The effect of care intervention for obese patients with type II diabetes

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Abstract
The incidence of type II diabetes mellitus (T2DM) is increasing worldwide and affecting the quality of people's life. This study was designed to evaluate the effect of care intervention on body weight and glycemic parameters in obese T2DM patients.

One hundred twenty-six obese T2DM cases were randomly divided into 2 groups. Patients in control group received conventional care, while patients in the intervention group received dietary, exercise, and psychology interventions on the basis of conventional care. Twelve months follow-up was performed to compare the changes of body weight and glycemic parameters in the 2 groups.

There were 119 patients completing the research, 60 in the intervention group and 59 in control group. The levels of fasting plasma glucose (FPG), 2 hours postprandial blood glucose (PBG2 h), hemoglobin A1c (HbA1c), and aldose reductase (AR) were all significantly decreased (all, P < .05) in intervention group compared with the control group after 12 months follow-up. Moreover, the body weight and BMI (body mass index) were also significantly reduced in intervention group, and the weight loss was significantly higher in intervention group than that in control group during the follow-up.

To implement care intervention for obese T2DM patients could strengthen the management of blood glucose, reduce body weight and complications.

Abbreviations: AR = aldose reductase, BMI = body mass index, FPG = fasting plasma glucose, HbA1c = hemoglobin A1c, PBG2 h = 2 hours postprandial blood glucose, T2DM = type II diabetes mellitus.

Keywords: intervention, obesity, type II diabetes mellitus

1. Introduction
Diabetes is one of the most common chronic diseases that significantly affects the quality of people's life and human health. The number of adults with diabetes both in developing countries and developed countries has been rising for decades. The large population of diabetes is a principal cause of increased mortality and health costs in the world. Type II diabetes mellitus (T2DM) is a heterogeneous disorder characterized by multiple defects in insulin action in tissues and commonly in elder people with high rates of obesity. T2DM is usually associated with micro- or macrovascular complications, including peripheral vascular disease, cardiovascular disease, diabetic neuropathy amputations, and renal failure. At present, drugs and dietary control are effective therapy strategies for T2DM to achieve acceptable glycemic level. The treatment goals for T2DM patients are effective control of blood glucose to avert the serious complications induced by high glucose concentrations.

Traditional methods of care alone are unable to achieve a good effect of diabetes control for patients with T2DM. Therefore, it is urgently needed to find new potential care-modifying treatments.

Over the years, exercise training has been used to positively affect patients with diabetes, playing an important protective role in altering the blood glucose, blood pressure, and insulin resistance. Exercise is a subset of physical activity and usually includes planned and repetitive bodily movements. Previous studies have indicated that exercise could improve the quality of life in people with diabetes. T2DM is one of the health-related consequences of obesity; thus, diet control is important for obese T2DM patients. It has been reported that diet proceeding in reducing the energy value of the diet had a beneficial effect on reducing body weight and BMI (body mass index), thus reducing the risk factors for obesity-related diseases, such as coronary heart disease. Most T2DM patients often lack of adequate knowledge about the importance of effective management the lifestyle including dietary and exercise and had been failure in a long-term of blood glucose control. To achieve long-term blood glucose control and weight management, psychological intervention is applied. It was reported that psychological intervention could enhance weight reduction among patients with overweight or obesity. A related systematic review and meta-analysis undertaken by Ismail et al demonstrated that psychological treatment could be helpful in long-term glycemic control and prevention of psychological distress in T2DM cases. The above intervention measures may be useful in optimizing the conventional intervention strategy for obesity T2DM patients.

The aim of this study was to assess the effectiveness of care intervention, including dietary intervention, exercise intervention, and psychology intervention in obesity T2DM patients with a period of 12 months.
2. Methods

2.1. Patients and general information

In this study, 126 type II diabetes (T2DM) patients were collected from Cangzhou Central Hospital. The definition of T2DM was conformed to the diabetes diagnosis standards promulgated by the WHO Diabetes Experts Committee. The conditions of the patients should meet the following inclusion criteria: male or female patients of nonchildbearing potential; adult group with age range 18 to 70 years; the BMI $\geq 30$ kg/m$^2$.

