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Publikace 1: Vlasakova M., Muzik J). Effect of Activity Tracker on Risk Factors of Metabolic Syndrome. The International Journal on Biomedicine and Healthcare (IJBH) 2016; 4(2), pp. 42-45. ISSN 1805-8698. Available at: http://www.ijbh.org/ijbh2016-2.pdf.

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Publikace 2: Oulická M, Mužík J, Mužný M. Overview and Multi-Criteria Analysis of Glucometers for Telemonitoring of Patient with Diabetes Mellitus. European Journal for Biomedical Informatics. 2013, roč. 9, č. 3, s. 22-25. ISSN: 1801-5603.

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Publikace 3: Oulická M., Mužík J, Holubová A, Brož J. Požadavky na přenosný glukometr – současnost a budoucnost, In Brož J. a kol. Léčba inzulínem. Praha, Maxdorf, 2015, ISBN 978–80–7345–440–1. (Kapitola v knize)

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Publikace 7: Holubová A., **Vlasáková M.**, Mužík J., Brož J.: Customizing the Types of Technologies Used by Patients With Type 1 Diabetes Mellitus for Diabetes Treatment: Case Series on Patient Experience. JMIR mHealth and uHealth [online]. 2019, 7(7). DOI: 10.2196/11527. ISSN 2291-5222. (Článek s IF: 4.301)

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Effect of Activity Tracker on Risk Factors of Metabolic Syndrome

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Abstract

Background: The insufficient physical activity together with other factors causes the overweight, high blood pressure, and diabetes mellitus. The use of pedometers has a positive influence on increasing of physical activity and decreasing of the body weight. The Activity tracker brings a new challenge for the assessment of physical activity. They are most popular among the users, because they offer more functionalities than standard pedometers.
Objectives: The aim of this study was to identify the impact of activity tracker using on the factors of the metabolic syndrome (complex of risk factors which occur often together and are likely to arise on the basis of insuline resistance).
Methods: Totally 172 English written articles published before June 2016 were found by searching in the Web of Science database. Six trials have met the defined criterias. The positive influence of activity tracker on metabolic syndrome factors was proved by five trials.
Results: The results of three studies point to significant decreasing of participant weights. Next study showed decrease in participant waist circumference and results of other studies pointed to reduction of risk in development of type 2 diabetes.
Conclusion: Results of these studies have indicated that the activity tracker has a positive influence on the high risk factors of metabolic syndrome. But the effect of using the activity tracker is ambiguous, hence there is a need of more high-quality random researches for assessment of these influences.

Keywords

Activity tracker; Electronic activity monitor system, Physical acitivity; Metabolic syndrome; Self-monitoring

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Introduction

Current status

The World Health Organization reports 38 million deaths of total 56 million were caused by noncommunicable diseases such as cardiovascular diseases, cancer, diabetes, chronic respiratory diseases and others in 2012 [2]. 31 % deaths from noncommunicable diseases are a consequence of cardiovascular diseases (11 % deaths from the cardiovascular diseases are a consequences of high blood glucose) and 3 % deaths from the noncommunicable diseases are due to diabetes. One of three adults had overweight and every tenth person was obese in 2014. The prevalence of diabetes mellitus is 8,5 % [1]. Most of the noncommunicable diseases is the result of four specific behavior (use of tobacco, low physical activity, unhealthy diet and harmful alcohol consumption). It leads to four key metabolic changes (high blood pressure, overweight/obesity, higher blood glucose level and higher cholesterol) [2]. The insulin resistance, abdominal obesity, hypertension and hyperglycemia with atherogenic dyslipidemia form the basic component of metabolic syndrome (MS) [3]. Healthy dietary habits, regular physical activity and normal body weight lead to prevention of risk factors [2].

The pedometers were used for measuring of physical (non)activity in recent years. Results of the studies indicate that using of pedometer can motivate users to increase physical activity, consequently decrease their body weight [4]. The applicable form of feedback is necessary for the right motivation as not always the pedometer inter-

vention led to increasing of physical activity. The feedback must be adjusted to a characteristic of each patient. It is important the user can understand it because it is the necessary condition for changing his behavior and keep new habits [5]. Pedometers are simple and available tool for physical activity assessment. Information from pedometer are easy to understand and easy to use for the users – which is good for their wide application [6]. It is necessary to set up achievable goals in order to keep motivation which could be changed based on actual measured data. Pedometers offer information about number of steps but nothing about motion intensity, frequency or duration of the activity [7].

Activity tracker

Activity trackers have a big potential in this way. They are more and more popular among users [9]. They offer simple data gathering, fast feedback to user and data sharing using computer or smart phone [8]. They provide more functionalities in comparison to pedometers – the caloric consumption, measuring of the hearth rate or quality of sleeping. Another option is providing of visual back feedback during physical activity, verbal encouraging and social comparing. Lewis [9] defined this device as **Electronic Activity Monitor System** (EAMS) – *a wireless device that objectively measures lifestyle PA and can provide feedback, simultaneously display the basic activity information which awakens self-monitoring of user activity behavior using device display or via application.*

Objective of the study

The aim of this review was to identify the connection between using of activity tracker and metabolic syndrome risk factors.

Methods

The articles were identified using the electronic database called Web of Science. Key words were following:*("Fitness and tracker" or "Digital and tracker" or "Activity and tracker" or "Wearable and tracker" or "Wearable and device" or "Wearable and technology" or "Pedometer" or "Self* and tracker") and ("Metabolic disease syndrome" or "Metabolic risk faktors" or "Diabetes" or "High pressure" or "Syndrom X" or "Metabolic syndrome" or "Insuline resistence" or "Cardiovascular disease").* The searching was focused only on English written full text articles which were published before June 2016. The study designs, systematic reviews and studies with underage participants have not been included in this study. The selection has been done in four steps – the selection of duplicities and sorting by the title, abstract and full text. The criterion was the activity tracker intervention, or connection of pedometer with application or computer with remote couching on metabolic syndrome risk factors. The chosen studies has been compared afterwards.

Results

The 172 studies were found based on of the selected key words and 77 of them eliminated in first two steps. The full text were assessed in 95 trials. Big amount of trials in the third step was due the intense research of the specific EAMS using. The 86 studies were eliminated, because the EAMS was used as monitoring of physical activity without patient feedback, or because the study subject was of other focus. Two studies were eliminated due Spanish full text and one full text was impossible to find [10]. The six studies were filtered and put on the review.

Characteristics of the studies

The chosen studies were very heterogeneous – in their duration, number of participants, following parameters and the way of intervention (Table 1). This is the reason why it was very difficult to draw a comparison. The longest study took 16 months [14], compared to the shortest which was four weeks study [16]. Three studies had much more than 200 participants [12, 13, 15], the average number of the participants was 182 but with the standard deviation (SD) equal to 178. The average number of participants which finished the study was 70 % (SD=25). The overweight was the input parameter in three studies [13, 16, 14]. Two studies involved workers participating in a company prevention programs [12, 15] and one study included only women who had gestational diabetes in the past [11]. The objectively measurable data were the results of five studies – it was a waist circumference, body mass index (BMI), blood pressure, fasting plasma glucose and 2-h glucose levels on a75-g oral glucose tolerance test and measuring of HBA1c. One study used for measuring a questioner assessing risk of developing type 2 diabetes mellitus for measuring - the Australian Type 2 Diabetes Risk Assessment Tool (AUSDRISK) [12]. The participants were divided into three groups based on the results from AUSDRISK high, intermediate and low risk of developing type 2 diabetes within five years.

The Outcomes of the studies

The common objective of all selected studies was using of EAMS as an intervention tool with the main goal to find out the effect on chosen metabolic syndrome risk factors. Kim study [11] did not monitor any positive influence on decreasing of metabolic syndrome factors. But other studies monitored a positive influence. Rowe-Roberts study [12] registered decreasing of AUSDRISK score in 23 % of participants. And higher physical activity was measured in the participants with high risk of developing type 2 diabetes in comparison with other groups – the median number of steps was 8588 whereas

the group of medium risk (7836 steps) and the group of low risk (7878 steps). Studies by Fukoa [13], Sepah [14] and Richardson [16] measured significant decreasing in participant body weights. The experiment of Freak-Poli [15] measured decreasing in the waist circumference by 1.6 cm (SD=5.9). The relationship among participants was common attribute in studies where participants came from the company prevention programs [12, 15]. These studies did not include the individual target program nor the structured behavioral program – in comparison with other studies. Although both studies measured significant positive influence on the monitoring parameters (decreasing AUDRISK score and waist circumference). None of the studies did not check the monitored parameters after the intervention with the goal to find out an influence on the metabolic syndrome risk factors in long term period.

Discussion

This systematic review summarizes the results of EAMS intervention on the metabolic syndrome risk factors including only studies available in database Web of Science published before June 2016. The results indicate the EAMS could have a positive influence on the factors of metabolic syndrome – it means on decreasing of risk of developing type 2 diabetes, body weight and waist circumference decreasing. However the results aren't unambiguous and more intense researches are needed.

Objectively measured data and subjective assessments should be evaluating parameter of future studies. Participants of the research should be able to use proactively all the features that EAMS offers – including goals set individually, understandable feedback and data sharing among like-minded users. The studies should focus on the subsequent assessment of EAMS impact in long period after intervention.

Limits of review

The big heterogeneity of chosen studies is the limit for this review which caused difficulties in comparison and assessment of the results. More preferable key words will be needed to choose in future work (including of a word "accelerometer") and increasing in the number of searched databases. Simultaneously it is necessary to choose a key for comparing the quality of studies and their assessment (determination of minimal study lenght, study type, number of participants who complete the study).

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Table 1: Characteristics of the studies.

Autor (year of publication)	Lenght of trial	Typ of trial	Number of participants	Participants in the end of the study	Information about participants	Rated values	Intervention	Study results	Device type	Participants knew each other before the start of the study	Share results on social networks	Individually targeted program	Structured behavioral program	Self-monitoring
Rowe - Roberts, D (2014)	7 months	Quasi-experiment	212	36%	AUSDRISK Score at Commencement High 21,2%, Medium 40,6%, Low 38,2%	AUSDRISK	activity tracker	Participants with high AUSDRISK scores at commencement seemed to be the most motivated to increase activity levels and continue using the device over the period of the study, this participants had the highest average steps per day over the pilot (8,588 compared to 7,836 for medium risk and 7,878 for low risk) . 23% of participants reducing their AUSDRISK score over the period of 7 months.	Fitbit Ultra	yes	yes	no	no	yes
Fukuoka, Y (2015)	5 months	RCT - 2arms	61	100%	age =55,2 (SD=9,0) , BMI= 33,3 kg/m2 (SD=6,0); 77% women	weight, BMI, hip circumference, blood pressure, lipid profile and glucose level	pedometer, mobil application, session, individalized goals	Intervention group lost an average of 6,2 (5,9) kg (−6,8% [5,7%]), The intervention group's steps per day increased by 2,551 (4,712) compared to the control group's decrease of 734(3,308) steps per day, The intervention group had greater reductions in hip circumference , blood pressure, intake of saturated fat, sugar-sweetened beverages, The intervention had no significant effect on fasting lipid or glucose levels.	Omron Active Style Pro HJA-350IT	no	no	yes	yes	yes
Sepah, SC (2014)	16 months	Quasi-experiment	220	65%	age ≥18 years, BMI of ≥ 24 kg/m2 , 62% women, diagnosis of prediabetes	weight, HBA1C	pedometer, private online social network, session, health coaching and a wireless scale	The average HbA1C regressed from within the prediabetes range (5,7%-6,4%) to the normal range (< 5,7%), average of 5,0% and 4,8% weight loss at 16 weeks and 12 months, respectively.	Omron HJ-320 Tri-Axis Pedometer	no	yes	yes	yes	yes
Kim, C (2012)	13 weeks	RCT - 2arms	49	42%	age ≥18 years, 100% women, gestational diabetes delivery within the past 3 years	fasting plasma glucose and 2-h glucose levels on a75 g oral glucose tolerance test	pedometers, webbased education, internet forum	No significant changes from baseline to follow-up were noted in the behavioural constructs or behaviours, particularly physical activity, between study arms	not specified	no	no	yes	yes	yes
Freak-Poli, RLA (2011)	4 months	Quasi-experiment	539	79%	age ≥18 years, 57% woman, participants were recruited from ten workplaces	waist circumference	pedometer, website, emails	Average reduction of weist cirkumference was 1,6 cm (SD=5,9).	not specified	yes	no	no	no	yes
Richardson, CR (2005)	4 weeks	Quasi-experiment	12	100%	BMI ≥ 30, at least one of the following cardiovascular disease risk factors: diabetes, hypertension, hypercholesterolemia, obesity, or coronary artery disease	weight	pedometer, website, session	Average weight loss was 1,9 kg over three weeks.	SportBrain First Step	no	no	yes	yes	yes

Příloha č. 2:

Publikace 2: Oulická M, Mužík J, Mužný M. Overview and Multi-Criteria Analysis of Glucometers for Telemonitoring of Patient with Diabetes Mellitus. European Journal for Biomedical Informatics. 2013, roč. 9, č. 3, s. 22-25. ISSN: 1801-5603.

en22 *Original Article*

Overview and Multi-Criteria Analysis of Glucometers for Telemonitoring of Patient with Diabetes Mellitus

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Abstract

Background: The telemonitoring is more and more used for compensation of diabetes in the last decade. Doctors are able to get an accurate and reliable data in real time using the telemonitoring. A remote monitoring affects the attitudes and behavior of patients and potentially improves their state of health. Conclusions of many studies show additional clinical implications of telemonitoring. But it has not been possible to generalize those conclusions yet.
Objectives: The aim of this study was to create an overview of current glucometers available on the market. And select those which would meet the required parameters for using in the telemonitoring with automatic data sharing.
Methods: The research is focused on researches from technical and grey literature and on websites of producers and medical device dealers. The questioning will be carried out in the Czech and English language. Multi decision making method helps to select a suitable glucometer.
Conclusions: Fifty five glucometers from nineteen producers have been found in the researches and by market survey. The summary table with all important parameters can be seen in the preview. Conclusions of the Multi decision making analysis showed using of Diamond Mini from ForaCare Inc. producer which is the most suitable for the project of the telemonitoring with automatic data sharing. It is necessary to consider the safety of sending data, data sharing and personal data protection before this glucometer will be used in our project.

Keywords

Diabetes mellitus, telemonitoring, self management, glucometer, smart phone

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1 Introduction

The World Health Organization states in its report [1] the 1.7% prevalence of diabetes mellitus disease for the year 2000 and predicts prevalence of 4.4% for the year 2030. The data are worldwide and refer to all age groups. The number of patients is expected to increase from 171 million in the year 2000 to 366 million in 2030. The WHO predicts rise in direct costs for treatment of diabetes from 2.5% of the annual national budget to 15% in connection with increasing number of diabetic patients. Diabetic patients often suffer also from other diseases which results in decreasing quality of life together with rising costs of provided health care.

The telemonitoring is more and more used for compensation of diabetes in the last decade[2]. Doctors are able to get an accurate and reliable data in real time using the telemonitoring. A remote monitoring affects the attitudes and behavior of patients and potentially improves their state of health [3]. The telemonitoring has an incentive

and educational effect for the patients [4]. Conclusions of studies focused on the impact of telemonitoring show additional clinical implications of telemonitoring. But it has not been possible to generalize those conclusions yet [5].

The telemonitoring is based on communication between sender and recipient in real time. This allows an immediate reaction of the doctor to the patient's impulse. The patient uses an interactive device which transmits data via the Internet to the doctor for checking patient's biological parameters. Then the doctor evaluates this data and makes decisions for the following steps [6]. Telemonitoring and gathering the data must not bother patients in terms of physical activity, time etc. Ideally this should be completely automatic [4, 7, 8].

Smart phones with installed applications which contain tools allowing the collection, evaluation and sending data to a doctor can be used for automatic operations [7, 9]. There are currently more than 137 mobile applications available for self-control of the diabetes [10]. The most important parameters are the level of glucose in blood, the dose of insulin, the physical activity and the diet [5]. The patient has to fill in manually most of these parameters in his diabetic diary.

Our goal is to create a telemonitoring system which would measure the patient's data and send them to a server as much as possible automatically. The goal is the patient should do the same procedures in the treatment of diabetes such as being without the use of telemonitoring. It should be possible to infer the influence of the telemonitoring to the compensations of diabetes on the basis of the feedback from patients and evaluation of their health status. Hence it is necessary to select such a technical device which allows automatic data sharing without additional burden for the patient

The aim of this study was to create an overview of current glucometers available on the market. And select those which would meet the required parameters and system of telemonitoring described above. Desired parameters are: detection of glucose in blood from 1.1 mmol/l to 33.3 mmol/l (it corresponds with 18 mg/dl to 594 mg/dl) and possibility to share data with a smart phone.

2 Methods

The survey was focused on researches from technical and grey literature and on websites of manufacturers and medical device dealers. Search keywords were: a glucometer, the measurement of blood glucose, ketones measurement, measurement – diabetes, glucose monitoring, regulation of glucose, glucose measurement, overview of glucometers, evaluation of glucometers, tests of glucometers. The questioning was carried out in the Czech and English language. The search was particularly focused on glucometers currently offered for sale. A summary table has been created and filled in with found devices and their parameters.

Entered parameters were: designation of the glucometer from the manufacturer; manufacturer; measuring range; measuring time; amount of the blood sample; blood draw location, glucometer memory size; weight; battery life; the ability to share data with a computer and connection specification; the ability to share data with smart phone and again connection specifications. These parameters were obtained from glucometer manuals. The availability on the Czech market, the indicative price and a link to the source are parameters stated in the comments.

The final product will be selected on the basis of a Multi decision making method of selected glucometers. This method is a simple and fast tool. Its conclusions should be objective decisions if comparable items are chosen. The criteria weight calculation formula (1) [11] has been used for assessment in this method. A represents the criteria weight, f is a number of preferences and n is a number of criteria.

$$A = \frac{2 \times f}{n \times (n-1)} \tag{1}$$

3 Results

3.1 Glucometers Overview

Fifty five glucometers from 19 manufacturers have been found in the researches and by market survey. Their list with all important parameters can be seen in the preview in the table in attachment. All glucometers detect level of glucose in the blood in the range from 1.1 to 33.3 mmol/l. Producers state that 42 devices are able to analyze the blood sample within 5 seconds, 11 devices should analyze the sample up to 10 seconds, two blood glucometers have not got this parameter specified. The memory size to store the measured data ranged from 99 to 4000 records. In some cases it is limited by memory of a smart phone to which the glucometer is connected. 20% of the glucometers state the minimum quantity of the blood sample of 0.3 μl, 22% states the quantity of 0.5 μl, 25% of 0.6 μl. One device required 2 μl of the sample and another one has no information about the sample quantity in its manual. The weight of the two glucometers was less than 20 grams; the weight of almost 70 % glucometers with battery was between 20 and 60 grams. 35 glucometers which represent more than 63 % of products allow blood draw from alternatives locations. Ten devices allow sampling from a thigh or a calf. Twenty models are available on the Czech market. Forty five devices have possibility of connection to a computer. Thirteen products via a USB cable, two by bluetooth. Another two glucometers is possible to connect via a special connector (e.g. used in iPhones). There are only three models which offer sharing data with smart phones – one via bluetooth and two via a special connector.

Only three glucometers have met the primary parameters – Diamond Mini a iDiamond form ForaCare Inc. and iBGStar glucometer from the producer Sanofi Aven-

Table 1: Evaluation of parameters of selected glucometers.

Evaluated criteria	Diamond Mini	iDiamond	iBGStar
C1	10	10	5
C2	10	0	0
C3	10	0	5
C4	10	5	5

tis. These were subsequently assessed by the multi decision making.

3.2 Selecting of Glucometer by Using the Multi Decision Making

Evaluating parameters for Multi decision making are:

- The availability of glucometer on the Czech market (marked C1).
- Possibility to connect devices with a smart phone via bluetooth (marked C2).
- An alternative sampling point of blood (marked C3).
- Equipped with a USB connector (marked C4).

Each parameter was rated from 1 to 10. Where number 10 is a maximum value. More satisfied parameters more assigned points. The Table 1 shows evaluation of parameters.

Criterion C2 – the possibility to connect devices with a smart phone, gives 3 preferences. The others received one preference. The criteria order was given. The criteria weights were calculated using the formula (1) [11]. Importance of each criterion was taken into consideration in the evaluation of parameters of selected glucometers (Table 2).

Conclusions of the Multi decision making analysis showed using of Diamond Mini from ForaCare Inc. producer is the most suitable for our project. This device gained more than double points in comparison with the competitors (Table 3).

4 Conclusions

The aim of the study was to carry out an overview of the currently available glucometers on the market. It is possible that not all glucometers were included in this thesis. Reason for leaving out some products is due to orientation on the Czech or English speaking market. Another reason could be difference in search expression. 55 devices from 19 producers were involved in the overview. Only three products have met requirements for using in the telemonitoring with automatic data sharing. Conclusions of the Multi decision making analysis showed the most universal and usable device which is Diamond Mini from ForaCare Inc. producer.

Before this glucometer will be used in this project, it is necessary to consider the safety of sending data, data sharing and personal data protection.

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Table 2: Criteria preferences.

Table of preferences	C1	C2	C3	C4	Number of preferences (f)	Hierarchy of criteria	Scale
C1	x	0	1	0	1	2	0.167
C2	1	x	1	1	3	1	0.500
C3	0	0	x	1	1	2	0.167
C4	1	0	0	x	1	2	0.167

Table 3: Weight calculation for each criterion of selected glucometers.

Evaluation the criteria	Scale	Diamond Mini	iDiamond	iBGStar
C1	0.167	1.67	1.70	0.83
C2	0.500	5.00	0.00	0.00
C3	0.167	1.67	0.00	0.83
C4	0.167	1.67	0.83	0.83
Sum		**10.00**	2.50	2.50

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Appendix 1: Glucometers review based on the market research.

