

Effectiveness of mHealth management with an implantable glucose sensor and a mobile application among Chinese adults with type 2 diabetes

Journal of Telemedicine and Telecare
0(0) 1–9
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DOI: 10.1177/1357633X211020261
journals.sagepub.com/home/jtt



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Abstract

Introduction: This study aimed to evaluate the effectiveness of mHealth management with an implantable glucose sensor and a mobile application among patients with type 2 diabetes mellitus (T2DM) in China.

Methods: A randomised controlled trial was carried out to compare the effectiveness of usual health management to mHealth management based on a model that consisted of the network platform, an implantable glucose sensor and a mobile app featuring guidance from general practitioners (GPs) over a four-week period. Patients ($N=68$) with T2DM were randomly divided into an intervention group and a control group. Before the intervention, there was no difference in body mass index (BMI), fasting blood glucose (FBG), postprandial two-hour blood glucose (2hPG) and glycosylated haemoglobin (HbA1c) between the intervention group and the control group ($p>0.05$). Patients in the control group received their usual health management, while patients in the intervention group received mHealth management.

Results: After health management, the mean BMI, FBG, 2hPG and HbA1c of the intervention group patients were all lower than those of the control group patients ($p < 0.05$), and the quality of life and self-management of the intervention group patients had significantly improved.

Discussion: mHealth management effectively showed significant reductions in BMI, FBG, 2hPG and HbA1c and improved quality of life and self-management among patients, which may be related to real-time feedback from an implantable glucose sensor and guidance from GPs through a mobile app. mHealth management is a very promising way to promote the health management of T2DM in China, and this study provides a point of reference for mHealth management abroad.

Keywords

Mobile health, type 2 diabetes, real-time monitoring, personalised health management, effect evaluation

Date received: 26 February 2021; Date accepted: 23 April 2021

Introduction

With the improvement of Chinese people's living standards and changes in lifestyle, China now has the most adult diabetics in the world, and this is predicted to increase to 120 million by 2045,¹ indicating a tremendous public health burden in China.² Patients with type 2 diabetes mellitus (T2DM) account for the vast majority of those with diabetes. Studies have shown that lifestyle changes (diet and exercise) can cause blood glucose fluctuations, and unhealthy lifestyles (e.g. high-sugar and high-oil diets, lack of exercise, etc.) are closely associated with an increased risk of

T2DM.^{3,4} So, T2DM is known as a disease caused by an unhealthy lifestyle. Therefore, in addition to drug treatment, lifestyle intervention is a key factor in the

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treatment of T2DM and a key part of out-of-hospital T2DM health management.⁵

In China, usual out-of-hospital T2DM health management adopts a telephone follow-up once a week and gives out public health education material about T2DM. However, such an approach is generic and does not provide a personalised health intervention. With the development of artificial intelligence and mobile technology, mobile health (mHealth) has been developed. mHealth is defined by the World Health Organization as health services supported by mobile technologies and devices including mobile phones, wearable devices, sensors and mobile applications (apps).⁶ In 2018, the Chinese government officially released a document entitled 'The Opinions on Promoting the Development of Internet+Medical and Health', which proposed the need to accelerate the construction of an mHealth management pilot based on artificial intelligence technology and medical intelligent devices.⁷ Hence, real-time monitoring and personalised health management for chronic diseases are becoming increasingly possible in China.

Real-time monitoring of blood glucose is very important for diabetes health management. The world's first continuous glucose monitoring (CGM) product was approved by the US Food and Drug Administration in 1999.⁸ In recent years, many innovative and practical CGM technologies have emerged. CGM products can provide comprehensive and continuous blood glucose information throughout the day, reflecting the fluctuation trend of blood glucose with changes in lifestyle (diet and exercise), which has great value in out-of-hospital lifestyle interventions.⁹

At present, the mHealth management of T2DM mainly adopts a single approach of transmitting health education and intervention programmes through an app^{10,11} and mobile phone text messages.^{12,13} During this process, the intervention plan is not adjusted according to the real-time changes in blood glucose, which often fluctuate based on changes in blood glucose and body mass index (BMI) over time.¹⁴ In addition, most T2DM intervention programmes adopt a general model, which often leads to a decrease in patient compliance, thereby reducing the effectiveness of the intervention.¹⁵

This study designed a mHealth management model that consisted of the network platform, a mobile app and an implantable glucose sensor that was supported by general practitioners (GPs). The GPs could adjust the intervention programmes in real time according to each patient's dynamic blood glucose changes. In addition, before the health intervention, this study collected patients' diet and exercise preferences and selected suitable food and exercise to formulate appropriate health intervention programmes, which greatly improved

patient compliance. The patients themselves were also able to observe the changes in blood glucose, which increased their self-confidence and sense of self-efficacy in health management. To evaluate the effectiveness of the mHealth management model for T2DM, we conducted a randomised study with a control group among patients with T2DM in a general hospital in Hangzhou City, Zhejiang Province, PR China.

