Original Article

'Her shape' intervention programme for obese women with high breast adiposity

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Background and Objectives: Nutrition and physical activity interventions is beneficial in reversing obesity. However far too little attention has been paid to the effect of these interventions on breast tissues. Thus, the aim of this study was to explore the effect of a home-based dietary and physical activity intervention (the Her Shape Program) on metabolic parameters, blood biomarkers and adiposity at the breast. **Methods and Study Design:** A randomized controlled study was conducted on obese women with high breast adiposity (<0.1 Sm^{-1}), aged 40-60 years in Klang Valley, Malaysia. Subjects were assigned to intervention (n=16) and control group (n=15). Intervention group received a home based health education package with close monitoring weekly, personal diet consultation and physical training in group. Assessment was ascertained at three time points; baseline, weeks 8 and 16. Outcome measures were the energy intake, physical activity, body composition, blood tests, blood biomarkers and electrical impedance tomography (EIT) quantitative values. Analyses were done using 2-way repeated measures ANOVA. **Results and Conclusions:** All subjects completed the program without any drop-out. The HSI group had 100% compliance towards the intervention program; their energy intake was reduced for approximately 35% and their activity score was increased for approximately 11%. A significant interaction effect was found in body weight, body mass index (BMI), total cholesterol/HDL, vitamin C intake and matrix metallopeptidase 9 (MMP-9) (p<0.05). Interestingly, their EIT extremum values were also significantly increased indicating a reduction of breast adiposity. The intervention program was successful in improving body composition, physical activities, MMP9 and breast adipose tissue composition.

Key Words: body mass index, caloric restriction, physical activity, EIT, home-based intervention

INTRODUCTION

In recent years, there has been an increasing prevalence of obesity among women in almost all countries around the globe including Asian countries.[1] Furthermore, Malaysian women lead the chart for highest prevalence of obesity and highest prevalence of inactivity compared with all other Asian counterparts.[2] Following this trend, a higher prevalence of chronic diseases and cancers was expected.[3]

It has been reported that women who gained more than 55 pounds after the age of 18 have 50% increased risk of developing breast cancer.[4] Several mechanisms have been postulated to explain the relationship between adiposity and breast cancer which include general metabolic alteration and local secretory function of the adipocytes itself. Besides the capabilities of fat tissues to influence hyperinsulinemia and increased production of estrogen, the tissues were able to release adipokines which may directly affect neighboring cells.[5,6] Based on the paracrine action of the adipocytes, high adiposity may contributes towards breast carcinogenesis; the condition that exposes mammary epithelium to excessive bioactive substances produced by the adipose tissue.[7,8]

Although there were growing numbers of health studies in women, there were still limited home-based interventions that is aimed at promoting self-empowerment to practice a healthy diet and physical activity.[9] The majority of the studies were done at specific venues with rigid schedule.[10,11] Therefore, there is a need to provide an efficient home based intervention program which is gender specific as both genders have different risk towards diseases. However, the biggest challenge was to package and

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deliver an appealing intervention program which promotes self-empowerment for women to reduce weight hence also focusing on lowering breast adiposity.[12,13]

Acknowledging these gaps, we developed the Her Shape program which is feasible to be conducted among Malaysian women. We combined self-empowerment techniques with healthy eating and simple yet efficient physical activity regime for the women to practice at their own time and venue. We hypothesized that the home-based dietary and physical activity intervention for women may improve their weight, blood biomarkers and ultimately reduce adiposity of the breast.

