

Body image, illness perception, and psychological distress in women coping with polycystic ovary syndrome (PCOS)

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Shulamit Geller 0, Sigal Levy and Ronit Avitsur

Abstract

Objective: While symptoms of polycystic ovary syndrome (PCOS) and psychological distress (PD) are directly linked, indirect effects are also apparent. The present study aims to develop an explanatory model for the effect of PCOS on women' PD and identify possible protective and risk factors. It examines the development of PD in women with PCOS and further investigates the association between body image, both positive (body appreciation) and negative (body dissatisfaction) dimensions, and PD as well as the potential mediating effect of illness perception on this association.

Methods: This study comprised a total of 316 women aged 20-50 (M = 30.9, SD = 6.3) - 197 women with PCOS and 119 healthy peers—who completed questionnaires regarding demographic characteristics, anxiety (GAD-7), depression (PHQ-9), body appreciation (BAS-2), body dissatisfaction (EDI-BD), and the Brief Illness Perception Questionnaire (BIPQ). **Results:** Significant differences between groups were found in all measures. Body appreciation mediated the link between PCOS and PD, while body appreciation and illness perception also mediated the link between symptom level and PD among PCOS patients.

Conclusion: Women with PCOS face considerable psychological strain and highlight body appreciation and illness perception as two underlying psychological mechanisms that contribute to the increased risk of distress. Interventions addressing both mechanisms may help improve PD in women with PCOS.

Keywords

body appreciation, body dissatisfaction, illness perception, PCOS, psychological distress

Introduction

Polycystic ovary syndrome (PCOS) is a heterogeneous chronic disorder affecting 6%-20% of women of reproductive age that is defined by a combination of signs and symptoms of androgen excess (the presence of excessive testosterone in females) and ovulatory dysfunction (Escobar-Morreale, 2018). Typical PCOS symptoms include oligomenorrhea, hirsutism, obesity, skin changes, infertility, and the frequent comorbidities of anxiety and depression (Van Niekerk et al., 2022; Yin et al., 2021). As PCOS affects women's physical well-being, it leads to increased PD (Himelein and Thatcher, 2006; Scaruffi et al., 2019). A systematic review and meta-analysis of 18 studies reported a median prevalence of clinically significant depressive symptoms in women with PCOS to be 36.6% compared to 14.2% in healthy peers (HP) (Cooney et al.,

¹School of Behavioral Sciences, The Academic College of Tel Aviv-Yaffo, Israel

²Statistics Education Unit, The Academic College of Tel Aviv-Yaffo, Israel

Corresponding author:

Shulamit Geller, School of Behavioral Sciences, The Academic College of Tel Aviv-Yaffo, 14, Rabenu Yeruham St., Tel-Aviv 6818211, Israel. Email: shulamit@mta.ac.il



2017). In 9 studies the median prevalence of anxiety symptoms was found to be 41.9% in women with PCOS compared to 8.5% in HP (Cooney et al., 2017). Longitudinal studies have also demonstrated a higher risk of conversion to PD symptoms in women with PCOS (e.g., Rowlands et al., 2016).

While PCOS and PD symptoms are directly linked, there are also indirect effects (Himelein and Thatcher, 2006; Malik and Ahmed, 2021) that need to be addressed in order to gain a better understanding of the entire link. The current study thus aims to identify the role of body appreciation and body dissatisfaction as well as illness perception in mediating the psychological impact of PCOS and related protective and risk factors.

Body image

Body image is an underlying theme in the relationship between PCOS, anxiety, and depression (Lee and Dokras, 2020). As a multifaceted psychological experience of individuals' positive and negative perceptions and attitudes toward their body and appearance (Cash, 2004), body image has gained increasingly widespread attention among health researchers (Rodgers et al., 2023). Characteristics emerging from positive body image include accepting one's body despite weight, body shape, imperfections and respecting one's body by attending to its needs as well as engaging in adaptive self-care behaviors (Avalos et al., 2005). Body dissatisfaction reflects negative perceptions and feelings about one's body (Peat et al., 2008), which might lead to both inadequate self-care in terms of health and protection and disordered eating (Stice et al., 2008).

