RESEARCH COMMUNICATION

A Model Obesity Control Program Focusing on a Healthy Diet and Gentle Exercise in Aichi Cancer Center Hospital

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Abstract

With the change of nutrient intake after the Second World War, obesity is becoming one of the most serious health problems in Japan. From a practical viewpoint for prevention of lifestyle related diseases, we planned an intervention trial of weight control for obese women. After obtaining informed consent, we recruited patients over 30 years old with a BMI of 24 or more for the present program. Forty patients were randomly assigned into study groups A (28) and B (12). Group A started the prevention program at the entry and group B started three months thereafter, according to the protocol. This trial was designed to evaluate effectiveness of intervention trial during the first 3 months by comparing values with those for the non- intervention subjects. At the baseline and after three and six months, participants were checked for body size, dietary intake and serum chemistry. They were stressed to make a record not only of food intake but also physical activity over the 3 months. Every weekend they returned their record diaries by mail and we provided appropriate comments by telephone and/or mail after reviewing them.

After follow up for 3 months, we observed significant improvement in BMI, waist and hip size. There was a 4.2 % decrease of initial body weight on average after intervention but a 0.3 % increase in the group without intervention, the difference between the two groups being statistically significant. With regard to change in key biomarkers in group A, decreased serum triglycerides appeared related to the reduction of BMI, but no link was apparent for total cholesterol.

Key Words: Intervention trial - obesity control - serum triglycerides

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Introduction

In Japan, Westernization of the lifestyle has progressed rapidly after the Second World War. The included remarkable change in dietary habits may be associated with the current anthropometric characteristics and chronological variation in cancer mortality (Tominaga, 1987; Kato et al., 1987). With the change of nutrient intake, obesity is becoming one of the most serious health problems in Japan. Morbidity has increased because of obesity-linked diabetes, coronary heart disease, and hypertension. Clinical trial studies have suggested that sustained weight loss can reduce or eliminate these obesity-related disorders (Chan et al., 1994; Colditz et al., 1995; Blackburn, 1995; Goldstein, 1992). It is possible to control obesity by lifestyle change, that is, by promoting gentle exercise and a healthy diet.

Breast cancer is the third most common cancer in the world and its incidence rate is highest in North America and Northern Europe, intermediate in Southern Europe and South America, and lowest in Asia and Africa. The incidence rate is more than 5 times higher in the US than in Asian countries. In Japan, the mortality rate from female breast cancer began to increase around 1965 and the trend for rise has become remarkable in recent years. The estimated number of new patients with breast cancer in 1995 was about 30,000, accounting for 15% of all neoplasms. Estimations of future cancer mortality and incidence predict that breast cancer will further increase to become a leading cancer in Japan in the 21st century. Therefore it is important to elucidate the risk factors for breast cancer and undertake primary prevention measures.

A number of risk factors for breast cancer have in fact

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been established, most related to reproductive events (Kelsey et al., 1993). Risk of breast cancer is increased by early menarche, nulliparity, late age at first childbirth and late natural menopause. A family history of breast cancer is associated with an overall risk increment of around two fold. Furthermore, an elevated Body Mass Index (BMI) increases the risk of breast cancer after menopause and extensive studies in western countries on positive correlations between breast cancer and BMI among post-menopausal women have generated positive findings (Le Marchand et al, 1988). A case-referent study using hospital-based epidemiologic research program at Aichi Cancer Center (HERPACC) data provided clear evidence that the risk of breast cancer in postmenopausal Japanese women is markedly increased by obesity (Hirose et al., 1999). From a practical viewpoint for primary breast cancer prevention, obesity is thus one of the most important targets. Therefore, we planned an intervention trial for obese women in Aichi Cancer Center Hospital.

