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Effects of community family doctors-led intervention for self-management and medication adherence in type 2 diabetes mellitus patients: study protocol of a cluster randomised controlled trial

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ABSTRACT

Introduction The management of diabetes has become a critical public health issue in China. The development of community-based type 2 diabetes management in China has not yet reached an ideal state, and the most suitable management methods for diabetic patients are still being explored. Few studies have used community-based family doctors to perform interventions of appropriate intensity. This protocol describes a planned randomised controlled trial to evaluate the effectiveness of a family doctor-led intervention model for diabetes self-management and medication adherence in type 2 diabetes mellitus patients.

Methods and analysis This is a Standard Protocol Items: Recommendations for Interventional Trials-compliant cluster randomised controlled trial. The study will be conducted at four CHCs (community health centers). The control group will receive conventional medical services and health education. The intervention group will receive an intervention led by community family doctors based on the conventional medical services and health education. It will include five parts: usual care, a medication reminder, a 4-week plan, a weekly phone interview and a monthly interview. The primary outcomes are changes in fasting blood glucose, glycosylated haemoglobin, self-management knowledge and behaviour, and medication adherence from baseline to the 3rd and 6th months. The secondary outcome is the proportion of people whose blood sugar and glycosylated haemoglobin are under control in the 3rd and 6th months.

Ethics and dissemination The study proposal was approved by the Biomedical Ethics Committee of the Medical Department of Xi'an Jiaotong University (no. 2021-1371). The findings will be published in peer-reviewed journals and presented at scientific conferences.

Trial registration number Chinese Clinical Trial Registry, ChiCTR2100051685.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ The intervention will last for only 6 months. It may therefore improve the knowledge of diabetic patients in the community, but may not be long enough to change their attitudes and behaviours.
⇒ This is the first study in the Shaanxi province to investigate the effects of a community family doctor-led intervention for self-management and medication adherence in type 2 diabetes mellitus patients.
⇒ Time limitations, the burden of responsibility and insufficient funds mean that the research will be conducted in only one city, so the generalisability of the findings will be limited.

BACKGROUND

Diabetes mellitus is one of the three most prevalent chronic non-infectious diseases in the world.[1] Patients often require lifelong therapy, and have varying degrees of quality of life, putting financial strain on them and the healthcare system.[2–4] Diabetes affects more than 537 million people globally, and its prevalence is increasing in many countries: the number affected is predicted to rise to 783 million by 2045.[5] China has the world's largest number of diabetes cases, and this figure is still rising.[5–7] The management of diabetes has therefore become a critical public health issue in China.[8] China has long aimed to build a community-based primary health system that would allow patients to receive basic and low-cost healthcare.[9] Currently, 87% of diabetes patients in China are treated in primary care,[10] and community diabetes management is an important element in the diabetes care system.

In 2011, the Chinese government proposed the establishment of a family doctor contract system.[11] General practitioners, community nurses, public health doctors and specialist doctors form a family doctor team. After signing contracts with residents, family doctors provide patients with basic medical care and Appointment Health Management

Services.[12] A number of studies have confirmed that type 2 diabetes can be well controlled through contracting with family doctors to provide treatment. The risk of complications and the medical burden can be reduced.[13–15] However, community-based type 2 diabetes management in China has not yet reached an ideal state, and the most suitable methods are therefore still being explored. The overall quality and ability of family doctors are also fairly low,[16 17] as is the level of service provision, and there are still gaps compared with services provided by tier-2 and tier-3 hospitals. Studies have shown that the control rate of diabetes in the community is still poor.[18–20] The diabetes management work of community family doctors therefore needs to be improved and strengthened.

Individuals with chronic diseases frequently forget to take their medication. Studies report that 20%–50% of chronically ill patients do not adhere to medication prescriptions.[21 22] People with diabetes also often have difficulty adhering to healthcare provider guidelines. Studies have found widely different medication adherence among patients with diabetes, but levels are generally poor.[23–25] In China, some studies suggest that more than 45% of patients with poor medication adherence[26 27] have poor knowledge and forget to take their medication. Medication reminders are therefore an important part of our intervention programme. A meta-analysis about text message intervention showed that daily reminders may lead to response fatigue and possible intrusion, and showed smaller effects than interventions that messaged several times a week or weekly. In Xi'an, an intervention programme with weekly medication reminders for hypertensive patients showed significant improvements.[28]

In the past, some type 2 diabetes interventions in the community have involved a team of doctors from tier-3 hospitals.[29] These interventions can deliver short-term effects, but patients frequently no longer receive any education or guidance following the short-term intervention. The economic cost is therefore large and only short-term effects are achieved. It is impossible to carry out long-term and continuous intervention. It is therefore essential to find a way to combine health education, drug treatment, diet and exercise guidance, and blood glucose monitoring that fits local conditions, as well as to explore a new and effective method of diabetes management in grassroots communities.

