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## Research Paper

# Effects of Macronutrient Distribution on Weight and Related Cardiometabolic Profile in Healthy Non-Obese Chinese: A 6-month, Randomized Controlled-Feeding Trial

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## ABSTRACT

**Background:** It has been suggested that the increase in carbohydrate at the expense of fat has contributed to the obesity epidemic in North America and some European countries. However, obesity rates in China have increased rapidly in parallel with a transition from the traditional low fat, high carbohydrate diet to a diet relatively high in fat and reduced in carbohydrate. Therefore, the current study aimed to determine whether the traditional Chinese diet was likely to be more effective than a diet with higher fat and lower carbohydrate – which is consumed in most Western societies, at weight control among a non-obese healthy population in China.

**Methods:** The 6-month, two-center, three-arm, randomized, parallel-group, controlled-feeding trial was conducted at People's Liberation Army General Hospital in north China and Zhejiang University in south China. We recruited healthy young adults (aged 18–35 years, body mass index <28) who lived in the university campus or the hospital dormitory during the whole study intervention period. They were required to eat only the foods provided, and to avoid excessive or unusual strenuous exercise during the trial. Participants were simultaneously enrolled and randomized using a computer-generated number (stratified by clinic center, age, sex, and body mass index) by data manager to one of the three isocaloric diets (1:1:1): a lower fat, higher carbohydrate diet (fat 20%, carbohydrate 66% energy); a moderate fat, moderate carbohydrate diet (fat 30%, carbohydrate 56% energy); a higher fat, lower carbohydrate diet (fat 40%, carbohydrate 46% energy). Protein provided 14% energy in all diets. We provided all food and beverages throughout the 6-month intervention. Laboratory personnel were masked to treatment allocation. Body weight was the primary outcome and measured each month. Data were primarily analyzed according to an intention-to-treat approach, supplemented with per-protocol analysis. The study was approved by the Ethics Committee at Zhejiang University. Each participant provided written informed consent. The study was registered at [ClinicalTrials.gov](http://ClinicalTrials.gov), number NCT02355795.

**Findings:** Between April 30, 2016, and October 30, 2016, 307 participants were randomly assigned to the lower fat diet (n = 101), the moderate fat diet (n = 105) and the higher fat diet (n = 101), and 245 (79.8%) participants completed the study. Reduction in body weight was significantly greater in the lower fat, higher carbohydrate group throughout the intervention (P < 0.001 for the interaction between diet group and time) than in the two other groups. Weight change at 6 months was –1.6 kg (95% CI –1.8 to –1.4) in the lower fat, higher carbohydrate group; –1.1 kg (95% CI –1.3 to –0.9) in the moderate fat, moderate carbohydrate group, and –0.9 kg (95% CI –1.1 to –0.6) in the higher fat, lower carbohydrate group. Reduction in waist circumference, total cholesterol, low-density lipoprotein cholesterol and non-high-density lipoprotein cholesterol on the lower fat, higher carbohydrate group were greater than those observed on the other two diet groups.

**Interpretation:** A lower fat, relatively higher carbohydrate diet, similar in macronutrient composition to that traditionally eaten in China appears to be less likely to promote excessive weight gain and be associated with a lower cardiometabolic risk profile than a diet more typical of that eaten in Western countries in healthy non-obese Chinese. Findings from studies in European and North American populations suggesting possible benefits of carbohydrate restriction may not apply to people of other ethnicities.

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## 1. Introduction

In the United States and many western countries, the prevalence of obesity and type 2 diabetes (T2D) has increased dramatically in parallel with a reduction in total fat and an increase in carbohydrate intake in the past several decades (Austin et al., 2011). This dietary change is considered by some to, at least in part, have contributed to the substantial increase in rates of obesity and T2D (Mozaffarian et al., 2011; Livesey et al., 2013; Te Morenga et al., 2013). Findings from several relatively short-term clinical trials and observational studies suggested that diets characterized by moderate restriction of carbohydrate, but relatively high in unsaturated fat improved blood lipid profile and lowered coronary heart disease (CHD) risk among individuals with high cardiometabolic risk (Jenkins et al., 2009; Halton et al., 2006). Some investigators have suggested that carbohydrate restriction rather than fat reduction should be recommended as the most appropriate nutritional approach to achieve overall reduction in obesity and cardiometabolic risk (Hu, 2010).

However, a very different situation prevails in China where over a similar period consequences of overnutrition have replaced those of malnutrition (Du et al., 2014; Zhai et al., 2014). Whereas some thirty years ago, rates of overweight and obesity were extremely low compared with the rest of the world, now nearly half the Chinese population is overweight and the majority are at high risk of cardiometabolic disease (Adair et al., 2014). Unlike the situation in the United States, from 1982 to 2011, energy intake from fat doubled from 18% to 32% (37% in Chinese megacities) and daily edible oil nearly tripled from 18 to 49 g (Jenkins et al., 2009; China NCD Report, 2011). Correspondingly, total daily energy from carbohydrate decreased significantly from 72% to 54% (47% in Chinese megacities) (Jenkins et al., 2009). Ecologic studies suggested that increased fat intake and corresponding reduction in carbohydrate might be an important contributing factor to increases in obesity and cardiometabolic disease (Campbell, 2004; Popkin et al., 1995). On the other hand, recent prospective cohort studies indicated that intake of carbohydrate, particularly white rice and highly processed wheat products are associated with increased CHD and T2D risk in Chinese adults (Yu et al., 2013; Villegas et al., 2007).

