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SPECIAL ISSUE - ORIGINAL ARTICLE

Automatic messaging for improving patients engagement in diabetes management: an exploratory study

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Abstract Mobile health systems aiming to promote adherence may cost-effectively improve the self-management of chronic diseases like diabetes, enhancing the compliance to the medical prescription, encouraging and stimulating patients to adopt healthy life styles and promoting empowerment. This paper presents a strategy for m-health applications in diabetes self-management that is based on automatic generation of feedback messages. A feedback assistant, representing the core of architecture, delivers dynamic and automatically updated text messages set up on clinical guideline and patient's lifestyle. Based on this strategy, an m-health adherence system was designed, developed and tested in a small-scale exploratory study with T1DM and T2DM patients. The results indicate that the system could be feasible and well accepted and that its usage increased along with adherence to prescriptions during the 4 weeks of the study. A more extensive research is pending to corroborate these outcomes and to establish a clear benefit of the proposed solution.

Keywords Mobile health · Diabetes self-management · Patient engagement · Adherence management

1 Introduction

There is an exponential growth in the incidence of non-communicable diseases, such as cancer, cardiovascular and respiratory diseases, and diabetes mellitus, leading to rising numbers of deaths worldwide [9]. The prevalence of diabetes mellitus (DM) in particular is increasing globally among all ages and constitutes a major worldwide health problem.

DM, or simply diabetes, is a metabolic disease associated with the presence of elevated glucose levels in the blood. There are two main types of DM: type 1 (T1DM), which refers to the body's inability to produce enough insulin; and type 2 (T2DM), which refers to the body's ineffective use of insulin, sometimes combined with complete insulin deficiency. The development of type 2 diabetes is associated with various risk factors such as excessive body weight, physical inactivity, high intake of saturated fatty acids. There is also a third type called gestational diabetes, which is sometimes developed by pregnant women and might precede the emergence of T2DM.

A problem often associated with chronic disease management is patients' adherence to treatments. The World Health Organization (WHO) defined adherence as "the extent to which a person's behaviour—taking medication, following a diet, and/or executing lifestyle changes, corresponds with agreed recommendations from a health care provider" [26].

According to this definition, adherence is a multi-factorial aspect that requires support in terms of education, self-management, interaction between patients and caregivers, and engagement. Measuring adherence is complex and, even if widely discussed, there is still no "gold" standard for measuring adherence through patient self-report [2, 10].

Adherence is particularly important with diabetes because of the significant consequences it may produce on patients even in the very short term [19]. A personalized education plan is therefore very important to provide the patient with the appropriate tools needed for the effective self-management of the disease [25].

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Generally, healthcare systems are not normally designed and organized to provide support for self-management treatment of chronic diseases. This is also the case of diabetes care. The lack of financial resources and the scalable nature of the problem make it difficult to offer educational and self-management support and education to the diabetes population [8, 15].

Diabetic patients have a crucial role in their own treatment, having to take, on a daily basis, relevant decisions about the actions needed for the management of their disease, such as dietary choices, glucose monitoring, medication intake, and maintaining a healthy lifestyle through physical. Patients' motivation and empowerment are perhaps the two most relevant intervening factors that directly affect self-management of diabetes care. It has been demonstrated that these two issues play an essential role in prescription adherence, as well as for the successful encouragement of healthy lifestyle and other behavioural changes [22, 23].

Mobile health technologies (m-health) can be used for offering self-management support programs to diabetes patients and at the same time surmounting the technical and financial difficulties involved in diabetes treatment [15].

Mobile communications and multimedia technology are playing significant roles in connecting with patients to improve adherence to prescribed medications [7]. Lots of adherence apps are actually present on the market for Android and Apple iPhone OS [4]. Even so, such solutions do not foresee a continuous follow-up from the clinician and frequently lack in horizontal methods like educational guidelines and customized automatic control. Moreover, it has not been proven yet that apps can actually modify patients' adherence and what patients could be benefited the most.

Effective communication is at the core of providing patient-centred care since it influences behaviours and attitudes towards a health problem [18]. Tailoring messages to patients has been identified as a key way of making suggestions and information more relevant to its intended audience and, as a result, more effective [3, 11].

Personalized text advices have proven to produce a positive impact on patients' empowerment, self-management, and adherence to prescriptions [5]. The effectiveness of the use of automatic short message reminders in DM has been preliminarily demonstrated in several studies [5, 12, 19].

Even if preliminary studies are promising, barriers to self-management of any chronic disease still exist and studies are needed to determine the real impact of education and support systems in patients' behavioural plasticity and actual treatment compliance [16, 23].

