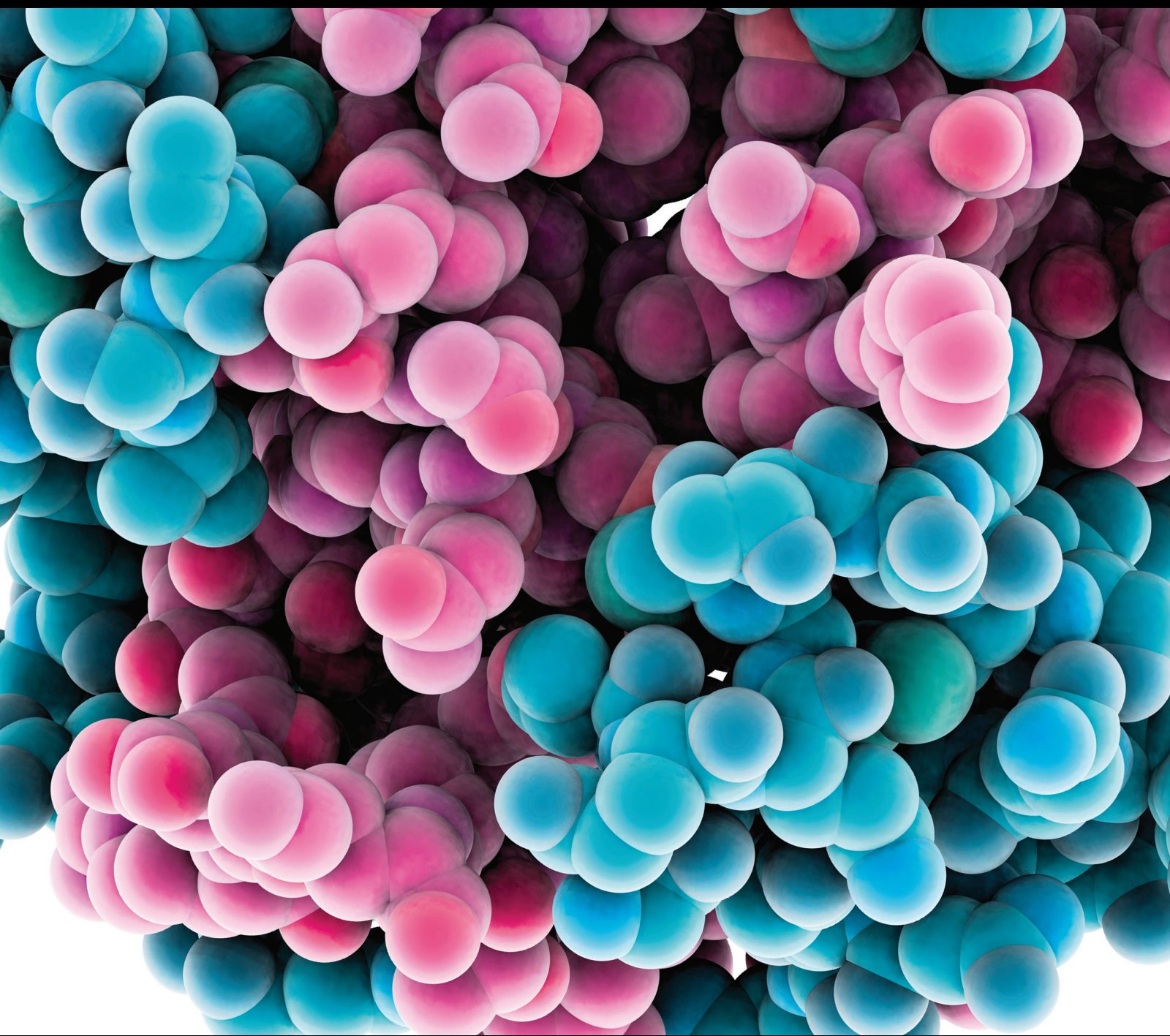
Journal of Diabetes Research

mHealth and eHealth for Obesity and Types 2 and 1 Diabetes

Guest Editors: Gianluca Castelnuovo, Giancarlo Mauri, and Kayo Waki



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Editorial Board

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Editorial

mHealth and eHealth for Obesity and Types 2 and 1 Diabetes

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Obesity and diabetes are universally recognized as multifactorial pathologies with a complex interaction between genetic, individual, and environmental factors. Clinical interventions, which typically focus on weight loss, reduction of obesity-related comorbidities, and change in dysfunctional behaviors, should be implemented in a multidisciplinary context with a clinical team composed of endocrinologists, nutritionists, dieticians, physiotherapists, psychiatrists, psychologists, and sometimes surgeons.

Significant limitations in the multidisciplinary chronic care management of obesity and diabetes concern costs and long-term adherence and compliance. mHealth (also m-health, mhealth, or mobile health) could be defined as the practice of medicine, public health, and clinical health psychology supported by mobile communication devices, such as mobile phones, tablet computers, PDAs, activity trackers, and other tools for health services and information. mHealth could be useful also for type 1 diabetes that often needs rigorous daily routines and an enduring self-management.

This issue features excellent articles, such as an interesting analysis of the opportunities of the activity monitors provided by M. Miyauchi et al. A. Booth et al. proposed a computer-based tool focused on self-management for people diagnosed with type 2 diabetes. Moreover, the important topic of patient engagement using new technologies is discussed by G. Graffigna et al. Opportunities of telemonitoring in the follow-up step of the weight reduction programs are provided by G. Stumm et al. Particular attention to usability issues in diabetes mHealth apps for the elderly is discussed by M. Isakovic et al. Finally the topics of personal health record and self-management support-coaching are proposed by M. van Vugt et al.

Care programs including the use of mHealth platforms and new technologies could overcome limitations connected to the traditional inpatient chronic care management by providing promising opportunities for enhancing weight reduction and reducing complications in terms of long-term efficacy and effectiveness across clinical, organizational, and economic perspectives.

New technologies can help clinicians and motivate patients in maintaining significant lifestyle behavior changes; improving health outcomes, quality of life, and well-being; and ensuring functional patient empowerment and engagement.

More research is needed, particularly in the cost-effectiveness field, where mHealth has to demonstrate its competitiveness in comparison with the traditional approaches.

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Research Article

Exercise Therapy for Management of Type 2 Diabetes Mellitus: Superior Efficacy of Activity Monitors over Pedometers

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We compared the efficacy of activity monitor (which displays exercise intensity and number of steps) versus that of pedometer in exercise therapy for patients with type 2 diabetes. The study subjects were divided into the activity monitor group ($n = 92$) and pedometer group ($n = 95$). The primary goal was improvement in hemoglobin A1c (HbA1c). The exercise target was set at 8,000 steps/day and 20 minutes of moderate-intensity exercise (≥3.5 metabolic equivalents). The activity monitor is equipped with a triple-axis accelerometer sensor capable of measuring medium-intensity walking duration, number of steps, walking distance, calorie consumption, and total calorie consumption. The pedometer counts the number of steps. Blood samples for laboratory tests were obtained during the visits. The first examination was conducted at the start of the study and repeated at 2 and 6 months. A significant difference in the decrease in HbA1c level was observed between the two groups at 2 months. The results suggest that the use of activity level monitor that displays information on exercise intensity, in addition to the number of steps, is useful in exercise therapy as it enhances the concept of exercise therapy and promotes lowering of HbA1c in diabetic patients.

1. Introduction

Diet and exercise therapy form the basis of treatment of type 2 diabetes mellitus (T2DM). These two approaches are well known to improve blood glucose control [1]. Exercise therapy has also been reported to be effective in improving blood glucose control and quality of life (QOL) [2, 3]. However, reduction of fat and improvement in insulin resistance are limited with diet modification alone [4].

As such, even while the effects of exercise therapy are well known, in reality, even when diet therapy is followed nearly by all patients, the percentage of patients who adhere to exercise therapy is only about 40% [5]. The reasons for this low rate are that exercise therapy is not easy to implement in patients with no physical training background, time restrictions, and inability to maintain motivation. Another reason is that the actual techniques and goals of exercise therapy are often difficult to understand by both the patient and the instructor.

Target indicators for exercise therapy include both the number of steps and strength [5], and moderate-intensity training is considered particularly effective. While 3–6 metabolic equivalents (METs) are proposed for exercise therapy of moderate intensity [5, 6], in actuality, checking the intensity level during training sessions is often difficult. For effective exercise therapy, the activity level should be appropriately increased by monitoring and being aware of the exercise intensity. Development of a simple and useful tool toward this end would help improve the outcome of treatment of T2DM. Using a conventional device that measures the number of steps (pedometer) and another device that measures the number of steps and exercise intensity and amount (activity monitor), the present study was designed to evaluate the effects of exercise therapy with awareness of training intensity with regard to improvement in blood glucose control.

2. Materials and Methods

2.1. Patients and Methods. The subjects were 200 adult patients with T2DM who visited our division at Tokai

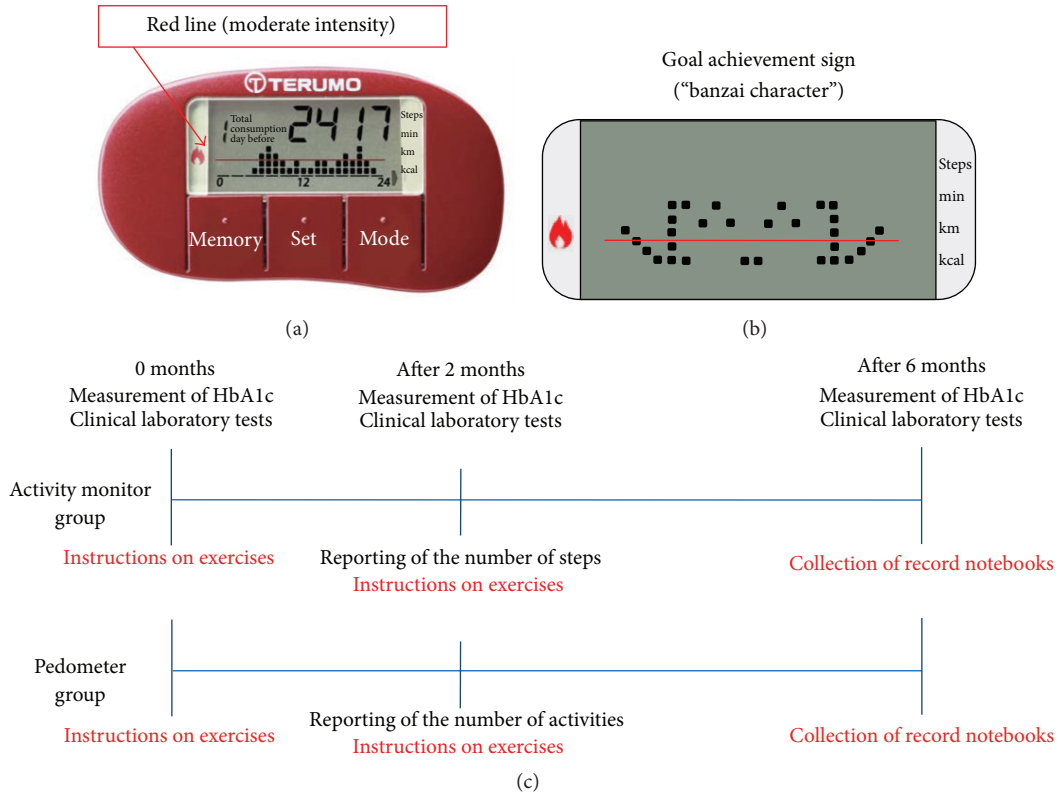

Figure 1: (a) On the activity monitor, for exercise of moderate intensity of 3 METs or higher, the intensity is displayed when the indicator exceeds the red line. (b) If the daily goal of moderate-intensity exercise of 20 minutes or longer and at least 8,000 steps is set and achieved, the user is notified that the goal has been achieved through a sign on the screen (a "banzai character"). (c) Study design.

University Hospital between March and April 2012 and were judged by their physicians as fit to receive exercise therapy. In addition, at the beginning of the study, the methods and purpose of the research and the voluntary nature of cooperation were explained verbally and in writing, and written agreement was obtained from all patients. This study was registered as a clinical trial (UMIN000018694), with the inspection and approval of the institutional review board for clinical research of Tokai University Hospital.

The number of steps and amount of physical activity were recorded digitally using an activity monitor (model MT-KT01, Terumo, Tokyo, Japan) with a triaxial speed sensor that measures the number of steps and the time spent walking at a moderate-intensity level. Another device, a modified MT-KT01, was used as a pedometer to count the number of steps during walking/exercise.

After randomly assigning 100 subjects each to the activity monitor group and the pedometer group, a target was set for the pedometer group, which was walking exercise of moderate intensity (3 METs or higher) for least 20 minutes a day and 8,000 steps. The same target of at least 3 METs (at or above the achievement line indicator in the activity monitor; Figure 1(a)) for a minimum of 20 minutes a day of exercise and 8,000 steps was also set for the activity monitor group. Both the pedometer and activity monitor were hung from a strap around the user's neck during waking hours.

The achievement of the target exercise was signaled by a display of the goal achievement sign (Figure 1(b)) on the activity monitor. The patients were asked to manually record the data of their activity monitor and pedometer in record sheets, which were collected during the outpatient visits. Clinical data measurements, including HbA1c level, were performed during the outpatient visits, with evaluation of the number of steps and target achievement ratio in the second month and final evaluation in the sixth month (Figure 1(c)).

Instructions were provided regarding the exercise on a pamphlet handed to each patient (Figure 2) at the beginning of the study. At 2 months after the start of training, the subjects were asked to report the number of steps and amount of exercise, as well as whether they had achieved the set targets. Those who self-reported that they had achieved the goals were instructed to continue, while those who had not done so were again provided information described in the pamphlet without any new intervention.

2.2. Statistical Analysis. The 187 patients who completed their 6-month follow-up were the subjects of the analysis (Figure 3). The pedometer and activity monitor data were compared, as well as changes in medications. Concerning continuation of exercise and achievement of targets, the analysis defined those with at least 80% of day count data and at least 80% of target exercise amounts as meeting the goals.

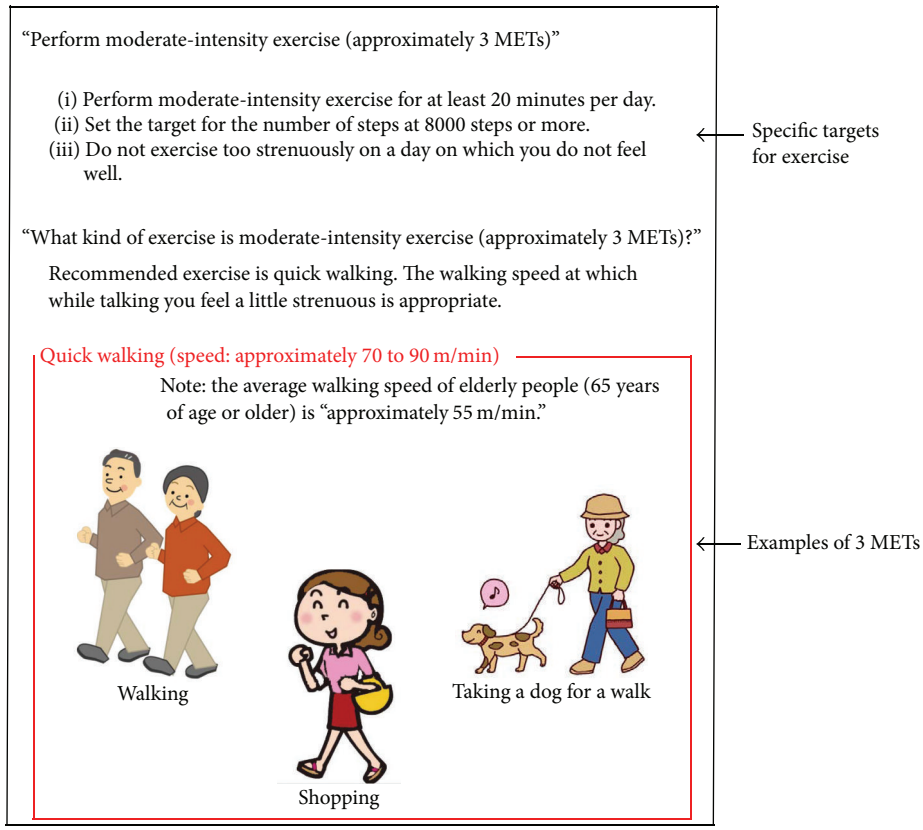

Figure 2: The explanatory pamphlet for exercise therapy. Examples of moderate-intensity exercises for the patients who participated in the study of both the activity monitor and the pedometer groups. The exercise goal of at least 20 minutes and 8,000 steps a day was based on the pamphlet.

Table 1: Clinical characteristics of the activity monitor group and pedometer group.

	Activity monitor group (n = 92)	Pedometer group (n = 95)	p value
Age (years)	62.7 ± 9.2	62 ± 10.6	0.97
Male	78.3%	56.8%	<0.005
Height (m)	1.63 ± 0.08	1.62 ± 0.09	0.12
Weight (kg)	72.6 ± 15.7	69.1 ± 15.4	0.11
BMI	27.2 ± 5.1	26.4 ± 5.4	0.21
HbA1c (%)	7.1 ± 1.1	7.0 ± 1.2	0.53
Systolic BP (mmHg)	122.8 ± 11.1	123.0 ± 10.9	0.98
Diastolic BP (mmHg)	70.9 ± 9.3	71.9 ± 9.5	0.79
UA (mg/dL)	6.0 ± 1.5	5.3 ± 1.3	<0.005
HDL cholesterol (mg/dL)	59.9 ± 17.2	60.9 ± 19.7	0.85
LDL cholesterol (mg/dL)	108.7 ± 24.9	112.0 ± 23.9	0.60
Triglycerides (mg/dL)	151.1 ± 103.8	138.3 ± 75.9	0.49

Values are mean ± SD.
BMI: body mass index; BP: blood pressure; UA: uric acid; HDL: high-density lipoprotein; LDL: low-density lipoprotein.

The HbA1c levels at the beginning of the study and at 2 and 6 months later were compared as main items by performing responsive examination. The Pearson chi-square test or Mann-Whitney U test was used for comparison of variables between the two groups, and the significance level was set at 5%. The statistical analysis software used was JMP Ver. 11.0.0 (SAS Institute Japan, Tokyo).

3. Results

3.1. Patients Background Characteristics and Changes in HbA1c Level. The clinical background data of the 187 patients who completed the 6-month follow-up are summarized in Table 1, and the delta changes in HbA1c level during the study are shown in Figure 4(a).

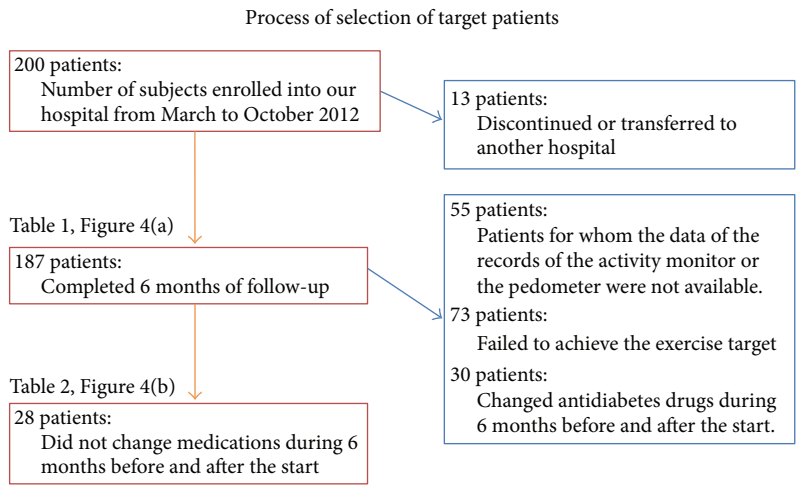

Figure 3: Patient selection process. After excluding those patients who cancelled, transferred to other hospitals, or dropped out, the data of 187 patients were subjected to analysis. After excluding patients with insufficient exercise therapy record data, unachieved exercise goals, and changes in medications in the 6 months before and after the start of the study period, data of 28 patients of each group were compared and studied.

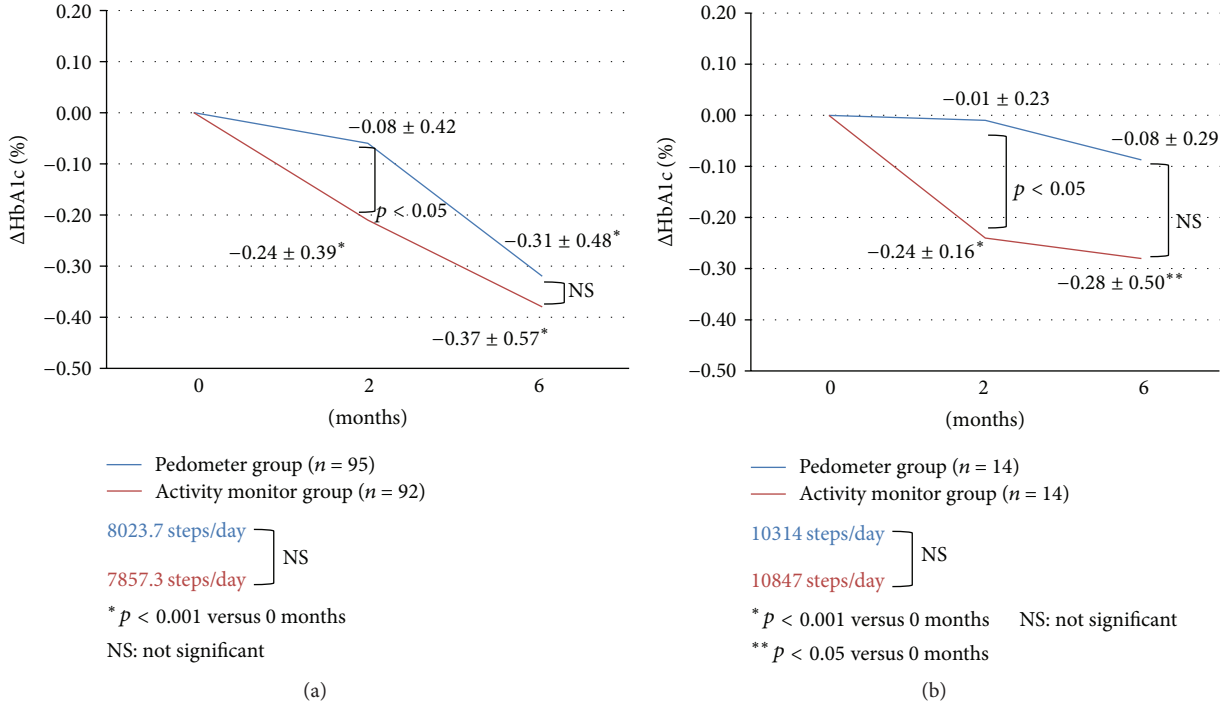

Figure 4: (a) Changes in HbA1c level after daily walking exercise for 2 and 6 months in the pedometer and activity monitor groups and all 187 patients. (b) Changes in HbA1c level after daily walking exercise for 2 and 6 months in 28 patients of the pedometer and activity monitor groups who achieved their goals and recorded no changes in medications throughout the study.

