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E-HEALTHCARE FOR DIABETES MELLITUS TYPE 2 PATIENTS – A RANDOMISED CONTROLLED TRIAL IN SLOVENIA

E-ZDRAVSTVENA OSKRBA BOLNIKOV S SLADKORNO BOLEZNIJO TIPA II – RANDOMIZIRANA KONTROLIRANA RAZISKAVA V SLOVENIJI

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ABSTRACT

Background. Telemonitoring and web-based interventions are increasingly used in primary-care practices in many countries for more effective management of patients with diabetes mellitus (DM). A new approach in treating patients with diabetes mellitus in family practices, based on ICT use and nurse practitioners, has been introduced and evaluated in this study.

Method. Fifteen Slovene family practices enrolled 120 DM patients treated only with a diet regime and/or tablets into the study. 58 of them were included into the interventional group, and the other 62 DM patients into the control group, within one-year-long interventional, randomised controlled trial. Patients in the control group had conventional care for DM according to Slovenian professional guidelines, while the patients in the interventional group were using also the eDiabetes application. Patients were randomised through a balanced randomisation process.

Results. Significant reductions of glycated haemoglobin (HbA1c) values were found after 6 and 12 months among patients using this eDiabetes application ($p<0.05$). Among these patients, a significant correlation was also found between self-monitored blood pressure and the final HbA1c values. Diabetic patients' involvement in web-based intervention had only transient impact on their functional health status.

Conclusion. This eDiabetes application was confirmed to be an innovative approach for better self-management of DM type 2 patients not using insulin. Both a significant reduction of HbA1c values and a significant correlation between the average self-measured blood pressure and the final HbA1c values in the interventional group were found. Nurse practitioners – as diabetes care coordinators – could contribute to better adherence in diabetes e-care.

Keywords:
diabetes mellitus, telemedicine, functional health status, HbA1c, family practice

IZVLEČEK

***Uvod**. Zdravstvena oskrba na daljavo in z uporabo interneta se za učinkovitejšo obravnavo bolnikov s sladkorno boleznijo (SB) pospešeno uporablja v osnovnem zdravstvu številnih držav. Namen raziskave je bil preizkusiti in ovrednotiti pristop k zdravljenju bolnikov s sladkorno boleznijo, ki temelji na uporabi sodobne informacijsko-komunikacijske tehnologije (IKT) in na ustrezno izobraženi medicinski sestri, kot koordinatorju tovrstne zdravstvene oskrbe v ambulanti družinske medicine.*

***Metode**. Petnajst slovenskih ambulant družinske medicine je vključilo 120 bolnikov s SB, ki niso bili zdravljeni z inzulinom. Oseminpetdeset bolnikov je bilo vključenih v intervencijsko skupino in 62 bolnikov v kontrolno skupino; randomizirana kontrolirana raziskava je trajala eno leto. Bolniki v kontrolni skupini so bili deležni običajne oskrbe, po slovenskih strokovnih smernicah, medtem ko so bolniki v intervencijski skupini lahko uporabljali še spletno aplikacijo eDiabetes. Randomizacija je opravljena po metodi uravnoteženega razvrščanja v skupine.*

***Rezultati**. Pomembno zmanjšanje vrednosti HbA1c je bilo ugotovljeno po 6 in 12 mesecih v skupini bolnikov, ki so uporabljali aplikacijo eDiabetes ($p<0,05$). V isti skupini je ugotovljena pomembna korelacija med vrednostmi samoizmerjenega sistoličnega tlaka in končnimi vrednostmi HbA1c. Uporaba aplikacije eDiabetes je imela le prehoden vpliv na funkcionalni status bolnikov, izmerjen z WONCA-COOP.*

***Zaključki**. Uporaba internetne aplikacije za vodenje in nadzor sladkorne bolezni lahko pomembno vpliva na zmanjšanje vrednosti HbA1c in na povezavo HbA1c s samoizmerjenimi vrednostmi krvnega tlaka pri sladkornih bolnikih, ki niso zdravljeni z inzulinom. Diplomirane medicinske sestre v vlogi koordinatorja e-oskrbe lahko prispevajo k boljšemu sodelovanju bolnikov s SB.*

Ključne besede:
sladkorna bolezen, telemedicina, funkcionalni zdravstveni status, HbA1c, družinska medicina

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1 INTRODUCTION

Diabetes mellitus (DM), defined as a "group of common metabolic disorders that share the phenotype of hyperglycaemia", is a very relevant and growing public health problem in all developed countries. Among the most important treatment goals for adults with diabetes are: good glycaemic control (HbA1c<7.0% and fewer hyperglycaemia symptoms), regulation of blood pressure and serum lipids, prevention of complications, and patient education about DM, nutrition and exercise. The measurement of glycated haemoglobin and self-monitoring of blood glucose are standard methods for assessing long-term glycaemic control (1, 2).

