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ORIGINAL ARTICLE

PREDIRCAM eHealth Platform for Individualized Telemedical Assistance for Lifestyle Modification in the Treatment of Obesity, Diabetes, and Cardiometabolic Risk Prevention: A Pilot Study (PREDIRCAM 1)

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Abstract

Background:

Healthy diet and regular physical activity are powerful tools in reducing diabetes and cardiometabolic risk. Various international scientific and health organizations have advocated the use of new technologies to solve these problems. The PREDIRCAM project explores the contribution that a technological system could offer for the continuous monitoring of lifestyle habits and individualized treatment of obesity as well as cardiometabolic risk prevention.

Methods:

PREDIRCAM is a technological platform for patients and professionals designed to improve the effectiveness of lifestyle behavior modifications through the intensive use of the latest information and communication technologies. The platform consists of a web-based application providing communication interface with monitoring devices of physiological variables, application for monitoring dietary intake, *ad hoc* electronic medical records, different communication channels, and an intelligent notification system. A 2-week feasibility study was conducted in 15 volunteers to assess the viability of the platform.

Results:

The website received 244 visits (average time/session: 17 min 45 s). A total of 435 dietary intakes were recorded (average time for each intake registration, 4 min 42 s ± 2 min 30 s), 59 exercises were recorded in 20 heart rate monitor downloads, 43 topics were discussed through a forum, and 11 of the 15 volunteers expressed a favorable opinion toward the platform. Food intake recording was reported as the most laborious task. Ten of the volunteers considered long-term use of the platform to be feasible.

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Abbreviations: (EMR) electronic medical record, (HRM) heart rate monitor, (SMS) short messaging system

Keywords: cardiometabolic risk prevention, eHealth, lifestyle intervention, telemedical assistance, type 2 diabetes

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Abstract cont.

Conclusions:
The PREDIRCAM platform is technically ready for clinical evaluation. Training is required to use the platform and, in particular, for registration of dietary food intake.

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Introduction

There has been an ongoing trend toward obesity and an increasingly overweight population in all industrialized countries as well as in many low-income countries. In Europe, obesity is estimated to affect between 10% and 40% of the adult population[1] and has reached epidemic proportions, with more than 1 billion overweight adults worldwide and at least 300 million of those considered clinically obese.[2] Similarly, the same trend is observed in pediatric populations, where obesity prevalence is approximately 20% in Europe, reaching higher levels in the southern regions, especially in Italy.[3]

The socioeconomic situation in industrialized countries has exerted powerful influences on total caloric intake, composition of diets, and the frequency and intensity of physical activity at work, home, and during leisure time.[4]

There has been a growing interest in both prevention and early treatment of obesity not only in terms of health but also in terms of costs. Efforts to prevent obesity and metabolic syndrome and their complications through the use of pharmacological agents have produced poor results, owing to the overriding effects of changes in healthy living habits. Hence, the treatments are aimed at behavioral change and the promotion of a healthy lifestyle, with proper diet and regular physical activity as its main components.[5,6]

There is sufficient evidence concerning the association between obesity and different cardiovascular risk factors such as type 2 diabetes, hypertension, and dyslipidemia.[7] Moreover, diabetes, obesity, hyperlipidemia, and metabolic syndrome represent the greatest threat in terms of cardiovascular disease and mortality from a public health perspective. A healthy diet and regular physical activity are powerful tools in reducing diabetes and cardiometabolic risk.[8–14] Since the Declaration of Saint Vincent in 1998, the World Health Organization and various international scientific and health organizations have advocated the use of new technologies to solve these problems.[15]

While eHealth is progressing, it is clear that more research is needed to better determine how technology can be incorporated into programs to enhance behavior change outcomes.

The present work is part of the PREDIRCAM project, which aims to develop and validate an innovative eHealth platform for the treatment of obesity and the prevention of cardiometabolic risk. The PREDIRCAM platform includes the latest information and communication technologies and has been designed by a multidisciplinary team that includes endocrinologists, dietitians, engineers, nurses, cardiologists, psychiatrists, bioscientists, and physical trainers.

Among the specific objectives pursued by PREDIRCAM, the following can be mentioned: development of methods for ambulatory monitoring of physiological variables and lifestyle, development of electronic communication channels between patients and clinical staff, development of decision support systems for therapeutic intervention and lifestyle modification, development of tools that ensure quality in documentation and clinical records, and the design of protocols to analyze the potential positive results of a “real-life” implementation through clinical practice.

