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WILL DIABETES CARE MOVE CLOSER TO RURAL PATIENTS IN CHINA?

Assessing the impact of an educational intervention for type 2 diabetes among patients and health care professionals in rural China

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Will diabetes care move closer to rural patients in China?

Assessing the impact of an educational intervention for type 2 diabetes among patients and health care professionals in rural China

THESIS FOR DOCTORAL DEGREE (Ph.D.)

By

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ABSTRACT

Aim: The overall aim of this PhD thesis was to increase knowledge on the feasibility and impact of an educational intervention to shift the management of type 2 diabetes mellitus from hospitals to primary health care institutions in rural China.

Study population and methods: All four studies were conducted in Jiangsu province. The educational intervention intended to improve collaboration between the hospital and PHC level, which would strengthen the knowledge and management of diabetes among primary care professionals and in turn lead to improved diabetes knowledge and improved fasting blood glucose (FBG) level among patients. Huaiyin, Jingjiang, and Gaochun county were selected from north, middle, and south part of Jiangsu Province, respectively. The intervention for health care professionals in the intervention areas consisted of three main components: team communication, regular meetings, and professional skills training sessions. Health care professionals in the control group continued with their routine work and had no extra intervention. Patient participants in the intervention areas received services, including health education lectures, periodical follow-up interviews with an annual physical examination, and special medical services. Patients in the control areas received routine services as usual. Baseline data were collected in November 2015, the two follow-up data collections were in October 2016 and July 2017, respectively. Questionnaires were used for patient participants and staff. Study I and Study II evaluated the one-year impact on the patients' diabetes knowledge, FBG level, and health-related quality of life (HRQoL). Study III concentrated on the impact among health care professionals in PHC institutions for one year. Study IV assessed the two-year impact on diabetes knowledge and FBG level, among patients in the intervention and control group.

Results: The educational intervention had a positive impact in improving diabetes knowledge, lowering FBG levels and improving HRQoL among patients with T2DM at one-year follow-up. A long-term (two years) positive impact was also found on diabetes knowledge and FBG level. The intervention had a differential impact on FBG level for patients in different counties, both at the first and second follow-up, and a two-year positive impact was found only in Gaochun county. The impact was also greater among certain patient groups, especially among females, married persons, low educated persons, and those in farming or house working. Moreover, the intervention had a positive impact among health care professionals in PHC on their professional diabetes knowledge, attitudes and practices regarding the intervention, and types of services they were able to provide.

Conclusions: The educational intervention, with improved collaboration between county hospitals and PHC institutions, and health education to patients, resulted in improved diabetes knowledge and FBG levels and improved some aspects of HRQoL among patient participants. The impact of the intervention was greater among certain patient groups and differed between the counties. The intervention had a positive impact among health care professionals in PHC on their professional diabetes skills, knowledge, attitudes, practices, and types of services they were able to provide. Improved collaboration between county-level hospitals and PHC, with educational efforts both to health care staff and patients with T2DM, appears to be a feasible and effective way of improving care of patients with T2DM in rural areas in China.

LIST OF SCIENTIFIC PAPERS

I. Chen S, Burström B, Sparring V, Qian D, Burström K. Differential impact of an education-based intervention for patients with type 2 diabetes mellitus in rural China. *Int J Environ Res Public Health*. 2019;16(15):2676.

II. Chen S, Qian D, Burström K, Burström B. Impact of an educational intervention in primary care on fasting blood glucose levels and diabetes knowledge among patients with type 2 diabetes mellitus in rural China. *Patient Educ Couns*. 2020;103(9):1767−1773.

III. Chen S, Qian D, Burström B. Shifting the care of type 2 diabetes mellitus from hospital to primary health care institutions through an educational intervention for health care professionals: An example from rural China. *Int J Environ Res Public Health*. 2020;17(6):2076.

IV. Chen S, Qian D, Burström B. Two-year impact of an educational intervention in primary care on blood glucose control and diabetes knowledge among patients with type 2 diabetes mellitus: A study in rural China. *Manuscript submitted*

CONTENTS

LIST OF ABBREVIATIONS

ATCM	The Administration of Traditional Chinese Medicine
BMI	Body mass index
CDC	Centres for Disease Control
DID	Difference-in-difference model
DKN-A	Diabetes Knowledge Scale
DKQ-24	Diabetes Knowledge Questionnaire
DKT2	Diabetes Knowledge Test 2
DQOL	Diabetes Quality of Life measure
FBG	Fasting blood glucose
HbA1c	Glycated hemoglobin
HFPC	The Health and Family Planning Commission
HRQoL	Health-related quality of life
LMICs	Low- and middle-income countries
NDR	National Diabetes Registry
NMU	Nanjing Medical University
NPC	National People's Congress
NRCMS	New Rural Cooperative Medical Scheme
PHC	Primary health care
RCT	Randomized controlled trial
SDGs	Sustainable Development Goals
T2DM	Type 2 diabetes mellitus
TPD	Triple Prevention strategy of Diabetes
TTO	Time trade-off
UEBMI	Urban Employee Basic Medical Insurance
URBMI	Urban Residence Basic Medical Insurance
WHOQOL-100	World Health Organization Quality of Life Assessment Instrument

1 BACKGROUND

1.1 GLOBAL BURDEN OF TYPE 2 DIABETES MELLITUS (T2DM)

Type 2 diabetes mellitus (T2DM) is becoming one of the most common chronic diseases all around the world (1), 8.5% of adults aged 18 years and older had diabetes in 2014 globally, more than 90% of whom had T2DM (1,2). It is estimated that by the year 2040, more than 642 million people might suffer from T2DM (2). Meanwhile, the prevalence of T2DM varies according to geographical region. The Eastern Mediterranean and the Middle East have the highest rate of T2DM, while India and China have the highest number of T2DM patients (3). The aging population, rapid urbanization, the unhealthy lifestyle, with increasing overweight and obesity are considered as possible reasons for the high prevalence of T2DM (4).

The low- and middle-income countries (LMICs) are facing a more difficult situation of T2DM than developed countries, and 80% of the T2DM patients live in the LMICs (2). A nutrition transition towards consumption of refined carbohydrates, high total fat, along with low intake of fiber was detected in many LMICs (5). The nutrition transition is considered to be strongly related to the increases in obesity, metabolic syndrome, and T2DM (6). Meanwhile, people in LMICs usually have low awareness on T2DM and its risk factors, as many of them are illiterate, or rural residents (7,8). Not only the poor awareness of T2DM, but also lack of information on healthy lifestyle, low-level of education, and limited access to blood testing are posing a huge obstacle to the prevention and management of T2DM (8). More seriously, the overall health care budget in LMICs remains low and focused more on communicable diseases, while the number of patients with T2DM and other chronic diseases has increased sharply (9,10). In many LMICs, little policy support, insufficient access to medical professionals, and poor affordability of medicine is hindering the development of the health care system for T2DM patients (11).

1.2 BURDEN OF T2DM IN CHINA

As one of the largest LMICs, China is also experiencing a dramatic increase in T2DM since 1980 (12). After the reform and opening-up policy in 1978, the standard of living of Chinese people has improved remarkably (12). However, the dramatic urbanization, the aging population, the rapid change of lifestyle, with increasing overweight and obesity has led to the rapid increase of T2DM in China (13). China conducted its first nationwide diabetes epidemiological survey in 1980, with a prevalence rate of only 0.7% (14). In 2013, the prevalence rate had increased dramatically to 11% (13,15). Older age, family history of T2DM, binge drinking, overweight, and obesity were all positively associated with T2DM prevalence in China (16). On the other hand, a healthier lifestyle (more vegetable and fruit intake, and more frequent physical activity), and higher education were protective factors of T2DM (16).

Prediabetes is the states which is defined by blood glucose level higher than normal, but lower than established thresholds for diabetes itself (17). Prediabetes is a high-risk state not

only for developing diabetes, but also the associated complications, including vascular complications, nephropathy, and neuropathies (17). It was estimated that 470 million people may have prediabetes by 2030 (17). Prediabetes becomes a huge threat for Chinese adults as well (16). It has been reported that nearly 36% of the population had prediabetes, indicating that more than 350 million people may develop T2DM if they do not change their lifestyle (18). Apart from the suffering caused by T2DM, a number of severe complications, including cardiovascular complications, nervous system disorders, and diabetic nephropathy, may also threaten patients (19).

The situation regarding T2DM in rural China is even worse, with a faster increasing rate of prevalence than in the urban areas, while the awareness and opportunities for treatment and control of T2DM are inadequate in rural areas (20). A trend was found that the epidemic peak of diabetes is slowly moving from major cities to small cities and rural areas in China, since 2007 (21). Proper and adequate diabetes care may not be accessible as the majority of the rural residents live in low-income conditions (22). The older patients often have low educational level or are even illiterate, which results in a poor quality of self-monitoring of blood glucose level, and low adherence to antidiabetic medications or insulin injections (23). Furthermore, an unbalanced lifestyle becomes another risk factor for rural residents, especially farmers (22). During planting and harvest seasons, farmers usually consume more sugar to deal with the heavy workload. On the other hand, during the traditional holidays such as Chinese New Year, they prefer to have high fat and oil dishes to celebrate the festival without any physical exercise (22).

1.3 THE HEALTH CARE SYSTEM IN CHINA

Under the health legislative system controlled by the National People's Congress (NPC), the Chinese health care system consists of health governing system, health service delivery system, and health financing system (24). The Health and Family Planning Commission (HFPC) and the Administration of Traditional Chinese Medicine (ATCM) compose the main body of the health governing system (24). The health delivery system is divided into two parts: the public health system and the medical service delivery system. The public health delivery system includes Centres for Disease Control (CDC), health education facilities (medical colleges and university-affiliated hospitals), and health supervision and management institutions (such as the Insurance Regulatory Commission and Ministry of Civil Affairs). (24). The medical service delivery system is composed of hospitals at different levels and primary health care facilities (24). Government input dominates the health financing system (24).

