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Effectiveness of a clinic-based randomized controlled intervention for type 2 diabetes management: an innovative model of intensified diabetes management in Mainland China (C-IDM study)

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ABSTRACT

Objectives Highly efficient diabetes management programs are needed for tackling diabetes in China. This study aimed to assess the effectiveness of a clinic-based intensified diabetes management model (C-IDM) in Mainland China.

Research design and methods A 2-year clinic-based randomized controlled trial was conducted among patients with type 2 diabetes in Nanjing, China. The C-IDM intervention components comprised four domains (disease targeting management, express referral channel, expert visit, patients' self-management) and an integrated running system (disease control centers, general hospitals and local clinics). Control group participants received their usual care, while intervention participants received both the C-IDM package and the usual services. The primary outcome variable was change of hemoglobin A1c (HbA1c). Mixed-effects models were used to compute effect estimates and 95% CI with consideration of both individual and cluster-level confounders.

Results Overall, 1095 of 1143 participants were assessed at study completion. The mean change in HbA1c was significantly greater in the intervention group than in the control group (mean difference (MD)=−0.57, 95% CI −0.79 to −0.36). Similar results were observed for change in body mass index (MD=−0.29, 95% CI −0.49 to −0.10). Participants in the intervention group were more likely to achieve normal HbA1c and body weight compared with their counterparts in control group after adjusting for potentially confounding variables (adjusted OR=1.94, 95% CI 1.35 to 2.81 and 1.79, 95% CI 1.13 to 2.85, respectively).

Conclusions The C-IDM model is feasible and effective in large-scale management of patients with type 2 diabetes in China. It has public health implications for tackling the burden of diabetes in China.

Trial registration number ChiCTR-IOR-15006019.

Significance of this study

What is already known about this subject?

- Type 2 diabetes is a severe public health problem worldwide, particularly in China. The development of highly efficient diabetes management programs is urgently required.

What are the new findings?

- Disease control centers, general hospitals and local clinics were integrated into a smoothly running system for this clinic-based management program of patients with diabetes. This innovative diabetes management model was feasible, with excellent compliance and highly effective, also with significant improvements in patients' glycemic and body weight control.

How might these results change the focus of research or clinical practice?

- Our clinic-based diabetes management model can be widely introduced throughout China, so large numbers of patients with diabetes can be managed by local general practitioners.

INTRODUCTION

Type 2 diabetes is a severe public health problem worldwide, particularly in China. The prevalence of type 2 diabetes was estimated to be 10.9% among Chinese adults (aged 18+ years) in 2013.[1] In China, two-thirds of the patients with diabetes have experienced diabetes-related complications, including heart attack, stroke, and kidney failure,[2] and diabetes causes a heavy financial burden at both the individual and societal levels.[3 4]

One potentially beneficial strategy to reduce the burden caused by diabetes is to introduce community-based comprehensive diabetes management with the aim of improving glycemic control and preventing

diabetes-related complications. In 2009, the Central Government of China launched a nationwide clinic-based public health service program, the 'Basic Public Health Service Program' (BPHSP).[5] Diabetes management was a key component of the BPHSP. All local patients with diabetes were invited to voluntarily join the program, which enabled them to receive free services from general practitioners (GP) based at local clinics, known as community health service centers (CHC). Cost-free diabetes-related services offered included blood glucose testing, disease and medication assessment, health education and physical examination. Although BPHSP was welcomed by the majority of registered patients with diabetes, its clinical effectiveness was not satisfactory. This might be mainly due to: (A) the BPHSP included only four service items and was not deeply attractive for patients; (B) assessment of the BPHSP mainly focused on process evaluation (eg, completeness of personal medical information recorded, service/interview frequencies) rather than clinical outcomes such as diabetic complication prevention.[6] Therefore, to improve the effectiveness of the management of patients with diabetes, innovative community clinic-based models, which consider glycemic control, complication prevention, lifestyle and behavior modification, are urgently needed in China.

To bridge this gap we developed a Clinic-based Intensified Diabetes Management program (C-IDM study), taking into account healthcare resources and healthcare insurance in China. Local public health institutes (Centers for Disease Control and Prevention, CDC), endocrinology departments of general hospitals (GH) and CHCs were integrated within the C-IDM model. This study aimed to evaluate the effectiveness of our C-IDM model against the usual BPHSP for diabetes management in Nanjing, China.

RESEARCH DESIGN AND METHODS

Study design

This C-IDM trial was a 2-year clinic-based, parallel-group randomized controlled trial (RCT) for patients with type 2 diabetes in Nanjing, China. The C-IDM trial was conducted between October 2015 and October 2017. The study was conducted in Dachang district (one of the 11 districts of Nanjing), an urban district with six CHCs and approximately 260 000 residents in 2015. The six CHCs were independently involved in this study.