Subjects and Methods

Study design

The study subjects were divided into two groups A & B. Group A was started on the program protocol at the entry, undergoing intensive intervention for the first three months, followed by a 3 month self-control period. Group B was recruited as a reference group, for which no education was given during the first 3 months, as a waiting period, but was then performed during the second 3 month period. This trial was designed to evaluate the effect of the intervention over the first 3 months by comparing groups A and B. Patients were measured for body weight, body fat, waist and hip size. Dietary intake was assessed using a validated semi-quantitative food frequency questionnaire (SQFFQ) (Tokudome et al., 1998; Tokudome et al., 2001; Imaeda et al., 2002) with a detailed dietary history of their usual diet one month prior to entry. A list of food items (119 items) regularly consumed was prepared and nutrient intakes were computed from the 24-hour diet.

At the baseline and 3 and 6 months thereafter, participants were checked for body size and dietary intake by SQFFQ. Simultaneously, blood samples were taken from all participants. Since reduction of body weight is also associated with improvement in several biomarkers, serum triglycerides, total cholesterol and HDL cholesterol were also measured.

Subjects

The study subjects were patients referred to the Department of Breast Surgery in Aichi Cancer Center Hospital. Women aged more than 30 years old with BMI more than 24 were recruited. They were randomly assigned into two study groups after providing informed consent. Allocation was made by asking subjects to pull a ball out of a box containing 10 red and 10 white balls (the first 20 to pick the former were allocated to group A (intervention group) and the remainder to group B (delayed-intervention). The total number of subjects recruited for our study was 40.

Dietary intervention

At the initial counsel, participants were instructed on selection of preferable foods, meal portion control, and recording of daily dietary intake. The primary investigator (K.H.) explained the diet plan in detail, counseled participants by using a model of recommendable menus and recipes and instructed them to maintain a food diary. They were prescribed a balanced diet providing 1,600 Kcal per day and recommended to control less than 25 percent of energy as fat. Although it might be argued that high fat diets increase the risk of breast cancer in western countries, dietary fat may play a role in the development of breast cancer in Japan. Since the contribution of fat intake to the total energy intake is remarkable, the investigator stressed the reduction of fat intake.

Recommendation for moderate exercise

The participants were explained that physical exercise is essential for healthy weight control and encouraged to undertake at least 30 minutes gentle exercise twice a week. The investigator gave instructions for an effective walking method by pamphlet and educational videotape. They were handed a pedometer and advised to walk at least 10,000 steps per day.

Data collection and statistics

We handed the weekly diary prepared for this intervention trial to the subjects and they were stressed to maintain accurate daily recording during the intervention period. The check points in this diary were 1) body size; 2) daily food intake and 3) physical activity, as shown in Table 1. Every weekend they returned the weekly diaries by mail. When the records were reviewed with each subject, they were given comments or instructions individually by telephone and/or mail. At each visit of 3 and 6 months,

Table 1. The Check Points in the Diary during the Intervention Period

1)	Body size The subjects measured their body weight at regular time of the day and made a graph of the body weight change.
2)	Daily food intake The subjects recorded the eating time, required time for eating and place (house or restaurant) of three meals (breakfast, lunch and dinner) and snack. They reported their daily food intake to the nearest volume or number of items.
3)	Physical activity The subjects recorded the type, frequency and duration of physical activities undertaken throughout the day.

anthropometric data were recorded from all subjects. Body fat (%) was measured using Model TBF-310 (Tanita Ltd, Tokyo, Japan). Weight measurements to the nearest 0.1 kg were taken by using the same model. Waist and hip circumferences were measured to the nearest 0.5 cm by using a nonstretchable tape measure. Waist circumference was measured midway between the lower rib margin and the iliac crest; hip circumference was measured at the widest point of the trochanter and buttocks area. The waist-to-hip circumference ratio was calculated. Biochemical measurements were conducted by standard methods in the Aichi Cancer Center Hospital.

Comparisons of values between the 2 groups were made using a two-sample t test. A paired t test was also employed to test whether there were significant changes from baseline to 3 months for each group. Values are given as mean ± Standard Deviations (SDs) in Table 2, and as mean ± Standard Errors (SEs) in Tables 3 and 4.