No.	Type of glucometer	Producer	Range of measurements (mmol/l)	Measurement time (s)	Memory range	The size of a blood sample (µl)	Weight (g) with battery	Possibility of connection with computer	Specification connection with computer	Connection with smarth phones	Specification connection with smarth phones	Posibility alternative place of blood sampling	Availability on the Czech market	Place of blood sampling
1	One Touch UltraEasy	LifeScan	1.1 - 33.3	5	500	1	40	yes	USB cable	no	-	yes	yes	finger, forearm, upper arm, hand, thigh, calf
2	One Touch Vita	LifeScan	1.1 - 33.3	5	500	1	58	yes	USB cable	no	-	yes	yes	finger, forearm, upper arm, hand, thigh, calf
3	One Touch Ultra	LifeScan	1.1 - 33.3	5	150	1	42,5	yes	USB cable	no	-	yes	yes	finger, forearm, upper arm, hand
4	One Touch UltraSmart	LifeScan	1.1 - 33.3	5	3000	1	79	yes	USB cable	no	-	yes	yes	finger, forearm, upper arm, hand, thigh, calf
5	One Touch Verio Pro	LifeScan	1.1 - 33.3	5	750	0,4	85	yes	USB cable	no	-	yes	yes	finger, forearm, hand
6	Diamond Prima	ForaCare Inc.	1.1 . 33.3	5	450	0,5	52	yes	USB cable	no	-	yes	yes	finger, forearm, upper arm, hand, thigh, calf
7	Diamond Mini	ForaCare Inc.	1.1 - 33.3	5	450	0,5	27	yes	USB cable, bluetooth	yes	bluetooth, iphone connector	yes	yes	finger, forearm, upper arm, hand, thigh, calf
8	iDiamond	ForaCare Inc.	0.5 - 33.3	5	iphone memory	0,5	34	yes	iphone connector	yes		not specified	yes	not specified
9	FreeStyle Lite	Abbot Diabetes Care Inc.	1.1 - 27.8	5	400	0,3	31	yes	data cable	no	-	yes	yes	finger, forearm, upper arm, hand, thigh, calf
10	FreeStyle Freedom Lite	Abbot Diabetes Care Inc.	1.1 - 27.8	4	400	0,3	45	yes	data cable	no	-	yes	yes	finger, forearm, upper arm, hand, thigh, calf
11	FreeStyle Optimum	Abbot Diabetes Care Inc.	1.1 - 27.8	5	450	0,6	42	yes	not specified	no	-	yes	yes	finger, forearm, upper arm, hand, thigh, calf
12	FreeStyle InsuLinx	Abbot Diabetes Care Inc.	1.1 - 27.8	not specified	495	0,3	66	yes	USB cable	no	-	no	no	finger
13	FreeStyle Optimum Xceed	Abbot Diabetes Care Inc.	1.1 - 27.8	not specified	450	0,3	42	yes	not specified	no	-	yes	no	finger, forearm, upper arm, hand
14	FeeStyle Lite	Abbot Diabetes Care Inc.	1.1 - 27.8	5	400	0,3	31	yes	not specified	no	-	no	yes	finger
15	Precison Xtra Overview	Abbot Diabetes Care Inc.	1.1 - 27.8	5	450	0,6	46	yes	data cable	no	-	yes	no	finger, forearm, hand
16	Accu Chek Performa Nano	Roche	0.6 - 33.3	5	500	0,6	40	yes	infrared	no	-	yes	yes	finger, hand
17	Accu Chek Aviva	Roche	0.6 - 33.3	5	500	0,6	60	yes	infrared	no	-	yes	no	finger, hand
18	Accu Chek Aviva Combo	Roche	0.6 - 33.3	5	1000	0,6	103	yes	bluetooth	no	-	no	no	finger
19	Accu Chek Performa	Roche	0.6 - 33.3	5	500	0,6	52	yes	infrared, cable	no	-	yes	yes	finger, hand
20	Accu Chek Mobile system	Roche	0.6 - 33.3	5	2000	0,3	129	yes	infrared	no	-	no	no	finger
21	Accu Chek Advantage	Roche	test strips	5	480	not specified	60	yes	data cable	no	-	no	no	finger
22	Accu Chek Aviva Active	Roche	0.55 - 33.3	5	200	1	57	yes	infrared	no	-	yes	no	finger, forearm, hand
23	Contour Link	Bayer	0.6 - 33.3	5	480	0,6	53	yes	not specified	no	-	no	yes	finger
24	Contour next USB Meter	Bayer	1.1 - 33.3	5	2000	0,6	34	yes	USB cable	no	-	yes	no	finger, forearm, hand
25	Contour XT Meter	Bayer	0.6 - 33.3	5	480	0,6	48	no	-	no	-	no	no	finger
26	Contour	Bayer	0.6 - 33.3	5	480	0,6	48	no	-	no	-	yes	no	finger, forearm, hand
27	Contour TS	Bayer	0.6 - 33.3	8	250	0,6	57	yes	data cable	no	-	no	yes	finger
28	Breeze 2	Bayer	0.6 - 33.3	5	420	1	not specified	yes	data cable	no	-	no	no	finger

No.	Type of glucometer	Producer	Range of measurements (mmol/l)	Measurement time (s)	Memory range	The size of a blood sample (µl)	Weight (g) with battery	Possibility of connection with computer	Specification connection with computer	Connection with smarth phones	Specification connection with smarth phones	Posibility alternative place of blood sampling	Availability on the Czech market	Place of blood sampling
29	Didget	Bayer	1.1 - 33.3	5	480	0,6	76	yes	Nintendo integrated card	no	-	yes	no	finger, forearm
30	SD CodeFree	Standard Diagnostics, Inc.	0.55 - 33.3	5	500	0,9	48	yes	data cable	no	-	yes	yes	finger, forearm, hand
31	SD-Check Gold	Standard Diagnostics, Inc.	0.6 - 33.3	5	400	0,9	50	no	-	no	-	no	yes	finger
32	SeNova	Chdiagnostics	1.1 - 33.3	10	250	0,6	60	yes	not specified	no	-	no	yes	finger
33	TrueZgo	NIPRO Diagnostics	1.1 - 33.3	4	99	0,5	17	no	-	no	-	yes	no	finger, forearm
34	TRUEresult	NIPRO Diagnostics	1.1 - 33.3	4	500	0,5	47	no	-	no	-	no	no	finger
35	TRUEtrack	NIPRO Diagnostics	1.1 - 33.3	10	365	1	47	no	-	no	-	yes	no	finger, forearm
36	TRUEbalance	NIPRO Diagnostics	1.1 - 33.3	10	365	1	47	no	-	no	-	no	no	finger
37	TRUEread	NIPRO Diagnostics	1.1 - 33.3	10	200	1	47	no	-	no	-	yes	no	finger, forearm
38	Clever Chek	BBI Healthcare	1.1 - 33.3	7	450	0,7	70	yes	USB cable	no	-	yes	no	finger, forearm, upper arm, hand, thigh, calf
39	Omnitest 3	B Braun	0.55 - 33.3	3	365	0,3	54	yes	data cable	no	-	no	no	finger
40	Omnitest plus	B Braun	0.6 - 33.3	5	250	1	41	yes	data cable	no	-	no	yes	finger
41	GlucoMen LX Plus	A. Menarini Diagnostics LTD	1.1 - 33.3	4	4000	0,3	75	yes	audiojack	no	-	yes	no	finger, forearm, hand
42	Glucocard MX	A. Menarini Diagnostics LTD	0.6 - 33.3	5	500	0,3	46	yes	not specified	no	-	yes	no	finger, hand
43	Glucocard G+	A. Menarini Diagnostics LTD	0.6 - 33.3	5,5	450	0,6	50	yes	audiojack	no	-	yes	no	finger, forearm, hand
44	Glucocard X	A. Menarini Diagnostics LTD	0.6 - 33.3	5	360	0,3	45	yes	not specified	no	-	yes	no	finger, forearm, hand
45	Glucofix mio plus	A. Menarini Diagnostics LTD	1.1 - 33.3	4	400	0,3	75	yes	not specified	no	-	no	no	finger
46	GlucoMed GM	A. Menarini Diagnostics LTD	0.6 - 33.3	7	250	0,5	39	no	-	no	-	yes	no	finger, forearm, hand
47	GlucoRx Nexus	TaiDoc Technology Corporation	1.1 - 33.3	5	1000	0,5	67	yes	USB cable	no	-	no	no	finger
48	IME-DC	Arctic Medical	1.1 - 33.3	10	100	2	57	yes	USB cable	no	-	yes	no	finger, hand
49	One Touch Ultra 2	LifeScan	1.1 - 33.3	5	500	1	42	yes	data cable	no	-	yes	no	finger, forearm, hand
50	Discreet all in One	Mendor	1.1 - 33.3	5	250	0,5	28	yes	data cable	no	-	no	no	finger
51	BGStar	Sanofi Aventis	1.1 - 33.3	6	1865	0,5	48	yes	not specified	no	-	no	no	finger
52	iBGStar	Sanofi Aventis	1.1 - 33.3	6	300	0,5	9	yes	not specified	yes	iphone connector	yes	no	finger, forearm, hand
53	CareSens N	Spirit Healthcare	1.1 - 33.3	5	250	0,5	50	yes	USB cable	no	-	yes	no	finger, forearm, hand, thigh
54	WaveSense Jazz	Aga Matrix, Inc	1.1 - 33.3	4	1865	0,5	48	no	-	no	-	yes	no	finger, forearm, hand
55	PURA	Ypsomed	0.6 - 33.3	5	500	1	not specified	yes	not specified	no	-	yes	no	finger, hand

Příloha č. 3:

Publikace 3: Oulická M., Mužík J, Holubová A, Brož J. Požadavky na přenosný glukometr – současnost a budoucnost, In Brož J. a kol. Léčba inzulínem. Praha, Maxdorf, 2015, ISBN 978–80–7345–440–1. (Kapitola v knize)

8. Současné požadavky na přenosný glukometr

M. Oulická, A. Holubová, J. Mužík, J. Brož

V roce 2013 Mezinárodní organizace pro normalizaci (International Organization for Standardization) přijala novou mezinárodní normu ISO 15197 (Požadavky na systémy monitorování glykemie pro sebekontrolu pacientů s onemocněním diabetes mellitus), která zpřísňuje kritéria pro glukometry užívané při self-monitoringu glykémií. Norma byla přijata do soustavy českých technických norem vydáním ve věstníku Úřadu pro technickou normalizaci, metrologii a státní zkušebnictví. Užívání normy se řídí zákonem č. 22/1997 Sb. o technických požadavcích na výrobky a související předpisy.

8.1 Východiska normy

Norma vychází především z možností, které přinášejí technologie pro sledování pacientů a dále z doporučení odborníků v oblasti diabetu. Její snahou je zlepšit přesnost glukometrů i snadnost jejich použití.

Současné technologie přinášejí řadu funkčních vylepšení glukometrů. Redukovala se pravděpodobnost výskytu chyb měření ze strany uživatele při self-monitoringu glykémie a dosáhlo se snížení bolesti provázející odběr krevního vzorku. Inovace se projevily i v minimalizaci objemu krevního vzorku potřebného pro měření, urychlení průběhu testu, zvýšení tolerance glukometrů k teplotním výkyvům a zejména snížení požadavků přístrojů na kódování a kalibraci. Prodloužila se životnost a stálost činidel a omezil se vliv objemu červených krvinek na průběh měření (hematokrit).

Výzkumy odborných lékařů prokázaly, že komfortní a jednoduchý self-monitoring pozitivně ovlivňuje ochotu pacientů pravidelně měřit glykémii. Výrobci glukometrů zároveň uvádějí, že četnost měření glykémie ovlivňují u pacientů: finanční náklady, snadnost ovládání a bolest spojená s vlastním měřením.

8.1 Základní požadavky na současné glukometry podle nové normy

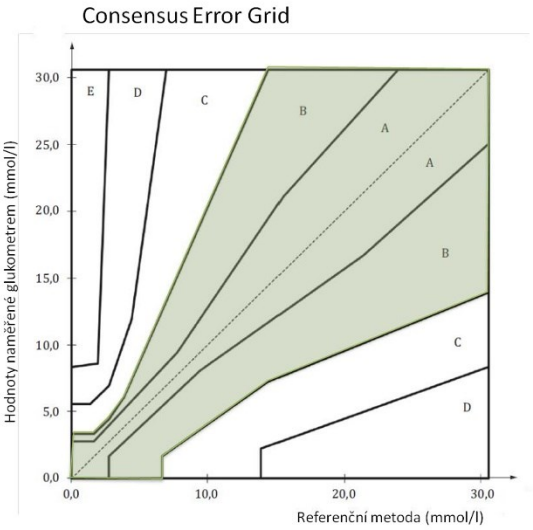
8.1.1 Přesnost glukometrů

Nepřesně změřená hladina glykémie glukometry může vést k chybám v množství dávkování inzulinu. U asymptomatické hypoglykemie je pravidelný self-monitoring prakticky jediný způsob včasného odhalení poklesu hladiny glukózy v krvi. Především důvody vedly ke zpřísnění kritérií pro přesnost glukometrů. Nově musejí glukometry splňovat přesnost i mimo laboratorní podmínky, zohlednily se tak běžné okolnosti měření mající možný vliv na výsledky testu.

Pro přijatelnost přesnosti glukometru byla stanovena dvě kritéria. Podle prvního kritéria musí 95 % výsledků splňovat následující podmínku:

- Při koncentraci glukózy <5,55 mmol/l nesmí chyba měření překročit rozmezí ± 0,83 mmol/l.
- Při koncentraci glukózy ≥5,55 mmol/l nesmí chyba měření přesáhnout ± 15 %.

Zvýšil se tedy požadavek na přesnost měření glukometru u vyšších hodnot glykémie (nad 5,5 mmol/l), míra přípustné chyby se snížila na ±15 % (z původních ±20 % v původní normě). Chybová tolerance je na škále glykémie stanovena konstantní veličinou (± 0,83 mmol/l) v hodnotách pod 5,5 mmol/l, nad nimi pak procentuálně (±15 %), dosud byla touto hranicí hodnota 4.2 mmol/l.



Druhé kritérium přesnosti systému požaduje, aby 99 % všech naměřených hodnot spadalo do pásma A a B chybové mřížky (Consensus Error Grid). Zbylé 1 % pak musí ležet v jejích odlehlých hodnotách (v pásmech C-E). První vydání normy (z r. 2003) obsahovalo požadavek, aby 95 % výsledků testů spadalo do oblasti A nebo B; na zbylých 5 % výsledků nebyla kladena žádná omezení (mohly tedy ležet i mimo oblasti definované mřížkou. Obecně uznávaná chybová mřížka (viz obrázek) byla vytvořena na základě výsledků průzkumu provedeném u 100 endokrinologů v r. 1994 při výročním sjezdu Americké diabetologické asociace. Jednotlivé zóny mřížky vymezují míru rizika, které představuje pro pacienta použití přístroje s přesností měření spadající do dané oblasti mřížky.

Glukometrem změřené hodnoty glykémie jsou v ní srovnávány s hodnotami vzešlými z metody referenční. Mřížka je rozdělena do několika pásem rizik (A-E). Oblasti A a B znamenají dostatečnou přesnost glukometru (odchylka glukometru má malý nebo žádný účinek na správnost léčebného rozhodnutí). Pásma C až E znamenají naměření hodnot, které zvyšují riziko terapeutické chyby. A to od nedostatečně přesného léčebného kroku až ke zcela protikladnému řešení, než které by bylo v dané situaci vhodné (např. pásmo E představuje vysoké hodnoty glykémie naměřené glukometrem, zatímco referenční (skutečné) hodnoty se pohybují v pásmu hypoglykémií.)

8.1.2 Vyloučení chybovosti vlivem dalších látek a hodnot hemoglobinu

Při vývoji glukometrů se hodnotí v rámci procesu řízení rizik vliv objemu červených krvinek (hematokrit) a rušivých látek v krvi na přesnost přístroje. Norma stanovuje kritéria přijatelnosti, která určují hranici akceptovatelného účinku látek na přesnost testů. Pokud vliv rušivých látek nevyhovuje stanoveným kritériím, musí výrobce uvést účinky látky v návodu

k použití přístroje. Mezi možné rušivé látky se řadí například paracetamol, kyselina askorbová, dopamin, heparin, ibuprofen, k. močová a další (úplný výčet níže). Záleží na každém výrobci, aby sám zvážil, zda mohou tyto látky mít potencionální vliv na přesnost měření jejich systému. Pokud výrobce neprovede zkoušky na možný účinek těchto látek, musí důvody uvést v analýze rizik.

Pokud účinky některé z rušivých látek nesplňují následující kritéria přesnosti měření, musí být jejich vliv popsán v návodu k použití:

- U koncentrace glukózy <5,55 mmol/l nepřesahuje průměrný rozdíl mezi zkušebním a kontrolním vzorkem 0,55 mmol/l *(v jednom z nich je přidána testovaná rušivá látka)*
- U koncentrace glukózy ≥5,55 mmol/l nepřesahuje průměrný rozdíl mezi zkušebním a kontrolním vzorkem 10 %.

Pokud vliv celkového objemu červených krvinek (hematokrit) nesplňuje některé z následujících kritérií, musí být popsán v návodu k použití:

- U koncentrace glukózy <5,55 mmol/l: rozdíl mezi průměrnou naměřenou hodnotou pro každou hladinu celkového objemu červených krvinek a průměrnou naměřenou hodnotou pro poloviční hladinu celkového objemu červených krvinek nepřesahuje 0,55 mmol/*l (testuje se vždy minimálně 5 celkových objemů červených krvinek při každé ze 3 koncentrací glukózy, vzorky jsou připravovány ze separovaných červených krvinek, ke kterým je přidáváno v různých poměrech příslušné množství plasmy)*

- U koncentrace glukózy ≥5,55 mmol/l: rozdíl mezi průměrnou naměřenou hodnotou pro každou hladinu celkového objemu červených krvinek a průměrnou naměřenou hodnotou pro poloviční hladinu celkového objemu červených krvinek nepřesahuje 10 %

8.1.3 Kvalita návodu k použití

Norma upravuje též požadavky na kvalitu návodu k použití. Krom možných omezení vyplývajících z účinků rušivých látek a objemu červených krvinek musí návod obsahovat popis a charakteristiku funkcí glukometru. V návodu k použití musí být uvedeno shrnutí výsledků hodnocení přesnosti glukometru (hodnocení opakovatelnosti, mezilehlé přesnosti a přesnosti systému) a musí být popsány možné vlivy prostředí na přesnost měření přístroje.

Je třeba, aby instrukce obsahovaly údaje ohledně jednotek, ve kterých glukometr měří (mmol/l, mg/dl). Výrobce je povinen uvést, zda hodnoty udávané přístrojem jsou plazma ekvivalentní, nebo zda se jedná o koncentrace glukózy v krvi. Veškeré informace musí být popsány takovým způsobem, aby byly srozumitelné i laikům.

Kvalita návodu je hodnocena uživateli z hlediska srozumitelnosti a užitečnosti. Zároveň je testována schopnost laika získat přesně naměřené hodnoty glykémie za použití pouze návodu k použití a měřicího přístroje.

V normě uvedené možné rušivé látky:

Paracetamol, Ibuprofen, kyselina askorbová, Ikodextrin , Bilirubin, L-3,4-dihydroxyfenylalanin, Cholesterol, Maltóza , Kreatinin, Methyl-DOPA , Dopamin, Pralidoxim-jodid, EDTA , Salicylát , Galaktóza, Tolbutamid , Kyselina gentisinová, Tolazamid, Glutathion, Triglyceridy , kyselina močová, Heparin, Xylóza

Literatura:

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Příloha č. 4:

Publikace 4: Mužík J, Holubová A, **Oulická M**, Mužný M, Poláček M, Fiala D, Kvapil M a Brož J. Telemonitorovací systém Diani – český přínos ke sběru a analýze dat pacientů s diabetes mellitus 1. typu. In: Diabetologie. 2017, s. 183-187. ISBN 978-80-7553-262-6. (Kapitola v knize)

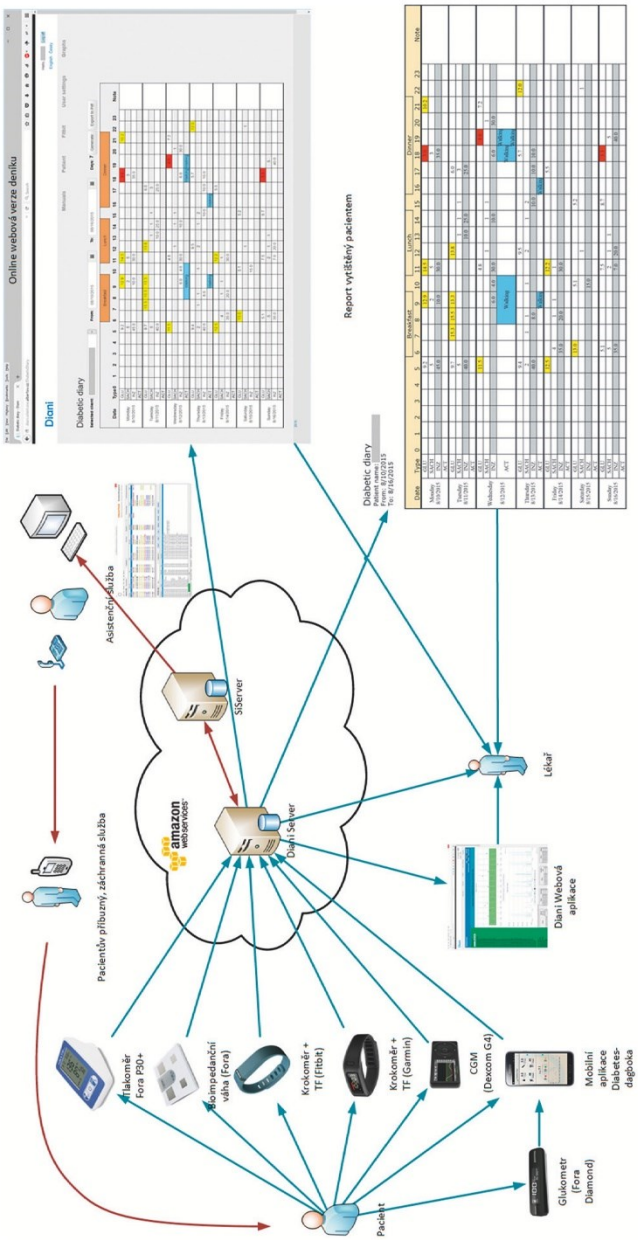
Telemonitorovací systém Diani – český přínos ke sběru a analýze dat pacientů s diabetes mellitus 1. typu

Jan Mužík, Anna Holubová, Martina Oulická, Miroslav Mužný, Milan Poláček, Dominik Fiala, Milan Kvapil, Jan Brož

Možnosti monitorace glykemie i dalších důležitých parametrů, jakými jsou například dávky inzulinu, obsah sacharidů v jídle, míra fyzické aktivity apod., přinášejí pacientovi a také jeho lékaři velké množství dat. Pro pacienta je složité všechna data konzervativní písemnou cestou zaznamenat a ještě složitější, a to jak pro něj, tak i pro jeho lékaře, tato data v plném rozsahu a ve všech souvztažnostech analyzovat.

