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PATIENT FACING SYSTEMS

User Centered Design to Improve Information Exchange in Diabetes Care Through eHealth

Results from a Small Scale Exploratory Study

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Abstract

Heterogeneity of people with diabetes makes maintaining blood glucose control and achieving therapy adherence a challenge. It is fundamental that patients get actively involved in the management of the disease in their living environments. The objective of this paper is to evaluate the use and acceptance of a self-management system for diabetes developed with User Centered Design Principles in community settings. Persons with diabetes and health professionals were involved the design, development and evaluation of the self-management system; which comprised three iterative cycles: scenario definition, user archetype definition and system development. A comprehensive system was developed integrating modules for the management of blood glucose levels, medication, food intake habits, physical activity, diabetes education and messaging. The system was adapted for two types of principal users (personas): Type 1 Diabetes user and Type 2 Diabetes user. The system was evaluated by assessing the use, the compliance, the attractiveness and perceived usefulness in a multicenter randomized pilot study involving 20 patients and 24 treating professionals for a period of four weeks. Usage and compliance of the co-designed system was compared during the first and the last two weeks of the study, showing a significantly improved behaviour of patients towards the system for each of the modules. This resulted in a successful adoption by both type of personas. Only the medication module showed a significantly different use and compliance (p=0.01) which can be explained by the different therapeutic course of the two types of diabetes. The involvement of patients to make their own decisions and choices form design stages was key for the adoption of a self-management system for diabetes.

Keywords Personal health records · User centered design · Diabetes management · mHealth · Co-design

Introduction

Modern health care systems are designed to treat acute diseases rather than managing chronic conditions [1]. Chronic diseases would require long-term care management programs to first stabilize patient's and then prevent or delay complications [2]. Diabetes Mellitus is a paradigmatic case of long-term care, being one of the most prevalent diseases worldwide, with more than 380 million patients with no cure [3].

The most common forms of diabetes are Type 1 Diabetes Mellitus (T1DM) and Type 2 Diabetes Mellitus (T2DM). An impaired insulin secretion causes T1DM, which leads to chronic hyperglycemia and accounts for 10% of all diabetes cases. T2DM is caused by an inadequate insulin secretion and an impaired insulin action, and accounts for almost 90% of all diabetes cases. Generally, T1DM is caused by

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an autoimmune reaction in individuals under 20 years of age, while T2DM is associated with aging, lifestyle and genetic predisposition among individuals over the age of 50. The clinical heterogeneity of these patients challenges the process of care, which is focused on maintaining blood glucose control [4]. It is paramount to involve both types of patients in the management of the disease inside their living environments.This requires taking medicines, following a proper diet, doing physical exercise and being informed and trained about self-management and decision making. Moreover, patients should be supported and followed-up by practice teams who check adherence to care plans, perform therapy readjustment and mitigate the risk of complications [4].

In this context, the Information Technology (IT) applications have contributed to perform an efficient and personalized follow-up of the disease [5]. These systems allow monitoring multi-parametric data and performing analysis of relevant parameters such as physiological measurements, laboratory examinations, and lifestyle data, thus enabling more precise follow-up of patients through better quality and more comprehensive interpretation of data and delivery of alerts, warnings, and support to decision making [5]. In order to achieve this, the main challenge is to understand how to manage data from different sources (food, insulin, blood glucose) and train patients to successfully use such technology.

State of the art systems include new ways to register daily-based events such as the quantification of the ingested meal contents in carbohydrates, proteins and fats, based on a picture of the meal to decompose the nutritional value and calculate the insulin dose [6, 7]. Other types of systems try to integrate real-time continuous glucose sensors, insulin pumps and a mobile-based tele-medicine system to create a closed-loop of communications with the doctor [8, 9].

Electronic Health Records (EHR) [10, 11], Personal Health Records (PHR) [12], mHealth [13] and eHealth [14] shall improve the prevention and treatment at the point of care through remote therapeutic decision-making and follow-up relying on adherence to care plan and towards data insertion through apps and sensors. These types of technologies have been assessed in several studies, focused on defining strategies to collect Observations on Daily Living (ODL) to support behavioural monitoring [15], exploring how ODL can be displayed to users in a meaningful manner [16, 17].

As regards platforms for the self-management of diabetes, one of the most used systems is "Bluestar" by WellDoc [18], which allows patients to track and record blood sugar levels offering a real-time response and clinical basis. In 2011, the Salzburg statement confirmed the potential of Decision Support Systems (DSS) in the shared decision-making and self-management of diseases [19, 20]. But, how patients and health professionals can use these technologies in the long term remains an unanswered question [21]. Patients need to be educated about the role they play in the process of care, the information they need to manage, and the criteria for selecting tools that would help them understanding the consequences of their decisions [22].