MATERIALS AND METHODS

Subjects

Subjects participated in this study were recruited among Malay women residing in Klang Valley, Malaysia. The criteria of inclusion were healthy (non-diabetic and no history of cardiovascular disease and malignancy) Malay women aged 40-60 years old, had a body mass index (BMI) of more than 25.0 kg/m^2 and breast Electrical Impedance Tomography (EIT) extremum value of less than 0.1 Sm^{-1} (Siemens per meter) with no history of mental or physical disabilities. The extremum value reflects the type of tissues that largely distributed at the scanned area. The cutoff point of 0.1 Sm^{-1} represents the high distribution of adipose tissues. Subjects must have literacy of reading and understanding Bahasa Melayu with the least requirement of education level of passing the Malaysian Certificate of Education (a national examination compulsory for fifth-year secondary school studentsin Malaysia). Subjects should also not be on any lipid lowering drugs, pregnant, participating in other weight reduction program or had changed their dietary pattern three months preceding the study. The women were screened at residential areas, community centers and work places around Klang valley. Eligible subjects were approached to participate. Only those who agreed to participate were explained of all information pertaining to the program and were consented.

Sample size calculation for screening was done using Open Epi toolkit for proportion with 95% CI (confidence interval), significance level (p) of 0.05 and has two sides, with the degree of accuracy is 5%. Sample size for the intervention was based on the standard deviation and mean difference of EIT from screening phase. Taking into account the 95% confidence interval, significance level of 0.05 and has two sides Z $\alpha/2/2$ is 1.96 and the degree of accuracy is 5%, therefore, the minimal numbers of required sample sizes for each group are as follows:

$$n = \frac{2 \times [Z(1-\alpha/2) + Z(1-\beta)]^2}{\Delta^2}$$

$$\Delta^2 = \left[\frac{\delta \text{ (mean difference)}}{\text{S.D (standard deviation)}}\right]^2$$

$$n = \frac{2 \times (1.96 + 0.8416)^2}{(0.15/0.11)^2}$$

$$n = 9$$

A total of 306 Malay women participated in the second phase but 221 were excluded as their EIT values exceeded 0.1 Sm^{-1}. There were 85 subjects classified as obese with high adiposity of the breast, but 30 were excluded due to various factors (age; body composition; health issues). After thoroughly screened, there were 55 subjects eligible for the intervention program, but 24 women were not interested to participate, therefore the total of women involved in the intervention program was 31.

Study design and sampling

A 4-month randomized, controlled study was performed to determine the efficacy of a home based dietary and lifestyle modification in improving obesity indices among Malay obese women with high adiposity of the breast. This study was approved by the National University of Malaysia Research and Ethical Committee, ethical approval number was NN-136-2011. Subjects were randomly assigned into two groups; Her Shape Intervention (HSI) (n=16) group and control (n=15) group. Those who were assigned to the HIS group must comply with the HSI intervention package which consisted of self-empowerment methods for dietary and physical activity regime.

Intervention package

Modules included were pamphlets, posters and handheld guide books in bilingual ie. English and Malay (Table 1). The construction of the modules were based on guidelines of writing health information materials by Wizowski et al (2008) and also SLIMSHAPE Program ©UKM.[14] Upon developing the modules, scientific facts, information and content from existing women health education materials were taken into consideration.[15] Guidelines on recommended physical activities and method in overcoming emotional constrain during practicing healthy diet were also included.

Intervention program

The HSI program was specifically designed to suit women. The package received by the HSI group is listed in Table 1. There were three group meetings with the HSI subjects throughout the four months. During the meetings, complementary dietary consultation and physical activity training were provided. Subjects were given detailed instruction verbally and reference guide on how to utilize the modules. In order to ensure good compliance, HSI subjects were contacted every week via telephone calls. Their commitment was assessed using the 'Daily Success Checklist' booklets which were given to them on the first meeting. The booklet contains 6 items which summarized their recommended daily dietary practice and physical activities. Each HSI subjects were requested to record their commitment by ticking the items they had successfully completed.

