

Effectiveness of a lifestyle modification programme in weight maintenance in obese subjects after cessation of treatment with Orlistat

Jean Woo MD,¹ Mandy M. M. Sea PhD,² Peter Tong PhD,³ Gary T. C. Ko MB,⁴ Zoe Lee PhD,⁵ Juliana Chan MD,⁶ and Francis C. C. Chow MB⁷

¹Professor, ²Manager, ³Associate Professor, ⁴Senior Medical Officer, ⁵Research Assistant, ⁶Professor, ⁷Consultant Physician, Department of Medicine and Therapeutics, The Chinese University of Hong Kong, Hong Kong, China

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Correspondence

Professor Jean Woo
Department of Medicine and Therapeutics
Prince of Wales Hospital
Shatin, N.T.
Hong Kong
China
E-mail: jeanwoowong@cuhk.edu.hk

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Abstract

Objective To examine the efficacy of a lifestyle modification programme in weight maintenance for obese subjects after cessation of treatment with Orlistat.

Methods Fifty-five subjects with and without diabetes mellitus were randomized to a lifestyle modification programme or to usual care at the end of 6 months' treatment with Orlistat. The intervention programme was nutritionist led, consisting of components of dietary management, physical activity, peer group support and discussion using techniques of self-monitoring, stimulus control and cognitive restructuring. Anthropometric indices, body composition, basal metabolic rate, blood pressure, fasting glucose, glycosylated haemoglobin, lipid profile, 24-hour urinary albumin excretion, dietary intake, physical activity level, and quality of life were assessed before and after the intervention period.

Results Subjects in the intervention group maintained their weight loss and favourable anthropometric, metabolic, dietary intake, physical activity and quality of life profiles, while most parameters deteriorated in the usual care group, being more marked in subjects with diabetes. The magnitude of weight gain was comparable to that lost during Orlistat treatment.

Conclusion A specially designed nutritionist-led lifestyle modification programme for obese subjects is effective in weight maintenance after treatment with Orlistat, in the absence of which the benefits of drug treatment were lost. The magnitude of the effect of lifestyle modification is comparable to that observed with Orlistat.

Introduction

The problem of obesity, with its burden of associated diseases, has reached epidemic proportions, such that the World Health Organization declared that it should be considered a disease [1]. It has been estimated that between 3% and 7% of total health care costs can be attributed to overweight and obesity [2]. While prevention is clearly important, effective management of those with obesity continues to be a public health challenge. Management options consist of lifestyle modification in terms of diet and physical activity, pharmacological methods, and surgery for the morbidly obese. Crucial to the success of most programmes is the inclusion of a component of behavioural modification, in improving compliance with therapy and ultimately maintenance of ideal body weight [3]. Although pharmacological treatment has been shown

to be effective in randomized controlled trials, the extent of weight reduction is less if there is no concomitant dietary modification or behavioural support [4]. Moreover, weight is frequently regained after cessation of drug therapy [5]. In view of the fact that obesity is not generally recognized as a disease by those affected, long-term pharmacotherapy may not be complied with unlike the situation with diabetes or hypertension. Therefore, it is possible that the major management strategy consists of behavioural modification, rather than a medical model of management involving drug prescription.

There are a variety of ways to achieve the former, varying from multidisciplinary teams consisting of dietitians, exercise instructors, psychologists, to multi-skilled individuals trained in the above areas. Achievement of results would depend on the design and content of the programme, and for the adoption into everyday

practice, the programme should be easily integrated within existing health services of countries. In this study, we examine the efficacy of such a programme designed for obese Hong Kong Chinese subjects, who had completed a 6-month treatment with Orlistat alone without any concomitant lifestyle modification, where Orlistat was discontinued and the subjects were randomized to participate in the programme and the other half to no further intervention. The magnitude of changes in outcomes measure was also compared with that achieved during therapy with Orlistat, indirectly providing an observation regarding the comparative efficacy of behavioural modification versus pharmacological therapy.

