Study to Evaluate the Changes in Polycystic Ovarian Morphology after **Naturopathic and Yogic Interventions**

Abstract

Background: Polycystic ovarian syndrome (PCOS) is one of the commonest endocrine disorders in women, with a prevalence ranging from 2.2% to 26% in India. Patients with PCOS face challenges including irregular menstrual cycles, hirsutism, acne, acanthosis nigricans, obesity and infertility. 9.13% of South Indian adolescent girls are estimated to suffer from PCOS. The efficacy of Yoga & Naturopathy (Y&N) in the management of polycystic ovarian syndrome requires to be investigated. Aims: The aim of the present study is to observe the morphological changes in polycystic ovaries of patients following 12 weeks of Y&N intervention. Settings and Design: The study was conducted at the Government Yoga and Naturopathy Medical College and Hospital, Chennai, India. The study was a single blinded prospective, pre-post clinical trial. Methods and Material: Fifty PCOS patients of age between 18 and 35 years who satisfied the Rotterdam criteria were recruited for the study. According to their immediate participation in the study they were either allocated to the intervention group (n=25) or in the wait listed control group (n=25). The intervention group underwent Y&N therapy for 12 weeks. Change in polycystic ovarian morphology, anthropometric measurements and frequency of menstrual cycle were studied before and after the intervention. Results: Significant improvement was observed in the ovarian morphology (P<0.001) and the anthropometric measurements (P<0.001) between the two groups. Conclusions: The findings of the study indicate that Y&N interventions are efficient in bringing about beneficial changes in polycystic ovarian morphology. We speculate that a longer intervention might be required to regulate the frequency of menstrual cycle.

Keywords: Anthropometric measurements, body mass index, polycystic ovarian syndrome, yoga and naturopathy interventions

> reduction of 5% weight can restore regular menstruation and improve response to ovulation.[5]

Introduction

Polycystic ovarian syndrome (PCOS) is one of the commonest endocrine disorders in women, with a prevalence ranging from 2.2% to 26% in India.[1] characteristics Reproductive associated with polycystic ovary syndrome (PCOS) are polycystic ovaries, hyperandrogenism, hirsutism, acne, androgenic alopecia, anovulation, amenorrhea, oligomenorrhea, and hypersecretion of luteinizing hormone (LH). Metabolic disorders associated with PCOS include hyperinsulinemia, insulin resistance, impaired pancreatic cell insulin secretion, and type 2 diabetes.[2] 9.13% of South Indian adolescent girls are estimated to suffer from PCOS.[3] Although PCOS has a heritable tendency, its etiology and pathogenesis remain uncertain.[4] However, weight loss is identified as the primary therapy in PCOS. Earlier studies suggest a

Studies have shown that yoga therapy orchestrates fine tuning and modulates neuroendocrine axis which results in

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Naturopathy

Naturopathy is defined as a drugless, noninvasive, rational, and evidence-based system of medicine imparting treatments with natural elements based on the theories of vitality, toxemia and the self-healing capacity of the body, and the principles of healthy living.^[6] Comprehensive systematic reviews have not only identified emerging evidence of the cost-effectiveness of various alternative therapies^[7,8] but also have a better quality of care without compromising patient outcomes.[9,10]

Yoga

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beneficial changes. It mainly improves reproductive functions by reducing stress and balancing the neurohormonal profile.^[11] It also reduces urinary excretion of catecholamines and aldosterone, decreases serum testosterone and levels, and increases cortisol excretion, indicating optimal changes in hormonal profiles.^[11] Alterations in brain waves (basically an increase in alpha waves) and decrease in serum cortisol level were observed during yoga therapy^[11,12] implicating reduction of stress level. Yoga as a form of holistic mind–body medicine is effective in reducing anxiety symptoms in PCOS patients.^[13]

Subjects and Methods

Participants

Study participants were the patients with PCOS of Government Yoga and Naturopathy Medical College and Hospital, Arumbakkam, Chennai, Tamil Nadu, India. Patients with PCOS of age between 18 and 35 years, who satisfied oligo/amenorrhea and polycystic ovaries of the three Rotterdam criteria, were included in the study. Following were the definitions of the three criteria:

Oligo/amenorrhea: Absence of menstruation for 45 days or more and/or <8 menses per year.^[14]

Clinical hyperandrogenism: Modified Ferriman and Gallwey score of 6 or higher.^[1] Biochemical hyperandrogenism: Serum testosterone level of >82 ng/dl in the absence of other causes of hyperandrogenism.

