OUTCOME OF DIETARY INTERVENTION ON WEIGHT AND ANTHROPOMETRIC INDICES OF OVERWEIGHT AND OBESE FEMALES: A RANDOMIZED CONTROLLED TRIAL

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ABSTRACT

Objective: To study impact of dietary intervention and counseling on weight and anthropometric indices of obese females.

Study Design: Prospective randomized controlled trial.

Place and Duration of Study: This study was conducted at Pakistan Navy Ship (PNS) Shifa, from Feb 2014 to Sep 2014.

Patients and Methods: Study subjects were 320 obese females from Karachi, Pakistan, aged 20 to 40 years. Before randomization all baseline anthropometric measurements were recorded. After that females were randomly placed into intervention and control groups. Anthropometry and 24-hour dietary recall were used for nutritional assessment. Intervention strategy was individualized diet plan by registered dietitian according to base line body weight and anthropometric indices of study subject. Primary outcome was the change in body weight and body mass index.

Results: The final analysis was run on 280 participants (intervention=127, control=153). Both intervention and control group were comparable with respect to anthropometric variables at start except intervention group had more body mass index (BMI) (28.024 ± 3.561). A significant change was observed in body weight (p=0.001), BMI (p=0.001), waist circumference (p=0.001), hip circumference (p=0.01), waist hip ratio (p=0.04) in an intervention group while control group only showed significant reduction in waist circumference (p=0.041). Intervention group showed significant improvement in dietary behavior which was depicted by increased intake of fruit and fiber consumption (p=0.001), reduction in consumption of simple carbohydrates (p=0.001), animal protein (p=0.001) and fatty food (p=0.001). Control group showed decrease in waist circumference in response to reduction in dietary fat intake and increase intake of fruits (p=0.001) and vegetables (p=0.042).

Conclusion: The results of our study have positively demonstrated that nutritional intervention among obese females was successful in reducing weight and BMI. Reduction inwaist and hip circumference and change in diet behavior were also observed as secondary outcome variable.

Keywords: Body Mass Index (BMI), Waist circumference (WC), Weight, Intervention.

INTRODUCTION

Overweight and obesity are defined as abnormal excessive accumulation of fat that impair normal body functions. It is an emerging public health issue and reaching the epidemic proportion[1].

According to World Health Organization (WHO) estimates overall obesity prevalence is doubled between 1980 and 2014. In 2014, almost 13% of adult population was obese and 39% was overweight. While taking in account gender difference prevalence of both overweight and obesity is more in females as compared to males. Prevalence of overweight was 40% in females and 38% in males while obesity prevalence was 15% and 11% in females and males respectively[2].

South Asian countries including India, Pakistan, Bangladesh, Sri Lanka and Nepal are currently confronting the obesity epidemic and its associated comorbid health disorders

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including diabetes, cardiovascular diseases, hyperlipidemia and various cancers. Underlying contributing factors include nutritional, demographic, socioeconomic transition, rapid urbanization, life style changes and genetic predisposition towards development of obesity[3].

Asians tend to have high body fat percentage at lower BMI as compared to other ethnic groups having same gender, age, BMI. This explains the reason why Asian population has increased risk of cardio metabolic disorders including cardiovascular diseases, hypertension and diabetes at BMI which is considered as normal according to international WHO Classification[4].

In 2000 the Western Pacific Regional Office of WHO (WPRO) proposed (lower BMI cut offs as compared to other ethnic groups) an alternative definition of obesity for Asian population. According to this revised classification, BMI 23.0-24.9kg/m^2 is taken as overweight and obesity is considered at BMI ≥25.0 kg/m^2)[5].

Asians are also more prone to develop central obesity which accounts for development of chronic non communicable diseases and its associated morbidity and mortality. Waist circumference (WC) and waist hip ratio is surrogate marker for assessment of central abdominal obesity. Cut offs for waist circumference and waist hip ratio is lower in Asians as compared to other ethnic group. For high risk Asian population, WC less than 80 cm for females and less than 90 cm in males is taken as normal[6].