Patients with diabetes complications such as diabetic nephropathy and diabetic foot, diabetes other than type 2, or other severe visceral organ disease were excluded from our study. In addition, the patients with psychological disorders would also be excluded from the current investigation.

All the included 126 patients were randomly divided into 2 groups, the intervention group (n = 63) and control group (n = 63). According to the matching principle, the patients were adjusted appropriately to make them in the 2 groups and were matched in age, sex, and weight. The baseline information of the patients in 2 groups is recorded in Table 1, including age, gender, BMI, fasting plasma glucose (FPG), and systolic and diastolic blood pressure.

The study was approved by the Ethic committee of Cangzhou Central Hospital and written informed consent was obtained from each patient before the performance of the study.

2.2. Conventional and intervention treatments

All the 126 T2DM patients received conventional treatment, including taking diabetes medications and monitoring their blood glucose, blood pressure. In addition to the conventional treatment, patients in the intervention group received dietary treatment, exercise intervention, and psychology intervention.

The dietary intervention mainly included dietary evaluation by the program-registered dietitians, receiving a hypocaloric meal plan, using diabetes-specific meal replacement for breakfast and lunch. All meal plans were low in glycemic index and low in sodium (<2300 mg/day).

On the basis of each participant’s health status and exercise capacity, an individualized exercise plan was designed by doctor and patients. The intensity level of exercise was set above the minimum required improve patients’ current exercise capacity but below a level that might evoke abnormal clinical symptoms. The exercise intervention included a balanced mix of aerobic exercise, resistance exercise, and core stability training. Patients were instructed to progress gradually from 20 minutes, 4 days/week to 60 minutes, 5 to 6 days/week.

Clinical psychologist or a social worker was invited to conduct group behavioral support sessions including basic mental health knowledge and the effects of medication on the behavior of those who suffering from illness. Patients were provided with handouts as reminders, and they were taught of self-monitoring of eating and exercise, behavioral goal setting, cognitive restructuring, assertive communication skills, and relapse prevention. The group sessions were performed once a month; besides, the patients received psychological guidance every 2 weeks through telephone.

2.3. Effect measurement

Main metabolic parameters were measured at baseline and 12 months intervention during their regular visit to hospital, including every 1 month during the first 6 months and then every 3 months in the last 6 months. These measurements included BMI, FPG, 2 hours postprandial blood glucose (PBG2 h), aldose reductase (AR), and HbA1c. Moreover, the occurrence of complications in the patients was observed during 12 months follow-up according to the criterion of Diabetes mellitus Prevention Guide.

2.4. Statistical analysis

All statistical analyses were performed using SPSS 18.0 software. Numerical data were presented as mean ± standard deviation (SD). Chi-square test or Student t test was used to analyze the differences between 2 groups. $P < .05$ was considered as statistically significant. As the clinic visits during the follow-up time were not rigorously scheduled, an approximation of each visit time to the nearest timeline was used.

3. Results

3.1. Baseline comparison

A total of 126 patients with the age range of 42 to 63 years were screened to join the study, and randomly divided into 2 groups. Before receiving any treatments, the clinical characteristics of T2DM patients in 2 groups at baseline were recorded and are summarized in Table 1. The results showed that there were no differences between the 2 groups in any of the clinical factors. Thus, data in the 2 groups were comparable. A total of 7 participants, 3 from the intervention group and 4 from the control group, were lost to follow-up. Outcome data were available for all the remaining participants who completed the study, 60 in the intervention group and 59 in the control group (Fig. 1).

3.2. Comparisons of glycemic parameters in the 2 groups

At the baseline time, the glycemic parameters did not show obvious differences between intervention and control groups ($P > .05$ for all) (Table 2). After 12-month follow-up, the patients in the intervention group had significantly lower levels of glycemic parameters, including HbA1c, FPG, PBG2 h, and AR than those in the control group ($P < .05$ for all) (Table 2). Besides, compared with the baseline, the levels of glycemic parameters in intervention group were also decreased after 12 months’ lifestyle intervention.