Changes in the functional health status of patients with chronic diseases could have a strong impact on the outcome measures of treatment. Studies suggest that the COOP-WONCA charts are a valuable and reliable tool for measuring functional health status in primary care (3, 4). Results from many clinical studies demonstrate the enormous potential of information and communication technology (ICT) to improve health-care outcomes for chronic diseases, including DM. For many researchers, diabetes mellitus is recognised as the chronic condition most suited for self-monitoring, telemonitoring, and the use of electronic Personal Health Records (ePHRs) (5-15). ePHR is defined as an "application through which individuals can access, manage and share their health information in a private, secure, and confidential environment." (16). PHRs could have an important impact on the cost and quality of chronic disease management (10, 11, 16, 17).

The use of ICT in the prevention, diagnosis, treatment, and monitoring of different medical conditions, including DM, is particularly important for primary health-care (PHC) providers (5, 7, 8, 18). In recent research, computer-supported decision-making, accessibility of personal e-health data, and e-prescription were identified by patients, as well as physicians and nurses, as the most important areas for further e-Health development in Slovenia (17).

Web-based interventions are increasingly being used in PHC practices in all developed countries, allowing more effective DM management (17-20). However, it remains a challenge over time to maintain patient interest in blood glucose (BG) control, even with the assistance of ICT (14, 21, 22).

Since 2011, so-called nurse practitioners who are educated and competent especially for disease prevention, health education and the management of the most common chronic diseases according to the prescribed protocols, have been introduced in many Slovenian family practices. The addition of nurse practitioners as diabetes care coordinators has brought better adherence to diabetes treatment and allowed the achievement of higher standards in primary healthcare for patients with DM (5, 17, 23-25).

Numerous studies, systematic reviews, and meta-analyses find a significant potential for contemporary ICT, including the use of electronic personal health records and mobile phone reminders, to improve the glycaemic control of DM type 2 patients not using insulin (5-7, 10- 14, 20, 22). Very few studies have examined the simultaneous effects of remote e-treatment and coordination by nurse practitioners integrated into local family practice teams on glycaemic control, blood pressure, serum lipids, body mass index, and the functional health status of diabetic patients (10, 17, 25).

1.1 Purpose and Objectives

The purpose of the study was to introduce and evaluate a new approach in treating patients with diabetes mellitus type 2, based on ICT use and nurse practitioners as the diabetes care coordinator.

The main hypotheses of the research were:

- web-based supported healthcare for DM type 2 patients not using insulin can significantly improve treatment outcomes compared to usual healthcare, and
- web-based supported healthcare has an effect on the functional health status of patients with DM type 2.

2 METHODOLOGY AND STUDY DESIGN

2.1 Participants and Sampling

This was an interventional, randomised controlled study of patients with DM type 2, treated only with a diet regime and/or tablets. Slovene diabetics treated with insulin are usually treated by diabetes care units, and were therefore not included in this study.

Patients were selected from 22 solicited family practices from 6 different regions in Slovenia (Posavje, Zasavje, Štajerska, Gorenjska, Primorska, and Ljubljana). To be included, family practices had at least 1,000 patients, a nurse with secondary-school training, and a qualified nurse with higher education (the diabetes care coordinator). This cluster sampling was chosen to give the best estimate for the Slovenian population of patients with DM type 2 not using insulin.

A computerised randomisation programme assigned patients to the interventional or the control group through a balanced randomisation process using the last four patients. Randomisation was carried out for all practices simultaneously, but not at the level of individual practices. Due to its design, the study could not be blinded; the staff at each practice was aware of patient allocation.

The randomisation process is presented in Figure 1.

The inclusion period was 3 months and the next criteria were the same for both groups:

- between the ages of 18 and 75;
- type 2 diabetes treated with non-pharmacological interventions or/and tablets (patients who are not using insulin);
- having Internet connection and access to a computer;
- having a mobile phone;
- sufficient Internet and e-mail skills (which were checked by a short questionnaire).

The time frame for the follow-up of each patient was one year.