Few studies use community-based family doctors to perform interventions of appropriate intensity.[30–32] There are few reports on interventions among diabetic patients in the community of Xi'an, Shaanxi province, and diabetes management is an urgent grassroots health problem in that area.

This protocol is for a randomised controlled trial to evaluate the effectiveness of a family doctor-led intervention model for diabetes self-management and medication adherence in type 2 diabetes mellitus (T2DM) patients. The aim of this study is to improve the self-management ability and medication adherence of diabetic patients, and to improve the indicators of diabetes, especially the value of glycated haemoglobin (HbA1c). If the intervention is effective, we will be able to provide intervention models to government departments and help them to develop educational guidelines for patients, to improve medication adherence and self-management skills, as well as strengthen community diabetes management.

METHODS

Study design

This is a Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT)-compliant cluster randomised controlled trial. The trial has not yet started. We plan to start recruiting patients in August 2022 and expect to complete enrolment and intervention within 18 months. The aim is to evaluate the effect of community-based family doctor-led intervention programmes on T2DM patients in the community. Multiple-stage sampling will be used in this study. All districts in Xi'an, Shaanxi province, China, are divided into high and low social and economic development categories according to the gross domestic product per capita in Xi'an in 2020.[33] One area will be randomly selected as a representative for each category. Of the 14 districts in Xi'an, we selected two districts: Yanta district, which has a higher socioeconomic status, and Baqiao district, which has a lower socioeconomic status. Two community health centers (CHCs) will be randomly selected from the two districts and randomly divided into an intervention group and a control group (1:1 ratio). Four CHCs will participate in this trial, two in the intervention group and two in the control group. T2DM patients will be randomly selected by research assistant using the CHC health management system (figure 1). The programme has been registered in the Chinese Clinical Trial Registry.

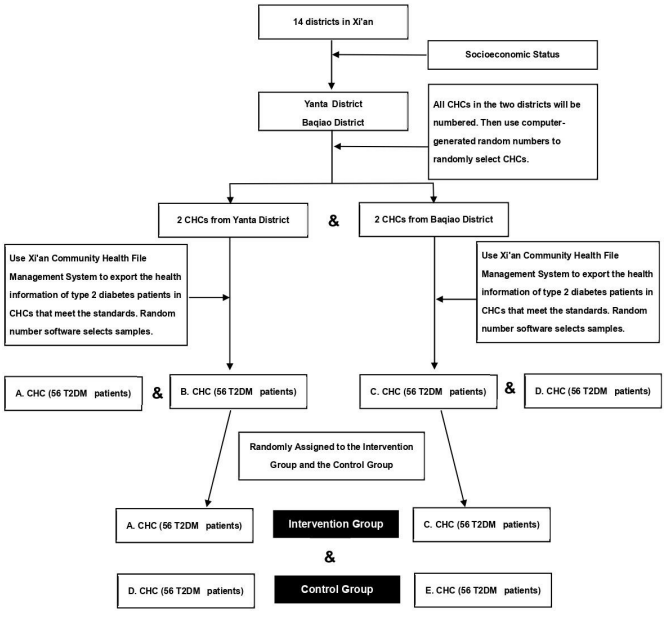

Figure 1 The sampling process. CHC, community health center; T2DM, type 2 diabetes mellitus.

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Study settings

The study will be conducted at four public CHCs in Xi'an, Shaanxi province. The CHCs provide primary healthcare services that combine prevention, treatment, rehabilitation and health. The CHCs meet residents' basic health service needs.

Sample size

The study will compare HbA1c in the control group and the intervention group at baseline and at the 3rd and 6th months. The sample size was calculated using the following formula[34]:

$$m = \frac{2\left(Z_{1-\frac{\alpha}{2}} + Z_{1-\beta}\right)^2 \sigma^2 (1+(n-1)\rho)}{\Delta^2}$$

Following the previous literature, the results of the UK Prospective Diabetes Study showed that a 1% reduction in HbA1c can reduce the risk of all diabetes-related endpoints and diabetes-related deaths by 21% (p<0.01), and reduce the risk of myocardial infarction by 14% (p<0.01). The risk of microvascular complications is reduced by 37% (p<0.01).[35] Assuming a SD of haemoglobin A1c levels of 2%,[36] an intraclass correlation of 0.05,[37] and an average of 12 participants per practice (cluster), we calculated that we needed 98 participants per study arm (each arm contains eight clusters) to detect a clinically relevant difference in haemoglobin A1c levels of 1%, with 80% power at the 5% significance level. Accounting for a potential loss to follow-up of patients, the study aimed to recruit 224 patients (112 in each arm, and 4 clusters in each CHC).