Methods

Study design

This was a parallel-group, two-arm randomised controlled pilot trial to assess the feasibility and to compare the effectiveness of a four-week mHealth intervention to usual health management for patients with T2DM. The trial groups were parallel in the sense that members of each cohort received only the allocated management without any crossovers. All procedures were approved by the Institutional Review Board of the Affiliated Hospital of Hangzhou Normal University (protocol code: 20190081).

Participants

The formula for calculating the sample size, $n = \left[(\mu_{\alpha}^2 + \mu_{\beta}^2) \sigma^2 \right] / \delta^2$, was adopted, where $\alpha=0.05$ and $\beta=0.01$. We referred to the glycosylated haemoglobin (HbA1c) of the preliminary experiment, where $\sigma=1.496$ and $\delta=0.923$. Finally, this study calculated $n_1=n_2=28$. Considering that some participants may be lost to follow-up, the sample size was expanded by 20%, and the sample size was finally determined to be 68. A total of 68 patients with T2DM were randomised by selection from a general hospital in Hangzhou City, Zhejiang Province, by GPs and were randomly divided into an intervention group and a control group. Participants were required to meet all the following criteria: (a) >18 years old and <75 years old; (b) be awake, alert, and responsive to stimuli; (c) no cognitive impairment; (d) able to complete the questionnaire independently; (e) able to understand mHealth management methods; (f) able to operate the mobile app correctly; and (g) gave informed consent. Patients were excluded if they (a) suffered from severe diabetic complications, (b) had difficulty communicating with others and (c) had any neurological conditions.

Intervention programme

The health management period for the two groups was four weeks.

Intervention group

Patients in the intervention group received mHealth management based on the mHealth management model that consisted of the network platform, an implantable glucose sensor, a mobile app and GP support. The specific model is shown in Figure 1.

First, the implantable glucose sensor was subcutaneously implanted to enable patients to monitor their blood glucose at any time. It could be used continuously for 14 days before the power ran out. The health management period was four weeks. So, on the 15th day, a second sensor was subcutaneously implanted and the first sensor was removed. The blood glucose values were automatically transmitted to the processor to produce a dynamic trend graph of the blood glucose values.

Second, both patients and GPs downloaded the mobile app. For patients, the app included four functional modules: (a) fill in the health information, (b) obtain real-time blood glucose values and a dynamic trend graph, (c) communicate with a GP and (d) obtain personalised intervention programmes. For GPs, the app included three functional modules: (a) obtain real-time information from patients and the processor, (b) fill in personalised intervention programmes for patients and (c) communicate with patients.

Third, the patients filled in the health information retrospectively at any time of the day, such as body weight, favourite food and exercise, diet conditions (the types and amounts of food they eat and cooking methods), exercise conditions (exercise type, time and feelings during exercising). The GPs were advised to urge patients to complete the records online daily in

order to ensure all information was recorded on the actual day rather than retrospectively.

Fourth, the processor combined the dynamic trend graph with the information on lifestyle changes to analyse the causes of any blood glucose fluctuations. If the blood glucose fluctuated wildly, the processor could analyse the types and amounts of food that the patient had consumed within two hours before the fluctuation and combine this with previous data to propose which food or which foods could cause such changes. The processor could then remind GPs and the patient that the food could seriously affect the patient's blood glucose. Therefore, once it was confirmed that a particular food caused dramatic changes to a patient's blood glucose, that food could be excluded from the patient's subsequent food table. Furthermore, the kinds of food that caused acceptable changes to the patient's blood glucose could be recommended. The same applied to exercise.