Subjects and method

Subjects

Sixty obese subjects aged between 18 and 50 years recruited from the outpatient clinic of a general district hospital with or without type 2 diabetes mellitus (DM), underwent a 6-month treatment with Orlistat (120 mg three times a day) to examine the effects on weight loss, cardiovascular risk factors, body composition, basal metabolic rate (BMR), dietary intake, physical activity level and quality of life. The Asian criteria of obesity [body mass index (BMI) $\geq 25 \text{ kg m}^{-2}$] was used [6]. These subjects received usual treatment provided by existing health services with respect to lifestyle modification, consisting predominantly of referral to dietitian for general advice. No lifestyle intervention was provided such as a hypocaloric diet to accompany Orlistat treatment. The results of this study had been reported elsewhere [7]. At the end of this period, subjects were randomized into two groups, with and without the lifestyle modification programme, for another 6 months. Five subjects declined to participate further at the end of the 6 months, leaving 55 subjects for randomization. Twenty-seven subjects (15 with DM) were randomized to the intervention group with monthly follow-up, and 28 (15 with DM) were randomized to the non-intervention group, and followed up three monthly (Fig. 1). The study was approved by the Clinical Research Ethics Committee of the Chinese University of Hong Kong. All subjects had given written informed consent.

Method

Interventions were held in groups for 6 months, and each group consisted of 5 subjects and one nutrition educator. The strategies consist of dietary management, physical activity and exercise management and peer group support. The content of the dietary management consisted of education regarding dietary knowledge such as a balanced diet, interpretation of food labels, food exchanges [8], healthy eating out techniques and healthy cooking methods. Moreover, the subjects were given an individualized tailored eucaloric menu plan which was calculated by the measured BMR at the end of Orlistat treatment, multiplied by 1.4 to estimate the total daily energy expenditure [9]. The composition of the diet plan was nutritionally balanced with 25% of energy as fat, 55% of energy as carbohydrate, 20% as protein, a maximum of 300 mg of cholesterol and 2400 mg of sodium per day. Alcohol consumption was limited to no more than 150 g of alcohol per week. The diet was divided into three main meals with a low-

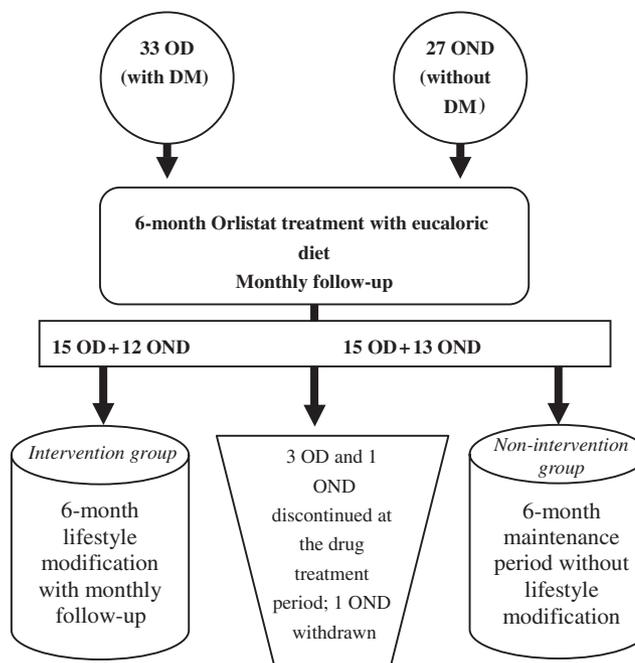


Figure 1 Study design. OD, obese diabetics; OND, obese non-diabetics; DM, type 2 diabetes mellitus.

calorie snack if desired. Subjects were required to hand in a daily food diary for every visit.

Apart from the diet regimen, during each monthly visit, the benefits of doing exercise were emphasized. Subjects were encouraged to do 30 minutes aerobic exercise two to three times a week. In addition, they were asked to walk at least 10 thousands steps every day and were given a pedometer (Digi-Walker TM, SW-700, Yamax, Japan) to record the steps they walked. Subjects were also asked to keep a daily activity log, which was checked during each visit.

Through peer group support and discussion during each visit, healthy lifestyle was introduced and reinforced, to be integrated into their daily life. Techniques used include self-monitoring, stimulus control and cognitive restructuring [10].