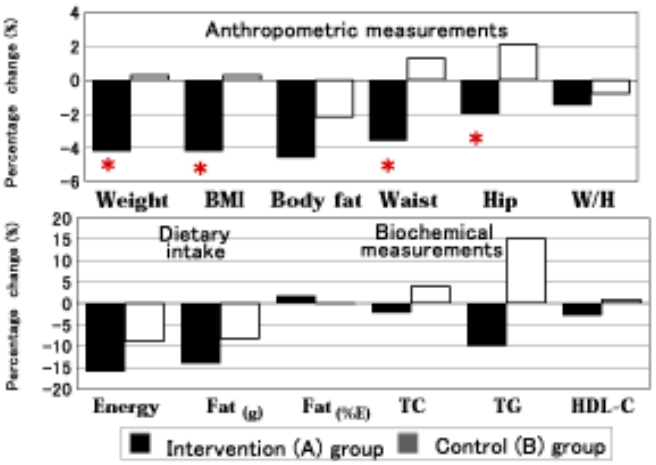

Figure 1. Comparison of the Change between Group A and B during First 3 Months.

Results

Twenty-eight patients were randomly assigned to group A (intervention group) and 12 patients to group B (control group). Baseline characteristics of subjects enrolled in the study are given in Table 2. There were no significant differences between the 2 groups in age, body size and biochemical parameters, with the exception of serum total cholesterol.

During the 6 months, patient attrition occurred and at the end of this period 5 had dropped out. Those in group A withdrew because of clinical events (n=2), domestic events or unknown reasons (n=3). Four patients in group B did not complete the 3 months - education program.

Body size change

All outcomes of the patients remaining at each milestone measurement are reported in Table 3. To assess the effect of this program protocol, we compared changes in body weight, body mass index, waist and hip size between groups A and B after the first 3 months. In group A, they lost 2.7 ± 0.5 kg, whereas in group B, they gained 0.2 ± 0.1 kg. The between-group difference was statistically significant. Weight-loss data were analyzed as a percentage of initial body weight on an available case basis. After 3 months, there was a 4.2 % decrease in group A and a 0.3 % increase in group B. This difference between groups was also statistically significant.

Table 2. Characteristics of Subjects Enrolled in the Study

	Group A (n = 23)	Group B (n = 12)
Age (yr)	55.8 ± 7.5	54.0 ± 7.9
Diet		
Energy (kcal)	2,014 ± 497	1,908 ±473
Fat intake (g)	63.9 ± 22.3	58.7 ± 23.2
Fat (%E)	28.2 ± 4.2	27.3 ± 5.4
Body size		
Height (cm)	155.3± 5.1	158.4 ± 3.1
Weight (kg)	65.7 ± 6.4	66.2 ± 5.9
BMI (kg/m^2)	27.2 ± 2.1	26.3 ± 1.7
Body fat (%)	34.1 ± 4.5	34.2 ± 2.7
W/H ratio	0.83 ± 0.05	0.82 ± 0.04
Biochemical measurements		
Total cholesterol (mg/dl)	222.9 ± 34.8	185.3 ± 40.6*
HDL- cholesterol (mg/dl)	55.8 ±12.5	56.5 ±10.7
Triglyceride (mg/dl)	223.6 ± 178.0	158.9 ± 82.8

Mean ± S.D.
* Significantly diffenret from group B (P<0.05).

Dietary change and biomarkers

At baseline, the average energy intake was 2,014 ±106 Kcal per day for group A (Table 3). After 3 months, reported energy intake were 1,635 ± 71 Kcal. Energy intake in group B also changed a little during this period, with no significant difference from group A. Dietary fat intake in group A decreased significantly during 3 months, but the percentage of energy from fat did not alter in the same period.

Subjects in group A experienced reductions in serum triglyceride, although improvements of total cholesterol was not clear in this period.