Based on the background characteristics of all the 187 patients, no clear difference was found between the two groups other than a significant preponderance of men in the activity monitor group and the value of uric acid in the blood being significantly low in the pedometer group (Table 1).

With regard to changes in HbA1c level, significant reductions in HbA1c level at 2 and 6 months after the start of the study were observed in the activity monitor group, compared to that before the start of study. Comparison of data of the two device groups showed a significant difference in the level of reduction in HbA1c level at 2 months between the pedometer and activity monitor groups (pedometer group: 0.08 ± 0.42%, activity monitor group: 0.24±0.39%). However, no significant difference was observed between the two groups at 6 months.

Changes in HbA1c at 2 and 6 months were also compared according to sex and uric acid level. There was no significant

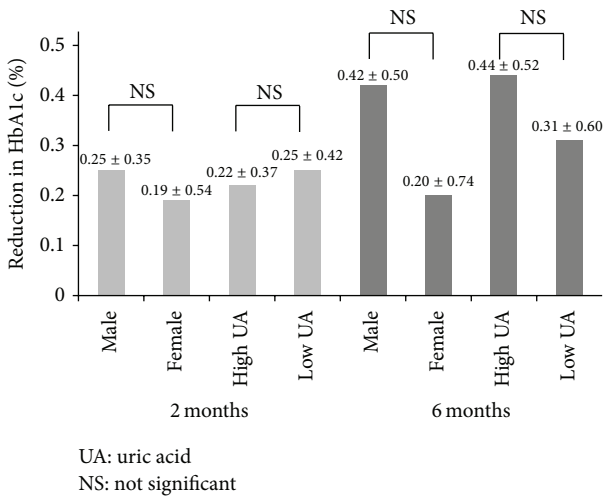

Figure 5: Comparison of the levels of reduction in HbA1c at 2 and 6 months according to sex and serum uric acid.

difference in HbA1c between males and females (Figure 5). After dividing the patients into those with high and low uric acid levels, using the median uric acid level as the cutoff value, we found no difference between the two groups (Figure 5).

Next, we excluded the data of 55 subjects with physical activity data less than 80% of those recorded at 6 months and 73 subjects with physical activity data less than 80% of the exercise target achievement rate. Thus, 59 patients continued the exercise therapy for 6 months, including 36 of the activity monitor group and 23 of the pedometer group. The continuation rate was 37.9% and 25.0%, respectively. The exercise therapy continuation rate of the activity monitor group was significantly better than that of the pedometer group ($p = 0.0282$).

Since no limitation was imposed in the present study on the use and changes in medications, the effects of the drugs were excluded. For meaningful analysis, however, we selected those patients in whom no changes in medications were made 6 months before and after the start of the study (i.e., for 1 year) and analyzed their data for the effects of exercise therapy only. The results showed that changes in HbA1c level purely due to exercise were noted in 14 subjects from each group (Figure 4(b)).

Significant reductions in HbA1c level from the time before to the time after the start of the study were observed in the activity monitor group but not in the pedometer group both at 2 and at 6 months. The decrease in HbA1c level at 2 months was significantly larger in the activity monitor group (0.24 ± 0.16%) compared with the pedometer group (0.01±0.23%). A similar trend was noted at 6 months, though the difference was not significant.

4. Discussion

The US guidelines recommend 150 minutes of exercise per week as appropriate exercise therapy. However, a recent study indicated that 90 minutes per month of low to moderate exercise is beneficial in Asians [7]. Thus, fast walking, which can be easily achieved on a daily basis, is considered moderately intense exercise in Asia. For this reason, this study was conducted by selecting walking exercise as the exercise therapy, which is considered the easiest to perform. This study was planned with a hypothesis that, as a resolution to the issue of "I do not have time to exercise," changing the daily activity itself to a level of moderate intensity is a sufficient exercise therapy, even if one just cannot take time to exercise, and that activity monitors have better results than pedometers as a measure of exercise efficacy.

The target activity was set in the present study at 3 METs, although moderately intensive exercise is effective in exercise therapy in T2DM patients [8]. Unconditionally speaking, even for moderate-intensity exercise, the exercise burden should be adjusted according to age. For those patients aged ≥ 65 years (constituting the majority of our patients and representing the majority of patients with T2DM in Japan), the 3-MET level is considered of moderate intensity [6]. We therefore set 3 METs and higher as the target activity in this study.

Our results showed reduction of HbA1c level in both groups when the patients of both groups exercised while being aware of the 3-MET target. These results confirmed that exercise therapy, at least for 6 months, contributed to the improvement in HbA1c in patients with T2DM. Furthermore, patients who wore the activity monitor, which provided feedback about their exercise intensity, also showed reduction in HbA1c level, which was significantly better at 2 months compared with the pedometer group. This difference was thought to be due to the motivation to exercise at a moderate level, combined with feedback from checking exercise intensity, with resultant more beneficial effects in the activity monitor group than the pedometer group. Considered together, these results suggest that the use of activity monitor seems to enhance the reduction in HbA1c level.

As shown in Figure 4(b), in the study that excluded the effects of medications, the decrease in HbA1c level was interestingly larger in the activity monitor group than in the pedometer group at both 2 and 6 months. This finding suggests that using an activity monitor is important in exercise therapy, as it provides information about exercise intensity, and that such monitor is particularly effective in the simple exercise therapy of walking as part of daily activities.

Furthermore, the most noteworthy result of this study was the difficulty of continuing the exercise therapy in the 6-month study period. Thus, the percentage of patients who continued exercise therapy for 6 months at ≥80% of the exercise therapy was less than 40% in both groups: 37.9% of the activity monitor group and 25.0% of the pedometer group, indicating the difficulty in continuing exercise therapy itself. Based on these results, we emphasize the need for motivating T2DM patients to continue exercise.

With regard to the provision of instructions or guidance to the patients regarding exercise therapy, in addition to its usefulness in maintaining motivation through the ability to recognize exercise intensity levels, even in patients who received instructions through the pamphlet only, checking that the target of 3 METs has been achieved during walking is useful in learning the appropriate walking speed.

Table 2: Clinical background of patients in whom medications were not changed throughout the study.

	Activity monitor group ($n = 14$)	Pedometer group ($n = 14$)	p value
Age (years)	65.8 ± 6.7	62.4 ± 9.9	0.58
Male	78.6%	71.4%	0.66
Height (m)	1.61 ± 0.08	1.63 ± 0.09	0.46
Weight (kg)	62.4 ± 12.7	68.3 ± 9.5	0.08
BMI	24.1 ± 4.0	25.9 ± 4.3	0.24
HbA1c (%)	6.6 ± 0.6	6.4 ± 0.9	0.27
Systolic BP (mmHg)	121.1 ± 10.8	121.6 ± 6.8	0.89
Diastolic BP (mmHg)	67.8 ± 8.1	73.5 ± 9.0	0.09
UA (mg/dL)	5.5 ± 1.6	5.6 ± 1.6	0.80
HDL cholesterol (mg/dL)	66.6 ± 18.7	60.3 ± 11.6	0.72
LDL cholesterol (mg/dL)	111.4 ± 34.9	103 ± 10.8	0.09
Triglycerides (mg/dL)	107.6 ± 59.7	127.1 ± 90.8	0.68

Values are mean ± SD.
BMI: body mass index; BP: blood pressure; UA: uric acid; HDL: high-density lipoprotein; LDL: low-density lipoprotein.

Therefore, this is possible not only by a physician but also through instruction provided by other medical staff. This demonstrates that the mere act of presenting exercise goals to patients before using activity monitors and incorporating moderate to high-level movement into their daily activities seemed to contribute to the efficacy of exercise therapy.

The present study has certain limitations. The reduction in HbA1c level at 6 months coincided with the summer season (from the fourth month after the start of the study). People tend to stay less outside for reasons such as to avoid heatstroke. Due to potential reduced physical activity and the effects of increased intake of glucose-rich sports drinks, further studies of longer duration are needed, especially studies that take seasonal variations into consideration. Table 1 shows that the percentage of males was significantly higher in the activity monitor group than in the pedometer group. This could contribute to selection bias. For this reason, we compared the extent of reduction in HbA1c at 2 and 6 months between males and females and between patients with high and low uric acid (Figure 5). We also analyzed background characteristics and HbA1c changes in 28 patients who did not change their medications during the 6-month period (Table 2). Another limitation of the present study is that it compared only the number of steps but not other parameters that could be used to evaluate whether the use of activity monitors actually increased the total amount of physical activity (e.g., walking duration, walking distance, and total calorie expenditure) in the two groups. Unfortunately, such data could not be stored in the pedometer device.

The only available explanation for the continuation of exercise by patients who did not achieve the exercise goals was the second explanation of the pamphlet provided during the consultation in the second month. However, it is difficult to say that this is completely the same as instructions given about exercise therapy in daily clinical consultation. Further studies are needed to select the best follow-up regimen and its relationship with the achievement of exercise targets in patients with T2DM.

5. Conclusions

We have demonstrated in the present study the importance of exercise therapy for patients with T2DM. The results showed that awareness of the level of exercise intensity through the use of an activity monitor that provides information about exercise intensity, not a pedometer, improved HbA1c level in the initial period of exercise. The results suggest that the use of devices with functions that allow verification of goal achievement in concrete terms contributes to the continuation of exercise therapy among patients.

Competing Interests

The authors declare no competing interests regarding this study.

Acknowledgments

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Research Article

Development and Evaluation of a Computer-Based, Self-Management Tool for People Recently Diagnosed with Type 2 Diabetes

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Aim. The purpose of this study was to develop and evaluate a computer-based, dietary, and physical activity self-management program for people recently diagnosed with type 2 diabetes. *Methods*. The computer-based program was developed in conjunction with the target group and evaluated in a 12-week randomised controlled trial (RCT). Participants were randomised to the intervention (computer-program) or control group (usual care). Primary outcomes were diabetes knowledge and goal setting (ADKnowl questionnaire, Diabetes Obstacles Questionnaire (DOQ)) measured at baseline and week 12. User feedback on the program was obtained via a questionnaire and focus groups. *Results*. Seventy participants completed the 12-week RCT (32 intervention, 38 control, mean age 59 (SD) years). After completion there was a significant between-group difference in the "knowledge and beliefs scale" of the DOQ. Two-thirds of the intervention group rated the program as either good or very good, 92% would recommend the program to others, and 96% agreed that the information within the program was clear and easy to understand. *Conclusions*. The computer-program resulted in a small but statistically significant improvement in diet-related knowledge and user satisfaction was high. With some further development, this computer-based educational tool may be a useful adjunct to diabetes self-management. This trial is registered with clinicaltrials.gov NCT number NCT00877851.

1. Introduction

In 2012, 21 million people in the USA [1] and 2.9 million people in the UK [2] had been diagnosed with diabetes, of whom 90–95% have type 2 diabetes. These rates are expected to increase by over 60% by 2025 [2, 3]. Diabetes is associated with an increased risk of cardiovascular disease and its risk factors including, hypertension, dyslipidemia (high blood cholesterol and triglycerides), and insulin resistance [4], all of which can be attenuated by lifestyle change [5]. Therefore, it is not surprising that diet and exercise are the cornerstones of the management of type 2 diabetes but these self-management aspects can be challenging for patients [6]. With 95% of type 2 diabetes management requiring self-care [7], continuous education is essential.

The UK National Service Framework for diabetes [8] states that "structured and ongoing education, and access to monitoring equipment are vital parts of diabetes care which empower people to effectively selfmanage [*sic*] their condition." National guidance recommends that structured

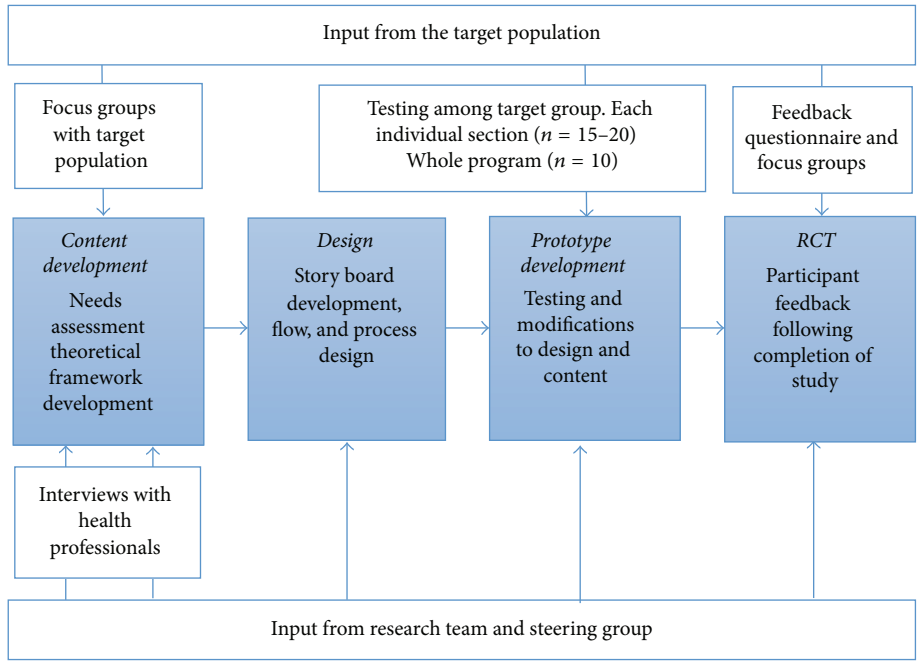

Figure 1: Development of the LWD program.

education should be an integral part of care planning; however its provision, particularly provision of tailored education, may be limited by access to trained educators and competing demands on healthcare staff. The UK Healthcare Commission (2007) reported that only 11% of people with type 2 diabetes had participated in any form of structured education, with attendance varying between 1% and 53% [9]. Opportunities exist to examine innovative approaches for delivery of education to people with diabetes, especially if such approaches can form a useful adjunct to the care offered by health care teams. According to Corben and Rosen (2005) [10], individuals with chronic diseases, including diabetes, are open to innovative health education methods and such individuals have stated that they would like information in as many formats and as early as possible after diagnosis. Computer-based tools represent one such approach that may help to support the diabetes education provided by health professionals. There is some evidence that the use of computer-based education can improve knowledge, motivation, and self-care behaviour in people with diabetes [11–15]. Modest improvements in blood glucose control are also evident [16]. In terms of priority areas for education, in a study of 245 people attending a diabetes clinic at a general hospital in the UK, the topic that respondents overwhelmingly wanted more information on was diet, followed by long-term complications and living a healthy lifestyle [17].

The aim of this study was to evaluate the effectiveness of a computer-based, dietary, and physical activity self-management program for people recently diagnosed with type 2 diabetes on knowledge, attitudes, skills (particularly goal setting), and behaviour.

2. Methods

2.1. Development of the Program. The program was developed based on existing theoretical frameworks and input from health professionals and the target population (Figure 1) (findings published elsewhere [6]). A qualitative study (structured interviews with health professionals and focus groups with patients) was conducted to gain insight into the issues that needed to be addressed by the program [6]. Overall, the LWD program focused on improving knowledge and addressing misconceptions and encourages self-monitoring of dietary intake and physical activity with goal setting used as a means of facilitating behaviour change. The central theoretical tenet for the development of the program was Bandura's self-efficacy theory [18]. Self-efficacy is recognised as one of the strongest predictors of health behaviour changes and is a component of the majority of psychological theories about behaviour change. A lack of knowledge has been identified as a factor limiting diabetes self-management [19] and as a barrier to behaviour change among people with type 2 diabetes [20]. Goal setting has shown promise for assisting with dietary and physical activity change [21, 22] and has been shown to be an effective behaviour change strategy among people with diabetes.

Five stand-alone sections of the program were developed: (1) A "food diary" allowed the user to record their food and drink intake, receive feedback on the balance of their diet, set goals, and save their data so they could revisit and review their goals. (2) A tailored "activity analyser" assessed current level of moderate and vigorous activity and provided feedback according to the users' stage of behaviour change [23] and

encouraged setting goals to help them meet physical activity recommendations. (3) The "fast facts" section contained information presented in a dictionary style and covered a range of topics related to type 2 diabetes, diet, and physical activity. (4) The "quick quiz" consisted of a series of quizzes each composing of 6 multiple choice questions, with immediate feedback, and was designed to allow individuals to assess their levels of knowledge on a range of topics and to address common misconceptions. (5) The "diabetes stories" section included short video clips of three people with type 2 diabetes talking about their experiences of managing their diabetes.

The development process is outlined in Figure 1. A prototype version of each section of the LWD program was developed and each section was then tested (with exception of the diabetes stories section which was not tested owing to time restrictions) by 15–20 participants who had diabetes and the research team. The individual sections were modified based on the feedback from testing and a complete version of the LWD program was compiled. This complete version was tested with 10 patients in order to examine overall ease of use and navigation. Some further minor modifications were made based on feedback from this testing and a full working version was produced for evaluation in the RCT described below.

2.2. Evaluation of the Program, a RCT

2.2.1. Recruitment. Ethical approval for the RCT was obtained from the Office of Research Ethics Committees Northern Ireland (ORECNI). Participants were invited to participate from primary care settings in the Belfast area as well as within the Regional Centre for Endocrinology and Diabetes, Royal Group of Hospitals, Belfast. Inclusion criteria were diagnosis of type 2 diabetes within the previous 24 months, access to a computer, and being stable on medication (i.e., no change in medications for the past 2 months). The exclusion criteria were being pregnant or lactating and having a medical condition where changes in diet or physical activity would be contraindicated.

2.2.2. Study Design. The study was registered on ClinicalTrials.gov identifier NCT00877851. After obtaining informed consent, participants were randomised to either the intervention group or the control group. The computer generated randomisation schedule was implemented using consecutively numbered envelopes and was stratified by recruitment site.

The intervention group received the "Life with Diabetes" program on an external hard drive (a USB stick) in order to allow setting, saving, and reviewing goals. Participants received a brief, 10-minute overview of the program and were asked to use the LWD program for 12 weeks. As a minimum level of usage, participants were encouraged to use the two self-monitoring and goal setting aspects of LWD (i.e., the food diary and activity analyser) at least once a week. Participants received a 2-3-minute phone call from the researcher (AB) at around week 4 and week 8 to answer any questions they had about the program and to encourage continued and regular usage. Participants were asked to keep a log detailing their usage of the program (date, length of time, sections used, and additional comments) throughout the intervention period. The control group received a list of useful web site addresses including Diabetes UK and were advised to continue with their usual care, consulting their health care team as they would usually do, for 12 weeks. The control group received the LWD program after completion of the 12-week study.

2.2.3. Primary and Secondary Endpoints. Primary endpoint was between-group differences in diabetes knowledge and setting and achieving goals. Secondary endpoint was between-group differences in dietary intake, physical activity levels, anthropometry, markers of cardiovascular risk (including blood pressure, lipids (HDL, LDL, triglycerides)), blood glucose control (HbA1c, fasting blood glucose), overall self-efficacy, and barriers to the management of diabetes.

2.2.4. Measurements. A baseline questionnaire recorded demographics, frequency and location of computer use, details of diabetes including month/year of diagnosis, current medications, whether participants had attended a group education session after diagnosis, where they received dietary information from, whether they had met with a dietitian, and if they had ever been advised on food intake and/or exercise by a health care provider.

2.2.5. Anthropometric, Clinical, and Biochemical Measurements. The following were assessed at baseline and completion: weight was measured, without shoes and outdoor clothing and after removal of heavy pocket items such as wallets and keys, on a calibrated scales. Weight was recorded in kilograms to the nearest 0.5 Kg. Height was measured without shoes on a stadiometer and was recorded in centimeters to the nearest 0.1 cm. BMI was calculated from weight and height [weight (Kg)/(height (m))^2]. Waist and hip circumference were measured over light clothing using an inelastic but flexible tape measure. Waist was measured at the midway point between the iliac crest and lower rib. Hip circumference was measured at the widest point around the gluteal protrusion. Blood pressure was measured twice from the right arm, using an automated Omron sphygmomanometer with the participant sitting quietly for at least five minutes. A 20 mL fasting blood sample was drawn from the antecubital vein and was processed within 2 hours. All samples were stored at −70°C for batch analysis at the end of the study. Dietary intake was assessed by 4-day food diary. Physical activity was assessed using the International Physical Activity Questionnaire [24].

2.2.6. Other Questionnaires. Knowledge of type 2 diabetes was examined using a shortened version of the validated Audit of Diabetes Knowledge questionnaire [25]. Scores are represented as percentage correct. Self-efficacy was examined using the validated Diabetes Empowerment Scale [26] with three validated subscales (managing the psychosocial aspects of diabetes, assessing dissatisfaction and readiness to change, and setting and achieving diabetes goals); each question is rated on a 5-point scale from strongly agree [5] to strongly

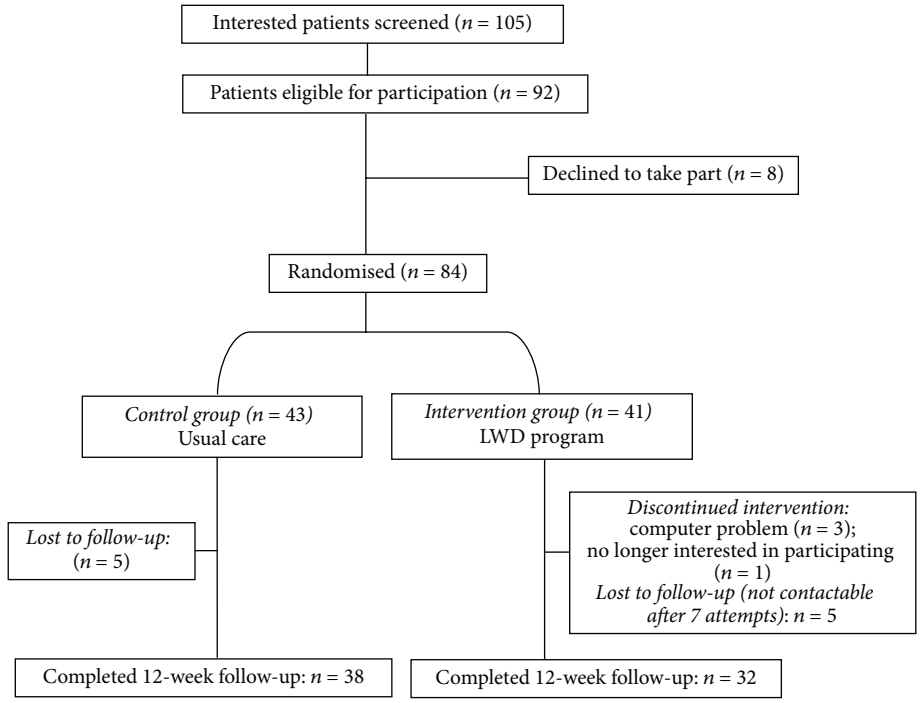

Figure 2: Flow of participants through the RCT.

disagree [1]. Barriers were assessed using a modified version of the validated Diabetes Obstacles Questionnaire (DOQ) [27]. Eleven additional statements were included that covered barriers and beliefs identified during focus group disucssions with the target populations during the development phase of this project. Each question is rated on a 5-point scale from strongly agree [1] to strongly disagree [5]. Diabetes-specific quality of life was measured using the validated Audit of Diabetes-Dependent Quality of Life [28]. Scoring ranges from −9 (maximum negative impact of diabetes) to +3 (maximum positive impact of diabetes). Generic quality of life was measured using the validated 36-item short-form health survey (SF36) [29]. Scoring ranged from 0 (lowest level of quality of life) to 100 (highest level of quality of life). Depression was evaluated using the validated, brief, 9-item Patient Health Questionnaire (PHQ-9) [30]. Depression Severity was as follows: 0–4 = none; 5–9 = mild depression; 10–14 = moderate depression; 15–19 = moderately severe depression; 20–27 = severe depression.

