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The effects of a lifestyle intervention program on physical outcomes, depression, and quality of life in adults with metabolic syndrome: A randomized clinical trial

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ABSTRACT

Background/objectives: Lifestyle modification is recommended as the primary intervention for metabolic syndrome (MetS). The study was to examine the effects of a lifestyle intervention program (LIP) on physical outcomes, depression, and quality of life (QoL) in Chinese adults with MetS.

Methods: A randomized control trial design was used. A three-month LIP guided by the Health Promotion Model was developed, including a lifestyle modification booklet, one session of discharge education, and six telephone follow-ups. Patients with MetS were recruited from the inpatient departments of a hospital and were randomized to receive either the LIP or usual care. The physical outcomes, depression (Depression subscale of Hospital Anxiety and Depression Scale), and QoL (Medical Outcome Study Short Form-12, SF-12) were measured at baseline, one-month (T1) and three-month (T2). The effects of the LIP were examined by the generalized estimating equation (GEE) model.

Results: The study recruited 173 participants, with 86 in the intervention group and 87 in the control. Continuous improvements were observed in all the study outcomes in the intervention group. The GEE model revealed significant improvements in body weight (T1: $p = 0.017$, T2: $p = 0.007$), body mass index (T1: $p = 0.015$, T2: $p = 0.009$), depression (T1: $p = 0.027$, T2: $p < 0.001$), and physical aspects of QoL at T2 ($p = 0.02$).

Conclusions: The current LIP was effective in losing body weight, improving depression and QoL of MetS populations in three-month observation. Considering its low-cost and convenience, the LIP could be applied in clinical practice to improve patient outcomes.

1. Introduction

Metabolic syndrome (MetS) is the coexistence of multiple cardiometabolic risk factors, including central obesity, hyperglycemia, hypertension, and dyslipidemia [1]. Consistent with the global epidemic of overweight and obesity, MetS has been increasingly prevalent, with a prevalence of 24.0% to 78.0% in western populations [2,3]. Although the prevalence of MetS in Chinese adults (21.3%) was lower than that in western countries [4], China still has the world's largest MetS population considering its 1.36 billion of whole population.

People with MetS have increased risks for cardiovascular disease (CVD) [5], diabetes mellitus (DM) [6], severe complications, and higher mortality [7]. In addition to the adverse impacts on physical health, MetS patients also perceived higher levels of depression [8,9], and diminished quality of life (QoL) [10]. The increased depression and impaired QoL were in return associated with adverse patient outcomes, such as poor adherence to regimen and high mortality [11,12]. MetS patients usually have more outpatient visits, longer inpatient stays, and higher medical costs [3,13]. Given its increasing prevalence, MetS has imposed heavy burden to the health care system. Effective interventions are urgently needed for the MetS population.

Lifestyle modification has been recommended as the primary intervention for MetS, such as healthy diet, regular exercise, and body weight management [1,14]. Previous studies employed various modalities of lifestyle interventions in MetS management, in terms of content, duration, and format, and reported positive changes in MetS management [15–19]. Exercise and dietary intervention were the most commonly covered content, followed by stress management and risk factor modification [15–17]. Most lifestyle modifications were implemented by the participants themselves [18,20,21], while some studies provided intensive interventions, such as on-site supervised exercise [15,19,22,23], or provision of food products/supplements [24,25]. The duration of the interventions varied from four weeks to two years [16,26]. Education

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and follow-ups, either individually or in groups, were the most common formats in delivering the interventions. The education sessions usually combined verbal education with written materials, such as booklets, manuals, leaflets, pamphlets, or computer-assisted education [15,19,22,27]. The follow-up sessions were provided through telephone calls [16,28], home visits [20], and clinic/center visits [17,24,27].

There are also some limitations in previous studies. Firstly, most of the studies were conducted in developed countries. Some of their interventions, e.g. computer-assisted education [27], on-site exercise [15,19,23,28], and provision of supplement [24,25], may not be feasible or suitable to be applied in developing areas with limited resources and facilities. Secondly, only a small part of the studies employed a conceptual framework to guide the development of their interventions [18,22,27]. A feasible lifestyle intervention program (LIP) guided by a suitable conceptual framework is needed for the MetS population.