Aplikace pro chytré mobilní telefony i desktopové počítače a tablety jsou dnes běžnou nabídkou řady výrobců a nabízejí pomoc nejenom ve výše uvedených případech. U pacientů s diabetes mellitus usnadňují ukládání hodnot glykemie, obsahů sacharidů v jídlech, dávek inzulinu či fyzické zátěže a jejich částečně automatizovanou analýzu nebo pacientovi připomínají, že nadešel čas změřit si glykemii či se vydat na svou plánovanou procházku či jinou fyzickou aktivitu.

Originálním českým příspěvkem k tomuto segmentu péče o diabetiky je telemonitorovací systém Diani. Je to telemedicínský systém, který umožňuje dálkové spojení s řadou elektronických přístrojů (aplikace chytrých telefonů, krokoměry, kontinuální monitory glykemie, zařízení na měření krevního tlaku apod.), ze kterých automaticky stahuje a ukládá

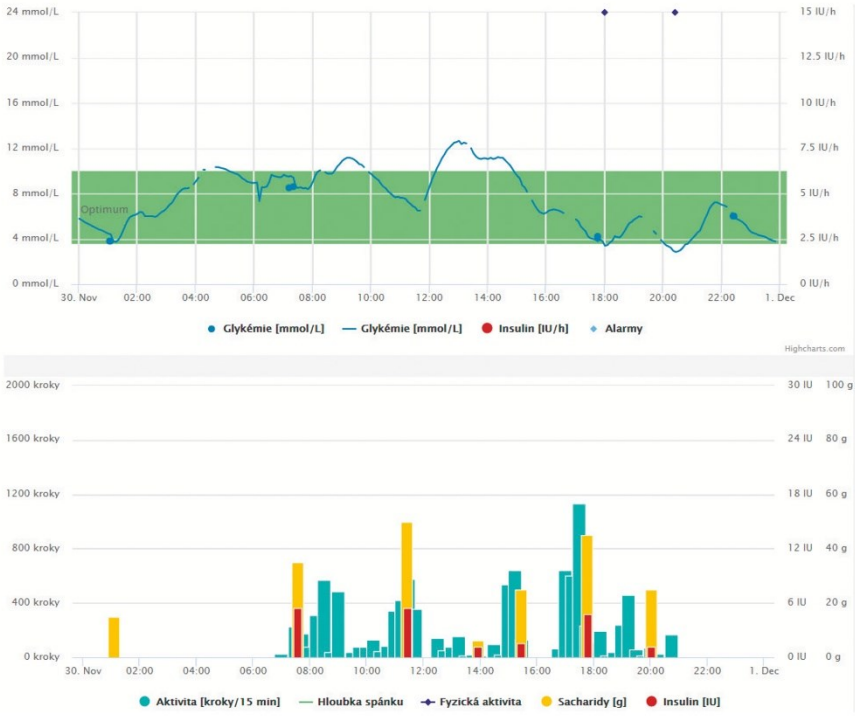

Online webová verze deníku
Diani
Diabetic diary
Report vytištěný pacientem
Diabetic diary
Asistenční služba
SiServer
Diani Server
Lékař
Diani Webová aplikace
Pacientův příbuzný, záchranná služba
Tlakoměr Fora P30+
Kompedanční váha (Fora)
Krokoměr + TF (Fitbit)
Krokoměr + TF (Garmin)
CGM (Dexcom G4)
Mobilní aplikace Diabetes-dagboka
Glukometr (Fora Diamond)
Pacient

Obr. 1

naměřená či pacientem vložená data a zobrazuje je pomocí webové aplikace.

Schéma systému je zobrazeno na obr. 1. Tvoří ho centralizované úložiště dat a řada modulů pro import dat ze zařízení, jako jsou glukometry, krokoměry nebo inzulinové pumpy. Pacient do systému vstupuje přes svůj soukromý zabezpečený účet. Stažená a uložená data si může zobrazit v několika modalitách (grafy, tabulky), veškerá data si může též stáhnout v různých formátech (pdf,csv) a zvoleném časovém období. Pacient též může umožnit svému lékaři (či komukoliv dalšímu) ke svým datům přístup přes další individuálně založený účet.

Data lze na internetovém serveru zobrazit v několika podobách. Na obr. 2 vidíme schematický časový graf, který názorně a přehledně ukazuje jednotlivé měřené hodnoty v časové souslednosti, a pacient či lékař si mohou snadněji udělat představu o jednotlivých veličinách a jejich



Obr. 2

Glykémie [mmol/L]		Sacharidy [g]		Insulin [IU]		Insulin [IU/h]		Aktivita [kroky/den]	
1:24 AM	4.6	6:53 AM	5	9:17 AM	5.5	10/30/2013		12:00 AM	14
9:15 AM	8.6	9:07 AM	0	10:37 AM	2.0	12:00 AM - 10:06 AM	1.0	12:15 AM	61
11:50 AM	9.8	10:06 AM	34	11:04 AM	0.0	10:06 AM - 2:00 PM	1.0	1:00 AM	14
1:38 PM	3.8	12:03 PM	60	11:54 AM	6.5	2:00 PM - 8:00 PM	1.2	1:15 AM	28
9:49 PM	6.3	1:23 PM	25	3:30 PM	3.5	8:00 PM - 12:00 AM	1.0	1:30 AM	13
9:52 PM	6.3	1:40 PM	20	3:57 PM	3.0	12:00 AM - 1:27 PM	1.0	9:00 AM	33
11:29 PM	9.2	5:08 PM	40	5:14 PM	0.0	1:27 PM - 2:02 PM	0.0	9:15 AM	18
11:31 PM	9.2	5:14 PM	0	6:32 PM	2.0	2:02 PM - 8:00 PM	1.2	9:30 AM	39

Obr. 3

vzájemných souvislostech. Pro přehledný výčet absolutních hodnot je možné využít klasickou tabulku, umístěnou pod grafem, kterou vidíme na obr. 3. Záznamem je možné libovolně listovat, vytisknout si ho podle zadaného časového intervalu či stáhnout ve formě pdf.

Zásadní součástí telemonitorovacího systému je mobilní aplikace diabetického deníku Diabetesdagboka (obr. 4), kterou pacient používá k zadávání dat do svého chytrého telefonu. Do této aplikace, kterou vytvořilo Norském centrum pro výzkum e-health a na jejímž vývoji se rovněž podílíme, pacient ukládá data o změřené glykemii, dávce inzulinu, množství sacharidů v jídle, případně poznámky o své aktuální činnosti (fyzická

Obr. 4

aktivita apod.). Zejména pacienti s diabetem 2. typu pak mohou zadávat i informace o aktuální hmotnosti, příjmu kalorií, požití antidiabetik či si nastavit své osobní cíle. Hodnoty glykemie jsou do aplikace přenášeny automaticky v případě, že pacient vlastní glukometr Fora Diamond, který umožňuje automatickou komunikaci s aplikací přes Bluetooth rozhraní.

Pacient má možnost data prohlížet prostřednictvím aplikace ve svém telefonu a data jsou přes internet automatizovaně přenášena do webové aplikace Diani.

Vkládání dat do aplikace usnadňuje aplikace pro chytré hodinky Pebble, která umožňuje, aby registrace jednotlivých položek probíhala jednoduchým stisknutím pouze několika tlačítek, přičemž se tyto záznamy automaticky přenášejí a ukládají do mobilní aplikace.

Pacienti, kteří nyní telemonitorovací systém v testovacím režimu využívají, jsou vybaveni i elektronickým krokoměrem Fitbit nebo Xiaomi. Takto získaná data jsou přímo přenášena do webové aplikace, kde jsou pak uložena a zobrazena. Další možností systému Diani je upload dat ze všech v České republice používaných kontinuálních monitorů glykemie (Dexcom, Medtronic, Freestyle Navigator) a jejich zobrazení z daného zařízení. V případě systému Dexcom je možné využít modul xDrip (Nightscout) a data přenášet automaticky a v reálném čase.

Součástí systému je i automatizovaná analýza některých dat. V současnosti probíhá testovací provoz systému umožňujícího vyhledávání problémových či potenciálně problémových situací, jakými jsou hypoglykemie, situace s větší krokovou zátěží a situace s rychlým poklesem glykemie.

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Original Paper

A Telemedicine System Intervention for Patients With Type 1 Diabetes: Pilot Feasibility Crossover Intervention Study

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Abstract

Background: Today's diabetes-oriented telemedicine systems can gather and analyze many parameters like blood glucose levels, carbohydrate intake, insulin doses, and physical activity levels (steps). Information collected can be presented to patients in a variety of graphical outputs. Despite the availability of several technical means, a large percentage of patients do not reach the goals established in their diabetes treatment.

Objective: The objective of the study was to evaluate the benefits of the Diani telemedicine system for the treatment of patients with type 1 diabetes mellitus.

Methods: Data were collected during a 24-week feasibility study. Patients responded to the World Health Organization Quality of Life – BREF (WHOQOL-BREF) questionnaire and a system evaluation questionnaire. The level of glycated hemoglobin (HbA_{1c}) and the patient's body weight were measured, and the patient's use of the telemedicine system and their daily physical activity level were monitored. All data were sent from the patient's device to the Diani server using a real-time diabetes diary app. Wilcoxon and Friedman tests and the linear mixed effects method were used for data analysis.

Results: This study involved 10 patients (men: n=5; women: n=5), with a mean age of 47.7 (SD 19.3) years, a mean duration of diabetes of 10.5 (SD 8.6) years, and a mean HbA_{1c} value of 59.5 (SD 6.7) mmol/mol. The median number of days the patients used the system was 84. After the intervention, the mean HbA_{1c} decreased by 4.35 mmol/mol (P=.01). The patients spent 18.6 (SD 6.8) minutes on average using the app daily. After the intervention, the number of patients who measured their blood glucose level at least 3 times a day increased by 30%. The graphical visualization of the monitored parameters, automatic transmission of measured data from the glucometer, compatibility, and interconnection of individual devices when entering data were positively evaluated by patients.

Conclusions: The Diani system was found to be beneficial for patients with type 1 diabetes mellitus in terms of managing their disease. Patients perceived it positively; it strengthened their knowledge of diabetes and their understanding of the influences of the measured values on the management of their disease. Its use had a positive effect on the HbA_{1c} level.

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KEYWORDS

diabetes mellitus; diabetes; telemedicine; telemedicine system; mobile health; mHealth; telemonitoring; quality of life; telehealth; compensation; evaluation; intervention; feasibility

Introduction

Diabetes Mellitus

Diabetes mellitus is a major public health problem that is approaching epidemic proportions worldwide [1]. The prevalence of diabetes mellitus is increasing at an alarming rate. The World Health Organization (WHO) reported the global prevalence of diabetes in adults (20 to 79 years) as 8.5% in 2014 [1] and 10.5% in 2021, and the estimated prevalence of diabetes is expected to rise to 12.2% in 2045 [2]. Between 5% and 10% of patients have type 1 diabetes [3]. In 2021, there were about 8.4 million people worldwide with type 1 diabetes. Of these, 83% were aged ≥20 years [4].

The increase in global health expenditure due to diabetes has been considerable, growing from US $232 billion in 2007 to US $966 billion in 2021 for adults aged 20 to 79 years. Direct costs of diabetes are expected to continue to increase. The International Diabetes Federation estimates that total diabetes-related health expenditure will reach US $1.03 trillion by 2030 and US $1.05 trillion by 2045 [5]. Health systems are under pressure related to the sustainability of health care provided at acceptable levels and with a high number of consultations in both primary care and hospitals. Social systems are exposed to increased costs because of the reduced working capacity. As a result of this pressure, patients with diabetes can develop feelings of reduced quality of life [6]. Regular checks on a person with diabetes by a health care provider are generally performed once or twice a year, so diabetes care is primarily based on self-care [6].

The overall average glycated hemoglobin (HbA_{1c}) for patients with type 1 diabetes was 66 mmol/mol (average HbA_{1c} values are 58-62 mmol/mol for patients aged 30 years and 58 mmol/mol for patients aged 65 years; data also include insulin pump users) [7].

Currently, different technological tools are available for patients with diabetes mellitus that can significantly facilitate their daily life with diabetes and, at the same time, adapt to their individual needs. Telemedicine systems (TSs) have the potential to offer a solution to the sustainability of health care systems, maintaining or increasing the quality and accessibility of health care and managing large amounts of health-related data with limited resources [8,9].

TSs have been increasingly used in the care of diabetes in the last decade [9-17]. Despite the benefits they offer their users [9,18-20], they have not yet been widely adopted as a tool for health care delivery [10], and the systems have not been adequate enough to meet their created plan for the care of diabetes [5,8,12]. During the recent COVID-19 pandemic, the situation generally improved.

However, the technologies themselves will not help the patients if they are unable or unwilling to fully use what the given technology offers. It is necessary to ensure frequent interaction with the technology. To find the right motivation for a given patient, it is necessary to know the patient's involvement in terms of treatment, in situations in which it is difficult to self-manage diabetes mellitus, as well as mental abilities and environment [21]. For long-term sustainable TS use by patients with diabetes, the associated expenditure of time, energy, and money must be at a tolerable level in terms of the patient's treatment burden [22].

Diani is a TS for the management of diabetes mellitus and other chronic diseases, which reports a significant improvement in HbA_{1c} values in patients with type 1 diabetes [21]. The feasibility of an intervention with the Diani TS might fill the knowledge gap in the implementation of TSs in the health care system; explore the reliability, accuracy, and efficiency of the system more closely; and help to identify patient requirements for a digital tool for diabetes care so that such technical solutions lead to their long-term use with a positive impact for all users, patients with diabetes, health care providers, and the national health system.

Objective of the Study

The main objective of the study was to evaluate the Diani TS for the treatment of patients with type 1 diabetes mellitus, especially its effect on HbA_{1c} and body weight. Specific objectives were to identify the benefits and limitations of the system from the perspective of patients, namely whether the system contributes to a sense of security, whether patients have educational benefits as a result of using the system, whether they feel more confident in managing diabetes care, what functions the system likes to use and which they have not used, and why. The parallel target was to monitor the patient's views on the operation and use of the system and to evaluate whether the Diani TS affects their health and quality of life. Furthermore, this study aims to determine how patients have used the system (frequency and duration of using particular sections of the Diani TS and access method).

Methods

Research Design

The study has been designed as a feasibility study focusing on the evaluation of the Diani TS based on a questionnaire survey of patients with type 1 diabetes mellitus and the use of the Diani TS, which also includes tracking patients' use of the system. The monitored parameters were HbA_{1c} and the body weight of the patient with diabetes. The study followed the principles of the randomized, crossover intervention study (real-world study) [23,24]. The study design was planned so that the observed parameters of diabetes self-management, involving the use of the Diani TS, are measured in the real conditions of the patient's daily life.

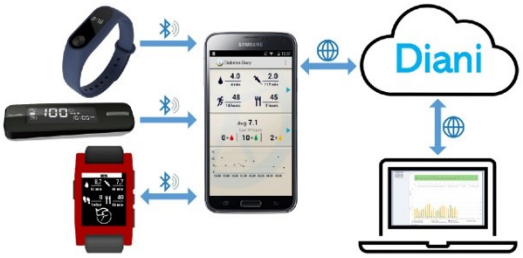
In a selected internal medicine clinic, which provides comprehensive diagnostic and therapeutic care to both outpatients and hospitalized patients with diabetes mellitus from

all over the Czech Republic, 10 patients were recruited and included in this study, with an emphasis on maintaining the highest representativeness.

Diani

The Diani TS configuration used in the study consisted of a web app (Diani), a mobile app called the Diabetesdagboka (DDB) diabetes diary (installed on the Samsung Galaxy J5 Android 8.1), a Fora Diamond MINI Bluetooth glucometer (FORA Care Suisse AG), and a Fitbit Flex smart bracelet (Fitbit Inc). A continuous blood glucose monitor (xDrip module, Nightscout) and a smartwatch (Pebble Classic), with the DDB app for the Pebble Smartwatch, were all connected to the system, allowing for an alternative way of entering information into the DDB app (Figure 1). The monitored data were downloaded from the device or automatically sent to a web application, where they were automatically sorted, aggregated, analyzed, and saved [21,25,26].

Figure 1. The Diani telemedicine system.



Study Outcomes

Primary Outcomes

HbA_{1c} values and patient body weight were determined at each of the 3 physician visits during the study (visits 1-3, as described below). The parameters were collected in a diabetological office, including taking a blood sample, which was evaluated by the internal hospital laboratory. The primary objective was to check whether there was a significant change in these values after the intervention. The secondary objective was to see if there was a change in these values at V3 (ie, at the end of the study).

Comparison With Prior Work

A growing number of studies discuss the influence of digital technologies on the compensation of diabetes mellitus disease [9,18-20,27]. Interventions are more often in the form of the use of mobile apps, web portals, email, SMS text messages, phone calls, and customized smart devices [6,9,27]. Interventions can include diabetes education, nutritional interventions, a physical activity plan, and blood pressure management [9,28,29]. Some technologies allow real-time data sharing, such as glucometers [29,30]. Feasibility studies include semistructured interviews or questionnaires focusing on the quality of life [9] and the usability and acceptability of the technical solution [6,9] in a standardized form [31] or created by the authors [6,27]. Technical equipment and consumables were provided to participants in some studies [29]. The study varies in scope in the number of patients (10 to 2378) and duration of 3 to 12 months [9]. A common problem is patient recruitment and a high patient dropout rate [9]. Telemedicine may be a useful supplement to usual clinical care to control HbA_{1c}, at least in the short term, but there was no evidence of a convincing effect on the quality of life [9]. Telemedicine interventions appeared to be most effective when they use a more interactive format [9].

Secondary Outcomes

To determine the characteristics of the group, patients completed the patient questionnaire at the initial visit (V1). To determine the possible impact of the Diani TS on diabetes self-management, selected questionnaire questions were submitted for completion at subsequent visits (V2 and V3). To study the impact of the Diani TS on the quality of life of patients, patients completed a standardized WHO questionnaire at each visit (V1, V2, and V3).

Another partial objective was to find the frequency of using particular Diani TS features and to register the time needed to enter and collect data. For this, a Matomo analytics application was used with a focus on tracking the patient's use of the Diani system at the time of the intervention. To evaluate the Diani TS and identify the strengths and weaknesses of the system, which is important for its further innovation, patients completed a product questionnaire (described in the *Key Instruments* section) during a postintervention visit.

Inclusion and Exclusion Criteria

The study included patients with type 1 diabetes mellitus, who were ≥18 years old, and who administered insulin subcutaneously by means of an insulin pen, using a personal glucometer, a smartwatch, and a smartphone. Exclusion criteria were pregnancy, insulin pump therapy, inability to use the Diani TS, and engagement with the study criteria.

During V1, eligibility and exclusion criteria were considered and assessed based on medical records, patient interviews, and laboratory tests.

Study Sample

The physician offered to participate in the study for all consecutive patients with type 1 diabetes treated with insulin for at least 1 year until the quota was reached.

