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Original Article

Physiotherapy Section

Management of Binge Eating Disorder in Polycystic Ovarian Syndrome using Different Modalities: A Randomised Controlled Trial

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ABSTRACT

Introduction: Difficulty in losing weight is a major problem in binge eaters. It becomes catastrophic when it is concurrent with Polycystic Ovarian Syndrome (PCOS). Weight loss programs don't benefit to cope with binge eating disorder and vice-versa; which is the most challenging component of weight management in PCOS females that manifest binge eating also.

Aim: To develop a management strategy which can address binge eating and weight management in PCOS females.

Materials and Methods: The present randomised, parallel group, active controlled trial was conducted from december 2021 to december 2022 in non-pregnant females of 18-45 years of age satisfying Rotterdam criteria of PCOS having BMI ≥18.5. Eating Disorder Diagnostic Scale (EDDS) was used as a screening tool. A total of 114 participants were randomised into two groups of 57 females each ,experimental group and control group control group (n=57). Experimental group performed aerobic exercises, resistance exercises, diet modifications and Rajyoga meditation while control group performed only diet modifications and Rajyoga meditation. Eligible and willing participants visiting Weight, height, waist circumference, hip circumference, Body-Mass Index (BMI), Waist-Hip Ratio (WHR), Eating Attitudes Test (EAT) score, Bulimic Investigatory Test, Edinburgh (BITE) severity score and BITE symptom score were assessed before start of intervention and after 12 weeks of intervention. Shapiro-Wilk test indicated data were non-normally distributed. Within group analysis (pretest vs post-test) was performed using Wilcoxon signed-rank test. The between group differences were compared (experimental vs. control) using Mann-Whitney U test. IBM Statistical Package for Social Sciences (SPSS) Statistics 22.0 was used for analysis with $p<0.05$ statistically significant.

Results: The mean ageof the participants was 26.35±4.97 years, mean weight was 73.53±16.73 kg, mean WHR 0.88±0.04 and mean BMI 28.81±5.90 kg/m^2 Reduction in weight, BMI, waist circumference, EAT score, BITE severity score and BITE symptom score were statistically significant within both groups (pre-test and post-test, $p<0.001$) while reductions in hip circumference and WHR were statistically significant only in experimental group (pre-test and post-test, $p<0.001$).

Conclusion: the present study results highlights the significant weight BMI binge eating symptoms in the intervention group. further researches can help the profeSSionalS in healthcare in treatment of pcos.

Keywords: Bulimia, Diet therapy, Exercise, Meditation

INTRODUCTION

The PCOS is most common endocrine disorder affecting 15-21% of the reproductive age women depending on diagnostic criteria used. It has wide spectrum of characteristics which can be grouped into metabolic, reproductive and psychological features [1]. Around 90-95% anovulatory women visiting clinics for infertility treatment are diagnosed with PCOS [2]. PCOS females exhibit menstrual irregularities, acne, alopecia, hirsutism, insulin resistance with compensatory hyperinsulinaemia, impaired glucose intolerance, metabolic syndrome, type 2 diabetes, obesity, sleep apnoea, negative body image, anxiety, depression, poor quality of life and eating disorders. These females are at increased risk for gestational diabetes, spontaneous miscarriage in first trimester of pregnancy, heart attack, Cardiovascular Disease (CVD), endometrial hyperplasia and non-alcoholic fatty liver disease [3-5]. A review article reported prevalence of binge eating symptoms around 6.8-58% in PCOS population [6]. Binge-Eating Disorder (BED) is recognised as a distinct eating disorder (DSM-5: American Psychiatric Association, 2013) [7]. It is one of the most common eating disorder in which patients eat larger amount of food in brief time (e.g., in 2h period) as compared to most people would eat in same time with loss of control over what or how much they eat [8]. A systematic review reported healthcare costs for BED to be 1762 to 2902 Euro [9]. Patients with BED also exhibit poor health related quality of life, suicidal thoughts and attempts, over weight, obesity, depression and lack of social functioning as compared to healthy people. They are at increased risk of developing metabolic syndrome and diabetes [7,10,11].

