Original Article

Individualised Lifestyle Intervention in Polycystic Ovarian Syndrome Women Who Desire Fertility: A Feasibility Study

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Abstract

Background: Polycystic ovarian syndrome (PCOS) is one of the common causes of anovulatory infertility among women in the reproductive age group. Women with PCOS and obesity often have difficulty in conceiving, and they are more prone for developing metabolic syndrome. Lifestyle modification plays a key role in women with PCOS, who are overweight or obese and is recommended as a first line management option. The earlier trials evaluating the role of lifestyle intervention in infertile PCOS women had methodological issues, smaller sample size and high dropout rates and none of these trials reported live birth as their outcome. **Aim:** The current study was planned to explore the feasibility of conducting large adequately powered multicentric trial in future in South Asian women with PCOS who desire fertility. **Setting and Design:** The study was done in the Department of Reproductive Medicine and Surgery & the Department of Endocrinology and Metabolism at a university level tertiary care hospital. The study is an open label, single center, randomized controlled trial. **Materials and Methods:** A total of 60 PCOS women aged between 18-40 years with body mass index of > 23 kg/m2 who desire fertility, were randomized to individualized lifestyle intervention and usual care. The primary outcome was the dropout rate, and the secondary outcomes were change in body weight, anthropometric parameters, clinical pregnancy rates and the quality of life specific to PCOS after the trial period. All the participants were followed up for 6 months and the outcomes were assessed. **Statistical Analysis:** Comparison between the intervention and control groups was done using statistical tests using the SPSS and R software. **Results:** The dropout rates were significantly higher in the individualized lifestyle intervention arm compared to usual care control arm (19/30, 63% vs 9/30, 30%, *P*=0.019). We did not find any statistically significant difference in anthropometric measurements, pregnancy rates (*P*=0.57) and clinical pregnancy rates (*P*=0.21) and quality of life specific to PCOS compared with sixth month visit from baseline visit. **Conclusion:** The current feasibility study showed significantly higher dropout rates in individualized lifestyle intervention arm compared to usual care control arm. The knowledge gained from the feasibility study has been used to design an adequately powered trial to evaluate effectiveness of individualized lifestyle intervention in women with PCOS who wish to conceive.

Keywords: *Dropout rate, feasibility, individualised lifestyle intervention, pilot study, polycystic ovarian syndrome, usual care*

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Introduction

Polycystic ovarian syndrome (PCOS) is one of the common causes of anovulatory infertility amongst women in the reproductive age group. The reported prevalence of PCOS is approximately 12% when diagnosed using the Rotterdam criteria.[1] Obesity has an association with PCOS and has been known to increase the risk of metabolic syndrome and cardiovascular diseases in women diagnosed with PCOS.[2] Women with PCOS and obesity often have difficulty in conceiving and those who conceive, experience a higher risk of gestational diabetes, gestational hypertension, preeclampsia and dysfunctional labour compared to women without PCOS.[3] Therefore, lifestyle modification plays a key role in women with PCOS, who are overweight or obese, and is recommended as a first-line management option.[4,5]

Lifestyle interventions are defined as modifications in diet, exercise and behavioural patterns aimed at improving the metabolic profile.[6] Earlier studies including randomised controlled trials (RCTs) have suggested that lifestyle interventions help in improving the menstrual pattern, metabolic parameters and the chances of conception in infertile PCOS women.[6-8] The trials evaluating the role of lifestyle intervention in infertile PCOS women had methodological issues, smaller sample size and high dropout rates. Some of these trials have reported attrition rates, ranging between 18% and 46% and none of the trials have reported live birth as an outcome.[9-11]

There is an ethnicity-related difference in the prevalence of PCOS with higher prevalence reported among South Asian women compared to East Asian and Caucasian women.[12,13] In addition, there are distinct androgenic phenotypes associated with PCOS, characterised by central obesity, which is more common in women from South Asia compared to PCOS women from East Asian and European countries.[14] In contrast, women from East Asian countries show a higher prevalence of PCOS phenotype characterised by irregular menstrual cycles and polycystic ovaries.[15] Compared to East Asian women, South Asian women have a higher prevalence of metabolic syndrome.[15,16] They also tend to accumulate more visceral fat, even when they are not overweight or obese and this less common phenotype may be missed by most physicians which may affect their fertility treatment plans.[17] Furthermore, lifestyle advice uptake in the South Asian population is complicated by the difficulty to change the conventional carbohydrate-rich diet, limited space for physical activity as well as associated social stigma which may hinder the uptake of medical advice.[18,19] The unique challenges in the South Asian context and limited health resources highlight the need for studying the impact of a simple yet structured lifestyle intervention in women with PCOS and infertility.

