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Effectiveness of a public dietitian-led diabetes nutrition intervention on glycemic control in a community setting in China

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Running Title: dietitian-led diabetes nutrition intervention

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ABSTRACT

Background: Diabetes mellitus requires lifelong treatment, most of which is accomplished in family and community settings. The present study was designed to identify the effectiveness of nutrition intervention provided by public dietitian on glycemic control in a community setting in China. **Methods:** Two communities were selected and randomly assigned to a routine care group (59 subjects) and a public dietitian-led intervention group (58 subjects) who received diabetic nutrition management for one year. The main measures included fasting plasma glucose, HbA1c, weight, body mass index (BMI), lipid profile, and blood pressure. **Results:** In the intervention group, there was significant improvement in fasting plasma glucose, HbA1c, cholesterol, and triglyceride levels relative to the control subjects ($p < 0.05$). Over the 12-month period, there was a decrease in energy intake, including reductions in absolute amounts (grams) of protein and fat in the intervention group. The energy percent values of carbohydrate, protein, and fat were 50.7%, 17.0%, and 32.3%, respectively, at baseline and 53.5%, 17.1%, and 29.9% (within the recommended range) after the intervention. There were significant improvements in total energy, absolute amounts of fat and protein, and the energy percent values of carbohydrates and fat. In the control group, however, these values were similar before and after the intervention, and the energy percent values of fat were still above the recommended range. **Conclusion:** In a community setting, a diabetes nutrition intervention led by a public dietitian significantly improved the glycemic control of type 2 diabetic patients.

Key Words: diabetes, public dietitian, diet, nutrition, community

INTRODUCTION

China now has the largest number of people with diabetes and is the global epicenter of the diabetes epidemic; 92.4 million Chinese adults (9.7% of the adult population) have the disease.¹ Among the labor force, diabetes presents a considerable burden, causing 19.12 disability-adjusted life years per 1000 people.² Health care use and costs are dramatically higher for people with diabetes than for people with normal glucose tolerance.³ According to

the International Diabetes Federation, healthcare expenditure on diabetes in China increased by at least US \$1.9 billion in 2010, reaching a total of US \$6.9 billion.

Nutritional therapy is an integral component in the prevention and management of diabetes mellitus. In clinical trials, such therapy has produced sustained improvements in levels of glycated hemoglobin (HbA1c).⁴ People with diabetes should receive individual, ongoing nutritional advice from a registered dietitian. Multiple studies have demonstrated sustained improvements in HbA1c at 12 months and longer when a registered dietitian provided follow-up visits ranging from monthly to three sessions per year.⁵⁻⁷ Ongoing medical counseling in nutrition by a trained dietitian leads to better long-term metabolic control.⁸ With specialist knowledge, the dietitian should be responsible for integrating information about the patient's clinical condition, eating, and lifestyle habits and for establishing treatment goals in order to determine a realistic plan for nutrition therapy^{9,10} and should take the lead in providing nutritional management.

For the United Kingdom, it is recommended that there be four full-time diabetes specialist dietitians per 250,000 people.¹¹ With about 2400 practitioners working in clinical nutrition in 2009, China has a serious shortage of clinical dietitians. Since 2005, however, public dietitians have become the major type of dietitian, and their numbers continue to increase. At present, nutrition therapy in China is mainly directed at hospitalized patients and is dominated by doctors and nurses.

Diabetes mellitus, one of the most common non-communicable diseases globally, requires lifelong treatment. Most treatment time of the patients is spent in family and community settings, and the patients need access to long-term and effective nutritional therapy. Since 2003, the Chinese Diabetes Society has made efforts to develop and promote guidelines on diabetes prevention and management. Despite these efforts, there is a gap between real-world clinical practice and standard care recommended in guidelines. A problem is how to implement the guidelines more extensively and provide effective nutritional therapy for patients with diabetes.

In view of these considerations, the hypothesis that patients receiving ongoing nutrition intervention provided by a dietitian would improve glycemic control relative to those not receiving the intervention was put forward. This study was designed to identify the

effectiveness of nutrition intervention on glycemic control in a community setting in China.