Various studies have evidence for two main theories related to binge eating in adults. Firstly, the restraint model states that strict diet programs lead to increased risk of overeating to compensate for caloric deprivation. Secondly, the affect regulation model states it as coping strategy for negative emotions [12]. Although Cognitive Behavioural Therapy (CBT) is first line treatment for BED but doesn't result in weight loss. It is hypothesised that more dietary restrictions are associated with binge eating [13].

The treatment guidelines presently focus on weight management in PCOS through diet and lifestyle modifications. But at the same time, it is more important to identify females with disordered eating patterns and realise the impact of dietary restrictions on their altered physiological and psychological parameters. A treatment approach which could address both weight loss and binge eating symptoms would be more beneficial for this population. Thus, aim of the present randomised controlled trial was to determine effect of 12 weeks of exercises, Rajyoga meditation and diet counselling on weight and binge eating symptoms in PCOS females. To our knowledge this was the first RCT to investigate effect of exercises (aerobic exercises and strengthening exercises), diet counselling and Rajyoga meditation on weight and binge eating together in PCOS females. Weight loss and improvement in BITE score was greater after exercises plus diet counselling and Rajyoga meditation as compared to diet counselling and Rajyoga meditation. It involves diet modifications

in "real world" which are not restricted to laboratory or research environment. Moreover, it is not comprised of restraint diet to break vicious circle of negative self-perception related to weight gain, physical appearance and infertility in PCOS, strict diet for some time to lose weight and achieving little weight loss, overeating due to dietary restraint, leading to binge eating and long-term weight gain. Rajyoga meditation fills mind with positive thoughts, positive self-perception and positive attitude towards disease and life. It teaches to be compassionate with own self in presence of disease. Rajyoga meditation can be taught in places where CBT is not available, to those who don't respond to CBT, who can't afford to visit psychiatrist because of social and/or cultural norms and costs related to it.

i. **Null hypothesis (H01):** There will be no difference for changes in weight and eating patterns between experimental group and control group in PCOS females.

ii. **Alternate hypothesis (H#1):** There will be difference for changes in weight and eating pattern between experimental group and control group in PCOS females.

MATERIALS AND METHODS

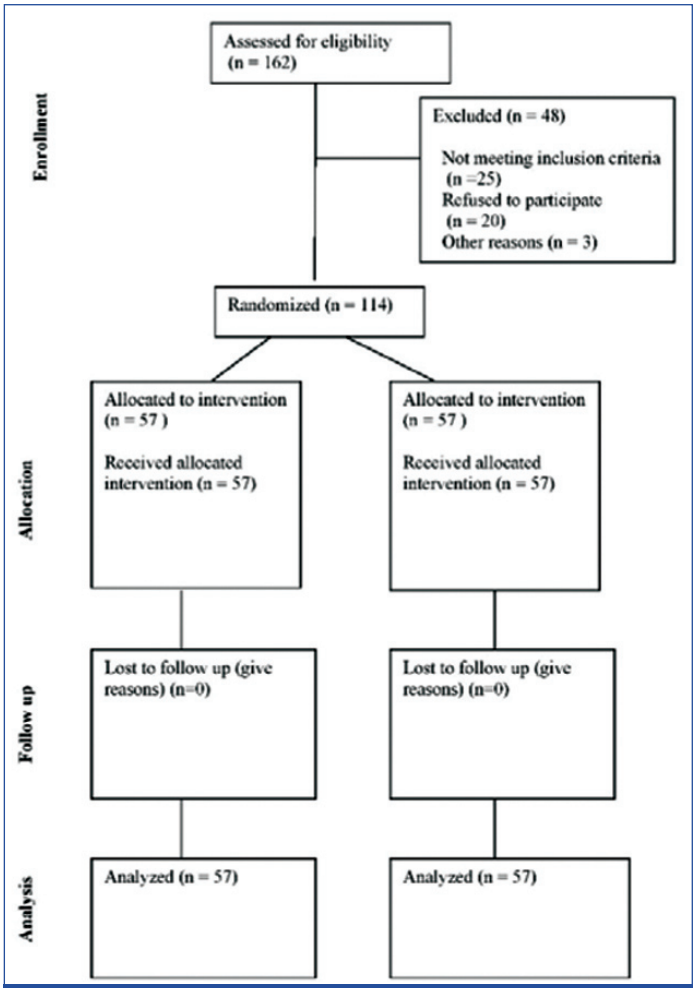
The present randomised, parallel group, active controlled trial was conducted in a hospital after obtaining Ethical Approval (IEC code number- 2021-001 DT-39) from Institute's Ethical Committee and it was registered in CTRI (CTRI registration number-CTRI/2021/11/038113). Females were enrolled from 01/12/2021 to 01/12/2022 on basis of inclusion criteria and exclusion criteria. Eligible females who were willing to participate in study and gave written informed consent were recruited.