Effect of intervention

Because both groups were provided the same education program for 3 months, we evaluated the effect of intervention by comparing the change in intervention trial period. Changes were evaluated in all subjects who completed the program protocol during the first 3 months (group A: n=23, group B: n=8). Outcomes in body size and dietary intake changed significantly after 3 months intervention (Table 4). Weight loss of 2.6 ± 0.4 kg was observed and waist and hip sizes were reduced 3.3 ± 0.5 cm and 2.3 ± 0.6 cm, respectively. Energy intake was 2,005 ± 89 Kcal at the starting point and 1,696 ± 72 Kcal after 3 months. Subjects whocompleted the intervention period almost reached the

Table 3 Dietary, Anthropometric and Biochemical Measurements during the First 3 Months

	Baseline	3 months	Change in 3 mo	Percent change*
Diet #				
Energy (kcal)				
Group A [n = 22]	2,014 ± 106	1,635 ± 71	-379 ± 101*	-15.9 ± 4.2
Group B [n = 12]	1,908 ± 136	1,741 ± 142	-167 ± 65*	- 8.9 ± 3.7
Fat intake (g)				
Group A [n = 22]	63.9 ± 4.8	51.2 ± 2.7	-12.7 ± 4.6*	-14.1 ± 5.5
Group B [n = 12]	58.7 ± 6.7	52.7 ± 5.8	- 6.0 ± 4.0	- 8.3 ± 6.8
Fat (%E)				
Group A [n = 22]	28.2 ± 0.9	28.3 ± 0.8	0.1 ± 0.9	1.9 ± 3.5
Group B [n = 12]	27.3 ± 1.6	26.8 ± 1.5	- 0.5 ± 1.4	- 0.1 ± 6.4
Body size				
Weight (kg)				
Group A [n = 23]	65.7 ± 1.3	63.0 ± 1.3	-2.7 ± 0.5*	-4.2 ± 0.7
Group B [n = 12]	66.2 ± 1.7	66.3 ± 1.7	0.2 ± 0.3	0.3 ± 0.4
BMI (kg/m^2)				
Group A [n = 23]	27.2 ± 0.4	26.1 ± 0.5	-1.1 ± 0.2*	-4.2 ± 0.7
Group B [n = 12]	26.3 ± 0.5	26.4 ± 0.5	0.1 ± 0.1	0.3 ± 0.4
Body fat (%)				
Group A [n = 23]	34.1 ± 0.9	32.4 ± 0.9	-1.7 ± 0.6*	-4.6 ± 1.6
Group B [n = 12]	34.2 ± 0.8	33.3 ± 0.7	-0.8 ± 0.6	-2.2 ± 1.7
Waist (cm)				
Group A [n = 23]	83.0 ± 1.3	79.9 ± 1.2	-3.1 ± 0.7*	-3.6 ± 0.8
Group B [n = 12]	81.1 ± 1.3	82.1 ± 1.2	1.0 ± 0.7	1.3 ± 0.9
Hip (cm)				
Group A [n = 23]	100.6 ± 1.0	98.5 ± 1.1	-2.1 ± 0.8*	-2.0 ± 0.8
Group B [n = 12]	99.3 ± 1.2	101.4 ± 1.2	2.1 ± 0.8*	2.1 ± 0.9
W/H ratio				
Group A [n = 23]	0.83 ± 0.01	0.81 ± 0.01	-0.01 ± 0.01	-1.5 ± 1.0
Group B [n = 12]	0.82 ± 0.01	0.81 ± 0.01	-0.01 ± 0.01	- 0.8 ± 1.2
Biochemical measurements				
Total cholesterol (mg/dl)				
Group A [n = 23]	222.9 ± 7.3	217.2 ± 7.7	-5.7 ± 5.5	-2.1 ± 2.7
Group B [n = 12]	185.3 ± 11.7	192.0 ± 11.4	6.7 ± 3.6	4.1 ± 2.0
Triglyceride (mg/dl)				
Group A [n = 23]	223.6 ± 37.1	169.6 ± 15.8	-54.0 ± 25.9*	-9.9 ± 8.1
Group B [n = 12]	158.9 ± 23.9	166.1 ± 27.8	7.2 ± 19.3	15.3 ± 17.9
HDL-cholesterol (mg/dl)				
Group A [n = 23]	55.8 ± 2.6	53.7 ± 2.3	-2.0 ± 1.4	-2.8 ± 2.3
Group B [n = 12]	56.5 ± 3.1	56.6 ± 3.1	0.1 ± 1.8	0.9 ± 3.2