We decided to plan a feasibility study to explore the possibility of conducting a larger adequately powered trial investigating the lifestyle intervention in infertile PCOS women who are keen to conceive. It is also important to identify the possible reasons for discontinuation of the intervention (dropout), and in some cases, non-compliance to the lifestyle advice amongst the participants; hence, we also planned a separate qualitative arm nested within the proposed feasibility study. It is important to note that the current study is not powered to investigate the effectiveness of the intervention or the lack of it. However, the study has helped in designing a larger RCT to evaluate the effectiveness of lifestyle modification in the South Asian PCOS population.[20]

Materials and Methods

Design and setting

A feasibility study was planned to explore the possibility of lifestyle intervention in women with PCOS who wished to conceive at the Department of Reproductive Medicine and Surgery and the Department of Endocrinology and Metabolism at Christian Medical College, Vellore, India, which is a tertiary-level hospital. The study was an open-label, single-centre, RCT. The study was initiated in August 2021 and the planned study period was 18 months. The study was conducted in accordance with the ethical standards conforming with the Helsinki Declaration of 2013. The institutional review board (IRB) approved the trial (IRB no 14028 dated July 30, 2021), and the trial was prospectively registered in the Clinical Trial Registry of India (CTRI/2021/12/038831).

Participants

Infertile women between the age group of 18 and 40 years, diagnosed with PCOS according to Rotterdam criteria and a body mass index >23 kg/m^2 were invited to participate in the current trial. Women with severe endometriosis, tubal factor, severe male factor and medical disorders such as ulcerative colitis and Crohn's disease which have special dietary advice, other endocrine disorders such as diabetes, hypothyroidism and diseases that could interfere with physical exercise and any lower limb pathology which precludes exercise, were excluded from the trial. Informed consent was obtained from eligible participants who were willing to join the trial. Those eligible participants who were not willing to participate, who dropped out of the trial after randomisation or were found to be non-compliant during the trial, were invited separately for the qualitative

study, which was nested within the current trial. The participants who were willing to participate in the qualitative arm of the study were directed towards investigators of the qualitative study and the resultant findings were presented as a separate study.

Randomisation

Eligible women who were willing and gave consent were randomised to individualised intervention or usual care control arm in 1:1 ratio, based on computer-generated random number. Allocation concealment was ensured using consecutively numbered, opaque, sealed envelopes and group assignment done by the principal investigator by opening the envelope. Since it was an open-label study, blinding was not feasible.

Study protocol

Individualised lifestyle intervention

Individualised lifestyle intervention involves a customised approach and advice on diet and exercise along with a follow-up and medical treatment as per the existing department protocol for those seeking fertility treatment.

The dietary patterns of the participants were assessed using 24-h dietary recall by a single dietician in the outpatient department. The recall helps to understand the composition of macronutrients, micronutrients as well as the total calories consumed in a day. After the dietary recall, each patient was given an individualised diet plan according to the recent consensus guidelines for the South Asian region.[21] Diet modification included a scaling down of calories consumed per day, refined sugars and fats, avoidance of carbohydrates and inclusion of fibre-rich foods. The participants' dietary compliance was assessed at 3- and 6-month interval using 24-h dietary recall by the dietician in the outpatient department. The physical activity was assessed using global-physical activity questionnaire (G-PAQ) and all the anthropometric measurements taken by a single physiotherapist in the same outpatient setting. Subjects who were engaged in physical activities such as cycling or walking (>30 min/day) as part of their routine were advised to continue the same. Subjects, who are mainly sedentary or are involved in mild physical activity as assessed in the initial interview, were encouraged to have a brisk walk for 30 min each day. This advice shall be individualised to each patient based on their existing weight and physical restrictions. The participants' compliance for physical activity was assessed at 3- and 6-month intervals using the G-PAQ questionnaire. The follow-up period was 6 months for each participant.

