

## ORIGINAL RESEARCH ARTICLE

# Efficacy of cognitive behavioral therapy and nutritional counseling to improve quality of life in breast cancer patients in south-western Nigeria

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## Abstract

The primary clinical goals of treatment for cancer, other chronic illnesses, and terminal diseases are to manage symptoms and improve the quality of life (QoL). The aim of this study is to investigate the three-way interaction effect of nutritional counseling (NC) and cognitive behavior therapy (CBT) on the QoL of breast cancer patients in south-western Nigeria. This study employed a pre-test–post-test quasi-experimental design with a  $3 \times 2 \times 3$  factorial matrix, involving 92 breast cancer patients. The first three levels were CBT, NC, and control, followed by two levels of psychological distress (PD), and three levels of risk of malnutrition (RoM). The instruments used include the European Organisation for Research and Treatment of Cancer QoL Questionnaire (general and breast cancer-specific;  $\alpha = 0.80$ ), the Hospital Anxiety and Depression Scale ( $\alpha = 0.83$ ), the Malnutrition Universal Screening Tool ( $\alpha = 0.81$ ), and the Functional Assessment of Cancer Therapy-Breast for screening. Data were analyzed using analysis of covariance and estimated marginal means at the significance level  $p < 0.05$ . There was a significant three-way interaction among treatment, PD, and RoM ( $F_{(4,73)} = 3.44$ , partial  $\eta^2 = 0.16$ ), with the greatest improvement (mean score = 131.52) in participants with low levels of PD and RoM in the NC group. This study underscores the synergistic impact of treatment, PD, and RoM on the QoL of breast cancer patients in south-western Nigeria. Breast cancer patients should be screened for distress and malnutrition risk and have access to appropriate psychological and nutritional care.

**Keywords:** Cognitive behavior therapy; Nutritional counseling; Multidisciplinary approach; Quality of life; Breast cancer patients

## 1. Introduction

Cancer is a complex disease that requires contributions from a range of healthcare professionals and specialist oncology consultants to address cancer patients' needs and to optimize treatment outcomes.<sup>1</sup> There is a global movement advocating for a multidisciplinary cancer team and approach to cancer management. Cancer treatment is multifaceted in nature, consisting of cancer and non-cancer issues, such as health behavior and preventive care measures. Advocacy and recommendations are seen as essential instruments for effective cancer care policy by numerous leading scientific societies.<sup>2</sup> The need for this approach and its value in achieving optimal patient care have been recognized since the early nineties.<sup>3</sup>

The multidisciplinary approach involves shared decision-making and comprehensive care for cancer patients across various medical specialties and support services.<sup>4,6</sup> It also addresses the social, psychological, dietary, physical, and survivorship needs of patients, tailored to their individual preferences and circumstances.<sup>4,5</sup> This patient-centered method is best understood through the bio-psycho-social model of health and illness.

The quality of life (QoL) of cancer patients, including those with breast cancer, is substantially affected by cancer and its treatment.<sup>7,8</sup> The side effects of breast cancer treatment modalities, such as fatigue, insomnia, cognitive dysfunction, reproductive and menopausal symptoms, and lymphedema in early-stage breast cancer patients who undergo axillary lymph node dissection, were among the most commonly reported symptoms affecting patients' QoL, especially their physical, psychological, and emotional well-being.<sup>9-11</sup>

Recent literature revealed a low QoL of breast cancer patients in south-west Nigeria, especially in the physical, psychological, and social domains, compared to women without breast cancer.<sup>12</sup> This could be attributed to the negative impact of physical and psychosocial factors, such as anxiety, worry, fear, fatigue, nausea, loss of appetite, vomiting, confusion over what to eat and what not to eat, difficulty meeting basic needs, and changes in body image.<sup>13,14</sup> Some of these elements may also increase their chance of malnutrition, which could be detrimental to their standard of living. Furthermore, concerns about the management of both short- and long-term side effects associated with the disease and its treatment could also negatively impair the patients' QoL.