Some of the most relevant present limitations are explained below:

- Lack of customization:
  - There are no innovative provisions for follow-up, designed in a way that meets the needs of a particular patients group while also conforming to clinical guidelines.
  - In many cases, there is a lack of integration between patients' personal health records and the application.
- Lack of dynamicity of text messages:
  - Especially related to patients' behaviour, risk factors, medical condition, lifestyle, environment, or patients' emotional state.
- Lack of decision support capabilities:
  - The only decision support capability currently provided is insulin dosage suggestions. This limitation could be addressed by the features such intelligent feedback tools for medication suggestions and personalized education based on the patient's actual conditions [6].

Our research seeks to determine whether a message sent in a proper time and with proper content has an impact on patients' adherence to therapy. In addition, we want to determine whether patients who receive tailored messages improve their willpower in managing their own disease, and if caregivers positively evaluate this approach. For accomplishing this aim, we propose a framework for designing automated feedback systems for chronic disease management, based on clinical, and lifestyle parameters associated with diabetic patients, and a method to measure objectively the adherence using closed-loop m-health systems.

The framework was developed and applied in the METABO project. METABO is an R&D project, co-funded by the European Commission [14] that integrates mobile infrastructure for supporting the monitoring, management, and treatment of T1DM and T2DM patients.

2 Materials and methods

2.1 The METABO system

The METABO system, shown in Fig. 1, is based on two main blocks: the Patient Mobile Device (PMD) and the professional control panel (CP).

Two different applications were designed for T1DM and TD2M patients, with specific interaction modalities implemented for each of them.

T1DM patients are usually younger and more motivated; therefore, they prefer a more personalized application on small devices. On the other hand, T2DM patients are generally older and less inclined to self-care; therefore, their application was designed to be very easy to

Fig. 1 METABO system architecture

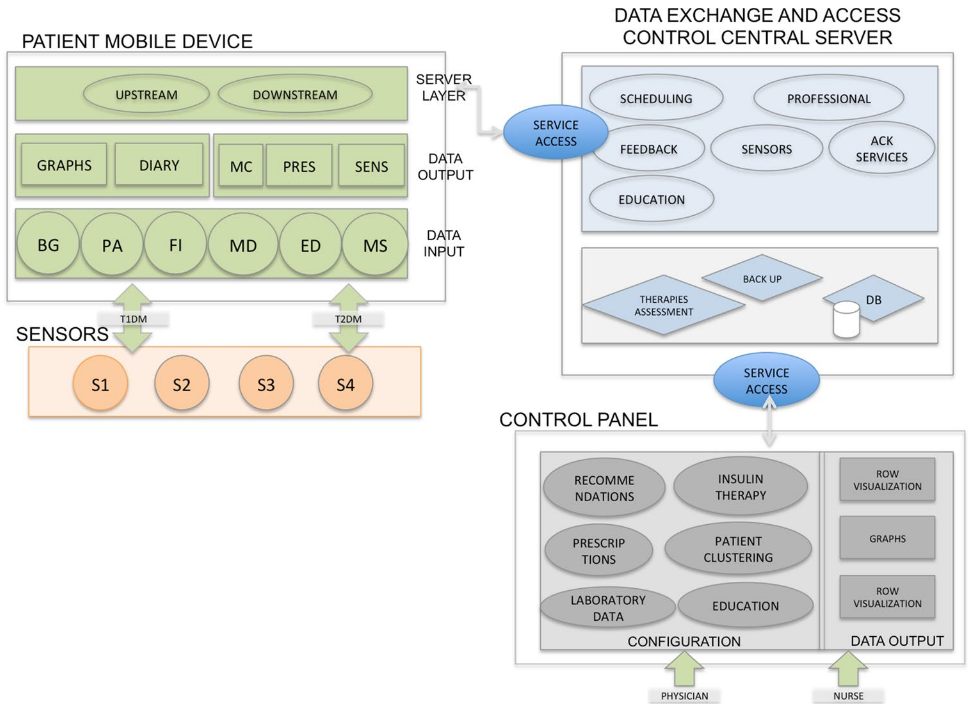

Fig. 2 Patient PMD application

use, with stronger emphasis on persuasion (i.e. with special attention on the content of text message). Figure 2 shows the PMD screenshot of message visualization module.

The system presents itself as an electronic diary to patients where they can report their daily activities. The CP is the application used by professional caregivers. It allows understanding the patient's health status, monitoring blood glucose, physical activity, diet, drug adherence, and education The CP also provides an interface for the doctor to add new content to the repository of messages and to directly send messages to his/her patients.

