Original Article

Exploring the Factors Associated with Attrition in a Lifestyle Intervention Trial amongst Women with Polycystic Ovarian Syndrome Desiring Fertility - An Interview based Study

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Abstract

Background: Previous studies exploring the barriers to weight management have suggested psychological, social and logistical barriers were important reasons for high attrition and non-adherence. **Aim:** The aim of this study was to assess the possible reasons for high attrition and non-adherence to lifestyle interventions in a trial setting amongst women with polycystic ovarian syndrome (PCOS) who wish to conceive. **Setting and Design:** The study was conducted in a tertary level hospital and employed a qualitative study paradigm. **Materials and Methods:** The study was nested within a feasibility study that explored the possibility of conducting lifestyle interventional trials in women with PCOS who wish to conceive. Eligible participants who refused participation in the trial were interviewed under three major categories: refusal before randomisation, refusal after randomisation and non-adherence. **Statistical Analysis Used:** Thematic analysis was used to analyse textual data. **Results:** The participants considered PCOS as a 'fairly common' condition and did not perceive the need to address the impact of PCOS on their health. The second recurring theme was the perception of being overweight as 'healthy' and 'normal' and downplaying lifestyle changes to focus only on fertility treatment for achieving pregnancy. Finally, the decision to pursue weight loss or to discontinue it seems to be a shared decision making among family memebers which limits the ability of the clinicians and healthcare practitioners to effectively deliver appropriate advice on lifestyle interventions. **Conclusion:** The current findings would help in planning and designing adequately powered randomised controlled trials to evaluate the impact of lifestyle intervention in women with PCOS.

Keywords: *Dropouts, infertility, lifestyle interventions, polycystic ovarian syndrome, qualitative study, South Asian women*

Introduction

Polycystic ovarian syndrome (PCOS) is a complex endocrine disorder affecting predominantly adolescent girls and women in the reproductive age group with a reported worldwide prevalence of 5%–20%.[1] The clinical manifestations are irregular menstrual cycles, excessive hair growth and inability to conceive.[2] Obesity is commonly associated with PCOS with a prevalence of approximately 50% amongst women diagnosed with PCOS.[3] Due to the link between obesity and the adverse metabolic, psychological and reproductive outcomes in women with PCOS, lifestyle interventions focusing on diet modification and physical activity are considered the first-line treatment option for women with PCOS.[4]

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The European Society of Human Reproduction and Embryology (ESHRE) guideline for PCOS recommends a weight loss of 5%–10% in women who are overweight or obese to achieve any significant improvement in clinical and metabolic parameters.[5] To achieve the recommended weight loss, lifestyle intervention needs to be inculcated as a part of the treatment programme for PCOS. The existing literature on the effectiveness of lifestyle intervention for women with PCOS shows some beneficial effects of weight loss on the hormonal parameters and improvement in reproductive outcomes but the evidence is of low quality.[4] The common methodological issues with trials evaluating lifestyle interventions include poor adherence and high dropout rates ranging between 18% and 46%.[6,7] It is important to explore the possible reasons for poor adherence as well as high attrition in the trials evaluating lifestyle interventions.

A study in patients with cardiovascular disease investigating the reasons for attrition following lifestyle intervention reported logistical and motivational factors to be the most important reasons for participant dropout.[8] A study conducted in Australia exploring the barriers and facilitators in weight management in women with PCOS reported that the women faced logistical barriers such as time and cost, motivational barriers such as feeling unrewarded and tired, environmental barriers such as depressive and defeating thoughts and relational barriers such as unsupportive partner and family commitment.[9] The recurrent themes pertaining to exploring predictors for dropout rates downsize to three main factors i.e., cognitive, emotional and situational factors.[9] Amongst the major factors for attrition, the sociocultural context is said to play a significant role in people's attitudes, consumption practices, socioeconomic conditions and gender roles.[10] A systematic review exploring the attrition in trials involving lifestyle interventions suggested exploring the predictors of dropout to aid in the planning and conduct of such trials to reduce participant attrition.[11]

