Improvement In Health-Related Quality of Life in Polycystic Ovarian Syndrome: A Randomized Controlled Trial

Renuka Jakhar[1]; Elina Dewanji Sen[1]; Preeti Rastogi[2]

[1] School of Medical and Allied Sciences, GD Goenka University, Gurugram.

[2] Department of Obstetrics and Gynaecology, Fortis Memorial Research Institute, Sector-44, Gurugram.

Abstract

Background: Various studies have reported poor health related quality of life (QOL) in females diagnosed with polycystic ovarian syndrome (PCOS) as compared to their healthy counterparts. Weight loss is the key component in management of PCOS and most often impact of PCOS on QOL is not addressed in these females. Aims: To develop a management strategy which can improve health related quality of life (QOL) in PCOS females. Methods and materials: 114 PCOS females were randomly divided into experimental group (n=57, exercise, diet counselling and Rajyoga meditation) and control group (n=57, diet counselling and Rajyoga meditation). Polycystic Ovary Syndrome Questionnaire (PCOS-Q) score was assessed before and after 12 weeks of interventions. Results- IBM SPSS Statistics 22.0 was used for analysis with two tailed $p<0.05$ statistically significant. Reduction in all 5 domains of PCOS-Q was statistically significant within both groups (pre-test and post-test, $p<.05$). Conclusions: The study shown statistically significant improvement in health related QOL in both the groups.

Keywords: polycystic ovarian syndrome, exercises, quality of life, PCOS-Q

Introduction

Polycystic ovarian syndrome (PCOS) is most common endocrine disorder of reproductive age females. Its prevalence varies from 15% to 21% on basis of diagnostic criteria used across the world. It is presented with wide range of features which can be categorised into metabolic, reproductive and psychological features (Pramodh, 2020). Majority of anovulatory females seeking treatment for infertility also suffer from PCOS (Hillman *et al.*, 2020). Most common problems encountered by these females are menstrual irregularities, acne, alopecia, hirsutism, insulin resistance with compensatory hyperinsulinemia, impaired glucose intolerance, metabolic syndrome, type 2 diabetes, obesity, sleep apnoea, negative body image, anxiety, depression, poor quality of life and eating disorders. PCOS is also a risk factor for gestational diabetes, spontaneous miscarriage in first trimester of pregnancy (Dennett and Simon, 2015), heart attack, cardiovascular disease (Azizi and Elyasi, 2017), endometrial hyperplasia and non-alcoholic fatty liver disease (Burnatowska *et al.*, 2023). Various studies suggest that calorie restricted diet for weight loss can also adversely impact QOL, decrease energy and result in easy fatigue (Booth, Wang and Turner, 2018).

The treatment guidelines presently focus on weight management in PCOS through caloric restrictions, strict diet and lifestyle modifications. But at the same time it is more important to identify females with poor quality of life and face difficulty to cope up various activities at home and workplace. Thus aim of this randomised

controlled trial was to determine effect of 12 weeks of exercises, Rajyoga meditation and diet counselling on QOL in PCOS females.

Materials and methods

Subjects and study design

In a tertiary care hospital in Gurugram, females diagnosed with PCOS and referred by the gynaecologist were considered for the study on basis of inclusion and exclusion criteria. Inclusion criteria for females—(1)18-45 years of age (2) not following any lifestyle modification program or on medication for PCOS since past 6 months (3) BMI≥18.5 (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. Exclusion criteria were not meeting inclusion criteria. Eligible females who agree for signed informed consent were randomly divided into two groups after the baseline assessment- Experimental group and Control group.

Sample size calculation

114 sample size was calculated using G* power analysis keeping an effect size of 0.61 with Type 1 error at 0.05 and power at 0.88. Each group comprised of 57 participants.

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% (Lim *et al.*, 2016). 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.

Strengthening Exercises

Intensity: 3 sets of 10 repetitions of each exercise with two/three minutes of rest between sets. Progression of load is based on successful completion of 3 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.

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 glycemic index food items (Thakur and Masand, 2018). A list of protein rich food items; high carbohydrate food items; high refined carbohydrates;

low/medium/high glycemic index food items and PUFA food items was provided to participants. 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 (Jakubowicz *et al.*, 2013). Failures/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 realizes truth of being (Gupta *et al.*, 2011) . With continued practice inner powers of the soul awaken and mind fulfills with love, peace and happiness (Sukhsohale *et al.*, 2012). As taught by Brahmakumaris World Spiritual University, Rajyoga meditation can be practiced anytime, anywhere sitting quite and comfortable with eyes open keeping mind and body relaxed (Rajoria and Singh, 2017). 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.