The PMD is the system used by the patient. It is meant to cover thoroughly the primary needs of T1DM and T2DM patients for self-managing diabetes and runs on smart phones. The main functionalities of the PMD are as follow: food intake (FI), for reporting daily diet; blood glucose (BG) and weight and blood pressure measurements (MS), for manually reporting physiological data; drug intakes (MD) and physical activity (PA), for reporting adherence to prescriptions; educational content and quiz (ED), for reading educational topics and answering quizzes; sensors (SENS), to allow patient downloading biomedical measurements from sensors; graphics trends (GRAPHS), to let the patient monitor his/her own progress; message communication (MS), for chatting with the medical doctor; and the messaging module (MF) for accessing messages and automatic feedback.

The PMD is connected with the CP through the central server (CS). The CS is installed in one of the research centres and is responsible for registration, security, authentication, data storage, synchronization, and scheduling and generating automatic feedback.

An automatic feedback module (AFM) has been developed to provide the patient with self-management and educational support through feedback messages about physiological status, prescription recommendations and tips. The automatic message composition was programmed with rules grouped in 18 scenarios, differing in terms of the type of diabetes (type 1, type 2 not insulin treated and type 2 insulin treated) and six profile variables: (1) sudden hypoglycaemic events, for people with clinical predisposition to suffer unexpected hypo/hyper glycaemic episodes, (2) changes in the environments, adjusted to diabetics that are sensitive to change of the environment, (3) physical activity, dedicated to people whose glucose metabolism is significantly connected to the training, (4) lack of motivation, for people with negative perception of the disease, anxiety or stress, (5) comorbidities, for diabetics having one or more additional disorders, and (6) Unstable diabetes control for diabetics with continuous changes on glucose levels.

The usage scenario is described as follows:

1. Clinical data and patient profile are collected during examinations and clinical tests.
2. The professional caregiver creates a new instance of the patient and inserts his/her baseline data in the CP.
3. The caregiver sets the medical and lifestyle prescriptions and decides what kind of input patient needs to annotate (FI, BG, PA, ED, MD), including insertion frequency and sets up thresholds, where needed.
4. The AFM module, basing on patient profile and prescriptions generates the automatic feedback.
5. The patient is given the PMD and after a training phase he goes home.
6. Based on actual patient's inputs, adherence is estimated, and feedback messages are delivered.
7. The professional opens the CP and checks which patients need to be analysed, based on the priority of generated alerts, as well as according to the scheduled visits.

2.2 The feedback generation strategy

The proposed strategy consists of a generic architectural description applicable to a generic ICT-based disease management systems and a set of design recommendations related to:

- Rules for composing personalized messages.
- Input data to be considered for generating feedback.
- How to include historical data about user interaction into the rules.

The main objective of this framework is to improve patient's prescription adherence and to persuade patients towards a general improvement in diabetes self-management, by means of text messages that are automatically selected and dispatched. Such objective includes the patient's adherence to drug intake, food intake, and physical activity prescriptions.

The framework is based on a feedback process that automatically responds to the inputs generated by the patients or under the command of a caregiver. The proposed approach includes all the process chain for generating, selecting and delivering messages. The architecture is depicted in Fig. 3.

Baseline Data is the database that contains the static information about patients, including clinical profile, physical exams, laboratory measurements, demographic and socio-economic data, motivational status, awareness on diabetes disease and computer literacy. These data are usually collected in a preliminary phase at the clinical centre, or through interviews and surveys. These data are not expected to change frequently; their update can be at most every 6 months.

The *Messages Repository* is a database that contains a set of predefined messages that have been defined by experts, including educational specialists, doctors and physiologists. In order to write efficient messages, strong attention has been given to the criteria that characterize their quality and rightness. We adopt the approach described in [1], where principles about both the content and syntax are defined as follows:

1. *Accuracy*: patients need clear messages and accurate information in order to make good healthcare decisions. That is why the content information must be precise and appropriate for the intended patients.
2. *Clear target:* message must be very clear and concise, focussed on patient issues.
3. *Adequacy with respect to place and time:* messages must be sent in the right place and in the proper time. The closer a reminder is to the time and place of the related activity, the more effective it will be.

