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Design and validation of polycystic ovary syndrome awareness educational tools for women in Uttarakhand

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Abstract

Background: Polycystic Ovarian Syndrome (PCOS) is a common endocrine complication in women in the reproductive age bracket, and there is little knowledge and awareness about its causes, symptoms, and management. Educational interventions may be beneficial in closing these knowledge gaps.

Objective: This study aimed to design, validate, and assess the reliability of an educational intervention tool to measure awareness of PCOS among women in the Sub-Himalayan region of Uttarakhand.

Methods: Two parallel questionnaires were developed: a nine-item scale for internal consistency testing and a five-item scale for face validity. A pilot validation was conducted with 40 respondents selected from the primary study cohort ($n = 300$). Reliability was assessed using Cronbach's Alpha, construct validity via Principal Component Analysis (PCA), and content validity through expert ratings using the Item-Content Validity Index (I-CVI) and Scale-Content Validity Index (S-CVI).

Results: The face validity test demonstrated overwhelmingly positive scores with an average of 1.08 to 1.28 (mean = 1.00), which showed that the tool was easy to understand, informative, and valuable. The Cronbach's alpha of the nine-item questionnaire was 0.878, indicating excellent internal consistency. PCA produced a two-component model that accounted for 64.44 percent of the variance, representing general awareness, lifestyle management, diet, and stress-related knowledge domains. There were high communalities (ranging from 0.513 to 0.833) across all variables. The expert review yielded an I-CVI and S-CVI of 1.00, evidence of excellent content validity.

Conclusion: The intervention tool was highly reliable, valid, and multidimensional in representing the construct, making it a powerful tool for measuring and improving PCOS awareness. It can be applied in community-based interventions and clinical education programs to enable women with PCOS to manage themselves better.

Keywords: PCOS, educational intervention, awareness tool, reliability, validity, Cronbach's alpha, factor analysis

Introduction

Polycystic ovary syndrome (PCOS) is a common, yet multidimensional endocrine complication in women of reproductive age in all parts of the world, with 9-36 prevalence rates depending on the diagnostic criterion and geographical differences (Salari et al.; Updated StatPearls Review, 2024) ^[13]. Menstrual abnormalities, hyperandrogenism, and polycystic ovarian morphology characterize the condition. It has been connected to the risks of long-term health issues, such as insulin resistance, type 2 diabetes, cardiovascular issues, infertility, and mental health (Azziz et al., 2016; Fauser et al., 2012; Teede et al., 2018) ^[9, 10, 8]. Although it is a heavy burden, there is a lack of awareness and knowledge about PCOS, especially in resource-based and rural settings where misconceptions and a delayed diagnosis are prevalent (Ganie et al., 2019; Joshi et al., 2014; Teede et al., 2018) ^[11, 12, 8].

Educational interventions have been identified as essential tools for increasing awareness, supporting lifestyle changes, and helping individuals self-manage PCOS. However, these interventions are predetermined by having valid and reliable measures to determine the level of awareness and the specific education required. Psychometric assessments provide researchers and medical professionals with evidence-based instruments to evaluate the outcomes of interventions and develop customized programs (Polit & Beck, 2006) ^[7].

The current research aimed to develop and test a structured intervention tool to evaluate PCOS awareness in women in the Sub-Himalayan Uttarakhand region. Multiple dimensions

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were also given attention regarding validation, such as face validity, internal consistency reliability, construct validity, and content validity. The study aimed to develop a standardized instrument to aid educational interventions in managing PCOS at both community and clinical levels, ensuring the tool is comprehensible, reliable, and multidimensional.

Methodology

Design of the intervention tool

A structured educational intervention tool was created to determine the awareness and perception of Polycystic Ovary Syndrome (PCOS). The instrument consisted of two parallel questionnaires: the first, with nine questions related to the internal reliability test, and the second, with five questions related to the face validity of the awareness material. The questionnaires were designed to measure multiple dimensions of PCOS-related awareness, including symptoms, lifestyle management, diet, stress, exercise, complications, and long-term risks.

Validation sample

A subset of 40 respondents, randomly selected from the 300 participants in the main study, was enrolled to undergo validation and a pilot study. The sample size is not large, but it is based on the recommendation in initial validation research (Polit & Beck, 2006) [7]. The response variability and manageability will be sufficient in the preliminary factor analysis.