Participants

Individuals were eligible to participate in this study if they: (1) were local physician-diagnosed patients with type 2 diabetes[7]; (2) had been registered with BPHSP at a CHC within Dachang district; (3) were aged 35–79 years; (4) had no uncontrolled complications, mental or physical disabilities; and (5) had not been involved in diabetes-related intervention programs other than BPHSP.

Participants were randomly recruited from each of the six CHCs in Dachang district. All patients with type 2 diabetes who voluntarily joined the BPHSP have a unique electronic medical record number within their local CHCs. All potentially eligible participants were identified, and computer-generated random numbers were used to select individuals who were then invited to participate in the C-IDM trial. Prior to recruitment, written informed consent was obtained from each participant.

Intervention components and implementation

Bodies involved in this program

Three bodies, the local CDC, GHs and CHCs, were involved in the C-IDM model, and were integrated into a running system within the model in order to manage patients with diabetes (figure 1). The role of each body is described as follows:

1. CDC: to design and coordinate this multicenter intervention program.
2. GHs: to organize endocrinologists and nurses to join the expert team; to train local GPs and nurses; to admit patients with type 2 diabetes referred from CHCs.
3. CHCs: to allocate specifically trained GPs and nurses to join this program. These healthcare professionals were responsible for: (A) implementing the C-IDM intervention and managing patients with diabetes; (B) collecting information regarding the intervention; (C) supervising patients' self-management activities; and (D) referring patients with diabetes to GHs.

Prior to initiating the C-IDM model, GPs and nurses from all six CHCs received 6 months of full-time specific training regarding acknowledge and skills for diabetes management at the endocrinology department of a GH. After completing the training examination, those healthcare professionals were qualified to participate in the C-IDM model.

Intervention components of C-IDM

Intervention components were developed with full consideration of the specific context of healthcare services, and associated insurance systems, cultural and social norms regarding illness in China. The C-IDM model comprised four domains: (A) comprehensive disease targeting management by GPs/nurses (targeting management); (B) an express bidirectional patient referral service between GH and CHCs (express referral); (C) systematically scheduled appointments with patients at local CHCs by senior endocrinologists and nurses from GH (expert visit); and (D) patients' health education and self-management (patients' self-management).

Targeting management

Learning from the Staged Diabetes Targeting Management model implemented in USA,[8] we developed five specific disease management goals and one diabetic complication screening approach, as well as personalized diet and physical activity assessment and advice. The five goals were: (1) HbA1c <7.0%; (2) blood pressure (BP) <140/80 mm Hg; (3) low-density lipoprotein <2.6 mmol/L; (4) smoking cessation; and (5) use of