2.2.7. Evaluation of the "Life with Diabetes" Program. At the end of the study, all participants in the intervention group completed a program evaluation questionnaire and were asked to participate in an optional focus group discussion. The aim of the focus groups was to gain some further in-depth feedback on the program. Focus group discussions were tape recorded and transcribed verbatim.

2.3. Statistical Analyses. Statistical analysis was carried out using SPSS for Windows, version 16 (SPSS Inc., Chicago, IL). A P value ≤ 0.05 was considered to be statistically significant. Data was examined for normality of distribution and no transformation of the data was necessary. Baseline characteristics between groups were compared using an independent samples t-test for continuous variables and a chi-square test for categorical variables where appropriate. Analysis of covariance (ANCOVA) was used to examine the effect of the intervention. In such analyses the 2 groups (intervention or control) were included as independent variables, and the baseline values were included as covariates. Paired samples t-tests were used to examine within-group changes in the study outcomes. Response to intervention was examined according to level of usage as a secondary analysis. Wilcoxon signed ranks test assessed movement between physical activity rankings (e.g., from low to moderate or high to moderate activity level). Pearson chi-square assessed differences between groups in change in activity rankings. As an additional analysis, the intervention group was split into "high users" and "low users" according to the LWD log books; those who reported using the program at least 12 times during the 12-week study were classified as "*high/normal users*"; those who reported using the program less than 12 times during the 12-week study and those who did not return a log book were classified as "*low users.*" ANCOVA was used to compare the outcomes of high versus low users.

3. Results

3.1. Sample. Figure 2 shows the flow of participants through the RCT. One hundred and eight people expressed interest in the study. Of these, 105 were screened (3 were not contactable after a minimum of 6 attempts), 92 were eligible to participate, eight individuals declined to participate before randomisation took place, and 84 were randomised (41 intervention, 43

Table 1: Baseline characteristics of participants randomly assigned to intervention and control group.

	Control ($n = 43$)	Intervention ($n = 41$)
Age (years) (mean (SD))	60 (10.7)	58 (9.1)
Female gender, % (n)	37 (16)	46 (19)
Married or living with partner, % (n)	79 (34)	76 (31)
Employment status, % (n)	—	—
Employed full time	33 (14)	32 (13)
Employed part time	14 (6)	12 (5)
Retired	40 (17)	34 (14)
Education % (n)	—	—
Secondary level	33 (14)	49 (20)
College	16 (7)	7 (3)
University	44 (19)	39 (16)
Ever been to a group education session, yes (%)	26 (11)	51 (21)
Visited a dietitian since diagnosis, yes (%)	65 (28)	73 (30)
Taking medication for diabetes, yes (%)	42 (18)	49 (20)
Taking insulin for diabetes, yes (%)	9 (4)	5 (2)
Weight (Kg) (mean (SD))	90.4 (15.1)	91.6 (15.3)
BMI (Kg/m^2) (mean (SD))	31.7 (4.9)	32.0 (5.4)
Waist circumference (cm) (mean (SD))	109.8 (11.5)	110.1 (10.7)
Hip circumference (cm) (mean (SD))	115.6 (10.2)	115.0 (11.2)
Waist to hip ratio ((waist cm)/hip (cm)) (mean (SD))	0.95 (0.07)	0.96 (0.06)
Systolic blood pressure (mmHg) (mean (SD))	136 (15.0)	136 (16.0)
Diastolic blood pressure (mmHg) (mean (SD))	82 (9.0)	86 (8.9)

control). Seventy participants (84.5%) completed the 12-week study ($n = 32$ out of 41 (78%) intervention group; $n = 38$ out of 43 (88%) control group). Baseline characteristics of all participants are presented in Table 1.

3.2. Primary Outcomes. There was no between-group difference in overall ADKnowl score from baseline to postintervention (Table 2) and no statistically significant improvement in the "diet and food scale" of the ADKnowl questionnaire in the intervention group compared to the control group ($P = 0.09$). There was also no significant between-group difference in the "setting and achieving goals" subscale of the DES5 on completion of the intervention.

3.3. Secondary Outcomes. There was a significant between-group difference in the "knowledge and beliefs scale" of the DOQ, with an improvement in the "knowledge and beliefs scale" in the intervention group, compared to the control group (mean (SD) 3.5 (1.0) versus 3.3 (0.6), resp.). There were no significant differences between groups after adjusting for baseline variables, for diabetes-specific quality of life (ADDQoL), depression (PHQ-9), or any of the anthropometric measurements or blood parameters shown in Table 3 after the intervention.

Overall there was no significant between-group change in dietary intake during the intervention (Table 4). There was a trend towards a between-group difference in carbohydrate intake, with intake decreasing in the intervention group and increasing in the control group (mean difference $P = 0.058$).

There was a trend for more people in the intervention group to change their category of physical activity in a positive way (moving from low to high, low to medium, or medium to high) during the intervention, with 33% of participants in the control group moving positively between categories compared to 22% of the control group. Figures for changing category of physical activity in a negative way (moving from high level of activity to medium level of activity, high to low, or medium to low) were 5% for intervention group and 16% for the control group. Overall, however, there was no significant difference between groups in change in physical activity over time.

3.4. "High" or "Low" Users Compared with Control Group. For the ADKnowl treatment subscale, there was a significant difference between the high users (62% correct) and control group (42% correct) at week 12 ($P = 0.032$ after adjusting for baseline values) but no difference between the low users (53%) and control (42%), $P = 0.347$. For the DOQ, the advice and support scale, there was also a difference between the high users (4.1 (SE) (0.5)) and control group (3.7 (0.6)) ($P < 0.01$ after adjusting for baseline values), but not between the low users (3.5 (0.7)) and control group (3.7 (0.6); $P = 0.98$). Both the high and low user groups scored higher on the "knowledge and beliefs scale" of the DOQ compared to the control group over the 12 weeks (3.7 (0.8), 3.6 (1.1), and 3.3 (0.6), $P < 0.05$ after adjusting for baseline values). There were no other statistically significant differences between the high users, low users, and the control group for any of the other parameters.

4. Participant Evaluation of the "Life with Diabetes" Program

4.1. Evaluation Questionnaire. All participants in the intervention group completed the evaluation questionnaire. A third of participants rated the overall program as "very good," half of the participants rated the overall program as "good," and 16% rated it as "acceptable." Ninety-two percent would recommend the program to others. Ninety-six percent of participants agreed that the information within the program was clear and easy to understand. Eighty-eight percent agreed that the program was easy to navigate. Some additional free text comments were included in the free text element of the questionnaire: "very encouraging," "thought it was great," "very helpful," and "motivating."

Table 2: Primary and secondary outcomes: pre- and postintervention questionnaire data according to randomisation.

	Control		Intervention		Mean difference (CI)	P^
	Baseline $n = 38$	Week 12 $n = 38$	Baseline $n = 32$	Week 12 $n = 32$		
Primary outcomes						
ADKnowl: overall score[a]	60 (14.3)	64 (14.2)	62 (13.8)	67 (10.4)	1.7 (−1.7, 5.1)	0.37
ADKnowl: diet and food (item-set 10, 11, 12)[a]	59 (16.0)	60 (18.4)	62 (17.4)	67 (15.8)*	5.1 (−0.9, 11.1)	0.09
ADKnowl: effects of physical activity (item-set 8, 9)[a]	40 (26.7)	42 (27.3)	41 (26.2)	47 (24.5)	5.2 (−2.9, 13.4)	0.31
ADKnowl: reducing the risk of complications (item-set 1, 15, 16, 17)[a]	88 (13.1)	89 (12.6)	89 (12.2)	89 (10.4)	−0.7 (−5, 3.6)	0.76
DES5: setting and achieving goals (items 5–14)[a]	3.8 (0.5)	3.8 (0.6)	3.6 (0.8)	3.8 (0.5)	0 (−.29, .29)	0.99
Secondary outcomes						
Diabetes obstacles questionnaire (knowledge and beliefs scale)[b]	3.4 (0.5)	3.3 (0.6)	3.1 (0.6)	3.5 (1.0)*	0.4 (0.1, 0.7)	**0.01**
ADDQoL: average weighted impact score[c]	−0.9 (1.0)	−0.6 (0.8)	−1.2 (1.3)	−1.0 (1.3)	−0.3 (−0.7, 0.2)	0.28
PHQ-9: overall score[d]	6.2 (5.9)	5.3 (4.7)	8.3 (7.9)	8.0 (8.1)	3.4 (−0.2, 6.7)	0.15
SF36 health survey: overall score	60 (23.8)	69 (18.0)	63 (27.9)	63 (30.4)	−4.8 (−10.4, 0.7)	0.09
SF36 health survey: mental health	69 (20.5)	70 (17.0)	65 (24.1)	61 (28.7)	−4.7 (−10.8, 1.4)	0.90
SF36 health survey: physical health	55 (25.2)	61 (18.4)	61 (26.8)	60 (29.5)	−3.9 (−9.0, 1.0)	0.12
SF36 health survey subscale: physical function	62 (31.1)	68 (26.9)	73 (29.7)	73 (31.9)	−0.6 (−7.7, 6.4)	0.86
SF36 health survey subscale: role limitations due to physical health	54 (44.4)	72 (38.6)	66 (44.2)	61 (47.1)	−14.9 (−29.3, −0.6)	**0.04**
SF36 health survey subscale: general health	53 (23.4)	58 (18.1)	55 (26.3)	55 (27)	−1.7 (−8.3, 4.8)	0.59
SF36 health survey subscale: vitality	48 (22.9)	52 (21.1)	51 (24.5)	51 (24.6)	−1.6 (−8.5, 5.3)	0.65
SF36 health survey subscale: social functioning	73 (28)	87 (20.1)	74 (31.7)	73 (34.7)	−12.2 (−20.8, −3.6)	**0.006**
SF36 health survey subscale: role limitations due to mental health	64 (41.8)	81 (36.5)	60 (46.7)	62 (48.2)	−11.7 (−28.5, 5.1)	0.17

[a]Percent of items correct (SD).
[b]Diabetes Empowerment Scale, scored from 1 to 5; a lower score indicates greater goal setting ability/confidence.
[c]Scored from −9 (maximum negative impact) to +9 (maximum positive impact).
[d]Patient Health Questionnaire (depression) score; a higher score indicates higher severity of depression.
^P value, between-group comparison at week 12, adjusted for baseline (ANCOVA).
*Within group change, $P < 0.05$ (paired samples t-test).

4.2. Focus Groups. Two focus groups were held, each with four participants. All focus group participants had positive views of the program. Many found the program "very motivating," "excellent," "very useful," and "very helpful" and stated that they felt it would keep them "focused and determined" and that it was "easy to use." They agreed that the format of the program (memory stick) was "handy" because of "the sheer ease of access." Participants also highlighted that while they find visiting a dietitian to be helpful, they appreciated being able to expand on those sessions by referring back to the program as they wished: "you're aware it's always with you when your dietitian's not" and "sitting for half an hour with the dietitian doesn't really help you much as having that food diary."

In addition to being the most highly rated section, the food diary was the most frequently discussed section. The food diary appeared to alert participants to healthier eating and areas of their diet they could improve. For example, "you think you're eating very healthily and all of a sudden you realize you're not," "it made me see that I was actually missing out on some things," and "it made me very alert to healthier eating." There were some indications of attempts at making dietary changes. For example, "you think next time I'll have like beans or peas with this," "trying to get a better balanced diet," or "tying to eat fewer biscuits." However, some admitted that they stuck to their traditional diets out of habit or a lack of motivation: "I'll eat the vegetables. Butter is my downfall" and "my diet isn't varied – hasn't changed for many years so I didn't change . . . I take the blame for that."

Table 3: Secondary outcomes: anthropometric and blood parameters before and after intervention[1] according to randomisation.

	Control		Intervention		P^*
	Week 0 $n = 38$	Week 12 $n = 38$	Week 0 $n = 32$	Week 12 $n = 32$	
Weight (Kg)	89.4 (14.9)	89.4 (14.7)	89.4 (13.7)	89.8 (13.8)	0.47
BMI (Kg/m^2)	31.3 (4.6)	31.3 (4.5)	31.3 (5.1)	31.4 (5.0)	0.81
Waist circumference (cm)	109.0 (11.7)	108.5 (11.6)	108.4 (10.1)	107.5 (9.8)	0.56
Hip circumference (cm)	114.9 (8.9)	114.3 (8.8)	114.2 (10.5)	114.4 (11.2)	0.47
Waist: hip	0.95 (0.07)	0.95 (0.07)	0.95 (0.06)	0.92 (0.16)	0.16
Systolic blood pressure (mm/Hg)	137 (15.2)	137 (15.1)	137 (14.9)	138 (14.2)	0.89
Diastolic blood pressure (mm/Hg)	82 (8.5)	83 (8.6)	85 (7.4)	85 (9.2)	0.83
Total cholesterol (mmol/L)	4.3 (1.2)	4.2 (1.0)	4.4 (1.07)	4.3 (0.96)	0.52
HDL cholesterol (mmol/L)	1.2 (0.27)	1.2 (0.33)	1.2 (0.32)	1.2 (0.30)	0.75
Calculated LDL cholesterol (mmol/L)	2.3 (0.97)	2.1 (0.91)	2.4 (0.93)	2.2 (0.77)	0.66
Triglycerides (mmol/L)	1.9 (0.70)	1.9 (1.04)	1.7 (0.75)	1.9 (0.94)	0.36
HbA1c (DCCT%)	6.4 (1.1)	6.5 (1.1)	6.4 (0.9)	6.4 (0.8)	0.94
Fasting glucose (mmol/L)	8.2 (2.5)	8.1 (2.3)	7.7 (1.8)	8.3 (1.9)	0.12
Insulin (mU/L)	12.8 (7.9)	16.2 (14.9)	15.4 (13.8)	19.8 (25.1)	0.43

[1]Data given as mean (standard deviation).
*Between groups at week 12 after controlling for baseline (one-way ANCOVA).

Table 4: Pre- and postintervention nutrient intake according to randomisation[1].

	Control		Intervention		Mean difference (CI)	P value*
	Baseline	Week 12	Baseline	Week 12		
Energy (Kcal)	1626.8 (494.0)	1697.2 (592.6)	1858.5 (453.6)	1804.7 (429.4)	28.8 (−257, 314)	0.841
Fat (% total energy)	33.3 (4.8)	30.6 (5.8)	31.6 (7.1)	33.0 (6.9)	2.1 (−1.0, 5.3)	0.182
Protein (% energy)	19.0 (3.5)	18.6 (3.0)	17.5 (2.8)	18.6 (3.6)	0.5 (−1.2, 2.2)	0.542
Carbohydrate (% energy)	43.5 (6.8)	47.4 (7.0)	45.3 (6.1)	43.2 (7.6)	−3.5 (−7.2, 0.1)	0.058
Sugars (g)	65.9 (25.7)	75.2 (29.5)	85.1 (31.4)	80.2 (43.6)	9.1 (−14.9, 21.7)	0.712
Sodium (mg)	2548.8 (897.3)	2710.4 (1263.1)	2771.1 (851.1)	2587.1 (868.3)	−259 (−853, 334)	0.384
Fibre (g)	13.7 (5.2)	15.9 (7.3)	13.4 (16.1)	14.8 (4.9)	−1.7 (−4.9, 1.5)	0.285

[1]Data given as mean (standard deviation).
*Between groups at week 12 after controlling for baseline (one-way ANCOVA).

After being asked what they found most enjoyable about the program, the quick quiz section was mentioned by most participants: "it was good to have something interactive" and "I did find the quiz very, very good." They would often challenge themselves to improve on their scores: "I got quite competitive until I got good scores." In addition to being enjoyable, they also "found it helpful" and "very informative."

The fast facts section was also heavily praised: "I was quite taken that it virtually covered everything," "they were excellent, certainly that was the section that I really got the most out of," "I really found that very informative," "I learnt quite a lot from it," and "the explanation of terms was very useful."

While the diabetes stories section was rated as the least helpful of the five sections with a score of just above five out of ten, participants expressed in the focus groups a solid appreciation of this section saying they found it "very helpful" and "reassuring." A typical quote was "the bit where real people, local people, actually talked you know about having diabetes and how they coped with it. I find that very reassuring" and "when you're diabetic everybody has an opinion especially people who have never had it . . . it's nicer to hear from people from you know that have had it with the experience of having it."

Finally, while some participants did find the physical activity section helpful (e.g., "it focused my mind on how I could be more active" and "I will go back to that section and see if I can improve on it"), many did not (e.g., "after a while I just sorta stopped going into it," "you take 30 minutes of exercise a day and all this and you know you're not doing it and there's no use going back into the activity and . . . doing that again"). However, some admitted that these may be an excuse for not exercising: "not that I take exercise very much [laughs]. It's probably another reason for avoidance."

5. Discussion

Diabetes education delivered by a team of educators, with some degree of reinforcement of that education at intervals, may provide the best opportunity for improvements in patient outcomes [31]. However, the quality and quantity of self-care education given to each individual are highly dependent on the skills and resources of the healthcare professional delivering that education [32]. In the UK, healthcare providers are increasingly pressurised by government driven targets; hence access to nursing or dietetic time for diabetes education may be limited [33]. Innovative, complementary methods of supporting diabetes education are therefore much sought after. Computer-based technology holds promise as an innovative means of supporting the work of health professionals; it can be used to reinforce and extend the education received in the healthcare setting and is readily accessible therefore facilitating opportunities for use on a regular and frequent basis to enhance knowledge and self-monitor key health-related behaviours.

The evaluation of this newly developed tool to aid self-management of diet and physical activity in people with type 2 diabetes indicated that it was highly valued by users and, alongside this, its short-term use was found to significantly improve barriers related to "knowledge and beliefs" about diabetes. There was also a trend towards a statistically significant improvement in overall health status as measured by SF-36 instrument. A secondary analysis of "high" users compared to the control group demonstrated small but significant increases in the "knowledge and beliefs scale" and the "advice and support scale" of the DOQ and a trend towards significance for ADKnowl "diet and food score." Although there was no significant change between the intervention and control group in self-efficacy, depression, diabetes-specific quality of life, body weight, or metabolic markers, there were indications of positive changes in dietary intake and physical activity between groups, albeit these were not statistically significant. The results, therefore, indicated that this tool did help patients to improve their knowledge, which is one of the key barriers to dietary self-management among people with type 2 diabetes [34–37]. Previous research has indicated that people with type 2 diabetes particularly want information on diet [17] and while enhanced knowledge will not necessarily always translate directly into a change in behaviour, it represents one positive step towards empowering people to make better choices [38–40]. It has been reported that knowledge-behaviour correlations are increased among individuals with increased self-efficacy and decreased among those with decreased self-efficacy [41]. However, the improvement in knowledge in this study was not accompanied by changes in self-efficacy, perhaps owing to the time-scale of the study or the level of usage of the program as discussed below.

The LWD program was highly rated by participants in feedback obtained from both questionnaires and focus group discussions. This is reassuring given the level of involvement the target group had in terms of the development of the program itself and the extensive usability testing that was undertaken. Including members of the target group in the development process is a robust form of program development and has been shown to improve participation and program success [42, 43]. The main attribute that participants appreciated most was having the LWD program on-hand so they could access it at their convenience. There is evidence that home-based instruction is a preferred-choice to group/classes in diabetes self-management [44]. Home-based instruction allows the individual to schedule educational activities around their existing lifestyle, in their own time, and in the comfort of their own home. In addition to the convenience of home-based instruction, this approach may help with retention and application of information as patients report that information received in face-to-face education sessions, while valuable, is difficult to recall at a later time [6]. Having an education tool on-hand, such as the one delivered here, can help to fill this "gap" in diabetes self-management and could be helpful and reassuring for patients, particularly when check-ups or follow-up appointments are frequently 6 months apart. It was also apparent in the focus group discussions that the participants were enthusiastic towards each individual component of the program, often stating that they found them motivating, reassuring, and helpful and that it kept them focused. Some suggested that they did learn new concepts and did attempt to make changes to their diet. Study completion rates were good, with only 16% being lost to follow-up; however only 40% of the intervention group appeared to use the program on at least a weekly basis. Future research on this program should assess ways to enhance compliance and regular use of the program as this may result in additional benefits. For example, embedding the program within current care packages alongside regular contact with a health professional, whether it be by email, letter, or phone call, may be of benefit. Additional changes might include enhancement of the physical activity component of the tool to focus on self-monitoring and goal setting behaviour which may help to increase engagement with this part of LWD. In general, this interactive program would be well suited to delivery via an "app" platform which would increase ease of access thus enhancing opportunities for engagement and regular use.

With regard to dietary intake, based on initial focus group discussions [6], the LWD program focused predominantly on helping the user to understand how to achieve a balanced diet. The program did not focus on calorie restriction and weight loss and, indeed, although some favourable changes in dietary intake were observed, there was no change in body weight following the intervention. Recent guidelines for management of type 2 diabetes [45] emphasise the importance of weight management as the primary goal for people with type 2 diabetes. Based on the findings of the trial and the increased emphasis placed on weight loss in clinical guidelines, it is clear that the issue of weight management needs to be enhanced within this educational tool.