Mean ± S.E., * Significantly different from basseline, P<0.05(paired t test).
_____Significantly different from group B, P<0.05(two-sample t test)
*Percentage change of baseline values (%).
Dietary data for group A were analyzed on the basis of available 22 cases.

recommendations of dietary intervention. Patients reduced their fat intake at 10.6 ± 3.6 g per day. Serum total cholesterol and triglyceride concentrations decreased over time, but without statistical significance.

Discussion

In Japan, health education programs for residents at health centers are common, although there have only been few studies on their practical effects. The purpose of the present study was to investigate the effects of health education program for outpatients in the hospital on weight control. Outpatients who had some symptoms and visited the hospital were concerned with their own health condition and they were thus motivated to participate in the intervention trial for health. Hospital visits offer a good chance to change

Table 4. Comparisons Between Before and After the Intervention

(n = 31)#	Before	After	After - before
Diet			
Energy (kcal)	1,965 ± 90	1,624 ± 63	- 341 ± 81*
Fat intake (g)	61.5 ± 4.0	50.9 ± 2.5	- 10.6 ± 3.6*
Fat (%E)	27.7 ± 0.9	28.2 ± 0.8	0.5 ± 0.7
Body size			
Weight (kg)	66.1 ± 1.1	63.6 ± 1.1	- 2.6 ± 0.4*
BMI (kg/m^2)	27.1 ± 0.4	26.0 ± 0.4	- 1.1 ± 0.1*
Body fat (%)	33.7 ± 0.7	32.4 ± 0.7	- 1.3 ± 0.5*
Waist (cm)	83.1 ± 1.1	79.8 ± 1.0	- 3.3 ± 0.5*
Hip (cm)	100.8 ± 0.8	98.5 ± 0.9	- 2.3 ± 0.6*
W/H ratio	0.82 ± 0.01	0.81 ± 0.01	- 0.01 ± 0.01*
Biochemical measurements			
Total cholesterol (mg/dl)	212.5 ± 7.2	209.3 ± 7.1	- 3.2 ± 4.5
Triglycerid (mg/dl)	215.5 ± 29.1	176.3 ± 18.1	- 39.2 ± 22.8
HDL-cholesterol (mg/dl)	56.5 ± 2.2	55.5 ± 2.2	- 1.0 ± 1.3
HDL-C/TC (%)	27.3 ± 1.2	27.2 ± 1.3	0.1 ± 0.7

Mean ± S.E.
Group A: n=23, Group B: n=8
* Significantly different from before, P<0.05 (paired t test)

behavior or life style and we observed significant weight loss on intervention in the present study.

In longitudinal clinical trials, dropouts are cause for concern because they may bias the interpretation of study results. In the present study, we experienced such loss of 3 (10.7%) and 4 (33.3%) cases in groups A and B, respectively. Since Group B was recruited as a reference group and the education program was delayed for 3 months, this may have effected their willingness to comply with the program protocol.

