



A practical “low-carbohydrate dietary care” model for elderly patients with type 2 diabetes mellitus

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Abstract

Diabetes mellitus (DM) is a complex, multisystem disease, affecting large populations worldwide. Type 2 diabetes mellitus (T2DM) is a complex polygenic disease that causes hyperglycemia and accounts for 90-95% of all diabetes mellitus cases. We conducted a randomized, controlled single-blind study to observe how dietary care with restriction of carbohydrate absorption affects glucose and lipid metabolism in elderly patients with T2DM. Participants in the control group (Group C) received usual care and in the experimental group (Group E) white common bean extract (WCBE) was given before meals. The trial was divided into two periods: intensive and maintenance intervention periods. Glucose and lipid metabolic parameters of both groups were monitored over the study period. Glycosylated hemoglobin (HbA1c) in Group E was lower than in Group C at the end of the 2- and 4-month, and significantly decline from baseline. The area under curve of oral glucose tolerance test (OGTT) glucose after 2- and 4-month intervention than baseline in Group E and were all significantly lower than in Group C after the intervention. Both High-density lipoprotein (HDL) and Low-density lipoprotein (LDL) also improved in group E ($P < 0.05$). In the clinical management of elderly patients with T2DM, this individualized model of care without restricting carbohydrate intake can effectively improve patients' glucose metabolism. The effect of this care model is similar to that of a low-carbohydrate diet care model. Therefore, this regimen could be a novel antidiabetic approach for patients with T2DM who are unwilling to restrict their carbohydrate intake.

Keywords: low-carbohydrate dietary care; type 2 diabetes mellitus; compliance.

Practical Application: The level of glucose metabolism in patients can be significantly improved when employing a personalized care model that restricts carbohydrate absorption in the therapeutic treatment of elderly patients with type 2 diabetes mellitus. This dietary management paradigm is analogous to the nutritional composition of elderly Asian patients with type 2 diabetes and satisfies the patients' significant requirement for carbohydrate consumption during long-term glycemic control. This method is therefore quite practical and scalable.

1 Introduction

Diabetes mellitus (DM) has become one of the most challenging public health problems worldwide. According to the International Diabetes Federation (IDF), the number of people living with DM is projected to reach 438 million by 2030 (Gerdtz & Regitz-Zagrosek, 2019). Currently 40% of persons with type 2 diabetes are 65 years or older, and diabetes is expected to increase in prevalence as the population ages (Bradshaw et al., 2021; International Diabetes Federation, 2021). In the vast majority of patients, the choice of medication to control blood glucose is still the primary therapeutic approach. Based on drug control of blood glucose, how to improve the clinical efficacy of drugs through a scientific, practical, and reasonable care program is an ideal goal for the current treatment of diabetes (Ahmad et al., 2022; Tan et al., 2022).

In the treatment of DM, the American Diabetes Association believes that medical nutrition therapy (MNT) plays a vital role in preventing diabetes and its complications or delaying the rate of complications. The mean goals of MNT for the treatment of DM are to achieve the intensive management of blood glucose, blood lipid, and blood pressure as well as to prevent or slow down the occurrence of chronic complications (Kirkpatrick et al., 2019; Wang & Hu, 2018). Some researchers believe that dietary nursing education for elderly diabetic patients to allow patients to master the correct dietary knowledge and basic skills is the primary way to achieve an appropriate diet and promote health. Thus, dietary nursing education is one of the most economical and effective health care strategies (Ha et al., 2019). However, a

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report indicate that the level of knowledge and attitude towards nutrition health was low in the Chinese elderly (Wang et al., 2020).

Carbohydrates become a health problem when rapidly digested and absorbed, especially when ingested in large amounts. Studies showed that carbohydrate intake may increase the risk of T2DM and may be associated with a lower intake of various nutrients and imbalanced macronutrient composition (Thomsen et al., 2022).

In addition to glycemic control, since insulin resistance in patients with T2DM increases the eagerness for carbohydrate intake, dietary interventions that reduce dietary carbohydrate intake are thought to improve glycemic control and T2DM outcomes (Gram-Kampmann et al., 2022). Interventional studies have shown that low-carbohydrate diet improves glycemic control and leads to reductions in cardiovascular disease risk in people with T2DM (Han et al., 2021). Furthermore, compared to the low-fat diet, a low-carbohydrate diet can lower blood glucose levels and the economic burden of Chinese T2DM patients (Weiman et al., 2021). However, dietary intervention requires patients to change their previous diet and living habits. For most patients, it is not easy to adhere to healthy dietary behaviors and form habits for a long time (Marks et al., 2021; Shaban et al., 2019).

Therefore, care models are needed in the treatment of T2DM that can reduce disruptions to patients' diets and lifestyles in order to improve their quality of life. Amylase inhibition can delay or hinder the breakdown of carbohydrates by inhibiting the activity of amylase or glycosidase, thereby decreasing glucose production. Among many portions of cereal and legumes, white common bean extract (WCBE) inhibits activity and biosafety, so it has a broader prospect in preventing and controlling DM and obesity (Kaur et al., 2019).

Here, we conducted a randomized, double-blind trial to apply WCBE to the diet of diabetic patients, instead of overly influence the structure of the patient's diet. This study aims to investigate the effects of this new model of care on glucolipid metabolism in patients with T2DM and to explore individualized practice approaches to achieve low carbohydrate absorption without restricting carbohydrate intake.