The phone calls were made by trained researchers with 2 main purposes; the first was to provide continuous support and reinforcement of the dietary and physical activity modification and the second aim was to provide personalized problem-solving training for the subjects on self-utilization of all modules given. They were also reminded to utilize the booklet during each phone calls session. Besides that, simple quiz that contained two to three questions based on the module will be asked during the phone conversation in order to assess their familiarity

Table 1. Discrimination of modules received by Her Shape Intervention (HIS) and control group

No	Month of dissemination	Module details	Recipients
1	0 month	Diet	
		1. Programme pamphlet (general pamphlet) 2. Excellent tips for body weight reduction 3. Healthy eating based on Malaysian Food Pyramid	HSI + control
		1. Eating habits pamphlet 2. Mirror exercise pamphlet (with demonstration) 3. Booklet of success checklist 4. Servings size index 5. Food calories index	HSI
		Physical activity 1. Poster for simple home exercise 2. Poster for stretching exercise	HSI + Control
		1. Slim SHAPE exercise DVD 2. Poster for chest and upper limb exercise	HSI
2	1 month	1. Craving buster pamphlet 2. Tips for healthy daily eating habits 3. Smart guidelines on shopping healthy food	HSI
3	2 months	1. Smart guidelines on preparing healthy dish for your beloved family	HSI
4	3 months	1. Smart guidelines on choosing prepared food at restaurants and night market	HSI

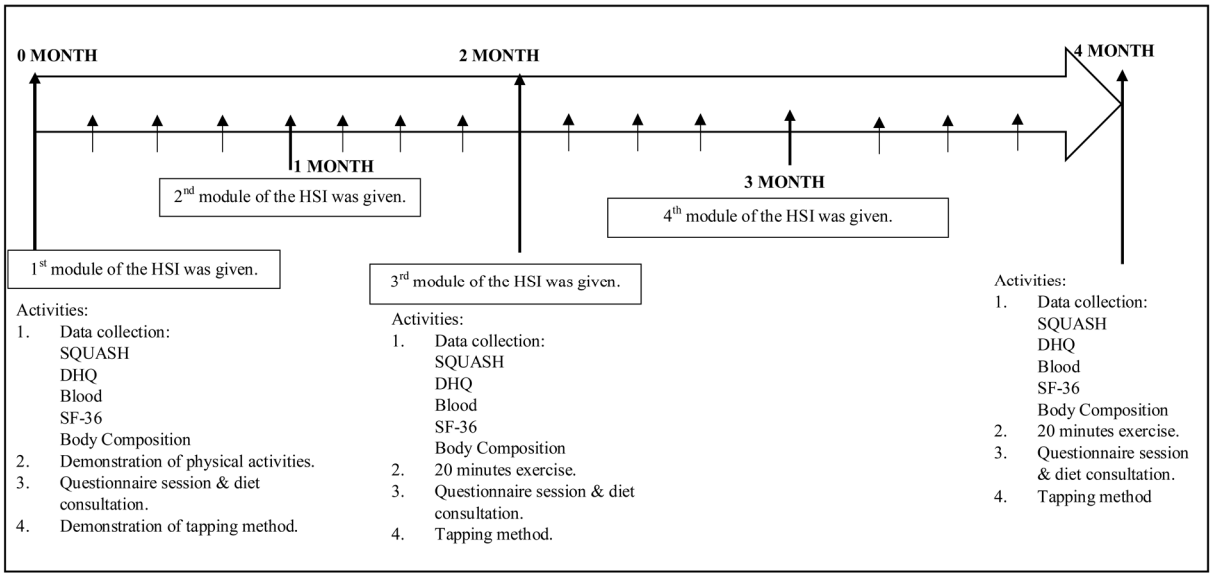

Figure 1. Activities throughout the program that were scheduled for all Her Shape Intervention (HIS) subjects only (N: 16)

with the module given. Figure 1 illustrates the activities scheduled for HSI subjects throughout the intervention program and the small arrows in between each month were the phone calls made for all subjects in the HSI group.

Those who were assigned to the control group were not exposed to any of the intervention program with an exception of brief dietary consultation during the first meeting. The package was given to them upon completion of the study as a token of participation.

Outcome measures

Subjects dietary intake were assessed using modified Dietary History Questionnaires (DHQ) adapted from Suzana et al (2000).[16] Their physical activities were assessed using Short Questionnaires to Assess Health-Enhancing Physical Activity (SQUASH) which were adapted from Wendel-Vos et al (2003).[17] Anthropometry and body composition were measured using SECA digital weighing machine (SECA, German) for weight, Portable Leicester Stadiometer for height and Maltron Bioscan 916 (Maltron International Ltd, UK) for fat percentage. All measurements were made in the morning at subjects' fasted state. These instruments were calibrated each time before measurement.