For the precise and accurate classification of level of obesity and for effective application of weight loss intervention strategies, better option is to use BMI and waist circumference in conjunction[7].

Pakistan is currently facing double burden of disease. Nutritional transition is taking place along with epidemiological and demographic transition. Our country is persistently facing the challenges caused by under nutrition and infectious diseases along with progressive upsurge in obesity caused by over nutrition. This nutritional transition is characterized by change in trends from traditional staple diet to higher calorie energy dense food which is predisposing towards increase in prevalence of obesity[8].

Obesity is leading cause of development of non communicable diseases. Premature deaths from non communicable diseases can be prevented by adopting healthy life style. According to WHO Global strategy on diet and physical activity proposed that 80% reduction in cardiovascular diseases, 40% in cancer and 80% reduction in diabetes is possible by promoting healthy diet and physical activity[9]. This emerging public health issue can be addressed by creating nutritional awareness. Aim of this study was to evaluate the effect of diet intervention among overweight and obese females. Since females are responsible for up bringing of their families, by creating awareness in most vulner-able group of society we can effectively address this public health issue and save the million lives and avoid sufferings.

PATIENTS AND METHODS

This was a two arm prospective randomized controlled trial. All females between 18-40 years of age, willing to participate in the study, BMI >23kg/m^2, ability to understand Urdu, not having attended any weight loss program in the preceding three month, presenting to the outpatient department of dietitian clinic, family OPD of PNS Shifa Hospital from February 2014 to September 2014 were included in the study. Females with underlying chronic illness, pregnancy, morbid obesity, endocrine disorder, on pharmacotherapy for obesity, polycystic ovarian disease, psychological disorder and those who were not willing to participate were excluded. Informed written consent was obtained from each study participant before enrolling the patients in the study. Ethical approval was obtained from hospital ethical review committee before conducting the study.

Study participants were recruited from BMI camp arranged by dietitian, sponsored by Pharmaceutical Company. During the camp all

participants were offered the free BMI, visceral and total body fat calculation through Bioelectric Impedance Analyzer. Another slot was recruited during the awareness lecture by registered dietitian on "Importance of Balanced Diet and Physical Activity". Overall 174 full filled eligibility criteria and out of these, 9 were excluded because they were not eligible or not willing to give informed consent. Finally, 165 participants that full filled eligibility criteria were enrolled.

Rest of the participants were recruited through family Out Patient Department (OPD) and dietitian clinic.

At the time of appointment, before randomization, all baseline anthropometric measurements including height, weight, BMI waist and hip circumference was recorded. After that female were randomly allocated to intervention and control groups by random number table. However, it was not possible to blind the dietitian and study participant to the allocation groups.

Body weight was measured to the nearest 0.1 kg in light indoor clothing without shoes, using a digital scale. Height was measured using same portable stadiometer. A correction of 0.5 kg was made for the weight of the cloths. According to BMI criteria for Asian population, normal weight (BMI=18-22.9kg/m^2), overweight (BMI=23-25.9 kg/m^2) and obese (BMI >26kg/m^2)[10] were categorized.

Waist circumference was taken as per WHO STEPS protocol. The WHO STEPS is a standardized instrument that allows the collection, analysis and dissemination of data regarding risk factor surveillance for non communicable disease in standardized manner. As per this protocol, waist circumference is measured by placing measuring tape

