Original Article

Nutritional intervention in the metabolic syndrome

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Objective: Through an interventional study in the metabolic syndrome, evaluate the feasibility of the standard nutritional intervention.
Design: Select metabolic syndrome patients from people who received a health check in our hospital and randomly allocate them into four groups. The standard interventional group received both the nutritional intervention and health education; the simple interventional group only received the nutritional intervention; the simple health educational group only received health education; the control group did not receive any intervention measure. Examine the related index of the metabolic syndrome of each group before and half a year after the intervention: waistline, blood pressure, triglyceride, fasting plasma glucose etc. K-W test and Chi-square test, Bonferroni correction was used in our study.
Outcomes: The index of the metabolic syndrome was significantly different for each of the four groups before and after intervention ($p<0.05$). Relative to the control group the total index for the standard nutritional interventional group and for, the simple health education group was significantly different, but there was no difference for the other indices ($p>0.05$) between the standard nutritional interventional group and simple nutritional interventional group, except that the waistline difference ($p<0.005$) showed statistical significance.
Conclusion: The standard nutritional intervention is an effective strategy for patients with the metabolic syndrome.

Key Words: nutritional intervention , metabolic syndrome, health education, blood pressure, fasting plasma glucose

Introduction
Metabolic syndrome (MS) is a common clinical syndrome , combining with several risk factors such as obesity, hypertension, dysglycemia and dyslipemia.[1] The common characteristic is the insulin resistance.

According to the diagnostic criteria of the Diabetes Section of the Chinese Medical Association, the prevalence of the metabolic syndrome in China's urban population is currently 14%-16% with a continuously rising trend.[2] The Chinese Medical Association has recommended that the MS population rebuild their life-style accordingly, particularly through nutritional intervention. The standard nutritional intervention includes a series of subsidiary products as well as a comprehensive interaction with patients. It is managed by a professional interaction service center and the medical staff in order to guarantee maximum compliance. We are still at the beginning of simple nutritional intervention in our country; doctors and the public have limited knowledge about the MS, short of standard intervention methods for life-style. Thus, an effective interventional method can not easily be put in to practice in timely.

Ambulatory patients are short of a proper understanding change their life-style, and clinics lack guideline for changing life-styles. Professional products can not usually be provided by the nutritional center, so that many interventional measures cannot be brought to effectiveness.

The study has established an efficient standard nutritional intervention protocol for MS patients consisting of health education and nutritional intervention. Our study cooperated with the Nuote nutritional center, uses the principle of low glycemic load foods, and has designed a standard comprehensive interaction nutritional interventional system. The present study has allowed us to demonstrate the preventive and therapeutic value of interventional measures for MS patients. It should contribute to improve patients' life expectancy and life quality, and decrease the economic burden for patients' families as well as for society.

Materials and methods
Subjects
Choose the 12478 people who received health check in our health check center during 2005. 3756 patients with the diagnostic criteria of the MS were enrolled in our study. Excluded were patients with nephritis, hepatopathy, pancreatitis, mental disease, ischemic heart disease, and those who did not want to attend our study. 906 patients were enrolled in our interventional study.

The diagnostic criteria: according to the criteria of the diagnose for MS which is established by the International Diabetes Federation (IDF): must be present (1) central obesity: the waist circumference of Chinese male (WC)

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≥90cm, the waistline of Chinese female≥80cm. (2) add randomly two items from the following four factors: hypertriglyceridemia (TG > 150mg/dl (1.7mmol/l). high density lipoprotein decrease of male <40mg/dl (1.03 mmol/l), of female <50mg/dl (1.29mmol/l). hypertension: systolic pressure ≥ 130mmHg, or diastolic pressure ≥ 85 mmHg. hyperglycemia: fasting plasma glucose (FPG) ≥100 mg/dl (5.6 mmol/l).[3] Excluded were patients with nephritis, hepatopathy, pancreatitis, mental disease, ischemic heart disease and other clinically evident macro vascular disease.