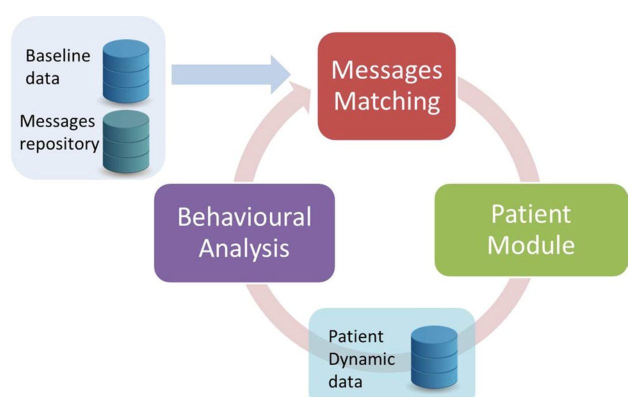

Fig. 3 Architecture for automatic feedback generation

4. *Suitability*: patients want a personalized experience, so health messages must seem to come from the patient's health coach and must be suitable to patient profile and mood.
5. *Quality and pragmatism*: message statements must be understandable but never enunciated aloud. A content like "You have exceeded the recommended daily calorie value today, try to follow strictly your food intake prescription" is less effective than: "You should try not to exceed the recommended daily calories. Think about how to manage your meals more effectively, starting tomorrow".
6. *Persuasiveness*: message must always encourage patients through positive social comparison, never too direct. Hence should suggest alternative plans to accommodate patient concerns and collaborative.

When inserted in the repository, messages are classified by a set of tags. As a first level of classification, three categories can be identified, according to their priority: alarms (Level 1), recommendations (Level 2) and tips and goals (Level 3). Alarms messages refer to short-term advices, such as elevated blood pressure, a disorder of glycaemic values, or forgetfulness of a medicine intake. Reminders messages are focused on long-term notifications like physical activities suggestions, in case patient is not complying with the training schedule assigned by the doctor, or diet indication, according by a recommended daily calories index. The tips and goals messages are smart suggestions to manage the disorder and overall health, including customizable educational topics or represent the achievement on specific objectives, like reducing weight in a certain period of time or improving knowledge levels through quizzes. Another level of classification is given by the topic of the message, this can include: drug intake, physical activity, metabolic, physiologic measurements (i.e. glycaemic levels, heart rate, and blood pressure), specific goals objectives, and education.

The *Messages Matching* module is in charge of retrieving patient's clinical and profile information from the baseline data and matching it with the messages repository in order to select the best set of messages for each patient. In addition to the static data provided by the Baseline database, dynamic behavioural data are also fed into this module from the Behavioural Analysis module, explained later. The matching module characterizes the patient profile, by identifying him/her to an appropriated area of focus. The goal is to identify meaningful patient characteristics based on treatment needs, attitudes and health care behaviours and use this information to implement message-based engagement strategies. A set of rules included into the module is responsible for selecting the right messages according to the type of patient. These rules are described with simple Boolean predicates, and consider, from one side, the classification variables of the messages, and on the other side, patients' information like clinical pathway and prescriptions, behavioural information, and baseline measurements. For instance, if a T2DM patient is less apt to undertake a physical activity plan, the analysis model may define a specific program of messages oriented to motivate the user while sensitize him/her through certain education messages. Based on behavioural information (i.e. patient's aptitude on interacting with the system), the time frequency and the numbers of the messages are specified within the rules for short- or long-term treatments. As an example of how to measure patients' behaviour, the system can count the times the user accepts reminders and the times he or she skips it. The Message Matching module operates autonomously, but shall work always under professional supervision, which may refine the selection of messages through a dedicated interface.

*Patient Modul*e: This block is installed on the patient's mobile device and is able to collect data from biomedical sensors, as well as user-inserted inputs like metabolic and physiological data and daily activities. The module has the fundamental task of providing the user interface to the patients and must be therefore simple to use and intuitive. All the information related to messages selection, dispatching, answers to questionnaires and quizzes, manual inputs as well as sensors data is locally stored and synchronized with the Dynamic Data module.

The *Dynamic Data* module is responsible for storing all the dynamic information gathered from the Patient Module in a centralized way. This database is complementary to the Baseline Data repository. One of its functionalities is to provide the interface to the caregivers to review their patients' data and set prescriptions.

The *Behavioural Analysis* module is in charge of extracting information from the patient's dynamic database and assessing the user behaviour and adherence to prescriptions, analysed to estimate the patient's adherence. The Behavioural Module processes patient device interaction and biosensor data, updates patients' behavioural information in their profile and provides the Message Matching module with information related to behaviour and adherence. Behaviour assessments are based on recognized methodologies like the transtheoretical model of behaviour change. Particularly for diabetes, this method has proven to be successfully integrated into medical management [21].

Moreover, the success of the usage of this strategy, based on processes to guide the individual through different stages of changes, has been proved in many fields like the smoking cessation [20] and dietary and physical activity [24]. In this sense, the usage of a system based on the framework can easily be extended to other chronic diseases.

