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Research Article

Implementation of a Solution for the Remote Monitoring of Subjects Affected of Metabolic Diseases: The Metabolink Project

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Abstract

Diabetes represents one of most serious public health disease. The aim of the Metabolink project was to develop a smart solution for elderly people with diabetes and obesity, in order to promote a healthier style of life, improve diabetic control trying to reduce overall cost for the community.

It consists of an app for Smartphone linked to a system and a process of data collection based on bi dimensional barcode (qr code) and NFC-tag technologies.

The system was accepted by all the patients and they learned efficaciously in a few hours to use it. Unfortunately we observed a drop-out of about 50% in the first month. Patients remaining in the study refer a slight improvement in the Quality of Life Enjoyment and Satisfaction Questionnaire (Q-LES-Q) and General Satisfaction Questionnaire (GSQ) and they decided to continue to use it after the end of the follow-up.

Keywords: Diabetes; Obesity; ICT; Prevention program; Life style; Phone app

Introduction

The diabetes represents one of most serious public health disease for the planet [1]. The WHO estimated about 60 million of subjects are affected in Europe. In Italy the rough prevalence is 5.8% [2]. The prevalence of disease in the next years will grow both as a result of the aging of the population and to the increase of the risk factors such as overweight and obesity, sedentary lifestyle and lack of proper nutrition education. Milestone studies have shown that an intensive glycemic treatment significantly reduces microvascular complications [3,4] with a moderate positive long-term effect on macrovascular complications [5]. The health care systems are called to face this disease that it has not only direct cost linked to pharmacological and complications treatment but also an indirect significant social cost [6]. It is therefore essential for the diabetic patient to carry out a continuous and accurate monitoring of clinically relevant parameters (as blood glucose, blood pressure) and to follow a health life style in order to reduce disease complications permitting to live better maintaining independence for much more longer time. Moreover the majority of patients with diabetes is older and frequently present significant comorbidity making the integrated management of the disease more complex. The aim of the Metabolink project was to develop a smart solution for elderly people with diabetes and obesity, in order to promote a healthier style of life, improve diabetic control (glcaemic control, blood pressure, adherence to a specific diet and treatment) trying to reduce overall cost for the community. The approval of the study for experiments using human subjects was obtained from the local Ethics Committees on human experimentation. Written informed consent for research was obtained from each patient or from relatives/legal guardian in the case of critically disabled demented patients prior to participation in the study.

Materials and Methods

The approval of the study for experiments using human subjects was obtained from the local Ethics Committees on human experimentation. Written informed consent for research was obtained from each patient or from relatives/legal guardian in the case of critically disabled demented patients prior to participation in the study.

The Metabolink solution was developed to provide a continuous health monitoring to patients who suffer from metabolic disease such as obesity or diabetes. A secondary goal is the collection of a wide and well-structured database for a large-scale analysis about metabolic diseases and the evaluation of their medical and anthropometric features. Patients can be remotely and constantly monitored by their careers. In this project the methodology used to select the more appropriate technologies was the Analytic Hierarchy Process (AHP) technique [7,8].

All made possible by the versatility offered in Smartphone apps and technology such as qr codes, wireless networking, non-intrusive sensors and MEMS (Micro Electro Mechanical Systems).

It consists of an app for Smartphone linked to a system and a process of data collection based on bidimensional barcode (qr code) and NFC-tag technologies.

Entering into detail the app can: 1) Record the food, the drug therapy and physical activity; evaluate weight, blood pressure, pulsations, glycaemia using measurements devices wireless connected

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Figure 1: Overall view.

with the Smartphone. 2) Show a diagram on patient's lifestyle trend. 3) Motivate patients in choosing a healthy lifestyle through periodic feedback from caregivers and the comparison of their own results with those anonymously published by the community. 4) Communication in real time to caregivers about recorded data and measured vitals. 5) Real time upgraded data about the Individual Plan (food, physical activity and drug therapy) provided by the caregiver. 6) Send alarms in case of "out of range" remote sensing.

In addition it is possible for the carers to access to the patients data to access in real time to the data through a connection to the DB and in this manner they can: 1) Manage their patients' database, medical history and Individual Plan. 2) Refer to diagrams about their patients' lifestyle trend (real time). 3) Receive warnings about patient's health. 4) Communication to the patient and review the diet, the physical activity or the therapy at any time; 5) Report and summarize data, providing statistics and exporting files for epidemiological survey.