The work reported in this paper describes the design and implementation of an application system for diabetes management integrating User Centred Design (UCD) principles into the development cycle. Our hypothesis is that UCD techniques allow identifying the most important elements for self-monitoring of the diabetes disease and, in turn, creating solutions that can support effective, sustainable and useful adoption of PHRs in diabetes management. The system was tested in a small-scale pilot including 20 T1DM and T2DM patients for a period of four weeks. The study endpoints were the usage, the compliance, the attractiveness and the perceived usefulness of the co-designed system. The paper is structured as follows: Section "Methods" describes the implementation of UCD methodolgy, descriptive statistics of the pilot study sample and the definition of the metrics assessed in the pilot. Section "Results" describes the personas, the characteristics of the system and the results of the evaluation. In Section "Discussion" we discuss the results from the pilot study and how UCD principles were effective to develop the system and Section "Conclusion" concludes the paper.

Methods

Extraction of user requirements and system definition

The complexity of diabetes mechanisms does not allow defining a single diabetic patient profile and, in turn, a single scope for a disease management system. It is under this assumption that the European research project 'METABO' started its activities: a consortium composed of biomedical and information technology researchers, health technology industries, clinical engineers, HCI experts, and research hospitals who worked more than four years on the definition, implementation and validation of a diabetes disease management platform [23]. UCD is a design methodology that aims at involving users in the design, development and evaluation of systems and products [24, 25]. The study study consisted of three iterative cycles, which were we considered as research phases in the development approach: usage scenario definition, user

archetype definition and system development, as described in Fig. 1.

The first cycle aimed at discovering the usage scenarios of a diabetes self-management system. To this end we defined a situation/problem-oriented representation of the disease involving patients and clinicians. Scenarios were based on international standards of care (by the National Health System in the UK [26] and the American Diabetes Association [3]) and six specific needs: sudden hypoglycemic events, changes in the environments, physical activity, lack of motivation, co-morbidities, unstable diabetes control [27]. Users collaborated in the definition of conceptual maps and scenarios which were evaluated with open-ended interviews. The second cycle focused on the definition of the user archetypes (personas). For this we firstly identified four type of form factors to support patients in the management of the disease: 1) sensors to allow physiological monitoring of blood glucose, physical activity and weight, 2) tools for collecting ODL and integrating the sensed data from the patient side, 3) tools for treatment and follow up from the practice team side, and 4) a system to allow exchange of data and establish a communication channel between patients and careers. These factors were used for the creation of mock-ups that were evaluated and refined through focus groups and face-to-face interviews with end-users. This cycle resulted in the definition of three main user archetypes, called PRIMARY PERSONAs according to UCD theory: T1DM patient, T2DM patient, and the Treating Professional (TP). The third cycle was devoted to the development of the system. According to Nielsen's gold standard "10 Usability Heuristics for User Interface Design" [25] we performed an heuristic assessment of the mock-ups and the usage scenarios. This stage resulted in the definition of use case and functional descriptors of the components of the system. These components were also assessed in usability tests and interviews with users representing the different personas, providing feedback and substantial changes in the final system. This system was afterwards tested in the pilot study.

Study description and data analysis

The system was tested in a small-scale exploratory pilot study in four clinical centers in Modena, Parma, Prague and Madrid from January 2015 to September 2015. The Medical Ethics Committee of each center approved the study protocol, and all patients gave their informed consent in order to be enrolled in the study. We recorded usage and compliance metrics of a group composed by 13 T1DM and 7 T2DM patients who used the PMDs during four consecutive weeks (Table 1). A total of 24 care providers used the Control Panel (CP), a desktop-based application designed for the treating professionals. However, in each of the four centers there were one or two diabetes specialists assigned as the main user of the CP. These specialists were assisted by other doctors, nutritionists and nurses.

The applications were designed to record all the interactions of the users with the system. To assess user behaviour, the number of accesses to each module was recorded together with a timestamp. The number of messages from each module (i.e. packages) was also recorded to evaluate the communication performance. A package is the simplest representation of a transaction of information regarding a specific module. For instance, an insulin intake package would contain information about the type of insulin and pumped dose. Records were compiled and analysed independently for T1DM and T2DM PERSONAs. Due to the non-parametric distribution of the observed variables, a Wilcoxon independence test was calculated to find out if the behaviour on the access to modules and communications had differences not attributable to chances. The Wilcoxon test was chosen as a particularly conservative method, sacrificing test-power for accurateness under possibly non-parametric conditions, and

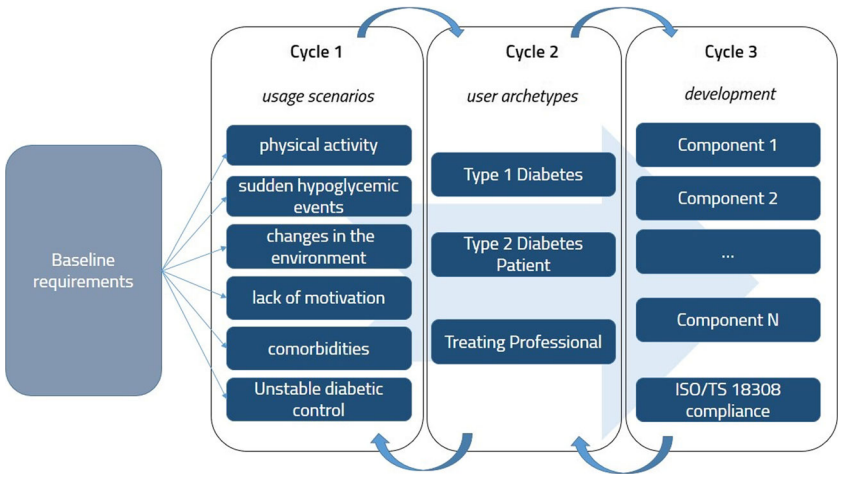

Fig. 1 Implementation of the UCD methodology in 3 cycles

Table 1 Demographic description of the study sample grouped by the PERSONA TYPE and homogeneity test