Polycystic Ovary Syndrome Questionnaire (PCOS-Q)

It is a validated tool consisting 26 items grouped in 5 domains: emotions, body hair, weight, infertility and menstrual problems. A 7 point scale is used to score each question where 7 indicate optimal function and 1 indicate poorest function. Score<5 of any domain represents adverse impact (Jones *et al.*, 2004).

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. P value of <0.05 was considered statistically significant.

Result

137 patients satisfied inclusion criteria, of whom, 23 withdrew before initiating the trial. 114 participants were randomized into two groups of 57 each (Figure 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 1). The study shown there was improvement in QOL in both the groups.

Table 2 reveals significant increase in score for all 5 domains of PCOSQ (p<.001 in all domains of experimental group and control group except p=.004 for infertility domain in control group). More the score in questionnaire lesser is impairment.

After 12 weeks of intervention, changes in all domains of PCOSQ are significantly different between the two groups except domain of body hair (Table 3). Domains of emotion and menses in experimental group improved more than twice as compared to control group (p<.001). In infertility domain this improvement is more than thrice in experimental group than control group (p<.001). Moreover improvement in domain of weight was also significantly more in experimental group (p=.041).

Discussion

Present study shows there was significant increase in score of all domains of PCOS-Q in both groups. Moreover, experimental group has shown significantly more improvement than control group in all domains except body hair. This result is in line with another study conducted in 2018 where PCOS women (age group 27-33years) followed lifestyle modification along with cognitive behavioural therapy improved more than females following lifestyle modifications alone (+3.7 vs. + 1.2 points) for 8 weeks (Cooney *et al.*, 2018). In 2017, a trial reported significantly more improvement in PCOS females allocated to herbal medicine and lifestyle group as compared to lifestyle group alone for all domains of PCOS-Q (Arentz *et al.*, 2017).

In another study (2016) PCOS females were randomised into three groups namely, DA (diet and aerobic exercise), DC (diet and combined aerobic and resistance exercise) and DO (diet only). All groups have shown significant improvement in all domains of PCOS-Q after 20 weeks except body hair (Thomson *et al.*, 2010).

To our knowledge this is the first RCT to investigate effect of exercises (aerobic exercises and strengthening exercises), diet counselling and Rajyoga meditation on health related QOL in PCOS females. Improvement in all domains of PCOS-Q (except body hair) was greater after exercises plus diet counselling and Rajyoga meditation as compared to diet counselling and Rajyoga meditation. It comprises “real world” diet which is not restricted to strict diet of laboratory or research environment. Rajyoga meditation helps in creating attentive positive thoughts, positive perception towards self, disease and the life. Small sample size and no follow up of participants is limitation of this study.

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.

Our study shows there is statistically significant improvement in all domains of PCOS-Q in both groups. However, exercises plus diet counselling and Rajyoga meditation shows greater improvements than diet counselling and Rajyoga meditation. And there is no significant difference in domain of body hair across groups.

Table 1: Characteristics of all participants in the study:

Anthropometric data	Mean ±SD
Age (yrs)	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 2: Result on questionnaire Polycystic Ovary Syndrome Questionnaire (PCOS-Q) within groups (pre vs post):

Domains of PCOS-Q	Experimental Group (mean ± SD)		p value	Control Group (mean ± SD)		p value
	Pre-test	Post-test		Pre-test	Post-test	
PCOSQ-emotion	4.57±1.54	5.23±1.28	<.001*	4.85±1.32	5.12±1.23	<.001*
PCOSQ-menses	4.42±1.50	5.62±1.14	<.001*	4.92±1.52	5.43±1.19	<.001*
PCOSQ-infertility	3.98±1.66	4.64±1.43	<.001*	3.13±1.90	3.30±1.81	.004*
PCOSQ-weight	3.16±1.81	4.13±1.69	<.001*	2.77±1.77	3.44±1.61	<.001*
PCOSQ-body hair	4.14±2.25	4.35±2.05	<.001*	4.46±1.90	4.65±1.73	<.001*

*p<0.05

Table 3: Result on questionnaire PCOS-Q across groups (experimental vs control):