The EIT examination was done by a qualified operator. In this study, the EIT procedures were done in supine position. Wet cloth was dabbed at the examined breast to moisture the surface area of contact with the electrodes. Then the device was placed on the breast with intention of maximizing electrode contact to the surface. The EIT device used in this study was EIT MEIK version 404 (Mobecomm Inc., Canada).

Three quantitative values that were analyzed in this

study were the extremum value, distribution discrimination percentage, and tomogram difference percentage. The extremum value is the mode value of electrical conductivity that appeared during the imaging session showing the highest component of cells at the breast, distribution discrimination percentage is the percentage in which the examined breast is discriminate from the normal curve of normal breast with matched characteristic, and the tomogram comparison is the percentage of difference between the woman's left and right breast. Each breast (left and right) were analysed independently as each breast will have separate values. The electrical conductivities that were highly appeared in the algorithmic calculation for each women in this study were taken into consideration.[18] Low conductivity values which ranged 0.0 to 0.1Sm^{-1} being most recorded (mode value) showed that the breast area being examined contained a high number of fat cells or high adiposity.[19]

A total of 15 mL of fasting venous blood was withdrawn from all subjects during baseline (0 month) and the final (4 month) meeting after completion of the program. Two main purposes for the blood withdrawal were for basic health screening which comprised of fasting blood sugar, HbA1c and lipid profile and the second purpose was for assessment of blood biomarkers that were previously related with obesity and risk of breast cancer (MMP9 and Adiponectin).[20-23] A total of 10 mL of blood for basic health screening were sent for analysis at Quantum Diagnostics (Kuala Lumpur, Malaysia). A total of 5 mL of blood was collected into serum separation tubes (Becton Dickinson and Co., USA) were centrifuged immediately to isolate serum from red blood cells. A commercially available enzyme-linked immunosorbent assay kits were used to determine the serum concentration of MMP9 and Adiponectin (R&D systems, USA).

Statistical analysis

Statistical analyses were performed by using IBM SPSS version 21.0 (IBM Corp, USA). Differences between two groups were analyzed using t test and proportions were evaluated with Chi Squared test (χ^2). A 2-way repeated measure analysis of variance was used to calculate changes at baseline, 8 weeks and 16 weeks for nutritional intake, physical activity and body composition. Values for the rest of the variables were compared at baseline and 16 weeks.

RESULTS

Subjects

Most of the subjects were middle aged (mean age of 49.8±5.2 years old) and all of them were married and still working during the intervention program. Subjects of both groups were matched with regards to age, age at menarche, family history of breast cancer, menopausal status, age at first pregnancy, and lactation history (Table 2).

Dietary intake and physical activity

Based on their self-monitored 'Daily Success Checklist' booklet, all HSI subjects had 100% compliance towards healthy diet intake and physical activities regime as recommended during their first group meeting. These were confirmed using self-monitored booklet and also weekly checklist made by the researcher through phone-call sessions. There was statistical significance in the interaction effect of total energy intake between both groups [$F_{(2,58)}$=11.3, p<0.05]. Although both groups had shown a reducing trend of total energy intake throughout the program, higher reduction was seen in the HSI group. Macronutrients intake shown that only carbohydrate intake had significant interaction effect [$F_{(2,58)}$=23.6, p<0.05]. Carbohydrates were drastically reduced after 4 months for the HSI group whereas protein intake increased in the intervention group after the four months. Time effect shown significant reduction of carbohydrates [$F_{(2,58)}$=49.7, p<0.05] and fat [$F_{(2,58)}$=7.57, p<0.05] intake and significant increment of protein [$F_{(2,58)}$=14.6, p<0.05] intake. Intake of vitamin C was significantly increased [$F_{(2,58)}$=10.9, p<005] in the HSI group as it was emphasized in the package and consultation to increase their intake of fruits and vegetables servings in every meal (Table 3).