2 Materials and methods

2.1 Inclusion exclusion criteria

Subjects were eligible if they met the following criteria: age 60-75 years, $6.5\% \leq \text{HbA1c} \leq 13.0\%$. Exclusion criteria were: type 1 diabetes mellitus, malignant hypertension, severe heart disease, renal failure, inflammatory bowel disease, gastrointestinal ulceration, autoimmune disease, cancer, medical or surgical weight loss within 3 months and antibiotic therapy within 3 months. Subjects with a poor compliance or who violated the protocol or were unwilling to continue participation in the clinical trial were also asked to withdraw from the study.

2.2 Sample size estimates

In this study, the sample size was calculated using a comparison of two independent samples, by using PASS15.0 software and reviewing the literature of similar studies with $\alpha = 0.05$ and $\beta =$

0.1, the sample size was calculated as 21 cases in the control group and 32 cases in the experimental group, taking into account the 10% missed visit rate, the sample sizes of the two groups were determined to be at least 23 and 38 cases respectively. In the course of this study, 24 and 43 cases were eventually enrolled in the control group and experimental group respectively.

2.3 Methods

All subjects were randomized to an experimental group (Group E) and a control group (Group C). After enrollment, the demographic data of the issues were recorded, including gender, age, medication history, disease history, and lifestyle. Group C received the usual dietary instructions for T2DM. Referring to "The dietary reference intakes for Chinese residents" issued by the Chinese Nutrition Society. Patients in Group E underwent personalized dietary pattern intervention according to the characteristics of WCBE as α -amylase inhibition. Combined with the labor intensity, age, weight and other factors of patients, they calculate patients' daily energy and nutrient content and develop the personalized nutritional formula to ensure that patients ingest enough carbohydrates and the proportion of nutrients is normal. Patients with a daily habitual carbohydrate intake of more than 65% should be supplemented with 3 grams of WCBE 15-30 minutes before the meal. Patients with a daily regular carbohydrate intake of between 50 and 65% received 1.5 g of WCBE. Glycosylated hemoglobin, OGTT blood glucose and OGTT insulin levels were also monitored in participants. Patients' average carbohydrate intake was recorded weekly to change the use of WCBE dynamically.

A statistician who was not involved in the trial developed a computer-generated random number system. The clinical trial is a single-blind trial in which investigators do not know to which group each issue is assigned. The statistician unblinds the grouping of all topics after completing the experiment. All participants underwent baseline biochemical measurements. All subjects underwent 2 phases of intervention: (1) 2 months of intensive intervention: All participants received daily telephone follow-up, self-monitoring of fasting blood glucose and 2-hour blood glucose every 3 days, weekly face-to-face interviews, and monthly nutritional evaluations. All subjects underwent biochemical investigations at the end of this period. We then randomly selected 19 participants in Group C and 26 participants in Group E to proceed to the subsequent intervention phase. (2) 2-Month Maintenance Phase: Participants were randomly selected from those who completed the first phase of the intervention to receive the intervention for an additional 2 months. During this period, they received only weekly telephone follow-ups. At the end of this period, participants underwent a third biochemical examination (Figure 1). There was no harm to the subjects during the whole process.

During the intervention period, the outcome measures included both primary and secondary measures. The primary outcome measures were changes in Glycosylated hemoglobin (HbA1c). Changing in fasting blood glucose (FBG) and HOMA-IR were the main secondary outcomes. Other secondary outcomes included changes in 0.5-h blood glucose (0.5-hPBG), 1-h blood glucose (1-hPBG), 2-h blood glucose (2-hPBG), 3-h blood glucose (3-

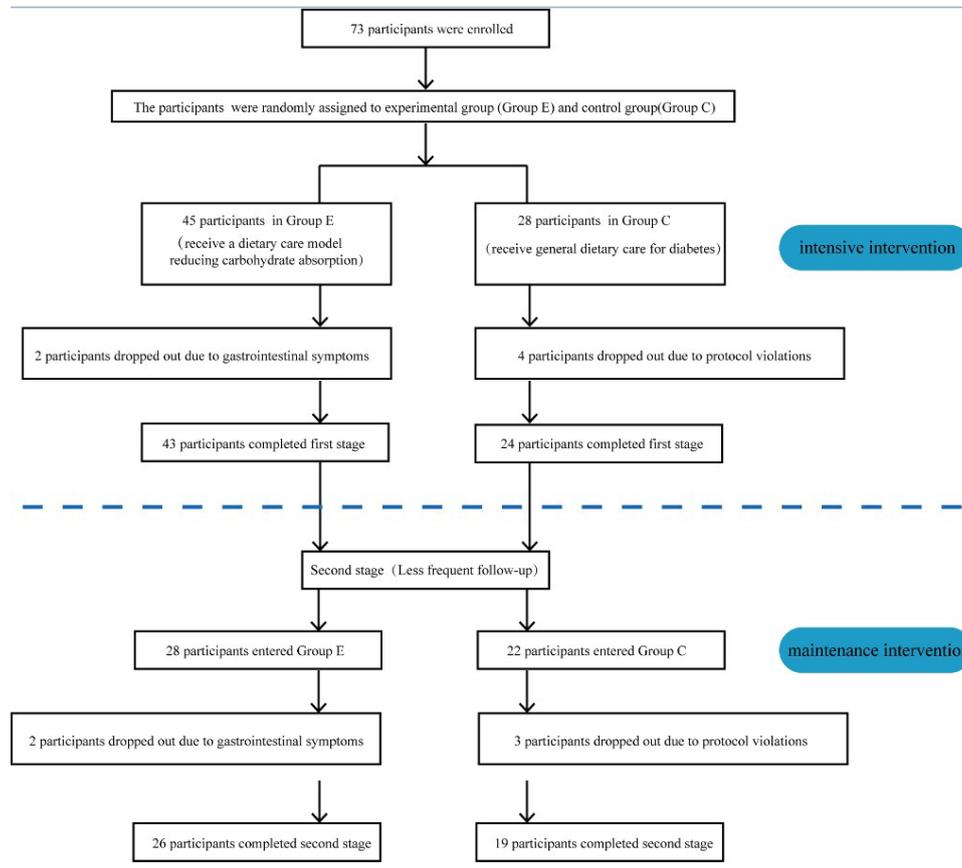


Figure 1. Experimental procedure.

