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The Effects of a Mobile Phone Application on Quality of Life in Patients With Type 1 Diabetes Mellitus: A Randomized Controlled Trial

Iefke Drion, MD, PhD[1], Loes R. Pameijer, MD[1], Peter R. van Dijk, MD, PhD[1], Klaas H. Groenier, PhD[1,2], Nanne Kleefstra, MD, PhD[1,3,4], and Henk J. G. Bilo, MD, PhD, FRCP[1,3,5]

Abstract

Background: The combination of an increasing prevalence of diabetes mellitus and more people having access to smartphones creates opportunities for patient care. This study aims to investigate whether the use of the Diabetes Under Control (DBEES) mobile phone application, a digital diabetes diary, results in a change in quality of life for patients with type 1 diabetes mellitus (T1DM) compared with the standard paper diary.

Methods: In this randomized controlled open-label trial, 63 patients with T1DM having access to a smartphone were assigned to the intervention group using the DBEES application (n = 31) or the control group using the standard paper diary (n = 32). Primary outcome was the change in quality of life, as measured by the RAND-36 questionnaire, between both groups. Secondary outcomes included diabetes-related distress (PAID), HbA1c, frequency of self-monitoring blood glucose, and the usability of the diabetes application (SUS).

Results: Patients had a median age (IQR) of 33 (21) years, diabetes duration of 17 (16) years, and an HbA1c of 62 ± 16 mmol/mol. No significant differences in the QOL, using the RAND-36, within and between both groups were observed after 3 months. Glycemic control, diabetes-related emotional distress, and frequency of self-monitoring of blood glucose remained within and between groups. Users reviewed the usability of DBEES with a 72 ± 20, on a range of 0-100.

Conclusions: The use of the DBEES application in the management of patients with T1DM for 3 months yields no alterations in quality of life compared to the standard paper diary.

Keywords
glycemic control, quality of life, mobile phone application, usability, type 1 diabetes mellitus, randomized controlled trial

In diabetes, the level of glycemic control is directly related to the occurrence of long-term diabetic complications.[1-4] In patients with type 1 diabetes mellitus (T1DM), self-management, for example, frequent self-monitoring of blood glucose (SMBG), is an important tool to achieve a good glycemic control.[5] Furthermore, it is supposed that self-management may result in more insight in the disease process, leading to better compliance. Besides a good glycemic control, improving quality of life (QOL) is an important goal, since QOL is inversely associated with depression, progression of disease, compliance of medication, and mortality.[6-8]

In recent years new technologies, such as mobile phone applications, have evolved that assist in and potentially improve the self-management of patient. The use of electronic applications replaces the classic paper diabetes diary increasingly, and thus may help reduce the effort to manage SMBG data.[9] The transition to an electronic diabetes diary, in which

[1]Diabetes Centre, Isala Clinics, Zwolle, Netherlands
[2]Department of General Practice, University of Groningen, UMCG, Groningen, Netherlands
[3]Department of Internal Medicine, University of Groningen, UMCG, Groningen, Netherlands
[4]Medical Research Group, Langerhans, Zwolle, Netherlands
[5]Department of Internal Medicine, Isala Clinics, Zwolle, Netherlands

Corresponding Author:
Iefke Drion, MD PhD, Isala, Diabetes Centre Zwolle, PO Box: 10400, 8000 GK Zwolle, Netherlands.
Email: i.drion@umcg.nl