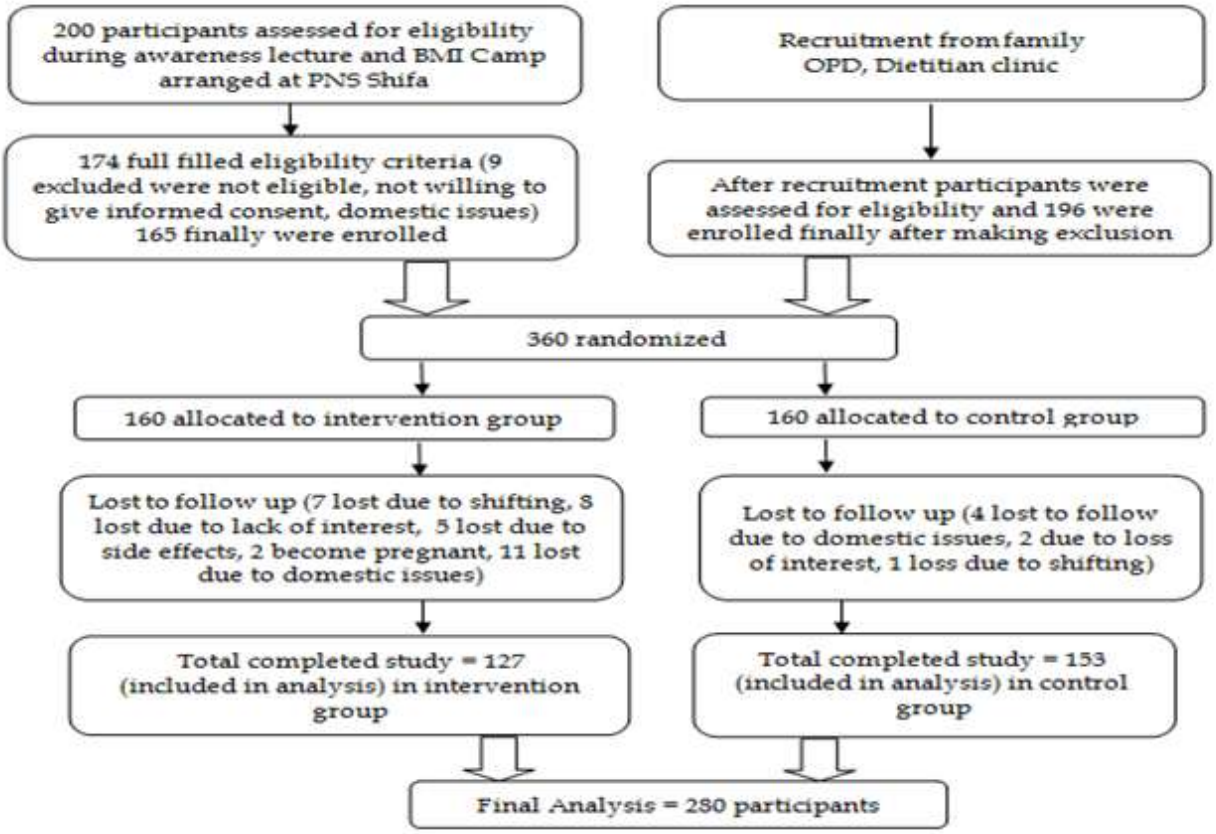

Figure: Flow diagram showing recruitment of participants and their follow up.

approximately at mid of upper border of iliac crest and lower margin of last palpable rib. According to WHO STEPS protocol, hip circumference should be recorded at the widest portion of the buttocks. Waist circumference up to 80 cm and hip circumference up to 90 cm was taken as normal. Precise measurement of waist hip ratio depends on accurate measurement of waist and hip circumference which depends on correct positioning and tightness of measuring tape. Position should be parallel to the level of floor from which measurement is taken and it should not be pulled tightly in order to avoid constriction[10].

Data were analyzed using Statistical Package for the Social Sciences (SPSS) version 22. The sample size calculation was based on formula n = [(Zα/2 + Zβ) 2× {(p1 (1-p1) + (p2 (1-p2))}]/ (p1 - p2)[2]. Based on above formula, the calculated sample size was 132 in each group. Therefore, total sample size 264 was required to detect a clinical important difference of 10% between the two groups with 80% power and a 5% level of significance. This 10% difference represent a 60% successful treatment rate in an intervention group

Table-I: Comparison of baseline anthropometric variables of intervention and control group.