Usual care (control)

It involves one-time referral to the dietician for dietary advice and exercise and continuing the medical treatment for fertility as per protocol. There was no planned follow-up for the control arm at 3 months.

For all the study participants, their routine fertility treatment (ovulation induction with oral agents or low-dose gonadotropins) was continued as per the treatment planned by the clinician. All the outcomes were assessed at 6 months directly for all the participants.

Study outcomes

The primary outcome was the 'dropout rate,' which was defined as the number of participants who did not follow-up two amongst the three visits in succession after randomisation per women randomised. The secondary outcomes were changes in anthropometric parameters, i.e., body weight, waist circumference, hip circumference, neck circumference and waist–hip ratio, clinical pregnancy rates and the quality of life specific to PCOS after the trial period.

The pregnancy rate was defined as a number of women with positive pregnancy tests during the study period per women randomised. The clinical pregnancy rate was defined as a number of women with ultrasound-confirmed gestational sac during the study period per women randomised. The pregnancy rates and the clinical pregnancy rates following lifestyle modification and following ovulation induction treatment were analysed. The quality of life which was specific for PCOS women was measured by using PCOS-quality of life questionnaire (PCOS-Q)-specific questionnaire.[22] Five domains were included in the questionnaire, i.e. emotion, body hair, weight, infertility and menstrual irregularities. The women's reply for each question was scored on a Likert 7-point Scale. The final score of each domain was measured by dividing the total score of the domain by the number of items in the domain. Lower scores indicate more problems, and higher scores indicate lesser problems. The follow-up duration for all the participants was 6-month post-randomisation.

Statistical analysis

This pilot study was performed to explore the feasibility of larger RCTs in the future. Hence, the planned sample size was 60 with 30 in each arm. The independent sample *t*-test was used for the analysis of continuous data with normal distribution and the Mann–Whitney *U* test for data with non-normal distribution with groups (intervention and control). The comparison of continuous data of the same individuals at baseline and 6 months was done using a paired *t*-test. A Chi-square/Fisher's exact test was performed for categorical variables within groups. Differences were considered significant at $P < 0.05$. All the statistical analyses were performed using SPSS 25.0 and R (IBM, Chicago, USA).

In 'intention to treat', all randomised participants (n = 30) were included in the analysis irrespective of the dropout rates. In 'per protocol' analysis, we analysed data for those who broadly adhered to the study protocol and reported at 6-month post-randomisation.

Results

Baseline characteristics

After screening an eligible pool of participants, out of those who were willing to participate, a total of 60 women were randomised into the individualised lifestyle intervention (n = 30) and usual care (control, n = 30) groups.

Following randomisation in the intervention arm, eight participants did not attend the baseline visit. At the 3rd-month visit, seven participants attended and 19 participants dropped out and at 6th-month visit, four participants attended, and 19 participants dropped out. A total of seven participants conceived during the 6-month period in the intervention arm [Figure 1].

In the control arm, three participants did not attend the baseline visit, at 6-month visit, 11 participants attended and six dropped out [Figure 1]. A total of 10 participants conceived during the 6-month period in the control arm.

The mean ± standard deviation age, P = 0.89, and body mass index, P = 0.49, of the participants were similar in both groups. The demographic parameters distribution was not significantly different between both groups [Table 1].

Outcomes

There was no significant difference in the anthropometric measurements, including weight,