Study participants

Family doctors from the CHCs will recruit patients who meet the following trial inclusion criteria: aged over 18 years; patients who have been diagnosed with T2DM with a course of 6 months or more; take at least one oral hypoglycaemic drug for treatment and control HbA1c level≥7%; no cognitive problems; ability to self-manage their lives and willingness to cooperate; stable condition; ability to engage in exercise; ability to perform basic exercises required for treatment; ability to listen, speak, read, write, etc, and ability to communicate effectively; informed of the study purpose and willing to participate and sign an informed consent form; ability to use a mobile phone and read short message service (SMS) communications.

The exclusion criteria are diabetes with serious complications, such as severe diabetic nephropathy or severe diabetic retinopathy; presence of other serious physical diseases; mental disorders or cognitive impairment; special types of diabetes (eg, gestational diabetes); tumours or chemotherapy, radiotherapy and other treatments in the last 6 months; participation in other research studies; declined to participate in the research. The inclusion and exclusion criteria will allow us to avoid selection bias and ensure the external validity of our research. All participants will be asked to provide written informed consent to ensure that they understand the trial. Family doctors will invite eligible patients by phone.

Data collection instrument

After reviewing the literature, we selected the simplified Self-management Knowledge, Attitude, and Behaviour (KAB) Evaluation Scale for diabetes patients with T2DM in Chinese communities. This was developed by the Chinese Center for Disease Control and Prevention and has been widely used.[38] Cronbach's alpha values for knowledge, attitude and behaviour are 0.86, 0.78 and 0.78, respectively.

We will use a questionnaire based on the KAB Scale. The questionnaire comprises six parts: basic social and demographic characteristics, physiological values and medication use, knowledge, attitudes, behaviour, and medication adherence. The social and demographics section assesses sex, age, occupation, education, monthly income, family history, drinking, smoking and complications. Physiological values and medications comprise height, weight, blood pressure, fasting blood glucose, glycosylated haemoglobin, insulin use and hypoglycaemic drug use.

The knowledge section contains 14 questions about diabetes-related basic knowledge; response options are yes, no and unclear. The knowledge score is calculated using the number of correct responses; the maximum score is 14 points (yes=1, no=0, unclear=0). Five questions will be used to explore participants' attitudes toward health education, diet control, exercise, prescribed medication and blood glucose monitoring. Likert scale responses will be used to obtain the attitude score. The maximum score is five points (very unimportant=0.2, unimportant=0.4, generally=0.6, important=0.8, very important=1).

Twelve questions were designed to evaluate self-management behaviour. The first seven questions are scored using a Likert scale (never=0.2, rarely=0.4, sometimes=0.6, often=0.8, always=1); the maximum score is 7 points. The remaining five questions are scored using yes/no responses; the maximum score is 5 points (yes=1, no=0); that is, the maximum score for the behavioural part of the questionnaire is 12 points.

Medication adherence will be measured using the Adherence to Refills and Medications Scale (ARMS).[39] This is a compliance scale developed for patients with chronic diseases across different cultural levels, and has been used in many chronic disease studies in multiple countries.[40–42] It has also been applied in Chinese patients with type 2 diabetes and showed higher specificity and sensitivity than other scales.[43] The ARMS is a self-report scale containing 12 items. Each item was structured for response on a Likert-type scale with responses of 'none', 'some', 'most' and 'all' of the time, which were given values from 1 to 4. Most items are written so that a lower score indicates better adherence, although the 12th item is reverse coded. Scores of ≥16 are classified as low adherence.[39 43]

Outcome indicators

The main outcomes are changes in fasting blood glucose, glycosylated haemoglobin, self-management knowledge and behaviour, and medication adherence from baseline to the 3rd and 6th months.

The secondary outcome is the proportion of people whose blood sugar and glycosylated haemoglobin are under control in the 3rd and 6th months. Following the Chinese Type 2 Diabetes Prevention Guidelines (2020 edition),[44] this will be defined as fasting blood glucose of 4.4–7.0 mmol/L and glycosylated haemoglobin<7% (most non-pregnant adult patients with T2DM).