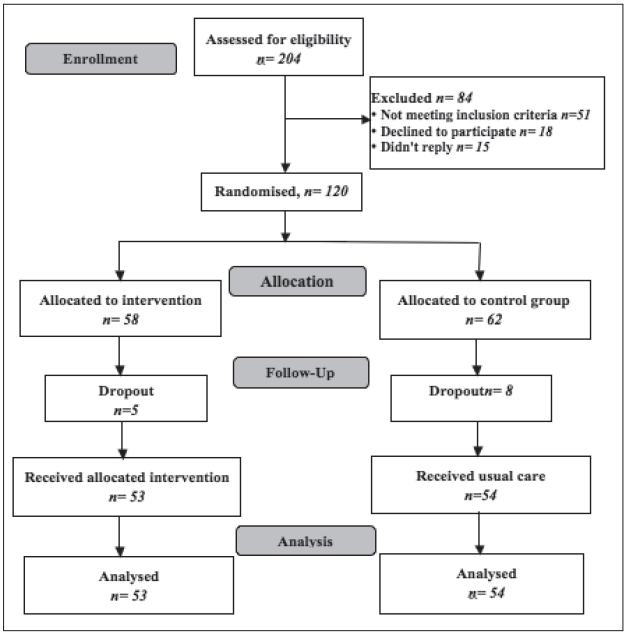

Figure 2. Flow diagram for the eDiabetes study.

2.2 Intervention

Patients randomised in the control group had the conventional care for diabetic patients, according to Slovenian professional guidelines. Patients in the interventional group had, in addition to conventional care, access to the eDiabetes application.

Nurse practitioners could comment about measurements made by patients in the interventional group and give advice about lifestyle. General practitioners gave advice about medications. Some medications, but not a significant number, were altered during the study period for both groups.

The comparison between the diabetes care offered to the control group and the interventional group is shown in Table 1.

Table 1. Comparison between conventional and eDiabetes care.

Parameters	Conventional diabetes care	eDiabetes care
No. of check-ups by nurse practitioner **in family practice**	2-4 times a year	2-4 times a year
No. of check-ups by family practitioner	2 times a year and for exacerbations	2 times a year and for exacerbations
Laboratory tests (HbA1c, FBG, creatinine, serum lipids, transaminases, albumin in urine)	1- 2 times a year	1- 2 times a year
Ophthalmologist examination	Once a year	Once a year
Internist and other specialists	For exacerbations	For exacerbations
e-consultation with nurse practitioner	NO	YES
e-consultation with family practitioner or specialists	NO	NO
SMS reminders	NO	YES
Access to eDiabetes application	NO	YES
Answering e-questionnaires	NO	Every two months

2.3 Software Description

The eDiabetes application, designed in collaboration with experienced ICT experts, consisted of a web portal for patients and health-care providers (26), with a patient-oriented interface for individualised care, and a web server for a repository and education material (http://eoskrba.si). The educational material included informational handouts, web addresses, articles, and instructions to help diabetic patients better manage their condition.

Every two weeks patients in the experimental group recorded data, including their body weight, blood pressure, diet, and physical activity. The last parameter was evaluated on a 7-point Likert scale. Every 6-8 weeks patients completed the COOP-WONCA charts. These are comprised of seven parameters designed to measure functional health status using words and pictures to represent and assess: physical fitness, feelings, daily

activities, social activities, change in health, overall health, and pain. These charts are rated using a five-point scale, with higher scores indicating a worse functional status (3, 4).

The application automatically sent users reminders by simple e-mail and SMS: "Please enter your blood sugar /or other parameters/ into the eDiabetes application". These reminders were sent if a user had not entered body weight, blood pressure, physical activity, and diet data within 2 weeks of the deadline or not completed the COOP-WONCA questionnaire within 8 weeks. Reminders were also e-mailed to the diabetes care coordinators.

In case of medical emergencies, a warning was issued to immediately contact the medical emergency services. More than 1000 SMS and e-mail reminders were sent during the study. E-mail communication between the patients and family practices was less common, with fewer than 100 such e-mails registered during the study. Nurse practitioners and physicians mostly commented directly with patients on the eDiabetes inputs during office visits.

2.4 Outcome Measures

The primary outcome measure was the change from baseline of HbA1c at 1 year. This outcome was calculated as the difference between baseline and final HbA1c for both groups.