MATERIALS AND METHODS

Research design and subjects

The study is a cluster, randomized controlled trial, with the cluster represented by a community. The communities were randomly assigned to the intervention and control groups, and the assignment was blinded to participants. To choose participating communities, we visited the Center for Disease Control and Prevention of Bengbu, a city in northern Anhui province, to obtain basic information in regard to communities and to select two communities with similar economic conditions and demographic characteristics as well as community facilities' and health workers' conditions. The investigators then visited the communities to identify diabetic patients who were willing to participate. Once a participant signed an informed written consent form, he or she was enrolled in the study. Starting in July 2012, 128 patients aged between 35 and 70 years with type 2 diabetes were recruited. They were received treatment at two community health service centers. Diabetes was diagnosed by primary physicians based on criteria established by the World Health Organization. Patients were excluded if they were pregnant, were undergoing dialysis, if they had received an amputation, or had comorbid blindness or systemic illnesses such as cancer or cardiovascular disease based on diagnosis of myocardial infarction or stroke, as determined on national insurance claim forms. Ethics approval for the study was obtained in March 2012 from the Clinical Research Ethics Committee of Bengbu Medical College ([2012]06).

Nutrition intervention

Patients in the control group received the routine care practiced at their community health service centers, which may have included a summary of basic dietary principles by clinicians. Patients in the intervention group received a nutrition education program by public dietitians (Table 1), a 6-hour program with one training session conducted per month over a 3-month period and were given an educational booklet regarding food types, importance and principles of nutrition therapy recommended by the China Medical Nutrition Therapy Guideline for Diabetes 2010. The purposes of the nutrition education program were to provide the

participants with basic knowledge about type 2 diabetes. The patients in the intervention group were also provided the traffic light diet (TLD) guide to teach basic skills and behaviors that are important for dietary management of this disease one per month over a 3-month period. The participants in the intervention group had access to individualized nutrition counseling from public dietitians to assist them in modifying their dietary habits and to reinforce the concepts of controlling portion sizes of foods every 2 months over a 6-month period. If the intervention patients needed dietary advice they could contact public dietitians by phone, email, or network tools.

TLD was designed, in conjunction with the Red, Yellow, Green system originally developed by Leonard Epstein for obesity management in pre-teens¹² and in consideration of the dietary pattern of Chinese patients with type 2 diabetes. In the TLD, food groups are assigned colors of the traffic light. RED light (stop and think): fat, processed meats, cake, and sugar-sweetened drinks. YELLOW light (good for you, but watch portion size): grains, meat, poultry, fish and shellfish, nuts, eggs, and oil. GREEN light (go, low in calorie-density and high in nutrients): vegetables, fruits, dairy, beans and legumes, and water. The TLD guide is provided to patients with type 2 diabetes to help them make healthier food choices.

Before and after nutrition intervention, the public dietitians obtained daily nutrient intake by asking the patients to recall the foods consumed during the previous 24-h period, a method of inquiry routinely used in clinical settings in China. Nutrient intake was analyzed by nutrient analysis software (Nutrition Calculator v2.1, Chinese Center for Disease Control and Prevention, China).

Measurement of clinical parameters

At baseline and at 1 year, anthropometric measurements and clinical laboratory measurements after an 8- to 10-h fast were obtained for both groups. In addition, both groups answered a public dietitian-administered questionnaire regarding demographic characteristics and dietary habits. HbA1c assays were performed using high-performance liquid chromatography (Variant II; Bio-Rad, Hercules, CA). Fasting plasma glucose, cholesterol, and triglyceride were analyzed by enzymatic assays using an autoanalyzer (Hitachi 7060; Hitachi, Tokyo, Japan).

Statistical analyses

The estimated sample size was 54 patients per community, calculated to have an 80% power of detecting a difference of 0.65 in HbA1c, assuming an alpha of 0.05, and a standard deviation of 1.2. Allowing for a 20% drop out rate, a total of 128 subjects were required to be recruited. Data are expressed as means \pm Standard Deviation (SD), number (n) or percentage (%). A *t*-test was used to analyze differences in continuous variables between two groups at baseline. An χ^2 test was used to analyze distribution of categorical variables. ANCOVA was used to determine differences between the two groups after a 1-year intervention. All statistical analyses were performed with SPSS (version 16.0). The significance threshold was $p < 0.05$.

