of the treatment improving health outcomes [4]. According to Wu et al. [5], it has been spotted that there is evidence of benefits of mHealth (mobile health) in the management of T1D since they are very useful for education and motivation and has a positive impact on clinical results, compliance with treatment, changes in the behavior of patients, the management of the disease and on increasing treatment adherence [6]. However, recent studies and market analysis have reported that education is included as a feature in only a few diabetes-related mobile applications [7].

In this paper, we present the design and development of a mobile application implementing an educational intervention module for the empowerment and activation of type 1 diabetic patients supporting them in their daily self-control to avoid and delay long-term complications.

II. MATERIALS AND METHODS

The study has been carried out in the framework of the INCAP project [8] funded by EIT (European Institute of Innovation & Technology) Health. INCAP provided an integrated care program for people who have type I diabetes and use an insulin pump. The solution was built on three pillars: a remote monitoring support centre, to optimize control of the disease for each patient; an educational program to empower patients; a communication channel connecting the hospital to primary carers.

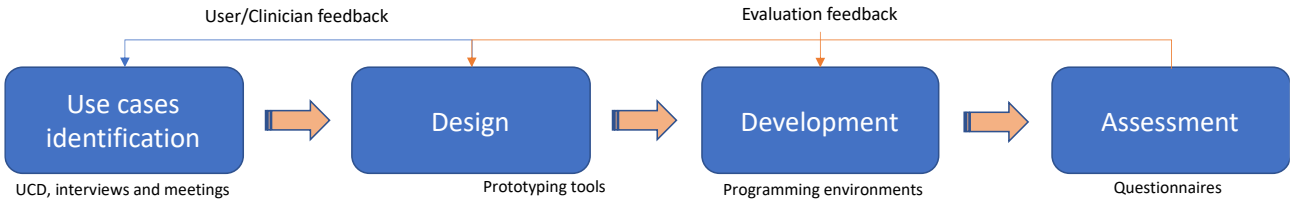

Figure 1. Methodology overview.

The following section described the methodology implemented to define and develop the digital solution proposed (Fig 1.).

A. USE CASES IDENTIFICATION

The method followed for the identification of the use cases consisted of continuous and repeated meetings and interviews with the health professionals of the Puerta de Hierro Hospital, located in the Madrid region, Spain, as they were partners in the INCAP project. Specifically, five

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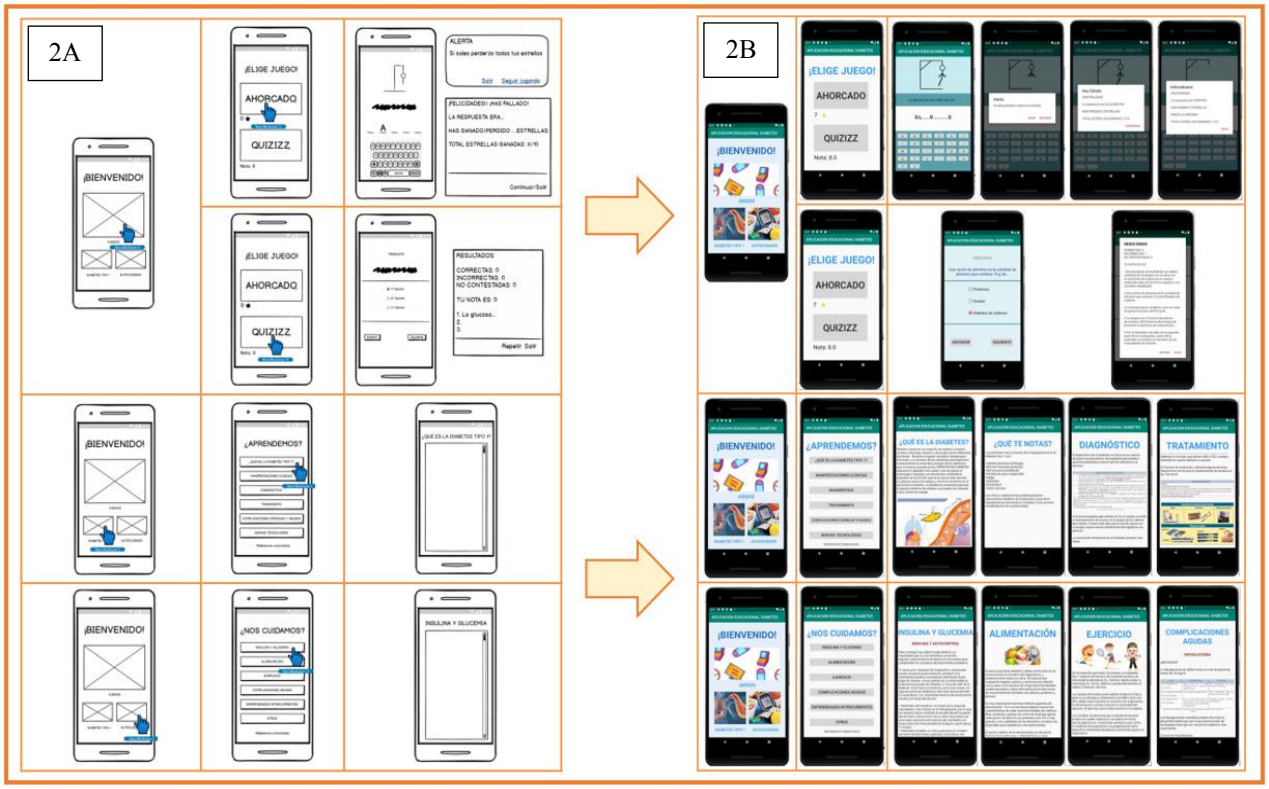