Variable	Intervention (n=127)		Control (n=153)		*p*-value
	Mean	SD	Mean	SD	
Weight (cm) (Mean ± SD)	72.271	9.652	71.882	2.12	0.628
Height (cm) (Mean ± SD)	160.123	4.121	161.121	5.12	0.077
BMI(kg/m^2) (Mean ± SD)	28.024	3.561	27.214	2.341	0.023*
Hip circumference (cm) (Mean ± SD)	89.273	1.788	89.244	3.716	0.935
Waist circumference (cm) (Mean ± SD)	80.061	1.274	80.135	5.31	0.878
Waist Hip ratio (cm) (Mean ± SD)	0.891	0.712	0.897	0.159	0.919

*p<0.05=statistically significant, A independent t-test is used find difference between baseline anthropometric indices of intervention and control group.

Table-II: Comparison of baseline and end line anthropometric variables of intervention group.

Variable	Baseline	End	Paired difference	95% CI of the difference		*p*-value
				lower	upper	
Weight (cm) (Mean ± SD)	72.271 ± 9.652	67.981 ± 6.347	4.290 ± 3.305	2.934	5.649	0.001***
BMI (kg/m^2) (Mean ± SD)	28.024 ± 3.561	26.362 ± 0.328	1.662 ± 3.233	1.161	2.115	0.001***
Waist circumference (Mean ± SD)	80.061 ± 1.474	78.371 ± 1.235	1.690 ± 0.239	0.589	3.781	0.001***
Hip circumference (Mean ± SD)	89.273 ± 1.788	88.365 ± 1.195	0.908 ± 0.593	0.706	2.105	0.012*
Waist Hip ratio (Mean ± SD)	0.891 ± 0.712	0.880 ± 0.564	0.011 ± 0.148	0.012	0.811	0.041*

Apaired t-test between baseline and post-test for the intervention group, *p<0.05 =statistically significant, ***p<0.001= very highly significant.

and 50% successful treatment rate in control group. By assuming 10% dropout rate, recalculated sample size was 292 females (146 in each group). However, more subjects were enrolled than calculated sample size, 160 in each group taking in account the attrition and drop outs[11].

Three twenty study participants were recruited and randomized into intervention and control group. There were 160 study participants in an intervention group and 160 were allocated into control group. Thirty three participants were unable to follow up in an intervention group and 7 among control were lost to follow up. Retention rate in an intervention group was 79.3% and within the control group it was found to be 95.6%. The final analysis was run on 280 participants (intervention = 127, control = 153). Details of study participant recruitment, lost to follow up and attrition rate of study participants is shown in flow chart (figure).

Baseline anthropometric indices were compared in intervention and control groups using t-test for quantitative variables (table-I). Comparison between baseline and end line anthropometric indices of two group was done

Table-III: Comparison of baseline and end line anthropometric variables of control group.

Variable	Baseline	End	Paired difference	95% CI of the difference		*p*-value
				lower	upper	
Weight (cm) (Mean ± SD)	71.882 ± 6.121	71.386 ± 2.347	0.496 ± 3.268	0.134	2.649	0.134
BMI (kg/m^2) (Mean ±SD)	27.960 ± 0.616	27.761 ± 0.328	0.199 ± 0.288	0.061	2.115	0.315
Waist circumference (cm) (Mean ± SD)	80.135 ± 0.599	79.019 ± 0.563	1.116 ± 0.036	0.289	0.781	0.041*
Hip circumference (cm) (Mean ± SD)	89.244 ± 3.756	89.161 ± 3.695	0.083 ± 0.061	0.026	0.105	0.513
Waist Hip ratio (cm) (Mean ± SD)	0.897 ± 0.159	0.893 ± 0.152	0.004 ± 0.007	0.001	0.005	0.812

A Paired t-test between baseline and post-test for the intervention group
*p<0.05 =statistically significant

Table-IV: Average intake of different food groups from 24 hour diet recall.