Sample size calculation: 114 sample size was calculated using G* power analysis keeping an effect size of 0.61 (taken from previous study) with Type 1 error at 0.05 and power at 0.88. Each group comprised of 57 participants [14].

Inclusion criteria: (1) 18-45 years of age; (2) not following any lifestyle modification program or on medication for PCOS since past six months; (3) as per International classification of WHO, BMI≥18.5 [14,15]; (4) non-pregnant and satisfy Rotterdam criteria of PCOS (to include 2 of 3 criteria in addition to exclusion of related disorder: (i) oligo-anovulation; (ii) clinical and/or biochemical signs of hyperandrogenism (iii) polycystic ovaries); (5) willing to participate in the study [3]. EDDS was used as a screening tool for females satisfying above criteria. Females meeting any 2 out of 3 features were eligible for the study: (1) 'yes' response to item 5; (2) 'yes' response to item 6; (3) score>2 to item 7 along with '0' response to items 15 to 18 [11].

Exclusion criteria: (1) pregnant females; (2) females of <18 or >45 years of age; (3) females having BMI <18.5; (4) females not diagnosed PCOS on basis of Rotterdam criteria; (5) females not meeting EDDS screening criteria; (6) following any lifestyle modification program or on medication for PCOS since past 6 months; and (7) not willing to participate in the study.

A total of 137 females were found eligible after screening but 23 refused to take part in study. A total of 114 eligible females who agreed for signed informed consent were randomly divided into two groups after the baseline assessment- experimental group and control group [Table/Fig-1]. All outcome measures were recorded before start of intervention and after end of intervention.



[Table/Fig-1]: Consort Diagram of the study.

Experimental Group

Aerobic exercises and strengthening exercises were performed alternately.

Aerobic exercises:

- Intensity: Depending on participants' activity level, initially intensity of exercises is kept light (40-55% of maximum heart rate) or moderate (55-70% of maximum heart rate, where maximum heart rate= 220-age of a person) and progressed weekly by 5%. Exercises were done on treadmill and stationary bicycle with a predetermined target heart rate.
- Duration: 60 minutes of exercise session (10 minutes warm up, 40 minutes exercises and 10 minutes cool down). At home, participants did brisk walking/jogging for 60 minutes [16,17].

Strengthening Exercises

- Intensity: Three sets of 10 repetitions of each exercise with two/three minutes of rest between sets. Progression of load is based on successful completion of three sets of 12 repetition of that load.
- Duration: 60 minutes (10 minutes warm up, 40 minutes exercises and 10 minutes cool down). In first two weeks, 50-60% of one repetition maximum load was used. In week 3 to 12, 65-75% of one repetition maximum load was used [17-19].