Figure 2. Flow diagram of the application screens with the low fidelity prototype made with Balsamiq (A) and once implemented and developed with Android Studio (B).

interviews were conducted with three endocrinologists and two nurses. The objective of holding periodic meetings was to agree on the purpose of the mobile application, identify the actors involved and establish the patient inclusion strategy. For this, the User-Centred Design methodology [9] was used, and it was also conducted through more online interviews with 15 end users where the requirements were collected, analyzed and used to design the final software solution.

B. DIGITAL MARKET ANALYSIS

A market study was conducted to understand the strengths and the shortcomings of the applications available for diabetic patients through the Play Store and AppStore, including diabetes and self-management as key words for the searching.

C. DESIGN AND DEVELOPMENT TOOLS

The different use cases were modelled using UML (Unified Modeling Language) [10], to visualize, specify and document each of the application requirements and to describe the different behaviors of the system.

Then, a low fidelity rapid prototyping, built in a short time and without using many resources, was done with the support of the Balsamiq wireframes program [11]. This allowed us to organize and design a model of the different screens that the application was intended to have. The rapid design was focused on the representation of the interfaces.

Finally, Java language and Android Studio [12] were used for software development and final implementation of the solution.

D. USABILITY MEASUREMENT TOOLS

For the evaluation of the solution, two different questionnaires were distributed. The acceptability was measured using a questionnaire consisting of 8 Likert items. These were scored from +2 to -2, except for items 3,6 and 8 which were inverted and scored from -2 to +2. In addition, the SUS (System Usability Scale) [13] usability questionnaire was used for the usability evaluation. The SUS scale is a Likert-style scale with 10 questions that can be scored from 1 to 5, where 1 means “total disagreement” and 5 means “total agreement”.

Finally, spider web graphs were produced for better visualization of the results obtained in the utilized questionnaires.

III. RESULTS

The previous methodology resulted in being able to determine the fundamental requirements to design the application flow to be able to carry out both the prototype of the application and the final development as well as carry out a preliminary evaluation of its usability and acceptability. The results are presented in the following subsections.

A. NEEDS IDENTIFICATION

Thanks to the different online interviews with professionals and patients, we understood that the digital system should be intended for all type 1 diabetic patients, adults, adolescents, and children, as well as all their family members, educators or people around them. The application must educate patients so that they acquire knowledge about

their chronic disease and sufficient skill to be able to make the multiple decisions necessary daily to favor their empowerment and activation to improve their adherence to treatment. In addition, the application should have a gamification module taking children into account, consist of a simple interface and use a close language to favor understanding and learning of all users, also the youngest.

B. DIGITAL MARKET RESULTS

The 16 background applications analyzed cover, some of the components to consider in the life of a diabetic patient (blood glucose, diet, and exercise). To a greater or lesser extent, they favor patient self-care and some of them also provide professional and social support remotely. However, it is striking the lack of an educational module to increase the motivation and safety of patients by providing them clinical information in an active way. None of the applications studied has a description of basic concepts that the patient should know with complete accuracy and only two have gamification to make using the app a more entertaining process which is necessary to increase user engagement and encourage the use of the application. Therefore, an unmet need to develop an educational application that complements all of these gaps has been identified with the aim of promoting patient empowerment, supporting his self-management and adherence to treatment.

C. FROM PROTOTYPING TO DEVELOPMENT

The low fidelity rapid prototyping is shown in Fig. 2A, and the final development of the application is shown in Fig. 2B. The interface has been designed to be intuitive and easy to use, but at the same time powerful and modular to meet all the functional requirements according to results from the meetings with the clinical professionals and users. The flow, modules and functionalities of the application are explained below:

A start screen is proposed, in which the user can choose between playing (gamification module) or acquiring information (information module), by clicking on different images.