Validation Process

- **Face Validity:** Five questions were posed to respondents to determine ease of understanding, knowledge gained, clarification of misconceptions, preparedness for self-management, and likelihood of recommendation. Responses were coded (1 = Yes, 2 = No, 3 = Unsure). Descriptive statistics (mean, median, standard deviation) were calculated.
- **Internal Consistency Reliability:** Reliability was estimated using Cronbach's Alpha on the nine-item questionnaire. A coefficient value of 0.70 or greater was considered acceptable for internal consistency (Cronbach, 1951; Nunnally & Bernstein, 1994).
- **Construct Validity:** Exploratory Factor Analysis (EFA) and Principal Component Analysis (PCA) were performed. Sampling adequacy was verified using the Kaiser-Meyer-Olkin (KMO) test, while Bartlett's Test of Sphericity was applied to check suitability for factorization. Components with eigenvalues greater than 1.0 were extracted. Factor loadings ≥ 0.40 were considered significant.
- **Content Validity:** A panel of ten domain experts rated seven items on a 4-point relevance scale (1 = irrelevant, 4 = highly appropriate). Item-Level Content Validity Index (I-CVI) and Scale-Level Content Validity Index (S-CVI) were computed using both average and universal agreement methods (Lynn, 1986; Polit & Beck, 2006) [7].

Ethical Consideration: Ethical clearance was obtained from the institutional ethics committee at HNBGU, with Ethical Registration Number EC/NEW/INST/2023/3552, prior to the commencement of data collection. Written

informed consent was obtained from all participants, and confidentiality of responses was strictly maintained.

Results

Designing of intervention tool for intervention education

Two parallel questionnaires were formulated and administered to determine the reliability and validity of the awareness tools used in the study. For the validation process, 40 respondents were selected from a total of 300 subjects in the main study. The administration of the first questionnaire involved the use of nine items and was based solely on assessing the internal reliability of the tool. The second questionnaire contained five questions that aimed at determining the face validity of the awareness materials. The initial pilot testing successfully justified the reliability and validity of the instruments used to measure the respondents' levels of awareness, as it demonstrated that the tools were reliable and valid for the population under coverage.

a) Reliability and validity of awareness tools

Table 1.1: Descriptive statistics on face validity items (n = 40)

Item No.	Questionnaire Statement	Mean	Median	Std. Deviation	Valid number
Q1	Was the information in the tool easy to understand?	1.13	1.00	0.46	40
Q2	Did you learn anything new about PCOS from the tool?	1.08	1.00	0.35	40
Q3	Did the tool help clarify any misconceptions about PCOS?	1.18	1.00	0.55	40
Q4	Do you feel better prepared to manage PCOS after using the tool?	1.28	1.00	0.68	40
Q5	Would you recommend this tool to others with PCOS?	1.13	1.00	0.46	40

Note: Responses were coded as 1 = Yes, 2 = No, 3 = Unsure

Table 1.1 revealed that the face validity of a given educational tool was measured based on five main questions about participants' perceptions, which were analyzed using descriptive statistics. The responses were coded so that the lower the score, the more positive the responses (1 = Yes). In each question, the average score ranged from 1.08 to 1.28, with medians all remaining at 1.00, indicating that most participants responded positively (i.e., "Yes") to the questions.

Q1 (Ease of understanding) had a mean of 1.13, implying that nearly all the participants found the material easy to comprehend.

Q2 (Learning something new) had the lowest mean (1.08) and the lowest standard deviation (0.35), indicating high concurrence with the tool in providing new information.

Q4 (Preparedness to manage PCOS) followed closely, with the highest mean (1.28) and standard deviation (0.68),

indicating a slight increase in the perceived impact variability. However, the median still indicated that most respondents answered 'Yes'.

Q3 and Q5, which concern clarifying misconceptions and the tool's recommendation, were also evaluated positively with low deviation.

All these findings support the tool's face validity, which means that participants found it comprehensible, educative, and recommended.

b) Reliability statistics for the questionnaire

Table 1.2: Reliability test uses Cronbach's alpha for internal consistency

Reliability measure	Value	Number of items
Cronbach's alpha	0.878	9

Table 1.2 illustrates that the validity of this questionnaire has been assessed using Cronbach's Alpha. The computed alpha value indicated high internal consistency of the scale,

with a Cronbach's alpha of 0.878 for the nine items. The general rule of thumb says that the value of Cronbach's Alpha should be 0.70 and above, and that a value of 0.80 or higher is good. Hence, this finding proves that the items included in the questionnaire are reliable enough to measure the same construct, and the scale is considered statistically valid enough to proceed with the analysis. This high-reliability index proves the validity of the questionnaire in measuring the variables under study in the present research.

c) Construct validity test: Exploratory factor analysis Principal Component Analysis (PCA) as a test of use