The PREDIRCAM project contemplates the development of a clinical trial aimed at testing if a technological platform is at least equally effective in improving behavioral changes as an intensive diet and physical exercise intervention program.[9] In this article, we present the architecture of this technological platform together with the results of a feasibility pilot study in which 15 volunteers not involved in the development of the platform participated for a period of 2 weeks. It is important to notice that the aim of this pilot was not to get results in terms of lifestyle modifications and their consequences; rather, the main objective was to assess the viability of the platform.

Materials and Methods

Technological Platform Architecture

The PREDIRCAM platform is composed of two main components: a web-based application and a heart rate monitor (HRM) for physical activity monitoring. The web-based application incorporates the following components:

- Front page: includes login system, language selection, and a summary of the latest information—news, next visit, new messages, new forum topics (see **Figure 1**).
- Electronic medical record (EMR): includes electronic forms to register clinical data and a manager to program and visualize clinical visits through a calendar. The EMR module is prepared to incorporate electronic records from different monitoring devices.
- Patient/visits manager: allows medical staff to create a patient profile and access patient data.
- Exercise module: includes a communication interface with a physical monitoring device as well as numerical and graphic tools to visualize exercise data.
- Dietary module: includes an innovative application to facilitate the laborious task of monitoring food intake and decision support tools to guide the user managing his/her diet.
- Communication module: includes a private messaging system and a public forum system between the users of the platform.

Figure 1. The PREDIRCAM platform front page.

- Notifications module: provides an automatic alarm system to notify both volunteers and clinical staff about possible events (there is feedback both positive and negative from the volunteers).
- Questionnaires: provide online questionnaires about personal traits and satisfaction with the use of the platform.
- Library: includes articles, recipes, and guidelines to follow a healthy lifestyle.

Implementation

The core of the web-based application has been implemented in Drupal™, a free, open-source content management system.[16] It is used as a backend system for many different types of websites, ranging from small personal blogs to web 2.0 collaboration and knowledge management systems used by large corporate and political sites. It is distributed under the GNU General Public License.

The exercise and notifications modules have been developed using JAVA^{TM} Applets. Both modules communicate with Drupal using the standard protocol XML-RPC.

Some of these modules have been implemented using, or adapting, core or third-party modules provided by Drupal (e.g., forums, private messaging, questionnaires, and library). However, the EMR module, the dietary module, the exercise module, and the notification module have been specially designed and implemented for the PREDIRCAM platform.

Multiple users with different roles are involved in the PREDIRCAM platform. These roles are patient, clinician, content manager, and administrator. To login to the platform, users have to introduce a unique user name and a password on the front page. Different functionalities and options are shown to the users depending on the user's role.

In order to guarantee data privacy, the permission system provided by Drupal is used. Furthermore, all data in the platform are anonymous. The study was approved by the local ethics committee (ethics approval number 08/107 EPI).

Electronic Medical Record Module

The EMR module contains all electronic forms for each programmed visit. Furthermore, it provides the following features:

- Automatic generation of electronic forms depending on the volunteer's randomization in the clinical trial,
- Visit programming and visualization using a calendar,
- Filtering of visit records according to different criteria (volunteer, past visits, and programmed visits), and
- Upload of electronic records from the monitoring device of physiological variables (e.g., arterial pressure monitor and bioimpedance monitor).

A system for logging all changes produced in the EMR is provided in order to meet EMR standards.[17] **Figure 2** shows two screenshots of the EMR module.

Dietary Module

Food intake monitoring is known to be a tedious task because it requires the laborious effort of registering every meal every day. Different approaches have been proposed to facilitate this task but usually to the detriment of the rigorousness regarding the nutritional estimations (e.g., 24 h recall).[18] In our work, we propose a relatively quick and easy method to register diet without impeding rigorousness.

The diet module includes the following components:

- Nutrition and Dietetics Higher Education Centre food database: a database with more than 6000 foods, mainly of the Mediterranean diet, with their nutritional information.[19] Furthermore, each food is accompanied by at least one picture with its associated mass or volume measure.