	T1DM (n=13)	T2DM (n=7)	*p*-value
Characteristic	n (%)	n (%)	
Gender			0.68
Male	9 (69%)	5 (71%)	
Female	4 (31%)	2 (29%)	
Studies			0.21
Undergraduate	2 (15%)	2 (29%)	
Secondary	3 (23%)	2 (29%)	
University	8 (61%)	3 (43%)	
PhD	0 (0%)	0 (0%)	
Marital status			0.40
Single	7 (54%)	2 (29%)	
Married	5 (38%)	5 (71%)	
Divorced	1 (8%)	0 (0%)	
Widowed	0 (0%)	0 (0%)	
Medical variables	$m \pm sd$	$m \pm sd$	
Age (years)	38.2±10.6	48.3±11.3	0.06
Duration of diabetes (years)	15.5±10.6	9.1±6.7	0.17
BMI	24.3±3.6	31.3±3.8	<0.001
Waist/Hip	84.7±15.2	109.5±13.5	0.02
Hb1Ac	7.6±1.3	7.8±1.4	0.50
FPG	179.6±70.8	144.7±46.1	0.10
Lifestyle			
Smoking	2 (15%)	2 (33%)	0.91
Alcohol	4 (31%)	3 (50%)	0.96
Limitations on diet	1(8%)	1 (17%)	0.75
Physical activity			
Days per Week	3.3±2.7	4.3±3.3	0.46
Duration (min)	41.5±43.3	36.4±32.2	0.87
Intensity (METs)	2.9±2.6	2.7±2.3	0.79

significance level was accepted for p values under 0.05 at 95% confidence interval.

Moreover, two more indicators related to the user response to technology and treatments were defined. First we calculated the Usage parameter in Eq. 1 which gives an approximation about the intensity of the subject's compliance to the system. The Usage is defined as the number of actions that a user should do (A) (monitoring blood glucose, insulin administration, eating a specific meal, etc.) and the number of prescribed actions not reported by the subject (B). To evaluate the compliance to the treatment we defined the level of Compliance in Eq. 2, which relates the number of actions recorded by the patient (R) over the number of prescribed actions (p) that the treating professional assigned to the patient.

$$Usage = (1 - B/A)\% \quad (1)$$

$$Compliance = (R/p)\% \quad (2)$$

Besides, the pilot study aimed at assessing the acceptance of the system in a real world context. This was achieved by analysing the user satisfaction and the usefulness perceived by its users and the user behaviour at the end of the pilots:

- User satisfaction: we used the AttrakDiff questionnaire [28]. The AttrakDiff is consists of 4 subordinate constructs, all of which are computed separately: pragmatic quality, the two hedonic qualities stimulation and identification, and attractiveness. Whereas pragmatic quality might be considered to be the best representation of user satisfaction, a product such as METABO should neither disregard the other dimensions, which are rather connected to the concept of "user experience". Our quality criterion consisted in having the confidence interval of the collected measures' mean value over a score of 3.
- Perceived usefulness: we constructed a questionnaire for assessing the usefulness measure based on Davis questionnaire [29] and some additional custom items.

Cronbach's alpha was used to check results homogeneity. The arithmetic mean value of all the remaining items was calculated and the quality criterion consisted in finding the scale's middle score outside the confidence interval of the collected measures' mean value.

Results

Personas and scenarios

The most frequent tasks that T1DM people perform are related to the daily annotation of medical and lifestyle data. The user needs to understand in real time how to deal with the multiple factors affecting blood glucose levels, without compromising their quality of life. Users demanded features to resemble as much as possible the actions they usually perform, for instance filling in paper diaries or notebooks where patients record their measurements and add comments. Data reviewing was spotted as more time-consuming and less suitable for doing on the move. However, it is an action that T1DM people may wish to perform, possibly comparing different sources of information to understand what is compromising an optimal glucose control (typically glucose vs. food intake vs. insulin injections).

In the case of T2DM, the main objective was on diabetes education, communication with health care professionals and empowerment to adopt a healthier lifestyle. TD2M people will usually not be insulin dependent, but likely to suffer from a number of co-morbidities, and probably have a complex medication regime. Empowering patients to change their routines and to adopt a healthier lifestyle entails the provision of educational and motivational materials in combination with a behaviour change strategy. Although an interface for recording measurements should still be present in the application, lifestyle management and communications with health professionals should be considered as a key factor.

The Treating Professional (TP) is a diabetologist, an endocrinologist, or a case manager who typically treats many patients per day (about 30 per day, as extracted from interviews) and has 5-10 minutes for each of them. In this time frame, they need to understand the patient profile, the clinical status, as well as the current treatment and, based on this, take decisions regarding changes in the treatment and respective counselling. In addition, nurses, educators, and nutritionists also participated in this provision of care schema. They need access to the same kind of information but not to the entire set and not to all the features with respect to the TP (they are defined as SECONDARY PERSONA).