### Table 1: Baseline characteristics of the T2DM patients in 2 groups.

| Characteristic                     | Intervention group | Control group | $P$  |
|-----------------------------------|--------------------|---------------|------|
| Age, y                            | 56.3 ± 5.2         | 57.1 ± 5.5    | .165 |
| Gender (male/female)              | 53/30              | 52/31         | .895 |
| Weight, kg                        | 90.5 ± 11.3        | 92.1 ± 12.2   | .663 |
| BMI, kg/m²                        | 32.6 ± 2.4         | 34.1 ± 3.1    | .338 |
| FPG, mmol/L                       | 8.82 ± 0.63        | 8.54 ± 0.88   | .096 |
| Systolic blood pressure, mm Hg    | 135 ± 16           | 139 ± 18      | .112 |
| Diastolic blood pressure, mm Hg   | 80 ± 8             | 82 ± 8        | .237 |
| T2DM duration, years              | 1.24 ± 0.38        | 1.27 ± 0.36   | .454 |
| PBG2 h, mmol/L                    | 10.7 ± 5.2         | 10.9 ± 3.8    | .155 |
| HbA1c (%)                         | 7.7 ± 0.9          | 8.3 ± 1.1     | .212 |
| AR, IU/g                          | 5.23 ± 1.19        | 5.26 ± 1.21   | .079 |

AR = aldose reductase, BMI = body mass index, FPG = fasting plasma glucose, HbA1c = hemoglobin A1c, PBG2 h = 2 hours postprandial blood glucose.
### 3.3. Comparison of body weight parameters in the 2 groups

The patients enrolled in our study were obese with BMI ≥30 kg/m². Here, we investigated the weight and BMI changes after intervention on dietary, exercise, and psychology in 1-year time. The results showed that both the body weight and BMI were significantly decreased \((P < .05\), Table 2) in the intervention group after 12 months follow-up. Weight loss in intervention group continued to be significantly higher than weight loss in control group over the following 12 months (Fig. 2).

At the end of the follow-up, no patient was found with complication in the intervention group, but 2 patients were observed with complications in control group, one with diabetic nephropathy and the other with diabetic peripheral vascular disease.

### 4. Discussion

Over the past decade, the prevalence of T2DM has increased rapidly worldwide, especially in low- and middle-income countries, which bear a disproportionate burden of the national T2DM epidemic. Poor management in diabetes results in hyperglycemia and eventually serious microvascular and macrovascular complications. It has been recognized that both complications and comorbid conditions determine the quality of life in T2DM patients and the poor quality of life leads to a high risk of mortality. Moreover, patients with T2DM are often associated with disorders in glucose metabolism and lipid metabolism, which will increase the degree of obesity. Thus, more than 80% to 90% of T2DM patients are obese. The excess body weight influences almost every aspect of life and it is difficult to treat the overweight in T2DM patients. Therefore, weight management is of great significance to patients with obese T2DM.

Accumulating studies have shown that exercise could improve sleep quality and prevent chronic illness for people. Vancampfort et al. conducted a cross-sectional study to assess the relationship between physical activity and chronic conditions. They concluded that those with chronic conditions were significantly less physically active and promotion of physical activity to populations may ameliorate associated depression and mobility difficulties. Physical inactivity is one of the major risk factors for the development of T2DM and its complications. Van der Heijden et al. conducted a systematic review to assess the effects of exercise training on quality of life, symptoms of depression, and anxiety in people with T2DM for at least 4 weeks’ duration. Although the author found that the effects of exercise training on quality of life in people with T2DM were conflicting, it still provided insight into the role of exercise training in T2DM. In the study by Cai et al., they systematically assessed the effectiveness of aerobic exercise, resistance exercise, combined exercise, and yoga on the quality of life in patients with T2DM.