The increased risk of depression and anxiety among women with PCOS may be attributed in part to a severe decrease in their quality of life due to body dissatisfaction (Castelo-Branco and Naumova, 2020). Specifically, some of the symptoms of PCOS that can contribute to body dissatisfaction compared with HP (Himelein and Thatcher, 2006) include physical changes caused by the disorder, such as weight gain (Scaruffi et al., 2019), acne, hirsutism, menstrual abnormalities, infertility, and pregnancy- related complications (Alur-Gupta et al., 2019; Lee and Dokras, 2020). It is worth noting however that body image perception does not reflect an objective evaluation of appearance, but rather a subjective one (Cash, 2004). A few cross-sectional studies of women with PCOS reported negative body image to be associated with depression independent of BMI when compared to HP (Himelein and Thatcher, 2006). Body image distress was also associated with increased anxiety in women with PCOS (Alur-Gupta et al., 2019; Kogure et al., 2019). However, as PCOS is not solely accompanied by body changes several studies have shown the body image levels of women with PCOS and HP to be similar (e.g., Morotti et al., 2013). Although findings regarding the association between body image in PCOS and PD are not conclusive, a possible mediated link has been suggested. For example, different aspects of body image distress, either fully or partially mediated the association between PCOS/HP status and depression and anxiety scores (Alur-Gupta et al., 2019; Himelein and Thatcher, 2006), and higher levels of depression and anxiety were also associated with poorer subjective body experience and attitude (Van Niekerk et al., 2022) and reduced feelings of femininity (Kitzinger and Willmott, 2002).

In the view of body image scholars, positive body image is not merely the polar opposite of negative body image; rather, it is a distinct construct. This means that positive body image is not simply the absence of negative body image, but involves its own unique qualities, such as appreciation for one's body, respect for its functions, and a sense of pride in one's appearance (Tylka, 2018, 2019). Interestingly, recent cross-sectional studies among women with endometriosis confirmed that greater body appreciation is associated with less PD (Geller et al., 2021).

Thus, given the potential impact of body image on both quality of life and PD among PCOS women, the present study aims to expand on the existing literature by investigating both dimensions of body image concurrently (Sullivan-Myers et al., 2023) in order to provide a more comprehensive understanding of how body image shapes the experience of living with PCOS, and to initiate therapy to improve coping with body image concerns (Lee and Dokras, 2020).

Illness perception

The Common-Sense Model of Illness Representations (CSM) is a cognitive-perceptual theoretical model that addresses the relationship between illness cognitions, coping, and health outcomes (Hagger and Orbell, 2003; Leventhal et al., 1980). According to this model, illness representations affect coping with illness, and, in turn, may influence health outcomes, PD, and well-being (Hagger and Orbell, 2003; Leventhal et al., 1980). Based on this approach, the individual's interpretations, beliefs, and unique personal understanding of the illness are important for the development of the PD associated with illness (Ringer 2021).

CSM suggests that there are five dimensions of cognitive illness representations: (1) identity – beliefs about how the medical condition is identified; (2) timeline – beliefs related to the duration of the illness; (3) consequences – beliefs regarding the impact of the health condition on life; (4) cause or underlying mechanism – the perceived reasons for the development of the illness; and (5) control – the perceived ability to manage or control the illness (Hagger and Orbell, 2003; Leventhal et al., 2016; Ringer 2021).

Illness perception and the CSM have served as a framework for the understanding of the development of PD in various types of health conditions: for example, inflammatory bowel disease (Kantidakis et al., 2021), diabetes mellitus (Knowles et al., 2020), gastroparesis (Woodhouse et al., 2018), asthma (Achstetter et al., 2019), osteoarthritis (Knowles et al., 2016), cancer (Dempster et al., 2012; Lee et al., 2023), heart conditions (McCabe and Barnason, 2012), and brain injuries (Snell et al., 2013), among others (Dempster et al., 2015).