Chinese residents now have three main types of health insurance: the Urban Employee Basic Medical Insurance (UEBMI), Urban Residence Basic Medical Insurance (URBMI), and the New Rural Cooperative Medical Scheme (NRCMS) (24). Twenty years after the health care reform, 95% of Chinese population was covered by the three health insurances (25). The UEBMI is established for the urban residents who work in the formal sector (26) and is financed by payroll taxes from both employers (6%) and employees (2%) (26). It is a

compulsory scheme covering the inpatient care by a Pooled Fund and outpatient care by an Individual Account (26). The URBMI is targeted for other urban residents. It includes, in particular, children, students, unemployed people, and migrant workers (26). The URBMI is a voluntary scheme financed by the insured residents and local government (26). The URBMI contains a Social Pooling Account for inpatient care and a Household Account for outpatient care (26). All rural residents can voluntarily participate in the NRCMS with local government (26). Similar to the URBMI, the NRCMS also has a Social Pooling Account and a Household Account (26). The reimbursement ratio of all three types of health insurance is increasing every year. In 2015, the inpatient care reimbursement ratio was 69% for the UEBMI, 53% for the URBMI, and 50% for the NRCMS (27).

Figure 1 illustrates the health care system in rural and urban China. The health care system in rural areas contains three different levels of care: county level, township level, and village level (24). Primary health care (PHC) in rural China consists of township health centres and village clinics, and almost all of them are publicly owned (28). The PHC institutions are the fundamental elements for providing generalist clinical care and basic public health services, as they offered 55% of outpatient care and 18% of inpatient care in 2016 (28,29). The PHC has been proven to be a critical factor for the effective management of chronic diseases, especially in LMICs (30,31).

However, the health care system and PHC in rural China are still facing challenges. The quality of PHC is poorly assessed, as few studies focused on the quality issue concerning outcome measures (28). The health care professionals from PHC institutions usually have low levels of training (also regarding chronic diseases), commonly in the lower level medical education, and have a heavy workload (28). The medical training for PHC doctors consists of three levels: medical college, junior medical college, and technical school (28). However, the majority of health care professionals in rural China only receive a three-year medical education in medical technical school or junior medical college and lack access to updates in medical knowledge and skills (32). Moreover, health care professionals in PHC are paid low wages and have minimal benefits, and high-quality care is not rewarded as well (24,32). Doctors prefer leaving the PHC institutions, and many doctors in village clinics work over their retirement age (24).

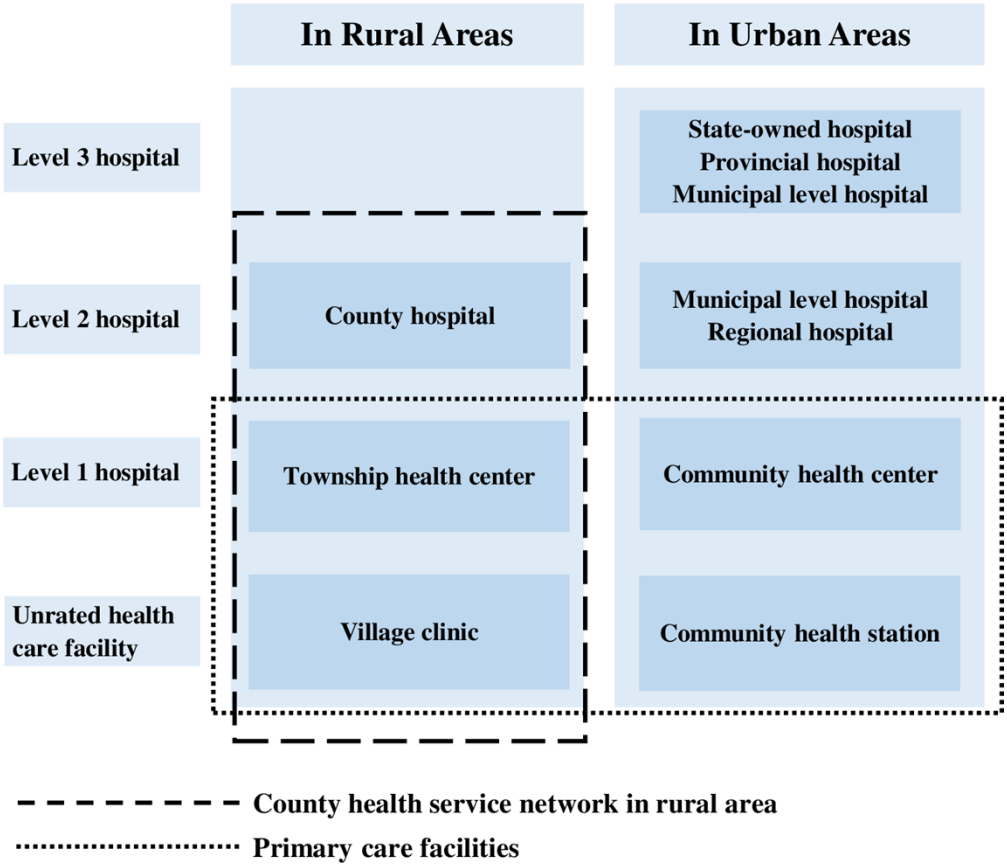

Figure 1. The health care system in rural and urban China (33)

1.4 HEALTH CARE REFORMS 2009−2020 AND "HEALTHY CHINA 2030"

After the market-oriented economic reforms and opening-up in 1978, the health care system also experienced a set of reforms (24). Market forces were introduced into the health care system: private health clinics were established, while some public-owned health care facilities were privatized (34). One of the impacts was that health care facilities became profit-driven, which led to a rapid increase in out-of-pocket medical expenditure (24). PHC was designed to conduct chronic care services, including for diabetes (36). However, costly hospital care remained dominant, and little collaboration was implemented between hospitals and PHC institutions especially in rural China (24,35). Due to the uneven distribution of health care resources, affordable and adequate diabetes care is lacking in rural China, or diabetes patients seek cheap but inappropriate care (36).

In response to the existing challenges, the central government launched an ambitious health care reform in 2009 (37). It aimed to provide universal coverage of essential health care services for all Chinese residents by 2020, with three sequential phases (38). From 2009 to 2012, the reform concentrated on five main targets: expanding public health insurance, strengthening primary care, establishing essential medicine program, providing public health care services, and pilot reforms of public hospitals (39). The second phase started in 2012 and ended in 2015, with a particular focus on public hospital reform (37). The health reform entered its third phase from 2015, and the ultimate goal was reconfirmed by the central government (37). The reform pushed the governments at all levels in China to put their

efforts to strengthen primary care, improve the generosity of public health insurance by unifying the three public insurance schemes: UEBMI, URBMI, and NRCMS to reduce the out-of-pocket health care expenses (24,37).

Moreover, the central government implemented another health policy "Healthy China 2030" blueprint in 2016, as an important part of the Sustainable Development Goals (SDGs) (40). It concerns not only the medical care for people's health, but also includes broad determinants such as environmental health, lifestyle, and health education (37,41). As one of the main threats to Chinese people, non-communicable diseases including diabetes, was especially focused in the "Healthy China 2030" blueprint (42). One of the major health targets is to enhance the collaboration between hospitals and PHC to provide diabetes care for patients (42).

1.5 INTERVENTION STUDIES FOR T2DM CARE GLOBALLY

Various types of intervention studies have been carried out in order to improve T2DM care globally (43-47, 50-55). Self-management including self-monitoring of blood glucose and peer support was used and showed a positive impact in controlling blood glucose level and improving diabetes knowledge (43,44). In recent years, new technology such as smartphone applications have been introduced in intervention studies for T2DM (45-47). It has been suggested that mobile and smartphone technologies could be an effective tool, as it is convenient in sharing data, enhancing communication, and improving glycemic control (46,47).

It is considered important to help diabetes patients to obtain the knowledge, skills, and abilities required for effective and sustained self-management (48). Therefore, educational interventions for people with T2DM is becoming another focus (49). T2DM education enables patients to acquire knowledge to modify their behaviour and to self-manage their conditions (48,50). Many educational intervention studies have been conducted in high-income countries (50-52). One study assessed the impact of an intervention in Sweden where patients in the intervention group received an empowerment group education for one year (51). Compared with the patients in the control group who received routine services, the empowerment group education improved patients' confidence in diabetes knowledge, and helped control the blood glucose level (51). Studies with similar designs are also found in LMICs, with a positive impact on strengthening patients' diabetes knowledge and changing lifestyles. Some of them have also reported that the educational intervention improved patients' health outcomes such as blood glucose level (53,54).

A systematic review of educational intervention studies all over the world, found that educational interventions significantly improved participants regarding self-efficacy, diabetes knowledge, while the impact on blood glucose level and body mass index (BMI) varied (55). The study recommended more involvement of the patient, and the educator should be trained beyond the primary preparation for the self-management program (55).

1.6 INTERVENTION STUDIES FOR T2DM CARE IN CHINA

There is growing concern about diabetes care in China in recent years (56). Along with the encouragement from the health care reform, different types of interventions with the aim of preventing and managing diabetes, have been implemented in order to improve the services for diabetes patients in China (56-57). Similar to the trends globally, educational interventions have also been implemented in China (58-63). Most of those studies have been performed in urban areas, with a relatively short duration (less than one year). Few studies have been done in rural China, and studies of the long-term impact of the educational intervention are lacking (61-63). A nutritional education intervention was conducted in a suburb area in Inner Mongolia Autonomous Region (63). After six-months of the implementation of the intervention, patients' nutrition knowledge, awareness and practice accuracy improved significantly. Patients' lifestyle also changed, having more healthy diets (63).

In most of the educational interventions, health care professionals usually act as the diabetes educator, who should be equipped with in-depth knowledge and skills, communication, and is to teach patients to manage daily conditions (48). Therefore, the educational intervention should include the aim of improving health professionals' medical knowledge and skills, as well as the ability to provide different types of diabetes services. However, there are only a few educational intervention studies that concentrate on health care professionals, especially those in PHC institutions (64-66). A training session was implemented for PHC doctors in eastern China. After 18 months, there was an improvement in professional skills and an increasing ability to provide a better quality of diabetes care (64).

