

## **Study Protocol and Statistical Analysis Plan**

### **Official Title of the Study:**

Psychosocial and Clinical Predictors of Depression, Anxiety, and Stress Among Breast Cancer Patients in Iraq: A Multivariate and Path Modeling Analysis

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# **Psychosocial and Clinical Predictors of Depression, Anxiety, and Stress Among Breast Cancer Patients in Iraq: A Multivariate and Path Modeling Analysis”**

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## **1-Introduction**

Cancer is one of the most pressing global health concerns. It is stated that there will be four million new breast cancer cases in 2030. World Health Organization (1). Anticipate that cancer numbers will increase significantly, especially in low- and middle-income countries(2). Beyond the physical and financial burdens, cancer is now widely recognized for its profound psychological toll. Emotional distress, such as depression, anxiety, insomnia, and anger, has been identified as a 'silent comorbidity' that can impact treatment adherence, recovery outcomes, and overall quality of cancer patients.

Breast cancer is the most commonly diagnosed cancer among women globally including the Middle East and Iraq. According to the Iraqi Ministry of Health (3). More than 5,000 new breast cancer cases are diagnosed annually, representing over 21% of total new cancer diagnoses in the country(2,3). Unfortunately, due to poor access to screening programs, and limited public awareness, most patients are diagnosed at advanced stages, particularly in underserved regions such as Al-Anbar (4). These patients are at greater risk of experiencing severe psychological consequences due to uncertain prognosis, aggressive treatment protocols, and social isolation (5)

Previous research in Al-Anbar has focused on breast cancer patients (4) Largely focused on pharmacological and economic variables, without exploring behavioral and emotional factors such as sleep quality, emotional regulation (e.g., anger), use of sedatives, or support systems. In the broader Middle Eastern context, recent literature from Jordan, Egypt, and Iran has emphasized the need for Integrated psychosocial evaluation in oncology practice, showing how untreated distress can Exacerbate the overall disease burden (6)(7)(8)(9,10)

A recent study conducted across inpatient and outpatient oncology settings in Jordan reported that 23.4% of cancer patients exhibited depressive symptoms. In comparison, up to 37.6% showed signs of severe anxiety, particularly among inpatients and patients with advanced-stage disease. However, the antidepressant treatment was prescribed for only

15.5% of patients with depression or anxiety (11). These findings highlight A major unmet need in clinical care and reinforce the importance of early screening and targeted psychosocial support in cancer patients.

In Iraq, mental health services incorporation into oncology care remains substantially inadequate. Mental health professionals are scarce in most oncology centers, and psychological screening is not routinely performed during cancer diagnosis or follow-up. Cultural stigma surrounding mental illness may also contribute to the underreporting of emotional symptoms and poor help-seeking behavior. According to a 2023 WHO-EMRO report, less than 15% of patients in Iraq received psychological support, even though studies consistently demonstrate a high rate of undiagnosed mood disorders in this group of patients (12).

The present study aims to examine the psychosocial, clinical, and economic correlations of depression, anxiety, and stress among breast cancer patients in Al-Anbar city. Applying a multidimensional analytic approach, including multivariate linear and logistic regression, ROC analysis, and path modeling. This study explains how individual, emotional, and treatment-related factors interact to shape mental health outcomes. The findings are intended to guide more culturally sensitive and systemically integrated psychological interventions for cancer patients in Iraq and the region.

## **2-Materials and Methods**

### **2-1 Study design**

This is a cross-sectional observational study that was conducted between January and May 2025 in Al-Anbar Oncology Centre, Al-Anbar, Iraq.

### **2-2 Study population and sampling technique**

The study population consisted of all patients diagnosed with breast cancer who attended the Al-Anbar Oncology Centre in Al-Anbar, Iraq, between January 5th and May 30th, 2025.. Patients diagnosed with breast cancer at any stage and who provided informed consent to participate were included in the study.

### **2-3 Sample Size Calculation**

The sample size was calculated using the standard formula for cross-sectional studies, with the following parameters: a 95% confidence level, a 5% margin of error, and an expected prevalence of psychological distress of 50% to yield the largest possible sample size. Based on these assumptions, the minimum required sample size was estimated to be 384 participants. To enhance the statistical power and compensate for potential non-response or incomplete data, a larger sample was targeted. Consequently, a total of 500 breast cancer patients were enrolled in the final analysis, exceeding the minimum requirement.