Analysis of Food Description										
Number of Servings	Intervention Group					Control Group				
	Before Intervention		After Intervention			Before Intervention		After Intervention		
	Mean	SD	Mean	SD	*p* value	Mean	SD	Mean	SD	*p*-value
Carbohydrate	8.18	1.38	6.17	1.60	0.001***	8.47	1.78	8.57	1.65	0.623
Animal Protein	6.48	1.87	5.41	1.30	0.001***	6.67	1.66	6.30	1.78	0.552
Fat	2.02	1.19	1.03	0.92	0.001***	2.23	1.13	1.12	1.67	0.001***
Fruit	0.11	0.41	1.25	0.68	0.001***	0.25	0.67	0.51	0.18	0.001***
Vegetables	2.51	1.24	3.67	1.09	0.001***	2.39	1.33	2.70	1.21	0.042*
Fiber	0.42	0.62	2.14	1.06	0.001***	0.54	0.91	0.49	0.82	0.628
Tea	2.54	0.63	2.07	0.58	0.501	2.54	0.57	2.51	0.58	0.571

A independent t (Wilcoxon signed-rank test) non parametric test, *p<0.05 = statistically significant, **p<0.01 =highly significant, ***p<0.001= very highly significant.

using paired t-test (table-II & III). The 24 hour dietary recall (24 HDR) was analyzed for the number of servings from each food group. Raw data were converted into categories and categories were entered in MS Excel. Data were analyzed using SPSS version 21. Data appeared skewed so a nonparametric test, the Wilcoxon, was run for significance (table-IV). A *p*-value of less than 0.05 was considered as statistically significant.

Intervention group visit protocol was;

- During their first visit all baseline measurements were recorded.
- All participants were called in dietitian OPD at fortnightly basis.
- They received eight counseling sessions in four months.

Control Group visit protocol was;

- During their first visit all baseline measurements were recorded.
- At end of study data were collected during the interactive session on the "Concept of Portion control"
- They received two awareness lectures in four month duration.

A 24 hour dietary recall menuat breakfast, snacking, lunch and dinner was used to assess average number of servings of carbohydrates, protein and fat in meal. Detailed description of all food items and their amount of serving was calculated as per description of food items. Participants were advised to keep the record and maintain food dairy of dietary intake of three week days and two days on week end. Revised Food Composition Tables of Pakistan Organized by the Department of Agriculture, NWFP, Agriculture University Peshawar; UNICEF Islamabad and Ministry of Planning and Development Government of Pakistan were used to make analysis of food group.

RESULTS

Both intervention and control group were comparable with respect to anthropometric characteristics except BMI which was more in intervention group (28.024 ± 3.561) as compared to control group (27.214 ± 2.314) (p=0.023). Detail of anthropometric variables is shown in table-I.

After intervention, significant change in weight, BMI, waist (p<0.001), hip circumference (p=0.012) and waist hip ratio (p=0.041) was observed inan intervention group. Details are shown in table-II. Intervention group showed improvement in dietary behavior. Details are given intable-IV. Control group only showed significant reduction in waist circumference (p=0.041) as shown in table-III. Control group also showed reduction in fat consumption increase intake of fruits and vegetables. Detailed breakdown of average intake of different food groups from 24 hr diet recall are shown in table-IV. Nutritional intervention protocol is shown in table-V.

DISCUSSION

Our study results have positively demonstrated that nutritional intervention among obese females was successful in reducing weight and BMI by improving dietary intake. Results of study also demonstrated reduction in waist and hip circumference, positive change in diet behavior by limiting fat intake, energy dense food and increase intake of fruits as secondary outcome variables.

