

Effect of High Fibre, Low Calorie Balanced Diet in Obese Women with Hirsutism: A Randomised Clinical Trail

ATEFEH KROUNI¹, SEDIGHE FOROUHARI², MARZIEH AKBARZADEH³, MOHAMMAD HOSSEIN DABBAGHMANESH⁴, FARIDEH JOWKAR⁵, MOUSA SALEHI⁶, ELNAZKHAYER⁷, FERDOWS MOHAMMAD ALIAN⁸

ABSTRACT

Introduction: Hirsutism is both an endocrine and cosmetic problem therefore, it becomes necessary for investigations to be carried out to determine the probability of an underlying disease, its effect on sexual performance and reproduction. The appropriate diet composition for individuals with hirsutism has not been specified yet.

Aim: To investigate the effect of high fibre, low caloric balanced diet on some related hormone levels in obese or overweight women with hirsutism in Iran.

Materials and Methods: In the present randomised clinical trial, 50 obese or overweight women suffering from hirsutism were randomly assigned into two groups. The intervention group received a high fibre, low caloric balanced diet while the control group followed a normal diet for three months. The level of Body Mass Index (BMI) was measured and blood sampling (on the 3rd-5th day of menstruation) was carried out before and

12 weeks after the intervention, and the collected data were analysed using SPSS software version 22.0.

Results: Variations in BMI in intervention group was seen. There was an average reduction of 1.89 units in intervention group while it was increased by 0.3 units in the control group. This observed difference was statistically significant ($p < 0.001$). The observed variation in the level of free testosterone hormone in the two groups was significant ($p = 0.034$) i.e., mean \pm SD free testosterone in intervention group (before intervention was 0.49 ± 0.49 and after intervention was 0.43 ± 0.57) and in control group (before 0.38 ± 0.30 and after it was 0.49 ± 0.57). Moreover, there was a remarkable decrease in LH hormone and increase in Sex Hormone Binding Globulin (SHBG) was also observed.

Conclusion: A high fibre diet led to a decrease in BMI in the intervention group, and this decrease had a remarkable effect on improvement of androgenic parameters; as a result, it is recommended that the diet of individuals with hirsutism should be considered and attended.

Keywords: Fatness, Rich fibre diet, Rotundity, Sex hormones

INTRODUCTION

As the commonest endocrine disorder, the disorder related to irregular ovulation and menstruation is observed in gynaecological field. The commonest problems in this field are hyperandrogenism and hirsutism. Hirsutism is defined as an increase in the growth of terminal hair in women with male patterns [1]. Systematic reviews reported its prevalence as 5-10%, which varies in different communities and races. In different countries, different studies have focused on the prevalence of hirsutism, and different prevalence rates of increase in androgen rates have been reported. Prevalence of hirsutism among Taiwanese women was reported to be very low, 4.3% in English women, 7.1% in Spanish, 8.3% in Turkish, 38% in Greek, 5.4% in American and in Iran was 10.8% to 22.8% [2-5].

A large percent of these women were suffering from obesity or overweight, and the combination of these two problems caused negative effects not only on the quality of life among these individuals, but also on the efficiency of the treatments [6].

Obesity is a disorder that involves all age groups, races, and classes. Since it is associated with problems and complications during productivity age and pregnancy, it should be paid closer attention and followed up in such women. Although, there are numerous programs, treatments and attempts employed to cure obesity, this disease is still one of the health problems in developing and developed countries and is increasing day by day [7,8]. On the other hand, obesity can affect the emergence of hormonal and hyperandrogenism problems. The rate of hormonal changes in obese individuals is remarkably different with that of individuals with normal weight [9].