There are some methodological issues in this program protocol that require discussion. The reported dietary intakes by SQFFQ showed a decline in energy intake from baseline, with the greatest decline observed in group A. However, when the dietary data were compared with change in body weight, it appeared that patients reported less than they actually consumed. Furthermore, they became less compliant in accurate reporting of food consumption as the study progressed. This tendency to underreport food intake has been documented by other investigators conducting dietary intervention studies (Lichtman et al., 1992, Hyemsfiled et al., 1995). The failure of some obese subjects to lose weight is due to an energy intake substantially higher than reported and an overestimation of physical activity. This is one reason why changes in key biomarkers related to changes in body weight were not always clear in this study.

We analyzed weight changes at 3 months and showed that there was a significant difference in body weight losses or percentage weight loss data between group A and B. Some obese subjects repeatedly fail to lose weight even though they report restricting their dietary intake. There are also physiological explanations for short-term diet resistance that should be considered in subjects with unexpectedly slow weight loss. Longitudinal follow-up is needed in general to be investigated further.

In the current study, it was clear that reductions in energy intake and fat intakes were significant, but there was no significant change in percentage of energy consumed as fat and we did not observe improvement in the dietary balance. All subjects were instructed by a standard educational videotape about physical activity and they were encouraged to maintain diary records of food intake and physical activity. This analysis did not include the number of calories expended in physical activity and we need to develop techniques to provide quantitative values.

The benefits of the present intervention trial for obese women in Aichi Cancer Center Hospital included effectiveness, convenience, low cost and the relatively minimal time needed for professional intervention. This strategy not only promotes versatility but also supports the continuation of healthy eating patterns. We conclude that it is indispensable to continue lifestyle improvement.

References

Blackburn GL (1995). Effect of degree of weight loss on health benefits. *Obes Res*, **3**(supple), s211-6.

Chan JM, Rimm EB, Colditz GA, et al (1994). Obesity, fat distribution, and weight gain as risk factors for clinical diabetes in men. *Diabetes Care*, **17,** 961-9.

Colditz GA, Willett WC, Rotnitzky A, et al (1995). Weight gain as a risk factor for clinical diabetes mellitus in women. *Ann Intern Med*, **122,** 481-6.

Goldstein DJ (1992). Beneficial health effects of modest weight loss. *Int J Obes*, **16,** 379-415.

Heymsfiled SB, Darby PC, Muhlhemi LS, et al (1995). The calorie: myth, measurement, and reality. *Am J Clin Nutr*, **62**(supple), 1034s-41s.

Hirose K, Tajima K, Hamajima N, et al (1999). Effect of body size on breast-cancer risk among Japanese women. *Int J Cancer*, **80,** 349-55.

Imaeda N, Fujiwara N, Tokudome Y, et al (2002). Reproducibility of a semi-quantitative food frequency questionnaire in Japanese female dietitians. *J Epidemiology*, 12, 45-53.

Kato I, Tominaga S, Kuroishi T (1987). Relationship between westernization of dietary habits and mortality from breast and ovarian cancers in Japan. *Jpn J Cancer Res*, **78**, 349-357.

Kelsey JL, Gammon MD, John EM (1993). Reproductive factors and breast cancer. *Epidemiol Rev*, **15,** 36-47.

Le Marchand L, Kolonel LN, Earle ME, et al (1988). Body size at different periods of life and breast cancer-risk. *Amer J Epidemiol*, **128,** 137-52.

Lichtman SW, Pisarska K, Bernman ER et al (1992). Discrepancy between self-reported and actual caloric intake and exercise in obese subjects. *N Engl J Med*, **327**, 1893-8.

Tokudome S, Ikeda M, Tokudome Y, et al (1998). Development of data-based semi-quantitative food frequency questionnaire for dietary studies in middle-aged Japanese. *Jpn J Clin Oncol*, **28**, 679-87.

Tokudome S, Imaeda N, Tokudome Y, et al (2001). Relative validity of a semi-quantitative food frequency questionnaire versus 28 day weighted diet records in Japanese female dietitians. *Eur J Clin Nutrition*, **55**, 735-45.

Tominaga S (1987). Decreasing trend of stomach cancer in Japan. *Jpn J Cancer Res*, **78**, 1-10.