Randomisation

All CHCs in the two districts will be numbered. We will use computer-generated random numbers to randomly select CHCs. The Xi'an Community Health File Management System will be used to export the health information of type 2 diabetes patients in CHCs that meet the standards, sorted from 1 to n. Random number software will generate 224 patients as the study sample. Two CHCs in each district will be randomly assigned to either the intervention group or the control group. The family doctors and patients in the two CHCs will not be aware of their groupings. Research assistants will conduct the randomization process. Family doctors are only responsible for recruiting patients at CHCs. After the CHC-based family doctors have recruited patients, they will select eligible participants and complete the informed consent process. They will then use the Knowledge, Attitude, and Practice (KAB) Questionnaire and measure related physiological values to collect baseline information.

Data analysis

After the questionnaire is collected and screened, two research assistants majoring in statistics will use the EpiData V.3.1 database to double enter the data, and then use SPSS V.21.0 for statistical analysis. We will use the χ^2 test, independent sample t-test or Mann-Whitney U test to compare the differences between the two groups in terms of patient demographics; medication adherence; fasting blood glucose; glycosylated haemoglobin; and self-management knowledge, attitudes and behaviour. The t-test will be used to examine the differences in knowledge, attitude and behaviour scores; fasting blood glucose; and glycosylated haemoglobin between the intervention group and the control group before and after the intervention. Frequencies and percentages will be used to describe general data characteristics. Measurement data will be expressed as mean±standard deviation (x±s) and independent samples or paired t-test data will be used for comparison. Frequency data will be expressed as percentages (%) and the χ^2 test used for comparison. Repeated-measure ANOVA test will be used to examine the effects over time. The outcome indicators for participants who withdrew halfway will be excluded from the outcome indicator analysis.

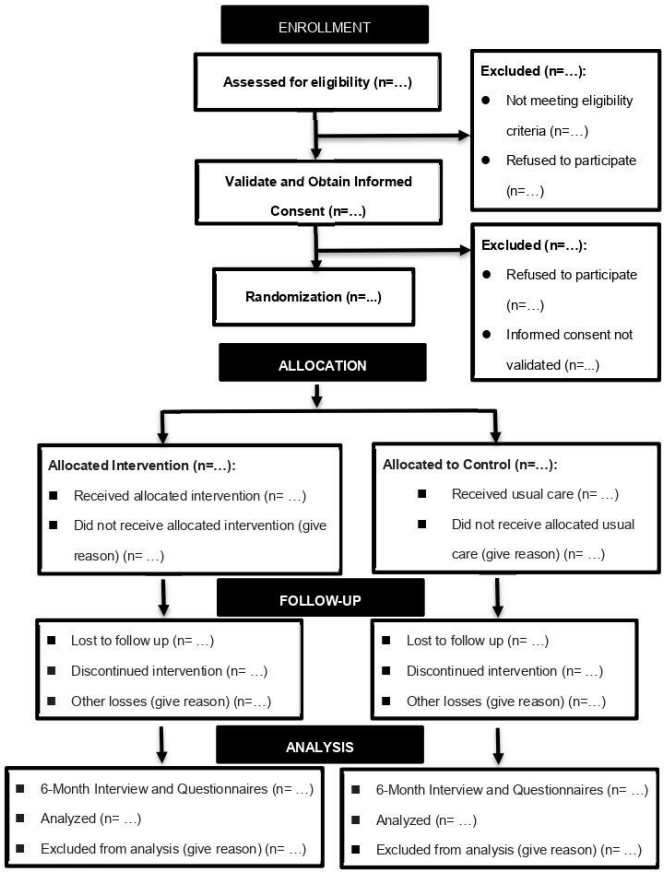

Figure 2 Flow diagram of progress through study phases. (The trial has not yet started, and we plan to start recruiting patients in August 2022.)

Control group and intervention group

The control group will receive conventional CHC medical services and health education. Conventional CHC medical services and health education include three fasting blood glucose tests; two face-to-face disease management coaching and a physical examination over a 6-month period. With the help of community family doctors, the questionnaire will be completed at baseline, the 3rd month, the 6th month and physiological characteristics (eg, height, weight, blood pressure, fasting blood glucose and glycosylated haemoglobin) will be measured.