A challenge with all such tools is likely to be the digital divide. A lack of desire to engage with technology was one of the main factors that influenced recruitment to the study. However, on a positive note, most of the people who took part in this study had never used a computer before and yet still managed to navigate their way through the program with ease which was reassuring as ease of use was a key priority

when the tool was being designed. Furthermore, the average age diagnosis for type 2 diabetes is decreasing and computer literacy is increasing [46, 47]. Since inception of this project, significant advances have been made in the use of mobile applications for health management [48]. Although this tool was originally designed to be delivered via personal computer, the new technologies available open up increased opportunities to modify the tool for use on a number of different platforms thereby increasing accessibility and potentially enhancing reach and effectiveness. Conversion to an app format would require a similar process of user involvement as for development of the original program in order to ensure usability is appropriate for the target group who will have specific usability requirements compared to other segments of the population [48].

The study did have some limitations. This was a trial of effectiveness and under these "real-life" circumstances compliance was not optimal; based on usage logs, only approximately half of the intervention group participants used the tool on at least a weekly basis as was recommended at the study outset. The "high user" group may represent a more highly motivated population and hence may not be as generalisable to the general population. However, despite this, some positive changes in knowledge-related parameters perceived health status, diet, and activity were observed and the trial has highlighted the need to focus attention on strategies that could be used to enhance usage, such as exploring alternative modes of delivery, such as app technology, and how this tool could be incorporated into existing diabetes care packages, as discussed above. With regard to the user feedback, only a quarter of the intervention group participants opted to take part in the focus group discussion at the end of the study. Feedback from these sessions was positive; however, it is possible that only the more motivated or interested participants opted to take part and therefore these discussions may not be representative of everyone who used the program. It was encouraging, however, that the positive attitude towards the program displayed in the focus group discussions was, for the most part, consistent with the findings from the evaluation questionnaire that was completed by *all* participants who used the program.

6. Conclusion

This short-term evaluation indicated that this newly developed computer-program, focusing on diet and physical activity self-management, was well received by participants and its usage resulted in small but statistically significant improvements in diet-related knowledge, as well as non-significant improvements in perceived health status, dietary intake, and physical activity. Based on these findings, further development of this tool is warranted. Consideration needs to be given to how the delivery platform can be widened to maximise impact, how this tool could be incorporated into existing diabetes care packages, and what level of health professional support is required to encourage usage and help maximise effectiveness of the tool. This tool may be a viable adjunct to diabetes self-management and could help to fill an important gap in patient care.

7. Implications or Relevance for Diabetes Educators

Health professionals are charged with delivering a large volume of information to patients, often within a limited time slot, and human resource issues can also mean there is limited capacity for patient follow-up. Self-management tools such as this can be a useful adjunct to HCP patient education and support and can help fill important gaps in the care pathway, such as the period between diagnosis and receiving structured education, or extended time periods between patient follow-up appointments. For HCPs to have confidence in the effectiveness of any such tool, however, they should be developed in close consultation with the end users and with HCPs and should undergo rigorous usability testing, as was undertaken during this study, before wider dissemination.

Competing Interests

The authors declare that they have no competing interests.

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Research Article

Long-Term Follow-Up of the Telemonitoring Weight-Reduction Program "Active Body Control"

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The Active Body Control (ABC) weight-reduction program is based on telemonitoring of physical activity and nutrition together with telecoaching by weekly counseling letters sent by post or by e-mail. The study presented here reports the results of a 1-year follow-up of 49 patients with the metabolic syndrome who had lost weight with the aid of the ABC program in the preceding year. The weight regain after the second year in patients not receiving any further care ("ABC discontinued" group; $n = 24$) and the potential benefit of continuing with the ABC program with monthly counseling letters ("ABC continued" group; $n = 25$) were investigated. The relative weight changes after the first year had been, respectively, −13.4% and −11.4% in the "ABC discontinued" and "ABC continued" groups, and after the second year they decreased by, respectively, 4.4 and 2.8%. However, this difference in weight regains between the two groups was not statistically significant. It is concluded that three-quarters of the weight loss after 1 year is maintained after the second year. The decision whether to continue with the ABC program after 1 year should be made individually.

1. Introduction

Epidemiological data show that the prevalence of obesity is increasing steadily despite the implementation of various weight-reduction programs. Either the measures used at present are insufficiently effective or the successful interventions are resources-intensive and not easily translated into routine primary care. In addition, long-term maintenance of the weight loss is a problem. New more effective and economic alternatives are therefore urgently needed.

Mobile technology and web-based approaches to lifestyle improvements are constantly being developed and can improve short-term weight losses. However, the published data differ markedly in the technologies used, patient populations studied, and study durations. Recent reviews agree that further research is necessary, especially with the aim of identifying success factors for long-term weight loss maintenance [1–3].

The Active Body Control (ABC) program is a lifestyle intervention that combines telemonitoring of daily physical activity and calorie intake with weekly individual feedback by experienced coaches over 6–12 months. This program was first shown to be effective in obese adults [4] and in patients with type 2 diabetes mellitus [5].

Below are presented data from a continuation of a preceding intervention study in which patients with the metabolic syndrome had participated for 12 months. As reported previously [6], these patients had reduced their initial body weight by 11.4%. To investigate the long-term effect of the ABC program, the patients were followed up

for another 12 months. The objective of this extension study was to answer two questions: first, to what extent the patients were able to maintain their weight loss, and, second, whether continuation of the telemonitoring and telecoaching in a subgroup can prevent or slow down weight regain.

2. Materials and Methods

2.1. Patients and Interventions. Patients recruited in several major companies and by the University of Magdeburg from several regions in Germany met the criteria for diagnosis of the metabolic syndrome according to the recommendations of the International Diabetes Federation [7]. The exclusion criteria were as follows: age below 30 or above 60 years and presence of diabetes mellitus, coronary heart disease, chronic heart failure, cerebrovascular disorders, or other conditions possibly also having a bearing on physical activity or body weight, such as psychiatric disorders, use of antidepressants, neuroleptic or cortisol therapy, thyroid dysfunction, active cancer or other severe diseases, disabling disorders of the motor system, pregnancy, or changes in oral contraception. None of these patients had taken part in an earlier study carried out by the authors. Details of the study design have been described previously [6].

All patients attended an initial 2-hour instruction meeting including an explanation of the Magdeburg Dual Diet. This consists of conventional calorie restriction, with reduction in the calorie intake by 500 kcal/day and preference for carbohydrates with low glycemic index. The importance of daily moderate but regular physical activity was emphasized. To this end, the patients were provided with the Aipermotion 440 model from Aipermon GmbH (Munich, Germany). The accelerometers were programmed individually for each patient and calculated the daily walking distances and daily exercise-related energy expenditure in kilocalories and in addition recorded meal calories in a simplified form. The actual balance between total calorie intake and calories used up by the basal metabolic rate plus physical activity could be checked by the carrier at any time. The validity of these measurements has been demonstrated satisfactorily by comparison with spiroergometry in various patient groups with heart failure [8] and by comparison with the 6-minute-walk test [9]. These data and self-reported daily body weights were transmitted once a week to a server in Magdeburg University Hospital by means of a USB connection to a home computer with automatic extraction of new data. During the first 12 months of the intervention, the ABC carers (physicians and ecotrophologists qualified in nutritional medicine) generated weekly individual report letters using the ABC platform (further details in [6]).

The study was then continued for a second year. All 49 patients who had finished the first year were randomized to one of two groups. In the first group the counseling was continued, but with lower intensity than during the first year ("ABC continued" group, $n = 25$). During the first year all patients had received counseling letters every week. This frequency was reduced during the second year to one letter per month. In the second group both telemonitoring and feedback by counseling letters were completely discontinued ("ABC discontinued" group, $n = 24$). At the end of the second year both groups were invited for a final medical examination. The design of the study is shown in Figure 1.

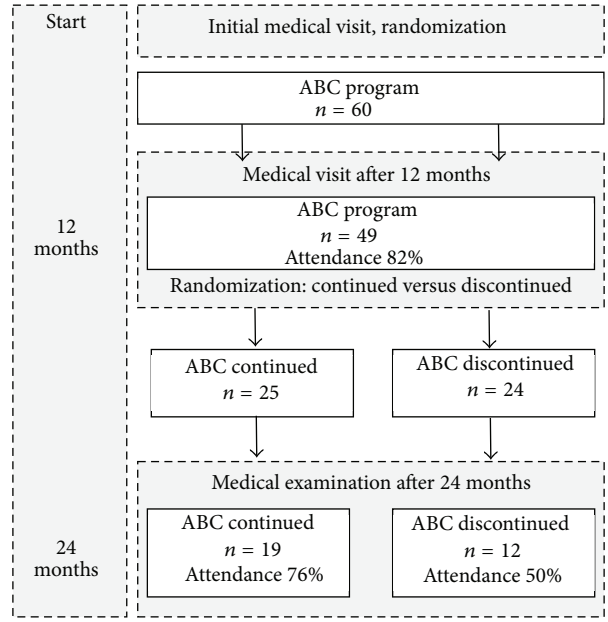

Figure 1: Study design: patients who completed the one-year program [6] were randomized into two groups. The "ABC continued" group continued telemonitoring and received telecoaching for a second year and was counseled by monthly letters. The "ABC discontinued" group was not contacted for another 12 months until the medical examination after 24 months.

The study had been approved by the Ethics Committee of the School of Medicine and all subjects had given their written informed consent.

2.2. Statistical Analysis. The patients were randomized to the "ABC continued" and "ABC discontinued" groups by lot.

Owing to the dropout rate before the final examination, the analyses can only claim to be exploratory. Nevertheless, methods appropriate for analyses with incomplete data were used, to avoid bias as far as possible.

Analyses for the outcome parameters including relative weight loss (in percentage of the weight at baseline) are based on a mixed model for repeated measurements (software SAS, PROC MIXED). Each outcome parameter was analysed separately. The model is based on differences of the outcome parameters from their corresponding baseline values as dependent variables. The baseline values are included as covariables. The study subjects are modeled as random factors (random intercept). All estimates given in the text are based on this model. Differences over time are constructed in such direction that positive values indicate an increase in the parameter in question and negative values indicate a decrease. The analysis is based on the intention-to-treat principle. Missing values due to loss to follow-up are not imputed explicitly in this approach, but all measurements available at the earlier visit are included in the model, so that missing values are implicitly taken into account.

Table 1: Demography of participants who were followed up for a second year. The mean weight in the "ABC discontinued" group was somewhat lower than in the "ABC continued" group, but the difference did not reach statistical significance ($p = 0.136$). The figures given are means and standard deviations.

	ABC continued ($n = 25$, 36% female)	ABC discontinued ($n = 24$, 29% female)	p: continued versus discontinued
Age (years)	50 ± 8	52 ± 7	n.s.
Weight (kg)	95.5 ± 15	88.1 ± 13.5	n.s.
Height (cm)	1.76 ± 0.1	1.76 ± 0.1	n.s.
BMI	30.9 ± 5.1	28.5 ± 3.9	n.s.

The estimates presented here are mean changes in the outcome variable from baseline to month 12 per group, mean changes in the outcome variable from baseline to month 24 per group, and mean changes in the outcome variable from month 12 to month 24 per group, all adjusted to a common average baseline value over all treatment groups and completed by 95% confidence intervals and unadjusted p values for the test against zero.

3. Results and Discussion

3.1. Results. Patients who completed the first year were randomized to the "ABC continued" and "ABC discontinued" study arms. Table 1 shows the demography of the patients who took part in the second year extension. The results of the randomization to the two groups turned out not to be quite optimal, since the mean body weight was higher in the "ABC continued" group than in the "ABC discontinued" group. However, the difference was not statistically significant in the nonparametric Mann-Whitney-Wilcoxon test, with $p = 0.136$.

Table 2 shows relative and absolute weight changes and BMI values after 12 and 24 months in the two groups, with corresponding levels of statistical significance of the differences. The weight regain values during the second year are given in columns difference 24−12 and p3*. It is apparent that significant weight regains had occurred, whether or not the ABC telemonitoring was continued. The regain was higher in the "ABC discontinued" group, with plus 4.4% points relative to the initial weight in comparison with 2.8% points in the "ABC continued" group. However, this difference in relative weight regain between the two groups was not statistically significant, as maybe seen from the column p4 contd. versus discontd.

3.2. Discussion. Various interventions aimed at weight reduction have been demonstrated to be effective in short-term studies, but long-term interventions and weight-loss maintenance have been addressed less frequently (reviews in [10, 11]). Existing data suggest that weight regain is a frequent problem and begins 12–24 months after the initiation of the weight reduction. To investigate the long-term effect of intervention by the ABC program, patients who had taken part in this program for 1 year were followed up for another 12 months. The objective was to answer two questions: first, were the patients able to maintain their reduced weight, and, secondly, can continuation of telemonitoring and telecoaching in a subgroup prevent or slow down weight regain?

The answer to the first question is unequivocal: the patients did regain weight during the second year. To obtain a relative assessment of the weight regain in our study we researched current literature for long-term results. It turned out that publications reporting long-term results are rare, in particular, ones with similar types of intervention and comparable time-points of the measurements. We identified seven long-term studies in which weight had been reduced by lifestyle interventions. Studies using formula diets or bariatric surgery were excluded.

The lowest weight regain, by 0.8% points relative to the original maximum weight loss, was observed in Volger's "brief lifestyle counseling" group [12]. 131 participants received monthly coaching during the second year. The relative weight change was only −3.5% after 12 months and −2.7% after 24 months, which is below the widely acknowledged minimum weight loss target of 5% required for obese patients [13, 14].

The other six trials analysed reached the minimum weight reduction of 5% relative to the baseline weight after 12 months [15–20], but only three of them, and also the ABC program, achieved this >5% target after 24 months ([18–20] Figure 2). Appel et al. used a web-based education approach in addition to group meetings in 139 obese patients and achieved a weight change of −6% in the first 6 months. After the second year the patients' weight had risen by 1.5% points despite monthly coaching [15] and had therefore missed the minimum target of 5% weight reduction. Similar results were reported for two other interventions. A weight change of −7.2% of the baseline body weight was observed in 772 participants in the commercial weight watcher program [16] after 12 months. Left unattended for the second follow-up year, they regained 2.7% points, which reduced the weight change to −4.5% of the initial body weight after 24 months. This result might even be overestimated, because it is based on only 26% of the initial participants who attended the final examination. A rather high weight regain was observed by Jakicic et al. [17], who used an intervention based on eating behavior and exercise in 191 women. After 12 months their body weight had changed by −8.9% but rose again by 3.5% after 24 months, resulting in a long-term weight change of −4.6%.

The goal of maintaining at least a 5% weight loss after two years was reached in the HELP-PD and the Look AHEAD trials. The Healthy Living Partnerships to Prevent Diabetes

Table 2: Relative and absolute weight changes and BMI values changes at 12 and 24 months in the group which continued to receive ABC telecoaching ("ABC contd.") after 12 months and in the group which did not receive further telecoaching ("ABC discontd."). The figures given are means and standard deviations.

	Study groups	12 months	p1 0 versus 12	24 months	p2 0 versus 24	Difference 24 − 12	p3 24 versus 12	p4 contd. versus discontd.
Weight change (%)	ABC contd.	**−11.4** *(−13.7; −9.1)*	<0.0001	**−8.5** *(−11.0; −6.1)*	<0.0001	**2.8** *(−4.3; −1.4)*	<0.0001	n.s.
	ABC discontd.	**−13.4** *(−15.8; −11.1)*	<0.0001	**−9.0** *(−11.6; −6.4)*	<0.0001	**4.4** (6.1; −2.8)	<0.0001	
Weight (kg)	ABC contd.	**−11.8** *(−14.3; −9.4)*	<0.0001	**−8.9** *(−11.5; −6.4)*	<0.0001	**2.9** *(−1.5; −4.4)*	0.0001	n.s.
	ABC discontd.	**−14.6** *(−17.03; −12.1)*	<0.0001	**−9.8** *(−12.6; −7.1)*	<0.0001	**4.7** *(−3.0; −6.5)*	<0.0001	
BMI (kg/m^2)	ABC contd.	**−4.1** *(−4.9; −3.3)*	<0.0001	**−3.1** *(−3.9; −2.3)*	<0.0001	**1.0** *(−0.5; −1.5)*	<0.0001	n.s.
	ABC discontd.	**−4.8** *(−5.6; −4.0)*	<0.0001	**−3.3** *(−4.2; −2.4)*	<0.0001	**1.5** *(−0.9; −2.0)*	0.0005	

p1 0-12: 0 versus 12 months (changes are losses over 12 months).
p2 0-24: 0 versus 24 months (changes over 24 months).
p3 24-12: 24 versus 12 months (smaller changes, weight regains in the second year).
p4 contd. versus discontd.: difference 24 − 12 months for continued versus discontinued intervention.

Study (HELP-PD) [18] used community health workers with well controlled type 2 diabetes and history of healthy eating and physical activity for peer coaching 301 type 2 diabetes patients. These subjects achieved a weight change of −7.2% after 12 months. Although their weight rose again by 1.8% points despite continued monthly coaching, the final weight change after 2 years was −5.4%. Still greater weight loss was obtained in the large-scale Look AHEAD trial [19], in which 2570 participants were assigned to an intensive lifestyle intervention with a calorie reduction diet including low fat and elevated protein intake as well as at least 175 minutes of physical activity per week. After 12 months the intervention group showed a weight change of −8.6% relative to the baseline. However, monthly face-to-face meetings and additional contacts once a month by telephone or by e-mail could not prevent weight regain by 2.6% points, which resulted in a 2-year weight change of −6.3%. It should be mentioned that the Look AHEAD Research Study Group has now published additional data reporting weight gains after 4 and 8 years [20]. The weight gain continued for up to 4 years, but then the participants appeared to stabilize. After 8 years a mean weight change of −4.7% was still present, and the intensive lifestyle intervention group produced clinically meaningful weight loss (≥5%) in year 8 in 50% of the patients with type 2 diabetes.

The highest initial weight loss was reported by Wadden et al. [21], who applied an intensive dietary and fitness training program in 99 women with a mean age of 42 years. An impressive −17.6% weight change loss was achieved after 48 weeks. However, the long-term weight progress was disappointing. The participants regained more than half of the initial weight loss, by plus 9.0% points, in the second year in the absence of continued treatment. The final weight change after 2 years was therefore −8.6%, which is very close to the 2-year weight changes in our two study arms.

Concerning weight regain, it may be concluded that weight regains in the second year are observed in all weight-reduction programs, including the ABC program. In order to maintain a medically relevant weight loss also after the second year, it is therefore very important that the weight reduction in the first year should be large enough and that the subsequent weight regain is moderate. From this point of view, the overall results of ABC program are quite satisfactory.

Our second question was whether continued ABC coaching in the second year, though less frequent, could still have a positive influence on the regain in a subgroup of our patients. The data of our study do not allow a clear answer. The difference in weight regain between the "ABC continued" and "ABC discontinued" group indicates a lower regain in the "ABC continued" group, but this difference was not significant, perhaps because of the small number of patients and the high dropout rate in the "ABC discontinued" arm. A more detailed analysis showed, however, 4 patients in the discontinued arm with a regain of more than half of the initial weight loss. In contrast, no weight regains of this magnitude were observed in any of the patients of the "ABC continued" arm. This tendency toward smaller weight regains with continued counseling has been mentioned repeatedly in the literature described above. However, until a clear benefit

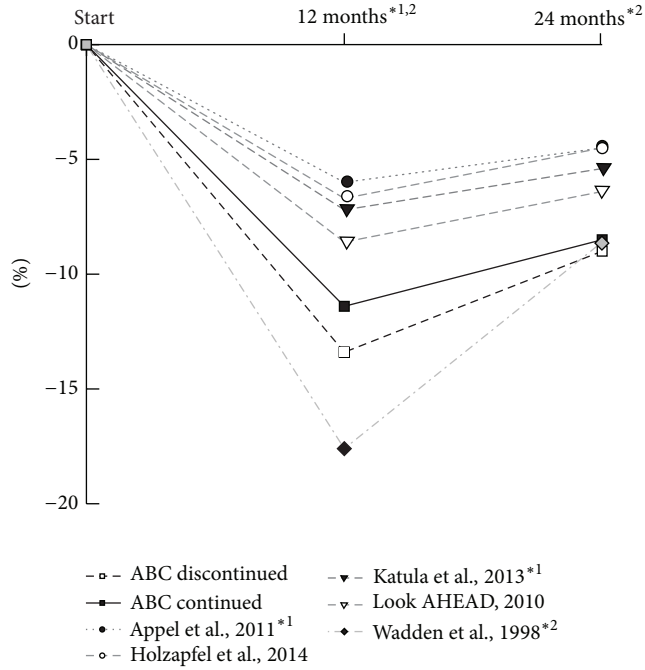

Figure 2: Comparison of weight-reduction data after 12 and 24 months in seven long-term studies including the present study. Only those studies are shown in which a minimum weight loss of 5% of the initial body weight was achieved after 12 months. *1Appel et al. and Katula et al.: weight measures at 6 and 24 months. *2Wadden et al.: weight measures at 48 and 100 weeks.

of prolonged coaching has been confirmed by studies with greater numbers of patients we recommend to make the decision to stop or continue coaching in each case on the basis of the individual situation, such as the patient's remaining excess weight, health status, willingness to cooperate, and social aspects.

A major difference between the ABC program and the other weight-reduction programs in Figure 2 is that the ABC program uses a telemedical approach, while all other studies relied mainly on repeated counseling sessions. There was only one face-to-face meeting in the course of the 24 months of the ABC program, as compared with, respectively, 28, 33, 44, and 66 such meetings in the studies of Wadden et al., Appel et al., and Katula et al. and in the Look AHEAD trial. Despite this short personal encounter, the weight reduction achieved in the ABC program was second best after 12 months and best after 24 months. We believe that this satisfying efficacy of the telemedical approach is due to the fact that it moves the obesity treatment from the counselor's office into the patient's daily life. The telemonitoring approach enforces the patient's continuous self-control which is boosted by the regular motivation letters from carers who are closely connected with the patients and who respond individually. It remains to be investigated whether additional face-to-face contacts would further enhance the efficacy of the ABC program.

The telemedical character of our program yields yet another advantage worth mentioning: the time expenditure

is much smaller. The single instruction meeting at the start of the program takes 2 hours for both carers and patients. Daily physical activity is measured automatically, and documentation of calorie intake is simple and takes the patient only a few minutes. The preparation of the regular individual report letter takes the carer 5 minutes.