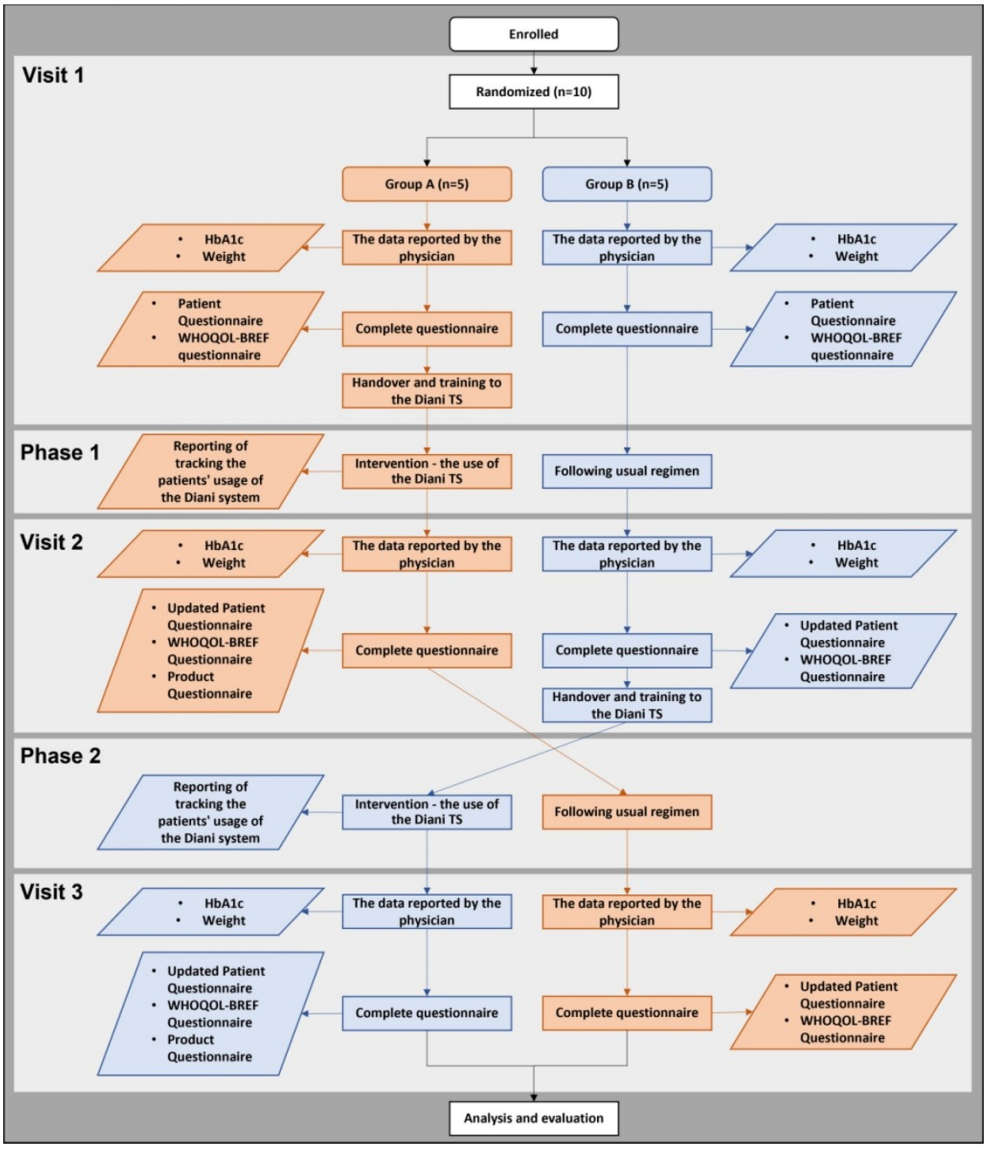
The study involved 10 patients (5 women and 5 men). The mean age of the participants was 47.7 (SD 19.3) years; the mean

duration of diabetes was 10.5 (SD 8.6) years; and the mean BMI was 26.9 (SD 3.6). The mean body weight of the patient at the time of study entry was 81.1 (SD 16.9) kg and the mean HbA_{1c} was 59.5 (SD 6.7) mmol/mol. The median number of days for which patients tested the system was 84.

Data Collection

Data for the Diani TS evaluation were obtained within the feasibility study, which had the characteristics of a randomized crossover intervention study. The total duration of the study was 24 weeks (Figure 2). The patients were randomly divided into 2 groups: group A and group B. Patients in group A used the system for the first 12 weeks; patients in group B followed their usual plan of care for diabetes. After 12 weeks, the patient's activity changed, the patients in group A followed their usual plan of diabetes care, and the patients in group B used the Diani TS for self-management of diabetes again for 12 weeks.

Figure 2. Study scheme (group A: orange; group B: blue). HbA_{1c}: glycated hemoglobin; TS: telemedicine system; WHOQOL-BREF: World Health Organization Quality of Life – BREF.



The study included 3 visits to the doctor: the initial visit (V1), then a follow-up visit (V2) after 12 weeks of study, and the third visit (V3) after 24 weeks of study.

Enrollment Visit (V1)

During V1, the physician evaluated the inclusion and exclusion criteria. The physician asked the patient if they were willing to participate in the project and asked them to sign an informed consent. The patients enrolled in the study received a set of questionnaires (the patient questionnaire, the World Health Organization Quality of Life – BREF [WHOQOL-BREF] questionnaire), which they completed during V1. If the patient was assigned to group A, a Diani TS monitoring kit was given and they were trained in the use of the system. The patients in group A were supposed to use the Diani TS between V1 and V2, optimally for 12 weeks. The data reported by the physician were obtained from medical records and recorded in the Diani web app. The data included HbA_{1c} and the patient's body weight.

Follow-up Visits (V2 and V3)

V2 and V3 took place within the usual practice in the clinic at 3 and 6 months after V1. The period between weeks 1 and 12 was referred to as phase 1 and the period between weeks 13 and 24 was designated as phase 2. During V2 and V3, the patient completed an updated patient questionnaire (questions from the Demographic section were omitted) and the WHOQOL-BREF Questionnaire. At the end of the intervention, patients completed the product questionnaire (group A at V2 and group B at V3). At V2, patients in group B received the Diani TS monitoring kit and were trained in how to use the system. Patients in group B used the Diani TS between V2 and V3 (weeks 12-24); patients in group A followed their usual plan of diabetes care during this time, as before the Diani TS intervention (without further intervention). The data reported by the physician were obtained from medical records and recorded in the Diani web application. The data collected were HbA_{1c} and the patient's body weight.

Key Instruments

The Patient Questionnaire

The patient questionnaire was developed by the research team involved in this particular study to obtain data describing important areas related to insulin therapy and diabetes in general. It focuses on the details of the patients and their technical skills in using conventional computing and smartphones in order to assess their ability to use the Diani TS. The questionnaire consists of 43 questions classified into the following categories: demographic data; self-management of diabetes and health, including patient's eating habits of the patient; physical activity; questions that determine the level of use of computer technology and smartphones.

The WHOQOL-BREF Questionnaire

The WHOQOL-BREF Questionnaire is a standardized questionnaire by the WHO. The questionnaire focuses on determining the quality of life of the patient. It is capable of detecting the current deterioration of health and capturing differences in the living conditions of people with long-term illness or disability [32,33]. The questionnaire consists of 26 questions. Twenty-four questions represent four areas, which are as follows: (1) physical health, (2) psychological area, (3) social area, and (4) environment. Two questions are evaluated separately; they deal with the evaluation of quality of life and overall health. Items are evaluated on a 5-point Likert scale.

The Product Questionnaire

The product questionnaire is a questionnaire created by this study's research team and focuses on the evaluation of the Diani TS by an intervention group. It is based on standard product evaluation research [34-37] and is adapted for study purposes. Due to the simplicity of the questions, the questionnaire was not validated. The questionnaire contains 18 questions that assess patients' experience with the use of the Diani TS, of which 5 questions were open for verbal evaluation of the system, describing both positive and negative characteristics of the system and possible suggestions for improvement.

Tracking the Usage of the Diani TS by the Patient

To track the patients' usage of the Diani TS, the open-source analytic framework for web analytics, Matomo, was used. This software monitors the digital visits of patients to the Diani TS and shows reports for further analysis. The objective was to identify how often individual users log into the system, how long they stay there, what sections of the system they use or what activities they perform (value registration, data viewing, etc), and in what way (access to individual features).

Study Interventions

The intervention consisted of using the Diani TS by patients to self-manage diabetes for a predetermined period of time. Patients had access to the Diani web app, the DDB mobile diabetes diary app, the Fitbit smart bracelet, the Pebble smartwatch with the DDB Companion for the Pebble smartwatch app, and the Diamond Mini glucometer.

Statistical Analysis Plan

The primary objective was to identify a potential change in HbA_{1c} and the patient's body weight after the intervention and at the end of the study (V3), at the selected significance level of .05. Another objective was, at the same level of significance, to identify a potential change in the patient's quality of life after the intervention. For this purpose, a regression analysis, the linear mixed effects (LME) method, and nonparametric tests (Wilcoxon and Friedman tests) were performed.

The secondary objective was to determine how frequently the patients used the Diani TS features and when they used them. As with the analysis of the characteristics of the group, the basic descriptive statistical analysis of the primary data (mean, SD, median, upper and lower quartiles, and minimum and maximum rates) was used here as well.

For nonstandardized questions, a list of individual responses, their categorization, and coding into numerical values were performed. For the free text questions, a thematic evaluation of the answers was performed.

Ethics Approval

All procedures were performed according to the Ethics Committee for Multicenter Clinical Trials of Motol University

Hospital and the 2nd Faculty of Medicine, Charles University in Prague, Czech Republic (approval date: November 4, 2016). All participants signed an informed consent form.

Results

Diabetes Self-management and Health

All patients agreed that they had been instructed on lifestyle changes and diabetes care during their treatment. Seven (70%) patients checked their blood glucose values at least 3 times a day before entering the study, and 10 (100%) patients checked their blood glucose at least 3 times a day after the intervention. Of these, 6 (60%) participants tested their blood glucose at least 4 times a day, which was 20% more than at the beginning of the study (Table 1). Using the LME method, it was found that during the Diani system use period, patients measured their blood glucose on average 1.8 times more often (P=.06).

When asked during V1, 4 (40%) patients said that they suffered from depression. This number of cases may seem high, the likely reason being that the term depression was not specified or defined in the questionnaire and patients could thus explain it in different forms. Three (30%) respondents did not feel like managing their lives due to type 1 diabetes mellitus. Seven (70%) patients said that the behavior change plan would help them better compensate for type 1 diabetes mellitus; 6 (60%) patients would like more information in the field of nutritional therapy and information about type 1 diabetes mellitus disease.

Seven (70%) patients reported that they could reduce the risk of health complications resulting from diabetes mellitus. Seven out of 10 participants stated that they had a diet plan, but only 2 participants always followed it and 4 occasionally, while the others only rarely or never. Nine (90%) patients stated that they had bigger problems counting carbohydrates and 4 (40%) of them did not manage this activity at all. At the same time, 6 (60%) patients reported eating the recommended portion sizes of food almost always. Half of the participants felt that it was difficult for them to manage their illness and all of them stated that they were motivated to work on their treatment.

Table 1. Comparison of outcomes before and after the intervention (N=10).

Intervention	Before	After
Diabetes self-management		
Blood glucose measurement frequency, n		
1× per day	2	0
2× per day	1	0
3× per day	3	4
4× per day	3	5
>4× per day	1	1
Targeted physical activity		
Type of physical activity,[a] n		
Cycling	5	4
Walking	9	8
Physical work (in the garden)	7	3
Housework	1	0
Running	2	1
Exercise (gym)	2	2
Dance	1	1
Length of physical activity, n		
I do not perform physical activity	1	0
1-29 min	0	0
30-59 min	5	6
60-119 min	1	2
≥120 min	3	2

[a]Multiple answers could be chosen for the question.

Physical Activity

At V1, 9 (90%) patients reported targeted, planned, and structured physical activity at least once a week, of which 6 (60%) reported, more than twice a week, mostly walking, gardening, or cycling. This activity usually lasted 30-60 minutes. After the intervention, the type of activities decreased (Table 1), but the duration of the activity increased slightly, and the

frequency remained the same. Three out of 10 participants felt their physical condition was deteriorating; after the intervention, 4 out of 10 patients had the same feeling.

Technical Experience

Nine (90%) of the patients had no experience with using any mobile diabetes diary application prior to participating in this particular study. One patient stated that he had experience with the DDB mobile app. None of the study participants had participated in any study that dealt with diabetes treatment assistance before entering our study.

The WHOQOL-BREF Questionnaire

The return rate of the questionnaires was 80%. For the first separate question on the quality-of-life assessment, 60% (n=6) of the participants rated their quality of life as good or very good at V1. At V2 and V3, 78% (n=7) and 89% (n=8) of the participants chose these answers, respectively. The second separate question focused on the evaluation of satisfaction with the participants' health. At V1, 30% (n=3) of the patients expressed satisfaction with their health; 44% (n=4) and 50% (n=5) of the participants were satisfied with their health at V2 and V3, respectively.

The Friedman test did not show significant differences in quality of life within the group between individual study phases. The Wilcoxon test did not show a change regarding the intervention or nonintervention groups.

The System Evaluation Questionnaire

As part of the system evaluation, all users marked the use of the system as socially discreet. Its use (data entry, daily use, and charging) was rated by 90% (n=9) of the patients as rather easy or easy. Similarly, 90% (n=9) of users reported spending more time thinking about diabetes mellitus as a result of using the system and managing to dose insulin better. For example, based on links to educational resources from the DDB app, there was new information for one of the patients that their insulin bolus could be adjusted by more than 2 units. Seven (70%) users feel safer as a result of using the system. In terms of time, 70% (n=7) of the patients evaluated working with the system to be rather undemanding or not at all demanding.

Patient-Reported Positive Aspects of the System

In open questions, users positively evaluated the graphical visualization of measured parameters (clarity of monitoring results and digital form), automatic transmission of measured data from the glucometer, and compatibility and interconnection of individual devices when entering data. One of the system benefits was also reported to be the simplicity of entering data into the mobile app and the generally simple operation of the system. The possibility of connecting a continuous blood glucose monitor and the smart bracelet, digitizing data, and a possible view from several types of devices (interconnection of the system with the internet) was appreciated. The chronological presentation of the key indicators was also positively assessed. These indicators enable the evaluation, comparison, and search for connections between carbohydrate intake, physical activity, and the size of the insulin dose. Patients acknowledged the opportunity to print the monitored values with the selected data filter and decide the amount of data, for easier perception of the information. In the Diani TS evaluation, users emphasized the power of the system in providing feedback to the user, which makes it easier for them to understand the measured values and information in context and as a result of their behavior, to improve diabetes management in the future.

Patient-Reported Negative Aspects of the System

The provided smartwatches were reported to be difficult to control (small and rigid buttons) and negatively evaluated. Users also requested the display of key values in a single graph and the depiction of trends in the development of the measured values (curve fitting). Furthermore, the need to link the Diani TS with Kalorické Tabulky (a Czech food composition database mobile app) was requested, and a requirement to automatically add up the registered values of the received carbohydrate intake over a predefined period was mentioned. Users also described the acquisition and registration of data as time-consuming. Another issue was the overuse of devices (both a smartwatch and a smart bracelet placed on the wrist). During the study, patients reported communication issues with the server. This outage was also described as unsatisfactory. This was mainly due to a poor internet connection on the users' mobile phone, Bluetooth being turned off in the device, or improperly timed technical maintenance of the server. However, these technical issues were eliminated during the study. During these episodes, all data were stored in the user's mobile phone and were uploaded to the Diani server after the connection was re-established, which occurred within 5-15 minutes.

Patients' Suggestions for Improving Diani

Suggestions for improving the system included the possibility of adjusting the limit values of the monitored blood sugar level. The need for retrospective control of data transfer (in the form of notification) and access to the application for devices operating on the iOS operating system were also wanted features. Additionally, the need to improve the smartwatch so that it is more user-friendly was also stated. Furthermore, a proposal to reduce a large number of items was mentioned in the web version of the application and to emphasize the monitoring of exceeding carbohydrate intakes was mentioned.

Five (50%) users expressed their readiness to pay for the use of the system; 3 (30%) users are not willing to pay for the system; and 2 (20%) are unable to decide. One (10%) user would be willing to spend 5%-10% of their monthly income on the system; 40% (n=4) users would be willing to spend between 1% and 5% of their monthly income; and 20% (n=2) user would be willing to spend less than 1% of their monthly income (n=2, 20% of the participants reached the average net wage in the Czech Republic [the median net wage for 2017 in the Czech Republic was CZK 25,021; US $1070]; the others had a lower wage or did not answer the question).

HbA_{1c} Level and Body Weight Changes

At V1, the mean HbA_{1c} level was 59.5 (SD 6.7) mmol/mol; after the intervention, the mean HbA_{1c} decreased by −4.35 mmol/mol (P=.01) (LME analysis). The effect comparing monitoring at V2 with V1 was −6.54 mmol/mol (P=.04); the effect comparing the use of the Diani TS at V3 with V1 was

−2.16 mmol/mol (*P*=.45). The mean HbA_{1c} at V2 was 60 (SD 9.8) mmol/mol and at V3 was 61.8 (SD 6.1) mmol/mol in participants who participated in the intervention in phase 1.

The average body weight of participants was 81.4 (SD 16.4) kg at V1, 81.1 (SD 16.9) kg after intervention, and 81.5 (SD 16.9) kg at V3. Statistical analysis did not show a significant difference (*P*>.05) in patients' body weight between the intervention or control groups; there was even no effect within one group during the study.

Patient Usage of the Diani System

For the duration of the study, the patients spent 41.6 (SD 31.7) hours on average using the DDB app, with a daily average use of 29.7 (SD 22.7) minutes. Of the total time, the daily average of 11.6 (SD 18.6, 67%) minutes was spent on manual physical activity registration, 3.5 (SD 4.6, 17%) minutes on the registered blood glucose level, 2.1 (SD 2.9, 9%) minutes on carbohydrate registration and 1.4 (SD 1.2, 7%) minutes on insulin dose registration. The remaining time includes inactive use of the application—viewing records, launching the application on the smartphone, and communicating with the server. On average, patients visited the DDB application 4.5 (SD 2.3) times a day and performed 31.3 (SD 23.9) activities per day; these activities include: registering items, viewing records, and editing data in the application. The average number of activities per visit was 7.1 (SD 2.9), and 29.4% (SD 13.3%) of the visits left the application immediately after viewing an item. The length of 1 visit lasted 14.2 (SD 11.9) minutes on average. As for the length of app use, the average time of the visit decreased during the intervention. Two users had a minimum number of entries in the DDB and were excluded from the objective evaluation of the system due to misrepresentation of results. A comparison of the average values of the daily number of visits and activities performed per day showed that one-third of patients used the system very actively and, conversely, 20% (n=2) of users used the system below average. Seven (70%) patients with a higher degree of involvement with the Diani TS actively used the system even a year after the study ended.

Discussion

Overview

This study was the first clinical trial to evaluate the Diani TS for users with type 1 diabetes mellitus. On the basis of the data obtained, recommendations were subsequently derived, and suggestions for further innovation of the Diani TS were determined.

Principal Results

The most significant result of the evaluation was the decrease in HbA_{1c} level associated with participating in the study and the increase in the frequency of blood glucose measurements during self-management control after using the Diani TS. This increase was observed in 50% of the participants and is interpreted as a positive effect of the system. The reason can be that the system allows the patient both to observe the data more and to display it in the context of activities and might motivate patients to improve the measured data.

Data from the patient questionnaire showed that determining the correct content of carbohydrates in the diet is a major challenge. Most (90%) of the respondents admitted that they had this problem; nevertheless, 60% of patients also stated that they consumed the recommended amount of carbohydrates in their diet. The focus on diet should be approached more actively. In the future, it would be interesting to focus on this topic and think about how to motivate patients to learn from the data they enter into the system and how to educate them to use the data and explain the importance of a well-balanced diet plan to compensate for the challenges of diabetes mellitus. This problem was the reason for the integration of the food composition mobile app Kalorické Tabulky [38] directly into the Diani TS.

Regarding the quality-of-life assessment (WHOQOL-BREF questionnaire), the trend curve indicated an increase in the perception of one's quality of life and health. Unfortunately, due to the low return rate of the questionnaires (80%) at the end of the first and second phases of the study, the results cannot be considered entirely reliable.

In general, the Diani TS was positively evaluated, in terms of graphics, functionality, and practical use. The system was perceived as user-friendly, well organized, and motivating by most of the participants. The participants appreciated the feedback provided by the Diani TS, especially concerning the complexity and orderliness of the monitored data submitted in real time. Based on comprehensive information, patients reported that they were able to perceive and understand the relationship between particular monitored values (physical activity, carbohydrate intake, and insulin bolus size), which allowed them to better estimate insulin dose. The system enabled patients to deepen their knowledge in their current understanding of blood glucose variations, in general. As a result of the use of the Diani TS, the patients stated that they felt safer and that it was easier for them to leave their comfort zone, for example, when traveling and sleeping outside their place of residence. Eliminating stressful situations like these can have a positive effect on the patient's quality of life.

The accessories of the system, namely the smartwatch, the use of which did not bring patients a large benefit compared to the efforts made to become familiar with them, were negatively evaluated. Proposals for additional innovations to the system were identified on the basis of subjective evaluation.

Based on the system logs, the operation of the system was not very time-consuming for patients. They did not spend more than 18.6 (SD 6.8) minutes a day registering the data, which was why the Diani TS was perceived as easy to use and the patients evaluated its use as discreet and not interfering with daily activities.

Limitations

During the study, there were some technical issues regarding the transfer of information from the glucometer to the Diani server. These issues were resolved during the first phase of the study. In case the problems were caused by users' lack of knowledge of the system, assistance for solving respective problems was provided by means of a telephone conversation or an electronic conversation. More detailed instructions on

using the system or video instructions may be appropriate in the future.

Difficulties in recruiting participants have been described in previous studies [39], and measures were therefore taken to reduce problems with recruiting participants for the study by minimizing inclusion criteria. Patients were strongly motivated to participate and remain in the study so that they could receive free glucose strips for glucometers and lancets; there was also the possibility of keeping the test set (glucometer, mobile phone, and smart bracelet) after the end of the study. Another important factor was the availability of new technologies and information in the field of diabetology. Still, there appeared difficulties in recruiting patients for the study, as only 10 of the 30 planned patients were recruited.

Comparison With Prior Work

Significant effects on the reduction of HbA_{1c} were confirmed among patients who used the Diani TS. The system also helped strengthen the patient's position in terms of a positive effect on compensating for type 1 diabetes mellitus. Patients expressed a generally positive perception of the system.

Similar studies have been conducted, but they differ in their study design, patient variability, and technologies used. These studies have similar results in terms of a positive effect on HbA_{1c} [6,9,40,41] and an unproven effect on the quality of life [9]; however, the results cannot be compared closely due to the diversity in data collection and evaluated information.

Conclusions

The feasibility study was a valuable first step in the evaluation of the Diani TS. It helped identify both the benefits and limitations of the system from the users' perspective, recorded their views on the operation and use of the system, and assessed whether the Diani TS had an impact on their health and quality of life. Based on the information obtained, new needs and demands of patients for the TS were identified, from which recommendations were derived, and suggestions for further innovation of the Diani system were determined. At the same time, the study was helpful as a real test of the system features. In the future, the methodological findings of the study will be used in the evaluation of the Diani TS extended with other components and functions. The study confirmed both that the Diani TS can be beneficial for patients with type 1 diabetes mellitus in managing their disease and that its use can (at least in the short term) increase interest and motivation to follow medical recommendations. The effectiveness of the TS for managing diabetes is limited by its acceptance of patients. We need more information about what motivates the long-term use of the system by patients with diabetes as well as the degree of influence imposed by personality.