Measurements

At the beginning and end of the weight maintenance period, anthropometric indices including body weight, waist and hip circumferences, body composition, based metabolic rate, glycated hemoglobin (HbA_{1c}), fasting plasma total cholesterol, high-density-lipoprotein cholesterol (HDL-C), triglyceride and calculated low-density-lipoprotein cholesterol (LDL-C), 24-hour urinary albumin excretion were measured. Dietary intake, physical activity level, quality of life as well as self-image were also assessed.

Body weight, waist and hip circumferences were measured in subjects wearing light clothing and without shoes to the nearest 0.1 kg and height to the nearest 0.5 cm. BMI was calculated as the weight in kilogram divided by the square of the height in metres.

Plasma glucose was measured by a glucose oxidase method (Diagnostic Chemicals Ltd reagent kit, Oxford, CT, USA). HbA_{1c} was measured by an automated ion-exchange chromatographic

method (Bio-Rad Laboratory, Hercules, CA, USA. Normal range 5.1–6.4%). Total cholesterol and triglyceride were measured in plasma, enzymatically with commercial reagents (Dimension, Dupont Instrument, Indianapolis, IN, USA). HDL-C was measured by the same enzymatic assay after precipitation of the HDL-C by the heparin-manganese methods [coefficient of variation (CV) = 1.5%]. LDL-C was calculated using the Friedewald's equation (CV = 2.3%) [11].

Body composition was measured by the dual-energy X-ray absorptiometry (QDR 4500 A Hologic, Waltham, MA, USA) (CV = 3.4%). BMR and respiratory quotient (an index of the ratio of carbohydrate to fat oxidation) were measured by indirect calorimeter (Deltatrac, TM Datex, Helsinki, Finland) using a computerized flow-through, canopy-gas analyser system, which was calibrated with the precision gas mixture before each measurement. Signals from the gas analysers were processed by the computer and oxygen consumption (VO₂), carbon dioxide production (VCO₂) and respiratory quotient were calculated once a minute for 25 min. For each set of data, the first 5 min were discarded and the mean value of the data for the remaining 20-min was used for calculations (CV = 3.2%). Total energy expenditure was then calculated by multiplying the measured BMR with 1.4 [9].

Dietary intake over a 1-week period of all subjects was assessed by using a local food frequency questionnaire, which has been validated elsewhere [12]. On the basis of the previous local dietary surveys, the food items chosen in the questionnaire were those most frequently consumed [13]. Before the interview, subjects were advised to make a brief record at home in advance. Each subject was then asked to complete the questionnaire including the food items, the size of each portion, the frequency of consumption on a daily and weekly basis. During the interview, portion size was explained to subjects by using food replica, food containers, and a catalogue of pictures of individual food portions. Data were scrutinized by the dietary pattern (for example, if meals were missed) to determine the number of times staple foods such as rice or noodles consumed over a 1-week period. The amount of cooking oil was estimated according to the 1995 Hong Kong Adult Dietary Survey [14]. The type of oil used was also recorded to estimate the quality of fat in the diet. Quantifications of nutrients were achieved by multiplying each food item's frequency of consumption by the portion size consumed, and the nutrient content of the food. The nutrient content was determined from food tables for Hong Kong, which were compiled from McCance and Widdowson [15], and two food tables used in China, as published by the Institute of Health, Chinese Medical Science Institute [16] and Zhongshan University [17]. Apart from this, the macronutrient contents were also validated by chemical analysis (unpublished data).

Physical activity level was assessed by a validated questionnaire [18], in which, the subjects reported the duration and frequency of each physical activity such as sleeping, walking and running, etc. over 1 week. Energy expended by these activities was calculated by multiplying with the metabolic equivalent (MET) of each activity and body weight of the subject. The higher the energy expended indicates the higher physical activity level.

Quality of life and obesity-related well-being were assessed by the SF-36 (Chinese) questionnaire [19] and ORWELL 97 [20] respectively. For the SF-36, higher scores indicate better quality of life of the subject, while higher Orwell score indicates lower obesity-related well-being.

Statistical analysis

Statistical analysis was performed using the Statistical Program for Social Sciences (SPSS, version 10.0). Unpaired *t* was used for between-group comparison in mean change in values between baseline and 6 months, between intervention and non-intervention groups and between diabetic and non-diabetic groups. Paired Student's *t*-test was used to compare baseline values for intervention and non-intervention groups, with values before treatment with Orlistat.