An important consideration is that different health conditions have unique characteristics and features that contribute to the development of illness representations and perceptions (Hagger and Orbell, 2003; Leventhal et al., 2016), which may have implications for mental health. Recently, the important role that illness perception plays in PD in women with PCOS was identified (Light et al., 2021). Specifically, reports of more symptoms (known as illness identity), higher perceived consequences, less personal control, and lower understanding of illness (known as illness coherence) were significantly associated with higher PD.

A wider exploration of illness perceptions among a distinctive population (e.g., Mediterranean) (Yin et al., 2021) may enhance understanding of the psychological mechanisms that contribute to the increased risk of distress (Cooney et al., 2017; Teede et al., 2018) as well as specific coping methods and treatment directions. The current study thus sought to examine the possible association between illness perception and PD in women with PCOS.

The current study

The main goal of this study was to shed light on the ambiguity about the variables affecting levels of PD among women with PCOS, thus advancing the move toward a more inclusive model. We aimed, more specifically, to investigate how both positive body image (operationalized as body appreciation) and negative body image (operationalized as body dissatisfaction) as well as illness perception patterns are related to PD among women living with PCOS. Within this context, our study hypotheses were as follows:

- (H1) Differences will be found between HP and women with PCOS, such that women with PCOS will present higher PD (i.e., increased levels of depression and anxiety symptoms), lower body appreciation, and higher body dissatisfaction.
- (H2) Body appreciation and body dissatisfaction will mediate the association between health status (HP vs PCOS participants) and PD symptoms of depression and anxiety, such that women with PCOS will present lower body appreciation and higher body dissatisfaction that will, in turn, lead to higher PD.

(H3) Among women with PCOS, body appreciation, body dissatisfaction, and illness perception will mediate the link between symptom level and PD, such that higher symptom levels will lead to greater image body dissatisfaction, lower body appreciation, and worse illness perception that will, in turn, result in higher PD.

Method

Study participants

This cross-sectional survey was carried out in Israel between 2021 and 2022 as part of a research project on PCOS and its association with psychological variables. Participants were recruited via two different methods: (1) relevant online forums in Facebook research assistants approached the administrators and after receiving their approval posted an invitation to participate in the study, and (2) a snowball/ convenience sample—research assistants approached potential participants among their acquaintances who were, in turn, asked to help expand the sample, in both methods those who volunteered to participate in the study were given a link to a survey and asked to complete it electronically. Before The study was conducted Qualtrics XM software. The study was approved by the institutional ethics committee (#2022004 30.11.2021). All participants signed informed consent before taking part. After providing digital informed consent, participants first completed the scales described below, which were presented in a pre-randomised order for each participant, before providing their demographic details.

Inclusion criteria were women aged over 20 who were fluent in Hebrew. HP and PCOS groups were self-reported. The diagnosis was not corroborated by medical records. A total of 537 women started the questionnaire: 295 reported being diagnosed with PCOS. The final sample comprised 316 women who completed all the questionnaires and provided the relevant demographic data: 197 reported being diagnosed with PCOS and 119 were HP. Participants were aged 20-50 (M=30.9, SD=6.3).

Measures

Demographic and personal information. This included weight (kg), height (m), age, education, marital status, and number of children. Women who reported being diagnosed with PCOS (by answering a yes/no question) also reported the time since their diagnosis and which of the PCOS symptoms they suffer from (irregular menstrual cycles, cystic acne, weight gain, hair growth, other).

Body image. Body appreciation was assessed by the Body Appreciation Scale-2 (BAS2) (Tylka and Wood-Barcalow,

2015a [Hebrew translation; Geller et al., 2020]) is a 10-item measure that assesses acceptance of one's body, respect and care for one's body, and protection of one's body from unrealistic beauty standards. Items range from 1 (never) to 5 (always). An overall BAS2 score was computed as the mean of all items, ranging from 1 to 5, with higher scores reflecting greater body appreciation. Internal consistency of the Bas-2 in the current study was satisfactory ($\omega = 0.94$).