hPBG), Cholesterol (CHOL), Triglycerides (TG), High-density lipoprotein (HDL) and Low-density lipoprotein (LDL).

2.4 Sample collection and laboratory measurements

Blood samples were collected from subjects at month 0, at the end of 2 months of intervention, and the end of 4 months of intervention. Venous blood was taken from subjects fasted for 10-12 h. Immediately after serum collection, the blood was placed on ice and transported to the laboratory for separation. Clinical laboratory measurements were performed at the Affiliated Hospital of Jiangnan University. The blood cell measurements were conducted on the automated hematology analyzer (Sysmex K4500; Sysmex Corporation, Japan).

2.5 Statistical analysis

Statistical Data were analyzed using Prism8 (GraphPadPrism, San Diego, CA) statistical software. The Mann-Whitney test and Wilcoxon test were used for intra-group and inter-group comparisons in each phase, respectively. Mann-Whitney test was used for age, and chi-square test was used for sex. $P < 0.05$ was considered statistically significant.

3 Results

This study enrolled 73 elderly patients with T2DM who met the inclusion criteria in the Affiliated Hospital of Jiangnan

University from December 2017 to November 2018. All patients were randomized 2:3 into Group C ($n = 28$) and Group E ($n = 45$). Anthropometric and biochemical measurements were taken at 0, 2, and 4 months. A total of 67 patients (Group C = 24/Group E = 43) eventually completed the intensive phase intervention and 45 patients (Group C = 19/Group E = 26) completed the maintenance phase intervention. There were no statistically significant differences in age, sex or medication regimen among the groups during the intensive and maintenance phases (Table 1).

3.1 Effects of a dietary care model to reduce carbohydrate absorption during an intensive intervention on glucose and lipid metabolism in elderly T2DM patients

Glucose metabolism

HbA1c is considered the gold standard for assessing long-term glycemic control in diabetic patients (Peng et al., 2018). The results of the within-group comparison showed that although there was no significant difference in HbA1c between Group E and Group C after dietary intervention for 2 months, there was a tendency to form a contrast. Group E showed a significant decrease in HbA1c after 2 months of dietary intervention compared to 0 months. However, it is worth noting that there was also a slight decrease in HbA1c in Group C, which may be related to our routine healthy diet education for patients in Group C and patient compliance improved in the initial stage. The oral glucose tolerance test (OGTT) is a glucose load test used

Table 1. Differential analysis of glucose and lipid metabolism in elderly patients with T2DM during intensive intervention.

General Information	E Group			C Group			P Value	
	Month 0	Month 2	P Value	Month 0	Month 2	P Value	Month 0	Month 2
Age (years)	67.791 ± 3.625	/	/	66.580 ± 3.581	/	/	0.2193 ^a	/
Gender (Females/Males)	18/25	/	/	16/8	/	/	0.0515 ^k	/
Plasma glucose homeostasis								
HbA1c (%)	8.049 ± 1.316	7.293 ± 1.104	< 0.0001 ^{***}	7.871 ± 0.766	7.633 ± 0.778	0.0150 [*]	0.7577	0.0822
Fasting Blood Glucose (mmol·L ⁻¹)	8.851 ± 2.138	7.864 ± 1.886	< 0.0001 ^{***}	7.818 ± 1.68	7.993 ± 1.734	0.8334	0.0874	0.4648
OGTT_0.5h PBG (mmol·L ⁻¹)	13.100 ± 2.633	10.727 ± 2.213	< 0.0001 ^{***}	10.740 ± 2.502	10.809 ± 2.139	0.8553	0.0011 ^{##}	0.6378
OGTT_1h PBG (mmol·L ⁻¹)	17.580 ± 2.219	14.447 ± 2.556	< 0.0001 ^{***}	16.035 ± 3.230	15.278 ± 2.279	0.1621	0.1394	0.0598
OGTT_2h PBG (mmol·L ⁻¹)	20.020 ± 3.357	16.660 ± 3.679	< 0.0001 ^{***}	18.032 ± 3.375	18.955 ± 3.640	0.1280	0.0674	0.0161 [†]
OGTT_3h PBG (mmol·L ⁻¹)	17.484 ± 4.126	14.839 ± 4.378	< 0.0001 ^{***}	16.962 ± 4.102	17.384 ± 4.029	0.7469	0.8002	0.0217 [†]
OGTT_Glucose_AUC (mmol·L ⁻¹ ·min ⁻¹)	3042.581 ± 465.946	2534.674 ± 496.165	< 0.0001 ^{***}	2751.750 ± 500.406	2790.417 ± 464.533	0.9944	0.0644	0.0227 [†]
HOMA-IR	21.380 ± 12.899	19.930 ± 11.847	0.0957	22.581 ± 13.699	22.123 ± 12.534	0.5297	0.6877	0.6347
Plasma lipid homeostasis								
CHOL (mmol·L ⁻¹)	4.811 ± 0.864	4.696 ± 0.849	0.2170	4.865 ± 0.892	4.555 ± 1.021	0.0907	0.9096	0.5921
TG (mmol·L ⁻¹)	1.669 ± 1.433	1.360 ± 0.597	0.5922	1.741 ± 0.822	1.847 ± 0.893	0.3941	0.1194	0.0155 [†]
HDL (mmol·L ⁻¹)	1.225 ± 0.348	1.539 ± 0.699	0.0033 ^{**}	2.593 ± 0.962	1.147 ± 0.234	< 0.0001 ^{***}	< 0.0001 ^{****}	0.0101 [†]
LDL (mmol·L ⁻¹)	2.919 ± 0.775	2.569 ± 0.950	0.0018 ^{**}	1.573 ± 0.808	2.760 ± 0.861	< 0.0001 ^{***}	< 0.0001 ^{****}	0.4221