RESULTS

Before the 1-year follow-up, six patients dropped out of the intervention group and 5 out of the control group, leaving 117 subjects. There were no significant differences in age, gender, disease duration, or education between the intervention and control patients (Table 2).

The primary outcome measure was glucose dysfunction, which was assessed in terms of changes in fasting plasma glucose levels and HbA1c from the time of the baseline assessment to the one-year follow-up assessment. In the intervention group, there were significant improvements in fasting plasma glucose and HbA1c relative to the control subjects ($p=0.001$ and $p=0.000$, respectively) (Table 3). Four secondary outcomes were also measured at the baseline and one-year follow-up assessment, namely, weight, body mass index (BMI), lipid profile, and blood pressure. In the intervention group, there were significant improvements in total cholesterol and triglycerides relative to the control subjects ($p=0.039$ and $P=0.016$, respectively) (Table 3). There were, however, no significant improvements in systolic blood pressure, or diastolic blood pressure between the intervention and control patients. In the intervention group, there was reduction trend in weight and BMI for male and female subjects relative to the control subjects, but still there was no significant difference.

The percentage of diabetic patients who had the target goal for HbA1c level of less than 6.5% was 25.9% before intervention and 41.4% after intervention and 22.0% and 23.7%, respectively, in the control group (Figure 1). Thus, the proportion of subjects achieving target

HbA1c levels after the intervention (but not in the control group) had increased significantly relative to baseline levels. There was no group difference at pre-intervention but a significant difference at post-intervention in the percentage of subjects achieving target HbA1c levels ($p < 0.01$, Figure 1).

Post-intervention, the intervention group had a mean decrease in energy intake of 124 ± 281 kcal/day, whereas the control group had a mean increase of 27 ± 271 kcal/day ($p < 0.01$). Over the 12-month period, there was a decrease in energy intake, including reductions in absolute amounts (grams) of protein and fat in the intervention group (Table 4). The energy percent values of carbohydrate, protein, and fat were 50.7%, 17.0%, and 32.3%, respectively, at baseline and 53.0%, 17.1%, and 29.9% after the 1-year intervention. In the control group, however, these values were similar before and after the intervention, and the energy percent values for fat were still above the recommended range. In the intervention group, there were significant improvements in total energy, absolute amounts of fat and protein, and the energy percent values of carbohydrates and fat relative to the control subjects ($p < 0.05$, Table 3)

DISCUSSION

This investigation showed that a diabetes nutrition intervention led by a public dietitian in a community setting significantly improved the glycemic control of patients with type 2 diabetes. The intervention group had a 6.80 mg/dl reduction in mean fasting plasma glucose, whereas the control group had a 4.27 mg/dl increase ($p = 0.001$). In view of its impact on diabetes-related complications, HbA1c levels are perceived as a better predictor of glycemic control than fasting glucose levels.^{13,14} The overall improvement in HbA1c (0.49%) is small relative to a previously study 0.9-1.9%¹⁵. Nonetheless, the relationship between HbA1c and diabetes complications is linear, as demonstrated in UKPDS findings.¹⁶ Hence, even small improvements in HbA1c improve the prognosis for diabetics.¹⁷

After 1 year, energy intake had decreased by 124 ± 281 kcal/day in the intervention group, but it increased by 27 ± 271 kcal/day in the control group. In the intervention group, there were concomitant reductions in the intake of absolute amounts of dietary protein and fat. But, there were no significant changes in carbohydrate intake. The amount of carbohydrate ingested is the primary determinant of post-prandial blood glucose response. A modest reduction in