Results

At baseline, there was no statistical significant difference between intervention and non-intervention groups in any measured parameter regardless of glucose tolerance status, although body weight, BMI, waist-hip ratio, % body fat, metabolic profile, blood pressure, urinary albumin excretion, dietary carbohydrate and protein intake, and quality of life were all more favourable compared with values before the treatment with Orlistat (Table 1). After 6 months, for all subjects in the group without further intervention, there was a significant increase in weight, BMI, waist and hip circumferences, and percentage body fat (Table 2). The magnitude of increase was comparable to the magnitude of the reduction obtained during the previous Orlistat treatment (Table 2). In contrast, subjects in the intervention group maintained their previous loss in weight, waist and hip circumferences. No difference between diabetic and non-diabetic subjects was observed.

Similarly, the metabolic profile deteriorated in the non-intervention group, with increase in fasting glucose, triglycerides, total and LDL-C. There was no difference between diabetic and non-diabetic subjects, with the exception of fasting glucose and HbA_{1c}, where deterioration occurred only in subjects with diabetes.

Daily total calorie, carbohydrate and fat intake increased in the non-intervention group compared with a decrease in the intervention group. The magnitude of increase in calorie intake was much greater than the decrease observed during the period in Orlistat, although the magnitude of increase in fat intake was less than the reduction achieved with Orlistat. Fibre intake increased in both groups with the increase in the intervention group being greater than non-intervention group. Physical activity increased in the intervention group, but decreased in the non-intervention group. The quality of life (SF36) score significantly decreased in the non-intervention group for diabetic subjects, compared with subjects in the intervention group, while no significant difference in change in the Orwell Score between the two groups was observed.

Discussion

In the management of obesity, pharmacological and lifestyle modification strategies are usually used in combination. However, there is a tendency for subjects to rely on drugs, with less emphasis placed on lifestyle modification, as there are less barriers to taking pills compared with changing lifestyle. While weight loss will be achieved by pharmacological methods, even in the absence of significant lifestyle changes [7], the important goal is the achievement of weight maintenance. Thus, the US National Institute of Health clinical guidelines on treatment of obesity emphasize that lost weight will usually be regained unless a weight maintenance

Table 2 Comparison of magnitude of change between intervention and non-intervention groups