The secondary outcome measures were the change from baseline of: (a) HbA1c at 6 months, (b) Body Mass Index (BMI) at 1 year, (c) Patients' Functional Health Status indicated by the COOP-WONCA Questionnaire at 6 months and 1 year, (d) blood lipids at 1 year, and (e) diastolic and systolic blood pressure at 6 month and 1 year.

The minimal clinically important difference (MCID) was set to one standard error of the mean in the outcome score (27, 28).

2.5 Power Calculation

A sample size of 60 patients per group was necessary to achieve 80% power at a two-sided 5% significance level and a hypothetical dropout rate of up to 15%.

No adjustment of the sample size was made for the potential clustering of scores within a single practice.

2.6 Data Analysis

The statistical analysis of data collected in the eDiabetes application and from the patient health record was performed using SPSS Statistics 21 and the EXCEL version of Microsoft Office 2010. The unequal variances t test was used to assess changes of the target interval outcomes between the two groups at baseline and within each group at 1 year. The Wilcoxon rank sum test was used to assess differences in the COOP-WONCA results (29). Multivariate analysis was used to find factors that might be related to changes of HbA1c. The degree of statistical significance was defined as $p<0.05$.

3 RESULTS

Twenty-two Slovene family practices applied to participate in the study, of which 15 enrolled at least one patient. Fifty-eight participants were randomly assigned to the interventional group and the remaining 62 to the control group. The first participant entered the study in April 2012 and the last consultation was completed in December 2013. Fifty-three participants in the interventional group and 54 in the control group completed the first office consultation, which included the study protocol's laboratory investigations. Participant characteristics are presented in Table 2.

Significant statistical differences ($p<0.05$) were also not found for any parameter regarding age, education, smoking status, or medication use.

Table 2. Baseline characteristics of participants.

Characteristic, number (percentage)	Intervention group	Control group	Total	Statistical difference (p)
Male, n (%)	36 (30)	37 (30.8)	73 (60.8)	<0.05
Female, n (%)	22 (18.3)	25 (20.8)	47 (39.1)	>0.05
Average age, years (SD)	56.3 (10.5)	54.7 (11.1)	55.5 (10.7)	>0.05
Education, n (%)				
Elementary school or less	4 (3.3)	5 (4.2)	9 (7.5)	>0.05
High school	13 (10.8)	13 (10.8)	26 (21.6)	>0.05
College or university	21 (17.5)	15 (12.5)	36 (30)	<0.05
Master, PhD or specialisation	8 (6.7)	11 (9.2)	19 (15.9)	<0.05
Unknown	12 (10)	18 (15)	30 (25)	<0.05
Diabetes duration in years (standard deviation)	5.1 (5.7)	5.7 (4.8)	5.5 (5.3)	>0.05
Only diet, n (%)	13 (10.8)	15 (12.5)	28 (23.3)	>0.05
Diet and oral antidiabetic medication, n (%)	21 (17.5)	20 (16.7)	41 (34.2)	>0.05
Diet, oral antidiabetic and other medication, n (%)	24 (20)	27 (22.5)	51 (42.5)	<0.05

Statistically significant differences ($p<0.05$) were not found between the initial or follow-up parameters of either group, or the average scores of the COOP-WONCA functional assessment charts. Total cholesterol was the only parameter with a significantly lower level in the control group (CHOL1, p=0.046), compared to the interventional group.

The paired sample t-test showed baseline glycated haemoglobin (HbA1c) as the only primary outcome measure in the interventional group having a statistically significant lower intermediate HbA1C (p=0.007, n=31) and final HbA1C (p=0.005, n=40) values compared to the initial one. Significant differences were not found between the intermediate HbA1c and final HbA1C values.

A secondary outcome measure, the intermediate average value of the COOP-WONCA score in the interventional group, was found to be statistically significantly lower compared to its initial average value (p=0.047, n=24).

Intermediate and final values of all other monitoring parameters (systolic and diastolic blood pressure, total cholesterol, triglycerides, low and high density lipoproteins, fasting blood glucose, body mass index, COOP-WONCA questionnaire score, body mass index, and moderate exercise level) were not significantly different compared to their initial values for either group. Descriptive statistics for baseline and final values of monitoring parameters, as well as of the four regularly self-recorded parameters, are presented in Table 3.

For the interventional group, the transient increase of the average COOP-WONCA score after 6 months (p=0.047, n=34) was caused mainly by elevated values of two of the seven sub-items: "feelings" (p=0.046) and "pain" (p=0.031).