As described above, knowledge is still lacking regarding the impact of educational interventions, among both diabetes patients and health professionals in PHC institutions. Few studies have focused on rural China. A review found that many educational interventions in China did not address the patient's behaviour change, health-related quality of life (HRQoL), body mass index (BMI), blood pressure, lipids, or medical costs (67). Long-term outcomes and adherence to diabetes education were vague and there were few studies on those topics (67).

This PhD thesis is nested in the project "Studying the Vertical Integration Strategy of Chronic Disease Service Based on Multiple Incentive Mechanism in Rural China" (ISRCTN13319989), conducted by Nanjing Medical University (NMU) (69). The project intended to shift the care of T2DM and primary hypertension from hospital to PHC, through implementing, together with the county-level hospital, an educational intervention for patients and health care professionals in PHC institutions (Figure 2). The green square in Figure 2 shows the position of the PhD thesis in the project, assessing the impact of the educational intervention.

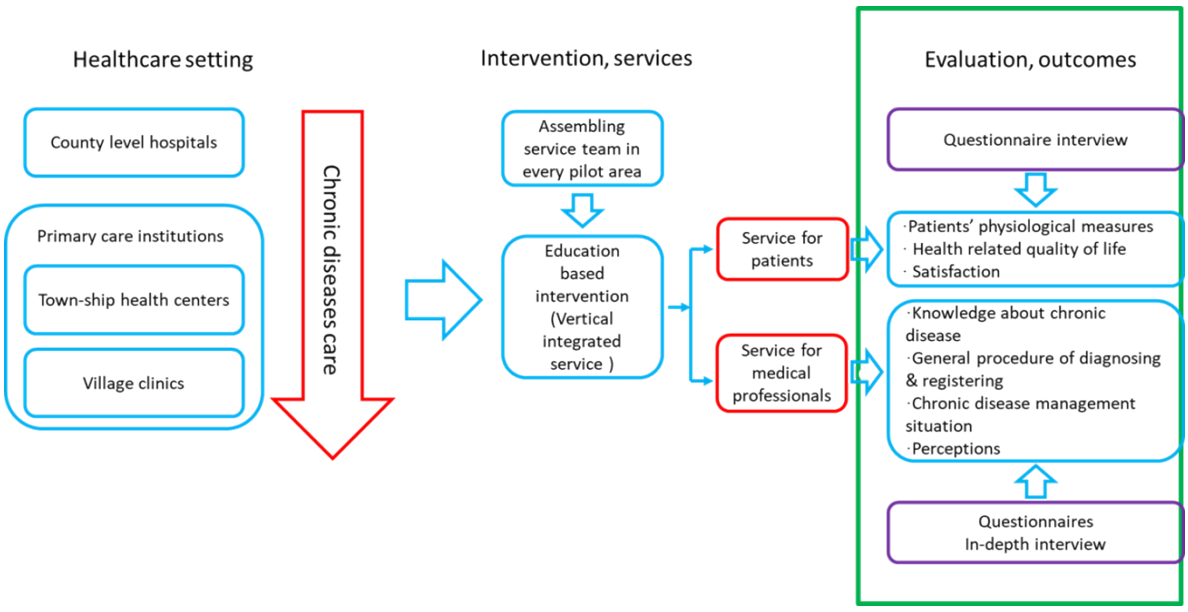

Figure 2. Logic model of the project "Studying the Vertical Integration Strategy of Chronic Disease Service Based on Multiple Incentive Mechanism in Rural China" (69)

2 AIM

2.1 OVERALL AIM

The overall aim of this thesis was to increase knowledge on the feasibility and impact of an educational intervention to shift the management of type 2 diabetes mellitus from hospitals to primary health care in rural China.

2.2 RESEARCH QUESTIONS

1. How did the intervention influence:
   a) patients' fasting blood glucose level and health-related quality of life? (Study I)
   b) patients' diabetes knowledge and fasting blood glucose level? (Study II)
   c) knowledge of diabetes care, attitudes towards the intervention, and services provided among health care professionals in primary health care institutions? (Study III)
2. What was the long-term (two years) impact on fasting blood glucose level and diabetes knowledge among patients? (Study IV)

An overview of Study I–IV is shown in Table 1.

Table 1. Overview of the four studies

	Study I	**Study II**	**Study III**	**Study IV**
Study population	T2DM patients	T2DM patients	Health care professionals in PHC	T2DM patients
Study setting (counties)	Jingjiang	Huaiyin Jingjiang Gaochun	Huaiyin Jingjiang Gaochun	Huaiyin Gaochun
Sample size and data sources	n=423 Baseline and first follow-up	n=1305 Baseline and first follow-up	n=241 Baseline and first follow-up	n=783 Baseline, first and second follow-up
Outcomes	FBG* and HRQoL**	Diabetes knowledge and FBG	Professional knowledge; perspective on the intervention; provided services	Diabetes knowledge and FBG

* FBG = Fasting blood glucose level

**HRQoL = Health-related quality of life

3 STUDY POPULATION AND METHODS

3.1 STUDY SETTING: JIANGSU PROVINCE

All four studies were conducted in Jiangsu province, located in the east part of China (Figure 3). Jiangsu province covers 107,200 km^2 with 80.5 million population in 2018 (70). Jiangsu province consists of 13 prefecture-level cities and 96 rural county administrative divisions (counties) that belong to the prefecture-level cities (70). Jiangsu province is known as "land of fish and rice", as it was China's major rice and fish producing areas in history (71). Since the reform and opening policy in 1978, Jiangsu province has become one of the most important industrial regions in China, with the second-largest gross domestic product among all provinces (70,71). Jiangsu province is divided into three parts according to geographical factors and economy: the north part (less economically developed), the middle part (average economically developed), and the south part (most economically developed) (72). The economic, education and health indicators in rural areas of Jiangsu province are all above the average level in China (70).

Jiangsu province is facing a serious situation of T2DM as the economy and lifestyle changed considerably in the last 30 years (Figure 4) (73). In 2009, the prevalence of T2DM was 8.5%, which was slightly lower than the prevalence rate in the whole country (74). However, the prevalence rate had increased sharply both in urban and rural areas in Jiangsu province. The number of T2DM patients increased 1.3 times compared with the number in 2002 (74). The south part of Jiangsu province has the highest prevalence rate, and the north part has the second-highest prevalence rate (74). In addition to the impact on health of T2DM, it was also estimated that the indirect economic losses caused by diabetes were 740 million RMB in 2010 (74,75). Although the T2DM prevalence rate in rural Jiangsu province is lower than in the urban areas, the insufficient diabetes care resources, the fast-increasing prevalence, and the poor awareness of diabetes are obstacles to improving people's health in rural Jiangsu province (74). Therefore, there is an urgent need to strengthen prevention and treatment of T2DM in rural areas in Jiangsu province.

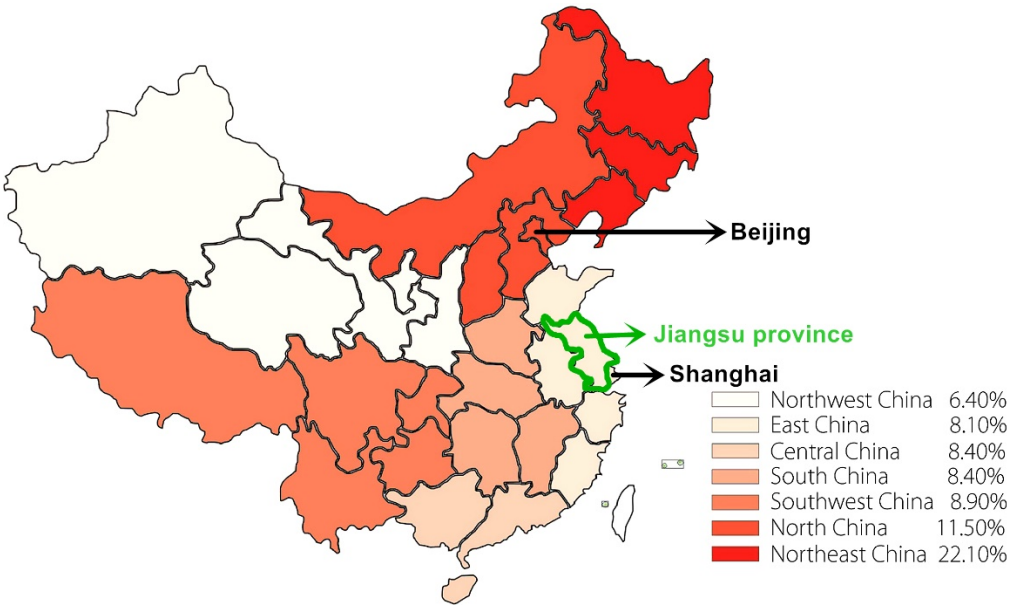

Figure 3. Prevalence of T2DM in geographic areas of China (73)

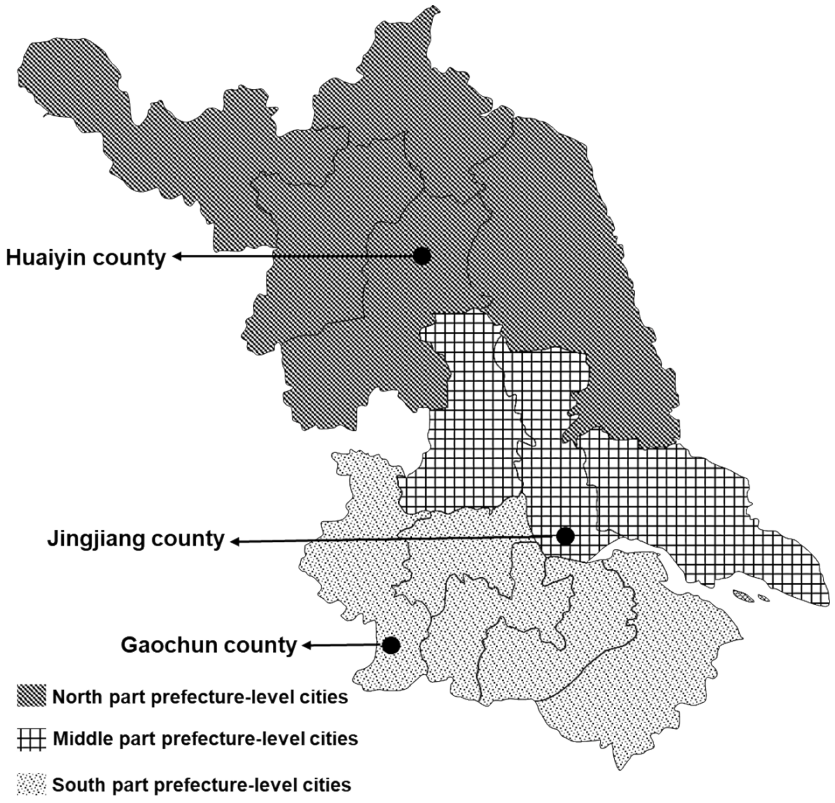

Figure 4. Map of all 13 prefecture-level cities in Jiangsu province, China

3.2 SELECTION OF INTERVENTION AND CONTROL AREAS, AND PARTICIPANTS

The research team in Nanjing Medical University (NMU) was responsible for selecting counties for the study. One county was randomly selected in 2015 from each part of Jiangsu province. Huaiyin county was selected from 37 counties in the north part. Jingjiang county was selected from 11 counties in the middle part. In the south part, Gaochun county was selected from 39 counties. There are 14 townships in Huaiyin county (70). Jingjang and Gaochun counties have eight townships, respectively (70).