The generalisability of the 'lifestyle intervention trial' findings is limited as there is a substantial variation in dietary habits and health-promoting behaviour across different geographical regions. The current study was planned to explore the reasons for the high dropout rate in the trials evaluating lifestyle intervention and the reasons for non-compliance to the recommended treatment in women with PCOS who wish to conceive. We aimed to study women with PCOS from the South Asian region as there is a paucity of studies from the region. In the current study, a qualitative approach was undertaken to understand the experience, attitudes and beliefs of participants who refuse to participate, drop out or are non-adherent in a trial setting. The current qualitative study was nested within a feasibility study focusing on an individualised lifestyle intervention in women with PCOS who wish to conceive. The results of the qualitative study would be helpful in the design and conduct of an adequately powered randomised controlled trial (RCT) to evaluate the effectiveness of individualised lifestyle intervention in women with PCOS who wish to conceive.

Materials and Methods

We planned a study to explore the feasibility of lifestyle intervention in women with PCOS who wished to conceive at the Department of Reproductive Medicine and Surgery, Christian medical college and hospital, Vellore, India. The study was initiated in August 2021 and was planned for 18 months. The current study was a qualitative study nested within the RCT to explore the reasons and factors for attrition. The results from the RCT found that a total of 15 participants had completed the study period. In the intervention group, the drop rate was 63% (19/30) with 2 participants conceiving spontaneously and only 4 reporting at the follow-up visit. In the control arm, the drop rate was 30% (9/30). Four participants were conceived in the control group. There was no significant reduction in the body mass index (BMI) in both groups at the end of the follow-up in both groups. Those participants who dropped out of the study were recruited in the qualitative arm. The ethical approval was obtained from the Institutional Review Board and the trial was prospectively registered under the Clinical Trial Registry (CTRI/2021/12/038831). All procedures followed were in accordance with the ethical standards of the responsible institutional committee on human experimentation and with the Helsinki Declaration of 1975, as revised in 2008.

Participants

The study population considered women attending fertility clinics who were diagnosed with PCOS as per Rotterdam criteria and wished to conceive (Rotterdam ESHRE/American Society of Reproductive Medicine-Sponsored PCOS consensus workshop group, 2004). Those women who have been identified to have a BMI of more than 23 kg/m^2 with no major comorbidities were encouraged to participate in the trial. The eligible women were enrolled in the trial after obtaining written informed consent. For the qualitative study, we invited participants at various stages of the trial. Those eligible participants who refused at the stage of invitation to participate were recruited under Stage 1 refusers. Those participants who agreed to participate after obtaining consent and later failed to attend the

dietary/exercise clinics were considered dropouts and were recruited under Stage 2 refusers. Finally, those participants who reported to dietary clinics but were non-adherent were recruited under Stage 3 refusers.[12] A separate information sheet and written informed consent were obtained for the qualitative interview. A purposive sampling technique was used to recruit participants under the conditions of three stages of refusals. The qualitative study was employed due to the exhaustive and in-depth approach to understanding the experiences, attitudes and beliefs of women with PCOS undergoing fertility treatment who have been sent for diet and exercise consultation [Table 1].

Data collection

Those participants who refused at any of the stages eligible were invited to the qualitative arm of the study. After the briefing, participant information and consent were obtained. The interview was recorded for transcribing verbatim in later stages for detailed analysis. Both face-to-face and telephonic interviews were employed at a mutually convenient time. A semi-structured interview guide was employed to direct the conversation of the participants to capture the necessary information. Questions explored their experiences of having to undergo the study (e.g. What was your experience of attending the diet/exercise clinic?) or their reasons for drop-outs (e.g. What were the reasons you disagreed to participate in the trial?) or explore some of the challenges (e.g. What were some of the challenges you had from participating in the trial?). The interview was conducted in the participant's native language (Tamil and Telugu) by a psychologist which was then translated to English for analysis and validated independently by a staff who was not involved in the trial. Other family members' participation was not encouraged. Each interview lasted between 30 and 45 min. Recruitment ended when data saturation was obtained.