There were significant interaction effect for their minutes/week physical activities [$P_{(2,58)}$=17.5, p<0.05] and also their activity score [$P_{(2,58)}$=18.0, p<0.05]. The increase in the mean of both physical activities domain for the intervention group was due to increased routine leisure time activity which was added throughout the 4 months program (Table 3).

Body composition

There was a significant interaction effect for BMI reduction [$F_{(2,56)}$=9.55 p<0.05] with subjects from intervention group had a higher reduction in BMI (-2.1±1.1 kg/m^2) compared with the control group (-0.5±0.2 kg/m^2). The intervention group lost between 5.6 to 10.3 kg body weight reduction compared with 2.1 to 5.2 kg body weight reduction in the control group. Significant time and group effects were also observed for their body weight (p<0.05) (Table 3).

Blood screening and blood biomarkers

Based on Table 4, fasting lipid profile and blood sugar parameters for the intervention group were improved after the 4 months program with a reduced level of all parameters and maintained HDL level. Despite the improvement of all parameters, only the cholesterol/ HDL level showed significant intervention effect [$F_{(1,29)}$=4.38, p<0.05]. This result was in contrast with the control group, in which upon completion the 4 months program there was increased level of all parameters with reduced level of HDL. Only fasting blood glucose showed improvement in the control group but the result was not clinically significant as their result of HbA1c was increased. There was a significant interaction effect on MMP9 reduction between both groups with higher reduction was shown in the intervention group [$F_{(1,29)}$=9.69, p<0.05]. Adiponectin on the other hand was increased for both groups.

EIT quantitative value

Among the HSI group, EIT extremum mean values for both breasts were increased from 0.06± 0.05 Sm^{-1} (right breast), and 0.10 +0.06 Sm^{-1} (left breast) at baseline to 0.17 +0.08 Sm^{-1} (right breast), and 0.19 +0.08 Sm^{-1} (left

breast). The interaction effects for both extremum values for the right and left breasts were statistically significant; right [$F_{(1,29)}$=5.86, p<0.05], left [$F_{(1,29)}$=13.0, p<0.05]. There were no significant changes noted in the other parameters.

DISCUSSION

Nutritional intake and physical activities play a big role in prevention of various pathological conditions.[24,25] Obesity is one of the risk factors for breast cancer through high adiposity which may promote cancerous cells.[26] EIT is a

Table 2. Characteristics of the intervention and control subjects

	Intervention (n=16)		Control (n=15)		p value*†
	n	%	n	%	
Age, years (mean±SD)	50.2±7.24		47.5±8.44		0.51
Age of menarche, years (mean±SD)	12.3±1.8		12.3±0.5		0.41
Family history of breast abnormality					
Yes	5	31.3	5	33.3	0.79
No	11	68.7	10	66.7	
Menopausal status					
Premenopause	13	81.3	13	86.7	0.92
Menopause	3	18.7	2	13.3	
Age of first pregnancy‡					
<30 year old	14	87.5	12	80.0	0.92
≥30 year old	2	12.5	3	20.0	
Lactation history§					-
Yes	16	100	15	100	
No	0	0	0	0	

*Independent t test for difference of mean, significant value was set at p<0.05.
†χ^2 for proportion, significant value was set at p<0.05.
‡Cut off point of age was based on women who have a first full-term pregnancy before the age of 25, the risk of developing breast cancer is about half that of women whose first full-term pregnancy occurs after the age of 30.[46]
§Exclusive breast feeding for at least six months.