carbohydrate intake is associated with improvements in glycaemic control. In this study, the foods in Green light proposed in the intervention group are mainly belonging to low glycemic index (GI) foods. Low GI diets have been associated with improvements in HbA1c. Thus the type of dietary carbohydrate would likely also lead to favorable changes. The proportions of dietary carbohydrate and protein intake increased $2.3\pm 8.2\%$ and $0.08\pm 3.6\%$, respectively, and the proportion of fat was reduced by $-2.4\pm 6.1\%$ after the nutrition intervention. Overall, the interventional subjects adjusted their diets to maintain intakes of carbohydrate, protein, and fat energy to 50–60, 10–20, and 20–30%, respectively, following the China medical nutrition therapy guideline for diabetes (2010) established by the Chinese Diabetes Society. Barakatun et al observed that the proportions of dietary carbohydrate reduced, while those of protein and fat increased after nutrition intervention administered by a dietitian for a 12-week period in individuals with type 2 diabetes as compared to the baseline levels.¹⁸ This difference may be attributable to a different diet background. Despite the significant reduction in total energy intake; however, there were no significant reductions in body weight in the intervention group. On one hand, the lack of weight loss in the intervention group might have occurred because most diabetic patients were taking a sulfonylurea drug, which stimulates storage of glycogen and lipogenesis. Use of these drugs is often associated with weight gain.¹⁶ On the other hand, in the present study, we did not have a specific intervention of physical activity for patients with type 2 diabetes. A combination of diet and physical activity results in greater weight reduction than diet alone¹⁹. Physical activity has benefits on cardiovascular risk reduction and glycemic control for people with type 2 diabetes,^{20,21} with a meta-analysis showing a mean weighted reduction of 0.45% in HbA1c.²² A limitation of the current study is that dietary consumption was only obtained at the beginning and end of the survey, which might bias the results.

In this study, food groups were assigned colors of the traffic light. The subjects were encouraged to eat more vegetables, fruits, dairy products, beans, and legumes as GREEN light. Vegetables contain fibre, nutrients, vitamins, and minerals that help maintain health and also contain phytochemicals, which contribute to protection from diseases such as diabetes and cancer. For patients with type 2 diabetes, the intake of fruit should not be restricted²³. Most guidelines recommend eating a diet with a high intake of fiber-rich food, including fruit.

Higher consumption of milk or yogurt is associated with a lower risk of the metabolic syndrome.²⁴ A high-fiber, bean-rich diet is as effective as a low-carbohydrate diet for weight loss, although only the bean-rich diet lowered atherogenic lipids.²⁵ This beneficial effect of intervention may be a result of attention to the diet guide of traffic light, which might promote positive behaviors of diabetic subjects, and not directly related to the diet.

The proportion of subjects who had the target treatment goal for HbA1c level of less than 6.5% increased significantly after the nutritional intervention relative to baseline levels ($p < 0.001$, Figure 1). Nutrition interventions are cost effective²⁶⁻²⁸ for high-risk groups²⁹ and type 2 diabetics³⁰ and are associated with fewer visits to physician and health services, with reductions of 23.5% and 9.5%, respectively.³¹ To our knowledge, the current study is the first in China to demonstrate that a public dietitian has a role in management of diabetic nutrition in a "real-world" community setting in China. Previous nutrition intervention in China has been mainly directed at hospitalized patients and has been dominated by doctors and nurses. The doctor's and nurse's knowledge level of nutrition management for diabetes mellitus can be relatively low³² Furthermore, 92.4% patients with type 2 diabetes are informed that diabetes needs diet therapy, but only 16.2% of those stick to it.³³ Dietitians in community-based teaching practices may provide residents with detailed information about disease-specific dietary counselling. Each region of Canada has a public health department employing one or more dietitians to provide advice to the population of that region.

Those with diabetes should receive individual, ongoing nutritional advice from a registered dietitian; this is necessary for better long-term metabolic control⁸. In the United Kingdom, it is recommended that there be four full-time diabetes specialist dietitians per 250,000 people.¹¹ Individualized medical nutrition therapy administered by a dietitian results in favorable diabetes outcomes.¹⁸ In China, professional teams of nutrition support for diabetic patients should be established, providing evidence-based diet education and individual nutritional advice to diabetic patients, and the lag time between new evidence being available and its transfer to patients in the community should be reduced.