After the selection of counties, the local HFPC in those three counties were asked to participate in the project and were responsible for selecting of townships. In each of the counties, 2–4 townships were randomly selected as the intervention areas. Subsequently, according to the socio-demographic features, the economic development situation, and the health care services, 2–4 townships were selected in the same county as the control areas. Finally, 18 townships (nine intervention, nine control) were part of the study. Table 2 shows the counties and townships, which took part in the project.

Table 2. The counties and townships selected in the project

Location	County	Intervention township	Control township	Implementation		
				One year		Two years
North	Huaiyin	Nanchenji Zhaoji	Yangzhuang Yuanji	*	#	*
Middle	Jingjiang	Dongxing Houhe Xieqiao	Chengnana Gushan Huifeng	*	#	
South	Gaochun	Qiqiao Zhuanqiang Yangjiang Dongba	Chunxi Yaxi Gubai Gucheng	*	#	*

* Intervention for patients with T2DM
# Intervention for health care professionals in PHC

The recruitment of patient participants was non-randomized. Doctors from township health centres contacted T2DM patients living in the townships, who satisfied the inclusion criteria according to their records. The inclusion criteria were: meeting the diagnostic criteria of the Chinese Guidelines on the Prevention and Treatment of T2DM (13); aged 35–75 years old; living in the current county for more than two years with no records of moving within the last year; having personal records in the chronic disease management information system in the township health centres; taking the chronic disease service provided by the primary care institutions; and willing to participate in the project and having preferable cognition and receptivity. Patients were excluded if they had severe diabetes complications, or they were diagnosed with any other severe disease, or they were pregnant or had psychiatric disorders.

The selection of the health care professional participants was conducted under the principle of voluntariness. Health care professionals in PHC institutions were invited to the project in

both the intervention and control areas. The inclusion criteria were: that they were frontline staff (not administrative or personnel staff); were willing to take part in the data collection; worked in the current institutions for at least two years; had no plan to leave.

3.3 THE IMPLEMENTATION OF THE EDUCATIONAL INTERVENTION

The intervention was designed by the NMU research team at the beginning of 2015 and was revised and improved by suggestions from HFPC, county-level hospitals, and Jiangsu Provincial Centres for Disease Control and Prevention. The implementation of the intervention began in November 2015, after the baseline data collection in October 2015.

The intervention for T2DM patients was designed to be conducted for two years in three selected counties, with collection of baseline data in 2015, and at the end of each year, one follow-up data collection would be carried out (Table 1). However, Jingjiang county discontinued the intervention at the end of 2016 due to administrative reasons. Finally, the intervention was conducted for two years in Huaiyin and Gaochun counties, with the first follow-up data collection in October 2016, and second follow-up data collection in July 2017. In Jingjiang county, the intervention was conducted for one year, with one follow-up data collection in October 2016.

The underlying logic of the educational intervention was to improve collaboration between the hospital and PHC level, with educational lectures and follow-up services to patients, which would in turn lead to improved diabetes knowledge and improved fasting blood glucose (FBG) level among patients. Professional skills training, team discussions, and regular meetings to discuss work progress would strengthen the knowledge and management of diabetes among PHC professionals.

The educational intervention was conducted by service teams, assembled by the county-level health authorities in the intervention areas. The service teams consisted of physicians, nurses, public health physicians, and diabetes specialists from all three levels of rural health care institutions (county-level hospitals, township health centres, and village clinics).

3.4 THE EDUCATIONAL INTERVENTION FOR PATIENTS WITH T2DM

In addition to the routine services, patients in the intervention areas received health education lectures, periodical follow-up interviews with an annual physical examination, and special medical services (i.e. helping patients with medical treatment, transfer treatment, return visits, and clinical care).

The education lectures were held every two months, usually lasted for about two hours for patients in the intervention group. The service teams used specific patient examples to make the lecture easy and interesting for the patients. The lectures included:

- basic information on diabetes, including typical symptoms, the basic epidemiological facts, the basic diagnosis criteria, and diabetes-related complications, such as foot ulcers;
- self-management strategies, including self-monitoring blood glucose at home, food recommendations, and suggestions about how to use medication;
- instruction on physical exercise and diet therapy;
- risk and dangers when having high blood glucose level, the need for balancing sugar, protein, and fat intake;
- recommendation on quitting smoking and drinking, eating bean products, and controlling cholesterol intake;
- prevention of diabetes, based on the Triple Prevention strategy of Diabetes (TPD), as recommended by the guidelines for T2DM in China (13).

Periodical follow-up interviews were offered every two months. Doctors in township health centres paid a home visit and measured blood glucose level among patients in the intervention area. The doctors also provided counselling according to blood glucose level and patients' eating or physical exercise records. Patients could also give feedback on their attitudes and feelings about the education lecture they had taken part in. County-level hospitals provided the annual physical examination. The examination contained a "routine package" (height, weight, blood pressure, and electrocardiogram), a "physical examination package" (ophthalmology, otolaryngology, and stomatology, etc.), and a "biochemical examination package" (blood test, liver and kidney function tests, blood glucose and blood lipid test, and test for some tumour markers). The annual physical examination was free for patients in the intervention area, the project and the county-level hospitals covered the fee.

Township health centres in the intervention areas took responsibility for the special medical services, which included helping patients with medical treatment, transfer treatment, return visits, and clinical care.

Patients in the control areas received routine services as usual, including clinic visits to a physician and referrals as required according to the patient's condition, FBG test every four to six months, and receiving diabetes knowledge leaflets once a year.

3.5 THE EDUCATIONAL INTERVENTION FOR HEALTH CARE PROFESSIONALS IN PHC

The intervention for health care professionals in the intervention areas consisted of three main components: team communication, regular meetings, and professional skills training sessions.

The team communication and regular meetings aimed to bring together doctors in the county-level hospital health care system and those working in the PHC system and to improve the diabetes service to patients. Some special cases were discussed during the team communication, and doctors in the county-level hospitals suggested the work plan of health care professionals in the PHC institutions during the regular meetings.

The professional skills training sessions were provided by the county-level hospitals and were designed to improve the professional skills and knowledge for those in PHC institutions in the intervention areas. The detailed contents of the training sessions were decided by each county-level hospital, and mainly focused on effective management of diabetes patients, instruction about diabetes medication and insulin injection, and using the unified health information system to record patients' situations. After the intervention, health care professionals in PHC institutions were expected to have increased knowledge on diabetes and provide more types of diabetes care services than before.

Health care professionals in the control group continued with their routine work and had no extra intervention.

3.6 OUTLINE OF THE FOUR STUDIES

The outline of Study I–IV is illustrated in Figure 5. Study I, Study II, and Study IV focused on the impact among patients with T2DM, while Study III concentrated on the impact among the health care professionals in PHC institutions. Study I and Study II evaluated the one-year impact on the patients' diabetes knowledge, FBG level, and HRQoL. Study IV assessed the two-year impact on diabetes knowledge and FBG level, compared with patients in the control group, after the implementation of the intervention.