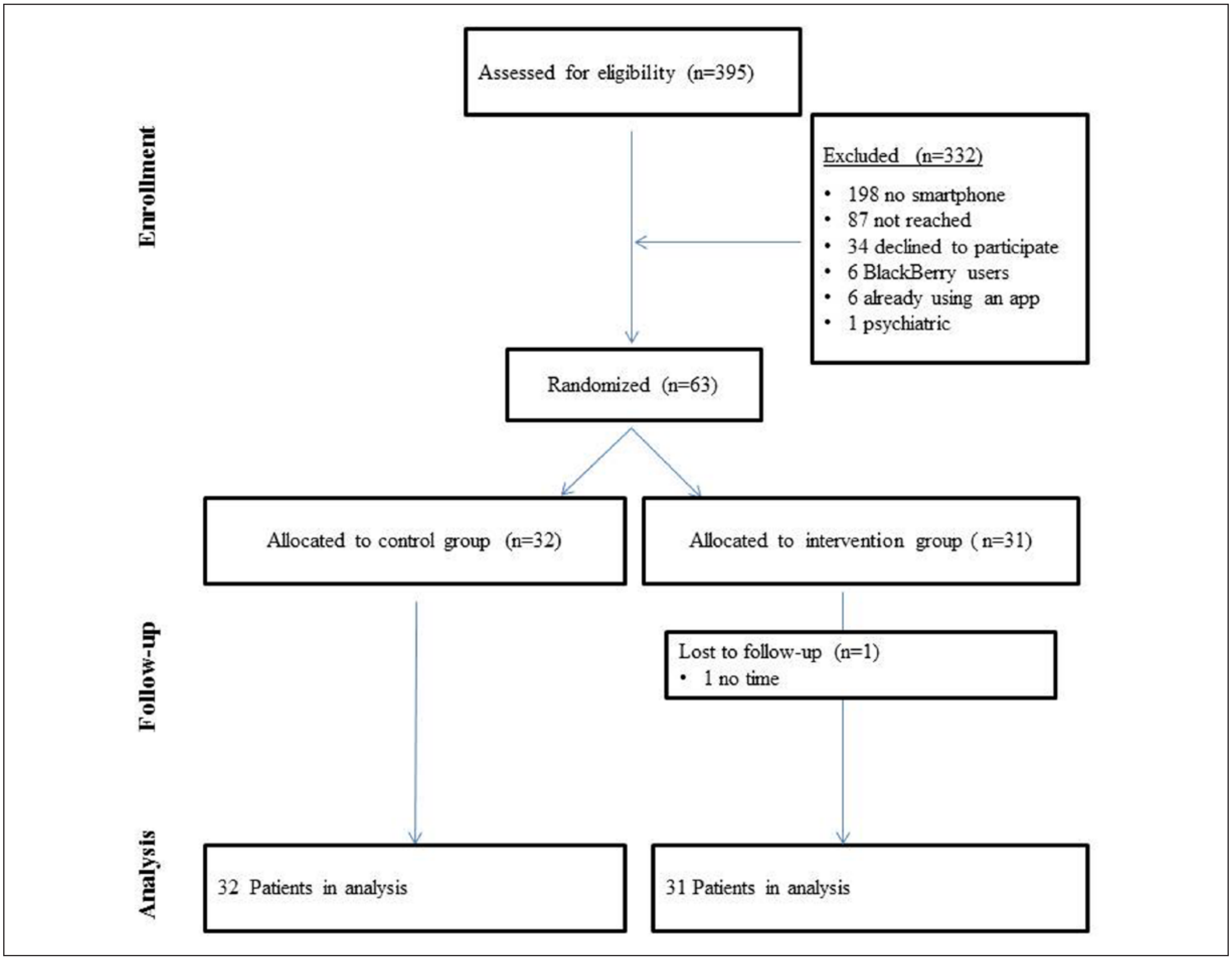

Figure 1. Patient flow chart.

also food intake, blood glucose profiles, insulin, and medication reminders can be stored, may simplify this self-care of patients. But whether this digitalization also causes changes in HbA1c is inconclusive. Moreover, the effects on QOL have not been studied yet.

This study was initiated to investigate the effects of a specific mobile application, the DBEES mobile phone diary application, on QOL for patients with T1DM.[10] Besides we investigated the impact on diabetes-related distress, HbA1c, SMBG, and usability of the diabetes application.

Methods

Study Design and Patients

This randomized, prospective, open-label clinical trial was conducted in the Isala hospital in Zwolle, the Netherlands. Patients with T1DM who planned to visit the diabetes outpatient clinic in the period September until October 2011 were identified and were, prior to their visit, informed about the study by letter. Subsequently, during their visit, patients were asked to participate in the study if they owned a smartphone (other than a BlackBerry) and were familiar with its use. Patients were included after obtaining informed consent.

All patients were over 18 years old, had T1DM, and were treated with multiple daily injections (MDI), continuous subcutaneous insulin infusion (CSII), or continuous intraperitoneal insulin infusion (CIPII). Patients were excluded if they had used a diabetes application in the 3 months prior to their visit, did not have internet or email access, or were unable to read Dutch.