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Conflicts of Interest

None declared.

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Abbreviations

DDB: Diabetesdagboka
HbA_{1c}: glycated hemoglobin
LME: linear mixed effects
TS: telemedicine system
WHO: World Health Organization
WHOQOL-BREF: World Health Organization Quality of Life – BREF

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Dlouhodobé využití telemonitorovacího systému Diani v léčbě diabetes mellitus 1. typu

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Mobilní a nositelná elektronika nabízí pacientům s diabetes mellitus nové možnosti sběru dat a jejich efektivnější analýzu. Aplikace pro chytré telefony Diabetesdagboka a webový portál Diani umožňují shromažďování a analýzu hodnot glykemie, dávek sacharidů a inzulinu a míry pohybové aktivity. Hodnoty jsou dostupné v příslušném mobilním telefonu, ale jsou též automatizovaně přenášeny do internetového portálu, kde mohou být doplněny o záznam z elektronického krokoměru a kontinuálního monitoru glykemie. Lze je též zobrazit v různých typech grafických výstupů a jsou dostupné nejenom pacientovi, ale i jeho lékaři. Kazuistika pacienta, který systém téměř 2 roky využíval, prokazuje významné zlepšení metabolické kompenzace (pokles průměrné hodnoty HbA1c o 18,6 mmol/mol v porovnání s předchozím obdobím).

Klíčová slova: diabetes mellitus, diabetický deník, HbA_{1c}, hypoglykemie, mobilní aplikace, telemedicína, telemonitoring, webové aplikace, webový portál.

Long term use of the telemonitoring system Diani in the therapy of a patient with type 1 diabetes

Mobile and wearable technologies offer patients with diabetes mellitus new possibilities for data collection and their more effective analysis. The Diabesdagboga smartphone application and the Diani web portal enable to collect and analyze glycaemia values, carbohydrates intake, insulin doses and the level of physical activity. The data are not only accessible in the corresponding smartphone but also automatically transferred to an Internet portal, where they may be completed by the records from an electronic pedometer and continuous glucose monitor. All these data may then be displayed in various types of graphical outputs and are available to both the patient and the physician. The case report of a patient who has used the system for almost two years shows a significant improvement in metabolic compensation (a decrease in the mean HbA1c value by 18.6 mmol/mol as compared with the previous period).

Key words: diabetes diary, diabetes mellitus, HbA1c, hypoglycaemia, mobile application, telemedicine, telemonitoring, web application, web portal.

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Úvod

Mobilní a desktopové aplikace pomáhající pacientům s různými onemocněními jsou dnes běžnou nabídkou různých výrobců (1–3). U pacientů s diabetes mellitus umožňují sběr dat týkajících se především hodnot glykemie, obsahů sacharidů v jídlech, dávek inzulinu či fyzické zátěže a jejich případnou částečnou analýzu. Mohou též upomínat na nutnost měření glykemie nebo pravidelnou fyzickou aktivitu (4, 5).

Českým, a navíc originálním, příspěvkem do této oblasti je internetový systém Diani. Jde o webový portál umožňující připojení celé řady elektronických přístrojů (chytré telefony a jejich aplikace, elektronické krokoměry, kontinuální monitory glykemie, měřiče krevního tlaku apod.) a automatizované stahování jimi měřených a ukládaných dat (6–9).

Na Obr. 1 jsou schematicky zobrazena zařízení, která je možno k systému připojit. Na webový portál může pacient vstupovat skrze soukromý zabezpečený účet. Jeho data jsou zde zobrazena ve formě grafů a tabulek. Případně je možné údaje stáhnout v řadě jiných formátů pro další elektronické zpracování. Se svolením pacienta může mít k jeho datům přístup i ošetřující lékař prostřednictvím svého vlastního účtu.

Data na internetovém serveru lze zobrazit v několika formách. Jednou z nich je schematický časový graf (Obr. 2), ve kterém lze názorněji vidět jednotlivé hodnoty a udělat si tak lepší představu o jejich možných vzájemných souvislostech. Pro přehledný výčet konkrétních hodnot slouží tabulka (Obr. 3). V neposlední řadě má pacient možnost zobrazit si několikadenní glykemický profil nebo si vytisknout naměřené hodnoty v libovolném časovém intervalu jako PDF report pro lékaře.

Nedílnou součástí systému (Obr. 4) je mobilní aplikace diabetického deníku Diabetesdagboka (dále Dagboka), kterou má pacient nainstalovanou ve svém chytrém telefonu. Do této aplikace, která byla původně vytvořena v Norském centru pro e-health výzkum a na jejímž vývoji se rovněž podílíme, pacient vkládá data o změřené glykemii, dávce inzulinu, množství sacharidů v jídle, případně poznámky o své aktuální činnosti (fyzická aktivita apod.) (10). Hodnoty glykemie jsou do aplikace přenášeny automaticky v případě, že pacient vlastní glukometr komunikující s aplikací přes Bluetooth rozhraní.

Data z deníku jsou automatizovaně přes internet přenášena do webového portálu Diani. Pacient má možnost data prohlížet i ve svém telefonu prostřednictvím mobilní aplikace Dagboka.

Ke vkládání dat o množství sacharidů a dávce inzulinu do aplikace Dagboka lze také použít chytré hodinky Pebble, které tuto činnost usnadňují a umožňují zadávat veškeré registrace jednoduchým stisknutím pouze několika tlačítek. Záznamy automaticky přenášejí do aplikace.

Pacienti, kteří celý systém v ověřovacím režimu využívají, jsou vybaveni i elektronickým krokoměrem Fitbit, naměřené hodnoty jsou též automaticky přenášeny do webového portálu Diani. Do něj lze také importovat data z kontinuálního monitoru glykemie stažená v surovém formátu z daného zařízení (Dexcom, Medtronic), případně je lze přenášet automaticky a v reálném čase s využitím modulu xDrip (Nightscout) (9).

Kazuistika

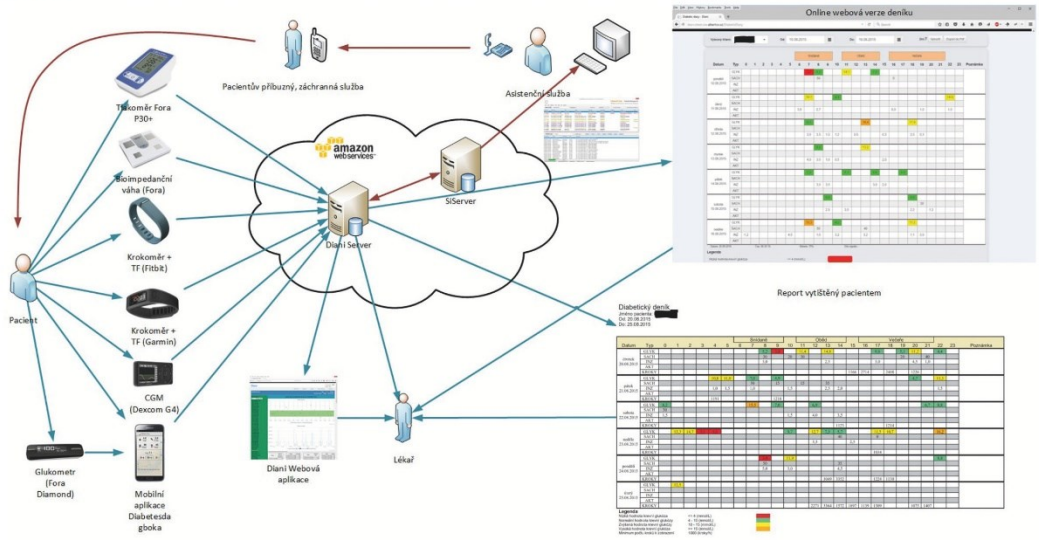
Jako příklad přínosu systému pro léčbu diabetu jsme zvolili pacienta, který jej v testovacím režimu používal nejdéle.

25letý pacient, muž, narozený v roce 1990 s diabetes mellitus 1. typu od roku 1992, léčený pomocí inzulinové pumpy od roku 2002 (Inzulin

Tab. 1. *Vstupní hodnoty základních parametrů*

	Srpen roku 2013
Výška	175 cm
Váha	71 kg
HbA_{1c}	80 mmol/mol
Cholesterol celkový	4,1 mmol/l
HDL-cholesterol	1,2 mmol/l
LDL-cholesterol	2,7 mmol/l
Triacylglyceroly	1,5 mmol/l

Obr. 1. *Schéma zapojení jednotlivých prvků Diani a ukázka tabulkových výstupů*



Novorapid, bazální dávka 23,3 j/den, bolusy 6-5-5 j), bez prokázaných komplikací diabetu a bez dalších onemocnění (Tab. 1). Pacient byl od roku 2013 sledován v Diabetologickém centru Ostrava, kde byl standardním způsobem edukován. Jeho přístup k léčbě byl hodnocen jako non-complientní. Pacient byl v rámci sledování na dobu 22 měsíců vybaven aplikací Dagboka pro chytré telefony, Pebble chytrými hodinkami, glukometrem FORA Diamond Mini a krokoměrem Fitbit Flex, v rámci předání byl edukován o jejich používání.

Aplikace Dagboka umožňuje pacientovi vedení a analyzování záznamů o změřených glykemiích, o množství sacharidů v požívaných jídlech, aplikovaných dávkách inzulinu a údajů o pohybové aktivitě. Pacient používá glukometr FORA Diamond Mini, který zajišťuje automatický přenos glykemií do aplikace bez nutnosti jejich manuální registrace. K zadávání dat pacient většinou používal chytré hodinky Pebble.

Data byla v reálném čase přenášena do webového portálu Diani, kde byla zpracována a zobrazována současně s automaticky přenesenými hodnotami nachozených kroků zaznamenaných krokoměrem Fitbit, pokud ho pacient používal (příklad různých typů záznamů na Obr. 2 a 3).

Pacient měl přístup na webový portál Diani přes svůj osobní účet. Mohl tak procházet veškeré své záznamy, případně je i vytisknout a předložit svému lékaři. Přístup k účtu byl po dohodě s pacientem umožněn i ošetřujícímu lékaři.

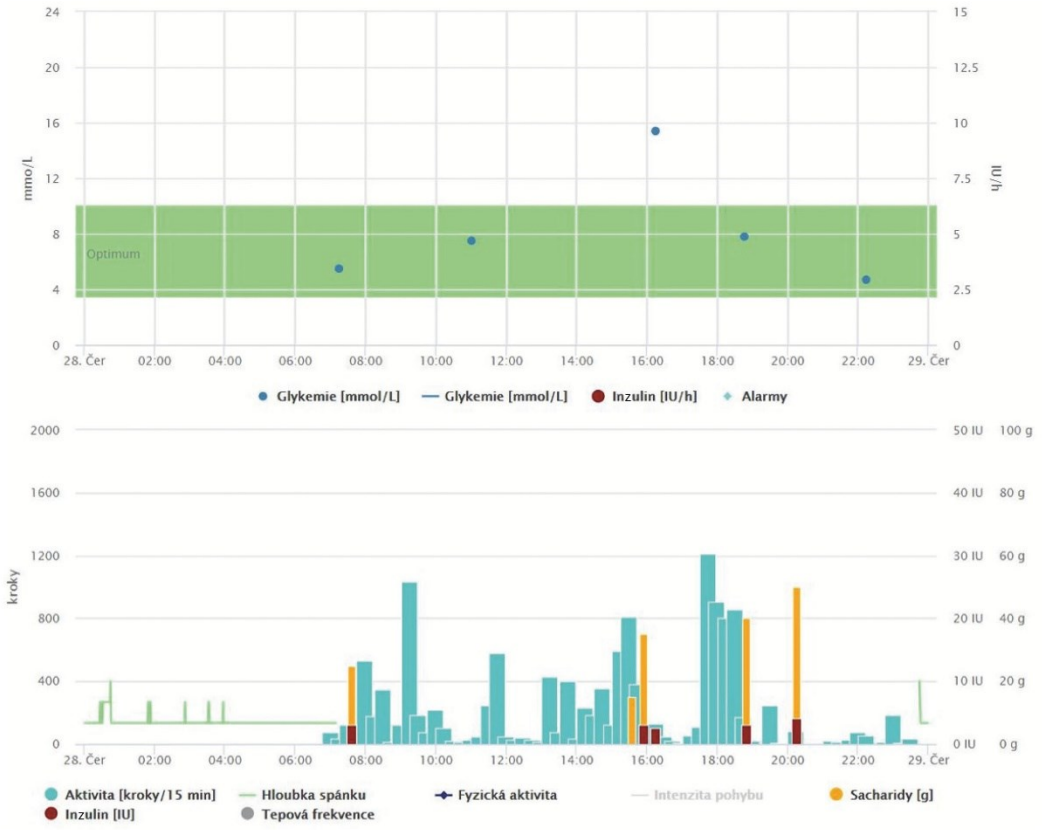
Výsledky

Hodnotili jsme výsledky HbA_{1c}, počet měření glukometrem, počet glukometrem ověřených hypoglykemií a průměrné hodnoty naměřených glykemií. Při somatickém vyšetření byl konstatován fyziologický nález, v laboratorním nálezu HbA_{1c} 80 mmol/mol, hodnoty dalších základních biochemických parametrů v mezích normy. Statistické výpočty byly provedeny s použitím Pearsonova korelačního koeficientu a testu hypotézy o nezávislosti (založeném na t-rozdělení).

HbA_{1c}

Je základním parametrem vypovídajícím o metabolické kompenzaci diabetu a s ní souvisejícím rizikem rozvoje specifických komplikací diabetu. Průměrná hodnota HbA_{1c} v období 7 měsíců (3 naměřené hodnoty) před zahájením používání telemonitorovacího systému byla 80,7 ± 2,49 mmol/mol. Průměrná hodnota v období, kdy pacient přístroje používal, byla 65,7 ± 7,36 mmol/mol, došlo tedy k jejímu výraznému snížení. Nejnižší hodnota

Obr. 2. *Uspořádání naměřených a zadaných hodnot v čase. V horní polovině obrázku hodnoty glykemií a k nim časově odpovídající hodnoty množství sacharidů v jídle, počtu ušlých kroků za hodinu a dávek inzulinu*



HbA_{1c} z období jednoho roku před zahájením měření byla 78 mmol/mol, nejnižší hodnota během používání zařízení byla 56 mmol/mol. Hodnoty jednotlivých měření HbA_{1c} jsou uspořádány v Tab. 2.

Hypoglykemie

Pacient systematicky nezaznamenával hypoglykemie ani v období před používáním systému, ani v době, kdy ho měl k dispozici. Navíc krátce před zahájením studie vyměnil glukometr, přesná data o měřeních tedy z tohoto období nemáme k dispozici. Subjektivně hodnotí frekvenci hypoglykemií v obou obdobích jako stejnou. Těžkou hypoglykemii v posledních 5 letech neměl, hypoglykemie poznává velmi dobře, na Goldově škále označuje číslo 1, tedy bezproblémové rozpoznávání hypoglykemií (11).

Frekvenci hypoglykemií jsme se nepřímo (pacient neměří hodnoty koncentrace glukózy v krvi při všech hypoglykemiích) pokusili ukázat analýzou dat získaných z měření glukometrem v průběhu používání systému Diani. Frekvence těchto dokumentovaných hypoglykemií (Tab. 2) se v jednotlivých obdobích pohybovala mezi 0–3,4/týden. Statistická analýza prokázala negativní korelaci mezi hodnotami HbA_{1c} a průměrným počtem hypoglykemií za týden (korelace -0,8053, p-hodnota = 0,0088).

Průměrné hodnoty glykemií

Průměrné hodnoty naměřených glykemií v období, kdy pacient používal systém Diani, jsou uvedeny v Tab. 2. Statistické testování ukázalo, že výsledky průměrných hodnot glykemií statisticky signifikantně pozitivně korelují s hodnotami HbA_{1c} (korelace 0,7053, významná, p-hodnota = 0,0338).

Frekvence měření glykemií

Frekvence měření glykemií je důležitým parametrem ovlivňujícím výslednou metabolickou kompenzaci (12). Průměrný počet měření na den v jednotlivých obdobích mezi lékařskými kontrolami v průběhu používání systému je uveden v Tab. 2.

Hodnocení systému pacientem

Za nejdůležitější přínos systému pacient považuje možnost přehlednějšího uspořádání a detailnějšího rozboru naměřených dat. V průběhu jeho používání výrazně stoupla frekvence měření glykemií, dle pacienta díky tomu, „že měření mělo větší smysl".

Pacient hodnotí systém celkově vysoce pozitivně, nároky spojené se zaškolením ani s jeho používáním nepovažuje za náročné ani z mentálního ani z časového hlediska. V průběhu užívání systému došlo něko-

Tab. 2. *Hodnoty HbA_{1c}, průměrné glykemie a počet měření/den v průběhu používání telemonitorovacího systému DIANI*

Datum (měsíc/rok)	7/2014	10/2014	1/2015	3/2015	5/2015	9/2015	2/2016	4/2016	5/2016
HbA_{1c} (mmol/mol)	78	62	75	69	71	61	61	58	56
Průměrný počet hypoglykemií/týden* ± SD**	0,3 ± 0,4	0,5 ± 0,7	0	0,5 ± 0,5	0,3 ± 0,4	1,8 ± 1,8	3,3 ± 1,7	1,9 ± 1,4	3,4 ± 1,8
Průměrná hodnota glykemie ± SD (mmol/l)***	11,3 ± 4,9	10,1 ± 4,6	9,4 ± 4,7	10,5 ± 4,8	11,9 ± 6,6	9,2 ± 4,5	9,7 ± 5,1	9,1 ± 4,6	9,1 ± 4,4
Počet měření glykemie na den****	2,0	1,1	0,4	1,6	2,5	3,2	4,2	3,4	2,6

**Hodnoceny jsou pouze hypoglykemie potvrzené měřením glukometrem*
***SD – směrodatná odchylka*
****Průměrná hodnota ze všech naměřených glykemií od začátku používání systému v obdobích mezi jednotlivými odběry HbA_{1c}*
***** Počet měření glykemií/den od začátku používání systému v obdobích mezi jednotlivými odběry HbA_{1c}*

Obr. 3. *Ukázka 3denního tabulkového výstupu z Diani znázorňující hodnoty glykemií (GLYK), množství sacharidů (SACH), dávky inzulinu (INZ) a počtu kroků za hodinu (KROKY), systém umožňuje i uložení poznámek k fyzické aktivitě (AKT). Barevně jsou znázorněny hodnoty v cílovém rozmezí (zeleně) a mimo něj (červeně a žlutě)*

									Snídaně				Oběd					Večeře								
Datum	Typ	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	Poznámka
čtvrtek 20.08.2015	GLYK									5,2	3,8		11,4		14,8				9,0		5,1	11,2		4,4		
	SACH									30		20	30								20		40			
	INZ									3,0					2,5				3,0			4,5	1,0			
	AKT																									
	KROKY																1166	2714		2488		1226				
pátek 21.08.2015	GLYK					10,8	11,0		7,0		4,9											4,7		11,3		
	SACH								30		15		15		35											
	INZ					1,0	1,5		1,0			1,5			2,5	2,0								1,5		
	AKT																									
	KROKY					1191					1218															
sobota 22.08.2015	GLYK	8,2							15,5		7,0			6,9									6,7	8,8		
	SACH	30																								
	INZ	1,5										1,5		4,0		3,5										
	AKT																									
	KROKY															1123				1214						

likrát k poruše spojení mezi mobilní aplikací a hodinkami Pebble, chyba se objevila i při upgradu mobilní aplikace. Potíže byly rychle řešeny on-line přístupem do systému. Pacient chce systém i nadále využívat.

Diskuze

Použití systému přineslo výrazné zlepšení hodnot HbA_{1c} (pokles průměrné hodnoty HbA_{1c} o 15 mmol/mol, rozdíl mezi nejvyšší hodnotou HbA_{1c} v období 7 měsíců před použitím systému a nejnižší hodnotou při jeho použití byl 28 mmol/mol), v průběhu používání systému hodnota HbA_{1c} nikdy nestoupla nad hodnotu vstupní. Za zlepšením vidíme ve shodě s pacientem možnost přesnějšího pohledu na hodnoty glykemie ve vztahu k dávkám inzulinu, množství sacharidů v jídle a fyzické námahy. Tomu odpovídá i to, že díky této možnosti pacient měřil glykemie v průběhu užívání systému tak, jak se s ním sžíval, s narůstající frekvencí a dle svého vyjádření podstatně častěji než v období před jeho použitím.

V průběhu sledování je patrný vzestup četnosti dokumentovaných hypoglykemií (analýza záznamů z glukometru), jejíž změny negativně korelovaly s poklesem hodnot HbA_{1c}. Z klinického hlediska se tato četnost pohybuje v širším rozpětí obvyklých hodnot, nicméně edukace o prevenci hypoglykemií je u tohoto pacienta jistě na místě.

Pacient sám hodnotí přínos systému pro léčbu svého onemocnění vysoce pozitivně, drobné technické potíže, které byly vždy vyřešeny on-line, ho nijak neobtěžovaly a chce v jeho užívání pokračovat.

Obr. 4. *Aplikace Dagboka na chytrém telefonu a schematické propojení přístrojů používaných pacienty s diabetem*

Závěr

V období používání tohoto telemonitorovacího systému přineslo výrazné zlepšení hodnot HbA_{1c}, analýza hodnot glykemií ukázala narůstající frekvenci hypoglykemií, které je nyní cílem edukace. Pacient užívání systému hodnotí vysoce pozitivně a chce v něm dále pokračovat.