Transparency and data saturation

The sample size was initially set as 12 based on the accounting of previous studies conducted on similar frameworks.[13] The study underwent analysis data by data and was fed into the nVIVO software as and when new data were transcribed. When the number of codes was repetitive, the interviews were stopped. The data got saturated at 15. All transcribed data will be made available upon request and the personal information is kept confidential.

Analysis

A thematic analysis framework was used to identify emerging themes related to the reasons, challenges and experiences leading to the decision to drop out.[14] The translated verbatim was analysed by a psychologist who was trained in qualitative research. To validate the quality of the translation, the reverse translation was done by another investigator. The verbatim was initially read and reread to assign codes. The assigned codes were categorised under different categories manually. The codes generated were manually fed into the nVivo software (Qualitative Research Software International, March 2020) to generate the codebook. Based on the revisions required after the rereading of the verbatim and code categories, the codes were restructured. The finalised codes were classified into different categories and themes were generated from the data. The themes were majorly classified into global themes (recurrent themes prevalent across the data sets), organising themes (middle order themes) and basic themes (lowest order of themes).[14] The transparency

Table 1: Demographic characteristics of the participants

Stage of refusal	Participant number	Years of seeking treatment	Urban/rural	BMI (kg/m^2)	Occupation
Before randomisation	2	2	Urban	24.5	Housewife
After randomisation	1	4	Rural	28.8	Housewife
	5	1	Urban	26.4	Housewife
	8	5	Urban	31.6	Housewife
	9	1	Urban	26.4	Housewife
Non-complaint	3	2	Rural	27.8	Housewife
	4	1	Urban	35.3	Nurse
	6	2	Urban	26.4	Housewife
	7	2	Rural	38.3	Housewife
	10	3	Urban	29.1	Housewife
	11	1	Urban	45.2	Unskilled work
	12	7	Urban	46.4	Teacher
	13	1	Urban	46.4	Housewife
	14	2	Urban	24.6	Housewife
	15	2	Urban	32.9	Housewife

BMI=Body mass index

of data was achieved through discussing data sets with co-investigators before the final theme generation. The final thematic network reflects participants' accounts of their interviews, memos and field notes by including reflections and inputs from the co-investigators.

Results

The findings of the study were illustrated in quotes extracted from the transcripts which explain the participants' accounts of their experiences. A total of 15 individual interviews were conducted amongst women who disagreed to participate in the feasibility study, who dropped out of the interventional arm and individuals who had difficulty adhering to the suggested intervention [Table 1]. These women were interviewed on their experience of undergoing the study, perceptions around weight loss and dieting and the reasons for non-adherence or dropout. Women who dropped out of the weight loss intervention reported that 'they are healthy, and they do not see the need for weight loss'. There were no significant differences in the demographic characteristics of the interviewed dropout women versus the participant group in the main RCT who were adherent to the trial [Supplementary Table 1]. The global theme under which three prevailing organising themes were identified. These themes could explain the reasons for the decision to withdraw from the intervention, barriers to follow-up at the weight loss clinic and the reasons for non-adherence [Figure 1].

Organising theme 1: I'm not overweight

One of the recurring themes from the data revolved around the perceived notions about their weight and the weight gain affecting fertility. Most participants saw themselves as 'normal' or 'medium' as they regarded themselves as healthy when they compared themselves with their other pregnant counterparts. Women in the intervention arm did not feel the need to attend the weight loss intervention due to the following overarching reasons encapsulated from the transcripts.

Perceived disease severity

Almost all the participants who have sought treatment for irregular periods for longer duration believed that 'PCOS' is common and curable. This prevailing belief is seen to be a deciding factor for pursuing health-promoting behaviours such as weight loss and diet. Since the perceived disease severity was low, the women in the intervention group wanted to focus on fertility treatments and not on their PCOS symptoms [Box 1].