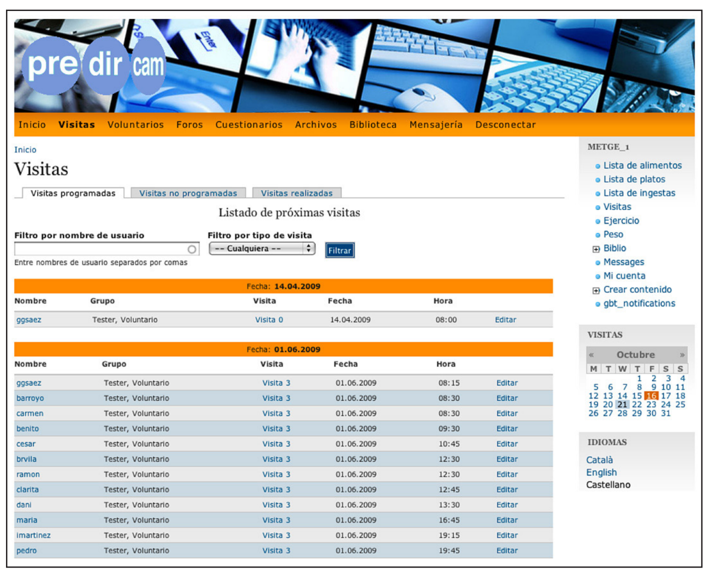

Figure 2. Screenshots of the EMR module showing the list of clinical visits for a particular subject.

- U.S. Department of Agriculture food database interface: allows automatic importation of foods from the U.S. Department of Agriculture food database.[20]

- Dishes database: a repository of common dishes of the Mediterranean diet, which can be directly used or easily edited.

- Registration interface: allows the user to enter the intake in an easy way. The interface is composed of the following components (see **Figure 3**):

    - List of dishes: list of dishes composing a selected meal.

    - Dish finder: a finder to look for predefined dishes as well as dishes previously introduced by the user. This includes notification that a dish is composed of a set of ingredients from a food database. If a selected dish is not equal to the ingested one, the system offers the possibility of editing the dish by adding or removing ingredients and changing their quantities. Finally, the user can decide if he/she wants to add the newly created dish to the database.

    - Dish creator: if a dish does not exist in the list of dishes, new dishes could be created.

    - Food finder: a finder to look for ingredients in the food database. When a food is selected, a set of pictures with their corresponding measures is showed to help the user choose the correct quantity.

    - Food warehouse: a practical way to guide users in how to follow a healthy diet. It consists of distributing the recommended weekly caloric intake into the different food groups (e.g., vegetables, fruits, meats). Then, through a bar graph, the user can track his/her intake and adjust the diet to it.

    - Macronutrients graph: shows the proportions of macronutrients (i.e., carbohydrates, protein, and fat) of the current diet and allows this to be compared with the prescribed one.

    - Personal assistant: informs the user about the diet via messages and gives advice on how to improve adherence to the prescribed dietary goals.

    - Intake list: provides summaries of the daily and weekly caloric intake and provides access to more specific information for each food item ingested.

    - Recipes list: provides a list of healthy recipes.