### **2-4 Questionnaire tool and data extraction**

Patients' data were collected from medical records (demographics data, medication use history, and clinical profile). Cost data was obtained from the finance department at the center. Financial data included all available direct medical costs, such as treatment and physician visits. Moreover, patients were contacted to estimate the indirect cost associated with breast cancer therapy. A validated assessment tool, the Generalized Anxiety Disorder 7-item (GAD-7) and the Patient Health Questionnaire (PHQ-9) were used to assess anxiety and depression [Spitzer et al., 2006; Kroenke et al., 2001]. The patients were asked to determine the degree of applicability of each item (question) on a 4-point Likert scale. The participants' responses varied from 0 to 3, with 0 denoting "Not at all" and 3 denoting "Nearly every day." Nine elements comprise the PHQ-9 instrument. Items are scored on a scale of 0 to 3, resulting in a total score that ranges from 0 to 27. A total score of 0–4 indicates minimal depression, 5–9 mild depression, 10–14 moderate depression, 15–19 moderately severe depression, and 20–27 severe depression. Seven elements comprise the

GAD-7 instrument. Items are scored on a scale of 0 to 3, resulting in a total score that ranges from 0 to 21. Mild anxiety is indicated by a total score of 5–9, moderate anxiety by 10–14, and severe anxiety by 15–21.

## **2-5 Ethical approval**

Ethical approval for this study was obtained from the Ministry of Health, Anbar Health Directorate, and the Al-Anbar Cancer Centre, Iraq (Approval No. 1060, dated January 28, 2025).

For any further inquiries, the ethical committee can be contacted via the official email: [anbarcancercenter@gmail.com](mailto:anbarcancercenter@gmail.com).

The study was conducted by the ethical standards of the Declaration of Helsinki.

## **2-6 Data Analysis**

Data was analyzed using IBM SPSS Statistics version 26. Descriptive statistics (mean, standard deviation, frequency, and percentage) were used to summarize demographic and clinical variables. The Kolmogorov-Smirnov test was applied to assess the normality of continuous variables, and due to non-normal distribution, non-parametric tests were used.

Bivariate analyses included Spearman's correlation coefficient to evaluate associations between psychological outcomes (depression, anxiety, stress) and continuous predictors such as sleep quality, cost, and number of children. The Kruskal-Wallis H test was employed to examine differences in distress levels across cancer stages.

Categorical associations were evaluated using Pearson's Chi-square test. Binary logistic regression analysis was conducted to identify predictors of severe anxiety. Additionally, multivariate linear regression models were constructed for each psychological outcome (PHQ-9, GAD-7, stress), and multicollinearity was assessed using the Variance Inflation Factor(VIF).

Receiver Operating Characteristic (ROC) curve analysis was used to assess the predictive accuracy of stress scores for severe anxiety, with Area Under the Curve (AUC) interpreted based on conventional thresholds. Conceptual path modeling was used to explore potential indirect relationships between stress and anxiety, mediated by sleep disturbance and impaired daily performance.

All tests were two-tailed, and a p-value of less than 0.05 was considered statistically significant.

### 3 - Results

A total of 500 breast cancer patients were included in the final analysis. Descriptive statistics revealed a high prevalence of psychological distress within the sample, with elevated scores in depression, anxiety, and stress domains.

Spearman correlation analysis revealed strong positive associations between sleep difficulty and psychological outcomes: depression ( $r = 0.85$ ), anxiety ( $r = 0.77$ ), and stress ( $r = 0.85$ ), all statistically significant at  $p < 0.001$ . Use of sedatives was also significantly correlated with elevated distress scores ( $r > 0.90$  across models).

Kruskal-Wallis tests demonstrated statistically significant differences in mean ranks of depression, anxiety, and stress across cancer stages ( $p < 0.01$ ), with higher distress in patients with advanced-stage disease.

Multivariate linear regression identified the following as significant predictors of psychological distress:

- PHQ9\_Total:  $\beta = 0.42$ ,  $p < 0.001$
- Anger:  $\beta = 2.08$ ,  $p < 0.001$
- Cancer Stage:  $\beta = 0.92$ ,  $p = 0.0014$

Psychological support was not a significant predictor ( $p = 0.606$ ).