Randomization was performed through a telephone call with an independent researcher who was asked to draw a nontransparent envelope. All envelopes contained tickets with an I (for the intervention group) or a C (for the control group). To ensure equal allocation rates within the 2 groups, block randomization was used. Figure 1 shows the CONSORT-flow diagram of this study.[11] Patients randomized to the intervention group needed to download the DBEES application on their smartphone.[10] Patients were asked to use the DBEES application and a personal web portal linked to the DBEES application. Patients could enter diabetes-related self-care data: blood glucose values, carbohydrate intake, medication, physical exercise, and notes. Patients in the control group kept their paper diary.

Data Collection

At baseline and after 3 months all patients completed the RAND-36 health survey and the Problem Areas in Diabetes questionnaire (PAID).[12,13] Moreover, data regarding age, sex, BMI, highest level of education, HbA1c (at baseline and after 3 months), diabetes duration, insulin therapy, and presence of diabetic complications were recorded at baseline. At the follow-up visit, the frequency of SMBG was determined by counting the number of SMBG measurements as registered in the glucose meter(s) of the patients from the start of the study until the follow-up visit. Moreover, patients in the intervention group filled in the System Usability Scale (SUS) questionnaire and some open questions about the usability of the DBEES application.[14]

The RAND-36 is a widely used measure of health-related QOL and consists of 36 items, clustered into 9 domains of health status (ie, physical functioning, role limitations due to physical health problems, bodily pain, general health, vitality, social functioning, role limitations due to emotional problems, mental health, and health change). The scores relating to each scale are summed and rescaled to a 100-point scale, where 100 is the best possible score and 0 the worst. The 9 scales of the RAND-36 can further be divided into 2 component summaries: a physical component summary (PCS) and a mental component summary (MCS).[15,16]

The PAID questionnaire was used to measure diabetes-related emotional distress reported by the patients. The PAID has 20 items related to negative emotions around diabetes, and those are scored on a 0-4 scale. The total score is calculated by counting all item scores and multiplying them by 1.25 to transform them to a 0-100 scale. A score ≥40 is indicative for severe emotional problems. The PAID has been validated and is a sensitive questionnaire.[17]

The SUS is a 10-item questionnaire, with 8 items about usability and 2 items regarding learnability. All items are scored on a 5-point scale. Questions regarding usability are summed and multiplied by 3.125; questions regarding learnability are summed and multiplied by 12.5. A score >70 is acceptable.[14] Validity, reliability, and sensitivity of the SUS have been extensively evaluated.[18,19] We translated the SUS into Dutch according to the guidelines for the process of cross-cultural adaptation of self-report measures.[20]

Outcomes

Primary outcome was the change in QOL, as measured by the RAND-36 questionnaire, between the intervention and control groups. Secondary end points included diabetes-related distress, measured with the PAID questionnaire, HbA1c, daily frequency of SMBG, and usability of the DBEES system, which was tested with SUS questionnaire.

Statistical Analysis and Ethical Considerations

To test the hypothesis that the use of a diabetes application leads to an improvement of 10 on the RAND score after 3 months (primary outcome measure) with a power of 81%, ($\alpha = .05$, 2-tailed), a sample size of 31 patients per group was needed. Taking into account a dropout rate of 10%, 34 patients per group had to be enrolled. Comparison of the RAND-36 and the PAID between groups was performed after 3 months from randomization using a Mann–Whitney *U* test. Within-group differences achieved after 3 months from randomization were evaluated using the Wilcoxon signed-rank test. Analysis were performed using the per-protocol principle.

Statistics were performed by SPSS 18.0 (Chicago, IL) and Stata version 11 (StataCorp, College Station, TX). Data were analyzed according to the intention-to-treat principle. The study protocol (clinical trials identifier number 11.0995n) has been approved by the local medical ethics committee. Informed consent was obtained from all patients.

Results

Patients

Of the 395 patients who were assessed for eligibility 332 (84%) were excluded (see Figure 1). The remaining 63 patients were randomized in a control group (n = 32) and an intervention group (n = 31). The 2 groups did not relevantly differ for any of the baseline characteristics (see Table 1). During follow-up 1 patient from the intervention group was lost to follow-up.

