

WeChat in the control of blood glucose in diabetic patients

Submission date 31/10/2017	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results <input type="checkbox"/> Individual participant data
Registration date 25/12/2017	Overall study status Completed	
Last Edited 11/04/2019	Condition category Nutritional, Metabolic, Endocrine	

Plain English summary of protocol

Background and study aims

Diabetes is a condition that causes high blood sugar levels over a prolonged period. Type 2 diabetes mellitus (T2DM) begins with insulin resistance, a condition in which cells fail to respond to insulin properly. The most common cause is excessive body weight and insufficient exercise. The prevalence of T2DM has been becoming a global health problem. China has a fairly large proportion (approximately 25%) of diabetes patients in the worldwide. In China, the prevalence of diabetes has increased by 9.7%, which was accounted for 92.4 million adults. The direct economic burden of diabetes had increased in China in the past decades and the direct medical cost had reached to \$9.1 billion. People with diabetes need to learn and maintain lifelong self-management behaviors, such as self-care activities associated to health care and daily life. Studies show that effective patient education might provide adequate information, support and monitoring that contribute to improve patients' adherence, which in turn, decreases the burden of diabetes chronic complications and improving the quality of life for diabetes patients. Wechat had become the most popular messaging communication app in China, which had a monthly-active-user of 549 million. Wechat platform has been implicated to solve the problems of prehospital electrocardiogram remote transmission and prehospital clinical data recording for ST-segment elevation myocardial infarction care. The aim of this study is to assess the effectiveness of health education on diabetes patients via Wechat platform on increased the basic self-care skills in patients with type 2 diabetes.

Who can participate?

Adults aged 18 to 60 years old who are diagnosed with T2DM.

What does the study involve?

Participants are randomly allocated to one of two groups. Those in the first group receive the usual care. Those in the second group receive the health education via the Wechat platform plus the usual care. Participants are followed up with blood tests and questionnaires to measure their insulin levels and self-efficacy abilities at six and 12 months.

What are the possible benefits and risks of participating?

Participants may benefit from improvements in adhering to a healthier lifestyle. Participants may experience discomfort when providing blood tests.

Where is the study run from?
The Second Affiliated Hospital of Hainan Medical University (China)

When is the study starting and how long is it expected to run for?
June 2015 to June 2019

Who is funding the study?
The Second Affiliated Hospital of Hainan Medical University (China)

Who is the main contact?
Mr Yonghui Dong

Contact information

Type(s)
Public

Contact name
Mr Yonghui Dong

ORCID ID
<http://orcid.org/0000-0002-0534-3868>

Contact details
Department of Orthopedics
Henan Provincial People's Hospital
Henan
Zhengzhou
China
450003

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Text message elevated awareness of self-care activities and glycemic control rate via Wechat among diabetes patient

Study objectives

Positive effectiveness of health education on diabetes patients via Wechat platform on increased the basic self-care skills in patients with type 2 diabetes.

Ethics approval required

Old ethics approval format

Ethics approval(s)

the Second Affiliated Hospital of Hainan Medical University, 02/10/2015, ref: 2015-037

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Home

Study type(s)

Prevention

Participant information sheet

No participant information sheet available

Health condition(s) or problem(s) studied

Diabetes

Interventions

Diabetic patients are randomly classified to either the control (n=60) and intervention (n=60) group by using a set of 120 random numbers, according to 1:1 ratio.

The hospitalised patients of intervention(n=60) group receive conventional health education and nursing care for diabetes and are also guided by the Wechat platform.

The participants of control group receive conventional health education and nursing care for diabetes alone.

The baseline information on social and demographic characteristics (including age, gender, and educational attainment level), personal medical and lifestyle (such as active physical activity) are collected by trained nurse of our department using the questionnaires. Self-care activities are assessed according to a self-administered scale which is consisted of 21 diabetic items and divide into six self-management behaviors (general and specific diet, medication taking, exercise, blood sugar testing, foot care, and smoking). The diabetes self-care activities are asked diabetic individuals during past seven days. If individuals are sick during past seven days, they are asked to recall seven days that they not sick. Nonsmokers scored 0, smokers scored 1; Score was calculated by individuals spend days during past seven day on question of exercise, medication, monitoring of BG score, foot care relative items. If they spent 0, 1, 2, 3, 4, 5, 6 or 7 days on the questions of self-care activities, they scored 0, 1, 2, 3, 4, 5, 6 or 7. Additionally, other

related to self-care recommendations from health care professionals' items are also included. Participants are followed up at six and 12 months.

Intervention Type

Behavioural

Primary outcome measure

1. HbA1c concentration is measured using the blood samples at six and 12 months
2. Self-Efficacy is measured using the Diabetes Management Self-Efficacy Scale questionnaire at six and 12 months

Secondary outcome measures

FPG and 2hPG is measured using blood samples at six and 12 months

Overall study start date

05/06/2015

Completion date

01/01/2018

Eligibility**Key inclusion criteria**

1. They were diagnosed type 2 diabetes by physicians according to World Health Organization (WHO) criteria
2. Aged 18-60 years
3. Possessed a mobile phone
4. Consented to receive text messages
5. Have the ability to read text messages
6. Voluntarily to participate in this study

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Upper age limit

60 Years

Sex

Both

Target number of participants

120

Key exclusion criteria

1. Diagnosed type 1 diabetes
2. Specific diabetes
3. history of serious diseases such as renal or hepatic insufficiency
4. Severe visual impairment
5. Psychiatric diseases
6. Other endocrine diseases

Date of first enrolment

12/01/2017

Date of final enrolment

01/06/2017

Locations

Countries of recruitment

China

Study participating centre

The Second Affiliated Hospital of Hainan Medical University

Henan

China

570311

Sponsor information

Organisation

Henan Provincial People's Hospital

Sponsor details

Zhengzhou 450003

Henan

Zhengzhou

China

450003

+86 18062559875

dongyonghuitjmu@gmail.com

Sponsor type

Hospital/treatment centre

ROR

<https://ror.org/03f72zw41>

Funder(s)

Funder type

University/education

Funder Name

The Second Affiliated Hospital of Hainan Medical University

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer reviewed journal.

Intention to publish date

01/01/2019

Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary

Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/12/2018	11/04/2019	Yes	No