The small time expenditure by the patients might contribute to their compliance with the program, which during the second year was relatively high (75%) and well comparable with the compliance figures reported in most of the other studies discussed here (77–94%). In general, however, the rates of compliance in weight-reduction studies can be very variable, ranging from 20 to 90% [22]. As an example of a commercial program, in the weight-watcher intervention described by Holzapfel et al. [16] it was only possible to bring back 26% of the participants for the 24-month visit.

Finally, the small time requirement of the ABC program results in low costs. Although the studies discussed did not specify the expense of their programs, Tsai et al. investigated the costs for a number of conservative obesity treatments over 2 years: the costs per kg-year were $219–$437 per kg in usual care with quarterly counseling sessions and $292 for an "enhanced brief lifestyle treatment" with monthly meetings [23]. Because of the greater weight loss, the corresponding figure for the ABC program is much better, $47 per kg-year.

4. Conclusion

The ABC telemonitoring weight-reduction program yields a weight loss that, in comparison with other programs, remains favorable even after two years. The decision to continue the program for a second year should be made individually.

Disclosure

4sigma is an independent company offering health services such as disease management, prevention programs, and medical hotlines. Dr. Stumm from 4sigma was responsible for medical advice, general project management, and coordination between the study partners and does not have conflict of interests. The manufacturer of the Aipermotion devices has terminated production and support of these instruments. Professor Luley has therefore bought the last production line and is now responsible for distribution and support. All other authors have nothing to disclose.

Competing Interests

The authors declare that there are no competing interests regarding the publication of this paper.

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Research Article

Usability Pitfalls of Diabetes mHealth Apps for the Elderly

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Diabetes mellitus has high prevalence in the ageing population and is often accompanied by other comorbidities, such as Alzheimer's disease, and general disabilities, such as poor eyesight. These comorbidities have redefined ways in which patients use mHealth apps, including diabetes apps. The latter have proven benefits for monitoring blood glucose levels and insulin tracking in the general population. In this paper, we analyse a diabetes monitoring app DeStress Assistant (DeSA), which was developed as a part of an EU project and tested in a hospital setting. Due to the increasing number of older adults, we wanted to ensure the app was suitable for that demographic. Based on a number of supervised tests, we show that the app, which was developed with the help of workshops and feedback from tech-savvy patients and clinicians, is difficult to use by elderly users. We demonstrate that with a small number of changes it is possible to raise the usability of the app in a number of categories. We summarise the lessons learned in the discussion. Our findings demonstrate that special care needs to be taken when developing mHealth apps for the elderly population.

1. Introduction

Age is associated with changes in sensory abilities; the most-studied age-associated sensory changes are vision and audition [1]. Colour vision, contrast sensitivity, and visual acuity all decline with age. Also, aspects of memory (e.g., keeping a lot of information active in working memory), online reasoning ability, and aspects of attention, such as attending to more than one source of information all show age-related declines [2].

With the increase in numbers of the aging population, we can also see an increase of chronic diseases such as diabetes mellitus. Type II diabetes affects 90% of people with diabetes around the world and is largely the result of excess body weight and physical inactivity [3]. Self-monitoring blood glucose (SMBG) systems have the potential to play an important role in the management of diabetes and in the reduction of risk of serious secondary clinical complications [4]. In that regard, mobile applications can be used as an effective tool in different self-monitoring techniques. They are useful for all user groups from people with no overt health problems to chronic patients. They have been tested on patients with type II diabetes, asthma, chronic obstructive pulmonary disease (COPD), and different psychiatric conditions [5–8].

In this paper, we investigate on a practical example how elderly people specifically use mobile applications for diabetes management. We describe the limitations that might be preventing them from adopting such digital mHealth solutions and outline and demonstrate how existing applications can be adapted to increase the usability and adoption rate.

Our findings will also be put into practice with our involvement in the UNCAP [9] project, which is aimed at adapting digital health solutions and technologies for the aging population, thus helping them live independently while maintaining and improving their lifestyle.

The remainder of this paper is organized as follows. Section 2 presents the DeSA app and all its functionalities; Section 3 introduces the utilized methodology, where the moderating technique and the questionnaire are discussed. Section 4 combines the results from the individual evaluations and demonstrates the changes made to the app. Section 5 presents our discussion, and Section 6 concludes the paper.

1.1. The Rise of Diabetes Prevalence. One of the most important demographic changes to diabetes prevalence across the world appears to be the increase in the proportion of people over 65 years of age. Furthermore, the number of elderly

persons with type II diabetes is expected to grow in concert with the overall increase of the elderly population. The majority of people with diabetes in developed countries are older than 64 years. By 2030, it is estimated that the number of people with diabetes over the age of 64 will be more than 82 million in developing countries and more than 48 million in developed countries [11].

1.2. mHealth Apps. Mobile phones are becoming an increasingly important tool in the areas of health protection. The benefits include an increased feeling of safety, time and cost savings, shortened waiting queues, improved quality of life, and possibilities to develop additional health-related activities [12]. mHealth applications use mobile devices for collecting healthcare data, delivering healthcare data to physicians, researchers and patients, monitoring vital signs in real time and ensuring direct healthcare (i.e., telemedicine). Examples include the exchange of medical information via email, texting, smartphone apps, storing and forwarding pictures, and web-based video [13].

According to the IMS Institute for Healthcare Informatics [14], in the last years, the number of mobile health apps has soared with more than 165,000 mHealth apps available in the Apple App Store and Google Play. The number of apps in the Apple App Store has doubled since 2013, with more than 90,000 available apps. However, only 10 percent of mHealth apps can connect to a device or sensor that provides access to medical data.

There are more than 1,700 diabetes apps in all the app stores combined (Google play, Apple App Store, Blackberry, Windows, and Ovi Store) [15]. Researchers have examined outcomes of interventions using some of these mobile phone apps for diabetes. In [6], where studies of the clinical effectiveness of mobile-based applications were reviewed, they found 10 of the 13 studies in type II diabetes and 4 of the 7 studies on type I diabetes found mHealth to lead to benefits. Other studies [16, 17] have also found promise in using mobile app interventions.

1.3. Adoption of Apps. Considering the number of apps, the users are left to their own devices to find an app that they feel helps them manage their medical condition in the most beneficial way. After the app is developed and available on the market, the developers normally receive very little feedback and have no clear understanding as to what the consumers find engaging and useful, which can significantly undermine the potential effectiveness of the intervention. Regrettably, there is no simple formula for designing engaging and effective mHealth apps [18], and the matter has to be addressed on a case-by-case basis.

As opposed to fitness and well-being apps, mHealth technologies are frequently designed and developed within the scope of the existing structures of the health care system. However, when including patients as part of the design team, out-of-the-box thinking is encouraged, inspiring that designers or care providers who develop the technologies to think differently, unconventionally, or from a new perspective, finally leading to applications that are better tailored to patients' needs [19]. However, during such processes, many aspects can be overlooked. For example, the technology developers often fail to fully capture the tacit knowledge and develop useless solutions that do not address the real problems. Similarly, many other possible stakeholder groups can be overlooked, including the elderly. This is becoming unacceptable in an increasing number of fields, including diabetes, where the target market of the solution significantly overlaps with the elderly demographic group. If the capabilities and limitations of the elderly group are not considered in the design and development process of mHealth applications, most likely results will be poor adoption and inefficient use of the technology, thus negating all resources spent on trying to solve the problem.

2. The DeStress Assistant (DeSA)

The goal of the study was to ascertain whether an application that was designed for general population can be efficiently used by the elderly without modifications. In our tests we used an in-house developed diabetes application called the DeStress Assistant (DeSA) [20]. After the first round of tests, several modifications were made to the application, and the tests were repeated with a different set of users.

DeSA was designed and developed within the FISTAR project [21], with the goal of providing diabetes patients that live in remote areas a way to track their condition and keep in touch with their physician. During the design phase, no special consideration was given to the elderly demographic. Medical staff, diabetes patients, and their next-of-kin were involved during the design phase to ensure the best possible user experience and compliance with clinically related requirements. After the initial app was developed and tested in a hospital setting, with a group of patients of mixed demographic structure, we tested the app again, in a nonclinical setting, with a group of elderly users. This led to identification of the possible design flaws impeding the adoption of the application within the older demographic.

Since DeSA was developed based on feedback from multiple stakeholder groups (patients, next-of-kin, clinicians, medical device makers, developers, and information security specialists), it contains a broad spectrum of features. These include glucose diary, automatic logging of physical activity using the in-built motion sensors or add-on pedometers, macronutrient logging, self-reporting of stress, and weight and insulin boluses, as well as data logging reminders and sharing of logs directly with a physician.

DeSA is designed as a self-contained application that stores all the observation data on the phone. During the design phase, to comply with privacy regulations, special care was taken to ensure that data never leaves the device without the user's consent [23].

In a systematic review [22] of diabetes applications, only 17.7% of apps on the market at that time offered three or more functions and only a small number of apps offered the possibility of a connected glucometer device and transferring of data wirelessly and automatically via Bluetooth to the mobile device. DeSA was specifically designed to interface with the glucometer directly, by plugging the glucometer directly into the audio jack of the mobile device. This

Figure 1: Performing the blood glucose measurement.

eliminated several possible issues, including charging the batteries of the glucometer, and provided greater security and reliability than transferring data radio-based technologies such as Bluetooth (see Figure 1).

3. Usability Evaluation Methodology

It is recommended that applications be developed with the end user in mind [18]. This proves crucial if the application aims to be both useful and usable. With DeSA, multiple stakeholders were involved in the design and development process, where their needs, wants, and limitations were given special attention at each stage. With this study, we aimed to repeat the usability evaluation on an older population. To do so, the usability evaluation method needed to be adapted with the end user in mind.

The best way to ensure usability is to have the potential users (as well as other stakeholders) involved in the process of solution design and development. That way, the developers can understand the needs of the users and can address potential issues before the app is finished. However, once the app has been developed, and a lot of research and development resources went into it, changes become increasingly hard. The optimization problem that we wanted to address was how to improve the app without going through the whole process again and achieve maximum improvement with minimum effective modification. For this it was important to first identify and understand the most pressing issues the users face and based on the findings and modify the app accordingly.

The first step of the evaluation process is determining whether the app should be evaluated by the experts or by the end users. Based on the extensive previous evaluations performed both by general population and by domain experts, we have chosen to perform subsequent usability evaluations on end users alone. The users were all older than 50, with the average age of 64.2 years. Some had experience with touchscreen technology, while others did not. The first step of the evaluation was thus choosing a moderating technique and designing a suitable questionnaire, as follows.

3.1. Moderating Techniques. Effectively moderating usability tests plays a crucial part in understanding the needs of the users. The most common moderation techniques include the following [24]:

(i) Concurrent Think Aloud (CTA) is used to understand participants' thoughts as they interact with a product by having them think aloud while they work. The goal is to encourage participants to keep a running stream of consciousness as they work.

(ii) In Retrospective Think Aloud (RTA), the moderator asks participants to retrace their steps when the session is complete. Often participants watch a video replay of their actions, which may or may not contain eye-gaze patterns.

(iii) *Concurrent Probing* (CP) requires that as participants work on tasks—when they say something interesting or do something unique, the researcher asks follow-up questions.

(iv) Retrospective Probing (RP) requires waiting until the session is complete and then asking questions about the participant's thoughts and actions. Researchers often use RP in conjunction with other methods—as the participant makes comments or actions, the researcher takes notes and follows up with additional questions at the end of the session.

Our usability tests were performed in two phases on $N = 10$ users. The used moderating technique was the RP with the combination of CTA, which seemed to fit the target audience best. We decided not to use the CP technique, because we wanted to let the user navigate the app freely and not lose focus. Considering the age group, we also decided the RTA would increase the overall length of the session and likely cause them to lose focus. The elderly users were asked to perform a set of tasks in the application, while the moderator observed and provided limited assistance, if needed. After the participants completed the tasks, they were asked a set of questions, to determine how they felt using the app and to try and distinguish the possible difficulties they encountered while using the app.

3.2. Questionnaire. There is a wide variety of questionnaires available for testing usability and user experience. The questionnaire has to be designed specifically for the end users, and not the experts evaluating the application in question; even more importantly, it has to yield specific results. Questionnaires designed for experts typically involve testing by individuals familiar with technology and experience with using different mobile apps. For the improvement and adaptation of the app, more than just a degree of satisfaction is needed. We need to highlight specific issues that have to be handled in order for the app to be beneficial for the older demographic.

In the scientific literature, we encountered various tools used to assess the quality of mobile applications. One such tool is the Mobile App Rating Scale (MARS), developed by [25]. They considered existing guidelines for evaluating the usability of mHealth apps and came to the conclusion that they were incomplete and a reliable and objective instrument was still needed. For this reason, they developed

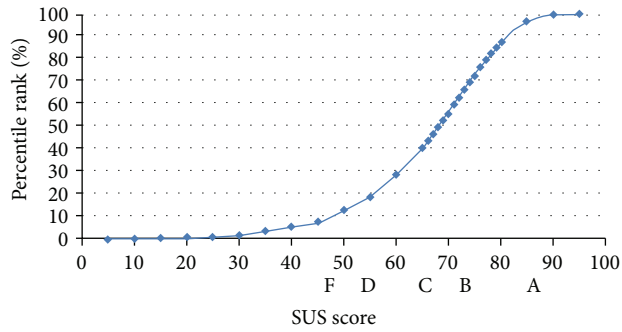


Figure 2: Association between percentile ranks, SUS scores, and letter grades [10].

a multidimensional scale for classifying and rating the quality of mobile health apps.

The largest drawback of the MARS scale, with respect to the elderly, is the fact that it recommends the evaluators complete a training exercise and thoroughly explore the app's content and functionalities. This means that users that are not familiar with the app will not be able to fully rate it. The questionnaire is also far too complex for the average user and it is not geared towards elderly users. In fact, the main reason for the training exercise is the complexity of the questionnaire.

After careful consideration, we decided to adapt the questionnaire developed by [22] instead of the MARS scale. Due to the complexity of most questionnaires and their target audience not being elderly users, we decided to use one that would allow us to gather as much useful information as possible and at the same time not confuse and strain the respondents. The questionnaire was not primarily developed for elderly users to evaluate the app but was adapted and yielded quick and specific results. However, some questions still had to be answered by an expert, because they were either beyond the scope of the performed test, or because they were based on experiencing rare occurrences. For example, the questions about fault tolerance can only be answered, if a mistake is made while entering data. Since the users in our case have not encountered that issue and could not know how or if the app manages erroneous input, they could not answer this question.

In addition to the chosen and adapted questionnaire (see Table 1), we also decided to use the System Usability Scale (SUS), as SUS has become an industry standard, with references in over 1300 articles and publications [26]. SUS was not intended to diagnose usability problems, but it can be used for benchmarking outside of a usability test. In our care, it would serve as a comparison of perceived usability between before and after the applied changes.

SUS provides a reliable tool for scoring the usability. It consists of a 10-item questionnaire with 5 response options for respondents, from "Strongly agree" to "Strongly disagree."

In order to get the best ranking (A), a score above an 80.3 is needed (see Figure 2). This is also the point where users are more likely to be recommending the product to a friend. Scoring at the mean score of 68 equals a C and anything below a 51 is an F (the bottom 15%).

Age-specific requirements, such as screen size, colour, and use of symbols normally familiar to younger users, can cause usability issues in older users. Also, differentiations between clickable and unclickable areas, all play an important role in the end user's desire to use the application. Our objective was to determine specific issues and relay that information to the developers as simply and clearly as possible, so the problems could be dealt with and the app could be optimised for older users. The results can also be used as a guide when designing applications for the elderly, as they offer certain guidelines and highlight important areas.

4. Results

The first test included users over the age of fifty, with the average age of 64. They were instructed to open the application and perform the following tasks: (1) measure their blood glucose level, (2) record their stress level, (3) view the data on the charts, (4) review the data in the logbook, and (5) send the data to their physician (see Figure 3). The moderator was observing the user and helping them with simple suggestions, if they did not know how to perform the task. After the test was completed, they were asked to answer the two chosen questionnaires and grade their experience.

The questions that were deemed unsuitable for the users, specifically the criterion of "general characteristics," were answered by an expert. This was done because we consider the fault tolerance/fault management to be an important aspect of mHealth apps and should be handled appropriately. If a user does not input an erroneous value during the test, they would never notice this feature was not available, but a regular user would encounter this problem eventually.

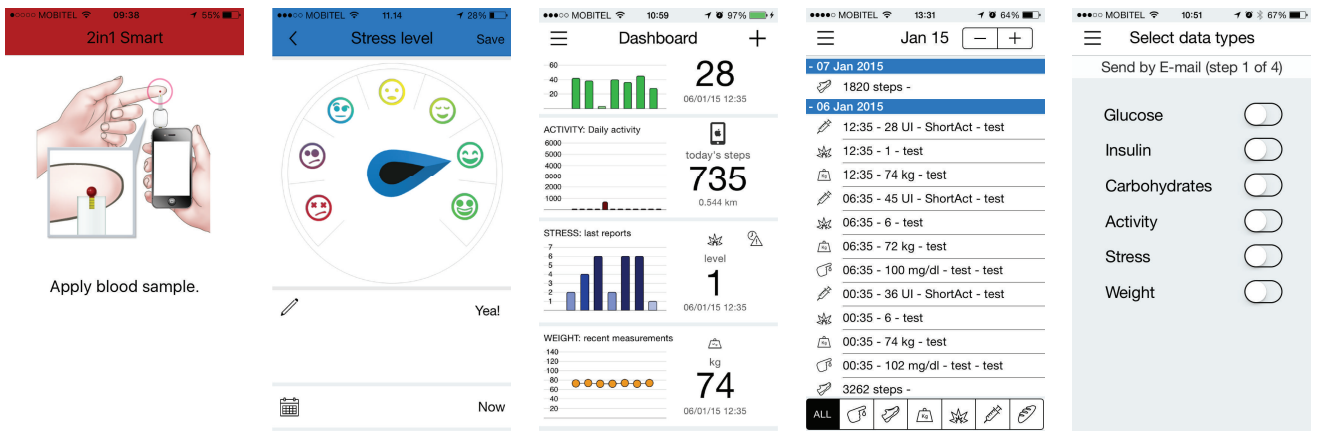
Analysing the results, the evaluations were in the range of 3.0 to 4.3, which corresponds to a moderate to good rating of the app. The app received the lowest rating for the criterion "comprehensibility," specifically the subcriterion of "simple comprehensibility and interpretability of displayed images and depictions," with a total average value of 2.6 (the rationale for the low score by the users was "The symbols do not look like buttons. They look like random images.", "I could not find the 'add' and 'menu' buttons", etc.).

The lowest scored characteristic was the "provision of additional explanations," with the average value of 1.8. This rating comes as no surprise, as there was no welcome wizard or any other help in the app. The app received the best rating for the criterion "presentation" (4.3) followed by "usability" (3.5) (the rationale for the good rating in "presentation" was "The screen size is very good. I can use the application without my glasses", "I like the colours used in the app and the text is big enough", etc.).

The criterion valued by the expert was rated the worst with the value of 1, due to the fact that the subcriterion of "high fault tolerance/efficient fault management" was not dealt with properly in the app. The data input was not limited to meaningful values and there was a lack of user feedback in the case of erroneous data input. Both of these problems were also detected by one of the users who had issues measuring blood glucose automatically and decided to input it manually. When they made a mistake while choosing

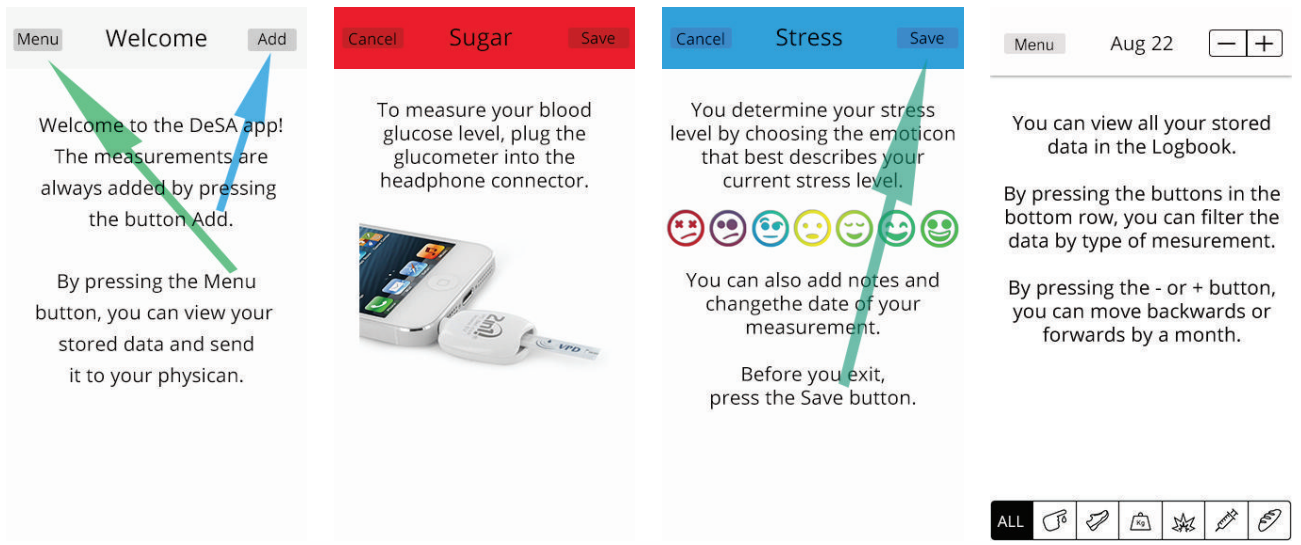
Table 1: Questionnaire used in testing, adapted from [22].