Table 1.3: KMO and Bartlett's test results

Test	Value
KMO measure of sampling adequacy	0.775
Bartlett's test of sphericity	$\chi^2 = 179.255$, $df = 36$, $p < 0.001$

Table 1.4: Factor analysis result

Correlation matrix										
		How familiar are you with PCOS?	The tool helps understand symptoms	The tool explains the diet for PCOS	A tool helpful for exercise for PCOS	The tool covers stress management	Likely to make a lifestyle change	The tool explains complications	Confidence in understanding PCOS	Understanding of long-term risks
Correlation	How familiar are you with PCOS?	1.000	0.395	0.267	0.531	0.225	0.753	0.478	0.434	0.423
	The tool helps understand symptoms	0.395	1.000	0.399	0.571	0.379	0.488	0.393	0.638	0.325
	The tool explains the diet for PCOS	0.267	0.399	1.000	0.207	0.530	0.249	0.575	0.252	0.200
	A tool is helpful for exercise for PCOS	0.531	0.571	0.207	1.000	0.452	0.563	0.367	0.697	0.583
	The tool covers stress management	0.225	0.379	0.530	0.452	1.000	0.294	0.396	0.456	0.429
	Likely to make lifestyle changes	0.753	0.488	0.249	0.563	0.294	1.000	0.571	0.436	0.584
	The tool explains complications	0.478	0.393	0.575	0.367	0.396	0.571	1.000	0.387	0.589
	Confidence in understanding PCOS	0.434	0.638	0.252	0.697	0.456	0.436	0.387	1.000	0.561
	Understanding of long-term risks	0.423	0.325	0.200	0.583	0.429	0.584	0.589	0.561	1.000
Sig. (1-tailed)	How familiar are you with PCOS		0.006	0.048	0.00	0.082	0.00	0.001	0.003	0.003
	The tool helps understand symptoms	0.006		0.005	0.00	0.008	0.001	0.006	0.00	0.020
	The tool explains the diet for PCOS	0.048	0.005		0.100	0.00	0.061	0.00	0.058	0.108
	A tool helpful for exercise for PCOS	0.00	0.00	0.100		0.002	0.00	0.010	0.00	0.00
	The tool covers stress	0.082	0.008	0.00	0.002		0.033	0.006	0.002	0.003

	management									
	Likely to make a lifestyle change	0.00	0.001	0.061	0.00	0.033		0.00	0.002	0.00
	The tool explains complications	0.001	0.006	0.00	0.010	0.006	0.00		0.007	0.00
	Confidence in understanding PCOS	0.003	0.00	0.058	0.00	0.002	0.002	0.007		0.00
	Understanding of long-term risks	0.003	0.020	0.108	0.00	0.003	0.00	0.00	0.00	
a. Determinant = 0.006										

The correlation matrix presented in Table 1.4 shows the interrelationships among the nine items included in the factor analysis of the PCOS awareness intervention tool. Most correlation values are moderate to substantial and statistically significant, suggesting that the items are appropriately interlinked for factor analysis. The strongest association is observed between familiarity with PCOS and the likelihood of making lifestyle changes ($r = 0.753$, $p < 0.001$), suggesting that a high level of baseline awareness is closely linked to readiness for behavior modification. Likewise, confidence in learning about PCOS is positively correlated with items such as exercise guidance ($r = 0.697$, $p < 0.001$) and symptom clarification ($r = 0.638$, $p < 0.001$), which demonstrates the importance of knowledge in increasing self-efficacy. Other items (related to diet, $r = 0.530$ with stress management, $p < 0.001$; related to stress management, $r = 0.452-0.456$ with exercise and confidence, $p < 0.01$) also show significant relationships, and the multidimensional nature of the PCOS education. Whereas some lesser correlations are found (e.g., diet with long-term risks, $r = 0.200$, $p > 0.05$), the general tendency shows consistency across areas. The non-existence of multicollinearity is demonstrated because the determinant value of 0.006 is significantly higher than the critical value of 0.00001, and the data are suitable for extracting the factors. The correlation structure highlights that the tool captures overlapping but distinct domains general awareness, symptom and complication knowledge, lifestyle guidance, and risk perception which justifies proceeding with exploratory factor analysis.