Table 1 Formulae estimation of Usage and Adherence

PRS	Usage	Adherence
FI	$\left(\left(\sum_{i-1}^{Nd} N\_\text{Meals}_i\right)/Nd\_\text{Pr FI}\right)\%$	$1-\left|\left(\sum_{i-1}^{Nd} N\_\text{Meals}\_Kcal_i - RDKcal \cdot Nd\right)/(RDKcal \cdot Nd)\right|$
GL	$\left(\left(\left(\sum_{i-1}^{Nd} Ngl\_\text{checks}_i\right)/Nd\_\text{Pr GL}\right)+\left(\left(\sum_{i-1}^{Nd} Ngl\_\text{checks}_i\right)/\text{Hyp}\right)\right)\%$	$\left(1-\left|\min\left(\sum_{i-1}^{Nd}\text{Hypo}_i+\sum_{i-1}^{Nd}\text{Hyper}_i\right),\delta\cdot Nd\right|\right)\%$
DI	$\left(\left(1-\left(\sum_{i-1}^{Nd} N\_\text{DI}_i+\sum_{i-1}^{Nd} N\_\text{II}_i\right)\right)/\left(\sum Nd\_\text{Pr DI}+\sum Nd\_\text{Pr II}\right)\right)\%$	
PA	$\left(\sum_{i-1}^{Nw} N\_\text{PA}_i\right)/Nw\_\text{Pr PA}\%$	$\left(\sum_{i-1}^{Nw}\text{METs}_i\cdot\text{Tact}_i\right)/Nw\_\text{Pr PA}\%$
ED	$\left(\sum_{i-1}^{Nw} N\_\text{ED}_i\right)/Nw\_\text{Pr ED}\%$	$\left(\sum_{i-1}^{Nw}\text{QR}_i\right)/Nw\_\text{Pr ED}\%$

Patients shall be allowed to activate/deactivate some categories of messages, and these settings can be used to analyse his/her preferences and the behaviour towards the system. A patient that is tired of receiving too many recommendations on practice exercises in the morning can choose to turn off the physical activity message module, through a specific feedback modules setting, or tell the system to remember him later: the patient's interaction is analyses by the behavioural analysis that automatically schedule the recommendations to another time of day.

The message matching module exploits the information provided by the behaviour analysis by selecting new messages from the messages repository. Useful information to this purpose can be: an indicator of the adherence to treatments, frequency of usage of the application, percentage of skipped and read messages, answers to educational quizzes, physical exercise data, nutritional data as well as physiological conditions which might indicate that the user is following prescriptions (like for blood glucose).

2.3 Usage and adherence indexes definition

Adherence to prescriptions is a multi-dimensional problem and not always easy to perform. As part of the framework, we suggest a set of indexes to estimate the patient's willingness to use the system (usage index) and his/her adherence to the treatments (adherence index). The indicators are split into the following groups: food intake (FI), glycaemic self-check inputs (GL), drug intake (DI), physical activity (PA) and educational content (ED). The formulae, shown in Table 1, refer to a 2 weeks base indexes calculation.

Usage index is estimated by calculating the number of warnings messages (L1) and reminders (L2) received for the specific missed prescriptions compared with the total of prescriptions. Food intake (FI) index corresponds to the percentage of data meals inputs (N_Meals_i) divided by the total number of prescribed meals during 14 days ($Nd\_\text{Pr}FI$). Glycaemic index (GL) is calculated as the percentage glycaemic self-checks (Ngl_checks_i) received during Nd days with respect to the expected and recommended (after a hypo/hyper event alarm) measurements. Drug intake (DI) usage, equivalent to the adherence, corresponds to the percentage of the ratio between drug and insulin intake's number, N_DI_i compared with prescribed drugs ($Nd\text{Pr}DI$) and insulin ($Nd\text{Pr}II$). Similarly, physical activity (PA) is calculated from number of weekly physical exercises N_PA_i, divided by the number of corresponding prescribed activities (Nw_PA). Finally, the educational content (ED) consists on the percentage of the ration between the number of weekly quiz filled up N_ED_i and the number of the prescribed quizzes $Nw\_\text{Pr}ED$.

The adherence column indexes correspond to the degree to which a patient correctly follows medical prescriptions. FI index consists of the percentage of the division between the ingested kilocalories per day and a recommended daily calorie index, whose value is arranged by the nutritionist. GL corresponds to the percentage of the numbers of hypo/hyperglycaemic episodes ($Hypo + Hyper$) compared with the number of instable glycaemic events (δ) supposed. PA adherence index comes from the weekly physical exercise, equal to the number of metabolic equivalent of task by the time spent (Tact) over a week, divided by the correspondent prescribed activities (Nw_PA). ED adherence index is calculated from the summation of the questionnaires results divided by the number of the prescribed quizzes Nw_PrED.