The beneficial effects of lifestyle interventions on depression and QoL have been widely reported in CVD patients [29,30]. However, previous studies focused on physical outcomes of MetS. Few studies involved depression or QoL [18,19,22]. Therefore, more empirical evidence is required to indicate the effects of lifestyle interventions on depression and QoL in MetS population. The current study aimed at examining the effects of lifestyle interventions on physical outcomes, depression, and QoL in the world's largest MetS population in China.

2. Materials and methods

2.1. Study design

The study was a two-armed randomized control trial.

2.2. Setting and participants

The study was conducted in a teaching hospital in Qingdao, northern China. The participants were recruited consecutively from the hospitalized patients in the medical wards. The patients were hospitalized mainly for medical diseases like DM, hypertension, and coronary heart disease (CHD). The participants were recruited on the day of discharge when the medical conditions were stabilized.

The inclusion criteria of the participants included: (1) Chinese citizens aged ≥18 years old. (2) With MetS following the International Diabetes Federation (IDF) definition, which revealed better performances in predicting CVD [31]. People with IDF-MetS typically have central obesity with a body mass index (BMI) ≥ 30 kg/m^2 or waist circumference (WC) ≥ 90 cm in men and ≥80 cm in women, plus any two of the following components: (i) blood pressure (BP) ≥ 130/85 mm Hg, or taking anti-hypertensive medicine; (ii) triglyceride (TG) ≥ 1.7 mmol/L, or taking specific medicine for increased TG; (iii) high density lipoprotein cholesterol (HDL-C) ≤ 1.03 mmol/L in men and ≤1.29 mmol/L in women, or taking specific medicine for decreased HDL-C; and (iv) fasting plasma glucose (FPG) ≥ 5.6 mmol/L, or taking medicine for DM [1]. (3) Able to communicate in Chinese and to complete the questionnaires independently.

Patients with any physician-diagnosed psychiatric illnesses (e.g., depression and schizophrenia), terminal illnesses (e.g., cancer and heart failure), with impaired bilateral hearing or vision, or having difficulty in performing moderate-intensity aerobic exercise were excluded.

WC, the core component of MetS, was selected to calculate the sample size [1]. Based on the findings of meta-analyses, the power analysis revealed that 128 participants would provide 80% statistical power in detecting an effect size of 0.50 on WC at a 5% significance level [32–34]. Considering an attrition rate of 20% [20,26], 160 participants, with 80 in each group, were required in the current study.

2.3. Intervention

All participants received usual care from the study hospital, including medical investigation and treatment, treatment-related nursing practices, and a 10-min brief discharge guide.

A three-month LIP guided by the Health Promotion Model (HPM) was developed [35]. The HPM provides practical conceptual framework to explain and predict heath promoting behaviors, and has been widely applied in lifestyle intervention studies [35]. Considering the feasibility of the LIP, it consisted of one session of individualized face-to-face education, a lifestyle modification booklet, and six telephone follow-ups. The face-to-face education was delivered individually on the day of discharge and lasted for 30–40 min. Within the framework of HPM, the education session included a brief introduction of MetS and its management (supplemented by the booklet), assessment of current behaviors and behavior-specific cognitions, provision of tailor-made advices (healthy diet, regular exercise, stress management, risk factor modifications, medication, and self-monitoring), and making behavioral modification plans with the patients. Laymen language was adopted throughout the education. The booklet, covering all aspects of MetS knowledge and management, was provided at the beginning of the education session. After discharge, six telephone follow-ups (20–30 min per call) were delivered bi-weekly to monitor the progress of lifestyle modifications, to re-assess patients' cognitions and context at home, and to provide ongoing support for further modifications. The patients were also reminded to read the booklet regularly to reinforce the core content of education.