These findings support previous evidence from experiences of the region that there is scope for improving dietary behavior through nutritional education andthese proved effective in bringing change in anthropometric variables and reducing risk of chronic diseases associated with obesity[12,13].

In this study, we found significant reduction in primary outcome variables including weight and BMI score at the end of intervention. Our study findings suggest that nutrition intervention can be effective strategy for weight and BMI reduction. Olfat studied the effect of three months dietary intervention on anthropometric variables including BMI and weight as a primary outcome measure. There was considerable weight

loss (19kg) at the end three months[14]. In contrast our study results showed reduction in mean body weight of 5 kg.This might be because of reason that dietary intervention in former study It was administered keeping in consideration baseline body weight and level of obesity with aim of moderate weight loss. Kalter *et al* showed that behavior modification intervention was

Table-V: Nutritional intervention protocol by registered dietition.

Intervention group (Structured Nutritional Intervention)
• There were total 8 counseling sessions at fortnightly intervals. Each session comprised of 20 minutes. • The first session comprised of diet history through food frequency questionnaire and 24 hour diet recall. The participants were asked about food allergies and food dislikes. • Main focus of nutrition intervention was to achieve moderate reduction in weight by giving the participants a balanced diet containing all food groups. • Weight-loss diets were adjusted at calorie restriction of 1400 kcal/day by dietician who recommended the amount of macronutrient and dietary fiber according to the dietary guidelines for Pakistan (Revised Food Composition Tables of Pakistan) • The diet plan providing 1400 calories was planned comprising of 5 meals per day. (250 calorie breakfast, 100 calorie snack at midmorning time, 500 calorie lunch, 150 calories snack at mid afternoon and 400 calorie dinner. • Each diet plan was given for two weeks and after two weeks the breakfast and dinner option was changed but the lunch remained the same in all 8 diet plans. • Dinners included lean meat and vegetables, fruits or low fat dairy products or soups but no bread or chapatti. • Participants were educated and counseled about portion size based on principal of food exchange system. • Refined flour, white breads, white rice, pastas and sugar were restricted and replaced with complex carbohydrates in form whole grain oat porridge, whole wheat flour and brown bread. • Participants were told to restrict high fat, fried food and bakery items. Moderate fat was allowed in the form of healthy oils like Canola and olive oil. • 1-2 serving of low fat dairy products like low fat milk and yogurt was included. • 3 to 4 servings of fruits and vegetables were included in all diet plans. • Participants were told to adapt healthy food choices while dinning out like avoiding deep fried food, fast food, frizzy and sugary drinks. • Participants were asked to increase intake of water to at least 8 glasses per day. • Moderate intensity physical activity like 30 minute daily walks 3-4 times a week was recommended. • Participants were counseled to adopt healthy life style like using staircase instead of elevators in daily life and active involvement in daily routine household work. • The intervention group was called for follow ups after every 2 weeks. They were interviewed about the diet compliance, counseled and given another diet plan.
Control Group:
• No intervention was given to control group except they received two awareness lectures, once at the beginning then at the end of session. Participants in control group were enrolled during the awareness lecture by registered dietitian on "Importance of Balanced Diet and Physical Activity". • At end of study data was collected during the interactive session on the "Concept of Portion control". Lecture was about trends in increasing portion sizes and to guide them about how much portion should be consumed while eating out. It was based on the concept that controlling portion sizes helps limit calorie intake and prevents weight gain.

was based on low calorie diet while in our study diet plan was administered on individualized basis as per dietary guidelines for Pakistan (Revised Food Composition Tables of Pakistan). successful in reducing cardio metabolic risk factors among overweight and obese women through reduction in weight and BMI[15]. Results of this study were in accordance to our study

with reduction of 3.5kg weight after initial 6 months and however, overall reduction in weight after 12 months intervention was 6 kg. Although, this study had long duration but weight loss pattern was in accordance to our study with maximum weight loss during initial 4 months of intervention[15].