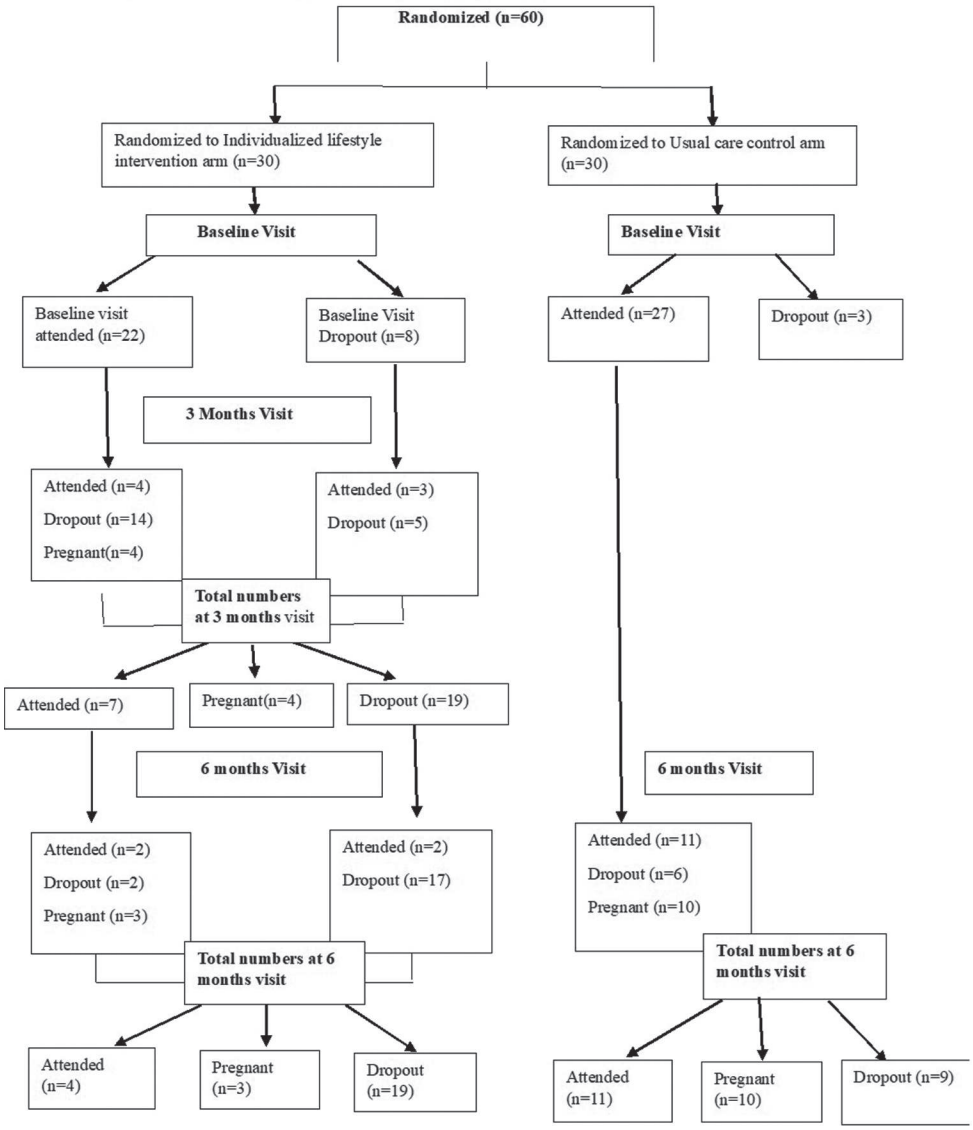

Figure 1: CONSORT flow diagram

waist, hip and neck circumference, as well as waist-to-hip ratio between the intervention and control groups at baseline and during the 6th-month visit [Tables 2 and 3]. This was analysed per protocol (4 participants in the interventional arm and 11 in the control arm). The women who completed the study period in the intervention arm (n = 4) had reduced calorie intake at 6th-month visit compared to the baseline visit (1852.0 ± 351.1 vs. 1766.7 ± 78.2 kcal, P = 0.76) though it was not statistically significant [Table 2]. Physical activity (GPAQ score) showed improvement at the 6th-month visit compared to the baseline visit in the intervention group, but it was not statistically significant (400.5 ± 221.9 vs. 509 ± 168.2 metabolic equivalents [minutes per week = the ratio of the rate of energy expended during an activity to the rate of energy expended at rest], P = 0.78) [Table 2].