The METABO system

The METABO system is conceived by patients as an electronic diary to support int he management of diabetes. The system included some intelligence to support them in what to do and when to do it, based on the treatment they agreed on with the doctor, helping them to properly visualize their record and allowing them to exchange messages with their caregivers. This intelligence is based on the dynamic comparison of the proposed diabetes management plan (e.g.: number of blood glucose measurements per day, number of insulin intakes, regularity of physical activity, etc..) and the actions recorded by the patient into the system. The modules contained in the system allowed to record information related toth Food Intake (FI), Blood Glucose (BG), Drug Intakes (MD), Physical Activity (PA), Education Module (ED), and a messaging module (MS) for communicating with the trating professional.

Patient interfaces, named Patient Monitoring Devices (PMD), consisted of applications running in Smartphones (HTC HD2 for T1DM and iPhone 4.0 for T2DM) and desktop PCs (Asus Tablet PC, named Patient Panel, for both patient PERSONAs). Smartphone applications were designed to provide better support for data recording, especially in mobility environments, while the Patient Panel was conceived for sensor download and content visualization activities. The Control Panel (CP) provided to the TP was a java desktop application for personal computers.

These devices were connected through web services to the Central Server (CS) was installed on a host machine, managing the PMDs and the CPs installed in all the centers, and executing registration, security, authentication, data storage, synchronization, interoperability, scheduling, and feedback services. Four type of sensors were provided to the patients (Fig. 2 - orange rectangle). T1DM patients were equipped with a Continuous Glucose Monitoring System and an activity holter. T2DM patients were equipped with a strip blood glucose sensor and a pedometer. Further details on the type of sensors and integration can be found in [9]. The system included an automatic delivery of feedback messages based on a database of predefined actions and rule engine, which evaluated a set of metrics related to the compliance of the patient and provided customized motivational messages. This automatic feedback component has been previously presented by co-authors [30]. The main purpose of this smart feedback mechanism was to let patients not only record data, but actively use and learn from it (which is the intended benefit of a PHR) and access information that may help them take better decisions.

The system was designed to execute actions based on the prescribed diabetes management plan and the events

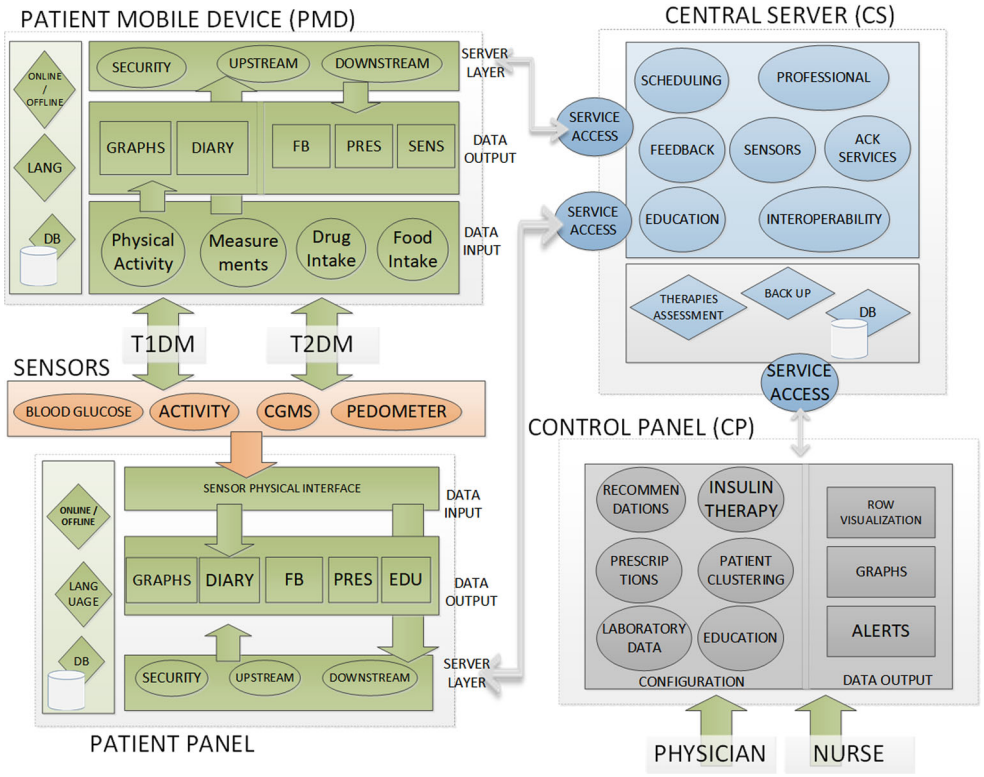

Fig. 2 System architecture

recorded by the patient. The Treating Professional (TP) had to define a plan for each patient containing a description of what the patient should record (food intake, blood glucose monitoring, physical activity, etc...), when this should be recorded (measurements per day, per week) and sets thresholds of normal and abnormal values for each type of record (e.g.: high blood glucose higher than 180 mg/dL). Thereafter the central server transformed this prescription into rules for the configuration of the patient applications (each patient with his/her corresponding management plan). Figure 3 displays examples of the patient application interface, showing the main window with records of blood glucose, insulin intake and physical activity (up-left corner); a summary chart of a given day combining diferent type of measurements recorded by the patient (up-right corner); the medication plan (down-left corner), a chart comparing the expected weight loss (green dots) and the actual weight loss (white line) in the down-center and a sample of the messaging exchange module with the treating doctor (down-right corner).