2.4. Study outcomes and measurements

A structured questionnaire was developed to collect data on physical outcomes of MetS, depression, and QoL. The physical outcomes included body weight, WC, BMI, BP, and fasting plasma tests of FPG, TG, HDL-C, low density lipoprotein cholesterol (LDL-C), and total cholesterol (TC).

The Depression subscale of Hospital Anxiety and Depression Scale (HADS-D), a 7-item four-point Likert scale, was used to measure depression [36]. The overall score of HADS-D ranges from 0 to 21 (0–3 for each item) and a higher score indicates a higher level of depression. An overall score ≥ 7 revealed good sensitivity and specificity in screening depression [36], which was also adopted in the current study. The HADS has established good psychometric properties in MetS patients [9] and in Chinese population [37,38]. In the current study, the HADS-D revealed a Cronbach's α of 0.79.

The Medical Outcome Study Short Form-12 (SF-12) was used to measure participants' QoL [39]. Two standardized scores were calculated for SF-12 [40]: the Physical Component Summary (PCS) and the Mental Component Summary (MCS) [39]. Both scores range from 0 to 100 and a higher score indicates better physical or mental health status [39]. The Chinese version SF-12 had been validated in the Chinese populations with good performances in validity and reliability [41]. In the current study, the Cronbach's α of SF-12 was 0.65 for PCS and 0.74 for MCS.

Moreover, demographic information (age, gender, marital status, education level, and employment), medical history of hypertension, DM, and dyslipidemia, and smoking history were collected in the questionnaire.

2.5. Data collection procedures

Ethical approval was obtained from the university and the study hospital. Eligible patients were invited to participate. After detailed explanation and obtaining written consents, baseline data collection (T0) was conducted by a research nurse through the structured questionnaire. Participants' body weight, height, WC, and BP were measured following the guidelines of World Health Organization [42]. Results of FPG, TG, HDL-C, LDL-C, and TC were retrieved from participants' medical records during the present hospitalization. According to the routine of the study hospital, patients usually received blood tests both at admission and before discharge. In the current study, only the most updated blood test results before discharge were retrieved in the baseline data collection.

Randomization was conducted on the day of discharge by opening an opaque envelope, which sealed a computer-generated randomization number indicating the group allocation. Both the intervention group (IG) and control group (CG) received usual care. Additionally, participants in IG received the LIP, which was implemented by the researcher.

Follow-up data were collected at one-month (T1) and three-month (T2) after discharge by the same research nurse who was blinded with the group allocation. The fasting tests of FPG, TG, HDL-C, LDL-C, and TC were measured in the same health check center of the study hospital at T2. The other study outcomes were assessed at both T1 and T2.

2.6. Statistical analysis

The SPSS version 20.0 (IBM Crop. Armonk, NY) was used for data analysis. Descriptive statistics, including frequency and percentage, mean and SD, and median and interquartiles range, were used as appropriate. Inferential analyses of the Chi-squared tests, Fisher's exact test, and independent *t*-tests were used to compare participants' characteristics at baseline. Generalized estimating equation (GEE) model with the working matrix of first-order auto-regressive [AR (1)] was used to examine the effects of the LIP. To reduce the possibility of committing a Type II error, variables with a $p < 0.1$ in the baseline comparisons between groups were treated as covariates in adjusted GEE models [43,44]. A two-tailed significance level of 0.05 was used in the study.

3. Results

A total of 245 patients were assessed and 173 agreed to participate in the study, with 86 in IG and 87 in CG. Sixty-five (75.6%) participants in IG and 64 (73.6%) participants in CG completed the data collection at T1. At T2, 72 participants in the IG and 70 participants in CG completed the data collection. The overall attrition rate was 17.9%, with 16.3% and 19.5% in IG and CG, respectively. Fig. 1 shows the study flow of the study.

The mean age of all participants was 55.62 years old (SD = 10.65), with a range of 24 to 78 years. Among the participants, 85 (49.1%) were men and most (97.6%) were married. Sixty-three participants (36.4%) were retired, while 96 (55.5%) were employed. More than half of the participants (62.5%) had completed high school education or

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