Reasonable diet control is one of the key factors to keep regular level of blood glucose and blood lipid. Previous studies have shown that rigorous application of combined diet and physical activity promotion programs was successful at reducing risk of diabetes by 50% to 60% during the active intervention period among people who are at an increased risk of T2DM. Recently, a review study was performed on the

#### Table 2

| Parameters          | Baseline | 12 mo |
|---------------------|----------|-------|
| Weight, kg          | IG       | CG    | \(P\) |
|                     | 90.5 ± 11.3 | 92.1 ± 12.2 | >.05 |
|                     | 82.1 ± 10.6 | 88.4 ± 12.6 | <.05 |
| BMI, kg/m²          | IG       | CG    | \(P\) |
|                     | 32.6 ± 2.4 | 34.1 ± 3.1 | >.05 |
|                     | 28.5 ± 2.6 | 32.6 ± 3.5 | <.05 |
| FPG, mmol/L         | IG       | CG    | \(P\) |
|                     | 8.8 ± 0.63 | 8.54 ± 0.88 | >.05 |
|                     | 4.64 ± 0.35 | 5.03 ± 0.32 | <.05 |
| PBG2h, mmol/L       | IG       | CG    | \(P\) |
|                     | 10.7 ± 3.2 | 10.9 ± 3.8 | >.05 |
|                     | 5.8 ± 2.1 | 7.6 ± 2.3 | <.05 |
| HbA1c (%)           | IG       | CG    | \(P\) |
|                     | 7.7 ± 0.9 | 8.3 ± 1.1 | >.05 |
|                     | 3.8 ± 1.6 | 5.9 ± 1.4 | <.05 |
| AR, IU/g            | IG       | CG    | \(P\) |
|                     | 5.23 ± 1.19 | 5.26 ± 1.21 | >.05 |
|                     | 1.23 ± 0.56 | 3.32 ± 1.15 | <.05 |

\(AR = \text{aldose reductase}, \text{BM} = \text{body mass index}, \text{CG} = \text{control group}, \text{FPG} = \text{fasting plasma glucose}, \text{HbA1c} = \text{hemoglobin A1c}, \text{IG} = \text{intervention group}, \text{PBG2}h = \text{2 hours postprandial blood glucose.}\)
effectiveness of dietary and physical activity in a wide range of clinical or community settings to reduce the risk of new-onset diabetes among adults and children at risk of diabetes. They found that the combination of dietary and physical activity could reduce diabetes incidence and improve other cardiometabolic risk factors. However, there was limited evidence for clinical events and more researches were needed.

Previous studies have shown that depressive symptoms were associated with worsened blood glucose levels and T2DM complications. Patients with depression were having decreased adherence to diabetes care regimens, increased functional disability, and decreased quality of life. To date, few existing literatures considered psychology intervention with community mental health for T2DM patients.

In this study, we performed care intervention on T2DM patients, who received the combination of dietary intervention, exercise intervention, and psychology intervention. After 12 months follow-up, patients in the intervention group had significantly lower levels of glycemic parameters, including HbA1c, FPG, PG2h, and AR, and the body weight and BMI were all decreased significantly compared with the control group. Moreover, during the follow-up, no patient was found with complication in the intervention group. Therefore, the care intervention was helpful to control blood glucose, reduce weight and complications in obese patients with T2DM. In a word, we comprehensively analyzed the combined effect of diet, exercise, and psychological intervention for T2DM patients, which was different from the previous studies only focusing on the regulation of exercise and diet. The results obtained in our study might provide a new approach to optimize the conventional interventions for T2DM patients. However, several limitations should be considered in this study. One is the sample size, and the other is that the study was conducted at a single tertiary care center. Moreover, the longer follow-up is recommended to maintain weight reduction. In addition, the long-term effects of care interventions on psychology status of obese T2DM patients need further researches. In conclusion, care intervention by combination of dietary, exercise, and psychology was effective to control body weight and glycemic levels. Further comprehensive studies are still needed in the future.

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