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Original Paper

Customizing the Types of Technologies Used by Patients With Type 1 Diabetes Mellitus for Diabetes Treatment: Case Series on Patient Experience

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Abstract

Background: Despite the fact there are many wearable and mobile medical devices that enable patients to better self-manage their diabetes, not many patients are aware of all the options they have. In addition, there are those who are not fully satisfied with the devices they use, and those who often do not use them effectively.

Objective: The study aimed to propose possible changes to the combination of devices used by 6 specific patients for diabetes self-management. We assessed the suitability of selected technical devices for diabetes control.

Methods: Data of 6 patients (3 men and 3 women) with type 1 diabetes mellitus, who had been using the Diani telemedicine system for at least 3 months, were analyzed. The suitability of selected technical devices for diabetes control was ascertained using the data obtained via the Diani telemedicine system, as well as the patients' subjective feelings and statements, their everyday life habits, and self-management of diabetes. Informed consent was signed and obtained from each of the patients included.

Results: Each of the presented case studies describes how a given patient handled the system and its specific components based on his or her lifestyle, level of education, habits related to diabetes management, personality type, and other factors. At the conclusion of each case study, the best composition of devices for patients with similar personal descriptions was suggested.

Conclusions: We believe this study can provide relevant guidance on how to help particular patients choose the technology that is best suited for their needs, based on the specific patient information we are able to obtain from them. Furthermore, clinicians or educators should be aware of available technologies a given patient can choose from. In addition, there is a substantial need for proper patient education in order for them to effectively use devices for diabetes self-management.

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KEYWORDS

type 1 diabetes mellitus; technology; self-management; wearable electronic devices; education; telemedicine

Introduction

Background

Diabetes mellitus is a metabolic disease associated with the development of chronic complications. Slowing down or stopping the progression of these complications is associated with sufficient diabetes control, that is, maintaining blood glucose values within the recommended targets.

Despite the fact that various types of mobile and Web apps, wearable medical or fitness devices, and telemedicine solutions

are being developed to help achieve the goals of diabetes control [1-5], not many patients are aware of all the options they have or are not fully satisfied with the devices they use and, besides that, they often do not use them effectively [6-10].

This is because of the lack of (1) time clinicians can spend with patients during consultation and (2) the information about all the technological possibilities [11-13]. Therefore, patients are often provided with a device without an option to make a choice for themselves or detailed consultation about both its proper use and the option that would fit them the most.

However, it is very important to learn from how different types of patients use a given technology to understand what does truly help them in their self-management, what increases their adherence, what are their preferences, or otherwise, what are the drawbacks and limitations that keep them from using the technology itself. A deeper understanding of a patient's needs and abilities with respect to the self-management can help us to both tailor a given device for a particular group of patients and assemble the set and types of devices that comply with a patient's needs the most.

Objectives

This study aims to analyze the way of using different combinations of technologies for diabetes self-management in 6 specific patients with type 1 diabetes mellitus (T1DM) and, based on such an analysis, to propose possible changes in such combinations that would improve patients' overall satisfaction and adherence to its use.

Methods

Aim

The study aimed to analyze the suitability of selected technical devices for diabetes control based on data obtained via the Diani telemedicine system, patients' subjective feelings and statements, their everyday life habits, and self-management of diabetes.

Inclusion Criteria

The inclusion criteria were adults with T1DM for a duration of at least 1 year who had used the Diani telemedicine system for at least 3 months; completed a minimum of 2 consultations with the doctor and the technology educator, that is, before and 3 months after the system use; and shared information about their daily regimen, self-management, and experiences with diabetes-related technologies so far during the consultations.

Study Sample

The study included 6 patients (3 men and 3 women with average age of 43 [SD 23] years) with T1DM for a duration of at least 1 year, using specific combination of devices and having an experience with the Diani telemedicine system for 3 months (n=3), 6 months (n=1), or 4 years (n=2) in different times for the last 4 years. All the participants were of Czech nationality.

Collected Data

The data obtained from the Diani telemedicine system included blood glucose values transferred from a connected glucometer and a continuous glucose monitor (CGM), step counts collected via an activity tracker in 1-min intervals, and carbohydrate intake (in grams) and insulin injections manually registered in a connected mobile app.

Telemedicine System

The Diani telemedicine system is being developed under the university project of the First Faculty of Medicine (Charles University in Prague) and the Faculty of Biomedical Engineering (Czech Technical University in Prague). The system consists of wearable technologies, namely an activity tracker, a blood glucose meter, a diabetes diary mobile app, a smartwatch, and a Web app into which all the data from the wearables are synchronized automatically. The blood glucose meter transfers measured glucose values into the diary mobile app via Bluetooth. The data from the activity tracker are synchronized via smartphone as well. Using the smartwatch, the user can not only track his/her last data registrations about blood glucose, carbohydrate intake, insulin dose, and physical activity (PA) but can also use the watch to make these registrations, which are then transferred to the mobile app via Bluetooth [14]. Occasionally, some of the patients may wear the CGM that enables them to transfer data to the Diani Web app (see Multimedia Appendix 1) either automatically (using the xDrip device, The Nightscout Project) or manually (uploading the raw data file through the Diani Web app) [15-18].

Patient Instructions

Before using the system, each of the patients was properly instructed by a technology educator on how to operate each of the system components, and they were free to decide which data and how frequently they want to enter the data into the diary. The patients could choose not to use any of the devices if they felt uncomfortable using them.

Before starting to use the system and during the monitoring phase, the patients took part in interviews with a doctor and the technology educator about their daily regimen, technology capabilities, life preferences, and similar topics. The technology educator was also tracking patterns of handling the devices while educating the patients on how to use them. During the phase in which the patients were using the system in their daily life, the educator was also monitoring their behavior of entering and collecting the data via the Diani Web app. These types of interventions represented the most important approaches to get relevant feedback about the usability of the system.

The study involving human participants was conducted in accordance with the Helsinki Declaration and has been approved by the ethics committee of the Motol University Hospital in Prague. Informed consent was signed and obtained from each of the patients included.

Outcomes

The outcomes included glycated hemoglobin (HbA_{1c}) obtained from the patient's records of his/her caregiver, the average number of data registrations, and the frequency of hypoglycemia.

Results

Data Analysis

A total of 6 patients who met the criteria for the intervention were analyzed, based upon the collected data and individual face-to-face consultation.

General description of each patient can be seen in Table 1. The results from data evaluation are shown in Tables 2 and 3.

Case Series

Each of the following 6 case series describes how a given patient was handling the system and its particular components based on his/her lifestyle, level of education, manners in diabetes management, personality type, and other factors. At the end of each case study, we then propose the best composition of devices for patients with similar personal needs.

Case Study 1

Patient Information

A 45-year-old woman was diagnosed with T1DM in 2013, and since then, she has been on multiple daily injection (MDI) insulin therapy. Besides her diabetes, she is not suffering from any other diseases or diabetes complications.

Daily Regimen and Self-Management

This patient performs PA such as cycling, workouts in a gym, and others for 2 to 4 hours daily. Being a teacher with a stable daily schedule, she can include regular PA into her daily activities.

To keep her blood glucose within the target range and maintain a slim figure, she maintains a lower carbohydrate diet (approximately 100 g/day) and healthy food intake, besides the PA performance. She is able to maintain her blood glucose mostly within the target range, with a very rare occurrence of clinically important hypoglycemia [19] (see Table 3). The only problem she has is that of higher blood glucose levels at night probably caused by the later effect of fatty cheese and nuts she is used to eating later in the evening.

Table 1. Demographic and baseline characteristics.

Patient #	Gender	Age (years)	Type 1 diabetes mellitus duration (years)	Current therapy regimen	CGM[a] use experience for the last 1 year (patients' subjective evaluation)	Duration of Diani system use
1	Female	45	5	MDI[b]	Few times a year	3 months
2	Female	29	13	CSII[c]	Full time	6 months
3	Female	24	19	CSII	Full time	4 years
4	Male	27	26	CSII	Few times a year	4 years
5	Male	45	4	MDI	None	3 months
6	Male	87	36	MDI	None	3 months

[a]CGM: continuous glucose monitor.

[b]MDI: multiple daily injection.

[c]CSII: continuous subcutaneous insulin infusion.

Table 2. Data obtained from 3-month period of using the Diani system.

Patient #	Number of days with continuous glucose monitor	Average number of self-measured blood glucose per day[a]	Average number of carbohydrate registrations per day[b]	Average number of insulin registrations per day[b]	Average number of physical activity registrations per day[b]	Average number of step counts per day[a]
1	18	4.4	5.5	4.1	1.47	14,367
2	72	5.9	3.6	3.8	0.34	9309
3	30	6.6	1.4	1.6	0.18	10,888
4	6	4.3	2.0	5.1	0.60	10,350
5	0	2.5	0	2.9	0.03	4299
6	0	3.2	0.6	0.4	0.05	—[c]

[a]Measured values automatically transferred to a connected mobile app.

[b]Data manually registered to the diabetes diary mobile app.

[c]Missing data.

Table 3. Glycated hemoglobin (HbA_{1c}) values and frequency of hypoglycemia.

Patient #	HbA_{1c} before using the system (mmol/mol)	HbA_{1c} after 3 months' experience (mmol/mol)	HbA_{1c} after 6 months' experience (mmol/mol)	HbA_{1c} after 4 years' experience (mmol/mol)	Average number of self-measured hypoglycemia <3.9 mmol/L per week during the first 3-month period	Average number of self-measured hypoglycemia <3.0 mmol/L per week during the first 3-month period
1	51	48	—[a]	—	2.6	0.08
2	65	54	47	—	4.8	0.38
3	66	63	69	47	5.7	1.03
4	78	62	69	54	4.4	1.91
5	63	54	—	—	0.6	0.07
6	67	71	—	—	1.3	0.78

[a]Not applicable.

Patient's Attitude to Technology

Since the last year, she has been using 3 sensors for CGM monitoring, but besides that she has relied on self-measured blood glucose (SMBG) alone. Considering her higher educational level and age, she is familiar with using a smartphone and wearable technologies and has no problem to intuitively and quickly learn how to operate a new mobile app or a device for self-management. She has no problems wearing an activity tracker on a full-time basis (during the day and at night). She is also conscientious with respect to registering data into the diabetes diary app (see Table 2) and regularly reviews her data via both mobile and Web apps. She is used to discussing her diabetes difficulties with her clinician, using collected data. Many of these features can be seen on a 1-day graph (Figure 1) representing her regular day.

However, what troubles her are devices that are uncomfortable to wear when performing PA (for this reason, she was not willing to use the smartwatch) or treatment-related devices that are visible to other people. She tends to conceal her disease from the people around her very carefully and makes any treatment actions as discreetly as possible. Therefore, she fully refuses to use an insulin pump and prefers to inject the insulin with a pen in private areas (despite the usefulness of flexible dosing during PA that the insulin pump could enable her). She is willing to wear the CGM sensor only in places that are not visible behind the clothes from the outside.

The biggest benefit she gained from the telemedicine system after she started to use it was that she realized her blood glucose was affected by certain foods and drinks which she had not been covering with insulin dose. Another new information was a postmeal spike after a larger portion of carbohydrate intake, which was connected to a too short time span between the insulin dose and carbohydrate intake. In the long run, she can benefit from controlling her stable total daily dose of carbohydrates and total daily step count, in addition to the blood glucose measurements. By tracking her daily step counts and intensity of PA for a specific sport, she was able to compare her activity level with other friends. The knowledge that there had been nobody who would make a better performance made her feel even more motivated to continue in such regimen. Wearing a CGM helped her mainly to control her blood glucose during PA and discover the postmeal spikes. The receiver clipped on her pants did not represent any obstacle for her.

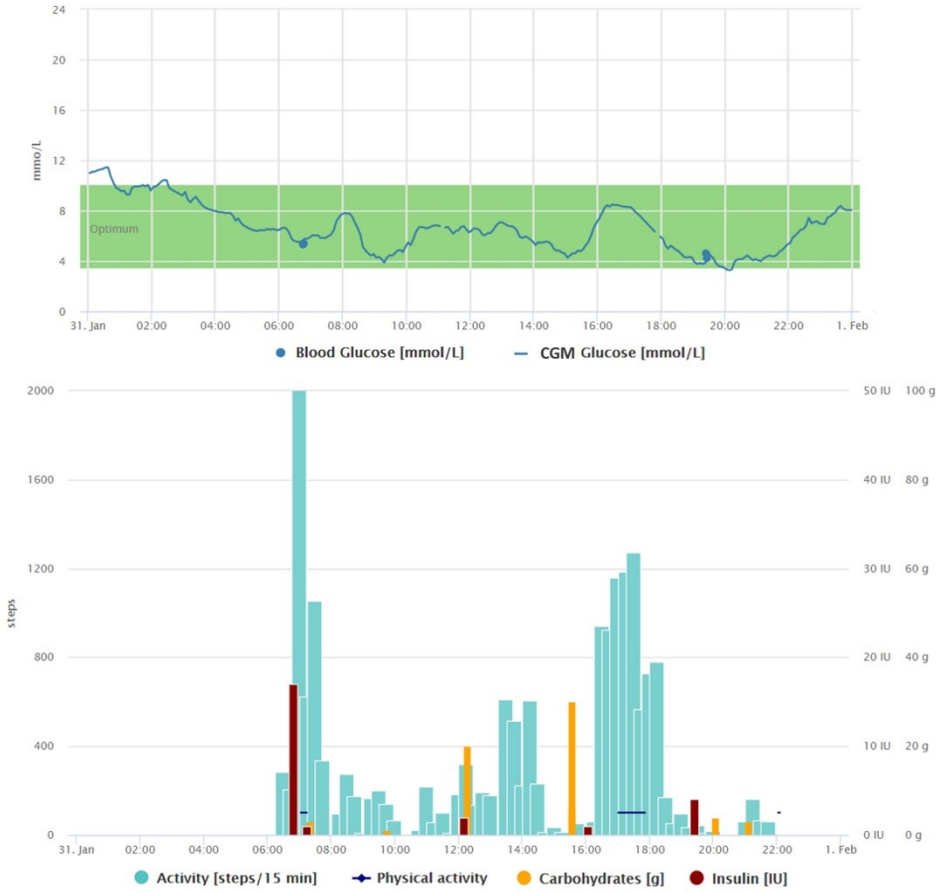
Suggestions for the Optimal Combination of Devices

The ideal tailored system for this type of patient could be a combination of devices that would transfer all the data into a mobile app or display the values on a screen of devices, which would not represent a stigma for them or be visible to the people around them. A thin wristband sensor for tracking activity and a sensor for glucose control would certainly be a good choice. No frequent notifications or alarms from the data analysis would probably be necessary, as this patient is able to review the data regularly. The alarms coming from the CGM system would need to be in vibration mode only to comply with the discretion requirements. Another option could be switching for a flash glucose monitoring, which would be a secret form of data capturing in case the patient would not mind not receiving alarms at night and could wear it on alternative places of the body. The implantable sensor could also work if being implanted in places, which the patient could cover with summer clothes.

Regarding the insulin therapy, insulin pen treatment still seems to be an option complying with the patient's requirements because of her rejection of wearing an insulin pump. However, improvement in this area could be at least a pen enabling to transfer data to a mobile app via Bluetooth. As the patient is capable of operating digital technologies, we could also try to shift her to a patch pump therapy, if that would be acceptable for her to wear, rather than the traditional pumps with tubing. She could then effectively reduce nighttime highs using a squared bolus or temporary basal rate settings for the high-fat snacks intake she has a difficulty to control.

A personal account for a Web app connected to a clinician's account for automatic data synchronization would be a matter of course.

Figure 1. Graphical interpretation of 1-day data registrations of the patient from case study 1, visualized by the Diani Web app. In the picture, we can observe patterns, such as the low-carbohydrate intake, high intensity of physical activity, and higher glucose values during the night. CGM: continuous glucose monitoring.



Average blood glucose per day [mmol/L]		Total carbohydrates per day [g]		Total insulin per day [IU]		Activity [steps/day]	
1/31/2018	4.9	1/31/2018	67.0	1/31/2018	7.0	1/31/2018	17811

Case Study 2

Patient Information

A 29-year-old woman has T1DM since 2005, and she has been on continuous subcutaneous insulin infusion (CSII) regimen since 2013. Besides her diabetes, she is not suffering from other diseases or diabetes complications. She is preparing for pregnancy.

Daily Regimen and Self-Management

This patient is specific in her motivation to improve her HbA_{1c} because she is planning for pregnancy. Being a high school teacher, her daily program is stable and regular. Some unexpected changes in her schedule or emergencies can, however, occur occasionally. These events mostly influence her ability to eat regularly and on time. She is used to maintaining a healthy food intake, but to a certain extent, she has to adapt to the menus at the school canteen during lunchtimes.

She likes walking a lot and she goes for a long walk every day, if the time allows her to do so. She is also educated in flexible dosing of insulin and tries to make changes in her insulin dosing herself based upon the collected data. From time to time, she struggles with nighttime hypoglycemia, mostly induced by evening walks.

Patient's Attitude to Technology

Regarding her technical abilities, she can learn how to use any device easily if she gets sufficient instructions and can turn to technical support or a more advanced person when she gets into trouble, for example, with Bluetooth connection or unpaired devices. She is a smartphone user, so any kind of mobile apps do not pose any obstacle for her to install and use.

She is not concerned about how many devices she has to wear or whether they are visible to the people around her. The accuracy of blood glucose measuring devices is more important to her than the design and size of the technology.

She has been on the CGM system full time since November 2017. At the same time, she started to use all the other equipment within the Diani system. She also took advantage of sharing CGM data with her T1DM friend as another motivation to achieve better blood glucose results while being observed by another person.

By wearing the activity tracker, she has been motivated to walk more and compete with friends who track their daily steps as well.

Regarding her manual registrations, she has entered her insulin doses and carbohydrate information into the diary almost daily, but some lack of data within a day or several days with a pause of manual registrations occurs. She reviewed her historical data more frequently at the beginning to identify problems that caused her blood glucose fluctuations. Once she stabilized her glycemia, she started reviewing the data only a few days before the visit to her diabetologist. She always prepares for the visit and downloads the data for the doctor.

The trend indicating her blood glucose improvement and the way she collects the data can be seen in Figures 2 and 3. Compared with Figure 2, we can see that the regular data registrations are reduced after the average blood glucose has stabilized.

Suggestions for the Optimal Combination of Devices

Ideal tailored system for this type of patient would certainly be an insulin pump in combination with a CGM system that would enable her to transfer data to mobile and Web apps. As we know she experiences nighttime hypoglycemia, the flash glucose monitoring would not be beneficial for her, despite the ability to use it in combination with a smartphone. Knowing her strong focus on device accuracy, the most accurate CGM device enabled with alarm and data transfer to a mobile app might be a good option for her blood glucose monitoring. Considering her motivation while sharing data, a device having such a function included would represent another preference point. Regarding the type of a pump, she is not an exacting user and uses its basic settings and functions (normal boluses, temporal basal reduction, and 1 basal profile). The most convenient option would ideally be a pump that can receive data from the CGM device, in addition to the CGM data synchronization with a smartphone. This would ensure both the ability of data sharing and assurance of data transfer to the pump in case the smartphone has weak signal or its battery level is low. If no such device is available to her, she could choose a pump that is at least comfortable to wear, easy to use, enables to export data for a doctor, and has good technical support.

Case Study 3

Patient Information

A 24-year-old woman was diagnosed with T1DM in 1999, and she started with CSII therapy in 2002. She suffers from knee pain because of patellofemoral dysplasia, which she was diagnosed with in 2017. Besides that, she is not suffering from other diseases or diabetes complications.

Daily Regimen and Self-Management

This patient is a university student and, in addition, has a part-time job. Therefore, her daily program is changing frequently, and she is often busy with work until late evening.

As she struggles with a higher insulin resistance and complications with her knees, she tries to reduce her weight by decreasing her total daily carbohydrate intake and incorporating different types of PAs in her daily program. From time to time, she makes an exception in her regular dietary plan and takes a high-carbohydrate food because she is able to anticipate the majority of her postmeal spikes using her knowledge from the CGM data. She is very well educated and able to keep her blood glucose in a tight target range, mostly thanks to her regular attendance of educational courses and CGM monitoring throughout the whole year.

Patient's Attitude to Technology

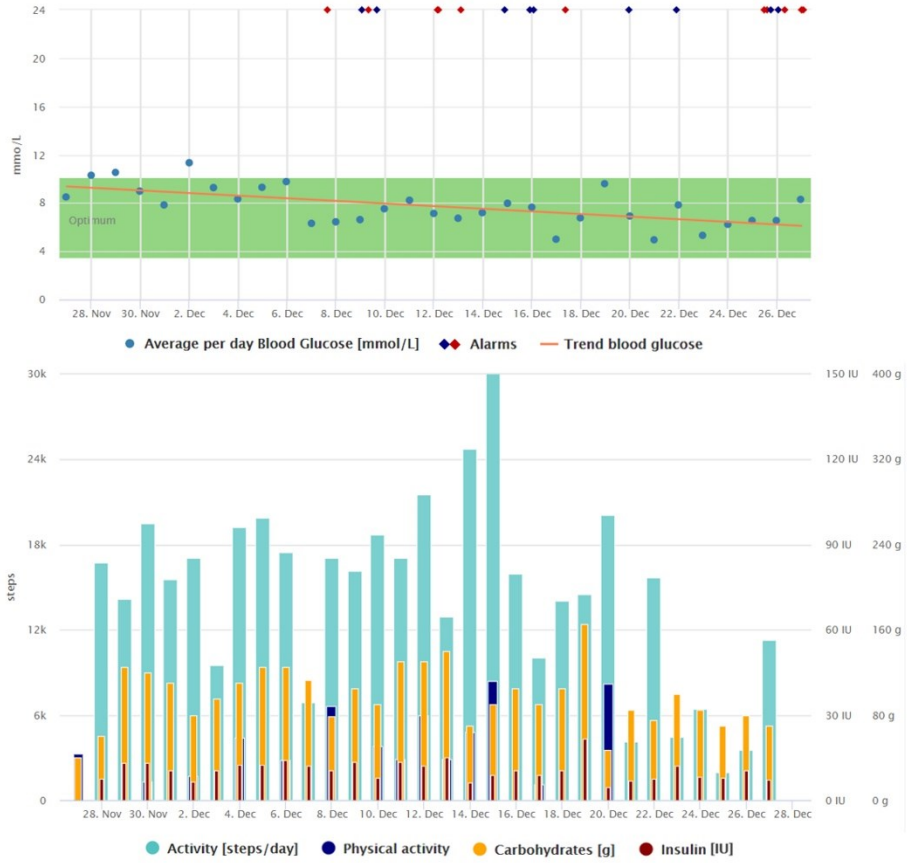
This patient is very interested in new wearable technology not only for diabetes treatment. Wearing any kind of mobile technology, even visible medical devices, is not perceived as a stigma by her.