For the health check a low-fat diet for three days before was required and subjects ate a bland diet for 12 hours beforehand. The waist circumference was measured as the horizontal perimeter from the inferior costal facet to the superior ilium, standing up, with a flexible rule (Chengfeng Zhejiang China, 1.6cm×1.5m), TG and FPG were measured by the automatic biochemistry analyser of Beckman LX20, USA (enzyme method). HDL-C was measured by the electrophoresis apparatus of Helena RET. USA (electrophoresis). Blood pressure was measured by the desk-sphygmomanometer of YUTU XJ11D (A medical apparatus company in Shanghai), twice at various times.

Method of intervention

The intervention in the 906 MS patients was as follows:

1. Study on groups: The MS patients were randomly allocated into four groups as follows after discussion with the ethics administration committee of the hospital and patient agreement.

Standard interventional group: 195 patients in this group received both the health education and the standard nutritional intervention.

Simple interventional group: 175 patients in this group only received the nutritional intervention, not receive the health education.

Simple health educational group: 281 patients in this group only received the health education, not receive the nutritional intervention.

Control group: 255 patients in this group neither received the health education, nor the nutritional intervention.

2. Measure of intervention:

2.1 health education: received a health education lecture by a fellow or attending doctor for 60 minutes in the edu cation class of health-check center. The content included diet, exercise, and the balance of mentality and so on. The patients were demanded for food ameliorate (low fat, low saturated fatty acid, high fibrin, low calorie diet) and exercise with appropriate quantity of motion.

2.2 Nutritional intervention: use the principle of low glycemic load foods (high protein, low fat, low sugar), start the process of dietary fat reduction. The patients were given the products (provided by the Nuote Nutritional Center, Hubin campus of Zhejiang university) comprising a nutritious snack or meal replacement bar; urinary ketene test strips; and a micronutrient supplement. There was extensive interaction with patients. The main ingredients of the nutritious bar were soybean protein, maltitol, dietary fibro, lacto protein, and vegetable oil, cocoa. Composition was liquid water content≤8%, protein≥20%, fat≤18%, carbohydrate≤35%, dietary fibre≥6%, reducing sugar ≤6%, lead≤1mg/kg, arsenic ≤0.5 mg/kg, copper≤15 mg/kg, flavacin B1≤ 5 mg/kg, and food additives were consistent with regulation GB2760.

The whole process included three phases: startup, loss of weight and maintenance. The daily calorie intake was limited to between 1300 to 1600 and exercise for over half an hour one day was required.

2.3 Interaction and evaluation: A standard training for every patient was required before the intervention,

They were helped to preparation in mind and resources and taught them how to use the subsidiary products and the principle of low glycemic load foods. Interaction included internet, short messages by mobile phone and telephone which enabled the patients to keep contact with the nutrition center, report the status of the diet and weight. The center dealt with the patients' problem everyday to assure the process of intervention with the frequency of once of two days on first week, and twice a week at least thereafter.

The metabolic index of the four groups was assessed after half a year's intervention, the differences among four groups, evaluated.

Statistical analysis

The values were presented as median and quartile range, the significance of difference among groups was tested with K-W test, the Chi-square test were used to evaluate equality of frequencies for discrete variables, multiple comparison were subjected to Bonferroni correction. A P-value less than or equal to 0.05 was considered statistical significant.

Results
Generalized case

3756 patients' accord with the diagnostic criteria of MS

Table 1. Background of study object on various groups $M(Q_R)$

	Gender M/F	Age	Waistline difference (cm)	Systolic pressure difference (mmHg)	Diastolic pressure difference (mmHg)	TG difference (mg/dl)	HDL-C difference (mg/dl)	FPG difference (mg/dl)
A	149/96	47.0 (23.0)	5.00 (6.00)	5.00 (4.00)	6.00 (4.00)	23.0 (25.0)	5.00 (4.00)	5.00 (5.00)
B	100/87	48.0 (21.0)	10.0 (9.00)	7.00 (7.25)	7.00 (7.50)	59.0 (60.25)	13.0 (13.0)	11.0 (10.0)
C	95/74	48.0 (23.0)	7.00 (10.00)	7.50 (8.00)	8.00 (8.00)	60.5 (55.0)	12.5 (13.0)	11.0 (10.0)
D	148/125	48.0 (22.0)	5.00 (5.00)	5.00 (4.00)	4.50 (4.00)	29.0 (25.25)	5.00 (5.00)	4.00 (5.00)