Technological features: 1) Smartphone integration with measurement devices available (such as NFC, Bluetooth) to simplify taking and communicating vital signs. 2) Physical activity intensity measurement using GPS and accelerometer sensor on Smartphone Figure 1.

We started the enrolment of patients at the outpatients department of the Geriatrics Unit to validate the solution from October 2015 to December 2015 using the following inclusion criteria: 1) Age ≥ 60 years, 2) Diagnosis of diabetes, and 3) Ability to provide informed consent.

Table 1: Demographic characteristics, clinical and quality of life assessment of the enrolled patients at the baseline.

	All N. 40	Cohort 1 n. 20	Cohort 2 n. 20	*P-value*
Gender (Males/Females)	24/16	11-Sep	13-Jul	0.747
Males (%)	60	55	65	
Age*	77.36 ± 4.37	76.67 ± 4.76	78.05 ± 3.86	0.006
range	69 – 87	70 – 87	69 - 85	
Educational level (in years)*	7.69 ± 6.27	7.84 ± 6.28	7.53 ± 6.32	0.805
range	0 – 18	0 – 18	0 - 18	
Social support network	30 (75.0)	16 (53.3)	14 (46.7)	0.737
Institutionalized N(%)	3 (7.5)	1 (33.3)	2 (66.7)	
Living alone N(%)	7 (17.5)	3 (42.9)	4 (57.1)	
ADL*	3.76 ± 1.77	3.85 ± 1.79	3.65 ± 1.76	0.406
range	0 – 6	0 – 6	0 - 6	
IADL*	1.73 ± 2.20	1.61 ± 2.19	1.88 ± 2.22	0.368
range	0 – 8	0 – 8	0 - 8	
MMSE*	15.32 ± 5.34	14.15 ± 5.65	16.70 ± 4.61	<0.0001
range	0 – 25.70	0 – 24.30	0 – 25.70	
ESS*	16.53 ± 2.74	16.85 ± 2.74	16.16 ± 2.71	0.065
range	8 – 20	8 – 20	Aug-20	
CIRS*	2.06 ± 1.32	1.84 ± 1.28	2.30 ± 1.34	0,021
range	0 – 6	0 – 6	0 – 6	
MNA*	22.28 ± 3.85	22.18 ± 3.94	22.38 ± 3.76	0.734
range	10.5 – 29.0	10.5 – 29.0	12.0 – 28.5	
N of medications*	1.28 ± 1.14	1.07 ± 1.08	1.53 ± 1.16	0.007
range	0 – 5	0 – 5	0 – 5	
MPI*	0.42 ± 0.18	0.42 ± 0.17	0.41 ± 0.19	0.922
range	0.00 – 0.88	0.00 – 0.79	0.00 – 0.88	
Q-LES-Q*	40.27 ± 12.58	41.57 ± 12.95	39.13 ± 13.02	0.556
range	20 - 65	27 - 65	20 - 56	

*All values as means ± standard deviation.

Table 2: Clinical, quality of life and satisfaction level assessment of the patients at the follow-up.

	All N. 40	Cohort 1 n. 20	Cohort 2 n. 20	*P*-value
MPI*	0.40 ± 0.14	0.39 ± 0.13	0.41 ± 0.16	0.667
range	0.00 – 0.88	0.00 – 0.79	0.00 – 0.88	
Q-LES-Q*	50.09 ± 10.81	57.80 ± 9.25	42.38 ± 12.36	<0.0001
range	25 - 69	40 - 69	25 - 60	
GSQ N (%)				
Soddisfatti	32 (80.00%)	19 (59.4%)	13 (40.6%)	0.048
Insoddisfatti	8 (20.00%)	1 (12.5%)	7 (87.5%)	

*All values as means ± standard deviation.

Two cohorts of 20 patients were included: 1) Cohort treated with Metabolink support in addition to the standard care (Cohort 1), and 2) Cohort treated with standard care (Cohort 2). Each patient of the first cohort were adequately informed and they was provided by a kit comprising a glucose meter, a scale, a blood pressure monitor, a count steps and a mobile-phone all with NFC interface. The follow-up lasts 2 months. Every patient received at the beginning and at the end of the study a complete clinical assessment including a standardized Comprehensive Geriatric Assessment (CGA) [9]. We choice to administer CGA to better define the cohort characteristics and to improve the outcomes in this kind of patients as largely documented in literature. To define our standardized CGA be have chosen tools validated and widely diffused worldwide in order to improve reproducibility and objectivity of the data presented.