Our study demonstrated the reduction in waist circumference at the end of intervention. Participants in an intervention group showed approximately 2cm reduction in waist circumference from base line till end of intervention. Maximum decrease was seen at 16 weeks. The result of our study is in accordance to recent comprehensive weight loss program OPTIFAST which was based on life style modification. This program was successful in reducing 10% body weight and along with significant reduction in waist circumference (123.2 ± 18.3 to 106.9 ± 15.2) by end of program[16].

In our study, intervention group showed improvement in dietary behavior. Change in diet behavior was evident from the results of 24 hour dietary recall which showed reduction in intake of simple carbohydrates and sugars which were replaced by complex carbohydrates and increase intake of fiber diet. Study also revealed reduction in amount of dietary fats intake. The result of our study is in accordance with previous interventional study in which significant improvement in dietary behavior was observed at the end of intervention[17].

In our study interestingly, participants of control group also showed reduction in waist circumference in spite of no change in BMI. Research has supported the fact that although obesity is heterogeneous disorder but excessive abdominal fat is linked with greater disease risk[18]. Waist circumference is a simple marker of assessment of abdominal obesity and strong predictor of health risk independent of BMI. Abdominal fat is more sensitive and change in waist circumference can occur even before change in body weight and other anthropometric indices. Previous evidence has also supported the fact that abdominal circumference is more susceptible to changes in dietand even short term intervention can lead to reduction in waist circumference and it can occur even before change in weight and other anthropometric indices[19].

Significant findings observed in control group with regard to dietary intake was reduction in fat consumption. This improvement can be due to health awareness lectures attended by participants of control group at the start and end of intervention. Evidence has also supported the fact that waist circumference is sensitive to changes in dietary fat consumption. Lee *et al* demonstrated the results of randomized control trial in which different diet regimens were given to participants and it was observed that low fat diet has significant effect on reduction of waist circumference and it occur even before change in weight and other anthropometric indices[20]. These findings suggest that reduction in dietary fat intake should be taken in account while designing weight loss regimens.

The limitation of study was that the program was conducted for shorter duration and there was no follow up to evaluate the long term effects of intervention and weight maintenance. This is important to evaluate whether study participants maintain their new dietary habits in the absence of continued contact with a dietician. Similar studies should be replicated with large sample size involving females from different ethnic groups and socio economic strata with long term follow ups to test whether this intervention can be effective strategy for obesity management at National level.

Strengths of the study was that the registered dietitian having professional experience had supervised the study and administered the structured diet plan on individualized basis, with close monitoring and follow ups to periodically assess the effect of intervention. This was also the reason for the success of intervention because females were in close communication with dietitian and principal

investigator which provided extra confidence and motivation. Interesting finding in our study was that modest reduction in dietary fat intake resultedin reduction of the abdominal fat as manifested by reduction in waist circumference in control group. This important finding in control group needs to be evaluated further by future research. Since, our study was conducted for shorter duration and control group received no structured intervention. This was the unique finding and provides basis for future prospective studies involving different diet regimens and different types of physical activity in order to investigate this finding in depth.

Despite of limitations, lack of funding and manpower, limited resources, the success of intervention has paved the way for further studies. There is dire need of integration of all concerned stake holders including public, private, health, education to integrate to make effective strategies to halt this problem. Community based primary prevention programs and clinical trial with more resources and man power should be introduced with aim of achieving maximum benefit with cost effectiveness.

CONCLUSION

The results of our study have positively demonstrated that nutritional intervention among obese females was successful in reducing weight and BMI. Study has shown improvement in secondary outcome variables such as improvement in anthropometric variables including waist and hip circumference, change in diet behavior. These findings support the evidence that there is scope for improving diet behavior through nutrition education, dietary counselling, and behavior change modification.

CONFLICT OF INTEREST

This study has no conflict of interest to declare by any author.

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