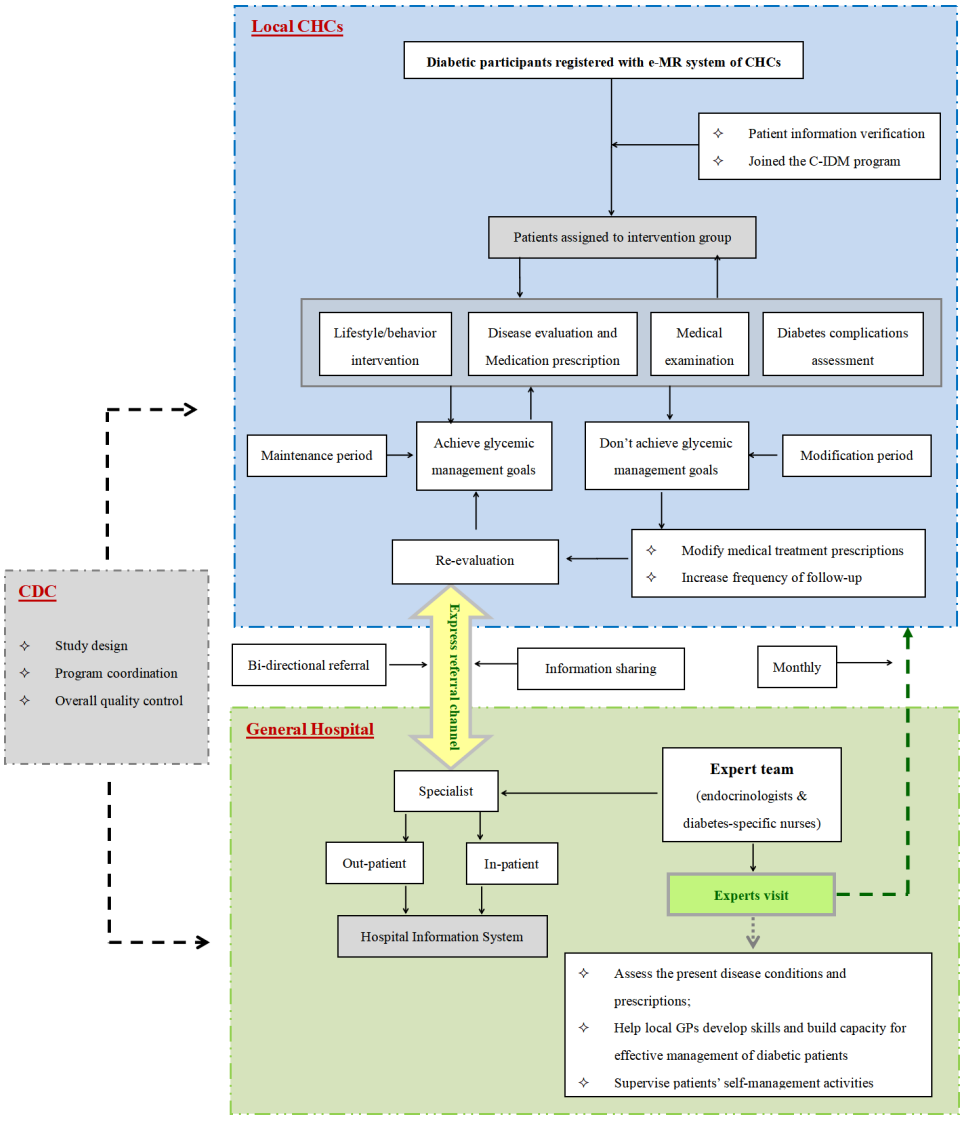

Figure 1 Intervention functioning system in the study. CHC, community health service center; C-IDM, Clinic-based Intensified Diabetes Management; e-MR, electronic medical record; GP, general practitioner.

aspirin when necessary. Diabetes complications screening included: fundus examination, diabetic foot diseases screening and urinary albumin excretion examination. We identified minimal screening frequencies for each diabetic complication.

Express referral

A bidirectional patient referral system between GHs and CHCs was established. If a participant's blood glucose was not under control, then with the consent, the patient would be referred from the local CHC to the endocrinology department of a designated GH for further evaluation and treatment. Subsequently, the patient would return to his/her CHC for regular management after achieving the glucose control target with modified treatment by GH endocrinologists. An express referral channel of this type was convenient and attractive for patients, as well as being highly efficient and cost-effective.

Expert visit

An expert team, including endocrinologists and diabetes specialist and nurses from GHs, were scheduled to visit patients at local CHCs monthly. The endocrinologists were on duty to assess the current condition of and prescriptions for (medication, lifestyle, and so on) each patient with diabetes, and to make any modification if necessary. Furthermore, the endocrinologists would discuss typical cases of patients with GPs as part of their continuing education to help develop skills and build capacity for effective management of patients with diabetes. Expert nurses from GHs were responsible for helping CHC nurses supervise and guide patients' self-management activities. The GHs involved in this study assigned 'Expert visit' as one of their hospitals' routine duties. All experts worked at local CHCs as they did at their own hospitals, and this duty was included as part of their employee assessment by the hospitals.

Patients' self-management

As diabetes is a lifelong chronic condition, patients are always encouraged to adapt appropriate lifestyle and behavior actions and to have sufficient self-management capacity, which are important for successful glycemic control. Patients with diabetes were invited to attend a health class to learn about their diabetes, and to join self-management activities in their local CHCs every month. Through attending the self-management activities, patients could support and help each other by sharing experiences on self-management, including strategies that improved self-monitoring blood glucose, preventing complications, insulin injection techniques, regular exercise, healthy eating and relieving mental issues.

BPHSP components

The BPHSP components included: (1) quarterly fasting plasma glucose (FPG) concentration test; (2) quarterly disease and medication assessment; (3) quarterly health education on lifestyle and behavior; and (4) annual physical examination, which mainly consisted of anthropometric measurements.[5]

Implementation of intervention

Participants within both control and intervention groups received the usual BPHSP service, while all the patients in intervention group additionally received our C-IDM intervention components.

Randomization

After participants from each CHC were randomly selected, they were randomly assigned to either the intervention or control group using random digits generated by Epical 2000 software. The randomization group was concealed from the potential participant until after they had consented to participate in the C-IDM trial.

Data collection and definitions

Anthropometric measures and questionnaire surveys were conducted for all participants at both baseline (October 2015) and postintervention (October 2017). Trained CDC research staff supervised and assisted with data collection at each CHC. Participants' sociodemographic characteristics were assessed using specific questionnaires. Variables recorded included gender, age, marital status, highest education level, income, smoking, drinking, and disease status. Current smokers were defined as individuals who smoked at least one cigarette per day or not less than 18 packs in the last year.[9] Alcohol drinkers were defined as individuals who drank alcohol on an average of two or more times per week in the last year.[10]

Based on a standardized protocol, participants' anthropometric measures (body weight and height) were recorded inside a quiet room. Height was measured without shoes to the nearest 0.1 cm and weight was assessed with light clothing to the nearest 0.1 kg. All those measures were conducted twice and the mean value of the two readings was used for our analysis. Body mass index (BMI) was calculated as body weight (kg) divided by the square of height (m^2).