Domains of PCOS-Q	Experimental Group diff. Score (pre-post)	% change (pre-post)	Control Group diff. Score (pre-post)	% change (pre-post)	Mann-Whitney on diff score b/w groups
PCOSQ-emotion	-0.65±0.58	14%	-0.27±0.19	6%	<.001*
PCOSQ-menses	-1.19±0.94	27%	-0.51±0.55	10%	<.001*
PCOSQ-infertility	-0.66±0.86	17%	-0.17±0.42	5%	<.001*
PCOSQ-weight	-0.97±0.78	31%	-0.67±0.57	24%	.041*
PCOSQ-body hair	-0.21±0.28	5%	-0.18±0.30	4%	.741

*p<0.05

References

Arentz, S. *et al.*, 2017. Combined Lifestyle and Herbal Medicine in Overweight Women with Polycystic Ovary Syndrome (PCOS): A Randomized Controlled Trial. *Phytotherapy Research*, 31(9),1330–1340.

Azizi, M. and Elyasi, F., 2017. Psychosomatic Aspects of Polycystic Ovarian Syndrome : A Review. *Iranian Journal of Psychiatry and Behavioral Sciences*, 2017, 11(2), e6595.

Booth, A. O., Wang, X. and Turner, A. I., 2018. Diet-Induced Weight Loss Has No Effect on Psychological Stress in Overweight and Obese Adults : A Meta-Analysis of Randomized Controlled Trials. *Nutrients*, 2018,10, 613.

Burnatowska, E. *et al.*, 2023. Emotional Eating and Binge Eating Disorders and Night Eating Syndrome in Polycystic Ovary Syndrome—A Vicious Circle of Disease: A Systematic Review. *Nutrients*, 15, 295.

Cooney, L. G. *et al.*, 2018. Cognitive-behavioral therapy improves weight loss and quality of life in women with polycystic ovary syndrome: a pilot randomized clinical trial. *Fertility and Sterility*, 110(1),161-171.

Dennett, C. C. and Simon, J., 2015. The role of polycystic ovary syndrome in reproductive and metabolic health: Overview and approaches for treatment. *Diabetes Spectrum*, 28(2), 116–120.

Gupta, S. K. *et al.*, 2011. Regression of coronary atherosclerosis through healthy lifestyle in coronary artery disease patients--Mount Abu Open Heart Trial. *Indian heart journal*, 63(5), 461–469.

Hillman, S. C. *et al.*, 2020. Women's experiences of diagnosis and management of polycystic ovary syndrome: A mixed method study in general practice. *British Journal of General Practice*, May, e322–e329.

Jakubowicz, D. *et al.*, 2013. Effects of caloric intake timing on insulin resistance and hyperandrogenism in lean women with polycystic ovary syndrome. *Clinical Science*, 125(9), 423–432.

Jones, G. L. *et al*, 2004. The Polycystic Ovary Syndrome Health-Related Quality of Life Questionnaire (PCOSQ): A validation. *Human Reproduction*, 19(2), 371–377.

Lim, A. J. R. *et* al, 2016. Sleep Duration, Exercise, Shift Work and Polycystic Ovarian Syndrome-Related Outcomes in a Healthy Population: A Cross-Sectional Study. *PloS one*, 11(11), p. e0167048.

Pramodh, S., 2020. Exploration of lifestyle choices, reproductive health knowledge, and polycystic ovary syndrome (Pcos) awareness among female emirati university students. *International Journal of Women's Health*, 12, 927–938.

Rajoria, K. and Singh, S. K., 2017. Therapeutic benefits of Raj yoga – a review. *Indian Journal of Traditional Knowledge*, 16 (June 2017), S88–S95.

Sukhsohale, N. D. *et al.*, 2012. Does Raja Yoga meditation bring out physiological and psychological general well being among practitioners of it?. *International Journal of Collaborative Research on Internal Medicine and Public Health*, 4(12), 2000–2012.

Thakur, J. and Masand, S., 2018. A Review on Life Style Modification: the Mainstay in

Polycystic Ovarian Syndrome. *International Journal of Research in Ayurveda and Pharmacy*, 9(3), 8–12.

Thomson, R. L. *et al.*, 2010. Lifestyle management improves quality of life and depression in overweight and obese women with polycystic ovary syndrome. *Fertility and Sterility*, 94(5),1812–1816.