The Mann-Whitney test (*) and Wilcoxon test (†) were used for intra-group and inter-group comparisons in each phase, respectively. Mann-Whitney test was used for age (*), and chi-square test was used for sex (†). P values < 0.05 was considered statistically significant. *P < 0.05; **P < 0.01; ***P < 0.0001; †P < 0.05; ††P < 0.01; †††P < 0.0001.

to understand islet cell function and the body's ability to regulate blood glucose. The results showed that FBG, 0.5-hPBG, 1-hPBG, 2-hPBG and 3-hPBG decreased significantly compared with baseline after 2 months of dietary intervention. HOMA-IR is a measure used to evaluate an individual's level of insulin resistance and the HOMA-IR index will gradually increase as the level of insulin resistance increases. The results showed no significant difference in HOMA-IR changes in Group E and Group C after 2 months of intervention. The area under the glucose curve in the OGTT showed a significant decreasing trend in Group E after 2 months, and it was different from Group C at 2 months.

Lipid metabolism

CHOL is an essential raw material for synthesizing adrenocorticotrophic hormone, sex hormones, bile acids, vitamin D, and other physiologically active substances. It is also the main component of the cell membrane, and its serum concentration can be used as an indicator of lipid metabolism (Kontush, 2020). The results showed no significant trend in CHOL after two months of the intervention diet. TG, a fatty substance in the blood, is mainly obtained from the diet and is lower in Group E than Group C at 2 months. HDL particles are small, can freely enter and exit the arterial wall, take up low-density lipoprotein, cholesterol, triglycerides and other harmful substances immersed in the intimal layer of the vascular wall, and transport them to the liver for decomposition and excretion (Mitra et al.,

2011). The results showed that HDL levels showed a significant decreasing trend in Group C and an increasing trend in Group E at 2 months. LDL is a lipoprotein particle that carries cholesterol into peripheral tissue cells and can be oxidized to oxidized LDL. When LDL, significantly oxidatively modified LDL (OX-LDL), is in excess, the cholesterol it carries accumulates on the arterial wall and quickly causes arteriosclerosis (Cucuzzella et al., 2021). The results showed that LDL levels increased in Group C and decreased significantly in Group E at 2 months. However, it is worth noting that due to the double-blind nature, we found a significant difference between the C and E groups at 0 months. HDL levels were significantly higher in Group C than in Group E, but LDL levels were significantly lower than in Group E. This discrepancy might be due to small and different sample sizes. With the intervention's progress, the difference between the two groups gradually narrowed at 2 months, and Group E developed better results, indirectly demonstrating that physical-based dietary intervention can regulate HDL and LDL in diabetic patients (Table 1).

3.2 Effects of a dietary care model to reduce carbohydrate absorption during maintenance on glucose and lipid metabolism in elderly T2DM patients

Glucose metabolism

We performed statistical analysis again for the patients who participated in the study (4 months). It was found that even if the

frequency of follow-up was reduced at a later stage, the overall results showed that HbA1c was significantly lower in Group E than in Group C after 4 months of dietary intervention. HbA1c also decreased significantly from baseline in Group E. OGTT results showed that blood glucose levels were significantly lower in Group E than Group C after 4 months of dietary care. Comparison of the results within groups indicated a decreasing trend in 0.5-hPBG, 1-hPBG, 2-hPBG and 3-hPBG compared with baseline, except for FBG, which was not significantly different from baseline. It is noteworthy that FBG, 0.5-hPBG and 2-hPBG in Group C showed increasing trend after 4 months, which may be related to our randomized double-blind, patients in the general nursing intervention group subjectively perceived the effectiveness of this model as poor. Patients are no longer willing to strictly control their diet and are associated with reduced cooperation and compliance in subsequent phases. The HOMA-IR results showed no significant change in HOMA-IR from baseline in Group E after 4 months of intervention. Still, because of the increase in Group C, a difference was formed between the two groups at 4 months. The reason for elevated HOMA-IR in Group C we used above. The area under the glucose curve in the OGTT showed a significant decreasing trend after 4 months in Group E, and it was different from Group C at 4 months (Table 2).

Lipid metabolism

Analysis of lipid metabolism results showed no differences in CHOL or TG between the E and C groups at 4 months.

HDL showed an upward trend in Group E and a downward trend in Group C at 4 months of intervention. LDL decreased in Group E but increased in Group C at 4 months of intervention. However, there were differences in HDL and LDL results between the C and E groups at baseline, with higher HDL levels and lower LDL levels in Group C than in Group E. With the progress of the intervention, there was a changeover phenomenon between the two groups at 4 months. Group E developed better results, indirectly demonstrating that physical-based dietary intervention can regulate HDL and LDL in diabetic patients (Table 2).