Main criterion/subcriteria	Description of characteristics	Assessment criteria
Comprehensibility	*Use of understandable semantics* (i) Avoidance of foreign language and technical terms (ii) Use of generally intelligible symbols and terms (on buttons) (iii) If necessary, provision of additional explanations	5-point Likert scale (1 = does not apply at all; 5 = does fully apply)
	Simple comprehensibility and interpretability of displayed images and depictions (i) Self-explanatory images and depictions, understandable without further support and explanations	5-point Likert scale (1 = does not apply at all; 5 = does fully apply)
	Simple, self-explanatory menu structures (i) Easily understandable and internally consistent menu structures (ii) Avoidance of strong hierarchical menu structures and too many functionalities	5-point Likert scale (1 = does not apply at all; 5 = does fully apply)
Presentation (Image and Text)	*Sufficient colour contrast* (i) Clear, distinguishable colours for images and depictions or choice of colour-neutral depictions (ii) Avoidance of excessively glaring colours	5-point Likert scale (1 = does not apply at all; 5 = does fully apply)
	Large size of operating elements (i) Sufficient size of screen as well as input and output fields	5-point Likert scale (1 = does not apply at all; 5 = does fully apply)
Usability	*Intuitive usability* (i) Ability to use the application without prior knowledge (ii) Ease of learning (iii) Fast achievement of a first feeling of success	5-point Likert scale (1 = does not apply at all; 5 = does fully apply)
	Simple recognition of click-sensitive areas (i) Simple distinction between click-sensitive and non-click-sensitive areas, also without prior knowledge of the features of the touchscreen technology	5-point Likert scale (1 = does not apply at all; 5 = does fully apply)
General characteristics	*High fault tolerance/efficient fault management* (i) Reducing probability of erroneous data input by limiting choice to meaningful values (ii) Efficient proofreading mode and/or helpful user feedback, for example, in case of erroneous data input	5-point Likert scale (1 = does not apply at all; 5 = does fully apply)



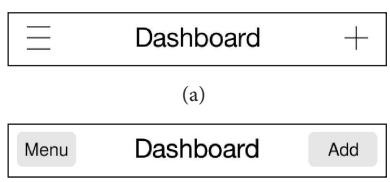
(a) (b) (c) (d) (e)

Figure 3: (a) Measuring glucose with the device, (b) assessing stress level, (c) chart overview, (d) logbook, and (e) sending observations by email.



(a) (b) (c) (d)

Figure 4: Added instructions for easier use.



(a)

(b)

Figure 5: (a) The buttons of the original app on first launch; (b) the changed buttons.

the blood glucose level, they were not alerted to a possible error.

The following categories of problems were represented the most:

(i) The app was missing a welcome wizard with instructions to help the user get started.

(ii) The icons used on buttons were confusing; there were problems differentiating between a button and an image or text.

(iii) The app was missing error notifications (e.g., in case of erroneous input).

(iv) The input data was not validated or limited to meaningful values (e.g., the possibility of choosing dates in the future).

The users found the first screen (dashboard) of the newly installed app confusing, due to the lack of any data or instructions. There were problems distinguishing the buttons on the screen; only the users with prior smartphone experience could find the add (+) button, but even these could not find the menu (≡) button (see Figure 5(a)). All the other users had to be aided in finding both buttons to initiate the testing procedure.

If the welcome wizard would guide the user and offer an explanation of the different button symbols and what they represent, the user might find the application easier to use. The two most common cognitive declines that accompany aging both affect the memory function, either the working memory, that is, the ability to maintain information actively as it is being processed, or the episodic memory, which has the ability to store new memories of events [27]. Therefore, it might be more beneficial to make the buttons clearer and simplify the use. This eliminates the need to read instructions every time the app is used. The buttons should have text or symbols with text, so the user knows what they represent.

The SUS score of the first test was 64.4 (see Figure 6(b)), which gives it a D grade or the percentile rank of 30%.

4.1. Improving the Usability. After reviewing the questionnaire results, modifications were made in the app's appearance and functionalities. The first step was to add a welcome wizard, which helps a new user learn how to use the app (see Figure 4).

The next step was to change the button symbols into text and enable the iOS accessibility functions which allow a user to enlarge text and, if needed, draw button shapes to make buttons more apparent (Figure 5(b)).

Additionally, error notifications and input checking (limiting values to meaningful numbers) were also added. Most users did not detect this problem, but it was observed by the moderator and could present a significant usability issue when used frequently.

Next, the text colour of the Add menu was changed to increase contrast, because some users had a problem with distinguishing black letters on the dark background.

4.2. Second Testing Phase. The second testing phase was performed on a different set of users with the average age of 65. The same moderating technique was adopted and the

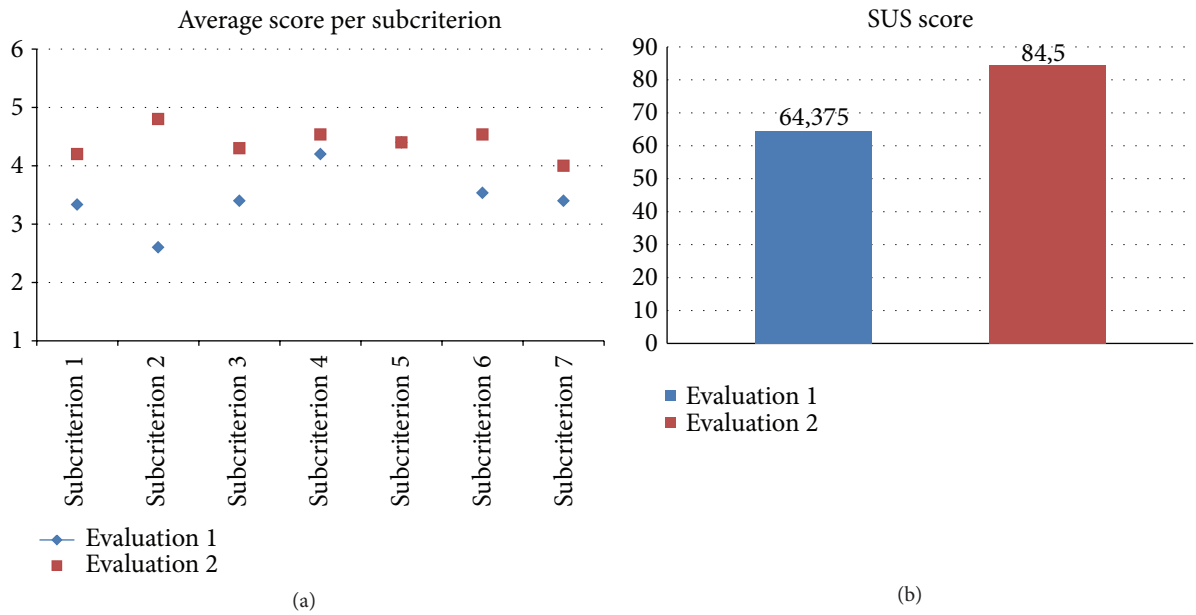


Figure 6: Questionnaire and SUS results.

users filled out both questionnaires (SUS and Table 1). The SUS results were slightly higher than the first evaluation with a score of 84.5 (see Figure 6(b)). All criteria rated better in the second evaluation, with the smallest difference in the criterion "presentation", which was already the best graded category in the first test (with the average score of 4.5). The biggest difference in the modified app was noticed in the "comprehensibility" criterion, where the grade went from 3.1 to 4.4. The increase was also very apparent in the "usability" criterion, with an increase from 3.5 to 4.3 (see Figure 6(b)).

5. Discussion

Since the average age of the population in developed world is increasing, the number of chronic conditions is also on the rise. For all interventions involving mobile apps, certain aspects should be considered when trying to involve elderly users. Our own experience has shown that not involving elderly users in the design and development process can cause significant usability barriers in that demographic. This is especially true when such app is meant to be used by the same target population that also has the highest prevalence of the disease.

During the evaluations, two users stood out; one of them had no experience with touchscreen devices, used an old mobile phone for making calls only, had never used the Internet or sent any text messages, and had never used a computer. The other one was an advanced user that had used different sports apps in connection with body sensors to track his physical activity. Interestingly, they both had similar usability issues regarding the app. The only important difference was the advanced user's lack of fear of technology. A common problem with elderly users is their reluctance to press buttons due to the fear of breaking something. The advanced user clicked around the screen until he found what he was looking for, while the others spent a lot of time observing the screen and trying to determine the correct step.

The presented results are generic findings that would improve the usability for most users. But there are of course users that could still have problems using the app, especially users with limited technical proficiency. Such users would benefit from having assistance until they get comfortable with using new technology. A similar approach will be used in the project UNCAP where the technology training and familiarization have started long before the service is available to the users. This means the users will already be acquainted with different aspects of using mobile apps. Such training with caregivers also gives the developers valuable insight into what users want and need.

The most important points to keep in mind when designing an app for the elderly are thus the size, visibility, and comprehensibility of buttons and symbols. It can also be beneficial to combine symbols with text to increase clarity. Most modern devices (including those running iOS and Android) have built-in accessibility support that can be enabled in the app, in case users need to enlarge the text size, enable voice over, invert colours, and so forth. However, in case of iOS, the app needs to specifically support it, which is highly recommended.

Additionally, helpful tips and explanations must be available to the user. They can be in the form of a welcome wizard or as an additional button, which is always available to the user in case they need assistance. Age-related memory decline and not being very familiar with the technology can cause the user to become easily confused; therefore, it is very important to give them the possibility of looking for help. The general trend in this area is worrying, with device makers making unsubstantiated claims about their devices being simple to use, while this may increasingly not be the case anymore.

Next, colour contrast needs to be taken into account for users with poor eyesight; when using stronger background colours, the designer has to make sure the text remains legible. This problem is further exacerbated with modern high-resolution screens, which allow even thinner fonts with poorer legibility [28]. This goes hand in hand with the recent shifts from skeuomorphic to flat design mobile operating systems, as it has a significant impact on the overall usability. For example, earlier versions of iOS implemented a skeuomorphic design, styling the user interfaces with the specific goal to resemble real-world objects. This greatly aided the first-time users and educated them on how to use the applications by analogy. By ensuring the app has all the accessibility functions enabled, at least some of the issues attributed to flat design can be mitigated.

Another important aspect lies in the overlap of usability and data integrity. Handling exceptions and faults, as well as validating user input, is of crucial importance both for ease of use and for ensuring clean and valid data. This is especially important in mHealth apps, where medical decisions can be later made based on faulty data, having significant impact on the well-being of the patient.

We understand that the test users did not use all of the functionalities of the app, which could affect the overall score significantly. In [22], the authors came to the conclusion that the presence of documentation and analysis functions reduced the usability score significantly. Since the DeSA app was not compared to other apps, we could not determine whether an application with fewer functions would be preferable to the users; however, we do estimate that the larger number of features makes the app harder to use.

6. Conclusion

In this paper, we performed an evaluation of an existing diabetes app in two consecutive test trials with elderly users, using two different questionnaires in parallel. The overall results show, that applications developed for the general population are not necessarily suitable for elderly users, which can be a significant problem, especially if they address the issues of the elderly users specifically. We demonstrated that, with a limited amount of modifications, an existing app can be significantly improved to better suit elderly users. This could also be facilitated by creating different profiles to optimize the app for different accessibility groups (e.g., poor eyesight and limited dexterity). A user could simply select their profile and the app would be configured to their preferences. Such personalization features would of course have significantly larger impact and reach, if they were consistently implemented in all of the major mobile device operating systems. Making apps that would suit any and every user would be a very difficult if not impossible task. In particular, if one develops apps meant for a wide audience. The best one can currently do is focus on some characteristics that most users of the target group have in common and try to adapt the app to best suit their needs. Considering the number of older users that will need the help of mHealth apps in the future, it is increasingly important to focus our efforts on delivering beneficial solutions that will suit this demographic. This will hopefully help them take control of their disease and prolong their independence.

Conflict of Interests

The authors declare that there is no conflict of interests regarding the publication of this paper.

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Research Article

Uptake and Effects of the e-Vita Personal Health Record with Self-Management Support and Coaching, for Type 2 Diabetes Patients Treated in Primary Care

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We studied the use, uptake, and effects of e-Vita, a personal health record, with self-management support and personalized asynchronized coaching, for type 2 diabetes patients treated in primary care. Patients were invited by their practice nurse to join the study aimed at testing use and effects of a personal health record. Patients were followed up for 6 months. Uptake and usage were monitored using log data. Outcomes were self-reported diabetes self-care, diabetes-related distress, and emotional wellbeing. Patients' health status was collected from their medical chart. 132 patients agreed to participate in the study of which less than half (46.1%) did not return to the personal health record after 1st login. Only 5 patients used the self-management support program within the personal health record, 3 of whom asked a coach for feedback. Low use of the personal health record was registered. No statistical significant differences on any of the outcome measures were found between baseline and 6 month follow-up. This study showed minimal impact of implementing a personal health record including self-management support in primary diabetes care. Successful adoption of web-based platforms, as ongoing patient centered care, is hard to achieve without additional strategies aimed at enhancing patient motivation and engaging professionals.

1. Introduction

Type 2 diabetes mellitus (T2DM) is a chronic metabolic disorder characterized by hyperglycemia and an increased risk of developing micro- and macrovascular complications [1, 2]. The estimated world prevalence of 387 million T2DM patients is rapidly increasing [3]. To deal with the increasing number of people with T2DM, and burden on diabetes health care, alternative treatment options are being considered. Successful treatment of diabetes builds on empowering patients in their daily self-management of the disease, with a focus on healthy eating, being active, and taking medication as recommended [4–6]. A patient centered approach is called for to improve both medical and psychological outcomes [7–10]. Patient centered care is characterized by shared decision making between patient and professional, guided by the preferences, needs, and values of the patient [11]. One way of supporting patient centeredness is by using a personal health record (PHR) [12, 13]. In general, PHRs are web-portal environments with which patients can get an overview of their health outcomes, communicate with their care provider, and read information regarding their disease. PHRs support a patient centered approach by allowing patients to get more involved in their own disease management and decision

making process. It has been shown that a PHR could be beneficial for people with T2DM [14]. Therefore, PHRs aimed at empowering patients with their self-care could have the potential of decreasing the workload of diabetes care providers and improve (cost-)effectiveness of diabetes treatment [15–18].

For these reasons, the foundation Care Within Reach (in Dutch: Stichting Zorg Binnen Bereik, founded by Philips and Achmea, a Dutch health insurance company) created the "e-Vita" PHR which advocates a patient centered approach for supporting people with T2DM who are treated in primary care in the Netherlands. Like comparable PHRs, e-Vita provides access to diabetes education and personal clinical outcome measures which are retrieved from the digital medical records of primary care practices. Additionally, e-Vita offers the opportunity of reading messages that were sent by the care provider and an additional self-management support program (SSP) [19]. An SSP is uncommon for PHRs and was added to further support patients in their diabetes self-management and to possibly uphold usage rates, which are known to be an issue for PHR [20, 21]. The SSP is based on the principles of personal goal setting and goal evaluation for behavioral change, guided by the Health Action Process Approach (HAPA) model from Schwarzer [22]. The SSP within e-Vita allows patients to choose from 4 predefined behavioral goals (diet, exercise, medication adherence, and stopping smoking) as advised by the Association of American Diabetes Educators (AADE) [5]. To support patients in achieving these goals, they can formulate self-chosen action plans, after which they are encouraged to carry them out. Eventually, patients are prompted to evaluate their behavioral goals and action plans with help from the SSP, based on graded tasks and barrier identification [23]. After goal evaluation, patients are encouraged to restart the behavioral goal setting and action planning procedure [21, 24]. Within the SSP, a coaching functionality was added, consisting of asynchronized messaging between coach and user, to enhance the effectiveness of the SSP and stimulate further continued usage of the e-Vita PHR [20].

In the current study, we looked at the uptake and effects of the e-Vita personal health record with self-management support program and additional asynchronized coaching, in a sample of type 2 diabetes patients treated in primary care.

2. Research Design and Methods

2.1. Design Overview. The scientific data comes from an overall 2-year e-Vita PHR project, which were made available for multiple research institutions to conduct longitudinal cohort studies and (cost-)effectiveness studies [19, 25]. Data for this study were obtained from a randomized controlled trial (RCT) with the e-Vita PHR and the SSP, which was part of the bigger overall 2-year e-Vita PHR project [21]. The study was approved by the medical ethical committee of the VU University Medical Center.

2.2. Setting and Participants. Participants for the e-Vita project were approached within 52 primary health care practices with the possibility of reaching approximately 8300 T2DM patients for a study period of 2 years. For the current study, participants were enrolled for an inclusion period of 6 months between July 1, 2013, and December 31, 2013. Patients who visited their primary care physician for routine checkup were made aware of the study and the availability of the PHR by their practice nurse. Patients received information about the study, and if they agreed to participate, they had to sign an informed consent and fill out questionnaires at different time-points during the study period. When patients expressed interest in using the PHR, the practice nurse registered the patient into the PHR (online registration) and provided a brochure with information regarding the login procedure. After registration, the patient received automated login codes via e-mail. Patients could use the PHR, without having to participate in the study.

In general, the health care practitioners who agreed to facilitate the study and PHR received financial compensation if they were able to include patients in the overall e-Vita project. However, there were no direct incentives for patients nor professionals to participate. By doing so, we tried to resemble standard care as much as possible. Inclusion criteria were a diagnosis of T2DM and age of ≥18 years. Exclusion criteria were mental retardation or psychiatric treatment for schizophrenia, organic mental disorder, or bipolar disorder currently or in the past, insufficient knowledge of the Dutch language, life expectancy of <1 year due to malignancies or other terminal illnesses, and/or cognitive impairment.

2.3. Coaching. Between July 1, 2013, and December 31, 2013, patients who logged into the PHR for the first time were informed about a study and were asked for consent to participate in the study, by selecting an option "yes I agree to participate." Patients were able to use the PHR without being randomized, and then they would not be included in the current study. After consent, participants were randomized into 2 groups. Participants remained blinded for group allocation. Some participants were able to ask for feedback from a coach after they had set a goal and planned an action within the SSP (coaching group; CG) and others could not (noncoaching group: NCG). The feedback of the coach would mainly contain positive appraisal and constructive advice for improving the planned action of the patient by commenting on specificity, measurability, attainability, realism, and the time frame. Additionally, participants received personal messages from their coach, which consisted of one welcome message (0 weeks) and 2 encouraging reminders at 4 weeks and 8 weeks after enrollment to keep using the PHR and the SSP. All messages contained additional instructions on how to use the SSP within the PHR.

2.4. Measurements. The *use* of the PHR and the SSP was tracked objectively by collecting anonymized log data, which contained information about time, date, and type of actions performed within the PHR.

For baseline (T0) and follow-up measurements after 6 months (T1), the following information was obtained.

Diabetes self-care (general diet, specific diet, fruit intake, carbohydrate intake, fat intake, 30 minutes of exercise behavior, specific workouts, blood glucose control, medication

adherence, foot care, and shoe check-up) was measured by the Summary of Diabetes Self-Care Activities (SDSCA), measured on an 8-point scale (α = .47) generating mean scores ranging from 0 to 7 days a week [26, 27].

Diabetes-related distress was assessed by the Problem Areas In Diabetes care survey 5-item version (PAID-5), measured on a 5-point Likert scale (α = .86) with total sum score ranging from 0 to 20, where elevated distress is defined by scores >8 [28].

Emotional wellbeing was measured with the World Health Organization Wellbeing Index 5 items' questionnaire, measured on a 5-point Likert scale (α = .86). The total sum scores are transferred from 0 to 100, where higher scores indicate better mood [29, 30].

Health status (glycemic control (HbA1c), Body Mass Index (BMI), systolic blood pressure, diastolic blood pressure, cholesterol, and smoking status) was extracted from patients' health care records, covering the same time period of when patients participated in the study. Additionally social demographic information was obtained (gender, age, education, occupation, and prescribed medication).

2.5. Statistical Analysis. Percentages were calculated to examine login, use of the PHR, SSP, and coaching functionality. Analyses were conducted using SPSS software. We applied a two-sided 5% level of significance for all statistical analyses. Longitudinal linear regression, using Generalized Estimation Equations (GEE), was applied to investigate the differences on outcome variables over time and between the two groups. Analyses were based on intention-to-treat. All analyses were corrected for age, gender, T2DM duration, complications, ethnicity, and outcome baseline values.

3. Results

3.1. Inclusion. In the overall e-Vita project, 1378 patients participated, 947 of which expressed interest in using the PHR, and 405 patients were eventually registered by the practice nurse to use the PHR [25]. For the current study, from July 2013 until December 2013, 165 people were registered by their practice nurse to use the PHR, of which 132 (80%) agreed to participate in the current study. Of the 132 people who agreed, 66 (50%) were able to use the coaching functionality within the SSP. More than half of the participants were male (59.1%). Mean age was 67.9 (SD = 10.4). The baseline sociodemographic, clinical, and medical characteristics of the study sample are summarized in Table 1.

3.2. Use. During the period from July 2013 to July 2014, 128 (96.9%) participants logged into the PHR after randomization and inclusion. Of these 128 people, 59 (46.1%) participants (28 CG and 31 NCG) never returned to the PHR during the study period. An overview of frequencies of the number of logins is presented in Table 2. Six participants (5 CG and 1 NCG) used the SSP within the PHR. The demographic information of these 6 people is shown in Table 3. Three participants used the coaching functionality within the SSP and asked for feedback on their set goals. Their goals can be grouped into *healthy eating* (n = 3), *being active* (n = 3), and *quitting smoking* (n = 1). Table 4 shows the actions per session of the three participants who asked for feedback. In general, 1 participant used the SSP in combination with the *overview of personal clinical outcome measures*, while 1 participant used the SSP in combination with the *diabetes education*. One participant only used the SSP without using other components.

Participants in the coaching group received 3 additional personal messages from their coach in the form of a welcome message and 2 reminders. 16.7% logged in within one week after receiving the welcome message, compared to 4.5% of the NCG. 9.1% logged in within one week after the first reminder, compared to 7.6% of the NCG. 15.2% logged in within one week after the second reminder, compared to 7.6% of the NCG, who did not receive a welcome message or reminders. The number of logins after the reminder messages is presented in Table 5. Throughout the study period, 2 e-mail messages with news updates were sent from the e-Vita PHR to all 132 participants of this study. 82.9% of the participants logged in within one week after receiving the first general message (85% CG and 80.9% NCG). 31.8% of the participants logged in within one week after receiving the second general message (25% CG and 41% NCG).

3.3. Outcome Measures. A total of 68 participants (51.5%) filled in the follow-up questionnaire (T1). For these participants (CG: 29, NCG: 39), statistical analyses showed that there were no significant differences in time on any of the outcome measures between baseline and T1 follow-up for the two groups.

4. Discussion

The aim of this study was to assess the uptake and effects of a personal health record with a self-management support program and additional asynchronized coaching, for type 2 diabetes patients treated in primary care. Our most important findings are discussed below.

4.1. Inclusion of Patients. The inclusion rate of the current study was dependent on the overall 2-year e-Vita PHR project. As mentioned by Roelofsen et al., the inclusion rate of participants for the overall 2-year e-Vita PHR project turned out to be lower than anticipated, which may have had influence on the inclusion of the current study. In the overall e-Vita project, 70.6% of the approached patients were interested in using the PHR. However, only 42% of these patients were enrolled by their care provider [25]. The care providers involved in the e-Vita project indicated that lack of integration of the PHR with work routines, lack of knowledge about the PHR, lack of time, and PHR related usability problems were the main reasons for not using the PHR in daily routine care and not referring or enrolling patients [31]. Eventually, for the 2-year e-Vita project, only 27% of people who were registered to use e-Vita logged in at least once. It was later uncovered that difficult login procedures with e-Vita may have discouraged patients to log in [31]. Therefore, it was possible that patients with low technological skills may not have been included in the current study.