Binary logistic regression showed that PHQ9 and anger significantly predicted severe anxiety, with odds ratios of 1.32 and 1.27, respectively ( $p < 0.001$ ). Stage of disease also emerged as a significant factor in anxiety prediction.

Receiver Operating Characteristic (ROC) curve analysis yielded an Area Under the Curve (AUC) of 0.74 for stress in predicting severe anxiety, indicating a fair level of discriminative ability.

Finally, conceptual path analysis demonstrated that the relationship between stress and anxiety was primarily indirect, mediated through sleep disturbance and daily performance impairment. The direct path from stress to anxiety was negligible ( $r = -0.01$ ), suggesting a mediated mechanism of action.

**Table 1.** Descriptive Statistics of Study Variables

Variable	N	Minimum	Maximum	Mean	SD
Total Cost	500	80	34785	3721.69	4456.79
PHQ9_Total	500	1	27	17.99	6.11
GAD7_Total	500	1	21	12.79	3.81
Cancer Stage	500	0	4	2.52	1.09
Children	500	0	5	2.53	1.63
Metastatic	500	0	1	0.36	0.48
Stress Level	500	0	4	2.64	0.79

The descriptive characteristics of the study variables are presented in **Table 1**. Depression and anxiety scores were moderately high, while stress levels were also elevated. Treatment cost showed substantial variability across participants.

**Table 2.** Spearman Correlation Matrix Among Study Variables

Variable	PHQ9_Total	GAD7_Total	Stress Level	Sleep Difficulty	Sleep Satisfaction	Total Cost

PHQ9_Total	1.00	0.79	0.66	0.85	0.49	-0.11
GAD7_Total	0.79	1.00	0.65	0.77	0.62	-0.10
Stress Level	0.66	0.65	1.00	0.85	0.55	-0.12
Sleep Difficulty	0.85	0.77	0.85	1.00	0.48	-0.08
Sleep Satisfaction	0.49	0.62	0.55	0.48	1.00	-0.09
Total Cost	-0.11	-0.10	-0.12	-0.08	-0.09	1.00

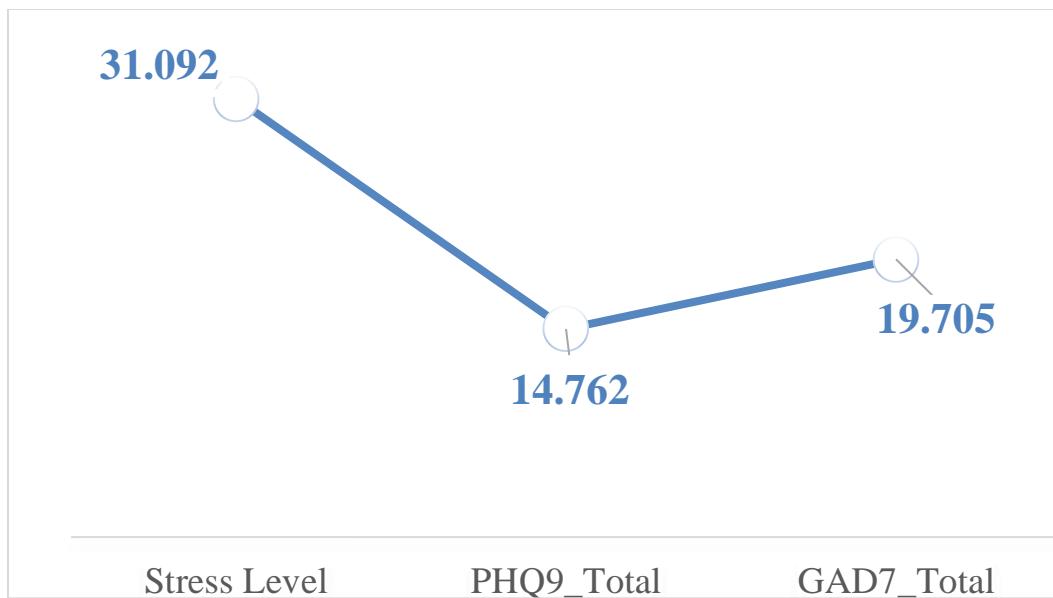
Spearman correlation coefficients between psychological outcomes and sleep-related variables are shown in **Table 2**. Strong positive correlations were observed between depression, anxiety, stress, and sleep difficulty.