Polycystic ovaries: Presence of >10 cysts, 2–8 mm in diameter, usually combined with increased ovarian volume of >10 cm³, and an echo-dense stroma in the pelvic ultrasound scan.^[15]

Patients who used oral contraceptives and intrauterine contraceptive devices or hormonal replacement treatments or insulin-sensitizing agents within previous 6 weeks or other metabolic disorders were not considered in the trial.

Ethical approval

The study was approved by the Institutional Ethical Committee of Government Yoga and Naturopathy Medical College.

Sample size calculation

Considering the restriction in study period given by the funding organization and the statistical power, the number of participants was fixed as 25 in each group. With 80% statistical power and 95% confidence interval, the required sample size was $19 \approx 20$ in each group.

Design

Single-blinded, prospective, pre-post clinical trial.

Methods

An interactive introductory lecture about the purpose and design of the study was explained. After obtaining the written consent from the participants, a detailed case history was taken. Prospective patients with oligomenorrhea were asked to do an ultrasonogram study.

Of the 54 patients who satisfied the criteria for the study, 50 patients who reported were recruited based on the sample size calculation. Twenty-five patients were in the wait-listed control group and 25 patients were in the intervention group. Convenience sampling was done. The primary objective was to study the ovarian morphology which was done at baseline and at the end of 12 weeks. The secondary objective was to document anthropometric measurements (body weight, body mass index [BMI], chest circumference, waist circumference, hip circumference, mid-arm circumference, and waist-hip ratio) and details of menstrual frequency at the end of every 4 weeks. The intervention group was subjected to 12 weeks of Y&N intervention. Complete adherence to the protocol was anticipated.

Patients involved in the study of both groups were assessed by anthropometric measurements and menstrual frequency every 4th week. There was no cutoff kept for attendance. Eighty-nine percent of attendance was maintained by the intervention group, which includes the absenteeism during menstruation.

Among the experiment group, there were three dropouts; one participant became pregnant during the study, another who could not continue with the intervention, and the third expired due to road traffic accident. In the control group, there were three drop outs. Two among them were identified to be relocated to another place thus unable to participate in the post assessment scan and the third

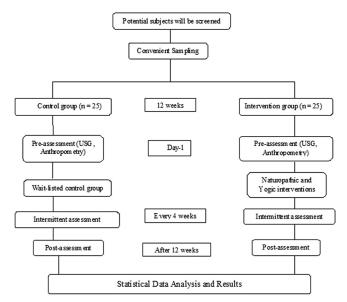


Figure 1: Illustration of the study plan

withdrawn herself from the study. Follow-up was made only with the participant who got pregnant and was found to have uneventful continuation of pregnancy until the end of the study.

Assessments

Transabdominal three-dimension ultrasonogram of the pelvis was carried out by a certified postgraduate female medical radiologist using Voluson® 730 PRO/Pro V (BT05, BT08) (GE Health Care – Kretztechnik, Zipf). Anthropometric measurements were recorded by trained internees of the institute. Both radiologist and the internees were blinded to the groups that the participants were recruited.

Intervention

Figure 1 illustrates the trial profile.

Naturopathy intervention

The idea of naturopathy interventions including hydrotherapy, mud therapy, manipulative therapy, fasting, and natural diet therapy was taken from the available text references. Naturopathy intervention was given for 6 days, every week for 12 weeks, excluding days of menstruation [Table 1].

Yoga intervention

The concepts for the yoga intervention were taken from traditional yoga scriptures that highlight a holistic approach to health management. Practices comprised asanas (yoga postures), pranayama, relaxation techniques, and kriyas. Yoga practice was given for 20 min for 6 days, every week throughout the study period, excluding days of menstruation [Table 2].