Table 1: Baseline characteristics.

	Total (n = 132)	CG (n = 66)	NCG (n = 66)	P value
Sociodemographics				
Gender				.239
Female	54 (40.9%)	37 (56.1%)	25 (37.9%)	
Male	78 (59.1%)	29 (43.9%)	41 (62.1%)	
Age	67.9 (10.4)	67.4 (10.5)	68.3 (10.4)	.602
<50	6	2	4	
50–64	47	30	17	
65–74	50	18	32	
>75	29	16	13	
Ethnicity[1]				1.000
Caucasian	91	45	46	
Non-Caucasian	1	1		
Education[2]				.866
No or school level qualifications	20 (15.2%)	10 (15.2%)	10 (15.2%)	
Professional or vocational	46 (34.8%)	21 (31.8%)	25 (37.9%)	
Bachelor's degree or higher	43 (32.6%)	22 (33.3%)	21 (31.8%)	
Employed	43 (32.6%)	18 (27.3%)	25 (36.9%)	.529
Medical outcomes				
Diabetes duration	5.82 (±4.62)	5.77 (±4.35)	5.86 (±4.91)	.917
BMI	30.19 (±5.16)	30.72 (±5.06)	29.67 (±5.25)	.284
HbA1c (mmol/mol)	48.50 (±7.49)	48.49 (±7.31)	48.52 (±7.33)	.985
Treated with tablets[3]	87 (65.9%)	44 (66.7%)	43 (65.2%)	.652
Treated with insulin[3]	15 (11.4%)	10 (15.2%)	5 (7.6%)	.172
Treated with tablets and insulin[3]	14 (10.6%)	9 (13.6%)	5 (7.6%)	.263
Systolic blood pressure (mm Hg)	135.57 (±15.58)	136.65 (±16.62)	134.53 (±14.58)	.473
Diastolic blood pressure (mm Hg)	78.47 (±9.58)	78.07 (±9.48)	78.86 (±9.74)	.670
Cholesterol (mmol/L)	4.34 (±.84)	4.19 (±.83)	4.50 (±.82)	.045
Smoking[4]	18 (13.6%)	9 (13.6%)	9 (13.6%)	.954
Outcome measures				
Emotional wellbeing	70.83 (±14.84)	71.21 (±13.02)	70.47 (±16.46)	.798
Diabetes distress	2.15 (±2.41)	2.37 (±2.51)	1.96 (±2.32)	.385
General diet	5.59 (±1.83)	5.88 (±1.57)	5.30 (±2.02)	.102
Specific diet	4.44 (±.84)	4.46 (±.83)	4.42 (±.86)	.814
Exercise	3.91 (±1.76)	3.90 (±1.95)	3.92 (±1.58)	.964
Foot care	1.80 (±2.13)	1.93 (±2.11)	1.68 (±2.15)	.542

Note. CG: coaching group; NCG: noncoaching group; BMI: Body Mass Index; HbA1c: blood glucose control; [1]n = 40 missing data; [2]n = 23 missing data; [3]n = 20 missing data; [4]n = 17 missing data.

4.2. Usage of the Personal Health Record. When looking at the usage of the PHR for people in the current study, the initial high login rate may indicate that patients were interested in using the PHR, which seems in line with recent research, which shows that the older population is increasingly using the Internet to maintain their independence [32]. However, the rapidly declining use could indicate that the aim of the e-Vita PHR, which was to support patient centeredness and promote healthy behavioral change, may not have matched the expectations or needs of the patients [24]. It could be that patients are not yet ready to embrace a patient centered approach and therefore do not feel compelled to use the PHR. The low usage may also indicate that the content of the PHR was not sufficient to support patient centeredness or not appealing enough to stimulate continued usage. Forgetting about the PHR can contribute to underuse as well [33]. Sending multiple personal and general messages to stimulate use of the PHR and the SSP did seem to influence some people to log in again but did not result in a substantial increase of usage of the SSP.

Research has shown that a perceived positive health status by patients may contribute to low use of a PHR [33]. The outcome measures in this study indicated that, besides BMI, patients were well controlled and had little room for improvements (e.g., glycemic control < 50 mmol/mol; cholesterol < 4.5 mmol/L; diastolic blood pressure < 80 mm Hg). This positive health status may have lowered the patients' perceived need for continuously using a PHR.

Table 2: Login frequency of participants in the RCT study.

Number of logins	Total (n = 132)		CG (n = 66)		NCG (n = 66)	
	Users who logged in	Average duration (m:s.ms)	Users who logged in	Average duration (m:s.ms)	Users who logged in	Average duration (m:s.ms)
1	128 (97.0%)	08:47.87	65 (98.5%)	10:18.06	63 (95.5%)	07:12.78
2	69 (52.3%)	07:50.90	37 (56.1%)	07:50.59	32 (48.5%)	07:51.25
3	44 (33.3%)	11:06.41	22 (33.3%)	15:03.73	22 (33.3%)	07:09.09
4	31 (23.5%)	10:28.03	18 (27.3%)	14:50.28	13 (19.7%)	04:24.92
5	24 (18.2%)	11:38.08	14 (21.2%)	10:00.00	10 (15.2%)	13:55.40
6	18 (13.6%)	07:11.56	12 (18.2%)	07:48.67	6 (9.1%)	05:57.33
7	17 (12.9%)	09:17.76	11 (16.7%)	08:06.18	6 (9.1%)	11:29.00
8	13 (9.8%)	06:55.85	8 (12.1%)	09:10.25	5 (7.6%)	03:20.80
9	10 (7.6%)	08:39.40	6 (9.1%)	07:15.50	4 (6.1%)	10:45.25
10	10 (7.6%)	12:09.60	6 (9.1%)	09:52.00	4 (6.1%)	15:36.00
11	8 (6.1%)	03:52.75	4 (6.1%)	02:59.00	4 (6.1%)	04:46.50
12	8 (6.1%)	06:09.37	4 (6.1%)	07:45.75	4 (6.1%)	04:33.00
13	6 (4.5%)	14:17.33	3 (4.5%)	23:58.33	3 (4.5%)	04:36.33
14	5 (3.8%)	03:37.00	3 (4.5%)	01:40.67	2 (3.0%)	06:31.50
15	3 (2.3%)	03:23.67	1 (1.5%)	01:00.00	2 (3.0%)	04:35.50
16	2 (1.5%)	26:19.50	1 (1.5%)	08:24.99	1 (1.5%)	44:14.00
17	1 (0.8%)	01:00.00	0		1 (1.5%)	01:00.00
18	1 (0.8%)	01:00.00	0		1 (1.5%)	01:00.00
19	1 (0.8%)	02:21.00	0		1 (1.5%)	02:21.00
20	1 (0.8%)	02:12.00	0		1 (1.5%)	02:12.00
21	1 (0.8%)	01:00.00	0		1 (1.5%)	01:00.00
22	1 (0.8%)	01:00.00	0		1 (1.5%)	01:00.00
23	1 (0.8%)	06:49.00	0		1 (1.5%)	06:49.00
24	1 (0.8%)	01:00.00	0		1 (1.5%)	01:00.00
25	1 (0.8%)	04:16.00	0		1 (1.5%)	04:16.00

Note. CG: coaching group; NCG: noncoaching group; m: minutes; s: seconds; ms: milliseconds.

It is known that professional caregiver endorsement plays a vital role in encouraging patients to use the PHR [34]. Interviews with care providers revealed that they did not embrace using the PHR in their work routines [31]. Due to the relatively high quality of primary care and well-controlled T2DM patients in the Netherlands, it could be that care providers simply do not feel the need to integrate a PHR in daily care routines or recommend it to their patients.

4.3. Usage of the Self-Management Support Program. The SSP was developed to help sustain usage and to support patients with changing their health behaviors by endorsing goal setting and action planning. The well-controlled health status of the patients, and possible absence of perceived disease burden, may have contributed to low intentions for behavioral change and subsequent low usage of the SSP. When patients do not have intentions for behavioral change, then goal setting and action planning might not be considered as relevant or useful [35]. Therefore, at this stage, the SSP might be a mismatch with the needs and expectations of the patients who agreed to use the PHR. Interestingly, the clinical profiles of the 3 patients who did actively use the SSP did not indicate that they would highly benefit from using the SSP.

However, these patients had been recently diagnosed with T2DM. It could be that these patients were still adapting to their diagnosis and looking for information on effective coping strategies. For the SSP to be used more, it will need to match patients' needs and intentions for behavior change and should be further endorsed by the care provider. The lack of engagement and high attrition have been observed repeatedly in e-health. Most promising remedy appears to be "blending" of e-health with face-to-face consultations, thus affecting involvement of professionals. Having only the PHR target patients' risk perception, self-efficacy, and outcome expectancies, which are determinants of intention formation (motivation) for behavior change, does not seem to guarantee engagement in using the PHR for healthy behavior change. Both care provider and PHR should facilitate intention formation, by raising risk awareness, and increase outcome expectancy and self-efficacy [22].

Finally, the underuse of the SSP could also indicate that the "look and feel" was not attractive enough to stimulate use.

Table 3: Baseline characteristics of participants who used the self-management support module.

	User 1	User 2	User 3	User 4	User 5	User 6
Group	CG	CG	CG	CG	CG	NCG
Planned action and asked for feedback	Yes (2x)	Yes (3x)	Yes (2x)	No	No	No
Range of platform use from 1st login (weeks)	7	26	11	11	0	0
Sociodemographics						
Gender	Female	Female	Female	Female	Female	Male
Age	40	45	58	71	57	57
Ethnicity	White	White	—	White	—	White
Education	—	BScMSc	BScMSc	SLQ	Prof/voc	BScMSc
Employment	—	Full time	Part time	Retired	Part time	Unemployed
Medical characteristics						
BMI	30.11	26.33	23.34	43.12	—	34.72
HbA1c mmol/mol	41	43	47	50	—	43
HbA1c %	5.9	6.1	6.5	6.7	—	6.1
Diabetes duration in years	2	1	1	6	—	16
Treatment	Tablets	Tablets	Tablets	Tablets	—	Insulin/tablets
Psychological characteristics T0						
WHO5	—	68	80	64	72	92
PAID5	—	9	2	0	5	2
Behavioral characteristics T0						
General diet	—	6	7	7	3.5	5
Specific diet	—	4.67	4.67	5.33	5	6.33
Exercise	—	5.0	1.5	2.5	4	5.5
Medication adherence	—	7	7	7	—	7
Foot care	—	2	0	7	3.5	.5
Self-monitoring blood glucose	—	1.5	—	—	—	.5

Note. CG: coaching group; NCG: noncoaching group; BMI: Body Mass Index; HbA1c: blood glucose control; WHO5: World Health Organization 5 questionnaire; PAID5: problem areas in diabetes questionnaire; —: missing data.

The SSP may have contained too few introductory texts and may have not always been as intuitive in use.

4.4. Development and Implementation. The initial development and implementation protocol of e-Vita followed a linear process, in which patient focus groups were held but where pilot testing and development feedback loops were absent. Additionally, the study protocol required a controlled condition, which hampered the flexibility of the development process. The linear development process and initial lack of pilot testing before implementation could have caused a mismatch with patients' needs, which may have contributed to the underuse of the SSP in this study [36]. Currently, after the completion of this study, the development and implementation process adapted towards an iterative process, following a sequential process of development, feasibility and pilot testing, evaluation, and implementation, which is in line with the Medical Research Council (MRC) framework for complex interventions [37]. For future studies on PHRs, the Medical Research Council (MRC) framework for complex interventions could offer a solution for guiding development, implementation, and complex study processes [37].

4.5. Effectiveness of the Personal Health Record. Only 68 (51.6%) of the 132 users filled in the T1 follow-up measurements after 6 months, which hampered testing of program and coaching effectiveness. There were no differences in outcome measures over time, nor were there differences between the coaching and noncoaching groups. We analyzed the use of the PHR by the three users who asked their coach for feedback; however, the sample was too small to make statements on the effects of a PHR with additional asynchronized coaching.

5. Conclusion

To successfully implement a PHR in a standard care setting, both care provider and patient will need to see the added

Table 4: Actions per session of the three participants who asked for feedback.

User	Session	Used component within the PHR
User 1	8-Aug-13	Education
	4-Sep-13	Yearly checkups + education (9 topics, 13 views)
	6-Sep-13	Education (35 topics) + adding goal, action (*healthy eating, being active*) + education
	6-Sep-13	Yearly checkups + goals + information + education (2 topics)
	6-Sep-13	Reading feedback coach
	6-Sep-13	Yearly checkups + evaluating action + adding new goal, action
	4-Oct-13	Reading feedback coach
	15-Oct-13	Monitoring weight + BMI + yearly checkups
	10-Nov-13	Monitoring weight + BMI + yearly checkups + adding goal evaluation (incl. coaching feedback)
	14-Nov-13	Home
	18-Dec-13	Monitoring weight + BMI + waist circumference + yearly checkup
	16-Jan-14	Monitoring weight + blood pressure + yearly checkup + monitoring BMI
	9-Feb-14	Monitoring weight + yearly checkups
	22-Feb-14	Yearly checkups HbA1c
	28-Jun-14	Monitoring weight + yearly checkups + extra information + education (1 topic)
	5-Aug-14	Monitoring weight (BMI)
	6-Aug-14	Yearly checkups
	22-Aug-14	Coaching
User 2	31-Aug-13	Home + yearly checkups + coaching
	31-Aug-13	Education + yearly checkups
	8-Sep-13	Adding goals, action (*healthy eating*, *being active*, and *quitting smoking*) + education (5 topics)
	5-Oct-13	Adding evaluation; monitoring blood pressure
	7-Oct-13	Reading feedback coach
	23-Oct-13	Overview goals; monitoring blood pressure + yearly checkups
User 3	30-Dec-13	Education
	31-Dec-13	Yearly checkups + monitoring + extra information
	2-Jan-14	Home
	7-Feb-14	Goals + education (3 topics) + messages + yearly checkups + education (6 topics) + goals + extra information + education + extra information + goals + extra information + education + adding goals, actions (*healthy eating*, *being active)*
	7-Feb-14	Reading feedback coach + education
	11-Feb-14	Coaching + education (4 topics)
	27-Feb-14	Evaluating action (not added) + education (3 topics)
	8-Mar-14	Education (5 topics) + coaching + education (1 topic) + goals + coaching Button + extra information
	19-Mar-14	Home
	14-May-14	Education
	24-Aug-14	Home
	20-Sep-14	Explanation AlbCreatRatio; Cockroft

Note. A session is defined as a unique and new login moment.

value and engage actively in the process. In this study, the introduction of the PHR clearly had little impact and was not yet fully integrated into the clinical routine. Future studies should explore ways to effectively prepare both patients and professionals, building on principles of patient centeredness and self-management. Furthermore, for facilitating the use of self-management support programs within a PHR, patients first need to develop intentions for behavioral change, which can only be achieved if patients have sufficient risk awareness, experience a need for behavioral change, and feel self-confident in making these changes. To ensure uptake and effectiveness of a PHR in health care, an iterative process

Table 5: Number of people logged in within a week after a reminder or message.

Number of people logged in	Total (n = 132)	CG (n = 66)	NCG (n = 66)
PHR e-mail 1 (24-7-2013)	**34/132 (25.8%)**	**17/66 (25.8%)**	**17/66 (25.8%)**
	34/41 (82.9%)	17/20 (85.0%)	17/21 (81.0%)
PHR e-mail 2 (21-10-2013)	**29/132 (22.0%)**	**13/66 (19.7%)**	**16/66 (24.2%)**
	29/91 (31.9%)	13/52 (25.0%)	16/39 (41.0%)
Welcome message (IG only, sent immediately after 1st login)	14 (10.6%)	11 (16.7%)	3 (4.5%)
Reminder 1 (IG only, sent 4 weeks after 1st login)	11 (8.3%)	6 (9.1%)	5 (7.6%)
Reminder 2 (IG only, sent 12 weeks after 1st login)	15 (11.4%)	10 (15.2%)	5 (7.6%)
Platform use in weeks	9.75 (8.48)	9.97 (8.53)	9.50 (8.55)

Note. CG: coaching group; NCG: noncoaching group. At the moment of sending the e-mail messages, not all 132 participants were registered yet; e-mail 1 was sent to a total of 41 participants; e-mail 2 was sent to a total of 91 participants.

of continued development, feasibility and pilot testing, and evaluation is important.

Disclosure

Based on the information derived from the current study, the e-Vita PHR and the implementation protocols have been updated and improved.

Conflict of Interests

All authors declare that they have no conflict of interests.

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Research Article

The Motivating Function of Healthcare Professional in eHealth and mHealth Interventions for Type 2 Diabetes Patients and the Mediating Role of Patient Engagement

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eHealth and mHealth interventions for type 2 diabetes are emerging as useful strategies to accomplish the goal of a high functioning integrated care system. However, mHealth and eHealth interventions in order to be successful need the clear endorsement from the healthcare professionals. This cross-sectional study included a sample of 93 Italian-speaking type 2 diabetes patients and demonstrated the role of the perceived ability of healthcare professionals to motivate patients' initiative in improving the level of their engagement and activation in type 2 diabetes self-management. The level of type 2 diabetes patients' activation resulted also in being a direct precursor of their attitude to the use of mHealth and eHealth. Furthermore, patient engagement has been demonstrated to be a mediator of the relationship between the perceived ability of healthcare professionals in motivating type 2 diabetes patients and patients' activation. Finally, type 2 diabetes patients adherence did not result in being a direct consequence of the frequency of mHealth and eHealth use. Patient adherence appeared to be directly influenced by the level of perceived healthcare professionals ability of motivating patients' autonomy. These results offer important insights into the psychosocial and organizational elements that impact on type 2 diabetes patients' activation in self-management and on their willingness to use mHealth and eHealth devices.

1. Introduction

Diabetes currently constitutes a large and growing clinical problem, and its costs for society are high and are escalating. Worldwide, estimated 387 million adults are living with diabetes, and this number is projected to increase to 592 million by 2035 [1–3]. Effective prevention strategies are, therefore, crucial to slow the diabetes tide and its burden. Nearly 9 out of 10 new diabetes cases are type 2 diabetes, characterized by a gradual increase in glycemia [1]; obesity and physical inactivity are some of the most common risk factors [2].

Since type 2 diabetes requires long-term treatment, over the past 20 years the responsibility for the care of people affected by this condition has shifted away from hospitals to primary care settings. The long-term management of chronic conditions requires a revision of classical models of care in order to guarantee positive care outcomes [4] and enhance patient's quality of life [5]. To address this requirement and to manage the patients' care, a more effective synergy between healthcare organizations and territorial services is required [6–8]. Chronic conditions, such as type 2 diabetes, need long-term approach to care, which imply a higher synergy and service integration "outside" of the institutional boundaries of hospitals [9–11]. Thus healthcare organizations not only are concerned with the long-term management of type 2 diabetes patient but also are claimed to redesign their organizational models in accordance with local resources and demands of care. This requires a better integration with the resources (formal and informal; expert and lay) that are present in the territories [12, 13].

Integrated care organizational models are currently envisaged as the potential solution to improve quality and sustainability of healthcare services, particularly when the management of chronic condition (such as type 2 diabetes)

is concerned. However, to achieve the goal of an integrated system of care, the role of the patient, as main actor of such a process, needs to be questioned [14]. In order to guarantee the fruitful collaboration and dialogue between the lay territory of reference for the patient and his/her reference healthcare provider, type 2 diabetes patients need to be helped in enacting an active and cocreative role along their process of care, moving from the traditional passive position of recipients of care to the one of the real engaged consumers in the design and delivery of healthcare services [15–18]. Type 2 diabetes patients' engagement is regarded as a key factor to improve the quality and the sustainability of healthcare services [15, 17, 19]. Previous studies have shown how an engaged patient is more likely keen to act improved health behaviors [20], to have better clinical outcomes [21], to perceive a better quality of life [22], and to be more satisfied with their relationship with the healthcare system [23]. Furthermore, empirical researches have demonstrated how patient engagement may contribute to a reduction of healthcare costs and to better economically sustainable organizational processes [24, 25].

In such a frame, eHealth and mHealth interventions are emerging as a useful strategy to accomplish the goal of a better integrated system of care [11, 26, 27]. As technology-based interventions are becoming regular part of the health care environment, viewing these tools in light of the skills (knowledge and behaviors) required for patients to successfully use them becomes essential if the power of eHealth and mHealth is to be leveraged to deliver health care effectively. As a consequence, promoting patient's eHealth literacy, defined as the ability to seek, find, understand, and appraise health information from electronic sources and apply the knowledge gained to addressing or solving a health problem [28], becomes a priority to enhance the continuity of care. Indeed, eHealth and mHealth offer continuous monitoring of clinical parameters, allowing the "on-demand" communication with the reference healthcare professionals, and, consequently, they are able of empowering the patient in the self-management of the disease condition and his/her therapy [29, 30]. A systematic review showed a positive impact of mHealth on patient engagement in the management of chronic diseases [31]: diabetic patients who transferred daily glucose readings to physicians using a telematics system and received telephone medication regimen feedback improved their clinical outcomes and presented a better glycemic control [32]. Likewise, the use of text message interventions, such as reminders and updates through SMS, ensured a greater adherence to prescription and improved clinical outcomes [33]. Furthermore, studies confirmed the effectiveness of mHealth interventions in modifying type 2 diabetes patients lifestyles, especially those related to dietary behaviors and physical activity, by facilitating diabetes self-management processes outside the clinical setting [34–36].

However, mHealth and eHealth interventions in order to be successful need the clear endorsement from the healthcare system. Particularly, the reference healthcare professionals are the key actors, from the patients' perspective, that can legitimize the intervention process and can motivate type 2 diabetes patients in being compliant with mHealth and eHealth [37]. This underlines the role of healthcare organizational and professional cultures in enhancing or inhibiting the effectiveness of mHealth and eHealth interventions in managing type 2 diabetes. More attention is needed to explore how innovation through the introduction of new health technologies can be integrated in the systems of symbols, practices, and power relationships already existent in healthcare organizations [38]. Thus, the enabling role of healthcare professionals in the eHealth and mHealth interventions for type 2 diabetes needs to be further considered as a fundamental ingredient for their clinical success. Healthcare professionals should sustain type 2 diabetes patients' autonomy in care management and thus their motivation to adhere to the mHealth and eHealth intervention.

Based on these premises, the present study, carried out on a sample of Italian type 2 diabetes patients, was aimed at verifying the following hypotheses:

(1) The perceived ability of the healthcare professionals to support patients' autonomy influences the level of patients' engagement towards their care management.

(2) The perceived ability of the healthcare professionals to support patients' autonomy influences the level of patients' activation towards their care management.