3.3 Compliance analysis

In the intensive intervention phase, we conducted dietary health education for the patients once a day according to their actual conditions without much influence on diet structure. Some patients will experience increased satiety and reduced carbohydrate intake later. It is necessary to assess the average carbohydrate intake of patients dynamically and timely adjust the dosage of WCBE promptly. At the end of the intensive intervention phase, 24 subjects in Group C (males 8 and females 16) and 43 subjects in Group E (males 25 and females 18) completed the second biochemical examination. 10.5% of patients in Group C were weaned from the experiment, compared with only 4% of patients in Group E (Table 1). We then randomly selected 19 Group C participants (males 6 and females 13) and 26 Group E participants (males 13 and females 13) to continue the final phase of the intervention. To investigate the applicability and

Table 2. Differential analysis of glucose and lipid metabolism in elderly patients with T2DM during maintenance.

General Information	E Group			C Group			P Value	
	Month 0	Month 4	P Value	Month 0	Month 4	P Value	Month 0	Month 4
Age (years)	67.308 ± 3.232	/	/	66.320 ± 3.908	/	/	0.4388 ^a	/
Gender (Females/Males)	13/13	/	/	13/6	/	/	0.2166 ^k	/
Plasma glucose homeostasis								
HbA1c (%)	7.947 ± 1.428	7.135 ± 0.800	0.0002 ^{***}	7.879 ± 0.600	7.879 ± 1.027	0.7901	0.3010	0.0095 ^{##}
Fasting Blood Glucose (mmol·L ⁻¹)	8.692 ± 2.173	8.055 ± 1.434	0.1814	7.628 ± 1.536	9.921 ± 1.866	0.0017 ^{**}	0.0682	0.0014 ^{##}
OGTT_0.5h PBG (mmol·L ⁻¹)	12.725 ± 2.797	10.600 ± 2.027	0.0039 ^{**}	10.632 ± 2.365	12.715 ± 2.281	0.0039 ^{**}	0.0259 [#]	0.0086 ^{##}
OGTT_1h PBG (mmol·L ⁻¹)	17.295 ± 2.080	14.889 ± 2.364	0.0003 ^{***}	16.080 ± 2.955	18.089 ± 2.933	0.0602	0.3017	0.0015 ^{##}
OGTT_2h PBG (mmol·L ⁻¹)	19.915 ± 3.361	16.284 ± 4.078	< 0.0001 ^{****}	18.009 ± 2.893	21.031 ± 3.988	0.0095 ^{**}	0.0925	0.0005 ^{###}
OGTT_3h PBG (mmol·L ⁻¹)	17.335 ± 4.696	14.181 ± 4.240	0.0001 ^{***}	17.092 ± 3.483	19.271 ± 4.073	0.1042	0.9728	0.0004 ^{###}
OGTT_Glucose_AUC (mmol·L ⁻¹ ·min ⁻¹)	3005.423 ± 479.846	2511.346 ± 481.070	< 0.0001 ^{****}	2750.211 ± 436.241	3184.211 ± 544.963	0.0124 [*]	0.1826	0.0002 ^{###}
HOMA-IR	21.350 ± 12.840	19.800 ± 11.620	0.7467	22.560 ± 12.250	35.920 ± 26.490	0.0107 [*]	0.4928	0.0290 [*]
Plasma lipid homeostasis								
CHOL (mmol·L ⁻¹)	4.952 ± 0.863	4.898 ± 0.971	0.9842	4.852 ± 0.946	4.619 ± 0.822	0.1572	0.5274	0.2582
TG (mmol·L ⁻¹)	1.841 ± 1.630	1.395 ± 0.553	0.2962	1.741 ± 0.892	1.750 ± 1.010	0.5476	0.5349	0.5125
HDL (mmol·L ⁻¹)	1.205 ± 0.363	2.328 ± 1.153	< 0.0001 ^{****}	2.804 ± 0.864	1.256 ± 0.279	< 0.0001 ^{****}	< 0.0001 ^{****}	0.0006 ^{###}
LDL (mmol·L ⁻¹)	2.884 ± 0.974	2.129 ± 1.013	< 0.0001 ^{****}	1.304 ± 0.518	2.891 ± 0.736	< 0.0001 ^{****}	< 0.0001 ^{****}	0.0039 ^{##}

The Mann-Whitney test (#) and Wilcoxon test (*) were used for intra-group and inter-group comparisons in each phase, respectively. Mann-Whitney test was used for age (a), and chi-square test was used for sex (k). P values < 0.05 was considered statistically significant. *P < 0.05; **P < 0.01; ***P < 0.001; ****P < 0.0001; [#]P < 0.05; ^{##}P < 0.01; ^{###}P < 0.001; ^{####}P < 0.0001.

autonomy of patients to this dietary pattern, in the second stage, we reduced the frequency of follow-up and followed patients once a week. 13.7% of patients in Group C were taken off from the experiment, compared with only 7% of patients in Group E (Table 2).

Patients in Group C dropped out of the investigation because of prolonged diabetic diet control, resulting in a sense of burnout. The patient's autonomy became less controlled, and his diet was not following the diabetic dietary requirements. And the patient subjectively did not want to continue the experiment. We did not interfere excessively with the structure of the diet of the patients in Group E. The patients in Group E did not want to continue the experiment because of the production of bloating.