BP was objectively measured using Omron HBP-1300 equipment (Omron, Kyoto, Japan). According to the 1999 WHO/International Society of Hypertension guidelines on hypertension,[11] a participant was identified as hypertensive if his/her systolic or/and diastolic BP exceeded the recommended cut-offs (140 and 90 mm Hg, respectively). All participants who had been prescribed antihypertension medications were classified as hypertensive, regardless of their BP status.

A venous blood sample was collected from each participant to analyze HbA1c, FPG and lipid profiles. HbA1c was assessed using the quantitative high-performance liquid chromatography method (D-10 Hemoglobin Analyzer, Bio-Rad) at each CHC. Several approaches were implemented to ensure the quality of HbA1c laboratory tests. First, all analyzers were from the same factory, with the same brand and type. Second, all laboratory staff involved in this study were from a CHC and had at least 5 years' experience. Third, in addition to receiving overall training regarding the C-IDM study, prior to baseline and each follow-up blood sample test all laboratory staff received specific training regarding HbA1c testing, including blood sample collection and treatment. Fourth, the same standard test control samples were applied for all laboratories in CHCs.

Study variables

Outcome variable

The primary outcome variable was difference in change (endpoint baseline) of HbA1c between intervention and control group at study completion. Both the difference based on HbA1c values and the difference based on the proportion of participants who achieved their HbA1c goal of <7.0%[12] were analyzed. The secondary outcome measure was the between-group difference in change of BMI, assessed as both continuous and categorical (BMI <24 kg/m^2) measures.[13]

Independent variable and covariables

The independent variable was the treatment group (intervention or control). Covariables included age, gender, highest educational level, income, smoking status and alcohol consumption. All covariables were categorized: age-group=younger (35–49 years), middle (50–64 years) or older (65–79 years); gender=male or female; highest educational attainment=0–9, 10–12 or 13+ schooling years; monthly income=lower, middle or upper tertile; smoking=current or not current; and drinking=yes or no.

Sample size

The sample size was estimated using PASS11 (NCSS, Kaysville, Utah) based on the primary outcome, the between-group difference in change in HbA1c at study completion. We assumed that a between-group difference

in HbA1c of 0.5% would be observed, the SD of HbA1c was 1.5% for local patients with type 2 diabetes,[14] and that α=0.05 (two sided) and β=0.1 (ie, power=90%). After considering potential non-recruitment and loss to follow-up, the total required sample size was estimated to be approximately 1060. For convenience, we aimed to recruit 200 participants from each CHC, and 1200 participants in total.

Statistical analysis

The differences in participants' characteristics between the intervention and control groups at baseline were assessed using t-tests (for continuous variables) or χ^2 tests (for categorical variables). Between-group differences at study completion were estimated using mixed-effects regression models. Treatment group was included as the main fixed effect, and age, gender, highest education level, income, smoking status and alcohol consumption were included as covariables. CHC was included as a random effect to account for potential clustering effects. The effect estimates were reported as ORs and 95% CI for categorical variables and mean difference (MD) and 95% CI for continuous variables. The level of statistical significance was set at p<0.05. All analyses were conducted using SPSS V.20.0 (IBM).

RESULTS

Initially 1200 eligible participants were invited to participate in the study, 200 from each CHC. However, after randomization but before the intervention implementation, 57 patients withdrew their consent, and consequently baseline data were collected on 1143 participants (intervention vs control=585 vs 558). There were no differences between the 57 patients who withdrew consent and the 1143 included participants in terms of age and gender. At study completion, outcome data were collected for 1095 participants (intervention vs control=563 vs 532). For the 48 participants who did not have outcome data collected, they were absent from the data collection at study completion mainly due to sickness or unexpected events on the interview day. The baseline characteristics were compared between those who were, and were not, successfully followed up, and there were no significant differences. Participants' flow is shown in figure 2.

Participants' characteristics at baseline

Table 1 summarizes the selected characteristics of participants at baseline. Among the 1095 participants who completed the trial (follow-up rate=95.8%, 1095/1143), the mean (SD) age at baseline was 66.5 (8.7) years, 47.3% were men, 8% had at least 13 years of education, and