Diet Counselling

Participants visited dietician once a week for 12 weeks for a diet counselling session of 30 minutes during their visit to hospital. Session included diet modification tips: low calorie diet is achieved either with high protein intake or high carbohydrate intake. Increased dietary fiber, green vegetables and reduced high refined carbohydrates were advised. It was also suggested to replace fat to Polyunsaturated Fatty Acids (PUFA) and low glycaemic index food items. They were encouraged to avoid juices, cold drinks and transfats; and suggested that food should be eaten in absence of distractions like TV, mobile phone etc., 4-5 times a day at regular intervals without skipping the meal [20,21]. Failures or barriers in following these modifications were addressed in next subsequent visits.

Rajyoga Meditation

In 30 minutes, session participants were taught about the soul and supreme soul. They were taught to concentrate on supreme being and his divine attributes to pull in His energy. Slowly worldly thoughts reduce and mind realises truth of being. With continued

practice inner powers of the soul awaken and mind fulfills with love, peace and happiness. As taught by Brahmakumaris World Spiritual University, Rajyoga meditation can be practiced anytime, anywhere sitting quiet and comfortable with eyes open keeping mind and body relaxed [22-24]. Participants practiced 15 minutes meditation three times a day, i.e., early morning as soon as they get up, in the afternoon and just before sleep at night. The meditation commentary was phrased by senior Rajyoga teacher who has experience in teaching Rajyoga for 20 years. Meditation commentary was narrated by principal investigator once a week during participants' hospital visit. Participants were motivated to perform exercises, follow diet modifications and practice meditation regularly.

Control Group

The participants of control group visit hospital once a week. They were given one diet counselling session and one meditation session for 30 minutes each same as experimental group. Failures/barriers in following instructions were discussed in each subsequent visit.

Outcome measures

Weight, EAT score, BITE symptoms score and BITE severity score were primary outcome measures. BMI, Waist Circumference, Hip Circumference and WHR were the secondary outcome measures. Waist circumference was measured in centimeters (cm) using simple measuring tape at point midway between lower margin of last palpable rib and top of iliac crest. Hip circumference was measured in centimeters (cm) using same simple measuring tape at widest intertrochanteric distance keeping tape parallel to the floor. WHR was calculated using following formula

WHR=Waist circumference (cm)/ Hip circumference (cm) [25]

Questionnaire for screening eating disorder

EAT-26 (Eating Attitudes Test): It is a 26-item screening tool with 3 subscales namely dieting; bulimia and food preoccupation and oral control. Score>20 indicates individual is susceptible to developing an eating disorder [26]. In the present study, females meeting any two out of three features were eligible for the study: (1) 'yes' response to item 5; (2) 'yes' response to item 6; (3) score>2 to item 7 along with '0' response to items 15 to 18.

BITE score (Bulimic Investigatory Test, Edinburgh): It is a measure of 33 items divided into 2 subscales-the symptom scale and the severity scale that helps in identifying presence and severity of bulimia or binge eating disorder with a maximum score of 30. It includes 30 yes/no type questions and 3 graded-responses type questions. Total score for all questions provides symptom score (score ≥15 signifies you have a lot of thoughts and attitudes consistent with an eating disorder) and scores for questions 6, 7 and 27 gives severity index (score ≥5 signifies an eating disorder) [26].

EDDS scale (Eating Disorder Diagnostic Scale): It includes 22 questions consisting diagnostic scale to diagnose anorexia nervosa, bulimia nervosa and binge eating disorder and symptom composite scale to assess overall level of eating pathology. A 'yes' response to item five and item six and score >2 to item seven indicates regular binge eating [27,28].

STATISTICAL ANALYSIS

Data were analysed on basis of intention to treat analysis. Data were summarised in mean±standard deviation (SD). Shapiro-Wilk test was used for normality check. Data were found to be non-normally distributed. Within group analysis (pre-test vs. post-test) was performed using Wilcoxon signed-rank test. The between group differences were compared (experimental vs. Control) using Mann-Whitney U test. Analysis was done using IBM SPSS Statistics 22.0. Percentage change was calculated using Microsoft Excel. The p-value of <0.05 was considered statistically significant.