System evaluation

We measured how patients used the modules during the entire duration of the study. Number of accesses to each module (sessions) and number of records on each module sent to the doctor application (data packets) were recorded automatically. Descriptive results are shown in charts for each week in the study, showing the trend of the average and standard deviation for the access and communications (data packets sent) for T1DM patients (Fig. 4) and T2DM patients (Fig. 5). According to the aggregated analysis (Figs. 4 and 5), the most frequently used modules were Food Intake and Medication. With respect to the overall access, T1DM average usage decreased from more than 70 sessions during Week 1 to 50 sessions in week 3 and less than 10 in Week 4. While the first decrease can be positively associated with the learning phase on the usage of the system (the patient needs less accesses to send the same data packets), low values in the last week may be related with the fact that T1DM were also sending sensor measurements through the continuous glucose monitoring and physical activity sensors, without the needs of accessing to these modules. This was not observed for T2DM, where the usage was acceptable in all modules until the end of the trial.

Statistical analysis are summarized in Tables 2 and 3 for each week in the study and Table 4 for the entire duration of the study. Table 2 shows the results of the behaviour analysis based on Wilcoxon independence test for the access to the modules, in which the two first weeks do not show a significant different behaviour, but the two last do. Table 3 shows the same analysis for the number of records sent from each of the modules for each of the weeks during the study duration, but in this case the behaviour is homogeneous (except to physical activity int he two last weeks). This test has also been applied to the average indicators for the entire

Fig. 3 T1DM Graphics (up); T2DM Drug Intake, Goal Achievements and feedback modules (bottom)

study duration (Table 4), confirming that he two type of users have a different behaviour while using the Medication module, whereas, the rest of the modules have a similar behaviour in the use and the communication.

In both cases, the prescribed usage (how many times the patients uploaded information compared to how often they were expected to do so) and compliance (how well the patients achieved what was prescribed) are above thresholds that were considered as acceptable by the clinical experts (what they could expect from a regular follow-up without the use of the system) and did not decrease substantially during the study duration. A more active role was observed in T2DM patients on the usage of the educational functionalities with respect to T1DM (70% out of the total number of patients using the education modules were T2DM). As regards the messages with the TP, T1DM exchanged an average of 4.9±3.9 messages, while T2DM an average of 6.6±3.0. The messages sent by the system (reminders, alerts, tips and recommendations) where 124.5±52.4 for T1DM and 188.3±57.4 for T2DM. This also shows a difference between the two type of patients, being T2DM more focused on education activities.

The compliance value represents the fit between the measurement values introduced by the patients and their prescription (Fig. 6). A Wilcoxon test was calculated to check for any significant differences between the first two weeks and the last two weeks. When taking the Bonferroni-correction into account, none of the pairs showed a significant difference, although the case of drug intake was close to significant with p =.01. In the last two weeks, the patients recorded manually their blood glucose tests less close to the prescribed intervals than in the first two weeks. Compliance of T2DM patients on drugs decreased in the last two weeks with respect to the compliance of the first two.