Perceived beliefs

Participants in the study expressed increased concerns over labelling them as 'overweight' as they strongly believed that they were healthy and did not need to pursue weight reduction. This was often expressed with increased dissatisfaction and sometimes seen crying during the interview as they called themselves 'just medium'. Due to this dissonance between their belief and their clinician's account, they dismissed the clinician's emphasis on weight reduction [Box 2].

Weight attribution

One of the common beliefs prevailing amongst South Asian women was normalising weight gain after marriage. This belief was said to be reinforced by the elders in their family. Weight gain after marriage was seen in a positive light and there is a perceived lack of control expressed by these women over their gained weight. These attributions were also seen in other conditions such as gaining weight was attributed to PCOS or irregular periods or side effects of medicines given [Box 3].

Need for credibility

Women in the intervention group were given weight reduction counselling by the primary investigator who was not their treating clinician. This tends to create disbelief amongst the participants as they expressed a lack of credibility in their suggested weight loss and intended to withdraw from the study. They expressed that they would be willing to lose weight and see the concerned dietician

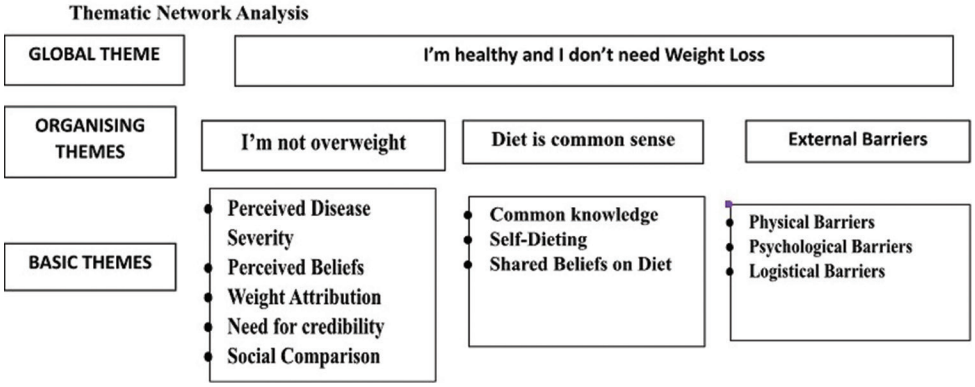

Figure 1: Arrangement of the themes identified from the analysis

Box 1: Perceived disease severity

'XX doctor from Arni told that I have PCOS but only a little bit. Nothing to be scared of. Then I thought about it, everyone has PCOS, having PCOS isn't a big of an issue. So, I left worrying about my periods' (participant 3, BMI 27.8 kg/m^2)

'Actually, I have heard many people experiencing symptoms, that they have a cyst. They were saying that they were taking treatments so we thought we too might get results if we take treatment' (participant 2, BMI 24.5 kg/m^2)

'Because PCOD is a normal phenomenon now and most people have it and they said it's not big of a problem to worry. They said it is a normal thing that can be cured' (participant 5, BMI 26.4 kg/m^2)

BMI=Body mass index, PCOS=Polycystic ovary syndrome, PCOD=Polycystic ovarian disease

Box 2: Perceived beliefs

'We are just medium but why is this happening to me and all I used to feel (cries)' (participant 3, BMI 27.8 kg/m^2)

'According to me, I'm not overweight. That's what I thought. That's all. If someone is overweight, they can reduce. For me it did not feel like a big deal' (participant 2, BMI 24.5 kg/m^2)

BMI=Body mass index

Box 3: Weight attribution

'I gained weight but like for everyone they say right, after marriage usually tend to gain weight, that's how it was also for me' (participant 5, BMI 26.4 kg/m^2) (participant 2, BMI 24.5 kg/m^2)

'Since I does not have regular periods, I started gaining weight' (participant 9, BMI 26.4 kg/m^2)

'By the end of the treatment, people started saying that I got fat taking those medications, so that's why' (participant 9, BMI 26.4 kg/m^2)

'After getting diagnosed with PCOS, I gained weight. I used to gain back the weight I have lost, so this cycle continues' (participant 4, BMI 35.3 kg/m^2)