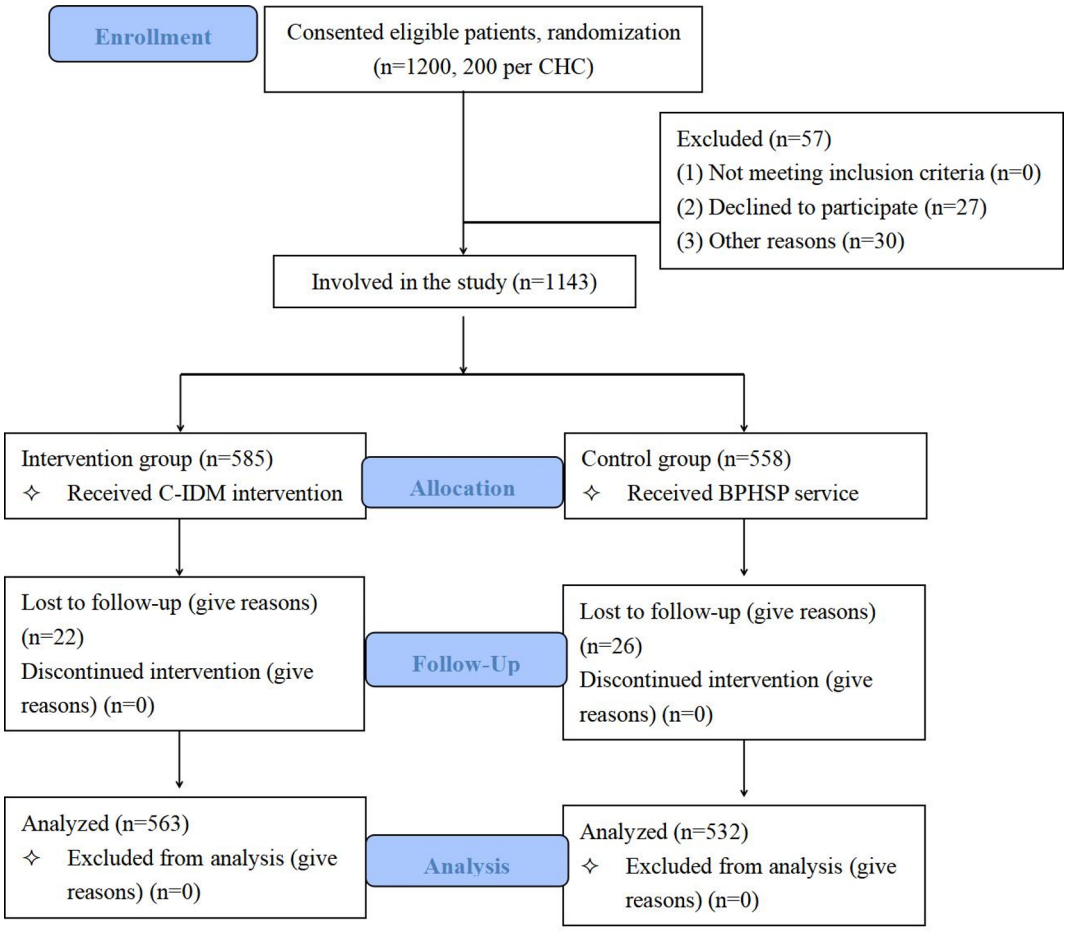

Figure 2 Study participant flow chart. BPHSP, Basic Public Health Service Program; CHC, community health service center.

Table 1 Participants' selected characteristics at baseline

	Intervention group (n=563)	Control group (n=532)	P value*
Age, years (SD)	66.29 (8.93)	66.70 (8.43)	0.44
Male, n (%)	272 (48.3)	246 (46.2)	0.47
Married, n (%)	517 (91.8)	493 (92.7)	0.60
Course, n (%)			
<5 years	222 (39.4)	201 (37.8)	0.57
5–10 years	150 (26.6)	157 (29.5)	
≥10 years	191 (33.9)	174 (32.7)	
Educational level, n (%)			
Primary school and lower	366 (65.0)	369 (69.4)	0.12
Middle/high school	145 (25.8)	130 (24.4)	
College and higher	52 (9.2)	33 (6.2)	
Monthly income, n (%)			
<¥2000	144 (25.6)	168 (31.6)	0.10
¥2000–¥3000	145 (25.7)	118 (22.2)	
≥¥3000	274 (48.7)	246 (46.2)	
Overweight/obese, n (%)	340 (60.4)	319 (60.0)	0.94
Hypertension diagnosed, n (%)	364 (64.7)	343 (64.5)	0.98
Smoking status, n (%)	127 (22.6)	104 (19.5)	0.21
Alcohol consumption, n (%)	87 (15.3)	75 (14.2)	0.51

*T-tests for continuous variables and χ^2 tests for categorical variables between intervention and control groups.

33.3% had been diagnosed with diabetes for at least 10 years. Approximately half (47.5%) of the participants had a monthly income of ≥¥3000. 60.2% were overweight/obese, and 64.6% were hypertensive. Rates of smoking and drinking were 21.1% and 14.8%, respectively. The balance between intervention and control groups was tested regarding the selected baseline sociodemographic and anthropometric characteristics, showing no significant differences.