GAMIFICATION MODULE:

- HANGMAN'S GAME. The user sees the classic game doll and a question with its corresponding hidden answer, but with lines that indicate the number of letters in the word answer and a keyboard with all the letters of the alphabet to "say" letter. The letters are no longer hidden as the user guesses them. As the user is playing and going to other questions, he is gaining or losing stars. If the person guesses the word directly, that is, by guessing all the letters the first time and without fail, 2 stars are earned. If the word is guessed, but having failed and, therefore, having some part of the doll's body, a star is earned. In case of losing and not being able to guess the answer, 2 stars are lost.
- QUIZ SCREEN. The user is asked a series of questions with three possible answers each. At the end of the game, the user acquires a grade that can be improved by taking another quiz. Each correct answer adds a point, unanswered answers neither rise nor fall, and incorrect answers subtract one point.

In this way, achieving user engagement is intended to promote patient learning through repetition. This gamification module is especially interesting in the case of paediatric patients, who are easier to get more involved in learning about their disease through a fun and interactive process.

INFORMATION MODULE:

- TYPE 1 DIABETES: the user can obtain information through different sub-modules.
  - What is diabetes?: general definition of type 1 diabetes.
  - Clinical manifestations: an overview of clinical symptoms and manifestations that can happen.
  - Diagnosis: possible diagnostic scenarios for complications based on blood glucose levels.
  - Treatment: basic information about insulin therapy, blood glucose monitoring and the importance of self-control, exercise, diet, nutrients and other treatments.
  - Chronic and Acute Complications: basic information on chronic and acute complications (hypoglycemia and hyperglycemia) that can develop as a consequence of type 1 diabetes.
  - New Technologies: general overview on new devices and trends towards improving diabetes management.
- SELF-CARE: the user can obtain information through different sub-modules:
  - Insulin and blood glucose: general information

Figure 3. Spider diagram of the global acceptability (A) and the total usability of the system (B).

about devices used, insulin administration techniques and areas, pen preparation techniques, insulin storage (also when travelling), methods for calculating the insulin ratio, the insulin sensitivity factor and the total insulin dose needed, information on how to self-monitor blood glucose during the day and how to use a glucometer.

- Food: information on how to calculate the number of carbohydrate servings needed daily and helps to schedule meals thanks to food tables.
- Exercise: information on the exercises to be performed and strategies to prevent hypoglycaemia during and after exercise. In addition, attitudes to be taken based on blood glucose, intensity and duration are detailed.
- Acute complications: information on how to act in case of hypoglycaemic symptoms depending on the level of consciousness and once the glycemia has been normalized.
- Intercurrent illnesses: information on how to act against intercurrent illnesses, mainly those that cause a decrease in blood glucose levels.
- Others: tips on self-identification, foot care, personal hygiene, and ophthalmologist visits. In addition, it is advised on the diabetic child at school.

With all this, the application itself is obtained, with multiple screens and different interfaces for the user: an informative and interactive process (thanks to gamification) supports the empowerment and activation of the patient to support their self-control and improve treatment adherence.

D. ASSESSMENT

The evaluation of the developed application was performed with 3 diabetic patients and 3 endocrinologists. After completing questionnaires with 3 users and 2 health professionals, using the acceptability questionnaire (Figure 3A), Utility of 1.95 points and Satisfaction of 1.6 points were obtained. These values are very close to 2, the highest value with which it could be evaluated, and therefore it can be said that the application has a very high utility, and its use produces great satisfaction for users and professionals.

Finally, considering SUS questionnaire for usability testing, 91 points out of 100 (Figure 3B) has been obtained. Observing the result, it is concluded that according to the Net Promoter Score (NPS) users would be promoters, that is, they would have great loyalty to the application. On top of that, it has been obtained a high and positive degree of acceptability.

As a result, the application could be considered acceptable for its main objective, the knowledge of the chronic disease to improve the empowerment and activation of type 1 diabetic patient, improving adherence to treatment and self-control.

IV. CONCLUSIONS

Mobile technology could be a useful instrument for health education in diabetes, contributing to improving this disease management and the metabolic control of the patients. The main objective of our work was to develop a mobile application that would support type 1 diabetic patients in the self-control of their disease, their empowerment, and improvement of their treatment adherence.

The need for such an application was evident from the market analysis, as the existing ones lack educational modules and gamification for the empowerment and activation of the patients.

Therefore, a functional application has been developed for type 1 diabetic patients for their empowerment and activation in making decisions related to their health, favoring self-control of the disease and improving treatment adherence. In this way, the quality of life of these patients may improve, avoiding unnecessary suffering and reducing the number of deaths due to complications derived from it due to poor performance in the face of the disease. In addition, being an educational application for type 1 diabetes, equipped with a gamification module, it is an innovative tool since, according to the gaps identified during the market analysis, the vast majority of the applications focus on monitoring the disease and not so much in patient education. Although the application developed was evaluated with a small group of end-users and professionals, the results obtained suggest good acceptability for this type of digital solutions for type 1 diabetic patients.

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