	Intervention			Non-intervention			Changes observed with Orlistat		
	All (n = 27)	DM (n = 15)	Non-DM (n = 12)	All (n = 28)	DM (n = 15)	Non-DM (n = 13)	All (n = 56)	DM (n = 30)	Non-DM (n = 26)
Anthropometry									
Weight (%)	-0.15 ± 0.35	-0.12 ± 0.55	-0.17 ± 0.47	3.3 ± 0.74***	3.9 ± 0.94***	2.5 ± 0.32***	-4.2 ± 1.8	-3.3 ± 1.7	-4.9 ± 2.1
Body-mass index (%)	-0.15 ± 0.14	-0.12 ± 0.2	-0.17 ± 0.18	3.2 ± 0.27***	3.9 ± 0.47***	2.5 ± 0.21***	-4.1 ± 1.9	-3.3 ± 1.6	-4.9 ± 2.1
Waist circumference (%)	0.19 ± 0.23	-0.12 ± 0.33	0.7 ± 0.5	3.0 ± 0.73***	3.9 ± 0.23***	2.0 ± 0.12***	-4.5 ± 2.4	-3.6 ± 1.4	-5.1 ± 2.3
Hip circumference (%)	0.17 ± 0.22	0.19 ± 0.17	-0.14 ± 0.21	3.0 ± 0.91***	3.8 ± 0.17***	2.1 ± 0.13***	-2.7 ± 1.2	-1.6 ± 0.8	-3.6 ± 1.5
Waist to hip ratio (%)	0.05 ± 0.07	-0.03 ± 0.03	0.87 ± 0.72	0.05 ± 0.08	0.1 ± 0.03	-0.07 ± 0.1	-1.5 ± 0.7	-2.1 ± 0.9	-1.2 ± 0.5
DEXA-assessed body fat (%)	0.19 ± 0.15	0.81 ± 0.45	-0.65 ± 0.43	4.4 ± 0.94***	4.71 ± 1.04***	4.0 ± 0.32***	-4.5 ± 3.1	-4.4 ± 3.1	-4.8 ± 3.2
DEXA-assessed lean mass (%)	0.88 ± 0.44	0.02 ± 0.2	1.91 ± 0.38	1.27 ± 0.37	1.52 ± 0.87	0.79 ± 0.41	-0.5 ± 1.5	0.7 ± 0.5	-1.8 ± 0.7
Metabolic profiles									
Fasting glucose(%)	9.2 ± 10.3	11.3 ± 11.2	4.8 ± 12.1	25.9 ± 12.8***	45.2 ± 18.7***	3.5 ± 3.2	-11.8 ± 10.2	-18.2 ± 9.8	-5.0 ± 2.3
HBA _{1c} (%)	0.02 ± 0.04	5.0 ± 2.8	-6.9 ± 3.8	7.2 ± 6.3	15.6 ± 3.5***	-4.1 ± 2.4	-8.2 ± 7.0	-11.6 ± 5.7	-3.6 ± 2.2
Total cholesterol (%)	6.5 ± 3.5	5.7 ± 2.2	5.6 ± 3.2	9.7 ± 3.3***	9.2 ± 2.7***	10.3 ± 2.7***	-9.4 ± 4.4	-9.4 ± 5.4	-9.5 ± 3.7
LDL-C (%)	9.7 ± 4.7	3.2 ± 2.1	14.9 ± 4.7	10.9 ± 3.7	8.2 ± 1.9	12.5 ± 3.3	-11.9 ± 6.3	-9.9 ± 5.3	-13.5 ± 5.4
HDL-C (%)	7.4 ± 5.3	6.6 ± 3.9	7.1 ± 2.2	0.9 ± 1.1	0.81 ± 0.7	0.67 ± 0.7	-0.1 ± 0.5	-0.7 ± 0.3	+0.4 ± 0.2
Triglycerides (%)	-3.9 ± 2.7	4.3 ± 2.4	-13.9 ± 2.9	19.3 ± 7.9***	18.2 ± 4.7***	20.4 ± 4.7***	-11.2 ± 10.2	-1.6 ± 1.1	-19.7 ± 8.7
24-h UAE (%)	2.2 ± 1.3	2.1 ± 0.9	1.7 ± 1.1	7.9 ± 2.1*	9.8 ± 2.7**	4.0 ± 1.1*	-4.5 ± 1.7	-3.1 ± 1.0	-6.7 ± 2.1
Daily nutrients intake									
Total calorie intake (kcal)	-197 ± 98	-152 ± 97	-243 ± 121	103 ± 78**	77 ± 54*	130 ± 75*	-27.5 ± 30.7	-21.7 ± 38.4	-30.0 ± 31.3
Carbo-hydrate (g)	-17.3 ± 8.5	-20.5 ± 7.8	-15.7 ± 7.4	7.9 ± 3.7**	3.7 ± 1.0**	9.2 ± 2.2**	48.2 ± 17.4	45.1 ± 18.7	50.8 ± 19.3
Protein (g)	5.2 ± 3.7	4.7 ± 2.1	5.9 ± 3.1	7.2 ± 3.7	4.0 ± 0.9	3.7 ± 1.2	2.7 ± 3.0	2.2 ± 2.9	3.3 ± 3.4
Fat (g)	-9.3 ± 5.2	-7.7 ± 3.2	-10.7 ± 5.7	5.5 ± 2.3*	5.1 ± 1.1*	7.0 ± 1.9**	-21.8 ± 8.9	-20.9 ± 9.7	-23.8 ± 7.4
Fibre (g)	4.7 ± 2.2	5.0 ± 2.2	4.2 ± 2.7	1.2 ± 0.7*	1.1 ± 0.5*	1.5 ± 0.8	1.4 ± 1.5	1.2 ± 1.7	1.5 ± 1.3
Daily energy balance									
BMR (kcal)	-14.4 ± 155.4	-20.6 ± 178.2	-8.7 ± 137.5	24.8 ± 157.8	60.9 ± 180.2	-11.2 ± 28.2	11.5 ± 204.3	-141.6 ± 31.2	155.6 ± 30.2
BMR/kg body weight (kcal/kg)	-1.0 ± 0.4	-1.3 ± 1.8	-0.6 ± 1.8	-1.1 ± 0.4	-0.6 ± 0.5	-1.6 ± 0.4	-0.1 ± 1.1	-1.0 ± 0.7	0.8 ± 0.3
Physical activity (kcal)	209 ± 112	179 ± 98	233 ± 137	-193 ± 123*	-173 ± 102*	-212 ± 137*	175.4 ± 104.3	120.4 ± 89.7	233.2 ± 127.1
Quality of life									
SF-36	48.7 ± 20.1	43.9 ± 19.2	55.2 ± 23.4	30.1 ± 14.2	-2.3 ± 3.2*	34.1 ± 12.9	37.8 ± 22.4	49.7 ± 25.9	25.2 ± 10.5
ORWELL	-0.3 ± 2.1	8.7 ± 2.7	0.4 ± 0.9	-0.9 ± 0.7	10.3 ± 5.3	9.3 ± 3.7	-7.5 ± 4.3	-7.9 ± 5.9	-7.3 ± 4.8