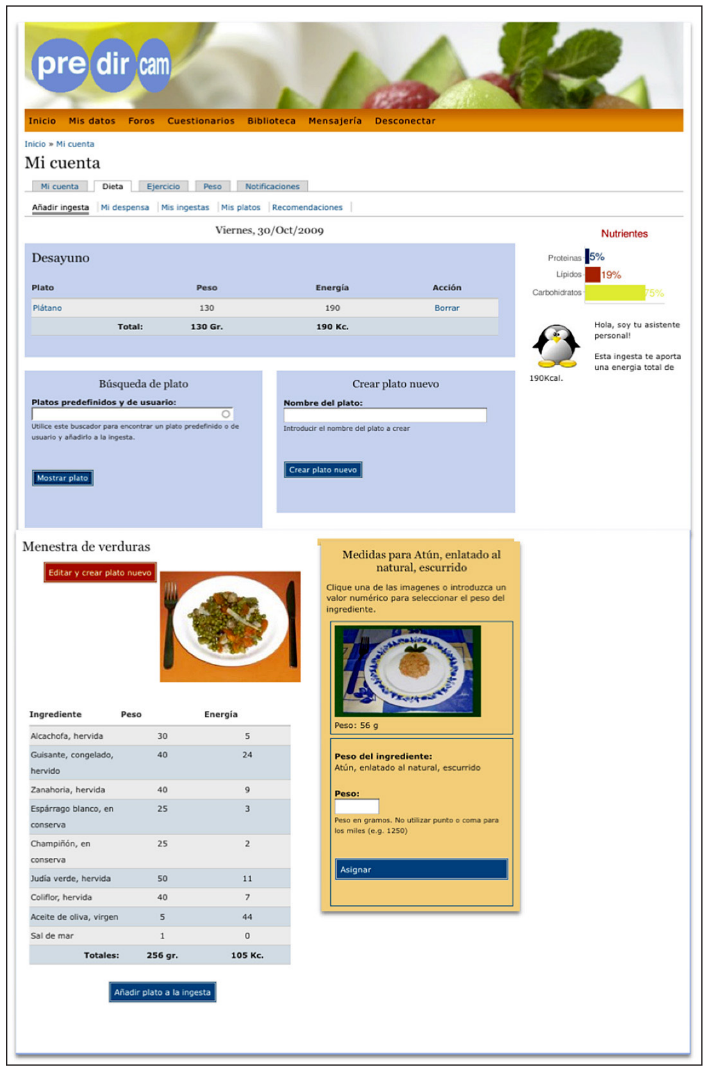

Figure 3. Registration interface of the diet module, including list of dishes, dish creator, food finder, food warehouse, macronutrients graph, personal assistant, ingestion list, and receipts list.

Exercise Module

The exercise module allows an easy and accurate monitoring of the physical exercise carried out by the patients using the platform.

Following an evaluation of different physical monitoring devices available on the market (Actiheart, SenseWear), we chose the RS400 HRM from POLAR^{TM}.[21] The information provided regarding physical activity (i.e., heart rate, duration, and energy expenditure) combined with its usability, communication interface, precision (Actiheart versus Polar), and economic cost makes it a suitable system for monitoring physical activity.

The exercise module is composed of the following components:

- An infrared communication interface: allows the data registered by the HRM to be uploaded to the web-based application through a built-in infrared port or a standard USB infrared reader device;
- A graphic interface: shows the information regarding the executed exercises (e.g., duration of activity and caloric expenditure). Using a calendar and a timeframe selection, it is possible to select the desired period to be visualized (see **Figure 4**);
- A graphic interface: compares the cumulative weekly caloric expenditure and the prescribed goal (**Figure 4**)
- In case of exercising without the HRM, the user can manually log the exercise by selecting the type of activity from a list (e.g., running, cycling) and introducing its duration.