By causing insulin resistance, obesity leads to problems in individuals suffering from Poly Cystic Ovary (PCO). Therefore, weight

decrease through increased insulin sensitivity can be useful [10,11]. Since medical treatments of hirsutism and PCO are expensive and accompanied with side effects, today most of the studies put emphasis on the role of nutrition in such individuals. Some researchers believe that using low calorie diet to a large extent leads to the modification of hormonal disorders and menstruation in these individuals [12,13]. Some studies highlighted the advantages of diets that are limited to carbohydrates, and some referred to the importance of decrease in fats and increase in proteins. At present, there is no special diet for such individuals. On the other hand, due to hormonal and metabolic changes, such individuals face numerous problems in losing weight [14-16]. The present study was carried out in order to investigate the effect of high fibre diet on hirsutism related hormones in obese or overweight women suffering from hirsutism.

MATERIALS AND METHODS

The present study was a randomised clinical trial (IRCT Code: 2014102119624N1) carried out from July 2014 to March 2015 on 50 women of 18 to 45-year-old who had referred to the clinics affiliated to Shiraz University of Medical Sciences in Iran and were diagnosed with hirsutism. They were randomly selected using a purposive convenience sampling method and based on the study's objectives. The study inclusion criteria were: BMI \geq 25, no special diet or medicine; no pregnancy or breast feeding and no smoking. The study exclusion criteria was presence of medical problems including hyper- and hypothyroidism, adrenal hyperplasia, kidney and liver problems, lack of tendency to cooperate with the study, any problem while using the high fibre diet and pregnancy.

The executive protocol of the experiment was explained to the participants. Afterwards, the advantages and limitations caused by the proposed diet were explained, and in case of the individual's

willingness, the consent letter was signed by the participants. After that, the demographic questionnaire was filled out, and then the researcher designed questionnaire (Cronbach's coefficient $\alpha=0.7$) of daily and weekly diet for three days was filled by all of the participants, so that their base diet could be determined and if the individuals' diet was not balanced based on that questionnaire, they were excluded from the study. Balanced diet is a diet consisting of a variety of different types of food and providing adequate amounts of the nutrients necessary for good health [17].

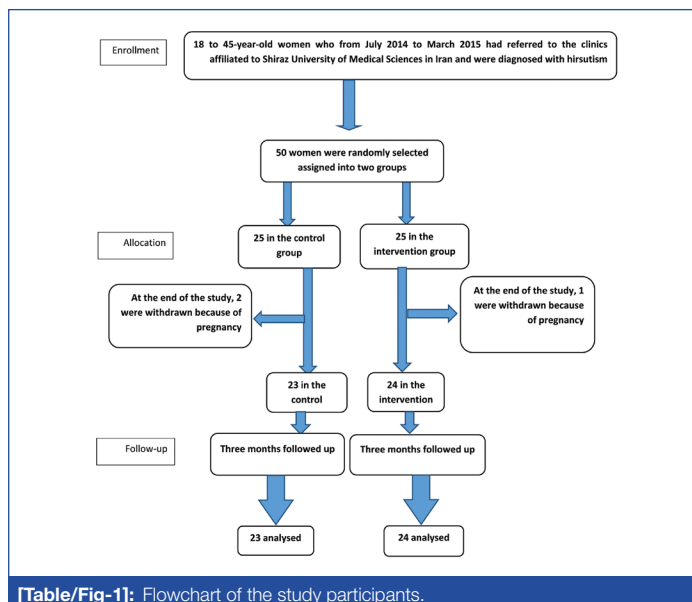
The hirsutism score was calculated using Freeman-Galway scale [18]. In order to measure the hormones of 17-Hydroxypregnenolone (17OHP), free testosterone, androstenedione, Dehydroepiandrosterone Sulfate (DHEAS), Sex Hormone Binding Globulin (SHBG), Follicle Stimulating Hormone (FSH), and Luteinising Hormone (LH), 10 mL fasting blood was taken from the participants before and 12 weeks after the intervention. Blood sampling was carried out on a random day for individuals with an irregular menstruation and on day 3 to 5, for those with a regular menstruation.

All participants (control and intervention groups) received same basic diets but the intervention group diet was supplied by higher amount of fibre foods containing 600 gm fruits, 50 gm nuts and 300 gm Vegetables to provide 20-35 gm of fibre daily.