Among the 58 participants in the interventional group, 49 used the application eDiabetes. During the observation period, forty-five participants entered at least once all the five self-monitoring parameters, which were weight (SELF-WT), systolic blood pressure (SELF-SBP), diastolic blood pressure (SELF-DBP), fasting blood glucose (SELF-FBG), and COOP-WONCA charts. The average number of these data entry per participant in the intervention group was: 13.26 for SELF-WT, 12.06 for SELF-SBP and SELF-DBP, 12.96 for SELF-BG, and 9.2 for COOP-WONCA.

The average intermediate level of the self-recorded blood glucose (SELF-FBG) was significantly lower in comparison to the initial average level (EFBG1, p=0.006, n=46), as well as to the final average level (EFBG3, p=0.033, n=42). Average values of the other three self-recorded parameters (SELF-SBP, SELF-DBP, and SELF-WT) did not vary significantly. Significant positive correlation was found between the final HbA1c and the self-measured diastolic blood pressure (p=0.01, n=37). A significant negative correlation was found between the number of inputs to the application and the average values of self-recorded systolic blood pressure (SELF-SBP, p=0.004, n=46), as well as to the EHbA1c-3 values (p=0.006, n=45). Significant correlation between the number of inputs and other self-measured parameters was not found.

Regression analysis showed four predictors of lower final values of HbA1c in the interventional arm. These were: lower baseline HbA1c ($p<0.001$, ß=0.802), lower average value of self-measured systolic blood pressure ($p<0.001$, ß=0.624), lower final value of total cholesterol (p=0.018, ß=-0.225), and lower value of self-measured fasting

Table 3. Baseline and final values of key monitoring parameters.

PARAMETER, unit	STUDY GROUP	MEAN (SD) BASELINE	MEAN (SD) FINAL
HbA1c, %	Interv.	7.1 (1.5)	6.4 (0.9)
HbA1c, %	Control	6.8 (1.2)	6.7 (1.5)
SBP, mm Hg	Interv.	138.4 (16.4)	137.0 (17.8)
SBP, mm Hg	Control	136.9 (17.4)	138.3 (18.4)
DBP, mm Hg	Interv.	84.5 (11.4)	84.6 (7.9)
DBP, mm Hg	Control	83.3 (10.5)	82.9 (9.4)
CHOL, mmol/l	Interv.	5.1 (1.3)	5.1 (1.4)
CHOL, mmol/l	Control	4.6 (1.1)	4.4 (1.1)
TG, mmol/l	Interv.	2.5 (1.4)	2.5 (1.4)
TG, mmol/l	Control	2.0 (1.1)	2.0 (1.1)
LDL, mmol/l	Interv.	3.0 (1.1)	3.0 (1.3)
LDL, mmol/l	Control	2.6 (1.0)	2.5 (1.0)
HDL, mmol/l	Interv.	1.1 (0.3)	1.1 (0.3)
HDL, mmol/l	Control	1.1 (0.4)	1.1 (0.3)
FBG, mmol/l	Interv.	8.1 (2.2)	8.0 (2.1)
FBG, mmol/l	Control	8.0 (2.6)	8.2 (2.6)
BMI, kg/m2	Interv.	32.6 (5.1)	32.0 (4.7)
BMI, kg/m2	Control	31.8 (4.9)	31.8 (5.1)
WONCA, score	Interv.	2.1 (0.7)	2.2 (0.5)
WONCA, score	Control	1.9 (0.6)	1.9 (0.7)
SELF-SBP, mm Hg	Interv.	135.0 (1.7)	134.03 (14.3)
SELF-DBP, mm Hg	Interv.	82.4 (10.2)	81.3 (7.3)
SELF-WT, kg	Interv.	97.9 (17.8)	96.1 (14.2)
SELF-FBG, mmol/l	Interv.	7.7 (2.2)	7.2 (1.5)

Legend: HbAc=glycated haemoglobin; SBP=systolic blood pressure; DBP=diastolic blood pressure; TG=triglycerides; LDL=low density lipoproteins; HDL=high density lipoproteins; FBG=fasting blood glucose; BMI=body mass index; WONCA=questionnaire about functional health status; SELF-SBP=self-measured systolic blood pressure; SELF-DBP=self-measured diastolic blood pressure; SELF-WT=self-measured weight; SELF-FBG=self-measured fasting blood glucose; interv=interventional; SD=standard deviation.

blood glucose (p=0.005, ß=-0.384). R2 values showed that 81.1% of EHbA1c-3 variance was explained by the above-mentioned predictors (R=0.901, RSquare=0.811, Adjusted R Square=0.783 and Std. Error=0.4671).