In conclusion, this research provides evidence to support the positive impact of nutrition management administered by public dietitians in improving outcomes among subjects with type 2 diabetes in community setting. All people with diabetes should be offered access to a

dietitian and have a personalized assessment and nutritional plan as part of their regularly updated care. Further work in larger studies is required to determine lasting effects of the nutrition intervention by public dietitians for diabetic patients in "real-world" community settings.

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CONFLICTS OF INTEREST AND FUNDING DISCLOSURE

All of the authors declare that they have no conflicts of interest.

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Table 1. Nutrition intervention provided by public dietitian

Period	Intervention	Purpose	Content
First	Nutrition education program	To provide the participants with basic knowledge	A 6-hour program with one training session conducted per month over a 3-month period, to introduce food types, importance and principles of nutrition therapy
Second	Traffic light diet guide	To develop basic skills and behaviors that are important for dietary management	One per month over a 3-month period, to teach traffic light diet, food models, consumption calculation, meal plans, and label reading etc
Third	Individualized nutrition counseling	To solve actual puzzles in life	Every 2 months over a 6-month period, to assist patients in modifying their dietary habits and to reinforce the concepts of controlling portion sizes of foods etc

Table 2. Baseline characteristics of participants

Baseline characteristics	Intervention	control	<i>p</i> -value
N	58	59	-
Age (years)	63.31±6.41	62.02±7.35	0.313
Males (%)	25 (43.1)	21 (35.6)	0.406
Diabetes duration (years)	5.24±3.11	4.97±2.93	0.623
Education			
≤8 years primary school	35 (60.3)	41 (69.5)	0.300
>8 years primary school	23 (39.7)	18 (30.5)	

Data are means ±SD or n (%). A *t*-test or χ^2 test was used to test differences between the intervention and control subjects at baseline. $p < 0.05$ was considered significantly different.

Table 3. Changes of clinical parameters in type 2 diabetic patients after the intervention

Clinical measurements	baseline			after 1-year		
	intervention	control	<i>p</i> value	intervention	control	<i>p</i> value
n	58	59	-	58	59	-
Male						
Height (cm)	167.36±5.93	167.91±5.60	0.752	-	-	-
Weight (kg)	72.20±9.37	74.62±6.32	0.320	71.72±8.79	75.81±7.97	0.163
BMI (kg/m ²)	25.75±2.78	26.80±2.14	0.166	25.59±2.61	27.22±2.79	0.150
Female						
Height (cm)	160.73±6.38	159.18±3.70	0.228	-	-	-
Weight (kg)	65.88±10.25	66.92±8.07	0.633	64.88±10.43	67.13±7.05	0.052
BMI (kg/m ²)	25.42±2.93	26.70±2.68	0.057	25.02±2.97	26.78±2.39	0.121
Systolic blood pressure (mmHg)	126.71±11.57	128.12±13.77	0.550	127.14±9.09	129.44±14.16	0.408
Diastolic blood pressure (mmHg)	83.95±8.06	85.34±7.91	0.348	83.24±7.99	85.49±7.65	0.216
Glucose (mg/dL)	146.36±30.36	154.67±34.62	0.170	139.56±27.37	158.94±32.75	0.001
HbA1c (%)	7.55±1.14	7.78±1.29	0.313	7.06±1.02	7.77±1.22	0.000
Triglyceride (mg/dL)	164.06±73.23	165.39±82.83	0.927	147.43±72.04	173.47±69.62	0.016
Total cholesterol (mg/dL)	198.51±36.29	194.43±44.40	0.588	190.63±35.31	196.84±36.06	0.039

Data are means±SD. A *t*-test was used to test differences between the intervention and control subjects at baseline. The duration of diabetes and baseline values as covariates, ANCOVA was used to determine differences between the two groups after a 1-year intervention.