Statistical analysis of the quantitative variables was carried out through paired and independent t-tests. And for qualitative variables, chi squares test and McNemar's test or other non parametric tests were employed at a significance level of 5%. In doing so, SPSS 22.0 was employed, and the results were reported as mean \pm SD.

RESULTS

At the end of the study and after the intervention, there were 47 participants (24 in the intervention group and 23 in the control group); three were withdrawn because of pregnancy [Table/Fig-1].



[Table/Fig-1]: Flowchart of the study participants.

The mean age of the intervention and control participants was 28 ± 4.75 and 26.4 ± 6.05 years respectively. In the beginning of the study, there was no significant difference between the two groups in terms of their demographic factors. They were significantly different only with regard to their BMI ($p=0.020$) [Table/Fig-2].

After the intervention, BMI changes in the two groups were compared, based on which BMI in the intervention group dropped by 1.89 on average while the control group experienced an increase of 0.3 units in their BMI, which was significant ($p<0.001$)

After the hormonal parameters were measured in the beginning and end of the study, there was no difference between the two

groups in terms of the mean variation in hormones of 17OHP, androstenedione, DHEAS, and FSH. The difference between the two groups was significant only in terms of free testosterone hormone ($p=0.034$). The average changes in the intervention group at the level of LH dropped ($p=0.058$) and the mean changes in SHBG experienced a remarkable increase in the intervention group compared to the control group; however, this difference was not statistically significant ($p=0.068$) [Table/Fig-3].

Variable	Intervention Mean \pm SD	Control Mean \pm SD	p-value
Age	28 \pm 4.75	26.4 \pm 6.05	0.328
Menarche age	13.62 \pm 1.34	13.78 \pm 1.34	0.707
Hirsutism	9.33 \pm 2.66	9.13 \pm 2.22	0.779
BMI	31.03 \pm 6.47	27.46 \pm 2.97	0.020
FSH	4.1 \pm 67.34	5.2 \pm 2.78	0.408
LH	6 \pm 4.05	5.82 \pm 4.71	0.890
SHBG	29.93 \pm 16.47	29.59 \pm 15.85	0.942
17OHP	0.92 \pm 0.61	1.21 \pm 0.67	0.127
DHEAS	2.06 \pm 0.92	2.78 \pm 1.50	0.054
Free testosterone	0.49 \pm 0.49	0.38 \pm 0.30	0.815
Androstenedione	2.59 \pm 1.33	2.49 \pm 0.87	0.439

[Table/Fig-2]: Comparison of mean and standard deviation of age, age of menarche, BMI, hirsutism score and hormones in the intervention and control groups. 17OHP: 17-Hydroxypregnenolone; BMI: Body mass index; FSH: Follicle stimulating hormone; LH: Luteinising hormone; SHBG: Sex hormone binding globulin; DHEAS: Dehydroepiandrosterone sulfate

Hormones	Intervention Mean \pm SD	Control Mean \pm SD	p-value
FSH	-0.44 \pm 1.48	-0.30 \pm 2.91	0.839
LH	-1.08 \pm 3	0.73 \pm 3.42	0.058
SHBG	5.47 \pm 12.93	-0.48 \pm 7.59	0.068
17OHP	0.10 \pm 0.77	0.34 \pm 1.1	0.394
DHEAS	0.14 \pm 0.39	0.05 \pm 1.39	0.507
Free testosterone	0.06 \pm 0.19	0.1 \pm 0.31	0.034
Androstenedione	-0.35 \pm 1.14	0.28 \pm 1.22	0.072

[Table/Fig-3]: Comparison of the difference in mean changes in the level of the hormones before and after the intervention in the intervention and control groups. 17OHP: 17-Hydroxypregnenolone; FSH: Follicle stimulating hormone; LH: Luteinising hormone; SHBG: Sex hormone binding globulin; DHEAS: Dehydroepiandrosterone sulfate

DISCUSSION

With regard to the effect of diet composition on weight loss and hormones in women suffering from PCOS, contradictory findings were achieved, and the appropriate diet composition is still under question. Some studies compared full protein diet with simple sugar diet and concluded that the former led to more decrease in weight and BMI [19].