**Table 3.** Kruskal–Wallis Test for Differences Across Cancer Stages

Variable	Chi-square (H)	df	P-value
Stress Level	31.092	3	<0.001
PHQ9_Total	14.762	3	0.002
GAD7_Total	19.705	3	<0.001

The Kruskal–Wallis test results (**Table 3**) indicate significant differences in depression, anxiety, and stress levels across cancer stages ( $P < 0.05$ ).

**Figure 1.** Chi-square (H) Values for Stress, Depression, and Anxiety



**Figure 1** shows the Chi-square (H) values for stress, depression, and anxiety. Stress exhibited the highest value (H = 31.09), followed by anxiety (H = 19.71) and depression (H = 14.76), all indicating significant differences across groups ( $P < 0.05$ ).

**Table 4.** Multiple Regression Analysis of Factors Associated with Depression, Anxiety, and Stress among Patients

Outcome	Predictor	B	T	P-value	VIF	R <sup>2</sup>
Depression (PHQ-9)	Use of Sedatives	4.842	10.817	<0.001	1.766	0.702
	Sleep Difficulty	4.52	11.221	<0.001	4.866	
	Sleep Satisfaction	0.364	2.01	0.045	1.021	
	Children	0.075	0.626	0.532	1.039	
	Total Cost	7.5E-5	2.209	0.028	1.022	

	Metastatic	-0.13	-0.408	0.684	1.048	
Anxiety (GAD7)	Use of Sedatives	4.064	12.807	<0.001	1.766	0.615
	Sleep-related Worry	1.521	6.193	<0.001	3.655	
	Sleep Satisfaction	0.539	1.886	0.060	4.866	
	Children	0.205	1.889	0.060	1.039	
	Total Cost	3.0E-5	1.246	0.213	1.022	
	Metastatic	0.203	0.896	0.371	1.048	
Stress Level	Use of Sedatives	1.856	29.413	<0.001	1.766	—
	Sleep-related Worry	0.149	3.048	0.002	3.655	
	Children	0.037	1.705	0.089	1.039	
	Metastatic	0.084	1.865	0.063	1.048	
	Total Cost	3.4E-6	0.711	0.477	1.022	

The results of the multiple regression analysis are summarized in **Table 4**. Use of sedatives and sleep-related worry were significant predictors of stress, depression, and anxiety scores.

**Table 5:** Binary Logistic Regression – Predicting Severe Anxiety

Predictor	Odds Ratio (OR)	95% CI	P-value
Depression (PHQ-9)	1.32	1.18 – 1.56	<0.001

Anger	1.27	1.11 – 1.49	0.002
Stress Level	1.14	1.03 – 1.35	0.017
Psychological Support	0.54	0.33 – 0.91	0.021
Cancer Stage	0.61	0.33 – 0.87	0.049