BMI=Body mass index, PCOS=Polycystic ovarian syndrome

Box 4: Need for credibility

'One sir was there, he only told me to lose weight, but the doctor did not say anything' (participant 2, BMI 24.5 kg/m^2)

'Only then a doctor sir came and told me that I have to reduce my weight. My doctor told me, I'm not fat. When sir said like this, I could not understand why they are saying. So, I just thought I will consult with my doctor and then go' (participant 9, BMI 26.4 kg/m^2)

BMI=Body mass index

Box 5: Social comparison

'It was very difficult to accept because there are so many people who are so fat but did then not get pregnant!' (participant 3, BMI 27.8 kg/m^2)

'Because people who are fat or overweight are getting pregnant right and compared to them, I'm far better than that. So, I feel if it is not mandatory to do' (participant 6, BMI 26.4 kg/m^2)

BMI=Body mass index

if their treating physician suggested it. The presence of a credible source was instrumental in enhancing health-promoting behaviours in women who were undergoing treatment for fertility under a clinician [Box 4].

Social comparison

One of the mediating factors for perceiving weight reduction as a lesser priority was due to their comparison to their counterparts who are overweight. These women expressed often in the interview that weight cannot be an issue in conception because they see more women conceiving despite being overweight. This social norm comparison reinforced their behaviour towards weight maintenance negatively [Box 5].

Organising theme 2: Diet is common sense

This theme encapsulates the prevalent beliefs around diet and food consumption behaviours amongst women who undertook the weight loss intervention. Another key factor for behavioural non-adherence was due to the common misinterpretations around existing diet knowledge fuelled by cultural beliefs, hindsight bias over their food consumption habits and higher dependence on self-dieting.

Common knowledge

Most of the women in the intervention believed that they were already aware of the dietary intake and the steps to be taken for dieting for weight loss. They consider it to be the common man's knowledge hence, dismissing the dietary recommendation. After the first diet consultation, the participants were convinced that they already knew the information indicating hindsight bias. This became a key reason for dropouts in clinical trials aiming for weight loss. This was also reinforced by the dietary advice given by family members, unfiltered information available on the Internet and YouTube videos. These sources of information were seen as credible and accessible in contrast to visiting diet clinics which were seen as redundant and time-consuming [Box 6].

Self-dieting

Most patients perceived themselves as having control over their diet due to their previous experiences with attaining successful weight loss. Some of the common dieting steps undertaken by these women are decreasing their carbohydrate consumption, especially their rice intake, avoiding junk food or decreasing their overall quantity of food. Apart from these, few participants reported consuming herbal remedies as suggested by YouTube channels. These steps were seen as satisfactory by the participants as opposed to visiting a dietician [Box 7].

Shared beliefs on dieting

Certain dietary habits were discouraged due to common practices present in these cultures for women who are

Box 6: Common knowledge

'My husband also says the same thing to reduce the weight. He told me that, "I'm telling you from the beginning to lose weight and they are saying the same thing which I told you without taking any money." (participant 3, BMI 27.8 kg/m^2)

'No usually when it comes to diet, you ask anyone they tell you to avoid rice and all and even if I go there, they are going to tell the same thing' (participant 5, BMI 26.4 kg/m^2)

'Already I knew what they are going to tell. Isn't it common' (participant 9, BMI 26.4 kg/m^2)

BMI=Body mass index

Box 7: Self-dieting

'I take normal regular food which they cook at home but at very lesser quantities. I take lots of fruits and cut short my consumption by half. I just reduce the quantity' (participant 4, BMI 35.3 kg/m^2)

'I actually follow a YouTube channel wherein they suggest an ayurvedic alternative to cure PCOS. I have been taking that for 4 days now since the 1st day of periods' (participant 3, BMI 27.8 kg/m^2)

'I take little food, avoid junk food and oil consumption' (participant 3, BMI 27.8 kg/m^2)

'I take millet in the morning and some soups. I tried eating less rice' (participant 9, BMI 26.4 kg/m^2)

'I lost around 3–4 kg with dieting' (participant 4, BMI 35.3 kg/m^2)