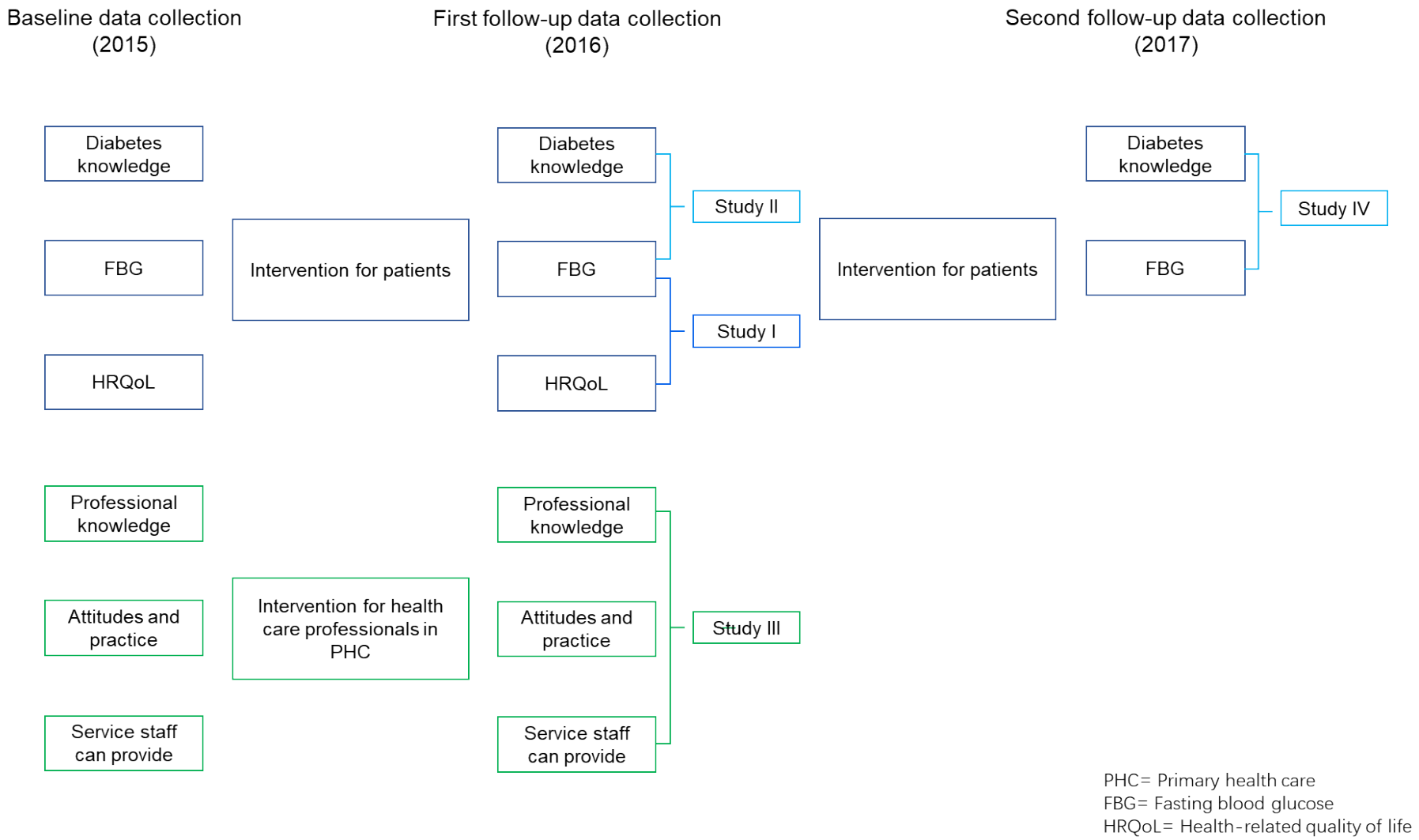

Figure 5. Outline of Study I–IV

3.7 DATA COLLECTION

All four studies used the database collected in the larger project. Questionnaires were used to collect data; one was for patients with T2DM, and two were for health care professionals (69). The questionnaires are found in the Appendix.

The questionnaire for patients contained information regarding socio-demographic characteristics, diabetes knowledge (nine questions), and the HRQoL instrument EQ-5D-3L. The patients' socio-demographic characteristics included age (in years); sex (male vs. female); marital status (married/cohabiting vs. single); level of education (low vs. high); occupation type (farmer/housework vs. other); and the duration (in years) of being diagnosed with T2DM. Participants with primary school or less were classified as having low education; those with higher than primary school (middle school/high school/junior college/bachelor or higher) as having high education. Participants' blood glucose level was measured with a venous blood sample after completing the questionnaire.

For health care professionals, one questionnaire was used to collect participants' socio-demographic information, diabetes professional knowledge (13 questions), and eight questions related to services which the health care professionals provided to the patients. The other questionnaire was on attitudes (three questions) and practices (six questions) regarding the intervention. Each of the nine questions had five response levels: from the worst to the best. Participants' socio-demographic information was collected concerning age (in years), working experience (in years), sex (male vs. female), and medical education level (low vs. high). Participants with technical school degree or junior medical college degree were classified as having low medical education; those with medical college degree or higher degree as having high medical education.

The research team from NMU took the responsibility of collecting data. Face-to-face interviews were carried out with the patients. Before the data collection, research team members were trained how to clarify, if needed, the questions to patients and how to avoid misleading the patients when explaining. During the data collection, patients were told that no other patient participants would know the answers they provided, and their personal information was not recorded in the questionnaire. After each data collection, patients received a small gift (a towel) for participation reward. The health care professionals in PHC who participated in the intervention, were asked to complete the two questionnaires by themselves. They were not allowed to talk with other participants during answering the questionnaires. The county-level HFPC offered a special bonus to them for participating in the project.

3.8 OUTCOME MEASURES USED IN THE STUDIES

Blood glucose level (Study I, II, IV)

FBG level and glycated hemoglobin (HbA1c) are commonly used to measure the blood glucose level for T2DM (76-78). There are some discussions about the sensitivity and effectiveness between FBG level and HbA1c, but the conclusion varies (79-85). One study conducted in Taiwan found that HbA1c is more sensitive than FBG in detecting unusual blood glucose level (81). In contrast, another study in the United States found that FBG is more effective when separating diabetes patients from non-diabetes patients HbA1c (85). It is suggested that the combined use of FBG and HbA1c is a better way to monitor blood glucose level for patients with T2DM (84).

Blood glucose level in this project was measured by FBG level, because it is less expensive and easier to obtain than HbA1c in the rural areas. Some of the township health centres were not able to conduct the HbA1c test, and HbA1c was not collected at baseline in Jingjiang county.

Patients' diabetes knowledge (Study II, IV)

There are several existing questionnaires for measuring patients' diabetes knowledge, including Diabetes knowledge Scale (DKN-A), Diabetes Knowledge Questionnaire (DKQ-24), and Diabetes Knowledge Test 2 (DKT2) (86-88). In the current project, DKN-A was considered too difficult for our participants to understand as most of them had low educational level. DKQ-24 was considered out of date, as it was developed in 1983 (87). Although DKT2 is a newly designed questionnaire, it contains many questions and might take too long for participants to answer along with other questions related to T2DM.

As a result, the research team from NMU decided to add nine self-designed questions for diabetes knowledge in the current questionnaire for patients. The nine questions included basic knowledge on diabetes, self-management, and healthy lifestyle. A diabetes knowledge score was calculated based on response to nine questions (correct answer marked as 1, wrong answer marked as 0). The nine questions were pilot-tested before use, the Cronbach alpha was 0.76. The specific questions are shown in Appendix Table 1.

Health-related quality of life (Study I)

In Study I, HRQoL was used to evaluate the impact of the intervention among patients. Different types of instruments can be used to measure HRQoL, both in the general population and among diabetes patients (89-91). The World Health Organization Quality of Life Assessment Instrument (WHOQOL-100) and the EQ-5D can be used in the general population or among individuals with different health conditions (89,90). In contrast, the Diabetes Quality of Life measure (DQOL) is designed specifically for diabetes patients (91).

The generic HRQoL instrument EQ-5D-3L consists of two parts: a descriptive system and a visual analogue scale (EQ VAS) (90). The EQ VAS records the patient's self-rated health on a vertical VAS, where the endpoints of the scale are 0 (worst imaginable health state) and 100 (best imaginable health state). The descriptive system of EQ-5D-3L contains five different dimensions of health: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. Each dimension has three different levels of severity: no problems, some problems, and extreme problems. There are 243 different health profiles that can be created to describe the health status from the descriptive system (92). Those unique health profiles can be converted into a single index value by a value set, where full health is 1 and dead is 0 (92). Various national value sets have been developed by different methods (such as the time trade-off (TTO) method and the VAS method) (92).

There are three value sets developed based on a Chinese population (93-95). The value sets developed by Liu et al. (93) and Zhuo et al. (94) used the TTO method for health states that were described to those who valued them, and the study by Liu et al. was based only on an urban population. Sun et al. have developed a value set using the VAS method for health states that were currently experienced by the respondents in the general population (95). In Study I, we employed the experience-based VAS value set developed by Sun et al. to calculate the EQ-5D-3L index.

Health care professionals' diabetes knowledge and services they can provide (Study III)

We did not find any studies published in international journals about the impact of education-based interventions among T2DM medical professionals. Therefore, we decided to design and use two questionnaires for collecting data related to health care professionals' knowledge, services they can provide, and their perspective on the intervention.

In Study III, one structured questionnaire was used, which contained 13 questions related to diabetes professional knowledge and eight questions related to services which the health care professionals provided to the patients. A knowledge score was calculated as a sum of correct answers to each of the questions, with the total score 13 points. The Cronbach alpha for the professional knowledge questions and for the services type which the health care professionals provided was 0.71 and 0.82, respectively. The 21 questions related to professional knowledge and services the health care professionals can provide are shown in Appendix Table 2 and Appendix Table 3, respectively.

Professionals' perspective of the intervention (Study III)

Another questionnaire on attitudes and practices regarding the intervention was also used in Study III to measure health care professionals' perspectives on the intervention. It included four sections: conducting transfer treatment, evaluating cooperation with higher-level hospitals, general perspective about PHC institutions, and evaluating factors that affected the integrated care service. We extracted nine questions and divided them into two parts:

attitudes change (three questions), and participants' perspective on their practice before and after the intervention (six questions). All the nine questions had five response levels: from the worst to the best. 1 to 5 points were given to each question, in which 1 represented the worst, and 5 represented the best. Participants obtained an attitude score (total maximum score: 15 points) and a practice score (total maximum score: 30 points). The nine questions have been pilot-tested, the Cronbach alpha was 0.84. The questions are shown in Appendix Table 4.

3.9 MAIN STATISTICAL ANALYSIS METHODS USED

Difference-in-difference model

The difference-in-difference (DID) model is used to estimate the effect of an intervention or treatment, by comparing the changes in outcomes over time between a population that is enrolled in an intervention group and a control group (96). In Study I, the DID model was used regarding the FBG levels, mean EQ VAS score, and EQ-5D-3L index, to test whether there were differences in outcomes between the intervention and control group before and after the intervention. The DID model was adopted in Study II to test for differences in outcomes between the intervention and control group before and after the intervention regarding the diabetes knowledge score and FBG level. In Study III, to test for differences in outcomes between the intervention and the control group before and after the intervention regarding the knowledge score, attitude score, and practice score, a crude DID model without adjustment was adopted.

Analysis based on EQ-5D-3L

Participants who reported "some problems" or "severe problems" on the descriptive system in EQ-5D-3L were classified as having "any problems." The percentage of reporting any problems in the EQ-5D-3L dimensions, the mean EQ VAS score, and the EQ-5D-3L index were analysed by the Mann–Whitney U test and the Pearson's $\chi 2$-test/Fisher's Exact test. As described in the former section, mean EQ VAS score and EQ-5D-3L index were also analysed by DID model.