Finally, GPs received real-time information from patients and the processor in order to formulate personalised intervention programmes for their patients. The personalised intervention programmes were automatically transmitted to the patient through the mobile app, which comprised a dietary intervention programme, an exercise intervention programme and a health education programme. Before the dietary intervention programme was formulated, the processor calculated the total calorie intake per day according to the patient's somatotype, standard weight and physical activity and calculated the ratio of carbohydrate, protein and fat for each meal according to the calorie ratio of the three meals in order to control weight. Then,

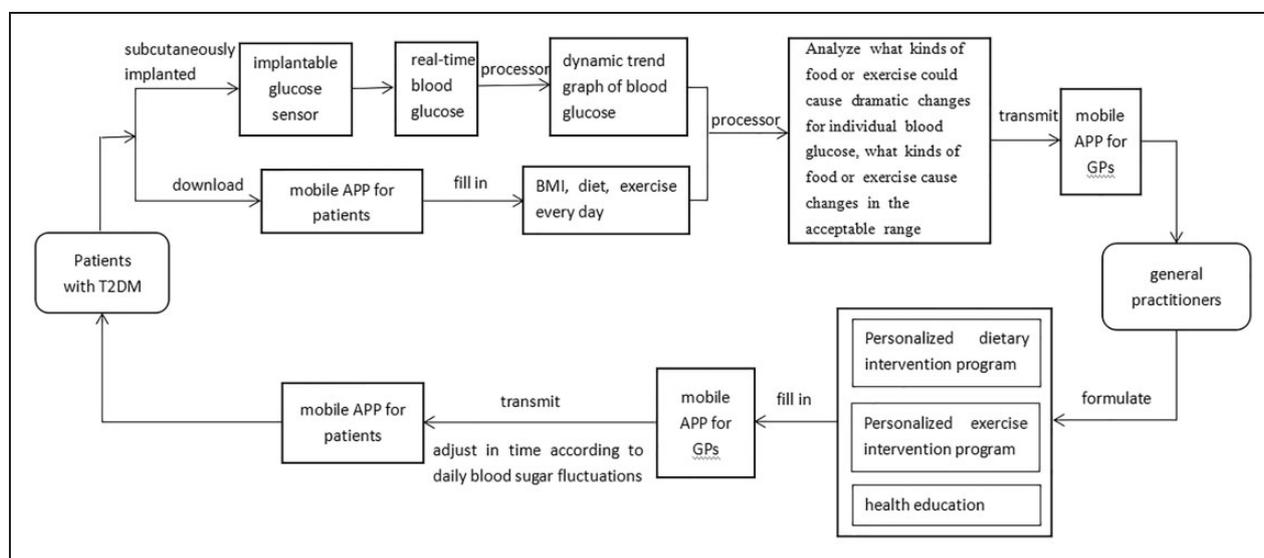


Figure 1. mHealth management model. T2DM: type 2 diabetes mellitus; app: application; GP: general practitioner; BMI: body mass index.

GPs combined the food glycaemic index, the total calories and the patient's diet preference distribution table to formulate a personalised dietary intervention programme. When formulating the exercise intervention programme, GPs first fully assessed the physical state of the patient, especially the assessment of cardiopulmonary function and the condition of the feet. Exercise needed to be done according to patient ability for those with weak cardiopulmonary function. They were advised that they should not feel panic, angina pectoris, dyspnoea or general discomfort while exercising. To prevent foot injury, patients were advised to wear soft shoes with slightly thick soles. Then, according to the patient's physical condition and exercise preference, GPs formulated an exercise intervention programme which involved exercising at least five times a week for 30 minutes each time. Health education was carried out once a week for 55–65 minutes each time via a video or voice call. The most important aspect of the model was to observe blood glucose fluctuations in real time in order to adjust the programmes every day.

Control group

Patients in the control group received their usual health management. First, GPs conducted telephone follow-ups once a week to obtain patients' blood glucose values and urged patients to go to the outpatient clinic for their review on time. Then, public health education material for T2DM were given out at the follow-up visits to increase relevant knowledge about T2DM. The materials comprised four themes, including basic knowledge of T2DM, reasonable diets for T2DM, exercise therapy for T2DM and the prevention of T2DM complications.

Effect evaluation indicators

The indicators used to evaluate the effectiveness of the intervention included BMI, fasting blood glucose (FBG), postprandial two-hour blood glucose (2hPG), glycosylated haemoglobin (HbA1c), quality of life and self-management ability. A basic information questionnaire for T2DM was used to collect objective information, including name, age, sex, height, weight, diabetes course, FBG, 2hPG, HbA1c and so on. The Diabetes Specific Quality of Life (DSQL) is a self-reported quality-of-life score with good validity, reliability and responsiveness, indicating that the score can be used to evaluate the quality of life of patients with T2DM.¹⁶ The DSQL includes four dimensions – physical function, mental health, social relations and the influence of treatment – with a total of 27 items. It is scored with a Likert five-point method, and scores range from 27 to 135, with lower scores indicating a

better quality of life. The Summary of Diabetes Self-Care Activities Measure (SDSCA) is used to evaluate patient self-management. The scale consists of 11 items, including five dimensions on diet, exercise, blood glucose monitoring, foot care and smoking.¹⁷ Response choices range from 0 to 7, with higher scores indicating better self-management ability.