BMI=Body mass index, PCOS=Polycystic ovarian syndrome

Box 8: Shared beliefs on dieting

'Even if I want to diet, my family says number They say if you diet, you will get sick and since you are trying to conceive, it will become a problem for conception' 'They say only if you eat, you will be stronger and be able to hold a pregnancy' (participant 5, BMI 26.4 kg/m^2)

'They are elders so they tend to ask me to eat and I cannot say no. I need to eat' (participant 2, BMI 24.5 kg/m^2)

BMI=Body mass index

Box 9: Physical barriers

'If I didn't eat, I developed stomach pain and tightening. I got difficulty passing stools and severe pain below calves. So, I did not follow the diet' (participant 7, BMI 38.3 kg/m^2)

'I have increased household work. My work starts at 4 am in the morning and I do not get time for exercising. Because we live in a village, there is always so much work in the house' (participant 1, BMI 28.8 kg/m^2)

'I have so much works at home, I'm already tired. So just want to finish work and rest. That's how I feel' (participant 6, BMI 26.4 kg/m^2)

'So whatever time I get, I feel like only resting. Exercise and all are not practical then' (participant 5, BMI 26.4 kg/m^2)

BMI=Body mass index

pregnant. Pregnant women or those trying for pregnancy were discouraged from dieting and were expected to eat in larger quantities. The quality of the consumption was not a priority, but the quantity of consumption was considered to be important. These beliefs were enforced by the elders in the family for which these women express utmost importance to their words due to respect. Due to the cohesive nature of the family environment in the South Asian population, dietary consumption is an interdependent choice that requires change in the social and family environment as well [Box 8].

Organising theme 3: External barriers

This theme encapsulates the external barriers affecting their adherence to weight loss intervention and acts as mediating factors for the existing perceptions towards weight loss. These barriers are not primary factors for dropping out from the intervention but are seen aiding in their decision to withdraw from the study.

Physical barriers

Women participating in the weight loss intervention expressed certain physical barriers such as increased weakness, pain and fatigue following diet and exercise. They expressed feeling extremely fatigued which led to discontinuation of the suggested intervention. Most of the women who participated in the intervention were homemakers who expressed having increased household work which gave them very little time for themselves. Due to these reasons, they report wanting to rest rather than spend their time exercising [Box 9].

Psychological barriers

Due to prolonged years of seeking infertility treatments and the recurrent failures to achieve a pregnancy, women undergoing weight loss intervention faced low mood and lack of motivation. Due to this increased burden to achieve a pregnancy, couples faced disappointment and disinterest at any delay in their treatment. Some of the women who have attempted weight loss have consequently faced failure to maintain the lost weight or have seen no overt results over their attempts. This perpetuates learned helplessness amongst women who are asked to adhere to the exercise and diet intervention [Box 10].

Logistical barriers

Some of the other factors affecting the adherence rates were the logistical barriers faced by the couples. Due to many women being homemakers, they tend to depend on their husbands to take them to the hospital. Most husbands could not take time off from their work and tended to overlook the diet appointments and ask their wives to try by themselves at home. Another common difficulty was the financial burden from repeated treatment failure leading to decreased participation in diet/exercise consultations. Few other participants reported living in a smaller village with lesser access

Box 10: Psychological barriers

'I'm not getting pregnant because I feel I used to get panic and my heartbeat used to race. That's the issue I think' (participant 3, BMI 27.8 kg/m^2)

'So many treatments we went through and finally, my mother-in-law said to go here to CMC since it's a lucky place. That's why I came after trying so many injections and medicines' (participant 3, BMI 27.8 kg/m^2)

'I am here for pregnancy. I need a baby. That is why I am here. I need a baby' (participant 9, BMI 26.4 kg/m^2)

'I lost weight and then I gained back. So, I did not go for another consultation' (participant 4, BMI 35.3 kg/m^2)

BMI=Body mass index, CMC=Christian Medical college

Box 11: Logistical barriers

'We are actually from Chitoor. And we have to come from here and my husband is busy with work so that's why' (participant 2, BMI 24.5 kg/m^2)

'We are seeking treatment by taking loans and everything, so in such situations for us having a baby is important' (participant 9, BMI 26.4 kg/m^2)

'It is a village here madam, we don't get much. We have to survive with what you have in home' (participant 7, BMI 38.3 kg/m^2)

BMI=Body mass index

to transportation and food which led to decreased adherence to diet suggestions.