Body dissatisfaction was assessed using the Body Dissatisfaction (EDI-BD) subscale of the Eating Disorder Inventory (EDI-2) (Garner et al., 1983 [Hebrew translation; Niv et al., 1998]). This 9-item scale assesses dissatisfaction with overall weight and specific areas of the body (e.g., stomach, thighs) ranging from: 1 (always) to 5 (never). An overall EDI-2 score was computed as the sum of all items, ranging from 9 to 45, with higher scores reflecting greater body dissatisfaction. Internal consistency of the EDI-2 in the current study was satisfactory ($\omega = 0.90$).

Depression. Depression was assessed using the 9-item Patient Health Questionnaire (PHQ-9) (Kroenke et al., 2001 [Hebrew translation; Geulayov et al., 2009]). All items are rated on a 4-point scale ranging from 0 (not at all) to 3 (nearly every day). All scores are summed to obtain a global score, which ranges from 0 to 27 with higher scores indicating higher levels of depression. Internal consistency of the PHQ-9 in the current study was satisfactory ($\omega = 0.85$).

Anxiety. Anxiety was measured using the Generalized Anxiety Disorder Scale (GAD-7) (Spitzer et al., 2006). The GAD-7 is a 7-item generalized anxiety measure (panic disorder, social anxiety disorder, and post-traumatic stress disorder). All items are rated on a 4-point scale ranging from 0 (not at all) to 3 (nearly every day). Total scores were obtained by summarizing the scores of all items and ranged from 0 to 21 with higher scores indicating higher levels of anxiety. Internal consistency of the GAD-7 in the current study was satisfactory ($\omega = 0.91$).

The Brief Illness Perception Questionnaire (BIPQ) (Broadbent et al., 2006 [Hebrew translation; Benyamini et al., 2012]). The BIPQ is an 8-item questionnaire that measures illness perceptions across eight domains. The illness perception dimensions are consequences, timeline, personal and treatment control, identity, understanding, and emotional response. The questions are scored on a 0–10 scale and then added together. A higher BIPQ score indicates a greater perceived psychological burden of illness (range 0–80). Internal consistency of the BIPQ in the current sample was acceptable ($\omega = 0.62$).

Statistical analyses

Descriptive statistics are presented as M(SD) or N(%), as appropriate. Group comparison was done using a one-way

Table 1. Group comparison of sociodemographic variables [Data are M(SD) for continuous variables and N(%) for categorical variables].

Measure	PCOS (N = 197)	HP (N = 119)	Þ
Age	29.5 (5.3)	33.3 (6.9)	<0.001
BMI	26.5 (6.1)	23.3 (4.1)	<0.001
Being partnered	159 (80.7)	99 (83.2)	NS
Having children	61 (31.0)	54 (45.4)	0.01

Note: NS = not significant, HP = healthy peers. In the categorical variables, counts are for being partnered, having children.

ANOVA for continuous variables and a chi-square test for dichotomous variables. Pearson correlation coefficients were calculated to evaluate the association between the study variables. The main study hypothesis was tested using process model 4 (Hayes, 2013). This model tests for direct effect of PCOS on psychological distress, namely the effect controlling for the mediators, and the indirect effect, namely the part of the correlation accounted for by the mediators. All analyses were done using IBM SPSS v29. Results were considered significant if p < 0.05.

Results

Group comparison—PCOS and HP

The final sample comprised 316 women who provided full data regarding both the outcome measures and the demographic variables. A group comparison of the sociodemographic variables is provided in Table 1; correlations among the study variables are presented in Table 2. We found that women with PCOS were younger than the HP, had higher BMI and were less likely to have children.

Since depression and anxiety significantly correlated with age (r = -0.25 and r = -0.24, respectively, p's < 0.001), BMI (r = 0.22, p < 0.001 and r = 0.11, p < 0.05, respectively) and having children (r = -0.24 and r = -0.15, respectively, p's < 0.001), these variables were considered as potential covariates in the subsequent models. In addition, being partnered significantly correlated with depression (r = -0.16, p = 0.005) and was included in the analyses in which depression was the outcome variable.