Meanwhile, the literature has proposed some therapeutic interventions to mitigate the negative effects of cancer and its treatment on QoL.<sup>15</sup> Specifically, Rueda *et al.*<sup>16</sup> and Mokhtari-Hessari and Montazeri<sup>17</sup> suggested that non-

invasive interventions, including education, counseling, and psychotherapy, such as nutritional counseling (NC) and cognitive behavior therapy (CBT), respectively, could significantly improve the general well-being of women with breast cancer. However, there is a dearth of information on this approach. This study explored the three-way interaction effect and compared the relative effectiveness of multidisciplinary approach interventions in enhancing the QoL of breast cancer patients in south-western Nigeria.

### 1.1. Theoretical framework

Our study was anchored in the bio-psycho-social model proposed by Engel.<sup>18</sup> The model explains and emphasizes the interconnections among individuals' biology, psychology, and socio-environmental factors.<sup>19,20</sup> However, in the present analysis, we focused specifically on biological and psychological factors related to quality of life. Philosophically, the model proposes that human health and illness are affected by multiple factors, from individuals' societal and environmental contexts to molecular mechanisms, thus helping professionals at the clinical practice level understand individuals' subjective experiences and social behavior, which are essential contributors to health outcomes such as QoL.

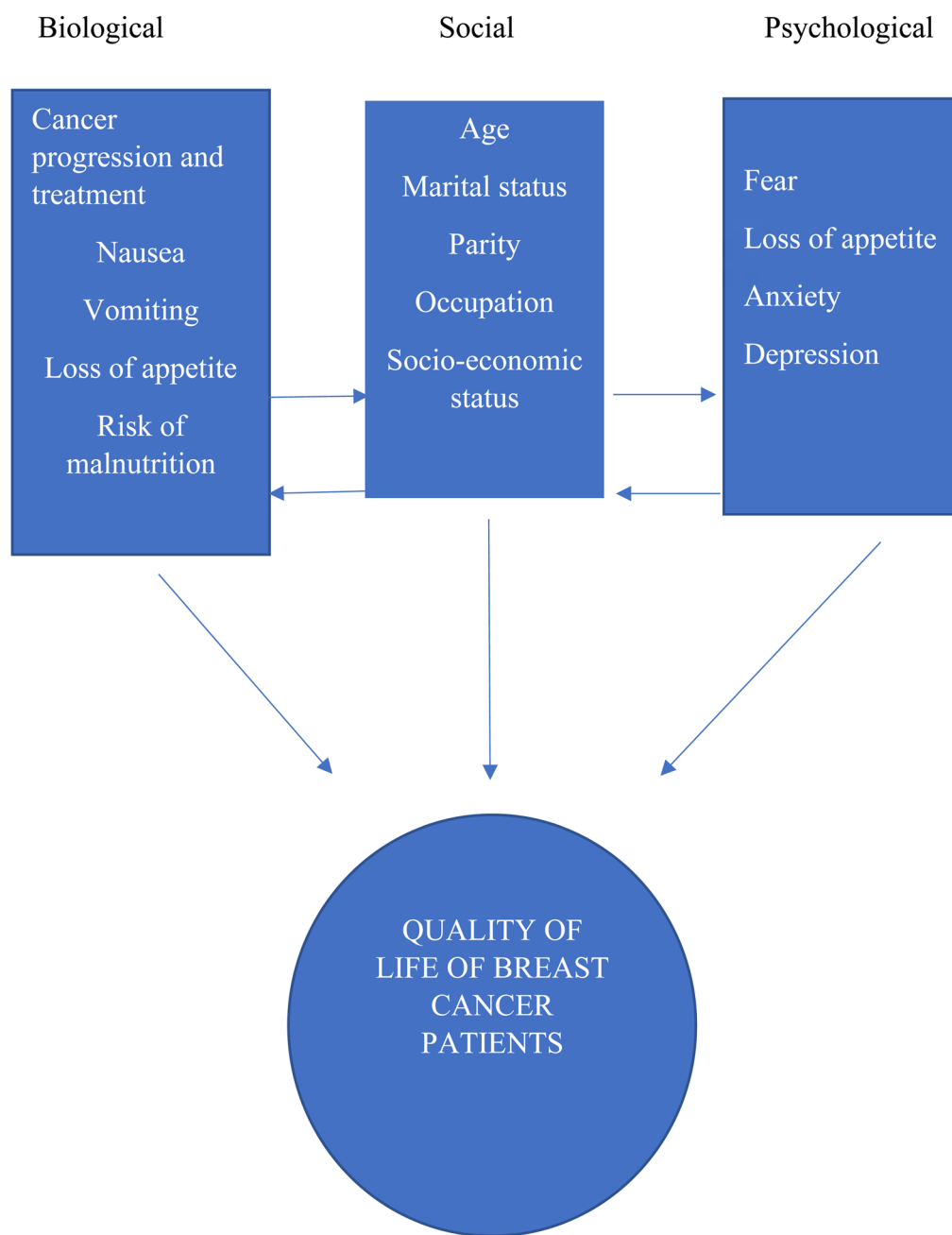
Figure 1 shows the integration of the bio-psycho-social model to enhance the QoL among breast cancer patients in south-western Nigeria. Breast cancer patients are conceptualized as systems interacting with three primary subsystems: psychological, social, and biological. These subsystems represent interconnected factors influencing QoL, as depicted by the arrows.