QOL

As shown in Table 2, there were no significant differences in the RAND-36 scores between groups. In both groups scores on the general health subscale of the RAND-36 remained unchanged. There were no significant differences between the treatment groups for the other RAND-36 subscales and component scores after 3 months.

Glycemic Control, Diabetes Distress, and SMBG

Glycemic control, diabetes-related emotional distress (PAID), and SMBG frequency remained unchanged in both groups after 3 months, without significant differences between the groups. The intervention group reviewed the usability of DBEES with a 77 (14). The median SUS usability score was 72 [34] and the SUS learnability score 100 [0].

Table 1. Baseline Characteristics.

	All patients (n = 63)	Control group (n = 32)	Intervention group (n = 31)
Age (years)	33 [21]	35 [18]	33 [23]
BMI (kg/m^2)	26 ± 4	25 ± 2.9	26 ± 5
Duration DM (years)	17 [16]	15 [14]	18 [17]
HbA1c (mmol/mol)	62 ± 16	64 ± 18	59 ± 14
Sex (male)	40 (63)	20 (61)	20 (65)
Complications			
Retinopathy	16 (25)	7 (21)	9 (29)
Nephropathy	1 (2)	1 (3)	0 (0)
Neuropathy	12 (19)	7 (21)	5 (16)
Highest level of school education completed			
Primary school	2 (3)	1 (3)	1 (3)
Low level	1 (2)	0 (0)	1 (3)
Intermediate level	23 (36)	13 (39)	10 (33)
High school	9 (14)	6 (18)	3 (10)
University	29 (45)	13 (39)	16 (52)
Treatment			
CSII	42 (66)	21 (64)	20 (66)
MDI	22 (34)	11 (33)	11 (36)

Abbreviations: BMI; body mass index; CSII, continuous subcutaneous insulin infusion; DM, diabetes mellitus; MDI, multiple daily injections. Data are presented as n (%), mean (± SD), or median [IQR].

Table 2. Between- and Within- Group Differences.

	Control group (n = 32)			Intervention group (n = 31)			
	Start	3 months	Within group[a]	Start	3 months	Within group[a]	Between groups[b]
Clinical parameters							
HbA1c (mmol/mol)	62 (57, 66)	63 (57, 69)	1 (−4, 6)	61 (57, 65)	63 (58, 67)	1 (−1, 2)	−2 (−6, 5)
SMBG (number/day)		3.8 (1.7)			3.5 (1.8)		
Quality of life							
RAND-36 subscales							
Physical functioning	95 (90, 100)	95 (92, 98)	0 (−3, 3)	100 (95, 105)	95 (90, 100)	0 (0, 0)	0 (−3, 3)
Social functioning	88 (75, 100)	88 (75, 100)	0 (0, 0)	88 (76, 99)	100 (94, 106)	0 (−6, 6)	0 (−6, 6)
Role physical	100 (87, 113)	100 (87, 112)	0 (0, 0)	100 (89, 111)	100 (89, 111)	0 (0, 0)	0 (0, 0)
Role emotional	100 (100, 100)	100 (100, 100)	0 (0, 0)	100 (100, 100)	100(100, 100)	0 (0, 0)	0 (0, 0)
Mental health	84 (78, 90)	80 (76, 84)	0 (−4, 4)	84 (77, 91)	84 (79, 89)	0 (−1, 1)	0 (−4, 4)
Vitality	63 (55, 70)	63 (55, 70)	−5 (−13, 3)	70 (59, 81)	65 (56, 74)	0 (−5, 5)	5 (−4, 14)
Bodily pain	78 (61, 94)	78 (70, 85)	0 (−5, 5)	90 (80, 100)	90 (81, 99)	0 (−8, 8)	0 (−10, 10)
General health	65 (52, 78)	60 (50, 70)	−5 (−10, 0)	70 (59, 81)	60 (53, 67)	−5 (−12, 2)	0 (−8, 8)
Health change	50 (37, 63)	50 (37, 63)	0 (0, 0)	50 (50, 50)	50 (39, 61)	0 (0, 0)	0 (0, 0)
RAND-36 component scores							
Physical	80 (73, 87)	77 (67, 86)	−1 (−7, 5)	84 (76, 92)	83 (76, 91)	−1 (−5, 3)	0 (−1, 1)
Mental	80 (74, 87)	81 (76, 85)	1 (−4, 6)	82 (72, 91)	83 (78, 88)	1 (−3, 4)	−1 (−7, 5)
Problem Areas in Diabetes	14 (9, 20)	15 (11, 19)	0 (−2, 2)	14 (9, 18)	14 (10, 17)	−1 (−4, 1)	−1 (−4, 2)

Abbreviation: SMBG; self-measurement of blood glucose. Data are presented as median (IQR). The 3 months columns show the mean variation at visit 0 and visit 1 with respect to baseline values.
[a]Calculated using the Wilcoxon signed rank test.
[b]Calculated using the Mann–Whitney *U* test.