H1 regarding group differences in PD and body image (both body appreciation and body dissatisfaction) was

Table 2. Pearson correlations among the study variables (All p's < 0.01).

	Depression	Anxiety	Body appreciation
Anxiety Body appreciation Body dissatisfaction	.70 48 .34	38 .25	73

Table 3.	Group	comparison	in the	main	outcomes	(Data	are
M(SD); all	p's < 0	0.01).					

Measure	PCOS (N = 197)	HP (N = 119)	
Depression	9.0 (5.7)	5.6 (4.3)	
Anxiety	7.0 (5.1)	4.1 (3.9)	
Body appreciation	3.2 (0.8)	3.6 (0.8)	
Body dissatisfaction	29.5 (8.6)	24.4 (7.9)	

tested using ANOVA models. The results, presented in Table 3, showed significant differences between the groups in depression, anxiety, body dissatisfaction and body appreciation. The results remained similar when controlling for the demographic variables mentioned above.

H2 regarding the mediation effect of body image on the link between PCOS and PD was tested using the Process Macro Model 4. The results are presented in Figure 1 (depression) and Figure 2 (anxiety) and show a significant direct path confirming that women with PCOS have higher PD in addition to an indirect path through body appreciation. No mediation through body dissatisfaction was found.

Women with PCOS only

Of the total number of women participating in the study, 197 reported having PCOS. Illness duration, which ranged between 0 and 30 years (M = 9.0, SD = 6.5), did not significantly correlate with the study outcomes. The number of PCOS symptoms varied between 1 and 5 (M = 2.6, SD = 1.0), was positively correlated with depression (r = 0.26, p < 0.06)

0.01), anxiety (r = 0.13, p = 0.038) and body dissatisfaction (r = 0.37, p < 0.01), and was negatively correlated with body appreciation (r = -0.33, p < 0.01). Prevalence of PCOS symptoms was: irregular menstrual cycle (N = 171, 90%), hair growth (N = 120, 63%), weight gain (N = 104, 54%), cystic acne (N = 88, 46%), and other (N = 17, 9%).

Hypothesis 3. regarding the mediation effects of body image and illness perception on the link between symptom level and PD was tested using Process Macro Model 4. The results are presented in Figure 3 (depression) and Figure 4 (anxiety) and show significant indirect effects through body appreciation and illness perception. There was no significant direct path between symptom level and PD. No mediation through body dissatisfaction was found.

Discussion

The current study sought to examine some of the mechanisms associated with the development of PD in women coping with PCOS. It specifically aimed to explore how positive and negative dimensions of body image (appreciation and dissatisfaction, respectively) as well as illness perception patterns relate to PD in women living with PCOS.

Similar to previous studies (Cooney et al., 2017), the current findings indicated that women with PCOS reported higher levels of depression and anxiety than healthy participants. This increased distress was accompanied by increased body dissatisfaction (Alur-Gupta et al., 2019; Lee and Dokras, 2020).

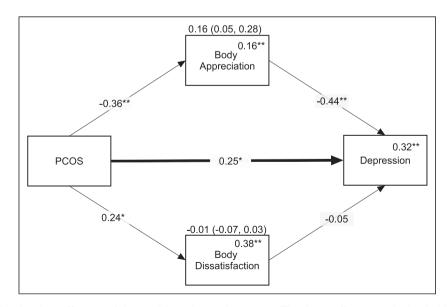


Figure 1. Standardized path coefficients of the model predicting depression. The direct effect is marked in bold. Numbers above the endogenous variables are multiple squared correlations; indirect paths (coefficient, (95% CI)) are shown above the mediators *p < 0.05, **p < 0.01.

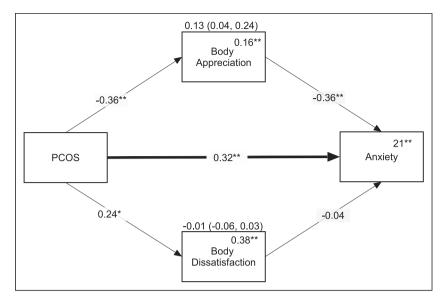


Figure 2. Standardized path coefficients of the model predicting anxiety. The direct effect is marked in bold. Numbers above the endogenous variables are multiple squared correlations; indirect paths (coefficient, (95% CI)) are shown above the mediators *p < 0.05, **p < 0.01.