Discussion

This study examined the possible reasons for attrition and non-adherence in a trial setting to assess the feasibility of conducting an RCT for evaluating the effectiveness of lifestyle interventions in South Asian women with PCOS was being explored. The participants in the study expressed less confidence in the weight loss measures due to the prevailing belief that PCOS is a fairly common condition prevalent in society. The study aligns with the 'health belief model' given by Kirscht *et al*. in 1966 which explains that behavioural change depends upon the perceived severity of the illness and the perceived susceptibility of the individual to the illness.[15]

The first theme that emerged repeatedly was needless stress on weight loss as perceived by the participants due to a lack of understanding and ignorance about their medical condition (PCOS). In a qualitative study by Jones *et al*., poor weight management and infertility were seen to be significant contributors to decreased quality of life on the PCOS questionnaire in South Asian women.[16] The perception of disease and belief regarding being 'not overweight' in the current study is similar to the study findings by Pathak and Nichter involving 141 women with PCOS from India. These women considered PCOS as the 'new normal' and reported it as a consequence of stress due to the burden of day-to-day responsibilities [Box 11].[17]

In the current study, the increased weight of the participants was attributable to their sustained belief that weight loss is unnecessary due to the perception that they are 'healthy' despite the high BMI communicated at the initial assessment. Many of these women supposedly compared themselves to other overweight women in their community who were able to conceive naturally and questioned the need for resorting to weight loss measures. This belief was further perpetuated by normalising weight gain post-marriage at the level of society and comparison with their counterparts who shared the same belief. These social reference points eventually influence the decision-making about whether to continue or withdraw from lifestyle interventions. A qualitative study from the African continent had a similar finding, where women were expected to be overweight post-marriage and the weight gain was considered to be healthy.[18] A few findings regarding the perception of diet in the current study are similar to the study by Barua and Saikia where they found a discrepancy between their claimed dietary behaviours and the actual observed behaviour of the participants. They claimed to engage in moderate activity yet none of them followed any of the dietary protocol. They also observed that social relations, behavioural factors and the absence of health education are risk factors for obesity.[19]

Interestingly, we discern a dissonance in the data with respect to the acceptance of weight gain. The question arises that, if they believe that they are 'healthy', why would they attempt weight loss and feel dejected when there were no tangible outcomes? The theme invokes that weight loss was undertaken only with a belief that it results in regularising periods and aiding in pregnancy naturally.[20,21]

Another important theme in the current study was regarding the barriers to lifestyle intervention. Women with PCOS struggling to conceive have a different outlook on lifestyle interventions due to the social context and psychological burden of childlessness.[22] The average period of treatment attempts for fertility taken by these women was approximately 2½ years. At the time of recruitment for the study, they had already exhausted their finances, time and effort, which led to disinterest in continuing the intervention that was believed to distract them from their treatment focus or delay their fertility treatment. These are consistent with the earlier study findings of psychosocial burden which was often a significant

barrier for incorporating lifestyle interventions in a low-resource setting.[9,23]

In the current study, it was also observed that, in the South Asian population, decision-making is often a shared act involving extended family members which limits the ability of the clinicians and healthcare practitioners to effectively deliver appropriate advice on lifestyle interventions.[19] The themes that emerged indicate that exercising is often discouraged for women who wish to conceive by family elders as women are expected to avoid strenuous activities during this period. They were expected to eat more as the belief prevails that it would help them retain the pregnancy better, making the uterus more capable of holding a baby. Eventually, these women were not expected to diet and exercise as it was believed to reduce their chances of achieving a pregnancy. Due to the conflicting advice, often the women felt despondent due to their increasing age and the social pressure for having a child, which led to the belief that focusing on weight loss was not important. These findings have not been reported in the previous studies and are probably due to a dearth of studies from the South Asian region.[8,9,24] The perceived lack of control over their stress and health conditions also led to a state of 'learned helplessness' often reported by the participants in the current study.