Discussion

This randomized open-label study showed that using a digital diabetes diary application on the smartphone, neither has influence on the QOL, nor on HbA1c, in patients with T1DM. Although the DBEES smartphone application turned out to be an easy-to-learn and user-friendly application, it had no influence on diabetes-related problems and frequency of self-measurement.

This study is one of the first randomized controlled trials evaluating whether the QOL of T1DM patients improved when a digital diabetes diary was used. A previous randomized study in 130 T1DM patients with an application similar to the DBEES application evaluated HbA1c, weight, and the user-friendliness after 3 and 6 months.[21] No significant changes between the intervention and the control group were found for these variables. In a selection of patients the QOL (using the RAND-36) was tested. A significant improvement between the groups in 4 domains of the RAND-36 was found. However, at baseline the QOL in the intervention group was substantially lower than in the control group. Moreover, this study lacks information about the randomization process. Compared to our study, baseline QOL in the study of Rossi et al was lower. Since a lower baseline QOL makes it easier to observe significant improvements of QOL, this may account for a lack of change in the current study.[21]

Several studies have evaluated the effect of mobile phone applications on HbA1c. Recently a meta-analysis assessing the effects on health status and health-related QOL of computer-based diabetes self-management interventions in patients with T2DM was performed.[22] In the mobile phone subgroup (consisting of 3 trials with 280 participants) HbA1c decreased by −5.5 mmol/mol (95% CI −7.7 to −3.3). Also in this meta-analysis no effect was found on QOL. Another meta-analysis focusing on the effect of mobile phone interventions for diabetes on glycemic control reported a similar reduction of HbA1c values of a median follow-up period of 6 months.[9] The fact that in our study no effect on HbA1c was found may well be explained by the short follow-up time of the study. Furthermore, our study population already had a rather low baseline HbA1c, limiting further improvement. The same phenomenon could account for the absence of changes in QOL.

This is one of the few randomized controlled trials that primarily focused on the effect of the use of a digital diabetes diary mobile phone application on QOL. The open character of the study may have induced observer bias. A double-blind setup was unfortunately practically not feasible. Moreover, selection bias occurred since participants had to have a smartphone, and therefore a young study population was selected.

Based on the results of this study it can be concluded that after 3 months of using the DBEES applications, no changes in QOL were found between the intervention and the control groups. Also HbA1c and frequency of self-control did not change after 3 months. However, participants experienced the DBEES application as a good and simple way to record and track medical information related to their diabetes and an easy way to communicate with the diabetes nurses. An inconvenience of the use of the DBEES application according to the participants was that they had to enter all the diabetes-related information themselves in the application. Nowadays, a direct connection between smartphone and glucose meter can be made. Further research should focus on more advanced diabetes applications that enable, for example, carbohydrate estimations and linkages to other devices (eg, CSII or a continuous glucose sensor) or applications (health care software) than the currently used DBEES application, which was a high-end application at the time of study. In addition, future studies should be performed in larger groups with a longer follow-up to demonstrate what the advantages and disadvantages of using mobile phone applications are on the QOL of patients with diabetes.

Conclusions

Although T1DM patients experienced the use of a digital diabetes diary application on their smartphone to be easy and user-friendly, it had no influence on frequency of their SMBG, QOL, and glycemic control.

Abbreviations

CIPII, continuous intraperitoneal insulin infusion; CSII, continuous subcutaneous insulin infusion; MCS, mental component summary; MDI, multiple daily injections; PAID, Problem Areas in Diabetes questionnaire; PCS, physical component summary; QOL, quality of life; SMBG, self-monitoring of blood glucose; SUS, System Usability Scale; T1DM, type 1 diabetes mellitus.

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Declaration of Conflicting Interests

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