Statistical analysis

For continuous data, the descriptive statistics were reported as mean (standard deviation). For skewed data, the summary was reported as "Median (Q1, Q3)" and number and percentage for categorical data. The change was calculated for ovarian morphology, anthropometry parameters. The Shapiro–Wilk and Kolmogorov–Smirnov tests were used to test the hypothesis of normal distribution. Based on the normality test, the nonparametric Mann–Whitney test was used to assess the change difference between intervention and control groups. The analysis results were presented as median (Q1, Q3) with P value. All the tests were two-sided at $\alpha = 0.05$ level of significance. All statistical analysis was done using SPSS software version 21.0 (Armonk, NY: IBM Corporation).

Results

Table 3 shows the demographic characteristics such as gender, age, height, weight, BMI, chest circumference, waist circumference, hip circumference, mid-arm circumference, and waist-hip ratio of patients at baseline.

Nonparametric Mann–Whitney test was used to examine the difference between intervention and control group on the ovarian morphology change score and anthropometry parameters change score. Table 4 shows the evidence for statistical significance on the follicles antrum (P < 0.001), largest follicle size (cm) – length (P = 0.016), left ovarian volume (P = 0.032), and total assessment (P < 0.001).

Table 5 shows the evidence for statistically significant difference on the anthropometry parameters (P < 0.001) except waist–hip ratio.

Nonparametric Mann–Whitney test was used to find out the difference between two groups on the menstrual frequency. Table 6 shows that non significant difference between the two groups.

Discussion

This study revealed Y&N interventions are efficient in bringing about beneficial changes in polycystic ovarian

Table 1: Naturopathy intervention		
Therapies	Duration (min)	Frequency
Cold abdominal mud pack	10	6 days/week
Hydrotherapy		
Cold water enema	-	Once in 4 weeks
Cold hip bath	15	6 days/week
Hot foot immersion bath	10	Twice in a week
Massage		
Partial massage to abdomen	10	3 days/week
Partial massage to back	10	3 days/week
Fasting therapy		
Juices of fruits and vegetables and fluid fasting (first diet chart 1*)	-	Initial 3 days/month
Diet therapy		
Raw vegetables, fruits, sprouts, vegetable soup for breakfast, and short vegetarian meal for lunch (second diet chart*)	-	Next 18 days/month
Boiled vegetables, steamed food (third diet chart*)	-	Final 7 days/month

^{*} See annexure

Table 2: Yoga intervention

Yogic practice

Asanas

Supine series

Uttanpadasana, pawanmuktasana, naukasana, setu bandhasana Prone series

Bhujangasana, dhanurasana

Sitting asana series

Vakrasana, baddha konasana

Standing asana series

Katichakrasana, ardhakatichakrasana, dwikonasana, padahastasana

Pranayama

Bhramari pranayama

Surya bhedana pranayama

Nadi shodhana pranayama

Kriya

Kapalbhati

Mudra

Yoni mudra

Relaxation

Savasana

Table 3: Patients demographic characteristics at baseline

	Mean±SD	
	Intervention (<i>n</i> =22)	Control (n=22)
Gender (female), n (%)	22±50	22±50
Age (years)	23.77±5.33	25.05±4.83
Height (cm)	158±6	157±9
Weight (kg)	71±13	62±15
BMI (kg/m²)	28.29 ± 5.25	25.26±6.61
Chest circumference (cm)	96±9	90±11
Waist circumference (cm	97±12	90±10
Hip circumference (cm)	109±11	102±13
Mid-arm circumference (cm)	32±4	29±5
Waist-hip ratio	0.88 ± 0.05	0.89 ± 0.06

BMI = Body mass index, SD = Standard deviation

morphology in terms of number of antral follicles, length of the largest follicle in the right ovary, left ovarian volume, and total assessment of the ovarian morphology. The difference in polycystic ovarian morphology due to the reduction in the number of antral follicles may be confirmed by the assessment of reduction of excess androgens, which are associated with a characteristic poly follicular ovarian morphology. Thus, the decreased duration in intermenstrual cycles may have occurred not only in conjunction with reduction in number of antral follicles but also with the overall change in ovarian morphology.