Being connected fulltime through her CGM device since 2017 and having the motivation to undergo educational courses, she has learned a lot about how to make insulin adjustments based upon the arrow trends and actual glucose readings on her CGM system. Therefore, based on the trends, she gives herself correction boluses or suspends the basal rate often, rather than exactly counting carbohydrates in foods and reacting on upcoming situations too much in advance (see Figure 4).

She is able to register data into the diary properly as far as she has a good reason for doing so (eg, her blood glucose is suddenly, for unknown reasons, out of her control) and has a sufficient motivation (such as being pushed by her diabetes friends).

To keep her blood glucose in a very tight target range, she sets the hypo- and hyperglycemia ranges close to each other. This naturally results in more frequent alarms coming out of the CGM receiver, but it does not disturb her daily activities. However, this becomes a problem during the nights when she often does not hear the alarm and, thus, often does not wake up because of unstable glycemia values. To ensure that she wakes up once the alarm goes off, she started to change the tones in her new receiver settings every week once she got the version enabling that.

Figure 2. Graphical interpretation of 1-month data registrations of the patient from the case study 2, visualized by the Diani Web app. In the picture, we can observe everyday data registrations, high daily step counts, and decreasing trend of average daily blood glucose.



Although she is keen on trying new diabetes-related or fitness devices, she often comes up against technical issues, especially with her mobile phone. She uses many social media apps and games, listens to music, and uses a navigation app when driving a car, so she always needs an extra secure digital card and a phone that enables her to always be *online*. Lack of signal to connected devices is also a frequent issue she faces. Another issue is the fact that she lost some devices in the past, which were too tiny or not well fixed to her body, or the devices simply stopped working because of unknown reasons. Besides that, she is able to figure out most of the technical issues she encounters.

Suggestions for the Optimal Combination of Devices

Knowing all this information, this patient would certainly benefit from CGM technology and rely on its real-time values. Insulin pump is also the most convenient tool for her. However, as we know, losing the Bluetooth signal on her phone is a frequent issue. Therefore, she might benefit a lot from a pump that displays blood glucose values directly on the pump. An even better option would be a combination of displaying the data both on the pump and on the phone (similar to the previous case no. 2), as that would ensure the ability to arbitrarily change the alarm tone on her phone, in addition to receiving the 1-tone alarm from the pump. In connection to her ability to do her correction boluses based upon the glucose values and trends displayed on the pump, she could benefit from using a device that would automatically suspend the dosing before her glucose is predicted to reach a low level. It could help her to reduce hypoglycemia incidents (see Table 2), especially when overdone correction boluses occur. Considering a hybrid closed-loop system, if available in patient's country, this patient might have trouble handling its automatic delivery function because she might tend to manually interrupt its action mostly on high glucose levels to assume control of the insulin corrections and make the action faster.

Figure 3. Graphical interpretation of 1-month data registrations of the patient from case study 2, visualized by the Diani Web app.

Case Study 4

Patient Information

A 27-year-old man has T1DM since 1992, and he has been on CSII regimen since 2002. He started using the Diani system in July 2014, starting with the HbA_{1c} of 78 mmol/mol. Other than a laser operation he underwent because of early manifestations of retinopathy, he is not suffering from other diseases or diabetes complications.

Daily Regimen and Self-Management

Working in an administration office, this patient has a mostly regular working schedule. In his free time, he is physically very active (performing regular PA, such as floorball and volleyball). He is also very creative and likes gaming. He is a very competitive person when it comes to any games or sport matches.

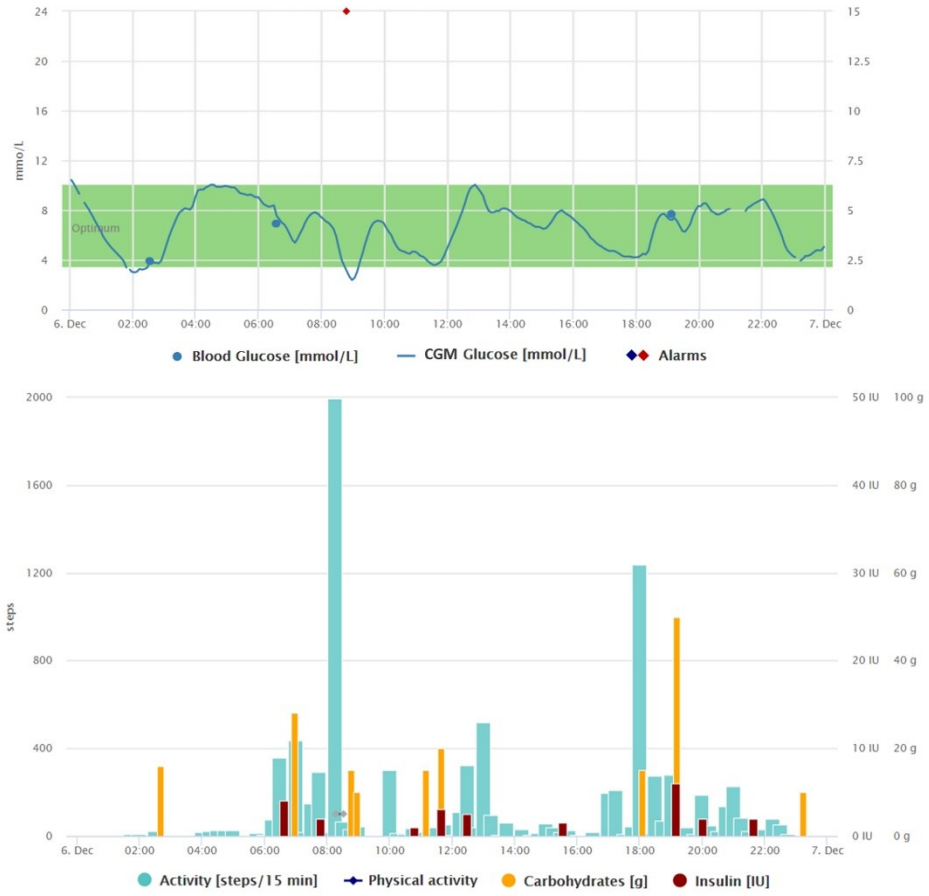
Regarding his eating habits, he often underestimates the timing of insulin injection for meals and sometime takes boluses too late. He also loves beer and is on a bit higher carbohydrate diet, which causes frequent postmeal spikes.

He tries to check his blood glucose regularly, but there are some days with only 1 or no measurements.

Patient's Attitude to Technology

This patient gets the sensor for CGM few times a year, but most of the time, he relies on SMBG alone. He is very competent technically and is able to learn, even intuitively, how to operate new mobile apps or wearables. He is also able to solve common problems with loss of connection and other minor technical complications on his own.

Figure 4. Graphical interpretation of 1-day data registrations of the patient from case study 3, visualized by the Diani Web app. In the picture, we can notice variable activities during the day composed of 1 high-intensity physical activity at around 8 am and then frequent changes between sitting and walking patterns. Regarding food intake, there are very different amounts of carbohydrates throughout the day. Patient's reaction on blood glucose level made by correction boluses is another typical pattern. CGM: continuous glucose monitoring.



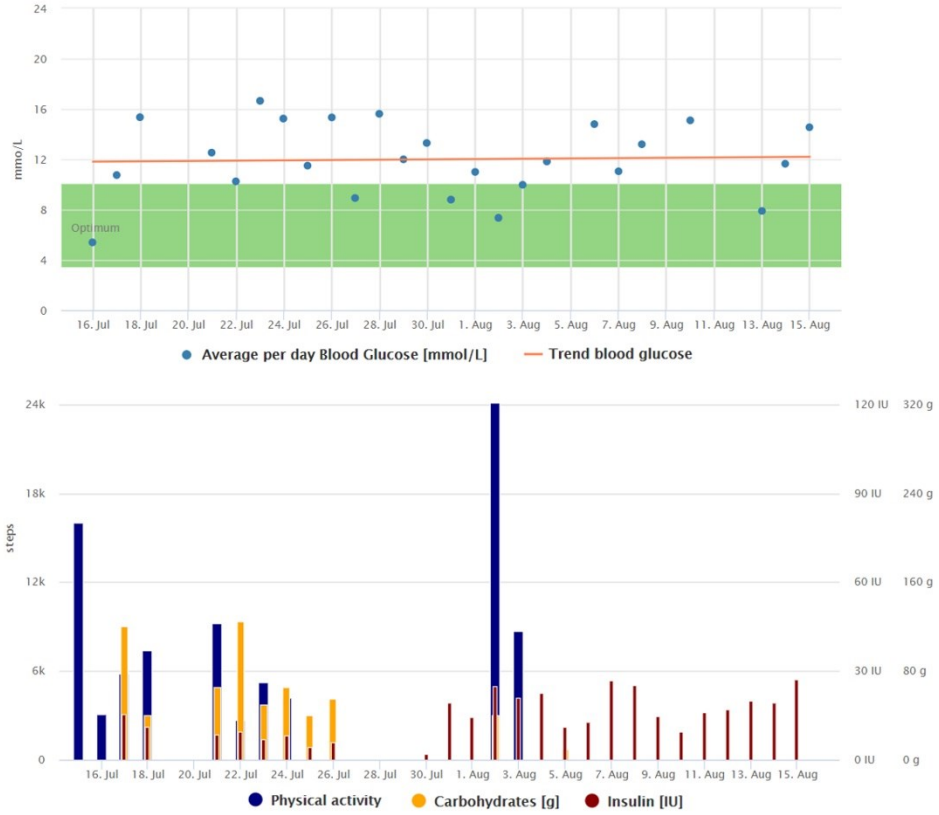
Considering his competitiveness, he is using an activity tracker all the time to set goals and compete with his friends in daily/weekly step counts.

However, it is difficult for him to register data into the diary manually. He is willing to enter more data when he gets motivation from the outside that, in addition, is often updated by some new stimulus. It can be a new tailored version of the app or another app that has a game basis, but it can also be a new device itself (a new *toy* he can play with). With respect to the long-term motivation, the best chance for him to better self-manage his disease is competing with his diabetic friends.

Figures 5 and 6 show the difference between the phase when he was not wearing the activity tracker and the period after he got the new device.

Although he uses just basic functions of his insulin pump, he has no problem to operate any kind of device and could benefit from more advanced functions (eg, square wave or dual wave bolus, bolus wizard) in case he got proper education in diabetes management.

Figure 5. Graphical interpretation of 1-month data registrations of the patient from the case study 4, visualized by the Diani Web app. In the picture, we can observe irregular data registrations and high blood glucose variability.



Suggestions for the Optimal Combination of Devices

Considering all these aspects, patients similar to this one might try to use, for example, a mobile app that is gamesome, includes functions for setting challenges, and enables users to take advantage of coaching services through a certified diabetes educator to increase the level of education in self-management issues. This patient might also be a good candidate for a hybrid closed-loop system, as it could reduce the burden of frequent blood glucose control and reduce the postmeal spikes caused by his eating habits and incorrect bolusing time.

If the hybrid closed-loop system is not accessible, we could consider a pump that suspends before low (it means the insulin delivery is stopped when low blood glucose limit is predicted to be reached within certain time). This could, in addition to other benefits, reduce hypoglycemia incidents, especially during PA. However, if the chosen pump is susceptible to falls and hits, the silicon case should be in place to protect the device while performing competitive sports.

Case Study 5

Patient Information

A 45-year-old man was diagnosed with T1DM in 2014. He has been on an MDI regimen right from the onset of the disease. Apart from diabetes and arterial hypertension, he is not suffering from other diseases or diabetes complications.

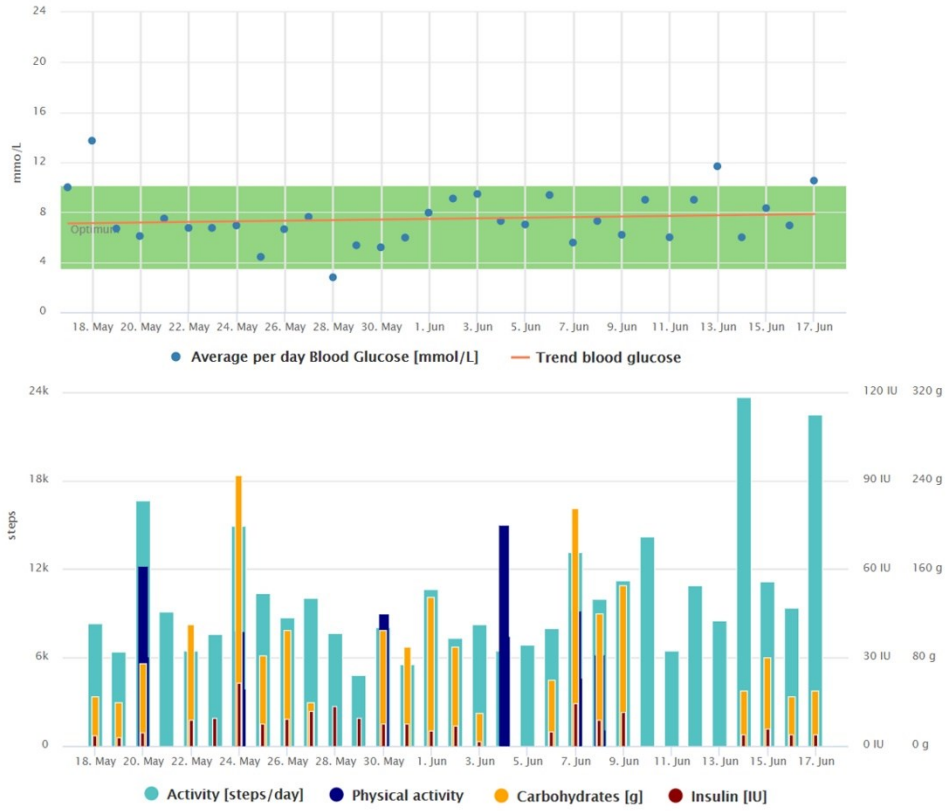
Daily Regimen and Self-Management

The patient has an irregular working regimen because of his frequent nighttime shifts. However, he performs PAs (walking, cycling, and working out) regularly and more than twice a week. He is used to complying with a fixed daily insulin dosing and tries to do proper carbohydrate counting using the nutrition tables on food packages.

Patient's Attitude to Technology

Before starting to use the Diani system, this patient had never used any mobile or Web app for diabetes self-management. Therefore, the only data he could check were the values displayed on his glucometer, which he had never reviewed before.

Figure 6. Graphical interpretation of 1-month data registrations of the patient from case study 4 after the patient got the activity tracker. The frequency of data registrations has increased, and the average blood glucose has decreased significantly compared with the average blood glucose trend in Figure 5.



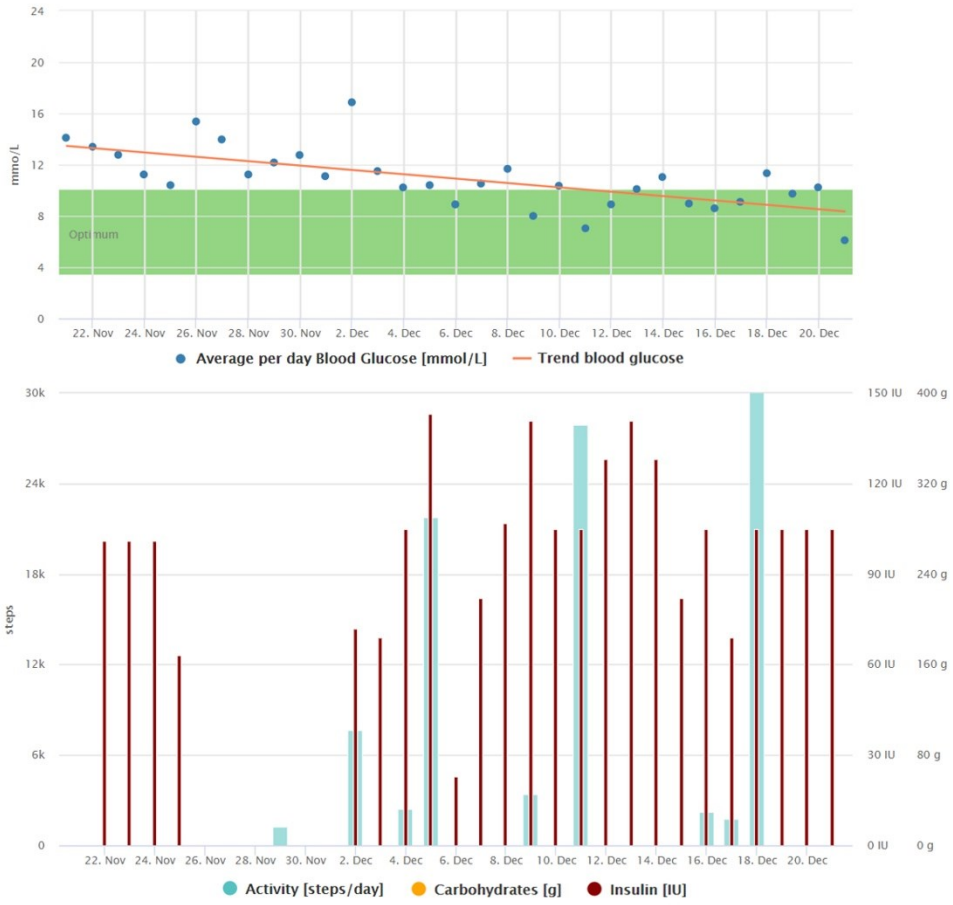
However, he had no problem with handling the smartphone and learning how to work with the mobile app and make data registration. He only had some minor issues when connecting the smartwatch to his phone at the very beginning, which he was able to manage on its own quickly once he got the proper instructions for the device pairing process.

The diabetes diary mobile app was the most beneficial tool for him as it was very easy to operate, the data were displayed in a well-arranged way, and the app was in his native language. Reviewing his data, he was motivated to achieve better results (changes in average blood glucose trends can be observed when comparing Figures 7 and 8). He was very happy about the automatic transfer of data from the glucometer to his phone. Insulin doses were, with the exception of a few PA comments, the only data manually registered by him (see Figures 7 and 8). On the basis of the last consultation, this patient feels much better both physically and mentally, and his quality of life has improved appreciably. He would also be willing to pay a monthly fee for the telemedicine service.

Suggestions for the Optimal Combination of Devices

As we can see, the patient was satisfied with the set of devices he was equipped with when using the telemedicine system. As an improvement, we could suggest to him to use an insulin pen that enables automatic transfer of data to the same mobile app into which the data from his glucometer are sent. Potentially, we could discuss how acceptable it would be for him to switch to an insulin pump that would be connected to a blood glucose meter and transfer the measured data to a user-friendly mobile app. The app should also have a bolus calculator and connected food database included to help him to better manage the carbohydrate counting.

Figure 7. Graphical interpretation of 1-month data registrations of the patient from case study 5, visualized by the Diani Web app. We can observe the decreasing trend of average daily blood glucose during the first month of using the telemedicine system.



Case Study 6

Patient Information

An 87-year-old man was diagnosed with T1DM in 1982, and he is still on an MDI regimen and SMBG measurement only. He suffers from diabetic peripheral polyneuropathy because of which his hands shake slightly, and he complains of leg pains, for which he takes the prescribed pills. He also suffers from diabetic retinopathy, proteinuria, corrected arterial hypertension, and hypercholesterolemia.

Daily Regimen and Self-Management

This patient is retired and as such has a very regular daily regimen and lots of free time he can spend on his hobbies and on the diabetes self-management. He is extremely motivated to learn new things and still has lots of energy to try or read about new methods in diabetes care. Thanks to his caring wife and his own carefulness and sense of precision, he has been keeping his paper-based diabetes records since the onset of his disease. He has read most of the diabetes books available in his native language and made notes about any unusual information that could help him to better self-manage the disease. He also performs daily PA (everyday walking, gardening, and working in his workshop). He was not used to checking his blood glucose regularly before he started to use the telemedicine system (1.7 times per day on average, calculated from 3-month records in his glucometer measured before he started to use the telemedicine system).

Figure 8. Graphical interpretation of 1-month data registrations of the patient from case study 5 after 2.5 months of using the telemedicine system. We can see the data registrations are more regular than those in Figure 7, and the average blood glucose has decreased and stabilized.

Patient's Attitude to Technology

He has already tried multiple types of activity trackers in the past. The device motivates him to maintain regular PA (walking or gardening). He is also able to use a personal computer to a certain extent, that is, for surfing on the internet, sending emails, and using Skype.

For him, the biggest problem he faced with the telemedicine system was that he had never used a smartphone before. Therefore, he first got the phone only to learn how to switch it on and off and how to open the diabetes diary app and use it. After a month, he came back to get the rest of the devices. As he only had a cable internet connection at home, he also got a subscriber identity module (SIM) card with prepaid data with the phone. Despite his efforts to handle the phone, he often had problems with operating, charging the devices, and losing the internet connection.