Propensity score matching

In Study II, there were significantly more low educated patients in the intervention group compared with in the control group. In order to consider potential selection bias and balance the distribution of socio-demographic covariates between the intervention and the control group, propensity score matching (PSM) was conducted (97). We used 1:1 ratio nearest neighbour matching without replacement technique, and included participants' age, sex, marital status, level of education, occupation type, duration of T2DM, and comorbidity as potential confounders and entered these into the PSM model.

Mixed-effects linear regression models

The mixed-effects linear regression model is an extension of simple linear models to allow both fixed and random effects, and are mainly used when there is non-independence in the data (98). Two mixed-effects linear regression models were adopted to investigate the associations between the diabetes knowledge score or FBG level and the interaction of time and group. The models were used to study whether these outcomes differed between the intervention and control group, at the different time points studied. Both models were adjusted for the participants' socio-demographic characteristics including age, sex, marital status, level of education, occupation type, and duration of T2DM.

3.10 ETHICAL CONSIDERATIONS

Ethical approval was obtained by the Nanjing Medical University Ethics Committee (2015; #300). Patient participants received written information about the aim of the project, that participation was voluntary and that they could decide to leave the study at any time and for any reason. Patients in the intervention area were informed that they would get additional diabetes services rather than the routine service, while patients in the control areas were informed that there would not be any changes in the diabetes services. All patient participants gave informed consent to participate. The research team at NMU was trained and collected the data from all patients. Health care professionals in PHC were invited to participate in the project. Those included in the intervention group, were informed that they would have some extra work to do in the following year. Two questionnaires were offered to them after gaining their permission.

To protect confidentiality, all analyses were carried out on group level, and traceability to individuals is therefore not possible.

4 FINDINGS

4.1 THE IMPACT ON DIABETES KNOWLEDGE SCORE AND FBG LEVEL AMONG PATIENTS WITH T2DM (STUDY I, II, IV)

In the analysis for patients in all three counties at the first follow-up, the diabetes knowledge score increased significantly in the intervention group, while FBG level decreased significantly in the intervention group compared to the control group. At baseline data collection, the control group had a higher mean diabetes score than in the intervention group (5.36 vs. 4.77). After the one-year implementation of the intervention, the mean diabetes knowledge score in the intervention group increased to 5.57. In contrast, the mean diabetes knowledge score decreased to 5.25 in the control group. The DID model showed that the diabetes knowledge score increased significantly more in the intervention group than in the control group (DID = 0.91 (CI95 % 0.64–1.18)). The FBG level in both groups decreased after one year. However, only in the intervention group, the FBG level dropped significantly, with the mean difference -0.58 mmol/l, (CI95% -0.75, -0.38). Therefore, the FBG level decreased significantly more in the intervention group than in the control group, (DID = -0.53 mmol/l (CI95 % -0.90 to -0.16)). Regarding the two-year impact of the intervention on the diabetes knowledge score and FBG level, positive associations were found between diabetes knowledge score and the interaction of time and group, the effect size was 0.96 (CI95% 0.69 to 1.24) in 2016 and 1.14 (CI95% 0.87 to 1.42) in 2017. However, the intervention had a positive impact on lowering participants' FBG level in the intervention group only in 2017, with an effect size of -0.46 (CI95% -0.90 to -0.02).

The intervention had a differential impact on FBG level for patients in different counties, both at the first and second follow-up. Patients in Jingjiang county had a different trend of FBG level at one-year follow-up. The FBG level decreased in the intervention group (mean difference = -0.41), while it increased in the control group (mean difference = 0.77) for patients in Jingjiang county. On the contrary, patients in Huaiyin and Gaochun counties had a decrease in FBG level in both the intervention and control groups. When comparing the FBG level in Huaiyin and Gaochun counties regarding the two-year impact, the intervention had a positive impact on controlling FBG level in the intervention group, the effect size was -0.76, (CI95% -1.32 to -0.19).

There was also a differential impact among individual patients. Improvement regarding the FBG level was greater among females (from 8.3mmol/l to 7.9mmol/l), married patients (from 8.2mmol/l to 7.9mmol/l), low educated patients (from 8.4mmol/l to 8.0mmol/l), and patients who were farmers or house working (from 8.4mmol/l to 8.0mmol/l), than among other patients.

4.2 THE IMPACT ON HRQOL AMONG PATIENTS WITH T2DM (STUDY I)

The analysis for EQ-5D-3L was conducted only in Jingjiang county. The mean EQ VAS score (from 74.8 to 77.2) and EQ-5D-3L index (from 0.87 to 0.90) increased among patients in the intervention group after one year. However, in the DID analysis there was no difference between the intervention and the control group regarding the mean EQ VAS score and EQ-5D-3L index at one-year follow-up. Fewer patients reported having problems in the dimensions mobility (from 22.5% to 11.3%), usual activities (from 13.1% to 3.8%), and anxiety/depression (from 23.5% to 14.1%).

The intervention seemed to differentially benefit some groups of patients, regarding the prevalence of any problems by EQ-5D-3L dimensions. Female patients in the intervention group improved more in the dimension of mobility and usual activities than male patients. The married patients improved in almost all dimensions except self-care, while the single patients had no improvement in either of the dimensions. Patients with low educational level improved more than high educated patients, regarding the dimension of mobility, usual activities, and anxiety/depression. For those who were farmers or house working, improvements were found in the dimensions mobility, usual activities, and anxiety/depression. On the contrary, patients in other types of work did not improve in any dimension after one year.

Patients in the control group also had some improvements regarding EQ-5D-3L. The EQ-5D-3L index in the control group increased from 0.89 to 0.93, and the mean EQ VAS score also increased in the control group (but not statistically significant). Fewer patients in the control group reported having any problem after one year, in the dimension of mobility (from 19.0% to 7.6%), usual activities (from 13.3% to 2.4%), pain/discomfort (from 42.4% to 31.4%), and anxiety/depression (from 15.7% to 8.6%).

4.3 THE IMPACT AMONG HEALTH CARE PROFESSIONALS IN PHC INSTITUTIONS (STUDY III)

The professionals in the intervention group experienced an increase in the diabetes knowledge score, with the mean score was 7.3 at baseline and 11.5 at the one-year follow-up. The mean diabetes knowledge score also increased slightly in the control group, from 7.3 to 7.4, but increased significantly more in the intervention group than in the control group after the intervention (DID = 3.65). At baseline data collection, the practice score and the attitudes score were higher in the control group (14.2 and 8.8, respectively) than in the intervention group (13.6 and 8.6, respectively). After one-year implementation of the intervention, the mean practice score in the intervention increased to 19.8, higher than in the control group (15.0). Similarly, the intervention group had a higher mean attitude score than the control group after one year (10.82 vs. 9.34). The DID analysis also showed that the health care professionals in the intervention group improved significantly more in their practice score and attitudes score than those in the control group (DID = 5.33 and 1.71, respectively).

Regarding the proportion of being able to provide different types of diabetes services, there was a substantial and significantly higher proportion of participants able to provide services in the intervention group than in the control group, for all types of services, except T2DM emergency treatment. At baseline, there was no significant difference between the intervention group and the control group. At one-year follow-up, the proportion of professionals being able to provide seven types of diabetes service (diabetes diagnoses, diabetes classification, insulin treatment, oral hypoglycemic agents, early control for T2DM, T2DM complication treatment, and T2DM non-drug therapy) in the intervention group had increased, compared to the proportion at baseline.

5 DISCUSSION

The educational intervention had a positive impact in improving diabetes knowledge, lowering FBG levels and improving HRQoL among patients with T2DM at one-year follow-up, especially among females and those in lower socioeconomic groups. A long-term (two years) positive impact was also found on diabetes knowledge and FBG level. Moreover, the intervention had a positive impact among health care professionals in PHC on their professional diabetes knowledge, attitudes and practices regarding the intervention, and types of services they were able to provide.

5.1 IMPACT AMONG PATIENTS WITH T2DM

The increased collaboration between the county-level hospital and PHC services, along with an educational intervention among patients with T2DM, had a positive impact on the diabetes knowledge and FBG levels among patients in the intervention group compared to the control group, at one-year follow-up. There was no process evaluation during the implementation of the intervention, and we did not have detailed information about how patients participated, for example the adherence to the intervention (such as the attendance rate for the education lectures). In addition, we have no information as to whether the patients who attended the lectures talked about contents of the lecture to those in the control group or those who did not attend the lecture. As a result, we do not know whether the improvement of FBG level and diabetes knowledge could fully be explained by the intervention. The level of changes in diabetes knowledge in this study is similar to that observed in previous studies in different settings, that showed a significant improvement in diabetes knowledge, after a short-term educational intervention among patients with T2DM (59,99-101). However, both Study II and Study IV had a longer duration of the intervention and had more participants than the other studies. Cai et al. conducted an educational intervention for T2DM patients in urban China (59), and found that the intervention improved the blood glucose level and level of diabetes knowledge, which is similar to what we found in Study I and II (59). However, Study I and II assessed the one-year impact in rural China, while the intervention in the Cai et al. study was conducted in urban settings for only three months (59).