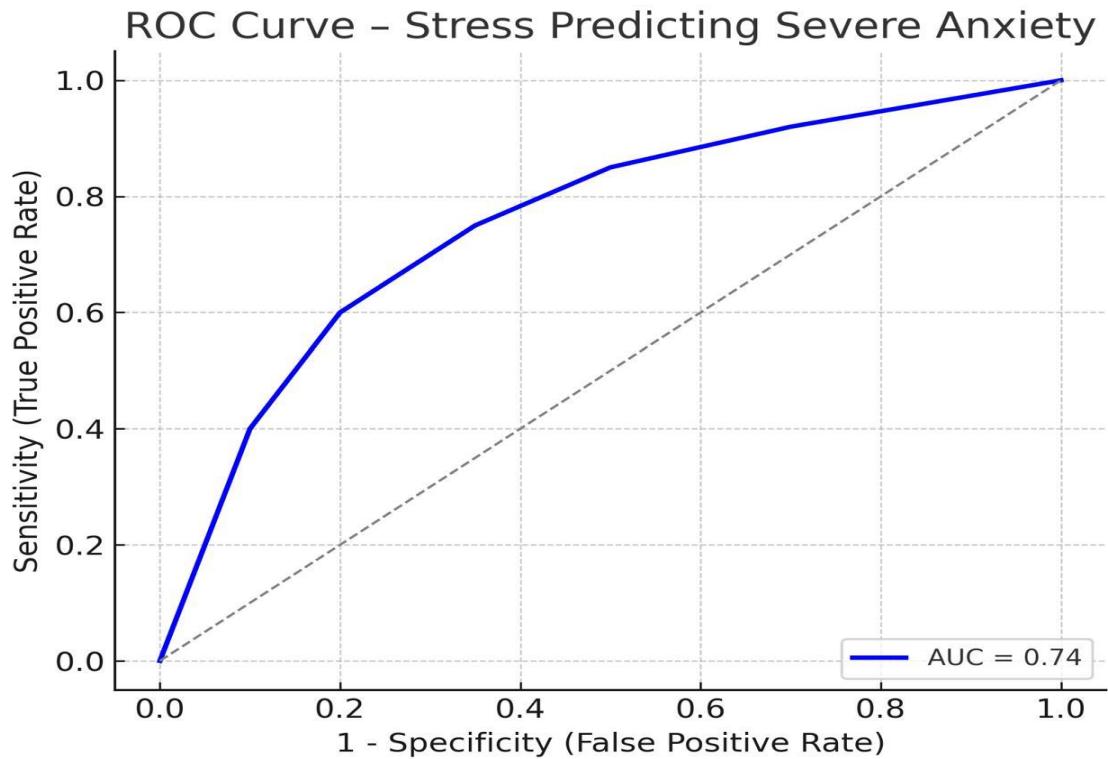
Binary logistic regression (**Table 5**) showed that depression, anger, and stress significantly increased the odds of severe anxiety, while psychological support and advanced cancer stage were protective. The corrected model (**Table 6**) confirmed these associations.

**Table 6.** Logistic Regression Predicting Severe Anxiety (Corrected Model)

Predictor	Coef. ( $\beta$ )	Std. Error	z-value	p-value	95% CI (Lower – Upper)
PHQ9_Total	0.42	0.06	6.92	<0.001	0.30 – 0.53
Anger	2.08	0.48	4.36	<0.001	1.14 – 3.02
Psych Support	-0.18	0.34	-0.52	0.606	-0.84 – 0.49
Cancer Stage	0.92	0.29	3.20	0.0014	0.36 – 1.48

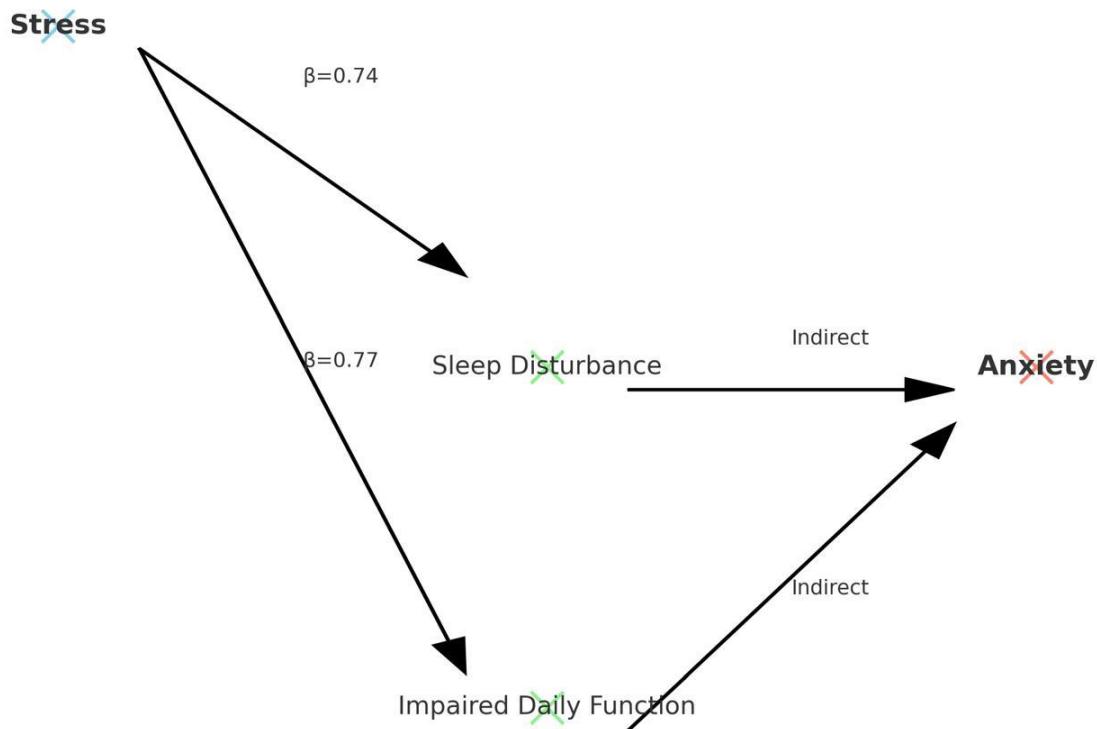
This table presents the corrected logistic regression model for predicting severe anxiety. PHQ9\_Total and anger were significant positive predictors, while psychological support did not show a significant protective effect in the adjusted model.