Administering the high fibre diet for 12 weeks led to a significant decrease in the level of free testosterone and LH and increase in SHBG in the intervention group as compared to the control group. However, changes in LH and SHBG were not significant, which can be attributed to the small size of the sample. The intervention group experienced a significant decrease in their weight while the control group had an increase in their weight and BMI.

Shishehgar F et al., in their study compared the dietary intake between PCOS and eumenorrhic with investigations of non hirsute women and reported that PCOS group consumed more food items with high glycaemic index ($p=0.042$) and less legumes ($p=0.026$) and vegetables ($p=0.037$) than control group. Noted that, compared to Shishehgar's study, present research was a clinical and interventional trials while there was no intervention in those research [20].

In the present study, the decrease in weight had a remarkable effect on the decrease in androgens. Since one of the problems of individuals with PCO and hirsutism is sterility, the researchers believed that if weight loss does not directly influence ovulation, it can increase the chance of response to infertility treatment medications. An increase in BMI leads to a decrease in ovarian response to common treatments with clomiphene [21,22]. In previous studies, it was found that lowering testosterone level and increasing the level of SHBG play an important role in the family level of Insulin Growth Factors (IGFs) and their binding proteins. An increase in these binding proteins leads to a decrease in free IGFs and synthesis of androgen through the cytochrome system of p450c17 [23]. On the other hand, recent studies have indicated that at least 50% of women with PCO suffer from an increase in serinephosphorylation of insulin recipient and thus the effect on enzyme p450c17. Abnormal serinephosphorylation leads to insulin resistance and an increase in the level of androgens in the blood of such individuals [24,25].

In some studies, decrease in androgen was obtained as a result of weight drop [14,26], and in the present study, a decrease in BMI resulted in a significant change in the level of some androgens like testosterone.

Mehrabani H et al., carried out a study aiming at examining the effect of low calorie, high protein, low glycaemia diet on sex hormones, inflammatory markers, lipids, and insulin on women suffering from PCOS compared to Conventional Hypocaloric Diets (CHCD). They randomly chose 60 obese women with PCOS and assigned them into two groups receiving 2 different diets for two weeks. The diets included CHCD with protein (15%), and Modified Hypocaloric Diet (MHCD) with protein (30%) and foods with low glycaemia. The results of the statistical analyses indicated that the level of testosterone dropped in both groups while other factors had no remarkable change [14]. The results of that study were similar to those of the present study. Moreover, the study period and the method were also similar. The present study, however, concentrated on high fibre, low calorie diet while that study focused on a decrease in dietary calorie and fibre was not examined.

A study carried out by Bhargavani A at USA aimed at investigating the relationship between nutrition and the concentration of insulin, estradiol, LDL, HDL, and TGSHBG. It consisted of 379 postmenopausal women in the control group and 615 ones in the intervention group for a period of 12 months. The intervention women were given recommendations on consuming lower amounts of fat and higher levels of grains, fruit, and vegetables. The results of that study indicated that there was a remarkable difference between the two groups before and after the study in terms of the amount of their LDL, HDL, and SHBG, and that insulin level and lower TG were correlated [26].

Those two studies [14,26] are similar to the present one with regard to high-fibre diet and increase in the level of SHBG. Study duration, sample size, the participants, and factors such as insulin and lipid were different in those two studies. These differences can explain the reason why the results are different.

In the study carried out by Gaskins AJ et al., the effects of high fibre diet was investigated among 259 women at their reproduction age, and they were followed up for two cycles of menstruation. The results of their study showed that the level of LH decreased by receiving high levels of fibre [27]. In the present study, a decrease in LH was observed; however, it was not statistically significant, which may be due to the smaller sample size compared to the study carried out by Gaskins AJ et al.