* Difference＝before intervention – after intervention. *A: control group; B: the standard nutritional intervention group; C: the simple nutritional intervention group; D: the simple health-education group. *The related index of metabolic syndrome was significantly different for each of the four groups before and after intervention ($p<0.05$)

Table 2. The standard nutritional intervention group and control group

	Waistline difference (cm)	Systolic pressure difference (mmHg)	Diastolic pressure difference (mmHg)	TG difference (mg/dl)	HDL-C difference (mg/dl)	FPG difference (mg/dl)
u	9.159	5.13	3.64	9.56	10.38	8.22
p	<0.005	<0.005	<0.005	<0.005	<0.005	<0.005

The total index between the standard nutritional intervention group and the control group was significantly different ($p<0.005$).

Table 3. The standard nutritional intervention group and simple health-education group

	Waistline difference(cm)	Systolic pressure difference (mmHg)	Diastolic pressure difference (mmHg)	TG difference (mg/dl)	HDL-C difference (mg/dl)	FPG difference (mg/dl)
u	8.14	4.98	4.83	8.25	10.28	8.87
p	<0.005	<0.005	<0.005	<0.005	<0.005	<0.005

The total index between the standard nutritional intervention group and the simple health-education group was significantly different ($p<0.005$).

Table 4. The standard nutritional intervention group and simple nutritional intervention group

	Waistline difference (cm)	Systolic pressure difference (mmHg)	Diastolic pressure difference (mmHg)	TG difference (mg/dl)	HDL-C difference (mg/dl)	FPG difference (mg/dl)
u	2.84	0.24	0.87	0.45	0.21	0.89
p	<0.005	>0.005	>0.005	>0.005	>0.005	>0.005

The index of systolic pressure difference, diastolic pressure difference, TG difference , HDL-C difference, FPG difference between the standard nutritional intervention group and the simple nutritional intervention group was no significantly different ($p>0.005$), only the waistline difference was significantly different ($p<0.005$).

among the 12478 people who received health check in our health check center during 2005. The prevalence rate of MS is 30.1% n our study. Excluded were the patients with nephritis, hepatopathy, pancreatitis, mental disease, ischemic heart disease, and those who did not want to attend our study.

Nine hundred and six patients were included in our study, and among those, 195 patients were put in the standard nutritional interventional group, five patients were lost to follow-up, three patients dropped out; 175 patients were put in the simple nutritional interventional group, four patients lost to follow-up, two patients dropped out; 281 patients were put in the simple health educational group, eight patients lost to follow-up; 255patients were put in the control group, 10 lost to follow-up.

Gender distribution and age distribution among the four groups showed no statistical significance ($x^2=1.259$, $p>0.05$ vs. $x^2=0.958$, $p>0.05$, respectively). The background data are shown in: table 1.

Comparison between the standard nutritional interventional group and other groups is made in table2-4. The total index between the standard nutritional interventional group and the control group, the simple health educational group showed statistical significance, but it showed no statistical significance in other index($p>0.05$) between the standard nutritional interventional group and simple nutritional interventional group, except that the waistline difference ($p<0.05$)showed statistical significance.

Discussion

Metabolic syndrome (MS) is on the rise in China with dietary changes and increasingly sedentary lifestyles seriously jeopardizing public health**.** According to the diagnostic criteria of the Diabetes Section of Chinese Medical Association, the prevalence of the MS in China's urban population is currently 14%-16% with a continuously rising trend.[2] According to the diagnostic criteria of the MS which were established by the International Diabetes Federation (IDF), the prevalence of the MS reached 30.1% among those examined in this study.

The pathogenesis of MS are as follows: insulin resistance (IR), gene mutation, obesity, inflammation, cell mutation etc.[4] The invasion of MS is related to genetic association and the environmental changes. The improper life-style characterized by a diet rich in sugar, fats and salt, physical inactivity, insufficient sleep, excessive mental stress and tobacco and alcohol abuse are all contributing risk factors for metabolic syndrome.