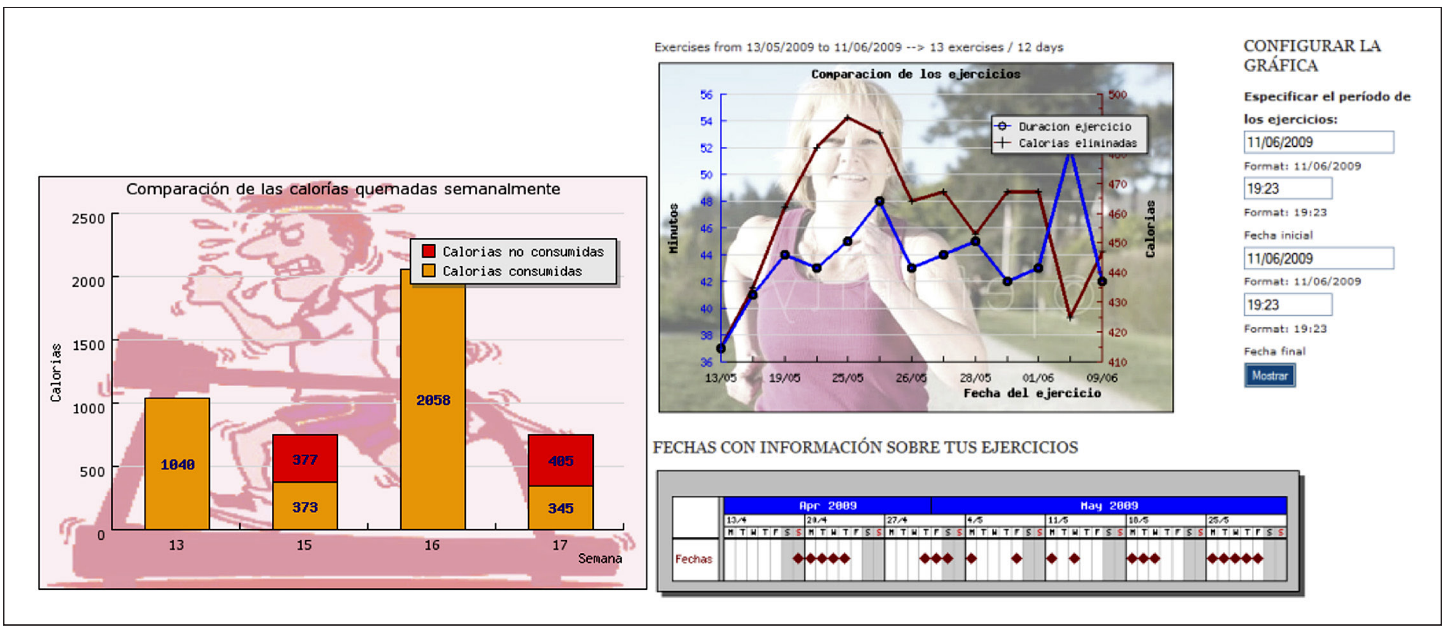

Figure 4. Left: weekly cumulative caloric expenditure (orange bar) and calories not expended with respect to the goal (red bar). Right: graphic visualization of information regarding the executed exercises (e.g., duration and caloric expenditure) and calendar showing the days when exercise was carried out.

Notification Module

The notifications module has two objectives: first, to notify the technical staff about patients' adherence to their prescribed therapy and, second, to notify the patients about their adherence to the individualized treatment. The notifications are shown to the technical staff through the web application, while patients can choose to receive the notifications via short messaging system (SMS) or via email.

Notifications are sent to patients under the following conditions: too infrequent access to the platform, failure to upload enough HRM data, too infrequent entry of food intake data, exceeding the prescribed caloric intake, not reaching the prescribed caloric expenditure, and successfully following the prescribed therapy.

Platform Usage Evaluation

To evaluate usage of the platform, we used data from our database as well as data from Google Analytics, a free web-based application that provides information about website traffic statistics.[22]

The studied parameters concerning platform usage were visits/volunteer/day, time/visit, pages/visit, number of food intakes introduced per day, HRM downloads and manually introduced exercises, automatic notifications sent by SMS and email, and the participation of volunteers in the internal forums.

Selection of the Participants

The feasibility study was conducted by 15 volunteers who were not involved in the development of the platform; some of them relatives of the personnel working on the development of the project. All of them had normal weight (body mass index between 18 and 25) and no important comorbidities (e.g., diabetes and hypertension).

Platform Usability Evaluation

To evaluate the usability of the platform, the participants were requested to complete a satisfaction questionnaire at the end of the pilot study. The questionnaire consists of different sections covering different aspects of the platform: experience with the platform, general impression, screens, user interaction with the platform, learning curve, capacity of the system, multimedia, evaluation of diet registration system, assessment of exercise registration system, evaluation of automatic notifications system, evaluation weight registration system, assessment of the homepage, questionnaires, and internal messaging system.

Results

Fifteen volunteers aged 38 ± 15 years with average skills on computer usage were recruited to carry out a feasibility study of the platform. The volunteers used the system for a period of 15 days. The main goal of this study was to debug, evaluate, and improve the functionality and usability of the platform and to evaluate the workload involved in collecting and analyzing data for both volunteers and expert staff.

Volunteers were asked to consult the home page regularly, record and visualize data for food intake and weight, download HRM and visualize the corresponding data, complete satisfaction questionnaires, respond to internal messages sent by clinicians, consult proposed readings on healthy habits, use the internal forums to report incidences, and receive notifications via SMS and emails.

The website received a total of 244 visits, representing an average of 16 visits per day or 1.1 visits per day per volunteer. The average time per session was 17 min 45 s. A total of 435 dietary intakes were recorded, which represents 23 ± 18 intakes per volunteer or 1.9 ± 1.2 intakes per volunteer per day. The approximate total time spent on diet registration was 2 h 12 min 37 s ± 1h 30 min 26 s and approximately 4 min 42 s ± 2 min 30 s for each intake.

With regard to HRM downloads, 59 exercises were registered on a total of 20 downloads at a rate of 1.7 ± 0.8 downloads per volunteer, 2.9 ± 1.4 exercises per download, and 9.8 ± 7.7 exercises per volunteer.

A total of 43 topics were discussed through the forum system (diet, exercise, and other), with more than 100 interventions.

Table 1 shows a summary of the satisfaction questionnaire completed by 87% of volunteers (n = 13).

Discussion

There was sufficient usage of the platform to enable conclusions to be drawn in preparation for a future clinical trial. It should also be taken into account that motivation among future clinical volunteers was likely to be generally high, as their health is involved (notice that volunteers involved in this pilot are healthy people).