Moreover, numerous studies like those conducted by Katcher HI et al., Cui X et al., Gann PH et al., and Bagga D et al., focused on the role of diet in the hormones and reported remarkable changes in the increase in the amount of SHBG as a result of consuming high fibre diets which is similar to the results of present study [28-32]. As opposed to the

previous studies, the study conducted by Goldin BR et al., referred to a decrease in SHBG as a result of low fat, high fibre diet [33].

In their study, Nicolas M et al., examined the relationship between obesity and hyperandrogenism in 23 women with hirsutism. They gave low calorie diet (1,500 Kcal/day) to the participants for four months. The results of their study showed a drop in BMI which led to a remarkable increase in SHBG; however, no change was observed in other androgens. With regard to decreased BMI, the results of that study are similar to those of the present one. Regarding androgens, however, the results of the present study indicated a significant change in the level of free testosterone ($p=0.034$) while the results of Nicolas's study showed no change in this hormone. Moreover, the present study, like the previous one, showed a statistically remarkable increase in SHBG in the intervention group [34].

Most studies put emphasis on the decrease in calorie and the type of diet composition like full protein or low carbohydrates and low fat, and their results are conflicting; therefore, the present study was carried out in order to examine the effect of high fibre diet on hormones related to hirsutism in obese women suffering from hirsutism since there were few studies focusing on high fibre diets. The hypothesis in the present study was that consuming high fibre foods led to a decrease in BMI and change in the level of hormones in the intervention participants. According to the results of the present study, a significant drop was observed in BMI and free testosterone of the intervention group, which confirms the hypothesis, and decrease in BMI and testosterone is one of the strengths of high fibre diet compared to normal diets. In theoretical terms, a decrease in androgens can have an effect on improving hirsutism state and menstrual and ovulation regularity, which was not possible in the present study due to the existing limitations; thus it is recommended that future studies consider this issue.

LIMITATION

In general, due to BMI difference in two groups and the time-consuming trend of weight loss, large number participants were being excluded, which is one of the limitations of the present study. The cultural situation and the climate dominating the family are effective in following the diet, which was also another limitation.

CONCLUSION

The present study indicated that high fibre diet can lead to a decrease in weight and some androgens like testosterone in obese and overweight women suffering from hirsutism. The results of the present study showed the importance of paying attention to changes in diet among women with hirsutism and polycystic ovary. Since health team has a special place in this regard and is encountering this group of women, it is necessary that they receive necessary trainings with regard to diet and health of this group of patients.

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PARTICULARS OF CONTRIBUTORS:

1. Student Research Committee, Shiraz University of Medical Sciences, Shiraz, Iran.
2. Infertility Research Center, Research Center of Quran, Hadith and Medicine, Shiraz University of Medical Sciences, Shiraz, Iran. Social Determinants of Health Research Center, Shahid Sadoughi University of Medical Sciences, Yazd, Iran.
3. Department of Midwifery, Fatemeh (P.B.U.H) School of Nursing and Midwifery, Shiraz University of Medical Sciences, Shiraz, Iran.
4. Endocrine and Metabolism Research Center, Shiraz University of Medical Sciences, Shiraz, Iran.
5. Molecular Dermatology Research Center, Shiraz University of Medical Sciences, Shiraz, Iran.
6. Department of Nutrition, School of Nutrition and Food Sciences, Shiraz University of Medical Sciences, Shiraz, Iran.
7. Department of Midwifery, Estahban Branch, Islamic Azad University, Estahban, Iran.
8. Midwifery Counseling Postgraduate Student, College of Nursing and Midwifery, Shahid Sadoughi University of Medical Sciences, Yazd, Iran.

NAME, ADDRESS, E-MAIL ID OF THE CORRESPONDING AUTHOR:

Dr. Sedighe Forouhari,
 Infertility Research Center, Research Center of Quran, Hadith and Medicine, Shiraz University of Medical Sciences, Shiraz, Iran.
 Social Determinants of Health Research Center, Shahid Sadoughi University of Medical Sciences, Yazd, Iran.
 E-mail: forouharism@yahoo.com

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