Table 4. Changes in nutrient intake in type 2 diabetic patients after the intervention

Nutrient intake	Baseline			After 1-year		
	intervention	control	<i>p</i> -value	intervention	control	<i>p</i> -value
Patient number	58	59		58	59	
Energy (kcal/day)	1831.7±321.5	1777.1±338.3	0.372	1707.7±169.8	1804.4±245.8	0.001
Carbohydrates						
Energy %	50.7±8.5	49.0±8.3	0.283	53.0±6.5	49.8±6.6	0.017
g/day	232.2±59.1	218.3±60.0	0.207	227.7±44.1	224.7±43.3	0.859
Protein						
Energy %	17.0±3.1	17.8±3.2	0.159	17.1±2.5	17.1±2.7	0.909
g/day	77.5±16.7	78.4±16.6	0.757	72.5±9.2	76.1±9.1	0.031
Fat						
Energy %	32.3±6.3	33.1±5.9	0.45	29.9±5.0	33.1±6.0	0.002
g/day	65.9±17.3	65.5±16.8	0.928	56.3±8.8	66.8±16.6	0.000

Data are means ± SD. A *t*-test was used to test differences between the intervention and control subjects at baseline. The duration of diabetes and baseline values as covariates, ANCOVA was used to determine differences between the two groups after a 1-year intervention.

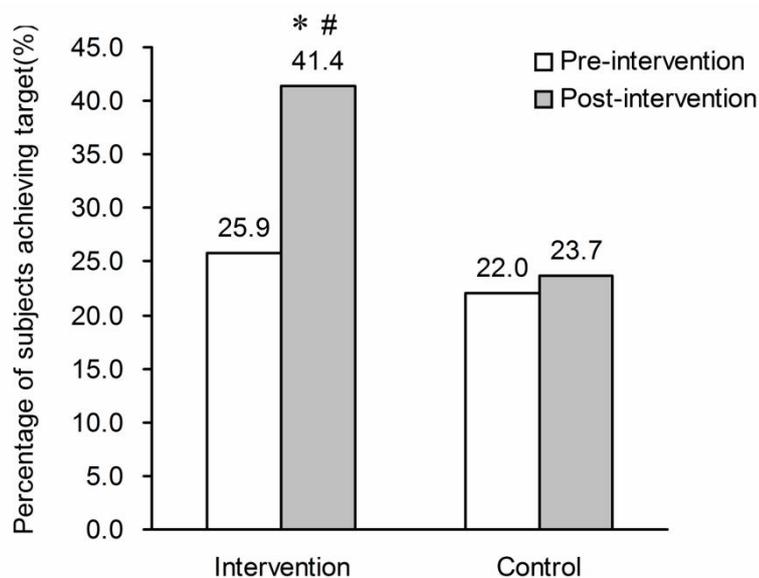


Figure 1. Percentage of patients achieving target HbA1c levels before and after the public dietitian-led nutrition intervention. The proportion of diabetic patients who had achieved the target treatment goal for HbA1c level of less than 6.5% had increased significantly after the public dietitian-led nutrition intervention (but not in the control group) compared to the baseline levels. There was no group difference at pre-intervention but a significant group difference at post-intervention in percentage of subjects achieving target HbA1c levels. *Significantly different from control, $p < 0.05$. #Significantly different from pre-intervention, $p < 0.05$.

基于社区的公共营养师主导的糖尿病营养干预效应研究

背景：作为一种需要终身治疗的慢性疾病，糖尿病患者的大部分治疗时间是在家庭和社区中度过的。本研究旨在探索公共营养师提供的营养干预对社区 2 型糖尿病患者血糖控制的影响。**方法：**2 个社区被随机分配到常规组(n=58)和干预组 (n=59)，干预组接受公共营养师主导营养管理 1 年，评价指标包括空腹血糖、HbA1c、BMI、体重、血脂、血压。**结果：**与对照组相比，干预组空腹血糖、HbA1c、胆固醇和甘油三酯水平显著改善 ($p < 0.05$)。干预组碳水化合物、蛋白质和脂肪占能比分别由干预前的 50.7%、17.0%和 32.3%变为 53.5%、17.1%和 29.9%，调整到糖尿病营养治疗指南推荐范围内；总能量、脂肪和蛋白质摄入量显著降低，碳水化合物和脂肪占能比显著改善，而对照组这些指标干预前后无显著变化，脂肪占能比仍然超出指南推荐范围。**结论：**公共营养师主导的糖尿病营养干预能显著改善社区 2 型糖尿病患者血糖控制。

关键词：糖尿病，公共营养师，饮食，营养，社区