The Executive Summary of the Third Report of the National Cholesterol Education Program: Adult Treatment Panel Ⅲ (NCEP -ATPⅢ) recommended that the most important therapy for MS is therapeutic life-style change (TLC), combined with medication if necessary.[5] The IDF recommended that the primary intervention for MS is to rebuild a healthy life-style: limiting calories (to lower weight by 5-10% in the first year); increasing physical activity and altering the diet .[3] The interventional study for diabetes has been widely supported in many Western Countries. [6, 7] The diabetes prevention research in Finland and USA showed that minor weight reduction can prevent the development of diabetes among the high-risk people with impaired glucose tolerance and obesity.[8, 9] However, both China's doctors and the public health programs still lack sufficient knowledge about how to implement these changes. Thus an effective interventional method can not easily be put in to practice in timely. Ambulatory patients lack proper understanding change their life-style, and clinics lack guidelines for changing these unhealthy life-styles. Professional products can not

usually be provided by the nutritional centers, so the nutritional intervention is not available yet in China.

Our study uses the principle of a low glycemic load food; refer to the Chinese dietary habits and recognizing the facts about nutrition, has designed a standard comprehensive interactive nutritional intervention system. Hypo caloric diets activate thyroxin kinase of the insulin receptor and reduce plasma glucose and insulin in plasma.[10] At the same time, weight reduction can improve insulin sensitivity and exert beneficial effects on all the other abnormalities which are part of the syndrome.[11] It has acquired a satisfactory effect. The outcome of waistline difference, systolic pressure difference, diastolic pressure difference, TG difference, HDL-C difference and FPG difference was significantly different among the four groups before and after intervention. The total index between the standard nutritional interventional group and the control group, the simple health education group was significantly different, but there were no differences in other indices, except that the waistline difference was different between the standard nutritional interventional group and simple nutritional interventional group.

The health education for the MS includes public education widely, retraining for medical staff, training to impart knowledge about MS to the patients and their families. This study is only focuses on the patients who took the health check in our hospital, a simple health education is held by general doctors. Though the content is focused on the MS, we are still lack of the relevant knowledge and effective interaction. So it is difficult to access that whether the patient could change their life-style based only on the content of the education. Thus the outcome of our study showed that the total index of the simple health education group was significantly different, among the simple nutritional intervention group and the standard nutritional intervention group, and there was no difference in the other indices, except that the waistline difference was different between the standard nutritional interventional group and simple nutritional interventional group. It should be more effective if patients can receive both of the nutritional intervention and the health education rather than just simple nutritional intervention or the simple health education alone.

Our study showed no statistical significance in other indices ($p>0.05$) between the standard nutritional interventional group and simple nutritional interventional group, except that the waistline difference ($p<0.05$) was different between the standard nutritional interventional group and simple nutritional interventional group. But the IDF definition for metabolic syndrome demonstrates the critical importance of waistline circumference or girth as this measurement reflects the quantity of abdominal fat. The waistline is more related to insulin resistance and the risk of cardiovascular disease. So the standard intervention can indeed change the index of MS.

However, the subjects of our study were all the people who received health checks in our hospital between ages 36-55. The occupations of many patients were as leaders of enterprises or business executives with life-styles characterized by smoking and drinking, so the prevalence of the MS of our study (30.1%) was much higher than the level of our urban population in China (14%-16%).

Up to now, the non-pharmacological treatment relating behavioral changes with regard to nutrition, physical activity and alcohol consumption, simple instructions, are not sufficient.[10] Usually long-lasting changes in life style are necessary in order to achieve healthy improvement. Therefore, ongoing health care programs on an individual or social basis are required in order to improve the nutritional status, and to increase physical activity.

As MS results in multiple complex risk factors, we must combine all types of intervention. Our standard nutritional intervention will help engender a lasting life-style change and provide a new approach to the prevention and treatment of metabolic syndrome.

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