The significant difference in the anthropometric measurements (body weight, BMI, chest circumference, waist circumference, hip circumference, and mid-arm circumference) between the two groups (P < 0.001) reaffirms the previous studies that a reduction of 5% of

body weight can restore regular menstruation and improve response to ovulation. [5]

The naturopathy treatments involved in the protocol are found to be effective as an individual treatment *per se* with reference to the improvement in function of pelvic viscera by altering the circulation.^[16-36]

Hydrotherapy

Cold hip bath

A short cold sitz produces active dilatation of the vessels of the lower abdomen. The thermic reaction produced heightens the nutritive processes in the parts concerned and excites contraction of the muscular structures of the viscera, thus influencing the pelvic organs, together with the various musculo-ligamentous structures which support the pelvic viscera. The prolonged cold sitz (15–20 min) causes very pronounced effects on the pelvic circulation. The contraction of the cutaneous branches of the internal iliac tends to produce hyperemia of the pelvic viscera. [16]

The hot foot bath

Very hot applications to the feet (10 min) stimulate the involuntary muscles of the uterus and other pelvic viscera. The dilatation of the blood vessels produced in the feet by this application extends to the upper parts of the limbs and to the vessels of the pelvic viscera. This is shown by the vigorous pulsation of the femoral artery after a hot foot bath. By this means, the uterus and ovaries receive an increased supply of blood, which renders the foot bath a useful measure for restoring the function of menstruation when suspended.^[17]

The cold enema

The enema renders service in encouraging the action of the liver and kidneys, and especially in cleansing the alimentary canal.^[18]

Mud therapy

Several peat substances are able to permeate the skin.^[19] One study that measured the circulation in the uterine artery after bath therapy showed that only the peat bath achieved the physiologic effect of prolonged vasodilatation and circulation. This effect lasted for several hours after the treatment. It is thought that absorption of peat substances takes place through the hair follicles and apocrine glands through diffusion and partial pinocytosis.^[20,21] Mud pack therapy decreases the proinflammation factors interleukin-1 and tumor necrosis factor-alpha and radical-mediated peroxidations, nitric oxide, and myeloperoxidase.^[22]

Massage

Soft-tissue manipulation has been found to decrease inappropriately elevated levels of cortisol. The effects of chronically high cortisol levels occur at the hypothalamic-pituitary-axis level and can disrupt and

Table 4: Analysis of change f	Table 4: Analysis of change from baseline to post measurement in ovarian morphology		
Change from baseline to post measurement	Median (Q1, Q3)	P*
	Intervention (n=22)	Control (n=22)	
Right			
Ovarian volume	1.67 (-3.8, 7.04)	-1.02 (-4.06, 3.7)	0.307
Ovarian size (cm)			
Length	-0.1 (-0.3, 0.7)	0.1 (-0.4, 0.3)	0.962
Width	-0.3 (-1, 0.4)	-0.2(-1, 0.3)	0.814
Thickness	0.5 (-0.6, 1.8)	0.3 (-0.2, 0.7)	0.557
Follicles antrum	5 (1, 11)	-4 (-6, 1)	< 0.001
Largest follicle size (cm)			
Length	-0.1 (-0.2, 0)	0.15 (-0.1, 0.3)	0.016
Width	0 (-0.3, 0.1)	0.05 (0, 0.2)	0.102
Left			
Ovarian volume	3.68 (1.1, 8.44)	-0.79 (-4.5, 4.33)	0.032
Ovarian size (cm)			
Length	0.25 (0, 0.8)	0.1 (-0.5, 0.4)	0.078
Width	0.2 (-0.7, 0.6)	0 (-1.2, 0.6)	0.411
Thickness	0.5 (-0.2, 1)	0.25 (-0.2, 0.8)	0.572
Follicles antrum	2 (-3, 6)	-3.5 (-5, 5)	0.076
Largest follicle size (cm)			
Length	0 (-0.2, 0.1)	0 (-0.2, 0.2)	0.854
Width	-0.05 (-0.2, 0.1)	0 (-0.1, 0.1)	0.291
Total assessment	6 (2, 10)	-3.5 (-10, 1)	< 0.001

^{*}Obtained from nonparametric Mann-Whitney test, Q1, Q3 (first quartile, third quartile)