Table 1.5: Communalities

Item	Initial	Extraction
Q1: Familiarity with PCOS	1.000	0.616
Q2: Helps understand symptoms	1.000	0.513
Q3: Explain the diet for PCOS	1.000	0.833
Q4: Helpful for exercise	1.000	0.698
Q5: Covers stress management	1.000	0.631
Q6: Likely to make lifestyle change	1.000	0.714
Q7: Explains complications	1.000	0.606
Q8: Confidence in understanding PCOS	1.000	0.609
Q9: Understanding of long-term risks	1.000	0.581

Table 1.6: Total variance explained

Component	Initial eigenvalue	% of variance	Cumulative %
1	4.615	51.281%	51.281%
2	1.184	13.159%	64.440%

Note: Only components with eigenvalue > 1 were retained

Table 1.7: Component matrix (Unrotated)

Item	Component 1	Component 2
Q1: Familiarity with PCOS	0.712	-0.329
Q2: Helps understand symptoms	0.715	0.038
Q3: Explains diet	0.533	0.741
Q4: Helpful for exercise	0.791	-0.269
Q5: Covers stress management	0.626	0.489
Q6: Likely to change lifestyle	0.784	-0.315
Q7: Explains complications	0.733	0.263
Q8: Confidence in understanding PCOS	0.769	-0.134
Q9: Understanding long-term risks	0.744	-0.166

PCA results

To determine the structure underlying the 9-item questionnaire on awareness and perception of PCOS, Principal Component Analysis (PCA) was done, as shown in Tables 1.3 and 1.4. This analysis was suitable, as the Kaiser-Meyer-Olkin (KMO) sampling adequacy measure, with an absolute value of 0.775, indicated that the data were adequate. Moreover, Bartlett's Test of Sphericity was significant ($p < 0.001$), which supported the factorability of the correlation matrix. The PCA extracted two components, of which the eigenvalues of the two components were greater than one, explaining a total of approximately 64.44 percent of the total variance. The first component explained the most significant percentage of the total variance, 51.28 percent. The second component explained the remaining 13.16 percent of the total variance. The communalities (extracted values) indicate that all items possess moderate to high shared variances in the underlying components, ranging from 0.513 to 0.833, which suggests that the factor solution effectively represents the items. Factor Loadings. In the component matrix, the majority of the items were found to have high load on the first component, especially the items that were related to (Table 1.7):

- Self-efficacy of knowledge related to PCOS (Q8: 0.769)
- Exercise recommendation (Q4: 0.791)
- Probability of modification of lifestyle (Q6: 0.784)
- Knowledge about long-term risks (Q9: 0.744)
- Description of complications (Q7: 0.733)

Poor loading was observed in component 2, which showed a strong correlation with Q3 (diet role) at 0.741 and a slightly weaker correlation with Q5 (stress management) at 0.489, suggesting the presence of a diet-stress awareness factor.

Model fit and residuals

Table 4.24 revealed that the percentage of abs (Elonex) values greater than 0.05 in the reproduced correlation matrix was approximately 75%, which is quite acceptable given that the correlation analysis is exploratory and based on two

factors. The answer to question 8 confirms the structure of the questionnaire. The tool has a good construct validity, where items are well clustered in the tool into two components:

1. Lifestyle management of PCOS: General Awareness and Confidence.
2. Specific refers to awareness of Diet and Stress.

These results confirm the reliability and multidimensional organization of the questionnaire, proving its effectiveness in assessing the degree of awareness among participants within the framework of PCOS complications.

I-CVI (Item level- content validity index) formula

$$I - CVI = \frac{\text{Number of Experts who Rated 3 or 4}}{\text{Total Number of Experts}}$$

Since you are using a 4-point scale, a rating of 3 or 4 is considered content valid (relevant).

Table 1.8: Given expert ratings (Total experts = 10)

Question	Experts rated 3	Experts rated 4	Total valid (3+4)	I-CVI (Valid/10)
Q1	3	7	10	1.00
Q2	3	7	10	1.00
Q3	2	8	10	1.00
Q4	5	5	10	1.00
Q5	1	9	10	1.00
Q6	4	6	10	1.00
Q7	1	9	10	1.00

Summary of I-CVI results

- All 7 items have an I-CVI = 1.00, which is excellent.
- This means 100% of the experts rated each item as relevant (3 or 4).

Calculate Scale-Level CVI (S-CVI)

You can compute S-CVI using either of the two methods:

a) S-CVI/average method

$$= \frac{\sum I - CVI}{\text{Number of Items}} = \frac{7}{7} = 1.00$$

b) S-CVI/Universal Agreement (UA)

$$= \frac{\text{Number of Items with } I - CVI = 1.00}{\text{Total Items}} = \frac{7}{7} = 1.00$$

Content validity analysis

To determine the content validity of the questionnaire, a panel of ten subject-matter experts considered seven items on a four-point relevance scale. It was on a scale of 1 (irrelevant) to 4 (highly appropriate) to get the Item-Level Content Validity Index (I-CVI); responses of 3 or 4 represented satisfactory responses on the relevance of the items indicated in Table 1.8.

