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Randomized controlled trial of changes in dietary carbohydrate/fat ratio and simple *vs* complex carbohydrates on body weight and blood lipids: the CARMEN study

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OBJECTIVE: To investigate the long-term effects of changes in dietary carbohydrate/fat ratio and simple *vs* complex carbohydrates.
DESIGN: Randomized controlled multicentre trial (CARMEN), in which subjects were allocated for 6 months either to a seasonal control group (no intervention) or to one of three experimental groups: a control diet group (dietary intervention typical of the average national intake); a low-fat high simple carbohydrate group; or a low-fat high complex carbohydrate group.
SUBJECTS: Three hundred and ninety eight moderately obese adults.
MEASUREMENTS: The change in body weight was the primary outcome; changes in body composition and blood lipids were secondary outcomes.
RESULTS: Body weight loss in the low-fat high simple carbohydrate and low-fat high complex carbohydrate groups was 0.9 kg ($P < 0.05$) and 1.8 kg ($P < 0.001$), while the control diet and seasonal control groups gained weight (0.8 and 0.1 kg, NS). Fat mass changed by − 1.3 kg ($P < 0.01$), − 1.8 kg ($P < 0.001$) and + 0.6 kg (NS) in the low-fat high simple carbohydrate, low-fat high complex carbohydrate and control diet groups, respectively. Changes in blood lipids did not differ significantly between the dietary treatment groups.
CONCLUSION: Our findings suggest that reduction of fat intake results in a modest but significant reduction in body weight and body fatness. The concomitant increase in either simple or complex carbohydrates did not indicate significant differences in weight change. No adverse effects on blood lipids were observed. These findings underline the importance of this dietary change and its potential impact on the public health implications of obesity.
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Keywords: obesity; dietary carbohydrate/fat ratio; simple and complex carbohydrates; body weight; blood lipids; randomized controlled trial.

Introduction

The prevalence of overweight has risen dramatically over the past three decades and is threatening to become a global epidemic.[1] A substantial proportion of adults are at increased risk of morbidity and mortality as a result of increased body weight. As a consequence, total costs of obesity-associated diseases have been estimated to be 4–7% of all health care expenditures in several developed countries. Efforts to reduce the prevalence of obesity have focused on the fat content of the diet. High-fat diets are energy dense and usually lead to an increase in energy intake.[2] This, together with the prevalence of low levels of physical activity, means a positive energy balance and weight gain is inevitable. However, the scientific evidence for the relation between dietary fat content and obesity has recently been challenged. Katan *et al*[3] have questioned the importance of low-fat diets in the prevention and treatment of obesity. Randomized controlled trials show only very limited weight reduction and the so-called 'fat paradox' can be seen in several countries where there is a poor association between dietary fat intake and percentage of the population that is overweight. Also a direct relation between dietary fat and energy density has been questioned on the basis that many low-fat foods currently available are claimed to be based on sugar or highly refined carbohydrates, leading to energy density values similar to those of their high-fat counterparts.[4]

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In controlled feeding studies in which body weight was maintained, low-fat diets were commonly associated with decreases in HDL-cholesterol and increases in triacylglycerol.[5] Both are risk factors for coronary vascular disease. In contrast to these effects in well-controlled feeding studies, there is a body of evidence from dietary intervention studies conducted in free-living populations where low-fat diets are associated with improvement of lipid profile.[6] The interpretation of these findings is complicated by the lack of dietary control plus compliance in large-scale long-term, free-living population studies when compared with well-controlled, smaller and mainly short-term feeding studies. Moreover previous research on low-fat diets may be confounded by the type of carbohydrate, including fibre intake. In addition, the number of randomized well-controlled intervention trials which have focused on the carbohydrate/fat ratio of the diet in overweight individuals is very limited.

The Carbohydrate Ratio Management in European National diets (acronym CARMEN) trial was a multicentre, randomized *ad libitum* feeding trial that tested the effects of altering the ratio of fat to carbohydrate, as well as simple to complex carbohydrate *per se*, on body weight and blood lipids in overweight individuals. A shop system where study foods were provided was used in the trial to maximize dietary compliance in an otherwise community-based population.

Methods

Study population

Five European research centres participated in CARMEN. Each research centre was required to enrol 80 subjects (40 male, 40 female) to the study. Recruitment criteria were 20–55 y of age; body mass index (BMI) between 26 and 35 kg/m^2; and free of endocrine, liver, kidney or haematological disease assessed by medical history and clinical blood and urine biochemistry. Exclusion criteria were: alcoholic excess (>28 drinks weekly for men, >21 for women); high-intensity exercise for more than 7 h weekly; use of prescribed or slimming diets; weight loss of more than 5 kg in the preceding 6 months; pregnancy; and lactation. Ethical committees at each centre approved the trial protocol; subjects signed an informed-consent form.

Study design

Subjects were randomly allocated on a 1–3 basis to either a seasonal control group or to an experimental group. The groups were stratified by age, sex and BMI. Subjects in the seasonal control group were weighed before and after the study and served only as a control for seasonal variation in body weight. During a 5 week run-in period, subjects in the experimental group were provided with a selection of commercially available food products, of typical macronutrient composition for each country, using a validated laboratory shop system.[7] After the run-in period, subjects were randomly assigned to one of the three experimental groups, stratified by age, sex, tertile of simple to complex carbohydrate and fat intake, as measured during the last week of the run-in. Throughout the intervention period of 6 months, subjects in the control diet group continued to be provided with a variety of products of typical macronutrient content. Subjects in the low-fat high simple carbohydrate group and the low-fat high complex carbohydrate group were provided with a variety of fat-reduced products and products with a high respectively low ratio of simple to complex carbohydrates, in order to reduce fat intake by 10 energy% and, at the same time, to increase either simple or complex carbohydrate intake from a ratio of 1.0 to 1.5 and 0.5, respectively.

Laboratory shop system

In each research centre a small shop was installed to provide subjects with a known and recorded choice of 100–150 food items. Selection of food products was based on the manufacturer's food composition, national food composition tables and food intake data, and was intended to achieve 70% coverage of total fat intake and 50% of total carbohydrate intake from the shop. A computer program was developed which ensured selection of the appropriate food items by means of a barcode scanner system. Intake was required to be between 75 and 125% of predicted daily energy requirements, based on predicted basal metabolic rate[8] and physical activity level as determined using an activity questionnaire.[9] As a number of products (eg bread, fresh fruit, fresh vegetables and fresh meat) were not provided by the laboratory shop, subjects were allowed to purchase additional foods in conventional supermarkets.

Subjects who did not attend the laboratory shop for more than 2 weeks without prior notice were excluded as non-compliers. During holiday absence (maximum 2 weeks) subjects were given instructions on the selection of a diet. Subjects with an absence or illness greater than two weeks were excluded.

Measurements

Total food intake, ie consumption of food items provided via the laboratory shop and consumption of food items bought in conventional supermarkets, was recorded at base-line, at the end of the run-in period, and after 1, 2, 4 and 6 month(s) of intervention, using 3-day or 7-day weighed dietary records. Energy and macronutrient intakes were calculated using computerized national food composition tables.