Table 1.
Results of Questions from the Satisfaction Questionnaire

	Agree (%)	Partially agree (%)	Partially disagree (%)	Disagree (%)	Do not know (%)
The platform is pleasant (overall impression, user interaction, etc.).	0	76.9	23.1	0	0
Learning to use the platform is easy.	15.4	46.2	38.5	0	0
The system is reliable.	0	69.2	23.1	7.7	0
The food intakes registration process is easy and intuitive.	0	30.8	30.8	38.5	0
Availability of editable predefined dishes is useful.	61.5	15.4	15.4	7.7	0
The storage of personal dishes is useful.	76.9	23.1	0	0	0
The process of downloading data from the HRM is easy and intuitive.	15.4	46.2	15.4	0	23.1
Receiving notification messages related to my level of activity on the platform is useful.	46.2	30.8	7.7	7.7	7.7
Receiving messages of congratulations on the progress in my physical activity is motivating.	53.8	30.8	7.7	0	7.7
Receiving notifications of my activity on the platform induces my behavioral change.	38.5	38.5	7.7	0	15.4
I would recommend the use of the platform to a person who wants to improve his/her healthy lifestyle.	53.8	46.2	0	0	0
I think the continuous use of the platform for a period of 6 months or 1 year is feasible.	38.5	30.8	15.4	15.4	0

In subjectively assessing their general impression of the platform, a high number of volunteers expressed favorable results (11 of the 15 volunteers). Although food intake recording is a laborious process (volunteers spent 1 h 6 min 19 s ± 58 s per week on this task), it should be noted that 10 of the volunteers considered it feasible for the platform to be used over long periods of time (6 months or 1 year).

One goal of the future clinical trial is that clinical volunteers register at least three food intakes per day. In the pilot study, this number was lower (1.9 ± 1.2 intakes per volunteer per day), but it is still a positive result that could be substantially improved once personal motivation for a lifestyle change is involved.

Regarding the somewhat unfavorable rating of the food intake registration process, it is important to note that pilot volunteers had no previous training in the use of the application and that the process of logging dietary food intake is inherently laborious. Nevertheless, using predefined dishes and reusing the ones already created by the volunteers can significantly reduce this burden. However, these tasks require a prior learning process that probably was not sufficiently allowed for during the pilot.

The notification messaging system to provide user feedback was evaluated positively as a motivational tool (84.6%) and to induce behavioral changes (77%).

As such, we conclude that the platform is ready to be clinically evaluated, and in the next 2 years, a clinical trial will be conducted. The study population will be obese subjects (type 1 or type 2 diabetes) aged between 25 and 65 years with a 12-month follow-up. In this population, the study will analyze the cost-effectiveness of providing telemedical assistance with a technological system and its ability through the continuous monitoring of lifestyle habits and individualized treatment of obesity to reduce weight- and cardiovascular-risk-associated parameters. Efficacy and security variables will be evaluated throughout the study. This platform could provide a means to enable lifestyle modifications to take place more effectively in order to increase the adherence of the patients to schedules, maintaining changes in behavior over longer periods of time in order to prevent cardiometabolic risk (especially diabetes) associated with obesity.

Several projects and enterprises have emerged with the aim of developing products based on information and communication technologies that enable the prevention and better treatment of diseases like obesity and diabetes. Some examples of initiatives that may fit within the World Health Organization recommendations are SenseWear WMS,[23] HEALTH PLUS,[24] HyperFit,[25] Microsoft HealthVault,[26] and PACE project.[27] These systems vary in their scope and characteristics, dealing differently with levels of coverage, target population, and technological platform used. Despite the heterogeneity of these studies, it could be concluded that eHealth interventions to modify behavior are still in the preliminary stages of development and the potential of novel technologies to impact health behaviors is just beginning to be evaluated. Several studies have shown positive results related to short-term weigh loss through the continuous use of technology-based systems in subjects with obesity[28,29] and in those at risk to develop type 2 diabetes.[30] However, few studies address the efficacy of telemedicine in helping to maintain weight loss efficiently in the long term.[31–33]

The main goal of the PREDIRCAM clinical study is to enable the transfer of its positive results to real-life scenarios. This platform could provide a way of improving the effectiveness of lifestyle modifications to increase the adherence of the patients to schedules, to maintain behavioral changes over long periods, and to assist or cardiometabolic risk prevention (especially diabetes) associated with obesity.

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