* $P < 0.05$; ** $P < 0.01$; *** $P < 0.001$ using unpaired test for between-group comparison (intervention vs non-intervention).

DEXA, dual energy X-ray absorptiometry; DM, type 2 diabetes mellitus; UAE, urinary albumin excretion; HDL-C, high-density-lipoprotein cholesterol; BMR, Basal metabolic rate.

programme consisting of diet therapy, physical activity and behaviour therapy is continued indefinitely [21]. Therefore, in combatting the epidemic of obesity, development of an effective lifestyle modification programme that can be integrated into existing health services would be an important public health strategy.

Various methods may be used in changing lifestyle, from advice given by doctors, nurses, dietitians or multidisciplinary professionals, individually or in groups. Those given by usual primary care providers appear not to be very effective. Thus Ashley *et al.* [22] observed that weight management provided by family doctors was not as effective compared with dietitians. Training of primary care teams in providing such service had no effect on patients [23]. This is not surprising as lifestyle change essentially involves behavioural change, so that programmes should contain effective strategies for behavioural change similar to that used for smoking cessation programmes rather than just provision of information in a prescriptive way [24]. Examples of programmes resulting in lifestyle changes consist of use of membership-based health centres or clubs rather than conventional doctors' surgeries [25], multicomponent intervention using motivational interviewing based on social cognitive theories [26], use of patient-held records [27], group therapy [28], and dietitian-led lifestyle case management [29]. Apart from weight maintenance, beneficial effects on blood pressure [30] and prevention on onset of DM [31] have been observed. Our study describes a nutritionist-led multicomponent group intervention, which was effective in maintaining weight loss and improvement in metabolic and cardiovascular risk factor profile after cessation of Orlistat. In the absence of such a programme, the improvements achieved with Orlistat were entirely lost, together with a deterioration in generic quality of life measures. Therefore, lifestyle modification may produce health benefits equivalent to pharmacological methods.

It is uncertain which is the key component in the programme that is effective in changing lifestyle. Further studies into the relative contribution of peer pressure, personality of the group leader, skills in motivational interviewing, frequency of meeting, and programme content would be of interest. Currently such a programme could be incorporated into the community primary care or social centres run by the government or non-government organizations, as well as in the private health care sector.

There are limitations to the study. The number of subjects is small, and the duration of the intervention programme was only 6 months. It is unknown whether subjects will be motivated enough to continue the programme for longer periods. Ideally subjects should maintain their goals with little input from intervention programmes after a period, perhaps maintained with group meetings at intervals, for example, weight-watchers. The duration of follow-up was not sufficiently long to provide information on this aspect. Furthermore, all subjects were obese, and presumably had stronger motivation to comply with the programme and modify their lifestyle. Overweight subjects may not have such a strong motivation. It is possible that there may be gender differences in response, on which we are unable to comment owing to the small numbers. The goals in weight maintenance may be different between genders, physical appearance being more important than health concerns in women compared with men. As response is likely associated with motivation, it is possible that different strategies may need to be devised for men and women.

Conclusion

In spite of these limitations, this study demonstrates that the lifestyle modification programme described is effective in weight maintenance, the magnitude of effect being comparable to that observed with Orlistat. Such a structured programme may be incorporated into existing health services in response to the increasing public health problem of obesity and related diseases.

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