Statistical analysis

All analyses were performed using IBM SPSS Statistics for Windows v20.0 (IBM Corp., Armonk, NY). Categorical variables are displayed as using frequencies and percentages. Continuous variables are presented as means and standard deviations. The chi-square test was used for quantitative variables. Before analysing the difference in the scores on the two scales between the control group and the intervention group, the Shapiro–Wilk method was used to do normality plots with tests. The results showed that the data conform to the normal distribution (DSQ: $p=0.534>0.05$; SDSCA: $p=0.430>0.05$). The independent samples *t*-test was used to analyse the changes between the control and intervention groups. *p*-Values <0.05 were considered as significant.

Results

Analysis of the basic situation of the two groups

The final sample was composed of 64 patients. Two people were lost to follow-up in each of the intervention group and the control group. The baseline demographic characteristics of the two groups are shown in Table 1. The two groups were observed to be homogeneous in terms of sex, education, marital status and average monthly income. The difference was not statistically significant ($p>0.05$; Table 1).

The results of age, BMI, FBG, 2hPG, HbA1c, quality of life and self-management ability between the two groups before the intervention are shown in Table 2, and the difference was not statistically significant ($p>0.05$).

Comparison of the effects of the intervention

After the intervention, the BMI of the intervention group was significantly lower than that of the control group, and the difference was statistically significant ($p<0.05$; see Table 3). There were significant differences in FBG, 2hPG and HbA1c between the two groups. The blood glucose-related indicators of the intervention group were significantly lower than those of the control group ($p<0.05$; Table 3).

The quality-of-life scale scores for the intervention group were significantly lower than those for the

Table 1. Baseline characteristics of the two groups of participants.

Variable		Control group (N = 32)	Intervention group (N = 32)	χ^2	p
Sex	Male	16 (50.00)	23 (71.88)	1.391	0.238
	Female	16 (50.00)	9 (28.13)		
Education level	Junior high school and below	23 (71.88)	21 (65.63)	5.075	0.280
	High/technical secondary school	4 (12.50)	6 (18.75)		
	College degree and above	5 (15.63)	5 (15.63)		
Marital status	Single	3 (9.38)	3 (9.38)	3.758	0.440
	Married	23 (71.88)	26 (81.25)		
	Divorced/widowed	6 (18.75)	3 (9.38)		
Monthly income (RMB)	≤2000	7 (21.88)	7 (21.88)	10.915	0.815
	2001–4000	3 (9.38)	2 (6.25)		
	4001–6000	3 (9.38)	4 (12.50)		
	6001–8000	16 (50.00)	15 (46.88)		
	≥8001	3 (9.38)	4 (12.50)		

Table 2. Objective indicators, quality of life and self-management of the two groups before the management.

Variable	Control group (N = 32)	Intervention group (N = 32)	t	p
Age (years)	59.46 ± 14.59	55.25 ± 13.80	1.186	0.240
BMI (kg/m ²)	24.32 ± 3.14	24.00 ± 3.13	0.408	0.684
FBG (mmol/L)	8.11 ± 1.41	7.81 ± 1.77	0.750	0.456
2hPG (mmol/L)	9.62 ± 1.63	9.51 ± 1.42	0.228	0.774
HbA1c (%)	9.14 ± 1.96	8.97 ± 2.12	0.333	0.740
Quality of life	54.87 ± 14.32	53.24 ± 9.72	0.533	0.596
Physiological condition	21.34 ± 6.65	22.36 ± 6.49	-0.621	0.537
Psychological condition	21.13 ± 5.63	19.84 ± 4.18	1.041	0.302
Social relationship	7.28 ± 3.62	6.13 ± 1.58	1.647	0.105
Influence of treatment	5.13 ± 1.82	5.03 ± 1.94	0.213	0.832
Self-management	35.31 ± 9.46	36.81 ± 10.66	-0.595	0.554

BMI: body mass index; FBG: fasting blood glucose; 2hPG: postprandial two-hour blood glucose; HbA1c: glycosylated haemoglobin.