RESULTS

A total of 137 patients satisfied inclusion criteria, of whom, 23 withdrew before initiating the trial. 114 participants were randomised into two groups of 57 each [Table/Fig-1]. At 12 weeks all participants (mean age 26.35±4.97 years, mean weight 73.53±16.73 kg, mean WHR 0.88±0.04 and mean BMI 28.81±5.90 kg/m^2) completed the study with more than 80% attendance, hence included in post-intervention data analysis [Table/Fig-2]. The study shown there was reduction in weight, BMI and binge eating symptoms in both the groups.

Anthropometric data	Mean±SD
Age (years)	26.35±4.97
Weight (kg)	73.53±16.73
BMI (kg/m^2)	28.81±5.90
WHR (waist-hip ratio)	0.88±0.04

[Table/Fig-2]: Characteristics of all participants in the study.

Effect on weight, BMI and WHR

Reduction in weight, BMI and waist circumference was statistically significant within both groups (pre-test and post-test) while reduction in hip circumference and WHR was statistically significant only in experimental group (pre-test and post-test). This indicated both interventions were effective in weight loss and reducing BMI. However, experimental group achieved statistically significant reduction in WHR [Table/Fig-3].

[Table/Fig-4] revealed weight and BMI change was -4% in experimental group which was double as compared to -2% in control group (p<0.001). In experimental group reduction in waist circumference was seven times and hip circumference was six times more than in control group (p<0.001). WHR achieved -1% reduction in experimental group while it was 0% in control group (p<0.001).

Effect on EAT score and BITE score

Reduction in EAT score and BITE score was statistically significant in both the groups (pre-test vs. post-test; [Table/Fig-5]). [Table/Fig-6] represented EAT score in experimental group and control group has reduced -5% and -7.08% (p=0.050) respectively although it was not statistically significant. BITE symptom score in experimental group and control group has significantly decreased by -9% and -5%, respectively (p<0.001). A significant reduction in BITE severity score was also noted in both the groups, 27% in experimental group and -22% in control group (p=0.0242).

Anthropometric measurement	Experimental Group (mean±SD)		p-value	Control Group (mean±SD)		p-value
	Pretest	Post-test		Pre-test	Post-test	
Weight (kg)	73.61±15.40	70.77±15.28	0.0001*	73.45±18.11	72.23±17.98	≤0.001*
BMI (kg/m^2)	28.62±5.55	27.51±5.50	0.0001*	28.99±6.27	28.52±6.24	≤0.001*
Waist circumference (cm)	85.73±9.41	79.67±8.90	0.0001*	86.93±9.24	86.12±9.50	≤0.001*
Hip Circumference (cm)	96.02±9.76	90.59±9.34	0.0001*	98.30±8.94	97.50±8.98	0.015*
WHR	0.89±0.03	0.88±0.04	0.001*	0.88±0.05	0.883±0.05	0.888

[Table/Fig-3]: Weight, BMI and WHR of participants at baseline (pre-test) and after 12 weeks (post-test) in experimental group and control group.
*p<0.05 is statistically significant

Anthropometric measurements	Experimental group mean diff. score (pre-post)	%change (pre-post)	Control group mean diff. score (pre-post)	%change (pre-post)	Mann-Whitney U	Mann-Whitney on diff score between groups (sig.)
Weight (kg)	2.84±1.65	-4%	1.21±1.09	-2%	524.000	≤0.001*
BMI (kg/m^2)	1.10±0.63	-4%	0.478±0.42	-2%	521.500	≤0.001*
Waist circumference (cm)	6.05±1.22	-7%	0.81±1.22	-1%	0.000	≤0.001*
Hip circumference (cm)	5.43±2.65	-6%	0.80±2.85	-1%	326.500	≤0.001*
WHR	0.01±0.02	-1%	0.00±0.02	0%	1033.000	≤0.001*

[Table/Fig-4]: Percentage change in weight, BMI and WHR of participants after 12 weeks in experimental group and control group.
*p<0.05 is statistically significant