2.4 Methodology

The METABO system was tested in a randomized controlled pilot. The main objective was to examine the feasibility and acceptance of the system. Secondary objectives were also the assessment of the effectiveness of system in terms of adherence improvement, glycaemic control, and quality of life. Statistical significance in this case was not sought.

Participants were recruited from four different clinical centres in Europe: Hospital San Carlos of Madrid (Spain), AUSL of Modena (Italy), Hospital of Prague (Czech Republic), and Hospital of Parma (Italy). The baseline assessment included demographics, diabetes status, profile information, knowledge about diabetes in general, usage of ICT platforms, opinion and experience about electronic devices, appraisal over the coexistence, adoption of good practices with diabetes.

Fifty-one out of 54 patients, who were enrolled, completed the trials. Twenty-six patients were assigned in the intervention group and equipped with the PMDs: 14 patients were T1DM and 12 were T2DM. The control group was composed of 25 patients that were treated through a standard care, without the usage of the METABO system.

Professional's intervention for both intervention and control groups was carried out by 24 care providers, including diabetologists, nutritionists, and nurses.

In order to evaluate the system acceptability and analyse the users' satisfaction, an online multi-language survey, using LimeSurvey, was produced for both patients and professionals, based on AttrakDiff questionnaire principles. The survey consists of eight questions, centred on evaluating the benefit of the system and the appreciation of the participants by means of a 1–5 Likert scale, where 1 corresponds to the most negative evaluation and 5 to the most positive.

3 Results

The results presented here are focused on acceptance and effectiveness of automatic feedback. The survey's results of the user's satisfaction are shown in Figs. 4 and 5. In the case of patients, attractiveness is 3.8 in average (SD = 1.1), which indicates a good appreciation. Answers related to kindness ($M = 3.5$, SD = 1.15) indicate that patients did not consider the messages to be annoying nor harassing. Even if only 33 % of the patients considered they would have not reached the assigned goals without the feedback assistant system (Persuasiveness, $M = 2.8$, SD = 1.35), more than 85 % acknowledged the helpfulness of the method ($M = 3.6$, SD = 1.91). Furthermore, 93 % of patients considered the messages reflect their true health status, confirming the accuracy of the system ($M = 4.3$, SD = 0.74) in terms of time precision in delivering messages. Messages' truthfulness was considered positively ($M = 3.5$, SD = 0.91), and system timeliness on dispatching message was even better ($M = 3.9$, SD = 1.09) and perceived adherence of patients (i.e. "METABO messages did not help me follow my medical prescription better than before") was also high ($M = 3.7$, SD = 1.10).

Acceptance was also measured with caregivers. Professionals found Control Panel functionalities highly useful ($M = 3.9$, SD = 0.94), in relation to monitoring patient's adherence and to adjusting remote feedback. Nonetheless, 35 % considered the system should inform them more actively about a problematic status or behaviour of a patient (system resoluteness with $M = 3.3$, SD = 1.12).