The intervention also had a positive impact on the diabetes knowledge score and FBG levels among patients in the intervention group compared to the control group, at two-year follow-up. The FBG level decreased significantly in both the intervention and control groups at the first follow-up, but increased again in both groups at the second follow-up. Some external factors may have affected those results. During 2015 to 2016, Huaiyin and Gaochun county participated in a national government initiative project held by the National HFPC (102), which aimed to encourage local HFPCs to establish a comprehensive prevention and control demonstration zone for chronic disease. This may have contributed to the observed decrease in the FBG level in 2016 for participants both in the intervention and control group (102). The reason for the increase of the FBG level at the second follow-up is not clear. An international literature review found that various factors, including illiteracy and lack of knowledge at baseline, posed a great challenge to effective health education with sustained

effects (103). Therefore, low educational level and lack of awareness of T2DM among patients may weaken the improvement brought by the intervention. We found a long-term effect in Gaochun county in 2017, but not in Huaiyin county. Gaochun may have had a better situation regarding diabetes care, as it has a higher health budget. Moreover, as part of Nanjing city (the capital city of Jiangsu province, with the largest number of level-3 hospitals), Gaochun has good cooperation with the large city-level hospitals (104). Some previous studies have also reported a long-term impact on blood glucose control of educational interventions for patients with T2DM in China (109,110), both of which reported a significant decrease in the blood glucose level among patients with the intervention. There are also similar studies in other countries (105-108). Johnson et al. conducted a two-year educational intervention for T2DM patients in the United States, and found that the blood glucose level (HbA1c), for patients receiving the education was significantly lower than among patients not receiving education, after two years of observation (105). However, a study in the United Kingdom showed no significant difference in the HbA1c level between patients with a structured group education programme and patients with usual care, at 3-year follow-up (106). The different design of the interventions may be one reason to explain the different impacts on the blood glucose level.

Some aspects of HRQoL measured by EQ-5D-3L were also improved in the intervention group compared to the control group in our study, but less systematically. The significant decrease in the prevalence of reported problems in the dimensions of mobility and usual activities may be due to the increased information and knowledge about physical exercise, healthy diet, and the importance of proper drug use in the intervention group. The mean EQ VAS score increased in the intervention group, which may indicate that the participants perceived that their health improved after having had more information and instructions about physical activity, diet, healthy lifestyle, and diabetes self-management.

Participants in the control group had a deterioration in the FBG levels and in the prevalence of reported problems in some EQ-5D-3L dimensions, but also improved in mean EQ VAS score and the EQ-5D-3L index. When comparing the intervention and control groups, it is surprising to see a decreased proportion of reported problems in the EQ-5D-3L dimensions and improved mean EQ VAS scores and EQ-5D-3L index in both the control and intervention groups, as the control group received no intervention. This might partly be explained by compositional differences between the intervention and the control group — participants in the control group were younger, and more of them were married and had a higher educational level, all of which are associated with better HRQoL (111,112). Another possibility, as no intervention was provided to the control group, might be that the changes in HRQoL may be due to the “Hawthorne effect” (113). We found only one educational intervention study which assessed EQ-5D among T2DM patients (114). Christoffersen et al. evaluated the effect of a participatory group-based education programme for T2DM patients, at three-months and 12-months follow-up (114). The EQ-5D-5L instrument was adopted in the study, but the results did not differ significantly between the intervention and control group (114).

There were also signs of a differential impact of the intervention by county, which may reflect differences in the local implementation of the intervention between counties, the different levels of economic development of the different counties, or the differing baseline level of diabetes knowledge in the different counties. Although the content of the intervention was the same in the different counties, as the implementation of the intervention was in the hands of the local HFPCs, it is possible that the quality and intensity of implementation varied between the counties.

There was also a differential impact among patients. The FBG level and some aspects of HRQoL measured by EQ-5D-3L improved more among females, those who were married, those with low education, and those in farming or house working. This might indicate that this intervention was better suited for persons with a low educational level than with a high educational level, and for farmers in rural China. The changes in blood glucose levels at one-year follow-up are similar to those observed in previous studies (115-119).

5.2 IMPACT AMONG HEALTH CARE PROFESSIONALS IN PHC

The professional knowledge improved significantly in the intervention group, indicating that the professional skills training sessions positively affected the participating health care professionals. Another possible explanation for the improvement is that the design of the knowledge questions was entirely based on the training sessions. Therefore, it might have been easier for those who attended the training sessions to get a higher score, although it might not reflect their real ability. However, health care professionals in the intervention group were able to provide more types of services than in the control group. The improved practice score and attitude score indicate that the participating health care professionals in the intervention group had more positive perspectives than those in the control group regarding cooperation with county-level hospitals, including transfer treatment, communication, and using the new information delivery system. This suggests that the intervention had a positive impact.

The local HFPC provided rewards for health care professionals who participated in the study, including a bonus (about 2000 RMB per year) and promotion opportunity. The larger project included interviews with health professionals (not included in this PhD thesis), and many interviewees responded that the bonus was not much, but the promotion opportunity was a big encouragement for them to actively participate. Therefore, it is possible that the improvement in the professional knowledge and skills, practices and attitudes toward the intervention was also partly caused by those rewards. A previous study in rural China showed a similar result as the present study. After an 18-months training session for PHC doctors there was an improvement in professional skills and an increased ability to provide a better quality of diabetes care (120). The design of the education training session in the present study is similar to peer education training, which is commonly used in chronic disease care in many countries (121,122). However, Study III also emphasized the collaboration between county-level hospitals and PHC institutions and is the only one to our knowledge which combined education sessions and cooperation with hospital-level professionals (64-66).

5.3 METHODOLOGICAL CONSIDERATIONS

This PhD thesis aimed to contribute to knowledge on diabetes care in rural China settings. In response to the urgent need for knowledge and management strategies for patients with T2DM, educational interventions supported by experts may be a way to strengthen diabetes care and enhance the collaboration between PHC and hospital care in China (123). Many studies in recent years have focused on educational interventions for diabetes patients in urban China to improve glucose control and empower patients themselves to better manage their disease (63,124). However, few studies have focused on patients with T2DM in rural areas in China (124). Moreover, the evidence supporting the impact of educational interventions is limited to short-term studies of typically under one year. Few studies with a long-term follow-up have been found in different settings (105-108). We only found two Chinese language studies which focused on urban China with an educational intervention longer than one year (109,110). No study was found with such long-term intervention in rural China. The current project was conducted in rural China, where the increase of T2DM is rapid. The intervention for patients lasted for two years in two counties, which allowed us to analyse the long-term impact of the educational intervention. Therefore, the project may be a contribution to current research.

The doctors and nurses in PHC institutions in rural China have a low level of training for chronic conditions, commonly in the lower level of medical education (28). As vital parts of delivery health care service, the knowledge and skills, as well as the ability to provide different types of services, become extremely important for health care professionals (32). Study III aimed to improve the professional knowledge and skills, by the collaboration with the hospital level, through the educational intervention for health care professionals in PHC in rural China. The results also indicated a positive impact among those professionals, and that it may be possible to implement in other rural areas in China. In the current project, the county-level hospital provided experienced doctors to educate the patients and health care professionals in PHC, which showed a positive impact both on T2DM patients and health professionals in PHC. County-level hospitals usually are able to attract more resources and higher quality resources (health workforce and health technologies) than PHC institutions (125). On the contrary, services delivered by PHC are deemed to be of poor quality, due to the shortage of health care resources (126). Therefore, collaboration between county-level hospitals and PHC institutions might be an effective way to shift services and resources from hospitals to PHC, and to provide more accessible as well as better-quality service for patients.

The project was not a randomized controlled trial (RCT), but based in a “real-life setting”. This may be both a limitation and an advantage to the study. There are many discussions regarding the RCT and studies in real-life settings (or real-life studies), each of them having their advantages and disadvantages (127-129). RCTs are commonly recognized as the “gold standard” for evaluating treatment outcomes because of their rigorous experimental design, randomization and blinding, and rigorous analysis methods (130). However, an RCT is usually implemented under optimally controlled conditions in the absence of confounding factors: highly selected patients, optimal management conditions, and ideal settings— thus

the information provided by RCT is “efficacy” under certain conditions different from real life (131). Studies in real-life settings can be considered complementary with RCTs (129), and reflect how treatments or interventions are administered in normal routine work and everyday life (127). A non-selected population can be included, with a larger sample size than RCT. Along with the natural practice setting, and allowing long duration, studies adopting a real-life setting may be used in health policy research (131). In the current project, it was not possible to conduct an RCT because of the complicated background factors of the project and the high cost of RCTs. Implementing an intervention in a real-life setting also may facilitate policy learning, and may give a more realistic assessment of whether an intervention is feasible under such circumstances. Nevertheless, the limitations of real-life settings cannot be ignored. In our studies, the intervention was implemented locally and the implementation was outside the control of the research team. Hence, the scope and intensity of implementation may have varied between different counties and townships, which may have affected the results. On the other hand, after the collaboration with NMU, the local HFPC gained knowledge and experience about supporting diabetes care in the administrative and management aspects, which may facilitate continued and sustained local implementation of the new way of working.

In order to deal with the different compositions between the intervention and control groups, caused by the non-selected population in the real-life setting, we used propensity score matching (Study II), DID model (Study I, II, and III), mixed-effects regression model (Study IV) and stratified analysis (all four studies) to deal with potential confounding.

Patients with T2DM in the control group also had improvements in certain outcomes, some aspects of HRQoL measured by EQ-5D-3L, EQ VAS, and EQ-5D index. This might be partly explained by the Hawthorne effect, meaning that participants may modify their behaviour in response to their awareness of being observed (113). The Hawthorne effect is a limitation in the project, which may underestimate the impact of the intervention.

Another limitation is that external influences, not possible to control in this project, may have affected the results observed. One example is the national initiative on chronic disease care in 2016, described for Huayin and Gaochun county. This coincided in time with the improvement of the diabetes knowledge score and FBG levels, observed in both the intervention and the control group in both counties in 2016. It is not possible to disentangle whether this improvement in FBG and diabetes knowledge was mainly a result of the intervention or of the national initiative.

The project was based on the collaboration between the NMU and the local HFPC. The research team in NMU designed the intervention, while the county-level HFPC controlled the implementation, and details of the implementation are lacking. As a result, the implementation is likely to have differed in the three counties, which may have affected the results observed. A more intensive implementation would be likely to lead to a stronger impact on the studied outcomes, but as we did not measure the degree of implementation this could not be studied.

We used self-designed questionnaires for patients and health care professionals to collect information regarding the intervention, which could be both an advantage and a limitation. The self-designed questionnaires were designed specifically for the intervention, so they precisely captured the issues we focused. Furthermore, some existing questionnaires (e.g., diabetes knowledge) were considered too difficult for our patients as many of them had low educational level. However, the validity and reliability of the questionnaires may be questioned as they were never used before the current project. The Cronbach alpha was calculated for the nine questions for patients' diabetes knowledge, 13 questions related to diabetes professional knowledge, and for the eight questions related to services which the health care professionals provide. The Cronbach alpha showed acceptable reliability for the self-designed questionnaires.