4 DISCUSSION

4.1 Discussion about Methodology

In terms of the distribution by age, gender, medication and diabetes duration in years, the computerised randomisation process resulted in the almost ideal allocation of patients in both study arms (p>0.05). Despite some evidence about lower Internet use among less educated and older diabetic patients (9, 14, 19), these two sub-groups were adequately represented among those meeting the inclusion criteria. Statistically significant differences (p<0.05) between patients in interventional and control group were found in 2 groups with highest education. Statistically important differences were not found when merging participants from the "College or university" and "Master, PhD, or specialisation" subgroups in one group, which means that distribution of participants by level of education could not affect the results.

The main barriers to more extensive enrolment in the study and better adherence of enrolled patients were: low motivation of practitioners and nurses in some family practices, patients' lack of computer and/or access to the Internet (n=29), and patients' lack of sufficient e-skills (n=17). The importance of PHC provider adherence to different forms of web-based diabetic care is well documented in the literature (5, 13, 16-18, 20-22).

4.2 Discussion about the Main Results

The results of this research confirmed the hypotheses about improvement in treatment outcomes compared to usual healthcare, and rejected the presumption of eDiabetes application impact on the functional health status of patients with DM type 2.

A significant negative correlation found between the number of inputs to the application and the average values of self-recorded systolic blood pressure (p=0.004), as well as to the EHbA1c-3 values (p=0.006) showed that a higher number of inputs correlated with lower final HbA1c and SBP values. This can be understood as confirmation of the impact of application on the improvement of key parameters and, consequently, as the most important result of the study.

The result of the regression analysis – the list of four significant predictors that help explain 81.1% of the final HbA1c values – is also a valuable part of this study. The connections between the final and initial HbA1c values, as well as between self-measured blood glucose and final cholesterol levels, were expected.

The main limitation of this randomised controlled trial was poor adherence of some primary-care practices and, consequently, a smaller number of enrolled patients in both groups.

4.3 Comparing the Results with Previous Studies

However, the strong correlation (p<0.001) between the final HbA1c values and the average self-measured systolic and diastolic blood pressure values was surprising.

There were very few similar reports in the reviewed literature, although significant changes in serum lipids have often been reported (5, 6, 11, 12, 14, 20, 22).

Statistically significant reductions of the HbA1C level in the interventional group, at the first follow-up and the final check-up, were already reported in several previous meta-analyses and systematic reviews (5, 6, 11, 12, 14, 20, 30). However, the patient population of this trial had well-regulated diabetes with slightly elevated baseline HbA1c (7.1% for the interventional and 6.8% for the control group).

The findings of the lower HbA1c and self-measured fasting blood glucose (SELF-BG) for the interventional group, compared to initial values and to the control group, were consistent with previous studies (5, 11, 12, 19-22, 31).

Despite the improvement of laboratory results in the interventional group, there is no clear impact of separate factors, such as nurse practitioners or diabetes care coordinators, educational materials accessible from the application, SMS and e-mail remainders.

5 CONCLUSIONS

The significant reduction of HbA1c values in the interventional group confirmed the application's potential to improve the regulation of DM type 2 in patients who are not using insulin. A significant negative correlation between the number of inputs to the application and the values of either EHbA1c or average self-recorded systolic blood pressure values also suggests the impact of application on the improvement of some key health parameters in these patients.

It seems that the overall impact of the application was also greater engagement of patients with their own healthcare.

Coordinating the care of both groups of diabetic patients was the key part of this study. Nurse practitioners played this important roleas "diabetes care managers".

A better integration of new ICT applications for chronic conditions into well-established forms of healthcare remains a major challenge for primary care.

ETHICAL ISSUES

The study protocol was approved by the National Medical Ethics Committee of Slovenia (No 132/06/11), and written consent was obtained from patients in the study. Anonymity and confidentiality were guaranteed to participants.

FUNDING AND STUDY REGISTRATION

The research was financed through the Slovenian Research Agency project L7-3653 (B) - E-health care process support.

These entities were not involved in design, implementation, analysis, or writing.

The study was registered in the ClinicalTrials.gov Protocol Registration System under ID: NCT01566981.

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AUTHOR DISCLOSURE STATEMENT

The authors declare they have no relationships, conditions or circumstances that present a potential conflict of interest with the material in this manuscript.

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