Questionnaire Scores	Experimental group		p-value	Control Group		p-value
	Pre-test	Post-test		Pre-test	Post-test	
EAT score	20.15±1.33	19.03±0.77	0.0001*	20.71±1.58	19.19±0.93	≤0.001*
BITE symptoms score	14.24±2.77	12.73±1.95	0.0001*	14.33±2.44	13.57±2.17	≤0.001*
BITE severity score	5.37±1.45	3.91±1.46	0.0001*	4.92±1.35	3.85±1.27	≤0.001*

[Table/Fig-5]: Scores of questionnaires at baseline (pre-test) and after 12 weeks (post-test) in experimental group and control group.
*p<0.05 is statistically significant

Questionnaire Scores	Experimental group		Control group		Mann-Whitney U	Mann-Whitney on diff score between groups (sig.)
	Diff. Mean Score (pre-post)	% change (pre-post)	Diff. Mean Score (pre-post)	% change (pre-post)		
EAT score	1.12±1.03	-5%	1.52±1.07	-7.08%	1956.00	0.050
BITE symptoms score	1.50±1.26	-9%	0.75±0.57	-5%	1060.000	≤0.001*
BITE severity score	1.46±0.00	-27%	1.07±0.08	-22%	1981.000	0.0242*

[Table/Fig-6]: Percentage change in questionnaire scores of participants after 12 weeks in experimental group and control group.
*p<0.05 is statistically significant

DISCUSSION

In 2019 a systematic review emphasised need to develop holistic approach based weight management strategies that can also deal with disordered eating in PCOS females [6]. Significant weight loss, decrease in BMI and WC reduction in experimental group (performing exercises plus diet modifications and meditation) as well as control group (following diet modifications plus meditation) is similar to other short duration (≤12 weeks) trials comprising weight loss interventions conducted on PCOS females [29-31]. On basis of limited evidence a systematic review reported that there is no significant difference in effectiveness of lifestyle modifications or weight loss interventions in women with and without PCOS [32].

In a 12-month RCT, 439 postmenopausal women with BMI≥25 kg/m^2 were randomised to four groups namely: (1) diet (n=118); (2) exercise (n=117); (3) diet + exercise (n=117); (4) control (n=87). Participants following dietary intervention alone had significant reduction in binge eating (-23.7%, p = 0.005 vs. control). The mean change in weight was -8.5% (p < 0.001) in diet group, -2.4% (p=0.03) in the exercise group, -10.8% (p < 0.001) in the diet + exercise group and –0.8% in the control group [33]. In this study, maximum weight loss was achieved in diet + exercise group followed by diet group. This is in line with our present study where weight loss was almost double in experimental group than control group.

In another 6-month RCT involving 139 young healthy adults (68.35% women) with mean age of 22.06±2.26 years and mean BMI of 24.95±4.57 kg/m^2 were randomised into three groups: control group following usual lifestyle, moderate-intensity aerobics plus resistance exercise group; and vigorous intensity aerobics plus resistance exercise group. The study revealed eating behaviour traits were not altered by either exercise regimen [34]. Earlier studies also mentioned that exercises alone don't have impact on eating disorders which indicated that reduction in binge eating in our participants was because of including diet counselling and meditation.

In 2020, 19 females with BED completed a 6-month trial where Control (CTRL) group received diet and Cognitive Behavioural Therapy (CBT) while CAAET group received combined aerobic and anaerobic exercise training along with diet and CBT. In both groups, there was a significant decrease in binge episodes, weight, and BMI. In CTRL group, decrease in scores was-BES (score) 23±9 to 15±7, BITE symptom score 14±6 to 9±3 and BITE Severity (score) 9±7 to 6±4. Also, change in weight was 107±32 to 102±28 and BMI was 38±10 to 36±9. On the other hand, in Combined Aerobic and Anaerobic Exercise Training (CAAET) group this decrease was-BES (score) 23±10 to 10±8 (p<0.05), BITE symptom score 15±7 to 7±4 (p<0.05), BITE Severity (score) 8±7 to 3±3 (p<0.05), weight 101±21 to 87±14 and BMI 38±6 to 32±3. Authors suggested that both groups showed similar improvements in BED symptoms and exercises were useful in maintenance of reduction in weight and BED symptoms for long term which was similar to our study [35].