The dropout rate was high in individualised lifestyle intervention arm compared to the usual care control arm and which was statistically significant (19/30, 63% vs. 9/30, 30%, P = 0.019) [Table 4]. There was no significant difference in pregnancy rates between the intervention and control groups (P = 0.57) [Table 4]. In the intervention group, 23% (7/30) of women conceived during the study period, with six out of seven pregnancies being clinically confirmed. Amongst these pregnancies, two conceived spontaneously and five were a result of ovulation induction treatment. In the control arm, 33% (10/30) of women conceived, with all 10 pregnancies being clinically confirmed. Out of these, four were spontaneously conceived, and six were a result of ovulation induction treatment. There was no statistically significant difference in clinical pregnancy rates in individualised lifestyle intervention arm compared to the usual care control arm (6/30, 20% vs. 10/30, 33.3%, P = 0.24). The quality-of-life scores were not significantly different amongst the women who completed the study period in the intervention group and the control group [Table 5].

Discussion

In the current feasibility study, a high overall attrition was noted. Furthermore, a significantly higher drop rate was observed in the individualised lifestyle arm compared to the control arm. We did not find any difference in anthropometric parameters or the quality-of-life score at 6 months amongst those participants who completed the trial. While no significant difference was noted in the pregnancy rates following the individualised lifestyle intervention compared to the control, it is important to note that the study was not designed to investigate the effectiveness of the lifestyle intervention.

An RCT (n = 37) conducted in North America to evaluate the effectiveness of a moderate-intensity exercise programme for a period of 16–24 weeks in women with PCOS reported a high drop rate of 62% in the intervention arm and 32% in the control arm. The high dropout rate was attributed to the participant's young age, and their potential obligations in commuting children to school and work.[23] An RCT (n = 161) was conducted in the United Kingdom to evaluate the effect of single exposure of face-to-face structured education programme on overweight and obese PCOS women with a follow-up period of 12 months.[24] The dropout rates were 42% in the intervention arm and 33% in the control arms. In this study, the higher dropouts were

Table 1: Baseline comparison of clinical characteristics between the individualised lifestyle arm (intervention) and usual care (control) arms

	Individualised lifestyle intervention (n=30)	Usual care control (n=30)	$P^{\#}$
Female age (years)*	25.87±3.61	26.0±4.17	0.89
Education, n (%)			
Up to secondary schooling	4 (13.3)	8 (26.7)	0.13
Higher secondary schooling	7 (23.3)	2 (6.7)	
Graduation	14 (76.7)	11 (36.7)	
Post-graduation	5 (16.7)	9 (30)	
Occupation, n (%)			
Unskilled	15 (50)	14 (46.7)	0.63
Skilled	3 (10)	5 (16.7)	
Semi-professional	2 (6.7)	4 (13.3)	
Professional	10 (33.3)	7 (23.3)	
Infertility duration (years)*	3.58±2.44	3.21±2.12	0.37
BMI (kg/m^2)*	30.83±4.62	30.34±4.64	0.49

*Presented as mean±SD, #Continuous variables were compared using student's t-test (normal) and Mann–Whitney U-test for non-normal distribution, Chi-square test was used for categorical variables. SD=Standard deviation, BMI=Body mass index

attributed to participant's busy schedules related to their job or studies.

A parallel three-arm randomised control trial was conducted on 104 sedentary overweight and obese PCOS women in Australia to evaluate the effect of aerobic and aerobic resistance exercise when combined with an energy-restricted high protein diet on metabolic risk factors and reproductive function.[25] The follow-up period was 20 weeks. The reported dropout rate was 46.6% in diet-only group, 58% in the aerobic exercise group and 60% in the diet and aerobic and resistance exercise group. Work commitments, personal reasons, unable to comply with study requirements and time restraints were attributed to having high dropout rates. Broadly, the dropout rates in these studies were similar to the current study findings. However, a three-arm pilot randomised control trial was done on 31 overweight and obese PCOS women in Norway to evaluate the effect of high-intensity interval training and strength training on metabolic, cardiovascular and hormonal outcomes and they reported an overall dropout rate of 19% at 10 weeks.[26] The relatively lower dropout rates reported in the above study could be due to the shorter follow-up periods.

A systematic review analysing 15 studies (observational and RCTs) on obese and overweight infertile women noted a median dropout rate of 24% in lifestyle intervention group,[27] and the author could not identify intervention or patient-related factors related to dropout. The current pilot study showed a significantly higher dropout rate and the reasons for higher dropouts and non-adherence were captured separately in a nested study, which would help us in understanding the hindrances and plan the larger trial accordingly. Broadly, the finding of the qualitative arm found that women participating in the study perceived a lack of need for weight loss intervention. This is due to widespread sociocultural beliefs prevailing over normalising weight gain after marriage and perceived lack of control over their weight gain. Most women do not see them as overweight which leads to non-adherence and eventually dropping out from the study.