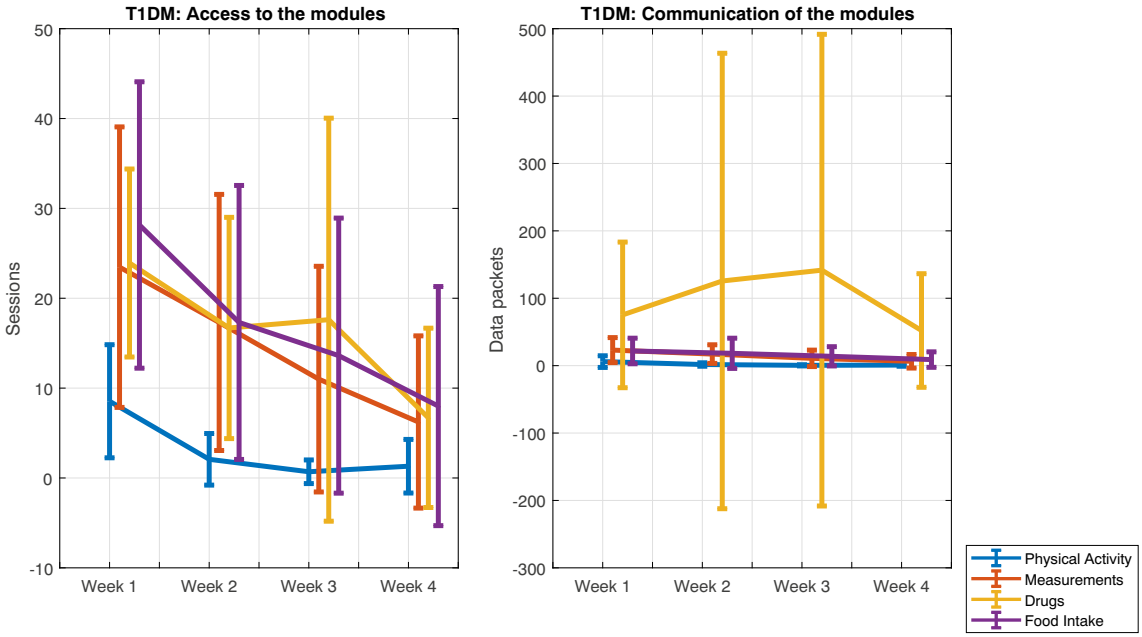

Fig. 4 Evolution on the average use (number of sessions) and average communication (number of packets sent to the doctor) for each of the modules in the applications for T1DM persona for each week

The adherence to physical activity prescriptions and food prescriptions (in the latter case concerning the number of meals entered) improved slightly. The intake of calories did not change over the course of the trial. Mean compliance was 65%.

Regarding the Control Panel, TP used the tool differently depending on the type of patient. For instance, this manifested itself in the manner professionals visualized the trends of patient's clinical data: T1DM patients were supervised based on complex charts (meal-oriented charts, blood sugar progression after meal charts, etc.) in 78% of the times. When monitoring T2DM patients, the professionals relied less on the combination of complex charts (40%) than on simple charts (60%).

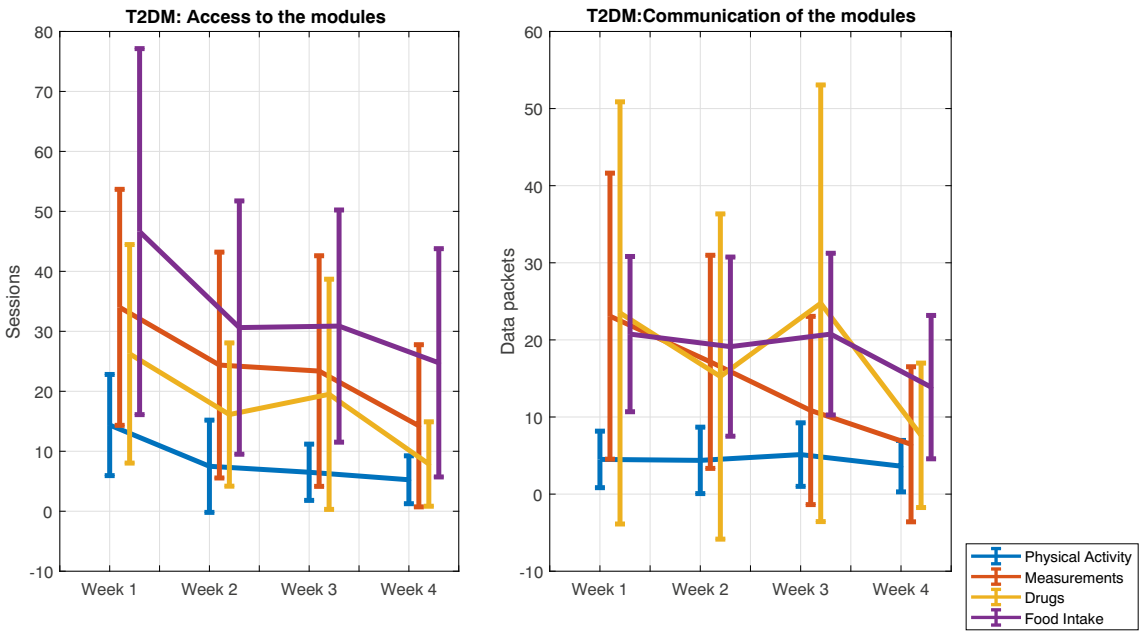

Fig. 5 Evolution on the average use (number of sessions) and average communication (number of packets sent to the doctor) for each of the modules in the applications for T2DM persona for each week

Table 2 Significance levels for the independence test of T1DM/T2DM for access during each week

Module	Week 1	Week 2	Week 3	Week 4
Physical Act	.15	.16	**<.001**	**.02**
Measurements	.19	.40	.09	**.04**
Drugs	.94	.71	.51	.32
Food intake	.14	.15	**.04**	**.02**

Bold entries signify level $p = 0.05$

System attractiveness and perceived usefulness

The efficacy and the efficiency of both T1DM and T2DM applications was measured using the AttrakDiff, which allows measuring the level of easiness-to-use interface. The user experience results for T1DM application are depicted in Fig. 7.

In the case of T1DM, the confidence interval of the pragmatic quality measure overlaps the middle point of the scale, even though the mean value is situated above this critical level. Thus, our quality criterion is missed, even though by the least extent possible. As the other values are far above the middle, one may assume that the users saw the application very positively. A hypothetical explanation could be that the T1DM participants were very used to smartphones and might have considered the windows mobile platform as inferior to iOS or Android based systems. Results from the Perceived Usefulness questionnaire were collected to assess the usefulness of the overall system within the diabetes treatment. Results show a general good level of the patient perceived usefulness (mean=4.60%; SD= 0.9).