Table 3. Result of dietary intake, physical activities and body composition

Parameter	n	Baseline±SD	Week 8±SD	Week 16±SD	p (η^2_p) Intervention effect
Nutritional intake					
Total energy (kcal)					
HSI	16	1672±368	1166±290	1086±258	0.002* (0.28)
Control	15	1221±322	1144± 370	1138±370	
Protein (g)					
HSI	16	63±19.4	127±39.2	109±34.3	0.08 (0.09)
Control	15	129±73.8	125±44.4	126±44.4	
Carbohydrate (g)					
HSI	16	92.8±68.6	56.1±16.8	55.4±16.6	<0.005* (0.16)
Control	15	97.6±47.2	58.1±43.9	58.1±43.4	
Fat (g)					
HSI	16	122±22.4	48.0±17.0	47.3±17.1	0.35 (0.03)
Control	15	57.3±15.8	45.5±16.0	44.8±15.5	
Vitamin C (mg)					
HSI	16	138±110	419±175	432±101	0.003* (0.21)
Control	15	340±260	321±159	301±166	
Physical activity					
Min/week					
HSI	16	3171±400	3280±406	3355±411	<0.05* (0.23)
Control	15	2546±574	2590±551	2598±542	
Activity score					
HSI	16	7457±853	7923±864	8298±820	0.001** (0.27)
Control	15	6040±1714	6239±1635	6279±1597	
Body composition					
BMI (kg/m^2)					
HSI	16	30.3±3.9	29.2±3.5	28.2±3.5	<0.05* (0.57)
Control	15	30.0±3.9	29.7±3.8	29.6±4.0	
Fat (%)					
HSI	16	42.7±3.2	41.8±3.5	41.4±3.7	0.27 (0.05)
Control	15	43.6±4.4	43.4±4.8	43.1±5.0	

*Two way repeated measures ANCOVA significant at p<0.05; **2 way repeated measures ANCOVA significant at p<0.01.
HSI: Her Shape Intervention group; η^2_p: effect size; The results were adjusted with subjects' age.

Table 4. Results of blood screening, blood biomarkers and EIT quantitative value

Parameter	n	Baseline±SD	Week 16±SD	p (η^2_p) Intervention effect
Blood screening				
Cholesterol (mmol/L)				
HSI	16	5.91±1.07	5.68±1.06	0.17 (0.06)
Control	15	4.41±1.21	5.62±0.73	
TG (mmol/L)				
HSI	16	1.46±0.63	1.25±0.46	0.16 (0.06)
Control	15	1.33±0.65	1.53±0.87	
HDL (mmol/L)				
HSI	16	1.33±0.26	1.33±0.24	0.22 (0.02)
Control	15	1.40±0.27	1.30±0.31	
LDL (mmol/L)				
HSI	16	3.94±0.96	3.85±0.30	0.54 (0.07)
Control	15	3.41±1.14	3.53±0.61	
Tot chol/HDL				
HSI	16	4.60±1.18	4.37±1.05	0.045(0.16)*
Control	15	4.06±1.42	4.58±1.47	
Glucose (mmol/L)				
HSI	16	5.47±1.89	5.36±1.60	0.59 (0.08)
Control	15	6.77±3.14	6.10±2.29	
HbA1c (%)				
HSI	16	5.91±0.84	5.87±0.76	0.54 (0.10)
Control	15	6.42±1.22	6.68±1.78	
Blood biomarkers				
Adiponectin (mmol/L)				
HSI	16	4.41±2.10	5.26±2.50	0.35 (0.06)
Control	15	2.92±1.80	3.17±2.35	
MMP9 (mmol/L)				
HSI	16	5.92±1.07	3.01±1.54	<0.05(0.17)*
Control	15	3.41±1.22	2.63±2.27	
EIT quantitative value				
EIT extremum (Sm^{-1})				
Right breast				0.02(0.18)*
HSI	16	0.06±0.05	0.17±0.08	
Control	15	0.06±0.05	0.09±0.08	
Left breast				
HSI	16	0.10±0.06	0.19±0.08	0.01 (0.38)*
Control	15	0.07±0.06	0.05±0.02	
Distribution discrimination (%)				
Right breast				
HSI	16	45.8±5.1	41.1±5.12	0.14 (0.01)
Control	15	43.5±3.9	42.6±3.8	
Left breast				
HSI	16	44.3±5.52	39.0±8.01	0.07 (0.09)
Control	15	43.6±3.89	44.1±3.79	
Tomogram comparison				
HSI	16	18.2±5.27	17.2±6.72	0.98 (0.06)
Control	15	16.4±6.32	16.6±4.53	