Intervention effectiveness: value of HbA1c and BMI

Table 2 shows the intervention effects based on the primary outcomes of HbA1c and BMI when treated as continuous variables. At study completion, among the five indices of outcome events, significant between-group differences in change were observed for HbA1c, BMI, and FPG. The mean value of HbA1c had a significantly greater reduction for intervention group participants than for control group participants (intervention vs control=−0.70 vs −0.14; MD=−0.57, 95% CI −0.79 to −0.36). Similar scenarios were observed for change in BMI (intervention vs control=−0.36 vs −0.04; MD=−0.29, 95% CI −0.49 to −0.10) and FPG (intervention vs control=−0.27 vs 0.10; MD=−0.40, 95% CI −0.72 to −0.03).

Intervention effectiveness: categorical status of HbA1c and body weight

Table 3 presents the intervention effects based on between-group changes in the proportion of participants who achieved the control goals of HbA1c and body weight at study completion. A significant difference was examined in the increase in the proportion of participants who achieved normal HbA1c between the intervention and control groups (intervention vs control=17.9% vs 6.8%, p<0.001). After adjusting for potentially confounding variables and CHC-level clustering effects, participants in the intervention group were significantly more likely to achieve their HbA1c control goal than participants in the control group (adjusted OR=1.94, 95% CI 1.35 to 2.81). Change in the proportion of non-overweight participants increased for both intervention and control groups, however it was greater in the intervention than the control group (intervention vs control=5.4% vs 0.5%, p=0.013). After adjustment, intervention group participants were more likely to achieve their body weight goal (adjusted OR=1.79, 95% CI 1.13 to 2.85). Significant effects were also observed for FPG, triglyceride and high-density lipoprotein.

Adverse events

No adverse events were reported by participants throughout the study.

DISCUSSION

In this clinic-based, parallel-group, multicenter RCT, the effectiveness of a new model of diabetes management against the usual BPHSP was examined among

Table 2 Changes in physiological outcomes (continuous variables) between intervention and control groups

	Mean (SD) at baseline			Mean (SD) after intervention			Change in mean values (95% CI)			
	Intervention	Control	P value†	Intervention	Control	P value†	Intervention	Control	MD (95% CI)	P value*
HbA1c (%)	7.76 (1.68)	7.58 (1.53)	0.06	7.06 (1.16)	7.39 (1.89)	<0.05	−0.70 (−0.84 to 0.57)	−0.14 (−0.32 to 0.02)	−0.57 (−0.79 to −0.36)	<0.001
BMI (kg/m^2)	25.11 (3.42)	25.06 (3.17)	0.82	24.75 (3.41)	25.03 (3.26)	0.16	−0.36 (−0.49 to 0.21)	−0.04 (−0.20 to 0.06)	−0.29 (−0.49 to 0.10)	<0.05
FPG (mmol/L)	7.72 (2.15)	7.84 (2.91)	0.42	7.46 (2.25)	7.95 (2.53)	<0.05	−0.27 (−0.47 to 0.06)	0.10 (−0.20 to 0.34)	−0.40 (−0.72 to 0.03)	0.02
Systolic BP (mm Hg)	130.75 (12.59)	133.55 (13.82)	<0.001	133.05 (15.30)	135.70 (15.58)	<0.05	2.30 (0.93 to 3.75)	2.13 (0.76 to 3.50)	0.22 (−1.45 to 2.37)	0.64
Diastolic BP (mm Hg)	78.02 (8.57)	78.92 (8.50)	0.08	79.00 (36.05)	80.67 (31.03)	0.41	1.00 (−2.20 to 4.03)	1.72 (−0.93 to 4.46)	−1.21 (−5.25 to 3.04)	0.60
Triglyceride (mmol/L)	1.75 (1.39)	1.80 (1.39)	0.59	1.75 (1.46)	2.06 (4.02)	0.09	0.01 (−0.13 to 0.14)	0.25 (−0.09 to 0.58)	−0.22 (−0.58 to 0.15)	0.24
HDL (mmol/L)	1.30 (0.37)	1.41 (0.54)	<0.001	1.37 (0.45)	1.46 (0.56)	<0.05	0.07 (0.03 to 0.11)	0.07 (0.01 to 0.12)	0.01 (−0.06 to 0.08)	0.86
LDL (mmol/L)	2.80 (1.41)	2.89 (0.80)	0.16	2.81 (0.94)	2.97 (1.47)	0.04	0.02 (−0.10 to 0.14)	0.09 (−0.04 to 0.21)	−0.07 (−0.24 to 0.12)	0.49
Total cholesterol (mmol/L)	4.81 (2.23)	4.96 (1.06)	0.15	4.67 (1.14)	4.98 (2.46)	0.01	−0.15 (−0.33 to 0.04)	0.02 (−0.19 to 0.23)	−0.20 (−0.48 to 0.11)	0.21

*Mixed-effects models were used to estimate the intervention effects with adjustment for community health service center (CHC)-level clustering effects, age, gender, education level, income, smoking status and alcohol consumption.
†T-tests for continuous variables between intervention and control groups.
BMI, body mass index; BP, blood pressure; FPG, fasting plasma glucose; HDL, high-density lipoprotein; LDL, low-density lipoprotein; MD, mean difference.