Compared to the global data, a study done in the United Kingdom (n = 161) with a dropout rate of 42% attributed the reasons to busy jobs and study schedules.[25] Another study in Australian women which showed dropout rates of 40%–60% showed that due to personal work commitments and time constraints, they were unable to comply with the requirements of the study.[26]

Overall, the data were able to provide the possible reasons for higher attrition in clinical trials which evaluated lifestyle interventions in women with PCOS. Considering the cultural and social context is vital in designing any intervention requiring behavioural change.[27] The current study suggests a need to improve methods to educate the women as well as their family members about PCOS. It is also important for the treating physician to be involved during the trial recruitment to build trust and allay any misconceptions. There is also a need to create a simpler trial pathway to reduce the logistical barrier for the participant as well as add behavioural modification along with lifestyle intervention. The current findings would help in planning and designing adequately powered RCTs to evaluate the role of lifestyle intervention in women with PCOS. This could help plan and design future lifestyle interventional trials with better acceptability amongst the participants and increased compliance.

The current study was one of few studies that explored the experiences of South Asian women with PCOS who dropped out of clinical trials or were non-adherent. Since the study included the South Asian population, the questions were able to generate a common theme across the interviews. One of the limitations of this study was non-inclusion of family members as most women reported having a significant influence of family members in their decision-making. Inclusion of family members would have improved the data quality. Furthermore, the study population included only those women with PCOS who desired fertility, the findings may not apply to those women with PCOS who have either completed a family or are not keen on fertility. In addition, even though a sample size of 15 rendered saturation of data, it could help to include varied populations and varied data collection methods such as focus groups to add value to the study objectives.

Conclusion

Due to the high degree of attrition in the trials evaluating lifestyle modification as an intervention, the study investigated the reasons for dropout and non-adherence using a qualitative line of enquiry. The study found that increased weight was not perceived as a health risk amongst women with PCOS who were attempting to conceive through fertility treatments. The pressing societal issues of childlessness, emotional factors and pre-existing beliefs were some of the common reasons for non-adherence. This study provides useful information for planning future lifestyle intervention trials aiming at weight loss and diet. The role of the behavioural change model is important while planning clinical trials which are designed to evaluate the effectiveness of lifestyle interventions in women with PCOS. Healthcare professionals need to consider the prevailing societal beliefs and the possible risks of underlying behaviours using self-help methods in health implications when communicating health information to patients and patient relatives.

Author contributions

MSK conceived the hypothesis. PK and MA were involved in the recruitment of participants who dropped out from the randomised trial. MA did the analysis and drafted the manuscript along with CP and MSK. MSK and ATK appraised the manuscript and participated in the critical discussion. All the authors approved the final version of the manuscript.

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Nil.

Conflicts of interest

Dr. MSK is the Editor in Chief of JHRS journal. He was not part of the peer review or editorial review process.

Data availability statement

The data supporting the findings of the study are available from the corresponding author on request.

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Supplementary Table 1: Demographic characteristics comparison between the dropout group (interviewed) and participant group (randomised controlled trial)

	Interviewed dropouts (*n*=15)	Participant group (RCT) (*n*=15)	*P*
Age (years)[#]	27.13±3.87	25.4±3.34	0.19
Education, *n* (%)			
Below 10th class	4 (26.7)	4 (26.7)	0.23
Higher secondary	0	1 (6.7)	
Graduation	6 (40)	9 (60)	
Post-graduation	5 (33.3)	1 (6.7)	
Infertility duration (years)[#]	2.40±1.72	4.0±1.99	0.26
BMI (kg/m^2)[#]	32.7±7.90	31.1±4.26	0.49

[#]Presented as mean±SD. RCT=Randomised controlled trial, SD=Standard deviation, BMI=Body mass index