The intervention group will receive an intervention led by community family doctors based on conventional CHC medical services and health education. The questionnaire completion procedure and the measurement of relevant physiological values will be the same as for the control group. The intervention will comprise five parts: usual care, a medication reminder, a weekly phone interview, a 4-week plan and a monthly interview.

Authors had access to information that could identify individual participants during or after data collection.

Patients visit to hospital for treatment and hospitalisation are permitted. A progress flow diagram of the study phase is shown in figure 2 and the comparison of the treatments received by control group and intervention group is shown in table 1.

Table 1 The comparison of the treatments received by control group and intervention group

Group	Intervention group	Control group
Treatments	Medication reminder	Usual care: conventional CHC medical services and health education (three free fasting blood glucose tests, two face-to-face disease management coaching, physical examination)
	Weekly phone interview	
	Four-week plan	
	Monthly interview	
	Usual care (conventional CHC medical services and health education)	

Procedures

The intervention will be led by CHC family doctors, and will comprise five parts: usual care, a medication reminder, a weekly phone interview, a 4-week plan and a monthly interview. CHC family doctor teams are made up of general practitioners, pharmacists, diabetes nurses, public health doctors and health educators. Before recruitment begins, family doctors will receive 7 days (more than 50 hours) of training from diabetes specialists, pharmacists, diabetes nurses, nutritionists and health educators in tier-3 hospitals to improve and standardise their level of diabetes management. This training will include didactic sessions, in-class exercises and field practice. At the end of the training, the teams from the tier-3 hospitals will assess the competence of the family doctors through field practice. Each family doctor must pass a competency test prior to beginning work. After patient recruitment, the family doctors will tailor a treatment plan to each patient. The treatment plan will include a drug treatment plan, diet control plan, exercise treatment plan and blood glucose monitoring plan.

For the medication reminder, the community family doctor will send a text message every Tuesday and every Friday at 8 to remind patients to take their medication on time. Previous research shows that only 31% of patients with T2DM in China show medication adherence.[45] During the baseline measurement, the community family doctor will advise patients to put their medication near the dining table and set an alarm clock as a reminder. The doctor will advise participants who plan to travel to keep their medication in their wallets or hygiene kits.

The 4-week plan is based on the Chinese Type 2 Diabetes Prevention and Control Guidelines (2020 Edition).[44] And it will collect educational content related to diabetes self-management. All content will be drawn from authoritative books and journals and integrated into educational and promotional materials. The materials will be discussed by endocrinologists, incorporated into diabetes health education and sent to the intervention group patients by the community family doctors using SMS messages. The specifics of the plan are as follows. In the first week, patients will receive push notifications about basic diabetes information; in the second week, patients will receive push notifications about medication-related content; in the third week, patients will receive push notifications about blood glucose monitoring; in the fourth week, patients will receive push notifications about diet control and exercise. The content will be provided over 4 weeks, which will comprise one cycle. The topics will form four modules: basic knowledge, medication, blood glucose monitoring, and diet and exercise. Starting from the second cycle, the intervention content will be adjusted according to the feedback and needs of patients in the previous week. A total of six cycles of SMS intervention will be carried out; that is, a total of 24 weeks. SMS push notifications will be sent two times per week: at 8 on Tuesdays and Fridays. The content of the first SMS cycle is shown in table 2.

Table 2 The content of the first short message service cycle

Week	Theme	The detailed content
The first week	Basic knowledge	Diagnosis and characteristics of diabetes
		Comprehensive control target
		People at high risk of diabetes
		Common complications and hazards
The second week	Medication guidance	Common types and adverse reactions of insulin and hypoglycaemic drugs
		The importance of taking medications as prescribed
		The harm of changing medication regimen at will
The third week	Blood glucose monitoring	The importance of blood glucose monitoring
		Principles of glucose monitoring
		The scope of application of different monitoring time points
The fourth week	Diet control	The benefits of a controlled diet
		Five factors that influence your blood sugar response
		How do diabetic patients eat fruit?
	Exercise therapy	Benefits of exercise
		Basic principles of exercise

In the weekly phone interviews, family doctors will evaluate the patient's disease management and adjust the treatment plan as required. They will also encourage patients to follow the treatment plan.