Table 5: Analysis of change from	of change from baseline to post measurement at anthropometry parameters		
Change from baseline to post measurement	Median ((Q1, Q3)	P*
	Intervention (n=22)	Control (n=22)	
Weight (kg)	6 (4, 8)	0 (-1.5, 2)	< 0.001
BMI (kg/m^2)	2.36 (1.6, 3.28)	0 (-0.49, 0.84)	< 0.001
Chest circumference (cm)	4.25 (3, 6)	0.75 (-1, 1.5)	< 0.001
Waist circumference (cm)	5 (3.5, 7.5)	-1.25 (-4, 1)	< 0.001
Hip circumference (cm)	6.75 (4, 9)	-0.25 (-2, 1.5)	< 0.001
Mid-arm circumference (cm)	3 (2, 4.5)	0 (-0.5, 0.5)	< 0.001
Waist-hip ratio	-0.01 (-0.03, 0.02)	-0.01 (-0.04, 0.01)	0.777

^{*}Obtained from nonparametric Mann-Whitney test, Q1, Q3 (first quartile, third quartile). BMI = Body mass index

Table 6	: Analysis of difference between cons	ecutive cycle (days)	
	Median (Q	1, Q3)	P*
	Intervention (n=22)	Control (n=22)	
LMP and first cycle (days)	35 (21, 132)	34 (20, 88)	0.874
First and second cycle (days)	30 (23, 90)	33 (21, 69)	0.715
Second and third cycle (days)	29 (25, 47)	33 (15, 55)	0.124

^{*}Obtained from nonparametric Mann-Whitney test, Q1, Q3 (first quartile, third quartile). LMP = Last menstrual period

create aberrations in neuroendocrine function. Soft-tissue manipulation has also been shown to raise low levels of dopamine and serotonin; this effect has implications in treating addictions, eating disorders, depression, and more. [23-27]

Juice fasting

Diluted juices provide a modest amount of calories and stabilize blood glucose levels.^[28]

Diet therapy

Refined sugars, white flour products, and other sources of simple sugars are quickly absorbed into the bloodstream, causing a rapid rise in blood sugar. In response, the body boosts secretion of insulin by the pancreas. High-sugar, "junk foods" diets definitely lead to poor blood sugar regulation, obesity, and ultimately type 2 diabetes and heart disease.^[29-31] The stress on the body that they cause,

however, including secretion of too much insulin, can promote the occurrence of PCOS, growth of cancer, and increases the risk of heart disease as well. A natural rich diet in fruits and vegetables can easily produce much higher K/Na ratios because most fruits and vegetables have a K/Na ratio of at least 50:1.[32]

Proposed specific dietary approaches in PCOS include high protein, low carbohydrate, and low glycemic index/glycemic load diets. A number of small studies assessing specific dietary approaches in PCOS show similar results for diets moderately increased in dietary protein or carbohydrate^[33-35] with one study reporting greater weight loss where a high protein supplement was added to a standard energy-reduced diet.^[36]

Yoga

It mainly improves reproductive functions by reducing stress and balancing the neurohormonal profile. It also reduces urinary excretion of catecholamines and aldosterone, decreases serum testosterone and LH levels and increases cortisol excretion, indicating optimal changes in hormonal profiles.^[11] Alterations in brain waves (basically an increase in alpha waves) and decrease in serum cortisol level was observed during yoga therapy.^[11,12]

Levels of corticotrophin releasing hormone, melatonin, growth hormone, prolactin, LH, thyroid hormone, cortisol, aldosterone, testosterone, adrenaline, and other neurotransmitters such as endorphins, serotonin, 5-hydroxy indole acetic acid, vanillylmandelic acid, dehydroepiandrosterone, gamma amino butyric acid, and 8-hydroxydeoxyguanosine are affected in yoga practice. There is improvement in insulin secretion and sensitivity and this ultimately decreases blood glucose level in diabetics. The benefits of yoga are also related to other risk factors such as high blood pressure, lipid levels, oxidative stress, coagulation profile, and immune status and may also influence the metabolic profile.^[37]

Limitation of the study

As transabdominal sonography relies more on subjective interpretation, similar study with evaluations on insulin sensitivity and hormonal assessments on more participants is suggested for further validation.

Conclusion

This study revealed Y&N lifestyle could be the first-line interventions for PCOS. Small changes in lifestyle in accordance to Y&N are known to improve symptoms and psychological well-being of PCOS patients. The rationale of this study was to focus on lifestyle improvement of PCOS patients in normalizing insulin resistance, improving androgen status, and aiding weight management thereby supporting the prevention of other related non-communicable diseases. There is evidence in clinical practice that Y&N interventions reduce symptoms of PCOS. This study

performed to assess morphological changes in the polycystic ovaries in relation to reduction of symptoms has substantiated the approach of Y&N interventions in PCOS.