A randomised trial by Mani H *et al*. reported spontaneous pregnancy rates of 8.1% versus 3.4% in a lifestyle intervention and control groups, respectively.[24] We did not find any statistical difference in spontaneous pregnancy and clinical pregnancy rates, but if dropouts were excluded, the pregnancy rates were higher in the intervention group (63.6% vs. 47.6%). A systematic review done by Moran *et al*. reported that multiple sessions of supervised lifestyle interventions helped to improve the anthropometric measurements amongst PCOS women.[28] In our current trial, we did not find any significant difference in anthropometric measurements

Table 2: Anthropometric parameters at baseline and end of the trial for participants who adhered to the protocol in the intervention arm

Individualised lifestyle intervention arm			
Anthropometric measurements	**Baseline (*n*=4)**	**6 months (*n*=4)**	***P*#**
Weight (kg)*	79.1±7.4	77.9±7.9	0.14
Waist circumference (cm)*	98.0±14.09	94.85±19.21	0.57
Hip circumference (cm)*	110.0±4.97	104.5±7.33	0.17
Neck circumference (cm)*	34.38±2.56	34.25±2.63	0.60
Waist hip ratio*	0.89±0.12	0.90±0.12	0.08
Calories intake (kcal)*	1852.0±351.1	1766.7±78.2	0.76
GPAQ adhered (Mets/week)*	400.5±221.9	509±168.2	0.78

*Presented as mean±SD, #*P* values calculated using paired *t*-test. SD=Standard deviation, GPAQ=Global-Physical Activity Questionnaire

Table 3: Anthropometric parameters at baseline and end of the trial for participants who adhered to the protocol in usual care and control arm

Usual care control arm			
Anthropometric measurements	**Baseline (*n*=11)**	**6 months (*n*=11)**	***P*#**
Weight (kg)*	79.3±12.4	77.5±11.4	0.39
Waist circumference (cm)*	94.86±11.07	94.50±11.0	0.27
Hip circumference (cm)*	111.55±10.62	110.59±11.03	0.32
Neck circumference (cm)*	34.64±1.18	34.59±1.16	0.28
Waist hip ratio*	0.83±0.08	0.85±0.08	0.32

*Presented as mean±SD, #*P* value calculated using paired *t*-test. SD=Standard deviation

Table 4: Comparison of the outcomes amongst the individualised lifestyle intervention and usual care control arms

	Individualised lifestyle intervention arm (*n*=30), *n* (%)	**Usual care control arm (*n*=30), *n* (%)**	***P*#**
Dropout rate*	19/30 (63)	9/30 (30)	0.019
Spontaneous pregnancy rate	2/30 (6.6)	4/30 (13.3)	0.35
Pregnancy rate with ovulation induction	5/30 (16.6)	6/30 (20)	0.38
Clinical pregnancy rate	6/30 (20)	10/30 (33.3)	0.24
Total pregnancy rate	7/30 (23.3)	10/30 (33.3)	0.57

*Dropout rate=The number of participants not completing the follow-up per women randomised at 6 months, #*P* value calculated using Chi-square test

Table 5: Comparison of quality of life – per protocol analysis in individualised lifestyle intervention arm and usual care control arm between first and final visit

	Individualised lifestyle intervention arm			Usual care control arm		
Quality of life domains	Baseline (*n*=4)	6 months (*n*=4)	*P*	Baseline (*n*=11)	6 months (*n*=11)	*P*[#]
Emotions[a]	4.06±1.43	3.90±1.45	0.83	4.44±1.17	4.83±1.21	0.82
Body hair[a]	6.27±0.95	6.67±0.58	0.08	6.38±1.19	6.49±1.07	0.20
Weight[a]	3.80±1.20	2.60±0.35	0.05	4.40±1.99	4.84±1.80	0.95
Infertility[a]	3.67±2.52	2.37±1.21	0.85	3.11±1.77	3.23±1.73	0.87
Menstrual irregularities[a]	4.02±2.68	3.37±1.60	0.92	4.76±1.30	4.67±1.24	0.64