4 Discussion

We adopt a personalized dietary care model, which is similar to the effect of a low-carbohydrate diet in reducing carbohydrate absorption. Notably, this new model does not restrict carbohydrate intake. Overall, this dietary care has a significant ameliorating effect on glucose metabolism in elderly T2DM patients. Even when the frequency of follow-up decreased in the second stage, the overall trend of glucose metabolism indicators was better in Group E than in Group C. After 2 and 4 months of intervention, there was no significant difference in the changes of CHOL and TG between the two groups, but the HDL levels in Group E after 2 and 4 months of intervention was higher than that of Group C. In addition, participants in Group C had a higher dropout rate due to their inability to adhere to long-term dietary control, whereas this outcome was not observed in Group E.

At present, several studies have demonstrated that the implementation of diet nursing education for diabetic patients and nutritional intervention can effectively control patients' blood glucose levels and improve the metabolic homeostasis of patients, such as lipid metabolism (Bai et al., 2021). At the same time, diet nursing intervention can also prevent or delay the occurrence and development of T2DM-related complications and reduce the mortality of patients (Franz et al., 2003; Khan et al., 2019). In addition, dietary care treatment can also reduce medical costs (Steven et al., 2016). Steven performed an 8-week very-low-calorie diet intervention followed by a 6-month normal caloric diet in 30 patients with T2DM and found fasting blood glucose, and HbA1c returned to normal in 13 patients (Gow et al., 2017). Several studies have also shown that early strict dietary control can play a reversal role for some patients with newly diagnosed T2DM and result in complete remission of the disease (Sarathi et al., 2017; Ley et al., 2014). Throughout the process of T2DM prevention and treatment, it is therefore important to provide effective dietary nursing interventions for patients.

In Asia, high consumption of refined grains such as fine rice and wheat flour has led to a shift in an unhealthy dietary pattern, contributing to one of the critical factors in the high incidence of T2DM worldwide (Cranney et al., 2022). To better achieve the ideal blood glucose level, diabetic patients need to adhere to long-term healthy dietary behaviors for life, which is undoubtedly a great challenge for most patients. Lack of nutritional awareness and difficulty in changing dietary habits in

elderly patients with T2DM reduces their compliance with dietary interventions. Therefore, there is a need for other care models to reduce excessive intervention in patients' dietary patterns. We incorporate WCBE into usual dietary instructions for patients with T2DM, which can be used to restrict carbohydrate absorption without limiting their carbohydrate intake. We don't tamper too much with the patient's dietary habits because of this, and we adjust the WCBE dose to match the patient's daily carbohydrate intake. Because of its high level of safety and maneuverability, as well as its capacity to regulate glucose and lipid metabolism in older patients with T2DM, this unique dietary care model seems promising. In addition, we will limit the impact of the intervention on the patient's diet structure and suitably advise patients who have lowered carbohydrate intake due to WCBE-induced satiety to raise their carbohydrate intake. This type of dietary pattern, which increases carbohydrate consumption, not only prevents glucose absorption but also regulates the gut microbiota. The mechanism of action of WCBE is similar to that of acarbose, which is extensively employed as a glycosidase inhibitor and has a carbohydrate catabolism inhibitory effect in the small intestine. As a result, when additional carbohydrates enter the large intestine, acarbose can kickstart the gut microbiota's glucose metabolism. Acarbose modulates the gut microbiota and stimulates GLP-1 release, which can help to increase insulin secretion and lower blood sugar levels (Zhang et al., 2019). In the future, we can also focus on the role of gut microbiota to investigate whether this dietary pattern without limiting carbohydrate intake can promote blood glucose homeostasis through intestinal mechanisms.

5 Conclusion

In summary, in the clinical treatment of elderly patients with T2DM, using a personalized care model that limits carbohydrate absorption can effectively improve the level of glucose metabolism in patients. This model can reduce the patient dropout rate, improve treatment compliance, and reduce the difficulty of care. In addition, this novel model can bring out the co-benefit for patients and nurses. On the hand, it can overcome the burnout of diabetic patients due to long-term dietary control and increase their compliance. On the other hand, the encouragement of patients will significantly promote the practicability of nursing, the progress of nursing education, and the efficiency of nursing care for patients.

Abbreviations

WCBE: white common bean extract. MNT: medical nutrition therapy. T2DM: type 2 diabetes mellitus. HbA1c: glycosylated hemoglobin. FBG: fasting blood glucose. 0.5-hPBG: 0.5-h blood glucose. 1h-PBG: 1-h blood glucose. 2-hPBG: 2-h blood glucose. 3-hPBG: 3-h blood glucose. CHOL: cholesterol. TG: triglycerides. HDL: high-density lipoprotein. LDL: low-density lipoprotein. OGTT: oral glucose tolerance test.

Ethical approval

This single-blind, randomized controlled trial was conducted in the Affiliated Hospital of Jiangnan University, Wuxi, China from December 2017 to November 2018. The trial was approved

by the Ethics Review Committee of the Affiliated Hospital of Jiangnan University (ID: IEC201711001) and registered as ChiCTR-IOR-17013656 in the China Clinical Trial Registry. Written informed consent was obtained from all participants before the intervention.

Conflict of interest

The authors declare that there is no conflict of interest.

Availability of data and material

Data is available on request from the authors.