The findings showed the seven items had 3 or 4 ratings from all ten experts. In particular, the I-CVI of every item was computed by dividing the number of professionals who gave a rating of 3 or 4, and it was found that the I-CVI = 1.00 for each item. This means that the experts fully agreed on the relevance of every item.

Included in the set of calculations regarding the I-CVI was also the Scale-Level Content Validity Index (S-CVI), which utilized the universal agreement method (S-CVI/UA) and average method (S-CVI/Ave) to calculate its value. The two computations reached a score of 1.00, indicating that each item was deemed not to be irrelevant in any of the opinions raised by the panel members.

These results demonstrate that the questionnaire possesses excellent content validity, with experts strongly agreeing that the included items are relevant and appropriate to the intended construct being evaluated.

Discussion

Reliability of the intervention tool

Internal consistency was high, with a Cronbach's alpha value of 0.878, indicating a high correlation above 0.70, the minimum level of internal consistency, and above 0.80, which is considered an acceptable value (Gliem & Gliem, 2003) ^[3]. This suggests that all nine items consistently measured the same underlying construct of PCOS awareness. Comparable studies that have developed educational interventions for chronic conditions have reported similar reliability levels (Basu *et al.*, 2018) ^[1].

Face validity

The Face validity analysis revealed a tremendous positive response from the participants, with mean values ranging from 1.08 to 1.28 and a median of 1.00 throughout. The respondents found the tool to be simple to follow, educative, illuminating, empowering, and referable. It is important to note that Q2 (learning something new) had the lowest mean (1.08) and the lowest standard deviation (0.35), which indicated a high level of agreement. These results are consistent with previous validations of education interventions for female health (Chaudhary *et al.*, 2021) ^[2], and in this context, clarity and simplicity played a crucial role in establishing acceptability.

Construct validity

Factor analysis confirmed the presence of a two-component solution, which explained 64.44% of the total variance. The items in Component 1 were associated with general awareness, confidence, and lifestyle management, while those in Component 2 were associated with diet and stress awareness. This framework highlights the multidimensionality of PCOS education, aligning with evidence that effective PCOS interventions should focus on general lifestyle changes and specific areas of management (Teede *et al.*, 2018) ^[8]. The communality values between 0.513 and 0.833 were justified, as all items were represented well in the extracted factors.

The adequacy and factorability of the sampling were evidenced by the KMO measure (0.775) and a significant Bartlett's Test ($p < 0.001$). These values are in the meritorious category (Kaiser, 1974) ^[4], affirming the strength of the factor solution.

Content validity

The experts' rating indicated unanimity, as all the items had an I-CVI of 1.00, and the S-CVI was also 1.00. This demonstrates excellent content validity, exceeding the suggested cut-off of 0.78 in I-CVI (Polit & Beck, 2006) ^[7]. The results indicate that domain experts unanimously considered all items to be relevant and representative of

PCOS awareness constructs. Such consensus has also been documented in validation studies of reproductive health education tools (Karjane *et al.*, 2020) [5].

Implications for intervention

The reliability, face, construct, and content validity indicate that the developed tool is psychometrically valid and contextually adequate. It is an effective tool for capturing various aspects of PCOS awareness and can serve as a sound basis for intervention-based education. The two-factor scheme aligns with the holistic management recommendations in the PCOS literature (Moran *et al.*, 2017) [6], emphasizing both general awareness and lifestyle behaviors, as well as specific dietary and stress-related strategies.

Conclusion

The validation procedure indicated that the created intervention instrument on awareness of PCOS has an excellent level of reliability ($\alpha = 0.878$), face validity, and healthy construct validity (two-component structure explaining 64.44% variance), as well as excellent content validity (I-CVI and S-CVI = 1.00). The tool was deemed understandable, educational, and valuable in enhancing self-management preparedness for PCOS. Participants found it user-friendly, and experts unanimously supported its applicability.

These results make the tool powerful for assessing awareness and informing educational interventions among PCOS women (especially in community and clinical research studies). Additionally, the multidimensional framework indicates that it can be used to implement focused interventions that tackle lifestyle and diet, stress, and long-term risk factors.

Further investigation into large-scale applications and intercultural validation is needed to warrant more generalizability. Incorporating this tool in intervention programs can help raise awareness and modify behaviors that will significantly prevent and manage PCOS.

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