[#]*P*-values calculated using paired *t*-test for in-between group comparisons, [a]Presented as mean±SD. Quality of life - PCOSQ, 26 items, 5 domains as mentioned, scored on a Likert 7-Point Scale with lower scores indicating more problems and higher scores indicating lesser problems. PCOSQ=Polycystic ovarian syndrome-quality of life questionnaire, SD=Standard deviation

amongst both the groups, probably due to the limited number of participants who completed the study. Few RCTs conducted on obese and overweight PCOS women reported an improvement in quality of life in certain domains of the questionnaire, i.e. emotion, fertility and weight.[24,29] We did not find any significant difference with respect to quality of life in all five domains of the PCOS-Q questionnaire, probably due to the small sample size.

The reasons for increased dropouts include the factors intrinsic to the woman such as personal and psychological factors and extrinsic factors such as social and work related.[25] Multiple sessions of supervised advice and counselling at each visit may help to address these concerns to some extent.[28] Improving the access between the physician and the patient, online or telephone support, self-monitoring, motivational interviewing and cognitive behavioural therapy would help to overcome the dropout rate.[30,31]

The current study is one of the first to explore the feasibility of conducting large adequately powered RCTs to evaluate individualised lifestyle intervention amongst South Asian women with PCOS. Since it was a feasibility study, the sample size was small, and it was not powered to detect any difference in the effectiveness of individualised lifestyle intervention versus one-time advice. The study also had a nested qualitative arm which helped explore the reason for high dropout rates and compliance-related issues and the qualitative study is currently under peer-review consideration.

In the current study, the dietician and physiotherapist were regular hospital staff who took up the additional responsibility of offering their services to the trial participants. Their distant location and appointments added to logistical constraints for the participants and may have contributed to the high dropout rates. Any future trial exploring the effectiveness of lifestyle intervention in women with PCOS who are seeking fertility treatment should consider delivering all the trial-related services such as lifestyle modification or fertility treatment advice in the same location. While a high drop rate was noted in the interventional arm, the attrition in the control arm was also higher than expected. The high dropout rate in the control group was reflective of the high dropout rate for the setting and this background attrition rate needs to be considered while calculating sample size for future trials.

In the present study, we did not account for partial compliance. For future trials, it is important to capture partial adherence to lifestyle intervention. We have proposed a mechanism to identify partial compliance based on the assessment of dietary intake and uptake of exercise at different points of contact during the trial.[20] This mechanism for identifying compliant, partial and non-compliant participants has been incorporated in the study protocol for a recently initiated large multicentric trial evaluating the effectiveness of individualised lifestyle intervention in women with PCOS who wish to conceive. The lessons from the current feasibility study were considered while designing the individualised lifestyle intervention in PCOS women (IPOS) trial. The dedicated dietician and physiotherapist were recruited, and services were provided with the fertility clinic to make more simpler patient care pathway and reduce participant attrition.

Conclusion

The current feasibility study showed that the individualised lifestyle intervention arm had significantly higher dropouts compared to the usual care control arm. The knowledge gained from the feasibility study as well as the qualitative arm has been used to design an adequately powered trial to evaluate the effectiveness of individualised lifestyle intervention in women with PCOS who wish to conceive. The funded trial has been initiated and the protocol published and the trial results will help in assessing the role of lifestyle intervention

on live birth rate, other reproductive outcomes and the quality of life amongst obese PCOS women who is anxious to conceive.[20] Furthermore, the current study findings are useful in planning a similar trial investigating lifestyle intervention in women with obesity in low-resource setting.

Authors contribution

MSK conceived the hypothesis. PK, CP and BJY performed the analysis. PK, CP and MSK drafted the manuscript which was approved by ATK, NK and all other authors.

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The authors would like to acknowledge the participant couples whose contribution was vital to the completion of the study.

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Nil.

Conflicts of interest

MSK is the editor in Chief of Journal of Human Reproductive Sciences. However, he did not take part in the peer review or editorial decision for the manuscript.

Data availability statement

Data will be made available at request to the corresponding author pending institutional regulations.

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