Given the different trends in fat and carbohydrate consumption in the Chinese population and populations in North America and Europe, despite a common trend towards increased rates of obesity and its comorbidities, we decided to conduct a randomized, controlled trial among our population to determine whether the traditional lower fat, higher carbohydrate diet or the western higher fat, lower carbohydrate diet is more effective at weight control and related cardiometabolic profile in modern Chinese.

## 2. Materials and Method

### 2.1. Study Design

This study was an observer-blinded, parallel, three-arm, randomized controlled-feeding trial conducted at People's Liberation Army General Hospital in north China and Zhejiang University in south China and was approved by the Ethics Committee at Zhejiang University. A summary of the protocol is available online ([https://www.researchgate.net/publication/317573056\\_Protocol\\_Optimal\\_Dietary\\_Macronutrients\\_Distribution\\_in\\_China\\_ODMDC\\_Trial](https://www.researchgate.net/publication/317573056_Protocol_Optimal_Dietary_Macronutrients_Distribution_in_China_ODMDC_Trial)). The trial is registered at [ClinicalTrials.gov](http://ClinicalTrials.gov), number NCT02355795.

### 2.2. Participants, Randomization and Masking

Recruitment began in January 25, 2015. Trial participants were healthy young adults and were recruited primarily using fliers and internet advertisements. Eligibility for the trial was determined from 3 screening visits and a 7-day run-in period (Table S1). Key inclusion criteria included overall good health, residence on the university

campus or hospital dormitory, age range between 18 and 35 years and body mass index (BMI) <28 according to the Chinese obesity criteria. Key exclusion criteria included blood pressure  $\geq 140$  mmHg systolic or 90 mmHg diastolic, total, LDL cholesterol  $\geq 6.19$  mmol/L and 4.12 mmol/L respectively, fasting triglyceride  $\geq 2.25$  mmol/L, fasting glucose  $\geq 6.11$  mmol/L, change in body weight exceeding 10% during the previous year and pre-existing chronic diseases. After the 3 screening visits, all volunteers participated in breakfast acceptability tests. They were provided with sample breakfast foods (lower fat bread, moderate fat cookies, higher fat cookies) identical to those which would be provided throughout the trial. After that, participants entered into a 7-day run-in period during which they were fed the moderate fat, moderate carbohydrate (MF-MC) diet.

Upon successful completion of run-in period, eligible participants were randomized (1:1:1) to either a lower fat, higher carbohydrate (LF-HC) diet, a MF-MC diet, or a higher fat, lower carbohydrate (HF-LC) diet, stratified by clinic center, age, sex, and BMI using a computer-generated random number list. Clinical staff and laboratory personnel who did the measurements were masked to group allocation. Meal providers were aware of participant diet assignment, but they were not involved in the rest of the trial, including later measurement and results analyses. Due to the obvious difference in the breakfast provided, blinding participants was not feasible, though they were not informed of the allocated treatment.

### 2.3. Procedures

The three diets were isocaloric, the primary distinguishing feature being their fat and carbohydrate content (Table 1). By replacing a proportion of energy derived from carbohydrates (white rice and wheat flour, the most consumed carbohydrate sources in China contributing to 70% and 17% total carbohydrate respectively) with fats (soybean oil, the most consumed edible oil in China rich in unsaturated fatty acids), we achieved the required distribution of fats and carbohydrates in the three diet groups, which represented macronutrient transition in the past 30 years in China. The LF-HC diet (fat 20%, carbohydrate 66% energy) corresponds to the macronutrient distribution 30 years ago during which obesity was rare in China; the MF-MC diet (fat 30%, carbohydrate 56%) is based on the current macronutrient intake in China and also the upper limit of fat intake recommended by the Chinese Nutrition Society and (Chinese Dietary Reference Intakes, 2014); and the HF-LC diet (fat 40%, carbohydrate 46%) approximates the current consumption of

**Table 1**

Nutrient targets and menu analysis of the 3 study diets.

Nutrients	LF-HC diet		MF-MC diet		HF-LC diet	
	Targets	Menu analysis <sup>a</sup>	Targets	Menu analysis <sup>a</sup>	Targets	Menu analysis <sup>a</sup>
Total energy (male), kcal <sup>b</sup>	2100	2094	2100	2096	2100	2103
Total energy (female), kcal <sup>b</sup>	1700	1697	1700	1698	1700	1704
Carbohydrate, %	66	66	56	55	46	46
Fat, %	20	20 (18)	30	31 (28)	40	40 (38)
Protein, %	14	14 (12)	14	14 (11)	14	14 (12)
Dietary fiber, g	14	14	14	13	14	14
Cholesterol, mg	300	289	300	289	300	289

LF-HC = lower fat, higher carbohydrate. MF-MC = moderate fat, moderate carbohydrate. HF-LC = higher fat, lower carbohydrate.

<sup>a</sup> Values were calculated using Nutrition System of Traditional Chinese Medicine Combining with Western Medicine, version 11.0 (Medical College, Qingdao University, Shandong, China). The nutrition system includes food composition data, permitting calculation of nutrient intake from the menus. Values in the parentheses are the results of chemical analyses of the menus prepared during the intervention period.

<sup>b</sup> Targets energy intake was determined from the 3-day dietary record at baseline.

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