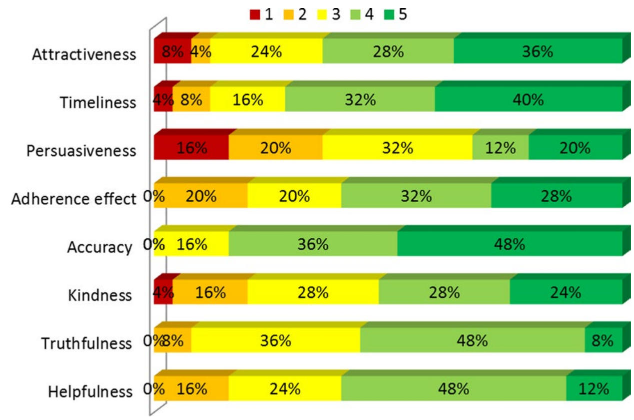

Fig. 4 Patient survey results

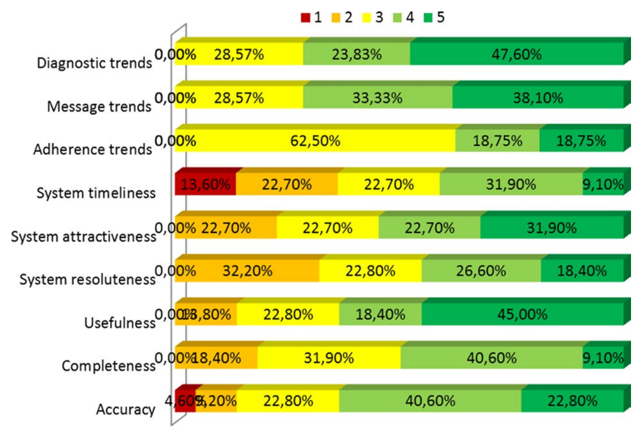

Fig. 5 Professional survey results

Accuracy ($M = 3.7$, SD = 1.08), completeness ($M = 3.4$, SD = 0.90), and usefulness ($M = 3.9$, SD = 0.94) were found high, indicating that dispatched information was correct, plausible and sent in a way that does not annoy physicians unnecessarily.

Results were also collected thanks to the log-files generated in the PMDs, the server and the CP and the entries of the data base. The messages sent to and from the METABO system and the log-files of the system and communication services were recorded over 4 weeks of the study. A total of 2,679 messages were submitted (2,591(L1) + 32(L2) + 56 (L3)), representing an average of 52 messages per patient. Information is detailed in Table 2.

As shown, all messages decrease over time indicating lesser warnings and reminders and an overall improvement of prescription adherence. With respect to tips and goal messages, the decreasing tendency indicates that some patients disabled these messages in the application's settings.

The average number of warnings (L1) per patient was 118.5 ± 32 for T1DM and 77.8 ± 15 for T2DM, while

Table 2 Number of messages sent during the trials

Type of message	Weeks 1–2	Weeks 3–4	Total
Warnings	1,423	1,168	2,591
Reminders	22	10	32
Tips and goals	38	18	56
Total	1,483	1,196	2,679

reminders (L2) was 12.4 ± 5 for T1DM and 20.8 ± 7 for T2DM. As expected, T1DM patients were more loaded with short-term advices, in accordance with their condition. Similarly, being the focus of type 2 on long-term sustainable lifestyle changes, T2DM received more recommendation advices, as for diet and physical activity.

Figure 6a, b shows the comparison of the adherence and usage indexes, both for T1DM and T2DM patients, between the first half and the second half of the trial.

In Fig. 6a, favourable outcomes are observed for usage: food intake (M =+4.39 %, SD = 28.06), blood glucose insertion measurements (M =+2.97 %, SD = 13.67), drug intake (M =+4.33 %, SD = 8.24 %), physical activity and education (M =+10.0 %, SD = 8.65; M =+12.89 %, SD = 6.26).

With respect to adherence, as it is possible to observe in Fig. 6b, results denote a general improvement on each prescription sub-group: food intake (M =+13.2 %, SD = 9.8), blood glucose insertion measurements (M =+5.5 %, SD = 3.76), drug intake (M =+7.85 %, SD = 16.98), physical activity (M =+5.32 %, SD = 17.21), and education (M =+10.0 %, SD = 8.65).

A complete analysis, summarized in Table 3, compares the difference (Δ) between Weeks 1–2 and Weeks 3–4 of the adherence and usage, in terms of mean (M), standard deviation (SD), minimum (min), maximum (max) and 95 % confidence interval (CI).

Even if some improvements, especially on adherences, can be considered small, these results have been reached during barely 1 month, revealing a high potential on the implemented methods.

In addition to the survey, the educational level has been measured for both control (CG) and intervention (MG) groups, in order to evaluate any improvements with respect to the diabetes's knowledge and self-management. Two quizzes of 22 questions were submitted before and after the pilot. The outcomes, shown in Table 4, indicate the intervention group has improved the mean of correct answers (M = +5.07 %, SD = 0.12), improving its level of knowledge, while the control group denotes a low decrease (M = −1.09 %, SD = 0.12).

Another result was derived from the analysis of the patient's diaries. Patients had to report the quantity of food intakes, the glycaemic measurements and the drug intakes