Table 3 Changes in physiological outcomes (categorical variables) between intervention and control groups

	Proportion (%) of participants achieving goal at baseline			Proportion (%) of participants achieving goal after intervention			Change (endpoint baseline) (%)		Adjusted OR (95% CI)*	P value
	Intervention	Control	P value†	Intervention	Control	P value†	Intervention	Control		
HbA1c <7%	37.1	40.7	0.244	55.0	47.5	0.015	17.9	6.8	1.94 (1.35 to 2.81)	<0.001
BMI <24 kg/m^2	39.3	39.7	0.940	44.7	40.2	0.147	5.4	0.5	1.79 (1.13 to 2.85)	0.013
FPG <7.0 mmol/L	45.5	44.6	0.810	51.9	44.2	0.012	6.4	−0.4	1.70 (1.20 to 2.39)	0.002
BP <140/80 mm Hg	43.6	34.3	0.002	43.4	34.7	0.004	−0.2	0.4	1.34 (0.97 to 1.85)	0.079
Triglyceride <1.7 mmol/L	64.5	60.6	0.202	66.5	56.2	<0.001	2.0	−4.4	1.57 (1.03 to 2.40)	0.036
HDL (>1.0 mmol/L for men and >1.3 mmol/L for women)	62.9	66.8	0.196	73.9	69.6	0.128	11.0	2.8	1.74 (1.15 to 2.62)	0.008
LDL <2.6 mmol/L	43.5	34.3	0.002	43.6	34.2	0.002	0.1	−0.1	1.32 (0.93 to 1.87)	0.122
Total cholesterol <4.5 mmol/L	40.6	32.8	0.008	44.3	36.7	0.012	3.7	3.9	1.23 (0.88 to 1.72)	0.225

*OR and 95% CI, estimated with mixed-effects models, presents the likelihood of achieving target goal among intervention participants compared with control participants at study end.
†χ^2 tests for categorical variables between intervention and control groups.
BMI, body mass index; BP, blood pressure; FPG, fasting plasma glucose; HDL, high-density lipoprotein; LDL, low-density lipoprotein.

patients with type 2 diabetes in regional Mainland China. Compared with their counterparts in the control group, participants in the C-IDM group had significantly reduced HbA1c and BMI, and were more likely to achieve their HbA1c and body weight goals. These findings suggest that the new C-IDM diabetes management model was more effective than usual care (BPHSP) for glycemic and body weight control for adult Chinese patients with type 2 diabetes. Significant effects were not observed for all variables, such as BP, lipid profile, food and eye complications. For BP and lipid profiles this may be because participants focused on reducing their glycemic level rather than their BP and lipid profile. The study period may not have been long enough to contribute to significant changes in diabetic complications between the two groups.

In the C-IDM study, HbA1c level was chosen to measure glycemic control, as it reflects glycemic level over the past 3 months.[12] A significant difference in the change of mean HbA1c values was observed between the intervention and control groups. The observed change, 0.57%, is lightly greater than the 0.5% assumed in sample size calculations. It is similar to those reported in similar clinical trials (0.5%–0.6%).[15–17] Considering the mean HbA1c values at baseline were smaller for participants in this study than in other studies,[15–17] the C-IDM model might be more sensitive for patients with diabetes even when their glycemic values are relatively low at baseline.

The proportion of participants with HbA1c under control is clinically important for reducing the risk of diabetes-related complications.[18] To aid glycemic control, participants in the C-IDM intervention group were encouraged to control their body weight using lifestyle and behavior modifications. Body weight was significantly lower in the intervention group than the control group at study completion.

The current number of patients with type 2 diabetes worldwide is very large, and increasingly alarming each year, particularly in China.[19] However, the service capacity of diabetic physicians in GHs is relatively limited, especially compared with the large diabetic population. For example, there were approximately 450 000 diagnosed patients with type 2 diabetes[1] and only 285 registered diabetic physicians in GHs in Nanjing at the end of 2017.[20] Therefore, it is particularly important to develop and employ clinic-based treatment strategies that are both feasible and effective for type 2 diabetes management. For effective management, patients' compliance to medicine prescriptions and lifestyle/behavior modification advice is critically important. Patients with diabetes who adhere to their physicians' advice and prescriptions are more likely to regularly take medication as prescribed, have appropriate testing and surveillance of biomarkers, and make appropriate lifestyle amendments. Additionally, a smoothly functioning system is necessary for a successful diabetes management program. In the C-IDM model, CDCs, GHs and clinics were all involved. Properly integrated implementation of these bodies can efficiently improve diabetes management effectiveness.[21]