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Author contributions

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References

- Ahmad, H., Kashif, S., Afreen, A., Safdar, M., & Ahmed, Z. (2022). Comparative effect of fenugreek and cinnamon on management of newly diagnosed cases of type-2 diabetes mellitus. *Food Science and Technology*, 42, e47720. <http://dx.doi.org/10.1590/fst.47720>.
- Bai, Q., Xu, J., Zhu, W., Huang, C., Ni, X., Zhao, H., Feng, X., Li, L., Du, S., Fan, R., & Wang, J. (2021). Effects of consumption of a low glycaemic index formula on glycaemic control in patients with type 2 diabetes managed by medical nutrition therapy. *Food Science and Technology*, 41(3), 768-774. <http://dx.doi.org/10.1590/fst.51320>.
- Bradshaw, C., Thomas, I.-C., Montez-Rath, M. E., Lorenz, K. A., Asch, S. M., Leppert, J. T., Wang, V., O'Hare, A. M., & Tamura, M. K. (2021). Facility-level variation in dialysis use and mortality among older veterans with incident kidney failure. *JAMA Network Open*, 4(1), e2034084. <http://dx.doi.org/10.1001/jamanetworkopen.2020.34084>. PMID:33449098.
- Cranney, L., McGill, B., Clare, P. J., & Bauman, A. (2022). Trends in risk factors and management strategies used by people with type 2 diabetes in New South Wales, Australia. *Preventive Medicine*, 157, 107004. <http://dx.doi.org/10.1016/j.ypmed.2022.107004>. PMID:35240142.
- Cucuzzella, M., Riley, K., & Isaacs, D. (2021). Adapting medication for type 2 diabetes to a low carbohydrate diet. *Frontiers in Nutrition*, 8, 688540. <http://dx.doi.org/10.3389/fnut.2021.688540>. PMID:34434951.
- Franz, M. J., Warshaw, H., Daly, A. E., Green-Pastors, J., Arnold, M. S., & Bantle, J. (2003). Evolution of diabetes medical nutrition therapy. *Postgraduate Medical Journal*, 79(927), 30-35. <http://dx.doi.org/10.1136/pmj.79.927.30>. PMID:12566549.
- Gerds, E., & Regitz-Zagrosek, V. (2019). Sex differences in cardiometabolic disorders. *Nature Medicine*, 25(11), 1657-1666. <http://dx.doi.org/10.1038/s41591-019-0643-8>. PMID:31700185.
- Gow, M. L., Baur, L. A., Johnson, N. A., Cowell, C. T., & Garnett, S. P. (2017). Reversal of type 2 diabetes in youth who adhere to a very-low-energy diet: a pilot study. *Diabetologia*, 60(3), 406-415. <http://dx.doi.org/10.1007/s00125-016-4163-5>. PMID:27889809.
- Gram-Kampmann, E. M., Hansen, C. D., Hugger, M. B., Jensen, J. M., Brønd, J. C., Hermann, A. P., Krag, A., Olsen, M. H., Beck-Nielsen, H., & Højlund, K. (2022). Effects of a 6-month, low-carbohydrate diet on glycaemic control, body composition, and cardiovascular risk factors in patients with type 2 diabetes: an open-label randomized controlled trial. *Diabetes, Obesity & Metabolism*, 24(4), 693-703. <http://dx.doi.org/10.1111/dom.14633>. PMID:34984805.
- Ha, K., Joung, H., & Song, Y. (2019). Inadequate fat or carbohydrate intake was associated with an increased incidence of type 2 diabetes mellitus in Korean adults: a 12-year community-based prospective cohort study. *Diabetes Research and Clinical Practice*, 148, 254-261. <http://dx.doi.org/10.1016/j.diabres.2019.01.024>. PMID:30703429.
- Han, Y., Cheng, B., Guo, Y., Wang, Q., Yang, N., & Lin, P. (2021). A low-carbohydrate diet realizes medication withdrawal: a possible opportunity for effective glycemic control. *Frontiers in Endocrinology*, 12, 779636. <http://dx.doi.org/10.3389/fendo.2021.779636>. PMID:34970224.
- International Diabetes Federation – IDF. (2021). *IDF diabetes atlas* (10th ed.). Brussels: IDF.
- Kaur, J., Jiang, C., & Liu, G. (2019). Different strategies for detection of HbA1c emphasizing on biosensors and point-of-care analyzers. *Biosensors & Bioelectronics*, 123, 85-100. <http://dx.doi.org/10.1016/j.bios.2018.06.018>. PMID:29903690.
- Khan, M. W., Priyadarshini, M., Cordoba-Chacon, J., Becker, T. C., & Layden, B. T. (2019). Hepatic hexokinase domain containing 1 (HKDC1) improves whole body glucose tolerance and insulin sensitivity in pregnant mice. *Biochimica et Biophysica Acta. Molecular Basis of Disease*, 1865(3), 678-687. <http://dx.doi.org/10.1016/j.bbdis.2018.11.022>. PMID:30543855.
- Kirkpatrick, C. F., Bolick, J. P., Kris-Etherton, P. M., Sikand, G., Aspry, K. E., Soffer, D. E., Willard, K. E., & Maki, K. C. (2019). Review of current evidence and clinical recommendations on the effects of low-carbohydrate and very-low-carbohydrate (including ketogenic) diets for the management of body weight and other cardiometabolic risk factors: a scientific statement from the National Lipid Association Nutrition and Lifestyle Task Force. *Journal of Clinical Lipidology*, 13(5), 689-711. <http://dx.doi.org/10.1016/j.jacl.2019.08.003>. PMID:31611448.
- Kontush, A. (2020). HDL and Reverse Remnant-Cholesterol Transport (RRT): relevance to cardiovascular disease. *Trends in Molecular Medicine*, 26(12), 1086-1100. <http://dx.doi.org/10.1016/j.molmed.2020.07.005>. PMID:32861590.
- Ley, S. H., Hamdy, O., Mohan, V., & Hu, F. B. (2014). Prevention and management of type 2 diabetes: dietary components and nutritional strategies. *Lancet*, 383(9933), 1999-2007. [http://dx.doi.org/10.1016/S0140-6736\(14\)60613-9](http://dx.doi.org/10.1016/S0140-6736(14)60613-9). PMID:24910231.