While body image concerns are known to play a role in mediating PD associated with several other chronic illnesses (Berk et al., 2020; Geller et al., 2021, 2022; Sullivan-Myers et al., 2023), the current study is unique in that it is the first to investigate the link between body appreciation and PD in women with PCOS. It thus expands on previous research on body image which has traditionally focused on the adverse

effects of body dissatisfaction with reference to PD rather than on body appreciation (e.g., Satinsky et al., 2012). Interestingly, although both aspects of this multidimensional construct correlated with PD, the positive aspect (body appreciation) significantly mediated distress (Linardon et al., 2022), while the negative one (body dissatisfaction) did not. Moreover, the association between

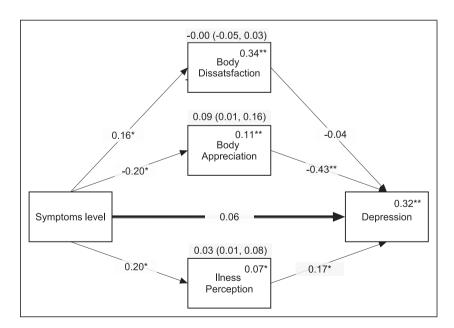


Figure 3. Standardized path coefficients of the model predicting depression. The direct effect is marked in bold. Numbers above the endogenous variables are multiple squared correlations; indirect paths (coefficient, (95% CI)) are shown above the mediators *p < 0.05, **p < 0.01.

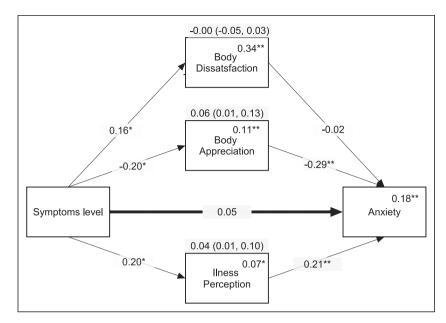


Figure 4. Standardized path coefficients of the model predicting anxiety among PCOS patients. The direct effect is marked in bold. Numbers above the endogenous variables are multiple squared correlations; indirect path (coefficient, (95% CI)) is shown above the mediator *p < 0.05, **p < 0.01.

PCOS symptom levels and PD was also mediated by body appreciation and not by body dissatisfaction. Together, these findings suggest that women with PCOS lack the protective benefits offered by body appreciation (Tylka and Wood-Barcalow, 2015b). As body appreciation is based on holding favorable opinions toward the body, it may be argued that coping with PCOS reduces women's ability to accept their bodies and to maintain inner positivity. This is possibly due to the appearance changes associated with PCOS (Sayer-Jones and Sherman, 2021), which may have impacted the deep connection and attunement with the body that are integral to body appreciation (Tylka and Wood-Barcalow, 2015b). Consequently, this may have contributed to a lack of confidence among women with PCOS in their ability to maintain a daily routine and cope with these changes. More generally, it can be speculated that reduced body appreciation affects how women with PCOS view their bodies, leading them to see their bodies in less functional terms. This perspective may also contribute to increased symptoms of anxiety and depression.

These findings align with the theoretical notion that body appreciation and body dissatisfaction are conceptually distinct constructs (Wood-Barcalow et al., 2010) which do not lie on the same continuum (Tylka and Wood-Barcalow, 2015b) but are based on the fundamental premise that both attitudes toward one's body can coexist (Gillen and Markey, 2019). Furthermore, the findings suggest that when developing therapeutic interventions for PD in women with PCOS, emphasis should be placed on promoting body appreciation rather than addressing body dissatisfaction. As

past research has indicated, individuals who appreciate their bodies are more likely to engage in preventive and protective behaviors (such as dealing with weight, exercising, or seeking medical care) (Thomas and Warren-Findlow, 2020). Therapeutic interventions may therefore help women with PCOS to regain control (Sayer-Jones and Sherman, 2021) and experience fewer mental health problems (Linardon et al., 2022).