Table 3. Objective indicators between the two groups of patients after intervention.

Variable	Control group (N = 32)	Intervention group (N = 32)	t	p
BMI (kg/m ²)	24.08 ± 4.18	22.12 ± 2.35	2.312	0.024
FBG (mmol/L)	7.84 ± 1.83	6.59 ± 1.03	3.367	0.001
2hPG (mmol/L)	9.18 ± 1.36	8.46 ± 1.28	2.181	0.033
HbA1c (%)	9.05 ± 1.88	7.81 ± 2.04	2.529	0.014

control group ($p < 0.05$; Table 4), meaning that the intervention group had better improvements in quality of life. In some dimensions of quality of life, including psychological condition, social relationship and the influence of treatment, patients in the intervention group scored significantly lower than those in the control group, meaning the intervention group improved

significantly in the three dimensions of quality of life ($p < 0.05$). In the physiological condition dimension, the difference in scores between the two groups was not statistically significant ($p > 0.05$; Table 4).

The patients in the intervention group had higher scores in the five dimensions of self-management than those in the control group, meaning that the

Table 4. Quality of life between the two groups after intervention.

Dimension	Control group (N = 32)	Intervention group (N = 32)	t	p
Quality of life	53.28 ± 10.55	42.34 ± 10.01	4.255	<0.001
Physiological condition	20.34 ± 8.02	17.50 ± 7.98	1.420	0.161
Psychological condition	20.47 ± 5.45	16.50 ± 4.13	3.284	0.002
Social relationship	7.44 ± 3.39	4.47 ± 0.81	4.820	<0.001
Influence of treatment	5.03 ± 1.94	3.88 ± 0.87	3.060	0.003

Table 5. Self-management of the two groups after intervention.

Dimension	Control group (N = 32)	Intervention group (N = 32)	t	p
Self-management	39.69 ± 8.32	55.69 ± 6.74	-8.453	<0.001
Diet	17.20 ± 5.47	20.25 ± 4.82	-2.367	0.021
Exercise	7.88 ± 2.24	9.88 ± 2.24	-3.668	0.001
Blood glucose monitoring	8.01 ± 2.32	11.13 ± 1.92	-5.861	<0.001
Foot care	4.43 ± 2.66	9.53 ± 3.06	-7.115	<0.001
Smoke	2.71 ± 2.18	4.91 ± 2.08	-4.130	<0.001

intervention group had better improvements in self-management ability. The difference was statistically significant ($p < 0.05$; Table 5).

Discussion

Effect of mHealth management on the BMI of patients with T2DM

After four weeks of health management, the mean BMI of the intervention group decreased and was lower than that of the control group, which was similar to previous mHealth studies.¹⁸ The reasons for the decrease of BMI value may be related to the personalised dietary intervention programme and real-time interactive health management.

BMI is widely used as a measure of weight status and disease risk, and a high BMI is one of the important risk factors related to T2DM. Studies have found that BMI is correlated with abnormal lipid metabolism and the incidence of chronic diseases.^{19–21} Therefore, individualised intervention in the lifestyle of patients with T2DM to control their BMI is conducive to the control of the deterioration of T2DM, among which dietary intervention is the most important measure. In order to control weight, the processor calculated the ideal amount of calorie intake per day according to the patient's somatotype, standard weight and physical activity and formulated the ratio of carbohydrate, protein and fat for each meal according to the calorie ratio of the three meals before the dietary intervention programme was formulated. However, the patients in routine health management did not receive a personalised recommendation for the nutrients ratio and

were not able to have real-time interactive communication with a GP. Hence, the BMI of the intervention group was significantly reduced after four weeks of intervention.

Effect of mHealth management on related indicators of glucose metabolism in patients with T2DM

After health management, the mean FBG, 2hPG and HbA1c of the intervention group were lower than those of the control group, as previously reported in other mHealth research.^{22–24} For T2DM, lifestyle intervention is key for out-of-hospital health management. mHealth management supported by an implantable glucose sensor and a mobile APP increased the accessibility of lifestyle interventions, which can be used in out-of-hospital health management for patients with T2DM. The personalised intervention programmes included a diet programme and an exercise programme, which were successful in intervening in the patient's lifestyle. In the implementation of the intervention programme, the intervention effect was reflected in time through the implanted blood glucose sensor, which strengthened patient compliance. Good compliance is an important guarantee for improving the effectiveness of health management for patients with T2DM.²⁵

The most important intervention in diabetes is dietary intervention. Therefore, the highlight of this study was collecting the favourite diet of each patient before making the dietary intervention programme. Then, based on the real-time feedback of blood glucose, any food that seriously affected blood glucose fluctuation was eliminated, and food that caused an acceptable fluctuation in blood glucose was recommended. Finally, GPs combined the food glycaemic index, the

total calories and the patient's dietary preference distribution table to formulate a personalised dietary intervention programme that not only effectively implemented health management but also improved patient compliance. Therefore, after four weeks of mHealth management, the blood glucose-related indicators in the intervention group were lower than those in the control group.