Discussion

We designed a system that supports the health management of diabetic patients in their living environments. The frequency of use and the information sent from the app remained similar among T1DM and T2DM patients; however T1DM patients were more likely to use less

Table 3 Significance levels for the independence test of data packets sent during each week

Module	Week 1	Week 2	Week 3	Week 4
Physical act	.77	.19	**<.001**	**.02**
Measurements	.51	.80	.21	.12
Drugs	.15	.39	.49	.48
Food intake	.91	.64	.19	.13

Bold entries signify level $p = 0.05$

Table 4 Wilcoxon independence test of overall records in access and communication of the modules among T1DM and T2DM users for the entire duration of the pilot study

Module	Access	Communication
Physical Act	.20	.34
Measurements	.20	.99
Drugs	.89	**.03**
Food intake	.06	.43

Bold entries signify level $p = 0.05$

features of the app. The PERSONAs definition supported the differentiation of user groups that finally resulted in tailored PHR registries. Placing the patient at the centre of the development process through UCD was the key.

Usage statistics show that the patients used the METABO system as much as expected, even though both usage and compliance levels were not excellent, they were acceptably high for such a new system. Both, patients and medical doctors, learned to use the system over time, while increasing their efficiency. T2DM users entered as many measurement values as T1DM ones. Initially, the T2DM PERSONA had been defined as an adult (over 60 years old) with a low level of IT literacy compared to the T1DM PERSONA. Therefore, we thought that T2DM PERSONA could be less capable and even reluctant to use the PMD for the self-management of the disease. We did not collect measures of IT literacy during the sampling procedure (Table 1). Results reject our initial hypothesis, as T2DM participants achieved a comparable level of use and communication metrics, and the differences between the first and the second half of the study on these indicators are smaller than the differences observed in the T1DM group.

Access to and communications from the modules in the mobile applications had different trends, but show statistically independent behaviours (Tables 2 and 3). Overall, the patients' compliance (2) related to the modules decreased, but we observed a correlation in T1DM patients regarding the drug prescription and also the food intake. The general compliance showed dramatic changes among the second half of the study. A possible explanation is that after the first two weeks of use, patients started to change their treatments to optimize the health outcomes. Figure 6 shows how the usage of the modules remained at similar levels, whereas the compliance was significantly reduced. The assessment of such indicators could be an interesting break-point to determine whether a patient is showing adherence to treatments irrespective to the short-term clinical outcome evolution. Stratification of patients according to their IT literacy and performance on communications, access and use objective metrics could lead to a better performance in terms of personalized medicine [31].

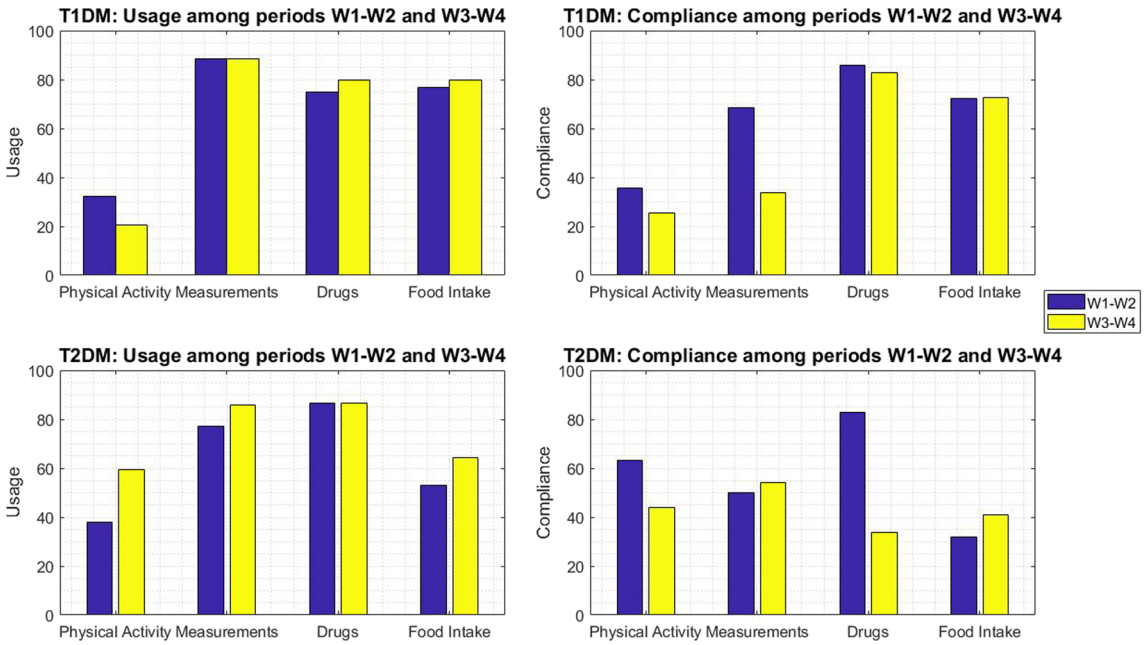

Fig. 6 Usage and Compliance metrics for each module compared during W1-W2 and W3-W4 periods for each type of patient