Multidimensional Prognostic Index (MPI) based on a CGA for predicting mortality risk in older patients was performed.

In this evaluation we included the following domains: 1) Functional status assessed by the Activities of Daily Living scale (ADL) [10] and 2) The Insturmental odd Activities of Daily Living scale (IADL) [11] scales; 3) Cognitive status assessed by the Mini Mental State Examination (MMSE) [12], 4) Comorbidity as assessed by the Cumulative Illness Rating Scale (CIRS) [13], 5) Nutritional status according to the Mini Nutritional Assessment (MNA) [14], 6) The risk of developing pressure sores assessed by the Exton Smith Scale (ESS) [15], 7) The number of drugs taken by patients at admission and 8) Co-habitation status, i.e. alone, in family or in institution.

MPI was expressed as three grades of risk: MPI-1 low risk (MPI value ≤ 0.33), MPI-2 moderate risk (MPI value between 0.34 and 0.66) and MPI-3 severe risk (MPI value > 0.66). To calculate the MPI is available an informatics, easy to use free tool. We assessed the quality of life using the Quality of Life Enjoyment and Satisfaction Questionnaire (Q -LES –Q) [16]. At the end of the study, we also assessed the satisfaction about received assistance though the use of the General Satisfaction Questionnaire (GSQ) [17].

Results and Discussion

During the enrolment period, 78 elderly patients with diabetes were screened. Among this patients, 38 (48.71%) patients dropped out because of the time commitment (n = 31; M = 22, F = 9), and inability to cope the ICT system (n = 7; M = 2, F = 5).

As shown in Table 1, the involved subjects (N = 40) were predominantly male (60.0%) with a mean age of 77.36 ± 4.37 years old. No statistically significant differences were present between cohorts at baseline about the gender, educational level, and social support network, ADL, IADL, ESS and MNA.

The Cohort 1 showed significantly an ageless advanced (76.67 *vs* 78.05, $p = 0.006$), a worse cognitive impairment (14.15 *vs* 16.70, $p < 0.0001$), less comorbidity (1.84 *vs* 2.30, $p = 0.021$), and less medications (1.07 *vs* 1.53, $p = 0.007$), than the Cohort 2.

Anyway, the MPI and Q-LES-Q did not shown significantly differences between two cohorts.

After experimental period, from a subjective point of view patients in Cohort 1 have appreciated the possibilities offered by the system and felt them more secure, showing an improvement (even if not signficatively) of 7.14% on the MPI.

In addition we have observed a trend with a slight improvement in Q-LES -Q in patients of Cohort 1 versus Cohort 2. Cohort 1 has shown an improvement of 39.0% on the Q-LES-Q score in respect to the 8.3% of the Cohort 2 ($p < 0.0001$).

The satisfaction about received assistance was significantly higher in Cohort 1 than Cohort 2 ($p = 0.048$) Table 2.

Conclusion

This study explored the application of the Metabolink system in the treatment of diabetes elderly patients. The system was accepted by all the patients and they learned efficaciously in a few hours to use it. Unfortunately we observed a drop-out of about 50% in the first month mainly due to the NFC implementation and complexity of diet module. Patients remaining in the study refer a slight improvement in the Q-LES-Q and GSQ and they decided to continue to use it after the end of the follow-up. The study presents several limitations: the relatively small sample size, the short follow-up and the relatively high percentage of drop-out determining an important bias to consider in the data extrapolation in other context. In particular, the reasons of drop outs were the time commitment and inability to cope the ICT system. For the future study, the prevention of this drop out causes through a more easy ICT system to use and a better organization about the experimentation time (to add more experimentation stages with different patients for every stage, and to reduce the time commitment of the patients) could reduce the drop out cases. Clearly the diabetes is a chronic disease that requires a multidisciplinary approach to be appropriately faced. It's clear that more work has to be done to produce a solution more suitable to the elderly population and validated with a consistent sample size but we think that this will be mandatory considering the demographic change, the associated increasing health cost and sustainability of the health and social national systems.

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