As he suffered from neuropathy, it was also difficult for him to handle the touchscreen because his hands were shaking, and he often clicked on more than 1 button at the same time or on the wrong one. This led to a wrong data entry (see Figure 9) or frequent calls to the technical support when getting to a page he did not know how to get out of. Thus, he spent more time dealing with technical issues than using the system effectively.

Suggestion for the Optimal Combination of Devices

In summary, besides the activity tracker that is simple to use even for an elderly person, the rest of the system is not a suitable solution for such a patient.

Another possible help could be occasional phone call checkups made by some diabetes educator to increase his adherence to regularly checking his blood glucose or connection to a remote assistance service that would track and control the patient via a smart device (SIM card and global system for mobile communication module based) and react in case of emergency.

Figure 9. Graphical interpretation of 1-day data registrations of the patient from case study 6. We can see some accidentally duplicated or zero values because of the patient's inability to operate the mobile app.

Discussion

Principal Findings

It is obvious, based on the case studies presented here, that there is no *one-size-fits-all* diabetes self-management tool, which would fully satisfy the needs of each particular patient.

To be able to give proper advice about the type of device that would be the most suitable for a given patient, specific information about the person is required. Such information includes, in particular, the patient's personality, his/her technical skills, daily regimen, his/her attitude to diabetes, obstacles in diabetes management, preferences in data visualization and devices' functionalities, willingness to learn new things, and motivational means that could help him/her use any system effectively and on a long-term basis.

From the case series, we could learn that a physically very active patient, who tends to conceal the disease from public, could only benefit from a technology that would not represent an obstacle when performing PA and would not be visible from the outside. On the contrary, there are patients who do not have any problems wearing any kind of devices and of any size, as far as the system is reliable and sufficiently accurate.

Although some patients would benefit from automatic functions of the most advanced pumps that suspend the insulin delivery, or work in hybrid mode, enabling them to reduce their hypoglycemia incidents and correcting their *mistakes* in bolusing, there are other patients for whom this system could be rather burdensome. These are patients who need to have their dosing under control, do not trust the system, and do not have the will to wait until the system corrects their blood glucose spikes.

Technical abilities, educational level, and age can also play a dominant role in technology acceptance and its use. Obviously, there are certain limits indicating that a given patient would not be able to operate some systems, even if proper education and technical support were provided.

Motivational tool embedded into technology is more related to a patient's personality. It can be, for example, the ability to share data with other patients/users or compete with friends who constantly push a patient to achieve good results, a function that is gamesome, or even just the ability to review data from the given device that proves to the patient that he or she is doing well or has achieved exceptional results.

It is also very effective to observe how patients handle a given technology in the present and after they get a new one and to check the data they collect regularly to learn more about their daily regimen, self-management, and potential changes in data entry and frequency of data registration over the long term.

With respect to the effect of the telemedicine system on patients' self-management and blood glucose value improvements, we can see a reduction in HbA_{1c} values in all but 1 of the 6 patients. However, because the patients were using the system in different periods of time, and because there could also be other factors that were not tracked but could have an impact on HbA_{1c} reduction, we cannot attribute this effect to our system only.

Conclusions

We believe this paper can provide relevant guidance on how to help particular patients to choose the best technology that is likely to suit them the most based on specific patient information we are able to obtain.

The input information we get about a patient represents one of the sources clinicians or educators can use to help a given patient to find the optimal combination of devices for diabetes self-management. Furthermore, clinicians or educators should be aware of available technologies a given patient can choose from. In addition, to achieve an effective use of chosen devices, there is a substantial need for proper education of the patients before they start using them.

Furthermore, with the rapid development of new and more advanced technological solutions (ie, hybrid and closed-loop systems), educators specialized in technical-related areas of diabetes management are needed to help with such customization and technical support of patients.

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Authors' Contributions

AH, MV, and JM were involved in technical education and support, patients' interviews, data collection, and monitoring. JB contributed to the patient interviews and clinical supervision. All authors contributed to the data analysis and its interpretation and to the editing of the manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Screenshots of the Diani Web application.

[PDF File (Adobe PDF File), 386KB-Multimedia Appendix 1]

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Abbreviations

CGM: continuous glucose monitor
CSII: continuous subcutaneous insulin infusion
HbA_{1c}: glycated hemoglobin
MDI: multiple daily injection
PA: physical activity
SIM: subscriber identity module
SMBG: self-measured blood glucose
T1DM: type 1 diabetes mellitus

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Systém pro telemonitoring fyziologických parametrů a režimových opatření pacientů s diabetes mellitus

Oblast techniky

Vynález spadá do oblasti technologií měření pro diagnostické účely, jakožto i systémy pro přenos měřených hodnot.

Dosavadní stav techniky

V současné době se stále častěji hovoří o epidemii diabetu – Světová zdravotnická organizace uvádí, že v roce 2014 trpělo 8,5 % lidí onemocněním diabetes mellitus, celkem 422 milionů lidí na světě. Nárůst onemocnění s sebou přináší vedle snížené kvality života pacienta i nárůst finančních nákladů pro zdravotní systémy států. Snahou příslušných zdravotních autorit je tedy minimalizovat dopady nemoci jak pro pacienta, tak na systém jako takový. Projevem onemocnění je zejména neschopnost organismu udržet hodnoty glykémie v mezích normy. To přináší zdravotní rizika pro pacienta, neboť glukóza je ve vyšších koncentracích pro tělo toxická a v dlouhodobém horizontu může vést k poškození některých orgánů i k selhání jejich funkce. Předejít vzniku rizikových faktorů lze zdravými dietními návyky, zapojením pravidelné fyzické aktivity a zachováním normální tělesné hmotnosti. Při kompenzaci diabetu je určující koncentrace glukózy v krvi (glykémie), příjem sacharidů v potravě, dávky inzulinu a jiných antidiabetik a intenzita fyzické aktivity. Z tohoto důvodu je potřeba tyto parametry dlouhodobě sledovat a vyhodnocovat.

Pro měření hladiny glykémie se běžně využívají glukometry - přístroje měřící hladinu glykémie z kapilární krve. Další možnost nabízí kontinuální monitory glykémie (CGM) - zařízení měřící glykémii v několikaminutových intervalech, které umožňuje pacientům reagovat na aktuální hodnoty glykémie i její trendy – tj. snižování či zvyšování glykémie. Zařízení obsahuje také alarmy varující před rizikem klinicky závažné hypoglykémie či hyperglykémie. Hodnoty glykémie jsou měřeny z podkoží pomocí zavedeného sensoru, k němuž je připojen vysílač. Ten každou hodnotu změřenou skrze senzor vyšle bezdrátově do přijímače, který naměřené hodnoty v reálném čase vykresluje do grafu.

Léčba diabetu se liší v souvislosti s typem a závažností onemocnění. Pacienti mohou v určitých případech změnit pouze životní styl (pohyb, stravovací návyky apod.), případně léčbu doplnit perorálními antidiabetiky či aplikací inzulinových dávek (diabetes mellitus 2. typu). V závažnějších případech (zejména diabetes mellitus 1. typu) jsou pacienti zcela odkázáni na intenzifikovaný inzulinový režim doprovázený přísným stravovacím režimem. Inzulin lze aplikovat prostřednictvím inzulinového pera či inzulinové pumpy. Pro záznam příjmu sacharidů v potravě a dávek inzulinu lze využívat samotných zařízení, případně různé formy diabetického diáře, např. mobilní aplikace v chytrém telefonu.

Na podporu a registraci fyzické aktivity mají velký potenciál tzv. „Electronic Activity Monitor System“ (EAMS) – bezdrátové zařízení, které objektivně měří fyzickou aktivitu a provádí zpětnou vazbu, např. formou zobrazení základních informací o činnosti, a které pomocí displeje nebo prostřednictvím aplikace vzbuzuje neustálou sebekontrolu aktivního chování. EAMS oproti klasickým zařízením zaznamenávajícím fyzickou aktivitu (krokoměrům) přinášejí svému uživateli rozšířené funkce týkající se zejména individuální zpětné vazby a možnosti sdílení výsledků na sociálních sítích.

Při kompenzaci onemocnění jsou v posledním desetiletí stále více využívány telemedicínské systémy. S pomocí telemonitoringu získávají lékaři podrobná a hodnotná data i v reálném čase. Vzdálená monitorace ovlivňuje postoje a chování pacientů a potenciálně tak zlepšuje jejich zdravotní stav. Telemonitoring má pro pacienty motivační a vzdělávací efekt, umožňuje též lékaři

včasněji a rychleji vyhodnocovat výsledky léčby. Telemonitoring je založen na komunikaci odesílatele s příjemcem v reálném čase, kdy je umožněna okamžitá reakce zdravotníka na podnět pacienta. Pacient využívá pro kontrolu biologických parametrů interaktivní zařízení, které pomocí internetu přenáší data k lékaři. Ten je vyhodnocuje a volí další postup. Aby byl telemonitoring účinným nástrojem při léčbě onemocnění, nesmí jeho používání pacienta nad míru fyzicky, psychicky ani časově omezovat.

Telemedicínský systém nabízí pacientovi nástroj, jak zvládat své onemocnění lépe, efektivněji a diskrétněji. Účelem telemedicínského systému je předcházet vzniku kritických stavů, a to nastavením správné kompenzace onemocnění, a zjednodušit denní život pacienta tak, aby nemusel neustále myslet na své onemocnění, a přitom měl svou léčbu pod kontrolou bez dalšího zatížení. Snahou je eliminovat psychickou zátěž pacienta plynoucí ze strachu a stresu z možných hypo/hyperglykémií nastalých v situacích, kdy bude např. sám doma, nebo naopak mimo domov a v případě, že tyto stavy nastanou, mu poskytnou alespoň vzdálenou podporu formou telefonické kontroly případně přivolání první pomoci.

Pouze pravidelné a dlouhodobé používání systému může přinést požadovaný efekt. Je potřeba, aby byl systém uzpůsoben požadavkům uživatelů při zachování své funkčnosti. Jeho použití musí být pro pacienta zcela automatizované, jednoduché a intuitivní, zpětná vazba musí být personalizována a upravena dle potřeby pacienta. Jeho použití nesmí pacienta obtěžovat, či více zatěžovat. Telemedicínský systém musí mít motivační charakter a posilovat psychickou pohodu pacienta a zvýšit jeho sebejistotu ve smyslu zvládnutí svého onemocnění. Toho je těžké dosáhnout, pokud je nastavení systému jednotné pro všechny pacienty. S tímto problémem se potýká většina mobilních zdravotnických zařízení a aplikací s možností sdílení dat. Nejčastějšími potížemi, na které pacienti naráží, jsou obavy o nabourání kontinuity dosavadní zdravotní péče, postrádání osobní konzultace s lékařem, potíže s dostatečnými technickými dovednostmi, popřípadě obtížné začlenění telemedicínského systému do běžného života pacienta.

V současné době neexistuje systém, který by integroval všechna výše uvedená zařízení, splňoval dané požadavky a byl zároveň napojen na dohledový pult, který by v případě vyhodnocení mimořádné situace přivolal první pomoc.

Podstata technického řešení

Podstatou technického řešení je spojení lokálního systému monitorování fyziologických parametrů diabetiků se vzdáleným dohledovým pultem pro sledování překročení maximálních přípustných hodnot a upozorňování na rizikové stavy.

Technickým řešením je systém tvořený spravující složkou, měřící složkou a komunikační infrastrukturou. Součástí komunikační infrastruktury jsou taktéž komunikační zařízení blízkých osob uživatele (nouzových kontaktů) a lékaře uživatele, kterými mohou být chytré telefony, tlačítkové telefony, klasické pevné telefony nebo osobní počítače.

Spravující složka má podobu vzdáleného serverového počítače vybaveného modulem pro záznam dat propojeného s dohledovým pultem. Webový server je dále připojen k osobnímu počítači lékaře uživatele, který jeho prostřednictvím může nahlížet do databáze naměřených dat fyziologických parametrů uživatele.

Měřící složka zahrnuje chytrý telefon a/nebo chytré hodinky, případně také v podobě chytrého náramku, sbírající údaje o fyziologických parametrech uživatele (glykémie, tepová frekvence, fyzická aktivita) a režimových opatřeních (množství aplikovaného inzulinu a konzumovaných sacharidů).

Dohledový pult získává data ze vzdáleného serverového počítače s tím, že při dosažení limitních hodnot sledovaných fyziologických parametrů chytrý telefon upozorní uživatele zvukovou a vizuální výstrahou a dohledový pult generuje a odešle SMS, e-mail či telefonní hovor, a to dle typu připojených komunikačních zařízení a dle preferovaných typů komunikace jednotlivých blízkých osob uživatele a lékaře uživatele.

Objasnění výkresů

Obrázek č. 1 schematicky zobrazuje vazby mezi jednotlivými složkami systému.

Příklad uskutečnění technického řešení

Příklad uskutečnění popisuje výhodnou sestavu systému skládající se z měřící složky 1, spravující složky 2 a komunikační infrastruktury 3. Měřící složka je tvořena monitorem 11 fyzické aktivity, glukometrem 12, inzulinovou pumpou 13, váhou 14 a tlakoměrem 15, přičemž všechny tyto komponenty jsou pro přenos naměřených hodnot bezdrátově připojeny prostřednictvím WiFi a Bluetooth k chytrému telefonu 100 s tím, že monitor 11 fyzické aktivity je k chytrému telefonu 100 připojen prostřednictvím chytrých hodinek 101. Chytrý telefon 100 je bezdrátově připojen ke spravující složce 2, a to konkrétně ke vzdálenému serverovému počítači 200 pro ukládání naměřených hodnot, k němuž jsou prostřednictvím virtuální privátní sítě připojeny dohledový pult 201 a osobní počítač 31 lékaře uživatele. Vzdálený serverový počítač 200 obsahuje sběrnicí propojené moduly, a to modul úložiště, modul výpočetní jednotky, modul řízení, modul webového rozhraní, modul komunikačního rozhraní a modul zálohovaného úložiště. Dohledový pult 201, který obsahuje komunikační rozhraní, zobrazovací zařízení, procesorovou jednotku, klávesnici a úložiště dat, je prostřednictvím internetu a služeb telefonního operátora připojen pro upozornění blízkých osob uživatele a lékaře uživatele o překročení limitních naměřených hodnot ke komunikační infrastruktuře 3, které sestává z chytrých telefonů, tlačítkových telefonů, klasických pevných telefonů a osobních počítačů blízkých osob a osobního počítače 31 lékaře uživatele.

Průmyslová využitelnost

Systém pro telemonitoring pacientů s diabetes mellitus je průmyslově využitelný pro omezení výskytu zdraví a život ohrožujících situací s užitím běžně dostupných komponent.

NÁROKY NA OCHRANU

1. Systém pro telemonitoring fyziologických parametrů a režimových opatření pacientů s diabetes mellitus skládající se z měřící složky (1) zahrnující chytrý telefon (100), k němuž je připojen monitor (11) fyzické aktivity, glukometr (12), inzulinová pumpa (13), váha (14) a tlakoměr (15) a dále spravující složky (2) a komunikační infrastruktury (3) **vyznačující se tím**, že spravující složka (2) obsahuje vzdálený serverový počítač (200), k němuž je bezdrátově připojen chytrý telefon (100) s tím, že ke vzdálenému serverovému počítači (200) je prostřednictvím virtuální soukromé sítě bezdrátově připojen dohledový pult (201), který je spojen s komunikační infrastrukturou sestávající z komunikačních zařízení blízkých osob uživatele a počítače (31) lékaře, přičemž počítač (31) lékaře je současně prostřednictvím virtuální soukromé sítě připojen také ke vzdálenému serverovému počítači (200).

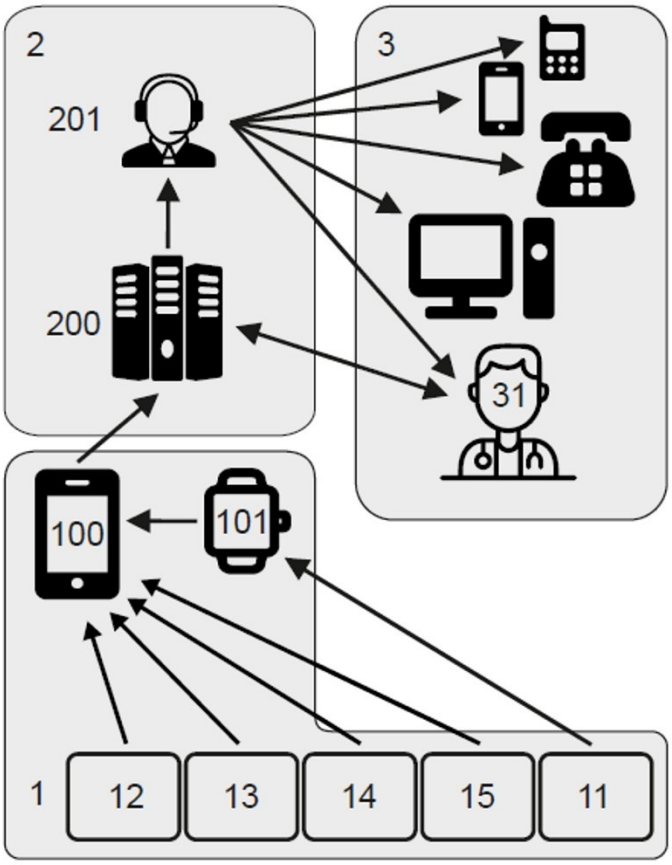
2. Systém podle nároku 1 **vyznačující se tím**, že monitorem (11) fyzické aktivity jsou chytré hodinky (101) nebo chytrý náramek.

3. Systém podle nároku 1 nebo 2 **vyznačující se tím**, že vzdálený serverový počítač (200) obsahuje sběrnicí propojené moduly, a to modul úložiště, modul výpočetní jednotky, modul řízení, modul webového rozhraní, modul komunikačního rozhraní a modul zálohovaného úložiště.

4. Systém podle kteréhokoli z nároků 1 až 3 **vyznačující se tím**, že dohledový pult (201) obsahuje komunikační rozhraní, zobrazovací zařízení, procesorovou jednotku, klávesnici a úložiště dat.

5. Systém podle kteréhokoli z nároků 1 až 4 **vyznačující se tím**, že komunikační infrastruktura (3) obsahuje alespoň jedno ze zařízení vybraných ze skupiny chytrých telefonů, tlačítkových telefonů, klasických pevných telefonů nebo osobních počítačů.

1 výkres



Obr. 1

Příloha č. 9:

Tabulka – Přehled glukometrů integrovatelných do TS Diani, stav k roku 2022.

n	Název glukometru	Výrobce	Rozsah měření (mmol/l)	Pobřebný objem vzorku (µl)	Doba vyhodnocení (s)	Možnost stahovat data do aplikace v chytrém telefon	Kopatibilní operační systé	Rozhraní pro stahování dat
1	iHealth GLUCO+ BG5S – chytrý glukometr	Andon Health Co.,Ltd.	1,1-33,3	0,7	5	ano	iOS, Android	Bluetooth + Mirko USB
2	Glukometr Beurer GL 50 evo	BEURER	1,1-35	0,6	5	ano	iOS, Android	Bluetooth + NFC
3	Glukometr Rightest Max Plus	BIONIME Corporation	0,6-33,3	0,75	5	ano	iOS, Android	Bluetooth
4	Biotter ISTEL ABRA SMART BT Glukometr souprava	DIAGNOSIS S.A.	1,1-33,3	0,5	5	*	iOS, Android	Bluetooth + Mirko USB
5	Glukometr FORA Diamond MINI, DM30a/DM30b	Fora Care Suisse AG	1,1 - 33,3	0,5	5	ano	iOS, Android	Buetooth
6	iHealth GLUCO BG5 chytrý glukometr	iHealthLabs Europe SARL	1,1-33,3	0,7	5	ano	iOS, Android	Bluetooth
7	iHealth ALIGN BG1 chytrý glukometr	iHealthLabs Europe SARL	1,1-33,3	0,7		ano	iOS, Android	Jack
8	mylife Aveo glukometr	i-SENS, Inc.	0,6-33,3	0,5	5	ano	iOS, Android	Bluetooth + Mirko USB
9	OneTouch Verio Flex glukometr	LifeScan Europe A Division of Cilag GmbH International	1,1-33,3	0,4	5	ano	iOS, Android	Bluetooth + Mirko USB
10	OneTouch Select Plus Flex glukometr	LifeScan Europe A Division of Cilag GmbH International	1,1-33,3	1	5	ano	iOS, Android	Bluetooth + Mirko USB
11	OneTouch Verio Reflect glukometr	LifeScan Europe GmbH	1,1-33,3	0,4	5	ano	iOS, Android	Bluetooth + Mirko USB
12	Glukometr SD-Gluco Navii NFC	SD Biosensor, Inc.	0,55-33,3	0,5	5	ano	Android	NFC
13	Glukometr Diawin Medisign G83	Tianjin Empecs Medical Device Co.,	0,6-33,3	0,5	5	ano	iOS, Android	Bluetooth + Mirko USB

Příloha č. 10:

Tabulka – Přehled CGM a FGM dostupných v ČR, stav k roku 2023.

n	Název CGM/FGM	Výrobce	Technolo	Možnost n	Vysílač	Životnost (dny)
1	Libre 2	Abbott Diabetes Care Ltd.	NFC/Bluetoo	ne	ne	14
2	Dexcom G6	DexCom, Inc	Bluetooth	ano	ano	10
3	Dexcom G7	DexCom, Inc	Bluetooth	ano	ne	10
4	Glunovo i3	INFINOVO MEDICAL Co.,Ltd.	Bluetooth	ne	ano	14
5	Guardian 3	Medtronic MiniMed	Bluetooth	ano	ano	7
6	Guardian 4	Medtronic MiniMed	Bluetooth	ano	ano	7
7	A8 Nano TouchCare	Medtrum Technologies In.c	Bluetooth	ano	ano	14
8	Eversense XL	Senseonics, Inc.	NFC	ne	ano	180
9	CT10 POCTech	Zhejiang POCTech Co., Ltd.	Bluetooth	ne	ano	10