HIS: Her Shape Intervention group; η^2_p: effect size.
*Two way Repeated measures ANCOVA significant at $p<0.05$.
The result was adjusted for subjects' age.

non-invasive device that provides an image and electrical conductivity values at specific areas of the breast. Each distinct type of cells has different physiological capabilities to conduct (conductivity) and to store electrical charge (capacitance).[27] Cancerous cells have high conductivity compared with normal cells whereas fat cells have very low electrical conductivity compared with breast cells.[28] Proper exercise and dietary changes can reduce the adiposity at the breast and have an impact on the EIT value.

This study demonstrated that a home-based nutrition and lifestyle intervention program for working women can successfully reduce fat intake and increase vitamin C intake. The increased intake of vitamin C may be due to increased intake of fruits and vegetables recommended in the Her Shape modules.[29] Diets high in fruits and vegetables tend to be lower in total saturated fat, and higher antioxidants which have protective properties towards cancer.[30] Previous dietary intervention studies which aimed at increasing fruit and vegetables consumption had also proved to increase intakes of vitamin C.[31] The Her Shape module also emphasized a low fat intake which was closely followed by the intervention group.

Intervention subjects showed a desirable increment of

their physical activities from 3171 min/week to 3355 min/week, with an approximately additional 158 min/week of scheduled moderate to intense physical activities. This amount of weekly activity in the HSI group is in accordance of International Association for the Study of Obesity (IASO) recommendation of more than 150-250 min/week of moderate intensity physical activity to prevent weight gain.[32,33] It should be borne in mind that the subjects were mostly working women for whom time is the most common barrier to perform physical activity. Her Shape has successfully implanted a concept of self-empowerment to increase physical activity by introducing them to the emotional freedom technique (tapping therapy) and introducing an exercise regime that was adjusted for social-demographic, neighborhood, social environment and interpersonal factors.[34,35]

Changes in eating pattern and physical activity among intervention subjects resulted in a 6.7% (~5 kg/4 months) reduction of body weight. It was in line with the recommendation of losing 8 kg/6 months for a short-term intervention program.[36] In addition, it resulted in improvement of BMI, EIT quantitative value (extremum value), blood cholesterol/HDL level and serum MMP9 level. It seems that healthy diet and effective physical activity can be practiced at home with proper determination, planning and support.

Control of blood sugar and cholesterol is important in preserving systemic health.[37] The changes of subjects' (intervention and control) blood sugar were insignificant after the 4 months. It was expected that the blood sugar result would not show much change as this study had strictly excluded women with known diagnosis of diabetes prior to the program. Despite both groups (intervention and control) managing to improve their eating habits and reduced their energy intake, only the intervention group showed improvement in their lipid profile after the 4-month. Findings in this study were in line with previous studies which pointed out that regular physical activities had a rapid effect on blood lipid profile.[38,39]

Adiponectin and MMP-9 are both proteins that are associated between obesity and breast cancer.[40-43] However, the data in this study showed that level of adiponectin was least affected after a short-term dietary and lifestyle intervention and based on previous literature the insignificant result may be due to no morphological changes of the breast (either benign or malignant) among subjects.[44] Further, plasma MMP-9 was also found to be elevated in breast cancer patients supporting the hypothesis of an active role of this protein in tumor progression.[45] It was very interesting to find out that the level MMP-9 was able to be reduced following the 4-month dietary and lifestyle intervention (Her Shape).

In conclusion, the home-based 4-month dietary and lifestyle intervention proved to be effective in reducing obesity related parameters and adiposity of the breast. Our data strongly suggest that increased in physical activities towards moderate level of activities with Met 3-6, low calorie and low fat diet were significantly effective at achieving ideal weight loss and reducing fat cells at the breast. This was generally a pilot study of a home-based and self-limited intervention that appears to produce desirable effects in a small targeted sample.

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AUTHOR DISCLOSURES

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