5.4 LESSONS LEARNED

Some general reflections can be made from this PhD project. In order to improve the care for patients with T2DM (and likely also patients with other chronic diseases) in rural China, the results from this study suggests some potential areas for interventions and further studies.

- *Strengthening the collaboration between hospital care and PHC*
  The inequality in the distribution of health care resources between urban and rural areas remains a major issue in China, where hospital care dominates (134). Bringing diabetes care and hospital resources (experienced experts and advanced equipment) to the PHC level could be an effective way to improve the quality of diabetes care in rural China. In the current project, the county-level hospital provided experienced doctors to educate the patients and health care professionals in PHC, which had a positive impact both for T2DM patients and health professionals in PHC. The collaborations could also include level 3 hospitals (Figure 1) in urban areas, i.e. collaboration between rural and urban areas in China.
- *Investing in education for health care professionals in PHC institutions*
  Study III showed that improved professional knowledge and skills made the doctors in PHC institutions able to provide more types of diabetes care services for patients. Health care professionals in PHC usually have lower level medical education, and have a heavy workload (28). Investing in education for them may improve the delivery of diabetes care.
- *Enhancing the diabetes education for patients with T2DM*
  China has put a lot of effort into medication and treatment for diabetes, while the awareness and knowledge are lacking for patients, especially in rural areas (4). The improved diabetes knowledge, FBG level, and HRQoL in our studies indicated that diabetes education for patients had a positive impact.
- *Establishing diabetes registry for all patients*
  China has no national data registry for patients with T2DM. Many of the health care professionals in PHC suggested to establish a database for T2DM patients to help them assess the quality of the service provided, with information about blood glucose

level, history of medication, inpatient/outpatient records, examination results, and life style change. Sweden has a nationwide database for all T2DM patients, a National Diabetes Registry (NDR), which can provide an example for China (133). The NDR is a key factor for quality improvement in diabetes care in Sweden, as it provides an assessment of diabetes care and offers GPs and diabetes nurses individualised information for each patient (133).

- *Reforming the management of local HFPC*
  When implementing the intervention, the local HFPC was not able to provide detailed information on the implementation. The situation may improve in the future as the central government has launched a reform in improving management for health care authorities (135). More efforts should be put in daily administrative work and recording more details in the management.

5.5 FUTURE RESEARCH

The educational intervention provided a model for how similar interventions could be conducted to assess their impact among both patients with T2DM and health care professionals in PHS, in other rural settings in China. The findings of the four studies also suggest questions that future research could address:

- Could a similar intervention have a positive impact in less-developed areas, for example, the north-west province in China?
- How does a similar intervention impact on patients' satisfaction with care?
- How does a similar intervention impact out-of-pocket expenses for diabetes care?

6 CONCLUSIONS

The current project focused on T2DM in rural China and has contributed to knowledge on the impact of educational interventions for both patients and health care professionals in PHC. The educational intervention, with improved collaboration between county-level hospitals and PHC institutions, and health education to patients, had a positive impact in improving diabetes knowledge, FBG levels and some aspects of HRQoL among T2DM patients. Furthermore, the intervention had a positive impact among health care professionals in PHC on their professional diabetes skills, knowledge, attitudes, practices, and types of services they were able to provide. The intervention among patients seemed to differentially benefit females, married persons, low educated persons, and those in farming or house working more than other groups. The impact of the intervention among patients also differed between the counties at one-year follow-up, and a two-year positive impact was found only in one county (Gaochun). Improved collaboration between county-level hospitals and PHC, with educational efforts both to health care staff and patients with T2DM, appears to be a feasible and effective way of improving care of patients with T2DM in rural areas in China.

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9 APPENDIX

Appendix Table 1. Patient diabetes knowledge questionnaire

No.	Question	Options		
1.	Do you know the diagnose criteria of diabetes (FBG)? †	Yes, it is ____ mmol/l	I do not know	
2.	Is dizziness a symptom of diabetes?	**Yes**	No	I do not know
3.	Is obesity a risk factor for diabetes?	**Yes**	No	I do not know
4.	Do people with a diabetes family history have higher risk of diabetes?	**Yes**	No	I do not know
5.	Is smoking or drinking a risk factor for diabetes?	**Yes**	No	I do not know
6.	Will monitoring your blood glucose help to control diabetes?	**Yes**	No	I do not know
7.	Will eating high fat or high sugar food help to control diabetes?	Yes	**No**	I do not know
8.	Will you be blind if the diabetes cannot be controlled?	**Yes**	No	I do not know
9.	Is it necessary to keep using medication if you have already controlled your blood glucose level?	**Yes**	No	I do not know

† The answer "Yes", and FBG greater than 7 mmol/l, is classified as the right answer.
Bold font is the right answer for question 2-9.

Appendix Table 2. Professional knowledge questionnaire

No.	Question	Options
1	Which of the following options is not a typical symptom of T2DM?	A. Too much drinking B. Too much urine C. Too much eating D. Lose weight E. Dizziness
2	Which of the following options is not a chronic complication of T2DM?	A. Diabetic nephropathy B. Diabetic foot C. Diabetic cardiomyopathy D. Diabetic neuropathy E. Diabetic ketoacidosis
3	According to the Chinese guidelines for diabetes prevention and treatment, which of the following options is the goal for glucose control measured by HbA1c?	A. <= 6.5% B. >= 6.5% C. <= 7.5% D. >= 7.5%
4	Which of the following options is the reason of polydipsia for diabetes patients?	A. Malabsorption of renal tubular B. High crude urine osmotic pressure C. Too much water intake D. Reduced aldosterone secretion E. Lack of vasopressin
5	What is the best insulin treatment plan for glucose control?	A. Premixed insulin injection twice a day. B. Short-acting insulin injection 3 times a day C. Short-acting insulin injection 4 times a day D. Short-acting insulin injection 3 times a day (before breakfast/lunch/dinner) + long-acting insulin before go to bed
6	What is the main side effect of biguanides?	A. Lactic acidosis B. Hypoglycemia C. Gastrointestinal reaction D. Allergic eruption

Continued in the next page

(Continued) Appendix Table 2. Professional knowledge questionnaire

7	Which of the following patients are not suitable for insulin treatment?	A. Type 1 diabetes B. Type 2 diabetes for long time, and BG are higher than criteria C. New diagnosed T2DM with high BG D. Suffering the complication
8	Scenario: A patient was in a coma due to diabetic ketoacidosis. After the insulin treatment, he/she revived, but felt palpitation, hungry, and became unconsciousness again. What should you do?	A. Increase the insulin dosage B. Add in glibenclamide C. Intravenous drip with sodium bicarbonate D. Fingertip blood glucose test E. Use respiratory stimulant
9	Scenario: female patient, been diagnosed for 10 years, felt toes numb in the last 2 months, acupuncture-like pain in double legs and urine incontinence. Physical examination result: malnutrition, interosseus muscle atrophy in both hands, muscle strength level IV, FBG 14.5mmol/L. Which of the following statements is correct?	A. Diabetics complicating cerebrovascular accident B. Diabetic neuropathy C. Diabetic microangiopathy D. Diabetic autonomic neuropathy E. Diabetic sensory neuropathy
10	Scenario: female patient, has T2DM, irregular hypoglycemic drug intake, has fever and cough for 4 days, with unconsciousness. Physical examination results: unconsciousness, BG = 34 mmol/L, Na = 155 mmol/L, blood urea nitrogen = 14.5 mmol/L. Which of the following options is the right diagnosis?	A. Ketoacidosis B. Hyperosmolar nonketotic diabetic coma C. Stroke D. Lactic acidosis E. Uremia
11	Scenario: male patient, 16 years old, with "overeating, overdrinking, polyuria, losing weight" for 3 months. BG = 21.7 mmol/L, positive urine-glucose, positive urine ketone. Which treatment is the most suitable one?	A. Sulfonylureas drugs for diabetes B. Biguanides C. Glucosidase inhibitor D. Thiazolidinedione E. Insulin
12	Scenario: female middle-aged patient, obesity, with less obvious "overeating, overdrinking, polyuria, losing weight". FBG = 6.0 mmol/L. 2h postprandial blood glucose = 9.2 mmol/L, urine glucose: (-). Which treatment is the most suitable one?	A. Oral hypoglycemic agent B. Injection of insulin C. Traditional Chinese medicine D. Physical exercise E. Diet therapy
13	Scenario: female patient, 23 years old, has T1DM. Been in a coma after interrupted insulin intake for 3 days. BG = 30.3 mmol/L. Which of the diagnoses should be considered priority?	A. Diabetic ketoacidosis and coma B. Cerebrovascular accident C. Hypoglycemic coma D. Ischemic heart failure E. Insensible diabetics with high osmotic pressure

Appendix Table 3. Service types health care professionals can provide

		Can you provide the service?	
No.	Type of service	Yes	No
1	Diabetes diagnose		
2	Diabetes classification		
3	Insulin treatment		
4	Oral hypoglycemic agents		
5	Early control for T2DM		
6	T2DM complication treatment		
7	T2DM non-drug therapy		
8	T2DM emergency treatment		

Appendix Table 4. Questions on attitudes and practices regarding the intervention

	Questions	Response level
		Worst → Best
Attitudes change		
1	How do you think about the communication with the county level hospital for transfer treatment?	
2	Do you think it is helpful for patients to enhance the communication between facilities?	
3	What do you think about the patients' information delivery between three-level health care facilities?	
Practice change		
1	In the last 12 months, have you ever transferred any patient?	
2	Are you familiar with the cooperation and communication between different health care facilities?	
3	How often do you communicate with doctors from other facilities?	
4	Do you have experience of coordinating with doctors from other institutions and providing service to patients?	
5	Do you have experience of providing service with a doctor from another facility?	
6	Are you familiar with the doctors who are proficient at diabetes and hypertension in county-level hospitals?	