(3) The levels of patients engagement mediate the association between the perceived ability of healthcare professionals to support patients' autonomy and the level of patients' activation.

(4) A higher level of activation is associated with a higher use of mHealth and eHealth technologies to seek information for managing type 2 diabetes care.

(5) A higher level of use of mHealth and eHealth technologies to seek information for managing type 2 diabetes care is associated with a higher patients' adherence to type 2 diabetes care.

2. Materials and Methods

2.1. Recruitment and Data Collection. This cross-sectional quantitative study included a sample of 93 Italian-speaking type 2 diabetes patients and was conducted on the basis of a structured questionnaire including validated measures (see Section 2.2) to assess the causal relations among the constructs under analysis (see research hypotheses stated above). Patients were recruited through the online panel provided by Research Now (http://www.researchnow.com/en-US.aspx). The panel covers a wide range of chronic conditions and counts more than 6.5 million registered subjects worldwide. Subjects belonging to the panel are carefully screened for authenticity and legitimacy via digital fingerprint and geo-IP-validation from the provider. All panelists are profiled on the basis of their sociodemographic, clinical, and lifestyle characteristics. The panel is certified to be statistically representative of all the covered populations. In our study, in order to guarantee data quality, respondents were asked to confirm their demographics (i.e., sex, date and place of birth, ethnicity, nationality, educational level, and place of residency) and clinical condition previously collected by the panel. To be

included in our study, patients belonging to the panel had to be Italian, affected by type 2 diabetes, aged over 18 years, and of both genders. Patients with dementia, cognitive impairments, active psychiatric disorders, blindness, deafness, or insufficient Italian language skills to meaningfully answer the questions or without informed consent were excluded from this study. All participants gave written informed consent before being enrolled in the study. Patients completed the study questionnaire between October and December 2014. Ethic approval was attained from the Ethics Committee of the Università Cattolica del Sacro Cuore, Milan (Italy).

2.2. Measures. Patient Health Engagement Scale (PHE-S) developed by Graffigna and colleagues [39] is a measure of patient engagement that is grounded in rigorous conceptualization and appropriate psychometric methods. The scale consists of 5 ordinal items and was developed based on the authors' conceptual model of patient engagement (PHE-model), which features four positions along a continuum of engagement (i.e., blackout; arousal; adhesion; eudaimonic project). These engagement positions result from the conjoint cognitive (thinking), emotional (feeling), and conative (acting) enactment of individuals toward their health management [15].

Patient Activation Measure (PAM) developed by Hibbard and colleagues [40], the 13-item Patient Activation Measure, is an interval-level, unidimensional Guttman-like measure that contains items measuring self-assessed knowledge about chronic conditions, beliefs about illness and medical care, and self-efficacy for self-care. The PAM focused on physical conditions, and it was designed to measure activation as a broad construct. In the present study, we used the Italian validated version of the PAM [41].

Morisky Medication Adherence Scale (MMAS-4). Medication-taking behavior was assessed using the 4-item Morisky Medication Adherence Scale. This simple 4-question survey assesses the likelihood of patients taking their drug therapy as prescribed. The items measure the degree to which the patients self-report nonadherence to prescribed medication due to forgetting, carelessness, stopping the drug when feeling better or stopping the drug when feeling worse. In the present study, we used the Italian validated version of the MMAS-4 [42].

Health Care Climate Questionnaire (HCCQ). This scale assesses patients' perceptions of the ability of the healthcare professionals in supporting their autonomy (versus "controllingness") and in motivating their initiative in care management. The HCCQ consists of 15 items on a seven-point Likert scale ranging from *strongly disagree* to *strongly agree*. The scale was firstly developed and validated on the diabetic population by Williams and colleagues [43, 44].

Demographic characteristics included age (<60; ≥60); gender (male or female); education (elementary school, junior high school, high school, college education, Ph.D. degree, or M.S. degree); occupational status (employed, retired, housewife, student, unemployed, or other); marital status (never married, married, divorced, or widowed).

Frequency of mHealth/eHealth Use. An ad hoc item was developed to assess patients' behaviors concerning the use of mHealth and eHealth technologies to seek information for managing type 2 diabetes care (i.e., "*I usually use internet or mobile devices to seek information for managing my care*"). The item has 7 response options on a Likert scale (never, almost never, occasionally, sometimes, often, almost always, or always).

2.3. Data Analysis. Data analysis was conducted in four steps. In the first step of analysis, descriptive analyses were conducted, with particular reference to sociodemographic characteristics of the sample. Furthermore, descriptive statistics were provided regarding the use of mHealth and eHealth technologies to seek information for managing type 2 diabetes care.

In the second step of the analysis, the psychometric properties of the instruments were assessed in terms of reliability by using Cronbach's alpha for metric variables or ordinal alpha via Empirical Copula for ordinal variables [45]. A Cronbach or ordinal alpha higher than 0.7 was considered acceptable.

In the third step of analysis, correlations between all the considered variables were calculated. Since every instrument produces a metric score, the linear correlation coefficient r was calculated and evaluated with a significance test.

In the last step, a Structural Equation Model with observed variables using ML estimation method was implemented [46], in order to evaluate the relationships between the considered variables and to explore the theoretical hypothesized model (see the 5 hypotheses stated above). In the model we considered *HCCQ* as an exogenous variable and mediator (*PHE*-S) and dependent variables (*PAM, MMAS-4,* and *frequency of mHealth/eHealth use*) as endogenous variables. The goodness-of-fit indexes were examined through Chi square test, RMSEA, CFI, and SRMR, particularly suitable for both large and small samples. Models with acceptable fit presented nonsignificant Chi square value, RMSEA < 0.08 CFI > 0.90 and SRMR < 0.08 [47]. To improve the goodness-of-fit, modification indices were considered.

2.4. Ethical Concerns. The study received approval from the Università Cattolica del Sacro Cuore Ethics Committee. Patients consented to participate in the study, and they were allowed to withdraw from the study whenever they wanted. The data were collected anonymously and analyzed in an aggregated way.

3. Results

Overall, 93 patients were invited to participate in the study and completely answered the questionnaire for the analysis. All patients (29 females) completed the survey, mean age of 58.3 (±12.4) years with a mean disease duration of almost 11 years. Sociodemographic and psychometric characteristics are summarized in Table 1. Mean, standard deviation (unless otherwise indicated), and a suitable reliability index (Cronbach's alpha or ordinal alpha via Empirical Copula) are reported for all the psychometric measures considered. All the psychometric measures presented a good or excellent

Table 1: Characteristics of the sample.

Sociodemographic characteristics	
Age (years)	M = 58.3; DS = 12.4
Gender (% female)	31.2
Disease duration	M = 14.4; DS = 11.1
Marital status (%)	
Never married	7.5
Married	79.5
Divorced	10.8
Widowed	2.2
Employment (%)	
Employed	43.0
Retired	44.0
Housewife	3.2
Student	2.2
Unemployed	5.4
Other	2.2
Education (%)	
Elementary school	5.4
Junior high school	14.0
High school	50.5
College education	23.7
Ph.D. or M.S. degree	6.4
Psychometric measures	
PHE-S	Median = 3 (range 1–4); entropy = 0.89; ordinal alpha = 0.82
PAM	M = 66.8 (range 0–100); DS = 18.3; Cronbach's alpha = 0.93
MMAS-4	M = 1.3 (range 0–4); DS = 1.3; Cronbach's alpha = 0.81
HCCQ	M = 66.8 (range 13–91); DS = 15.1; Cronbach's alpha = 0.92

Table 2: Frequency of mHealth/eHealth use.

I usually use internet or mobile devices to seek information for managing my care (%)	
Never	14.0
Almost never	5.3
Occasionally	5.3
Sometimes	19.4
Often	17.2
Almost always	19.4
Always	19.4

reliability, with a Cronbach's or ordinal alpha ranged from 0.81 to 0.93.

Table 2 reports the distribution of the ad hoc item (*frequency of mHealth/eHealth use*), created to assess patients' behaviors concerning the use of mHealth and eHealth technologies to seek information for managing type 2 diabetes care (i.e., "*I usually use internet or mobile devices to seek information for managing my care*"). Table 2 shows that much more than 50% of our sample used regularly (i.e., often, very often, or always) mHealth or eHealth technologies to seek for information for managing their type 2 diabetes care. Only 20% of the sample did not regularly use such technologies.

In Table 3 linear correlation coefficients between the considered psychometric variables are reported.

HCCQ presented a significant correlation with all the measures: a positive correlation with *PHE-S, PAM,* and *frequency of mHealth/eHealth use* and a negative correlation with *MMAS-4* were detected. *PHE-S* showed a significant direct correlation with *HCCQ* and *PAM*, while it had no significant correlation with *MMAS-4* and *frequency of mHealth/eHealth use*. *PAM* had a significant direct correlation with all the measures except from *MMAS-4*: *PAM* and *MMAS-4* were negatively correlated. *Frequency of mHealth/eHealth use* significantly only depended on *HCCQ* and *PAM*.

Considering the five hypotheses to be tested in the study and the detected correlations between the psychometric measures and the *frequency of mHealth/eHealth use*, a Structural Equation Model was implemented.

Relationships between patients' perceptions of the ability of the healthcare professionals in supporting their autonomy (*HCCQ*), patients' engagement (*PHE-S*), patient's activation (*PAM*), medication adherence (*MMAS-4*), and the *frequency of mHealth/eHealth use* were tested. Figure 1 shows the explanatory model of the hypotheses we wanted to verify.

Table 3: Linear correlations coefficients between psychometric measures and frequency of mHealth/eHealth use.

	HCCQ	PHE-S	PAM	MMAS-4	mHealth/eHealth
HCCQ	—	0.356**	0.406**	−0.315**	0.292**
PHE-S		—	0.428**	−0.244*	0.034
PAM			—	−0.222*	0.373**
MMAS-4				—	−0.090
mHealth/eHealth					—

* $p < 0.05$; ** $p < 0.01$.

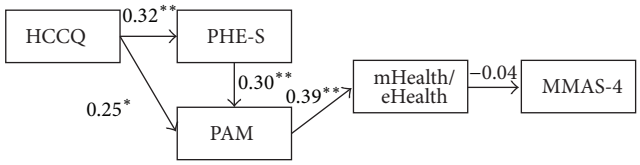

Figure 1: Structural Equation Model 1.

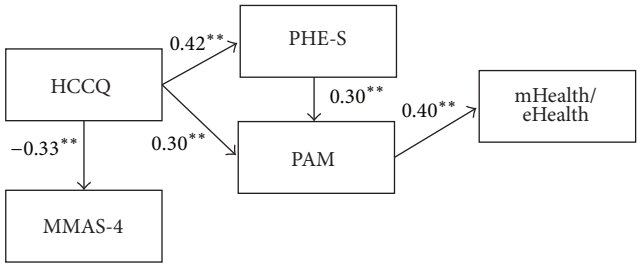

Figure 2: Structural Equation Model 2.

The model showed an exogenous observed variable (*HCCQ*), four endogenous observed variables (PHE-S, PAM, *frequency of mHealth/eHealth use,* and *MMAS-4*). The *PHE-S* mediates the relationship between *HCCQ* and *PAM*.

The model fit was deemed to be not acceptable ($\chi^2(5) = 15.50$, $p < 0.01$; CFI = 0.59; RMSEA = 0.15). Almost all the paths were found to be significant (** $p < 0.01$, * $p < 0.05$), except the path between *frequency of mHealth/eHealth use* and *MMAS-4* (−0.04, $p = 0.74$).

The hypotheses were only partially verified. On the basis of the evaluation of the modification indexes, the correlations, and the estimated paths, a modification of the model was hypothesized and tested. In particular modification indexes suggested to emphasize the direct relationship between *HCCQ* and *MMAS-4* and to delete the relationship between *frequency of mHealth/eHealth use* and *MMAS-4*. The *MMAS-4* resulted consequently from a high level of patients' perceptions about the ability of the healthcare system in supporting their autonomy (*HCCQ*). The *frequency of mHealth/eHealth use* resulting is strongly dependent on the level of patients' activation (*PAM*), but it did not seem to impact on patients' adherence (*MMAS-4*). Figure 2 shows the final model.

Model 2 presented an acceptable goodness-of-fit. Chi square test was not significant ($\chi^2(5) = 7.54$, $p = 0.15$). All the goodness-of-fit was satisfactory (RMSEA = 0.07, CFI = 0.90, and SRMR = 0.06). The estimated paths were significant ($p < 0.001$). The adjusted goodness-of-fit (AGFI) was superior to 0.90 (AGFI = 0.901). Overall, model fit indices significantly increased from Model 1 to Model 2.

4. Discussion

This study aimed to verify how the perceived ability of the healthcare professionals to support type 2 diabetes patients' autonomy and motivation to self-care initiative might impact on their level of activation and engagement and, consequently, on their adoption of mHealth and eHealth technologies to seek information for managing care. Furthermore, the study aimed to test the mediating role of patient engagement in the relationship between the healthcare professional motivating role and patient activation. Finally, the study explored the impact of mHealth and eHealth technologies use for health information seeking on type 2 diabetes patients' adherence.

Concerning the first two hypotheses, the study confirmed the crucial role of the healthcare professionals in influencing the level of type 2 diabetes patients' engagement and activation, according to other studies on chronic populations [17]. Furthermore, the level of type 2 diabetes patients' activation was confirmed in influencing patients' adoption of mHealth/eHealth technologies to support care management and seek health information [48, 49].

This study showed how the more clinicians are perceived by patients as able to motivate their initiatives towards self-care, the more the patients report higher level of engagement and activation in healthcare processes. Type 2 diabetes patients' perception and assessment of the healthcare professionals' ability to be aligned with their needs and expectations toward care management are, thus, demonstrated to be a crucial antecedent of the patients' ability to take an active role in their care management. The more the healthcare system is perceived as facilitating type 2 diabetes patients' autonomy, the more the patients show higher level of engagement towards their care management. To foster patients engagement in care management means to support the complex psychosocial elaboration of the illness condition and of the new medical requirements that individuals undergo when diagnosed with type 2 diabetes (and/or when new symptoms occur) [14, 50]. Consequently, the role of healthcare professionals appears pivotal in supporting type 2 diabetes patients engagement in adopting healthier lifestyles and gaining higher quality of life [29, 51].

Furthermore, as this study showed, high level of type 2 diabetes patients engagement is predictive of the patients

activation in self-management: the more the type 2 diabetes patient is engaged, the more he/she appears able to feel self-confident in assuming a proactive and empowered role in the care process. The huge impact of cognitions and behaviors is well reported in literature [14, 29]. However, patients' engagement is the result of a dynamic synergy among different experiential dimensions: patient engagement, indeed, is not only dependent on knowledge and skills related to the health condition and treatment management. It also implies patients' enactment of an adaptive emotional elaboration and acceptance of the new patient identity and of its consequences on quality of life [14, 22].

The level of type 2 diabetes patients' activation in its turn resulted to be a crucial antecedent of patients' attitude towards the adoption of mHealth and eHealth technologies to seek information for care management. Patients' activation refers to the patients' ability and willingness to directly manage their own health and health care [39]. To seek health and care information through mHealth and eHealth technologies to manage care might be considered as a behavioral manifestation of the patients' willingness of taking a "starring role" in the management of their care [50].

Different studies investigated the potential role of mHealth/eHealth technologies to support patient activation and used the patient activation as a compass to personalize the intervention with promising results [35, 52]. In this sense, our study provides further evidences on a crucial antecedent of patient activation: that is patient engagement. This concept might be useful when developing and delivering technological solutions, which are aligned with the complex emotional elaboration the patient undergoes when dealing with diabetes care and allow them to communicate with their referential health professional [53].

Moreover, our results confirmed the importance of questioning the readiness of the healthcare organization and of its employees in receiving and adopting technological innovations devoted to sustaining better integrated models of care [54, 55]. Implicit values and practices rooted into the organizational culture might play the role of enhancers or inhibitors of such organizational innovation. Relational, psychological, and pragmatic implications of eHealth and mHealth should be considered when planning and delivering such interventions in order to maximize their clinical and organizational effectiveness. Healthcare professionals' education oriented to uncovering of clinicians' experiential knowledge and attitudes towards patients' engagement should be a priority in this changing scenario [56].

Finally, it is interesting to note that the last hypothesis of this study was not confirmed. The level of patients' adherence was not proved to be directly dependent on the frequency of mHealth and eHealth adoption to seek information for type 2 diabetes care management, thus demonstrating that this is still a controversial topic according to other studies [57]. In this sense, spontaneous behaviors of information seeking through mHealth and eHealth sources are not an indication of greater patients' adherence. Health information obtained through online sources has been widely debated for their inaccurate and misleading nature which can lead to ineffective self-care regimens if not properly sustained by healthcare professionals [58]. Furthermore, the ability of mHealth or eHealth to foster type 2 diabetes patients' adherence might be dependent on the characteristics of the intervention and of the specific tools employed in it; mHealth and eHealth tools for information seeking probably need tailored and multiple strategies to promote adherence [57]. Patients' adherence resulted, on the contrary, from direct function of the healthcare professionals' perceived ability to support patients' autonomy and motivation towards their diabetes care. This result appears particularly interesting because it is a further empirical confirmation of the crucial role played by the healthcare organization and by its employees to enable the success of clinical interventions. Indeed, healthcare professionals seem to have a vicarious role in the proper use of health information and in the activation of patients towards managing their health and, consequently, in patients' adherence. Different studies confirmed that the quality of the relationship between healthcare professionals and patients is a crucial factor for improving the adherence of patients [59, 60]. Our results suggest the importance of supporting the introduction of new technological tools to innovate healthcare processes with a deep understanding of the psychosocial, relational, and pragmatic implication of such innovation: only "taking on board" the human resources implied in this organizational change, the challenge of innovating care process in an effective integrated model can be successful [61, 62]. Healthcare professionals, in particular, need to be accompanied to understand and accept the value of such tools to improve their ability to follow and treat their type 2 diabetes patients. Healthcare professionals are the enablers, from patients' perspective, of the mHealth or eHealth interventions' clinical potentials; they are perceived as the legitimators of the active role of the patient in the care process [17] and thus of the possibility to adopt new technologies within the type 2 diabetes care pathway within a shared decision making process [63].

Therefore, mHealth or eHealth initiatives for type 2 diabetes care should be designed and delivered having in mind the goal of sustaining the engagement of the different stakeholders implied in the healthcare process (i.e., the patients, their lay caregivers but also their healthcare professionals both inside and outside the hospital) [11, 14, 38]. This goal could be achieved by assuming a psychosocial and organizational view of the different level of needs and expectations towards the care process (and its innovation) carried out by the different stakeholders: to fail in this consideration may result in psychosocial and relational hindrances to the process of adoption of mHealth or eHealth and thus to their clinical effectiveness. This could also have an impact on the success of integrated care models featuring the adoption of new technologies [12].

Limitations. Although the results of our study appear interesting to cast light on the complex psychosocial and organizational dimensions implied in sustaining patient engagement and the adoption of mHealth or eHealth for seeking information for type 2 diabetes care in integrated care models, some limitations have to be considered. Firstly, the study was carried out on a fairly small sample of Italian patients.

However the sample features were enough to allow the robustness of the conducted statistical analysis. Furthermore, the sample of patients included in our study is not representative of the Italian type 2 diabetes population. However, we used it only to explore the relationships of the variables under analysis and not for an estimation of their dimensions: based on these considerations full representativeness is not necessarily required [64, 65]. Furthermore, our study was not conceived as an effectiveness evaluation of a real mHealth or eHealth intervention, but it took into account the spontaneous behaviors of patients when adopting mHealth or eHealth technologies to seek information for type 2 diabetes care management. This may be envisaged as a limitation because it does not allow the researcher to understand what technological and organizational characteristic of a mHealth or eHealth intervention may impact on patients' engagement and activation and on their adherence to treatment. Results should be interpreted with caution because of the explorative nature of this study. Furthermore, we only measured the frequency of spontaneous behaviors of mHealth and eHealth use to seek information for diabetes care instead of measuring also type of technologies adopted or type of information searched.

However, this analysis has the value of offering some precious insights into the patients' spontaneous attitudes and behaviors in a natural setting and should be considered as a "baseline" evidence of the general approach of patients to mHealth or eHealth and of the psychosocial and organizational dynamics that may impact on their effectiveness [66].

5. Conclusions

Type 2 diabetes requires a long-term approach to care and the good synergy between hospitals and primary care resources. To address this requirement, to "give back" an active role to patients in managing their health is crucial. mHealth/eHealth interventions for type 2 diabetes care are considered as an effective strategy to improve type 2 patients' empowerment and clinical outcomes. Moreover they are demenstrated to be powerful in enhancing patients-doctors communication, in fostering patients' satisfaction with care and in making healthcare cost-effective. However, in order to be effective, the introduction of such technological interventions needs to be supported by the reference healthcare professionals, who should legitimize the intervention process and sustain the autonomous initiative of the type 2 diabetes patients throughout it.

From this perspective, our study confirmed the important role of healthcare professionals' ability to foster type 2 diabetes patients' autonomy in enhancing their activation and engagement towards self-management, this being a precursor of patients' attitude to the use of mHealth/eHealth technologies. Furthermore, our study well highlighted how patient engagement, defined as a multidimensional psychosocial process resulting from the conjoint cognitive, emotional, and behavioral enactment of individuals toward their health conditions and their management [15, 17, 38], is a pivotal precursor of patient activation towards self-management and thus towards patients' use of new technological interventions. This finding is relevant and opens insights into the psychosocial and relational antecedent of patients' activation in self-management. The function of patients' activation in guaranteeing improved clinical outcomes, better patients' satisfaction towards healthcare, and reduced costs in services delivery has been demonstrated by several studies [67–69]. However, till now, still little is known about the factors that may support the increase of patients' activation [70]. This study, by focusing on type 2 diabetes patients, offers an important theoretical and pragmatic contribution by demonstrating the role of patient engagement in determining the level of patients' behavioral activation and self-confidence in type 2 diabetes care management.

Finally, the indirect relationship that our study showed between the frequency of mHealth/eHealth use and the level of type 2 diabetes patients' adherence, although it needs further confirmation, opens the door to interesting debate about how new technologies can be effectively designed in order to improve adherence. Too often, the debate about new mHealth/eHealth interventions for sustaining patient engagement in type 2 diabetes care management has been primarily focused on the technological ("hard") features of such interventions [71]. The psychosocial and organizational ("soft") aspects may mediate the effectiveness of mHealth and eHealth interventions and, consequently, deserve an enhanced attention, as an important complement of the analysis of the "hard" determinants of such interventions effectiveness [72].

Conflict of Interests

The authors declare that there is no conflict of interests regarding the publication of this paper.

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