Effect of mHealth management on quality of life in patients with T2DM

As a lifelong disease with a long course and high recurrence rate, there is not yet a radical cure for diabetes. Therefore, to evaluate the effect of health management, it is more suitable to use quality of life than the cure rate.²⁶ After four weeks of health management, the quality of life of patients in both groups had improved. However, the scores of patients in the intervention group were significantly higher than those in the control group. The results of the study were consistent with the results of existing domestic studies.^{27–29}

In this study, mHealth management included the ability for GPs and patients to communicate interactively in real time. The blood glucose values collected by the implantable glucose sensor could be automatically transmitted to the mobile app, thereby enabling information sharing. This alleviated problems with the shortage of medical resources, poor communication between GPs and patients and insufficient monitoring.²⁷ GPs could check patients' blood glucose fluctuations and supervise the implementation of patients' intervention programmes through the mobile app, which reduced fluctuations in blood glucose and prevented complications. At the same time, video, voice, pictures and other forms of information on T2DM diet, exercise, medicine and emotion management could be sent to improve the knowledge and skills of patients and eliminate their fear of the disease. GPs could conduct online Q&A and health knowledge live classes for patients, which strengthened humanistic care and enhanced doctor-patient communication. This mHealth management model could effectively improve the quality of life of patients with T2DM through comprehensive, multilevel and multidimensional interventions.

Effect of mHealth management on the self-management of patients with T2DM

After the health management, the self-management ability of the intervention group showed a more significant improvement than the control group, which was similar to previous investigations,³⁰ proving mHealth

management can more effectively improve patients' self-management behaviour.

Relevant studies have shown that awareness of diseases and active participation in disease health management are key factors affecting disease control.³¹ The mobile app of patients in the intervention group regularly reminded patients to record information on time, which helped patients to develop good living habits consciously. Twenty-one days is the habit-forming period. So, this study formulated a four-week health management period, which included a 21-day habit-forming period and a seven-day habit-consolidating period. Moreover, in the process of mHealth management for patients with T2DM, GPs carried out health education for patients and checked their learning effect four times in order to improve their awareness of disease development, complications, risk factors of the disease, compliance with treatment and being conscious of monitoring blood glucose. This kind of continuous mHealth management model that penetrates into patients' lives can effectively promote a good lifestyle and improve self-management behaviour.

There are several limitations to this study. First, patients were recruited from a tertiary A hospital in Hangzhou, Zhejiang Province. Therefore, these patients cannot represent all patients with T2DM in the country, which affects the transferability of the results. Second, the sample size of this study was 68 people, and so the sample size needs to be increased to improve the credibility of the results.

Conclusions

The results show significant reductions in BMI, FBG, 2hPG and HbA1c and an improvement in patients' quality of life and self-management ability. These positive effects may be closely related to real-time feedback from an implantable glucose sensor and personalised guidance from GPs. This promotes the cognition and compliance of T2DM patients and helps them acquire self-health management experience quickly. mHealth management makes it easy to obtain timely and effective out-of-hospital health management for T2DM because it is not limited by time and space. So, it not only improves the accessibility of lifestyle interventions but also promotes patients to improve their lifestyles over time. In summary, mHealth management based on the proposed model is a very promising way to promote the health management of T2DM in China and provides a point of reference for mHealth management abroad.

Acknowledgements

The authors are grateful to the Diabetes Health Education Group, whose members provided support for the recruitment

of participants, running of the community assessment clinic and biochemistry measurements. The authors would like to thank and acknowledge all the members for contributing to this work.

Declaration of conflicting interests

The authors declared no potential conflicts of interest with respect to the research, authorship and/or publication of this article.

Funding

The authors disclosed receipt of the following financial support for the research, authorship and/or publication of this article: This research was funded by Guozhen Health Technology (Beijing) Co., Ltd (grant number (2019)JY102).

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