Evidence suggests that a nation could save millions in health-care costs and provide a better quality of care without compromising patients' outcomes if alternative medicine is widely practiced. Comprehensive systematic reviews have identified emerging evidence of the cost-effectiveness of various alternative therapies, compared to the usual care. Thus, Y&N interventions could play a major role as an economical primary intervention in women's reproductive health.

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Conflicts of interest

There are no conflicts of interest.

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Annexure

First diet chart	
Timings	Foods to be taken
6:00 am	Luke warm water - 1 glass
7:00 am	Lemon honey juice - 1 glass
8:30 am	Fruit juice - 1 glass
10:00 am	Vegetable juice - 1 glass
11:00 am	Barley water - 1 glass
12:30 pm	Tender coconut water of 1 tender coconut
2:00 pm	Fresh and skimmed buttermilk - 1 glass
4:00 pm	Herbal tea - 1 glass
5:30 pm	Vegetable juice - 1 glass
7:00 pm	Fruit juice - 1 glass
8:30 pm	Water mixed with honey/jaggery - 1 glass

Points to be noted:

- 1 glass = 250 ml
- Milk and white sugar should not be added to the juices
- Honey or jaggery or rock salt can be added to the juices
- Fruits- pomegranate, papaya, apple, mosambi, orange, watermelon, grapes, muskmelon, pineapple, dry dates, dry and fresh figs, and dry grapes any one of these fruits can be used for the preparation of juice
- Vegetables-carrot, beetroot, cucumber, bitter gourd, ash gourd, and tomato any one of these vegetables can be used for the preparation of juice.

Second diet chart	
Timings	Foods to be taken
6:00 am	Luke warm water - 1 glass
7:00 am	Lemon honey juice/horse gram soup - 1 glass
8:30 am	Vegetable salad - 50 g, raw sprouts - 50 g, fruits - 2, fruit juice - 1 glass
11:00 am	Barley water - 1 glass
12:00 pm	Fresh and skimmed buttermilk - 1 glass
1:00 pm	Rice - 1 cup, moong dal/vegetable curry, boiled vegetables - 50 g, vegetable soup - 1 glass
4:00 pm	Herbal tea - 1 glass
5:30 pm	Fruit juice - 1 glass
7:00 pm	Vegetable soup - 1 glass
8:00 pm	Vegetable salad - 50 g, raw sprouts - 50 g, fruits - 2, fruit juice - 1 glass
9:00 pm	Water mixed with honey/jaggery - 1 glass

Points to be noted:

- 1 glass = 250 ml. Milk and white sugar should not be added to the juices
- 1 cup = 200 g
- · Raw sprouts green gram, brown Bengal gram, and groundnut any one of these can be used
- Honey or jaggery or rock salt can be added to the juices
- Fruits pomegranate, papaya, apple, mosambi, orange, watermelon, grapes, muskmelon, pineapple, dry dates, dry and fresh figs, and dry grapes any one of these fruits can be used for the preparation of juice
- Vegetables carrot, beetroot, cucumber, ash gourd, knol khol, drum-stick, broccoli, and tomato any one of these vegetables can be used for the preparation of soup
- Vegetable salad carrot, beetroot, cucumber, ash gourd, capsicum, green peas, and tomato can be used.

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Third diet chart	
Timings	Foods to be taken
6:00 am	Luke warm water - 1 glass
7:00 am	Lemon honey juice/horse gram soup - 1 glass
8:30 am	2-3 idlis + chutney/wheat dalia - 2 cups/oats porridge/2 fulka + boiled vegetables/black gram or fenugreek porridge
11:00 am	Barley water - 1 glass
1:00 pm	Rice - 1 cup, moong dal/vegetable curry, boiled vegetables - 50 g, vegetable soup - 1 glass
4:00 pm	Herbal tea - 1 glass
5:30 pm	Fruit salad/boiled sprouts - 200 g
7:00 pm	Vegetable soup - 1 glass
8:00 pm	2 fulka + boiled vegetables

Points to be noted:

As mentioned in the previous diet charts.