This study's examination of the relationship between PCOS symptoms and PD revealed that it is also mediated by illness perception. This finding is supported by previous reports suggesting a close association between negative perceptions of illness and PD in patients coping with chronic illnesses in general (e.g., Kantidakis et al., 2021) and with PCOS in particular (Light et al., 2021). In the current study, higher levels of reported symptoms were found related to deteriorating beliefs and perceptions regarding their illness, thus resulting in higher levels of anxiety and depression symptoms. In line with previous findings (Light et al., 2021), our results suggest that the psychological burden of living with PCOS might be attributed to specific illness beliefs, thus stressing that the attitudes, perceptions, and expectations of women with PCOS about their prognosis and treatment are of great significance for their psychological well-being.

The concepts of body appreciation and illness perception can be viewed as two independent mechanisms that explain emotional distress among women with PCOS. Primary care physicians, such as general practitioners, gynecologists, endocrinologists, and psychologists, can help to prevent or

alleviate PCOS patients' distress by promoting illness acceptance (Rzonca et al., 2018) and body appreciation (Linardon et al., 2022). Tailored conversations in clinical settings about the symptoms and consequences of PCOS (Light et al., 2021) and the use of tools that assess body image functionality (Alleva and Tylka, 2021) can complement the international guidelines for PCOS, which suggest discussing self-management strategies with patients while evaluating their physical and mental health outcomes (Teede et al., 2018). Such regular screenings of body image and illness perception will improve patients' psychological well-being and adherence to treatment while enabling their referral to appropriate mental health professionals in order to initiate early psychological interventions and support (Sayer-Jones and Sherman, 2021).

It is important to also consider the limitations of this study when interpreting the results. First, the cross-sectional design employed restricts causal conclusions. Nonetheless, our promising path analytic findings should encourage the design of longitudinal intervention studies that investigate body image, illness perception, and PD in women with PCOS. A second limitation concerns the validity of the model, which might be increased by controlling body functionality and different aspects of participants' illness perception and pain. Third, illness status was reported by the participants and their health status was not directly assessed. An additional examination by a medical professional would provide direct information for the association between illness and PD. The fourth limitation is the online recruitment of participants for this study. Previous studies have shown that the method of recruitment may affect the response of women with endometriosis (De Graaff et al., 2015), namely, individuals recruited online may be those experiencing more severe adverse effects of chronic illness (Armour et al., 2019). The current study should therefore be repeated using other recruitment methods. Fifth, body image dissatisfaction can be assessed in many ways, other questionnaires may have yielded different results than those obtained with the EDI-2 subscale used in the present study.

To the best of our knowledge, this is the first research to examine the correlation between positive and negative body image, illness perception, and PD among women with PCOS. The findings indicate that women with PCOS face considerable psychological strain and highlight two underlying psychological mechanisms that contribute to the increased risk of distress. Furthermore, the study suggests a need for further investigation into the protective role of body image appreciation and illness acceptance on PD among women with PCOS over a period of time. Other psychological factors (such as body functionality and pain and illness acceptance) that are known to influence PD and were not measured in this study should also be explored. The high prevalence of comorbid anxiety and depression among women with PCOS alongside the fact that it is

primarily a self-managed syndrome is significant for the advancement of clinical management and research.

Author contributions

All authors contributed to the study design and recruitment as well as the composition and revision of this manuscript.

Declaration of competing interest

All authors have completed the unified competing interest form at https://www.icmje.org/coi_disclosure.pdf. The authors have no competing interests to report.

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Ethics statement

Ethics approval

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards. The study was approved by the Research Ethics Committee.

Consent to participate

Informed consent was obtained from all participants in the study.

ORCID iD

Shulamit Geller https://orcid.org/0000-0001-7652-2233

Data availability statement

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to restrictions, for example their containing information that could compromise the privacy of research participants.

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