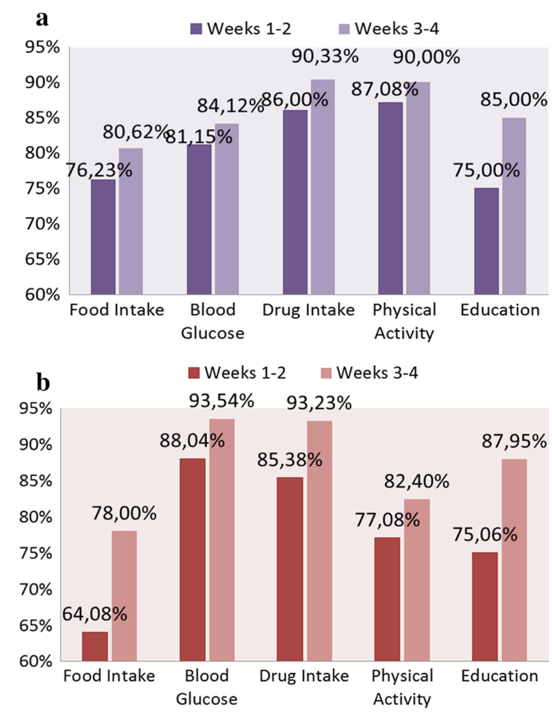

Fig. 6 **a** System usage during Weeks 1–2 and Weeks 3–4. **b** Prescription adherence during Weeks 1–2 and Weeks 3–4

Table 3 Statistical analysis of the number of messages during the trials

	M (%)	SD	Min	Max	CI
ΔAd_FI	13.2	9.8	20	70	3.77
ΔUsage_FI	4.39	28.06	−36	65	10.80
ΔAd_GL	5.5	3.76	−6	25	1.45
ΔUsage_GL	2.97	13.67	−30	40	5.25
ΔAd_DI	7.85	16.98	−20	80	6.53
ΔUsage_DI	4.33	8.24	−28	18	3.17
ΔAd_PA	5.32	17.21	−40	50	6.62
ΔUsage_PA	2.92	9.8	20	55	3.77
ΔAd_ED	12.89	6.26	−9	11	2.40
ΔUsage_ED	10.0	8.65	−3	36	3.33

Table 4 Analysis results from educational level quizzes for CG and MG

		CG	MG
V3-V0	M	−1.09 %	5.07 %
	SD	0.12	0.12
T test		7.28 %	

T test analysis reveals no significant differences between the groups ($p > 0.05$)

Table 5 Data input statistical analysis

	CG	MG	Diff.
Food intake			
M	77.86 %	92.13 %	14.26 %
SD	61.29	53.82	−7.47
Min	5.00	12.00	7.00
Max	251.00	186.00	−65.00
CI	25.61	21.53	−4.08
Glycaemic measurement			
M	81.50 %	88.21 %	6.71 %
SD	60.97	55.71	−5.26
Min	8.00	14.00	6.00
Max	258.00	186.00	−72.00
CI	25.48	22.29	−3.19
Drug intake			
M	73.73 %	151.75 %	78.02 %
SD	41.31	64.63	23.32
Min	8.00	8.00	0.00
Max	206.00	235.00	29.00
CI	17.26	25.86	8.59

daily. While CG inserted the data in a traditional diary, the intervention group MG used the PMD as a diary. The analysis reveals a significant inclination of the intervention group on storing its own data. Results are shown in Table 5.

4 Discussion and conclusions

The strategy of METABO platform was based on providing a continuous follow-up of clinician and lifestyle parameters, in the form of permanent feedback from system while minimizing caregivers' workload. We were interested in determining whether the system can lead to empower and engage patients to diabetes self-management. In order to achieve the mentioned goals, the diabetes mobile application needed to guarantee a robust service of all types of messages and be customizable according to the patient's profile and preferences.

With respect to the defined framework architecture, METABO platform includes some but not all the hypothesized technical features. More concretely, the automatic selection of messages based on the behavioural analyser had to be partially assisted by technicians because of some technical issues that were difficult to address in the 4 weeks of the trial. The system strategy was based on using methodologies that bring the patient to use these solutions endurably and to store the information according to the needs that the professional establishes together with them.

The clinical study offered the possibility to assess whether the usage of the framework results in some difference in terms of adherence outcomes, improved acceptance of technologies and diabetes-related quality of life aspects. The results of the feedback assistant presented so far within METABO have been encouraging in assessing health management in patients living environments, patients' engagement, adherence increase, and facilitated follow-up. However, a more extensive research will be conducted to establish a clear benefit of the proposed solution.

By using a day-to-day approach to help to understand more deeply patients' lifestyle and the challenges they come across and including their reactions with the system, the AE framework intervention can potentially provide a humanized approach to patient healthcare engagement.

Future updates will improve the implementation of the mentioned automatic functionalities and further trials should be conducted. Also a clinical trial with the use of AE functionalities, without physician intervention could be carried out. Moreover, these m-health solutions could be integrated with more automatized methods to provide feedback. A case could be the adoption of those non-invasive quantitative methods for the early detection of organ damages caused by metabolic syndrome, which have been proved to be suitable also in home monitoring applications, although for other cardiovascular disease [13, 17].

Additional investigation needs to be done correlating the technical results with the clinical and usability ones. Future research needs to provide results for longer periods of usage.

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