Some features of the METABO system have been previously implemented in diabetes management systems. Nevertheless, these implementations lacked the necessary tailoring of electronic tools to the specific needs of each PERSONA. In our research, we have tried to identify the benefits of user centered design in order to design, deliver and test a tailored solution for diabetes management. Furthermore, the integration of standard sensors for bio-signal acquisition is an essential element in order to implement a reliable information workflow, as confirmed by [32]. The designed system fills the gap identified in a recent review on T2DM mobile apps [13]: from the 89 apps analysed, a majority was of high quality with respect to a single dimension of the disease but only 4 out of 89 apps integrated all six dimensions, and less than half integrated at least four of them. The system was successful on helping patients in the management of heterogeneous data (data from different sources) as the Usage and Compliance (Fig. 6) remained stable when the access and the communication decreased (Figs. 4 and 5). This reflects that patients were capable of keeping adherence to the management plan while using more effectively the data recording tools in the application. The UDC based methodology of three cycles used in this study, which included patients and doctors, helped to understand how they perceive their role in the process of care, especially with respect to patients. This understanding allowed us to create a system that can support them in the management of the disease but also to encourage the process of learning the causes and consequences of their decisions related to diabetes. We think that patient empowerment, which involves understanding the consequences of their decisions

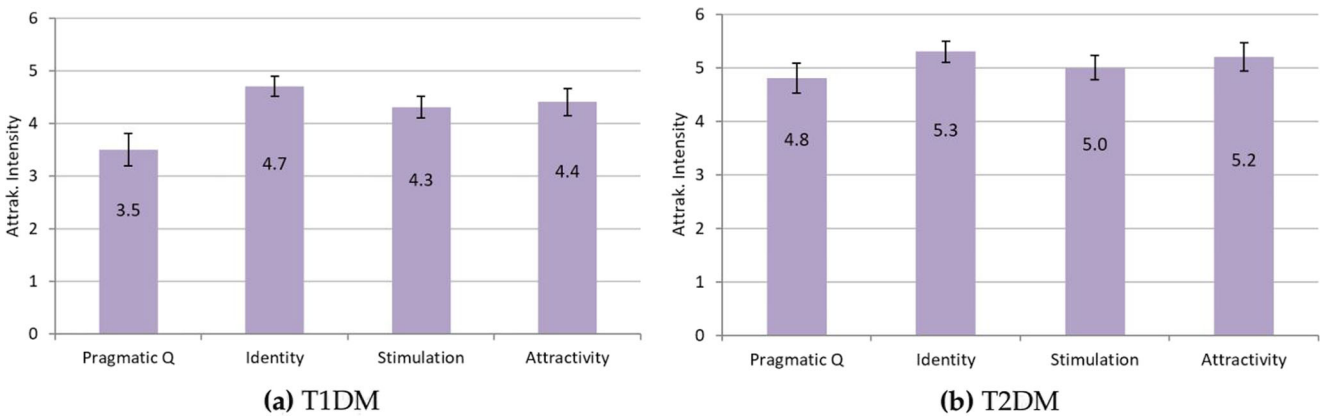

Fig. 7 AttrakDiff results per category

needs of integrated strategies combining the efforts at different levels: family, treating professionals, diabetes educators and other actors in the environment of the patients. We come to contribute to this major challenge by providing a system that facilitates the communication of patients and their treating professionals and provide attractive interfaces to follow the management plans.

Even though our study had a limited duration, we were able to determine significant differences in patient response with respect to therapeutic and lifestyle prescriptions. The observation period of two cycles of two weeks each was too short to assume any life-style changes, and moreover prevented us of thinking that a behaviour change may be sustained in the long run. We consider that a longer duration of the study would not have yielded any different findings in the observed metrics, and the differences on the use and communication values would continue as the trends observed in week 4. Patients play a critical role in choices of lifestyles by, for example, exercising, eating well, and learning about their diabetes and as Quinn and colleagues concluded in the WellDoc Study, some medication intensification strategies may be not required if the patient shows lifestyle pattern shift [18]. Therefore we come to conclude that the application of UCD principles in the design and development of self-management systems can ensure an effective use of information technologies for the long-term management of diabetes. The system presented in this study would be capable of reducing the morbidities and the appearance of critical events, such as sudden hypoglycaemia and hyperglycaemia by balancing the drug therapy in combination with diet, physical exercise and learning aspects of the patients, but a larger clinical evaluation is needed to confirm these hypothesis. Further investigation needs to be done correlating the technical results with the clinical and usability outcomes for longer periods of usage.

Conclusion

User Centered Design enabled us to design and implement a customized system for T1DM and T2DM diabetes management and support. This methodology empowered patients to make their own decisions, choices and helped to expand the concept of Personal Health Record as an addition to the Electronic Health Record. Our analysis shows that after an initial period, T1DM patients were more likely to use less features of the designed system, however the communications sent from the mobile application stood similar in T1DM and T2DM patients. This indicates that less use is not associated with a low compliance or adherence.

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Compliance with Ethical Standards

Conflict of interests The authors declare that they have no conflict of interest.

Ethical approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed consent Informed consent was obtained from all individual participants included in the study.

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