**Figure 2.** ROC Curve for stress predicting severe anxiety.



The ROC curve (**Figure 2**) illustrates the predictive value of stress scores for severe anxiety, with an AUC of 0.74 ( $p < 0.001$ ), indicating fair discriminative accuracy.

**Figure 3. Conceptual Path Model illustrating stress–anxiety relationships.**



The conceptual path model illustrates the indirect relationship between stress and anxiety, mediated by sleep disturbance and impaired daily functioning, with  $\beta$  coefficients indicating the strength of associations.

#### 4- Discussion

The present study provides a comprehensive psychosocial profile of breast cancer patients in Al-Anbar, Iraq, highlighting significant associations between psychological distress, sleep disturbance, disease stage, economic burden, and emotional regulation. The results of our study reveal that depression and anxiety levels were remarkably high among breast cancer patients, with strong correlations to sleep-related variables and the use of sedative medications. These findings are consistent with previous studies from Iraq and neighboring countries, which emphasize the underrecognized psychological morbidity among cancer patients (13).

Specifically, the elevated stress levels observed in our study appear closely tied to poor sleep quality and increased reliance on sedatives. This pattern is consistent with findings from Iranian oncology research, where 66.8% of cancer patients reported poor sleep quality (PSQI > 5), strongly associated with symptoms of anxiety and depression (14)

Similarly, (14) Demonstrated that more than one-third of cancer patients experienced subjective sleep disturbances, with 6.1% relying on sedative medication. These findings highlight disrupted sleep as a key contributor to psychological distress in oncological care and support the growing understanding that impaired sleep quality may serve as a potential clinical indicator of emotional dysregulation in cancer care.

However, other studies have reported conflicting results. For example, (15) found that while sleep disturbances were prevalent among cancer patients, they were not consistently associated with heightened anxiety or depression. Such discrepancies may be explained by differences in patient populations, cancer types, cultural factors, and methodological variations across studies.

The results of the current study revealed that advanced cancer stage was significantly associated with increased levels of psychological distress, particularly anxiety and depression. After adjusting for stage coding, regression models confirmed that advanced cancer stage predicted elevated anxiety scores ( $\beta = 0.92$ ,  $p = 0.001$ ), which aligns with previous findings from oncology populations in the region(16). This association may reflect the psychological impact of disease severity, poor prognosis, increased treatment burden, and concerns about disease progression and its potential complications.

Furthermore, Kruskal-Wallis analysis confirmed significant differences in mean ranks of depression, anxiety, and stress across cancer stages ( $H = 14.76$  to  $31.09$ ,  $p < 0.01$ ). These findings are supported by evidence from Iran and neighboring countries, where patients with stage III and IV breast cancer reported higher rates of emotional distress compared to the early stages of the disease (14). The increased psychological vulnerability in advanced stages underscores the need for stage-specific psychosocial interventions in cancer care protocols

Interestingly, total treatment cost showed a weak but statistically significant inverse correlation with psychological distress variables (e.g., PHQ-9\_Total:  $r = -0.11$ ,  $p = 0.017$ ). Although initially counterintuitive, this finding may reflect a perceived sense of security or access to higher-quality care among patients with greater financial capacity. Similar interpretations were reported in recent findings from Turkey, where patients with access to private sector services and higher financial resources exhibited lower levels of psychological distress despite elevated treatment costs, suggesting that financial ability may buffer emotional burden through enhanced control and perceived care quality (17).