In the monthly interviews, community family doctors will provide face-to-face guidance to patients once a month; each meeting will last for half an hour. The content of each meeting will be as follows: (1) distribution of self-devised relevant publicity and education materials to patients, and broadcast of relevant popular science videos to patients; (2) evaluation of the patient's condition and treatment behaviour over the past month, querying and recording of recent fasting blood glucose level, and urging the patient to implement various aspects of disease management; (3) in response to the patient's feedback on the content of the 4-week plan, face-to-face explanations of aspects that the patient does not understand. A total of five interviews will be

	STUDY PERIOD			
	Enrolment	Allocation	Post-allocation	
TIMEPOINT	$-t_1$	0	3mths	6mths
ENROLMENT:				
Eligibility screen	X			
Invitation to participate	X			
Validation and Informed consent	X			
Participant randomization		X		
INTERVENTIONS:				
Usual Care			←	→
Family doctor intervention			←	→
ASSESSMENTS:				
Weight/Height/BMI		X	X	X
Blood Pressure		X	X	X
Fasting blood glucose	X	X	X	X
Glycosylated haemoglobin	X	X	X	X
Refills and Medications Scale (ARMS)		X	X	X
Self-management Knowledge, Attitude, and Behavior (KAB) Evaluation Scale		X	X	X

Figure 3 Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) Checklist: schedule of enrolment, interventions and assessments. BMI, body mass index.

conducted during the intervention period. SPIRIT figure is shown in figure 3.

Ethics and dissemination

This study was approved by the Research Ethics Committee of Xi'an Jiaotong University (no. 2021-1371). The written informed consent of the participants will also be obtained during the investigation. We will inform participants that their information may be used for research purposes only and confidentiality will be guaranteed. All of the data will be stored in a safe place, accessible only to key researchers. Personally identifiable information such as the name or address of a participant will not publish in any paper or documents. Study results will be disseminated by peer-reviewed publications and conference presentations.

Patient and public involvement statement

Patients were not involved in the design, conduct or reporting of the study. A summary of the main trial results will be disseminated to the general public and study participants after the completion of the study.

DISCUSSION

This article describes the design of a 6-month randomised controlled trial led by family doctors of CHCs to improve medication adherence and self-management behaviour in patients with T2DM who receive diabetes community management. The study will provide a reference for efforts to improve the management of diabetes in the community, improve the self-management of diabetic patients and improve the prevention and treatment of diabetes.

This community family doctor-led intervention fully takes into account the current status of the integration of chronic disease care into community management, and makes full use of existing resources in the community. In addition, SMS messaging is widely used, low cost and highly scalable. One analysis of SMS interventions[46] found that interventions that use daily reminders can lead to reaction fatigue, be interpreted as intrusive and have less effect than interventions that send SMS messages every week or multiple times a week. To deliver as much information as possible and to avoid response fatigue, we have chosen to send SMS messages every Tuesday and Friday. If this intervention proves feasible and shows preliminary evidence of effectiveness, it could lead to larger-scale clinical trials that will benefit more diabetic patients and reduce diabetes-related morbidity and mortality.

Most intervention studies in China have focused on improving patient self-management behaviour and have not emphasised improvement in patient medication adherence.[47 48] Little attention has been paid to comparison of medication adherence before and after interventions. In contrast, in this study, we will collect data at 0, 3 and 6 months to check whether the intervention is effective in reducing fasting blood glucose and glycosylated haemoglobin levels and providing immediate feedback to T2DM patients (thus helping patients to understand the importance of complying with the intervention). SMS reminders and consultations led by community family doctors are low-cost methods that can easily be integrated into daily practice. We will send information to patients through community family doctors, and patients will be able to provide feedback and obtain answers to any questions they have.

There are several strengths of this proposed study. First, the study will use community family doctors in the intervention. Compared with hiring general practitioners to develop a new intervention team, this method is cost-effective and could improve the effectiveness of patient education. Second, because SMS is the main intervention method and no smartphones are needed, this intervention method is suitable for patients in urban and rural areas and for older people. Third, this study will serve as a reference for decision-makers to manage chronic diseases in the community. However, there are some study limitations. First, the trial will last for only 6 months. Therefore, the intervention may improve the knowledge level of diabetes patients in the community to a certain extent, but may not be long enough to change the attitudes and behaviours of patients. Second, owing to time limitations, the burden of responsibility and insufficient funds, the research will be conducted in only one city, so the generalisability of the findings will be limited. However, if our intervention is successful, this study could be conducted on a larger scale.

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Contributors This is a collaborative research, each of the listed people provided important intellectual contribution to study design. BR drafted the protocol. BR, NW, SLei, SLin, YC and LL drafted the final manuscript, while YX and BF revised the final

protocol. All authors contributed to data analysis, drafting and revising the article, and have read and agreed to the published version of the manuscript.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

Patient consent for publication Not applicable.

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