Another 16 week trial revealed 30-50% of participants shown equal improvements PED-t group (exercises plus diet) and CBT group in reducing binge eating from baseline to post treatment (p<0.001) [36]. These results were comparable to present study in which both the groups have shown improvement in binge eating symptoms.

In a RCT, patients admitted in hospital for Coronary Artery Bypass Grafting (CABG) were randomly divided into two groups: Rajyoga group (n=73) who underwent Rajyoga meditation training and control group (n=74) who did not receive any meditation training. Anxiety was reduced in Rajyoga groups significantly than control group on 2nd postoperative day (3.12±1.45 vs.6.12±0.14, p<0.05) and 5th postoperative day (0.69±1.1 vs. 5.6±1.38, p<0.05). Rajyoga group also shown serum cortisol level modulation more favourably than control group (p<.05) [37]. In a cross-sectional study happiness scores and self-satisfaction scores of regular Rajyoga meditators (n=25) were significantly higher (t=5.88, df= 48, p<0.001; t=4.47, df=48, p<0.001) as compared to those of non-meditators (n=25) of age-group 42.95±15.29 [38]. Rajyoga meditation was also found to be effective in reducing anxiety, depression, anger, increasing sense of well-being and reversing progression of coronary artery disease as shown by angiography in regular meditators [22].

Some of the psychological therapies suggested for disordered eating are Family Based Treatment (FBT), Multifamily Therapy (MFT), CBT, Specialised Clinical Supportive Management (SSCM), psychodynamic therapy, interpersonal therapy and behaviour

therapy [39]. Results indicate that this 3-dimensional approach can also be used for managing binge eating symptoms. A 16 week pilot study of lifestyle modifications revealed that WHR in women with PCOS observed in the post-test 2 (2nd month), post-test 3 (4th month), and post-test 4 (6th month) reduced significantly (p-value <0.001) which is in line with this study [40].

The effects of diet counselling and Rajyoga meditation with and without exercises are significant in PCOS females having binge eating symptoms seeking weight loss treatment. It may prove beneficial for this population. At the same time, it can be used to replace CBT. The study can be replicated with larger sample size, with only overweight and/or obese PCOS females having binge eating symptoms, for longer duration of interventions and follow up by different researchers and professional healthcare experts dealing with PCOS females.

PCOS females who need to lose weight and also suffer from binge eating symptoms may be managed using 3-dimensional approach of exercises, diet modification and Rajyoga meditation. It involves diet modifications instead of strict diet restriction or calorie restriction which can be followed by this population for longer duration and with more compliance. Moreover, positive thoughts during meditation helps to break vicious circle of - negative self -perception related to weight gain, physical appearance and infertility in PCOS, strict diet for some time to lose weight and achieving little weight loss, overeating due to dietary restraint, leading to binge eating and long-term weight gain.

Limitation(s)

For clinically significant improvements in PCOS related symptoms approx. 5-10% of initial weight loss is needed but this study shows statistically significant 4% weight loss in experimental group. Researchers were not blinded to assigned groups which could be one of the confounding factors as it can lead to biasness of measuring or reporting outcomes. Other factors like environmental or genetic may also alter the true effect of intervention given. Participants filled the questionnaire pre-intervention; there are chances that they might have answered differently post-intervention as they became familiar with questions. Moreover, this study doesn't involve follow up of participants.

CONCLUSION(S)

The present study shows there is statistically significant reduction in weight, BMI and binge eating symptoms in both groups. However, exercises plus diet counselling and Rajyoga meditation shows greater improvements than diet counselling and Rajyoga meditation. In future, the study can be replicated with larger sample size, with only overweight and/or obese PCOS females having binge eating symptoms, for longer duration of interventions and follow up by different researchers and professional healthcare experts dealing with PCOS females.

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