As for psychological support, logistic regression models from this study suggested a protective effect ( $OR = 0.54$ ), though this was not statistically significant in the adjusted model ( $p = 0.606$ ). The lack of significance may be attributed to limited availability or underutilization of structured psychological services in the region, a challenge frequently reported in Iraq and across low-resource Middle Eastern settings. (18,19). Nonetheless, the direction of effect emphasizes the urgent need to integrate psychosocial support into routine oncology care.

Among all predictors examined, depression (PHQ9\_Total) and anger emerged as the strongest independent predictors of severe anxiety in both logistic and linear regression models ( $\beta = 0.42$  and  $2.08$ , respectively,  $p < 0.001$ ). These findings support prior research indicating that depressive symptomatology often precedes or co-occurs with anxiety in cancer patients, especially when emotional regulation is compromised (11)

Although anger remains an underexplored emotional construct in oncology, its relevance is gaining traction. In Iraq, sociocultural norms that discourage emotional expression, combined with the psychological toll of cancer, may intensify internalized anger, contributing to emotional dysregulation. This perspective is supported by findings from the national report, which highlighted elevated psychological distress among cancer patients and emphasized the role of suppressed emotions in shaping anxiety and avoidance behaviors (20).

These findings emphasize the significance of addressing emotional dysregulation, particularly in patients presenting with overlapping symptoms of depression and anxiety.

This suggests that psychological screening tools should incorporate anger-related items to facilitate the early identification of high-risk cases.

The conceptual path model derived from the dataset suggests that stress influences anxiety primarily through indirect mechanisms, notably sleep disturbance and impaired daily functioning. While the direct association between stress and anxiety was minimal ( $r = -0.01$ ), robust indirect effects were observed via sleep problems ( $r = 0.74$ ) and functional impairment ( $r = 0.77$ ). These findings are consistent with regional studies from Egypt and Oman, highlighting sleep disturbance and fatigue as key mediators of psychological distress in oncology patients. (Al-Habsi et al., 2021; Gabra & Hashem, 2021; Hendy et al., 2025).

This structure reinforces theoretical frameworks such as the Transactional Model of Stress and Coping, where maladaptive emotional responses (e.g., stress) translate into clinical outcomes (e.g., anxiety) through sleep and functional capacity mediators. Similar models have been proposed in Jordanian studies (24). Though the present model uniquely incorporates performance and anger as variables of interest, adding depth to the psychosocial profile.

The inclusion of psychological support and its weak inverse association with anxiety ( $r = -0.07$ ) further suggests that strengthening emotional resources could buffer the transition from stress to anxiety. This model may therefore serve as a foundational structure for targeted interventions in Iraqi cancer care systems, particularly in resource-limited settings.

## **5- Clinical Implications**

The findings of this study underscore the urgent need to integrate routine psychological screening and targeted psychosocial interventions into oncology care for breast cancer patients in Iraq. The strong associations between stress, sleep disturbances, sedative use, and emotional dysregulation highlight the importance of early detection and management of psychological distress to improve treatment adherence and quality of life. Implementing multidisciplinary care models that include mental health professionals, sleep management programs, and culturally tailored counseling may mitigate the adverse psychological impact observed in advanced-stage patients. These results also suggest the necessity of

training healthcare providers to recognize and address hidden emotional symptoms, thereby promoting holistic cancer care in low-resource settings.

## 6-Conclusion

This study highlights the multifactorial nature of psychological distress among breast cancer patients in Al-Anbar, Iraq. Depression, anxiety, and stress were significantly linked to sleep disruption, sedative use, disease stage, and emotional dysregulation. Advanced cancer stage emerged as a key predictor of heightened anxiety and depression. These findings emphasize the need to integrate psychosocial assessment and targeted interventions into oncological care, particularly in low-resource settings, to mitigate psychological morbidity and improve quality of life in this population.

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