- Marks, B. E., Kilberg, M. J., Aliaj, E., Fredkin, K., Hudson, J., Riva, D., Román, C., Kelly, A., & Putman, M. S. (2021). Perceptions of diabetes technology use in cystic fibrosis-related diabetes management. *Diabetes Technology & Therapeutics*, 23(11), 753-759. <http://dx.doi.org/10.1089/dia.2021.0201>. PMID:34185606.
- Mitra, S., Goyal, T., & Mehta, J. L. (2011). Oxidized LDL, LOX-1 and atherosclerosis. *Cardiovascular Drugs and Therapy*, 25(5), 419-429. <http://dx.doi.org/10.1007/s10557-011-6341-5>. PMID:21947818.
- Peng, S., Wei, P., Lu, Q., Liu, R., Ding, Y., & Zhang, J. (2018). Beneficial effects of poplar buds on hyperglycemia, dyslipidemia, oxidative stress, and inflammation in streptozotocin-induced type-2 diabetes. *Journal of Immunology Research*, 2018, 7245956. <http://dx.doi.org/10.1155/2018/7245956>. PMID:30320140.
- Sarathi, V., Kolly, A., Chaithanya, H. B., & Dwarakanath, C. S. (2017). High rates of diabetes reversal in newly diagnosed Asian Indian young adults with type 2 diabetes mellitus with intensive lifestyle therapy. *Journal of Natural Science, Biology, and Medicine*, 8(1), 60-63. <http://dx.doi.org/10.4103/0976-9668.198343>. PMID:28250676.
- Shaban, E. E., Elbakry, H. F. H., Ibrahim, K. S., Sayed, E. M., Salama, D. M., & Farrag, A.-R. H. (2019). The effect of white kidney bean fertilized with nano-zinc on nutritional and biochemical aspects in rats. *Biotechnology Reports* 23, e00357. <http://dx.doi.org/10.1016/j.btre.2019.e00357>. PMID:31312610.
- Steven, S., Hollingsworth, K. G., Al-Mrabeh, A., Avery, L., Aribisala, B., Caslake, M., & Taylor, R. (2016). Very low-calorie diet and 6 months of weight stability in type 2 diabetes: pathophysiological changes in responders and nonresponders. *Diabetes Care*, 39(5), 808-815. <http://dx.doi.org/10.2337/dc15-1942>. PMID:27002059.
- Tan, D., Cui, J., Qin, L., Wang, Y., He, Y., Chen, L., & She, X. (2022). Hypoglycemic effect of Zingiber striolatum bud extract in db/db mice. *Food Science and Technology*, 42, e114321. <http://dx.doi.org/10.1590/fst.114321>.
- Thomsen, M. N., Skytte, M. J., Samkani, A., Carl, M. H., Weber, P., Astrup, A., Chabanova, E., Fenger, M., Frystyk, J., Hartmann, B., Holst, J. J., Larsen, T. M., Madsbad, S., Magkos, F., Thomsen, H. S., Haugaard, S. B., & Krarup, T. (2022). Dietary carbohydrate restriction augments weight loss-induced improvements in glycaemic control and liver fat in individuals with type 2 diabetes: a randomised controlled trial. *Diabetologia*, 65(3), 506-517. <http://dx.doi.org/10.1007/s00125-021-05628-8>. PMID:34993571.
- Wang, D. D., & Hu, F. B. (2018). Precision nutrition for prevention and management of type 2 diabetes. *The Lancet. Diabetes & Endocrinology*, 6(5), 416-426. [http://dx.doi.org/10.1016/S2213-8587\(18\)30037-8](http://dx.doi.org/10.1016/S2213-8587(18)30037-8). PMID:29433995.
- Wang, H., Qiu, B., Xu, T. C., Zong, A., Liu, L. N., & Xiao, J. X. (2020). Effects of resistant starch on the indicators of glucose regulation in persons diagnosed with type 2 diabetes and those at risk: a meta-analysis. *Journal of Food Processing and Preservation*, 44(8), e14594. <http://dx.doi.org/10.1111/jfpp.14594>.
- Weiman, D. I., Mahmud, F. H., Clarke, A. B. M., Assor, E., McDonald, C., Saibil, F., Lochnan, H. A., Punthakee, Z., & Marcon, M. A. (2021). Impact of a gluten-free diet on quality of life and health perception in patients with type 1 diabetes and asymptomatic celiac disease. *The Journal of Clinical Endocrinology and Metabolism*, 106(5), e1984-e1992. <http://dx.doi.org/10.1210/clinem/dgaa977>. PMID:33524131.
- Zhang, M., Feng, R., Yang, M., Qian, C., Wang, Z., Liu, W., & Ma, J. (2019). Effects of metformin, acarbose, and sitagliptin monotherapy on gut microbiota in Zucker diabetic fatty rats. *BMJ open diabetes research & care*, 7(1), e000717.