The C-IDM program, the Nanjing model, had some original and innovative practices relative to the previously designed diabetes intervention programs. First, this model integrates the CDC, GHs and local CHCs into a single system to maximize the utility of each institute in clinic-based diabetes management. As the main service providers, GPs located within CHCs play an important role as they provide routine primary care for local patients with diabetes within the C-IDM model. The GPs and nurses of CHCs are trained with type 2 diabetes management knowledge and skills as part of the C-IDM model, and so are able to provide regular primary-level health services to patients in a professional, effective and timely manner. The complicated type 2 diabetes cases can be handled at CHCs in two ways: (1) they could be referred to the diabetes department of a GH by GPs through the 'express referral channel', or (2) they could choose to receive medical treatment by diabetes specialists from GHs through the 'experts visit' service. In this study, we found participants preferred the latter approach, as they perceived they could receive medical services in CHCs with the same quality as that in a GH, but at a lower healthcare expenditure and without having to visit a GH. This may, in part, explain the high level of C-IDM participants' compliance in this study. Second, the C-IDM program includes comprehensive disease management and diabetes-related education and self-management. Subcomponents of diabetes-related education, including knowledge and skills regarding glycemic control, help patients modify their lifestyle and behaviors and enhance self-management adherence, with the flow-on effect of improving clinical outcome indicators.[22 23] This subcomponent is an essential component of a diabetes management model. In previous studies as few as 50% of participants have been able to complete the diabetes education intervention program.[24] Chinese people, particularly older adults, tend to join group activities based on shared personal interests.[25] For example, people who like Taichi or Qigong may undertake group-based exercise together. This cultural tradition and social convention might be able to improve participants' participation in and adherence to self-management group activities, and might partially explain the compliance and effectiveness of the C-IDM program. Finally, participants in the C-IDM group needed to pay for some necessary physical and biochemical examinations required as part of the intervention. On average, each participant might pay approximately ¥380 for all the required physical and biochemical examinations and tests annually. This amount of money is not high in the Chinese context, and it could be covered by the participant's healthcare insurance. For this modest expenditure patients with diabetes control their glycemic level and obtain satisfactory treatment effectiveness. This may be an additional reason to explain the observed compliance and effectiveness.

Considering the limited healthcare resources in China, the C-IDM model could maximize the effects of diabetes management in terms of both glycemic control and number of patients managed. Currently, in addition to Jiangsu province (in the eastern developed region of China), this Nanjing model has been implemented in other two provinces by the Chinese Center for Disease Control and Prevention: Shanxi province (in the central underdeveloped region of China) and Ningxia province (in the western developing region of China).[26] In total, approximately 2500 patients with diabetes had been registered with the C-IDM program in these two less developed provinces by the end of 2018. Preliminary evidence suggests those registered patients with diabetes were satisfied with their disease management, despite having to pay for some biochemical examinations and some screening for complications.[26] This suggests the C-IDM model could be implemented in a wide range of Chinese scenarios, including in less developed provinces.

The C-IDM trial has several strengths. First, this is the first study to examine the effectiveness of a clinic-based comprehensive diabetes management program that has been developed within the context of traditional culture, social convention and healthcare (service and insurance) system in China. Further, this study demonstrated the C-IDM model could feasibly be implemented, and that it had a significant and positive effect on diabetes control. Second, the sample size was sufficiently large to identify significant effects, and there was an excellent participation and retention rate. Third, the sample population was representative of overall patients with type 2 diabetes in Nanjing, as Dachang district and the CHCs are typical of those in Nanjing City. Finally, within each of the healthcare sectors (CDC, GHs and CHCs), employees involved in this model did not need to undertake jobs outside their regular duties, because their regular duties were integrated into a smoothly integrated and comprehensive healthcare system. This demonstrates the C-IDM models feasibility from the aspect of healthcare providers.

Some limitations also need to be noted. First, due to the nature of the intervention participants and healthcare professionals could not be masked to their study group, although participants were randomly assigned to either intervention or control group. There could potentially be contamination for control participants in terms of intervention approaches. However, if this was the case it would lead to an underestimation of the effectiveness of the intervention. Second, not all information was gathered through objective assessment. In particular, lifestyle and behavior data were collected via questionnaires, which may potentially cause recall bias, although validated questionnaires were used and interviewers were well trained to a standard protocol. Third, the cost-effectiveness evaluation was not conducted due to insufficient data. In future, long-term maintenance and economic effects of this model should be evaluated.

In conclusion, the C-IDM program, the Nanjing diabetes care model, was feasible and effective in large-scale management of patients with diabetes in one district of Mainland China. The Nanjing model may be translatable to other regions of China. These results have great public health implications for massive management of patients with diabetes by local GPs in China.

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Data availability statement Data are available upon reasonable request to FX.

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