For instance, biological side effects of cancer treatment, such as nausea, vomiting, and generalized body weakness, may trigger appetite loss, which can also stem from negative emotions. Social factors, including age, parity, marital status, and the financial burden of capital-intensive treatment, may shape patients' attitudes and perceptions of their disease. These elements, operating independently or collectively, negatively affect patients' QoL and their ability to manage biological symptoms and treatment. However, multidisciplinary interventions reversed these effects. Study participants demonstrated improved QoL, with both CBT and NC proving effective.

## 2. Methods

### 2.1. Study design

The study adopted a pretest-posttest, control-group quasi-experimental design with a  $3 \times 2 \times 3$  factorial design. It consists of treatment and control at three levels, psychological distress (PD) at two levels, and risk of malnutrition (RoM) at three levels, to evaluate the



**Figure 1.** Integrating the bio-psycho-social model to enhance quality of life (QoL) among breast cancer patients in south-western Nigeria

outcomes of two therapies to improve QoL.

**Table 1** shows the distribution of the 92 breast cancer patients according to the factorial matrix:

At the first level, which consisted of three variables: CBT (Group 1), comprising 32 breast cancer patients; NC (Group 2), comprising 30; and the control (Group 3), comprising 30 breast cancer patients.

The second level represented PD and was dichotomized into low and high levels. Among the participants that were exposed to CBT (Group 1), 14 had low, and 18 had high levels of PD, respectively. Among those exposed to NC (Group 2), 11 had low, and 19 had high levels of PD, respectively, while among the control group, 8 and 22 had low and high levels of PD, respectively.

The third level represented the RoM and was categorized

into low, moderate, and high. In the CBT group, out of the 14 breast cancer patients with low PD, 6 had low, 4 had moderate, and 4 had high RoM, respectively, while out of 18 participants with a high level of PD, 9 had low, 5 had moderate, and 4 had high RoM, respectively. In the NC group, out of the 11 breast cancer patients with low PD, 1 had low, 3 had moderate, and 7 had high RoM, respectively, while out of 19 with a high level of PD, 10 had low, 7 had moderate, and 2 had high RoM, respectively. In addition, among the control group, out of the 8 breast cancer patients with low PD, 2 had low, 3 had moderate, and 3 had high RoM, while out of 22 with a high level of PD, 14 had low, 6 had moderate, and 2 had high RoM, respectively.

## 2.2. Study setting

**Figure 2** shows the study locations in the map of south-western Nigeria. The study data were collected at three tertiary hospitals in the south-west of Nigeria, including University College Hospital (UCH), Ibadan, Oyo State; Federal Medical Center (FMC), Idi-Aba, Abeokuta, Ogun State; and FMC, Ido-Ekiti, Ekiti State. The hospital names were retained, and all study documentation referred to the three hospitals.

## 2.3. Population

The target population for this study consisted of women diagnosed with breast cancer in south-western Nigeria, while the study population included breast cancer patients receiving oncology care at the three selected tertiary hospitals in south-western Nigeria.

## 2.4. Sample and sampling techniques

The participants for the study were selected using a multi-stage sampling procedure. The explanations of the stages were as follows:

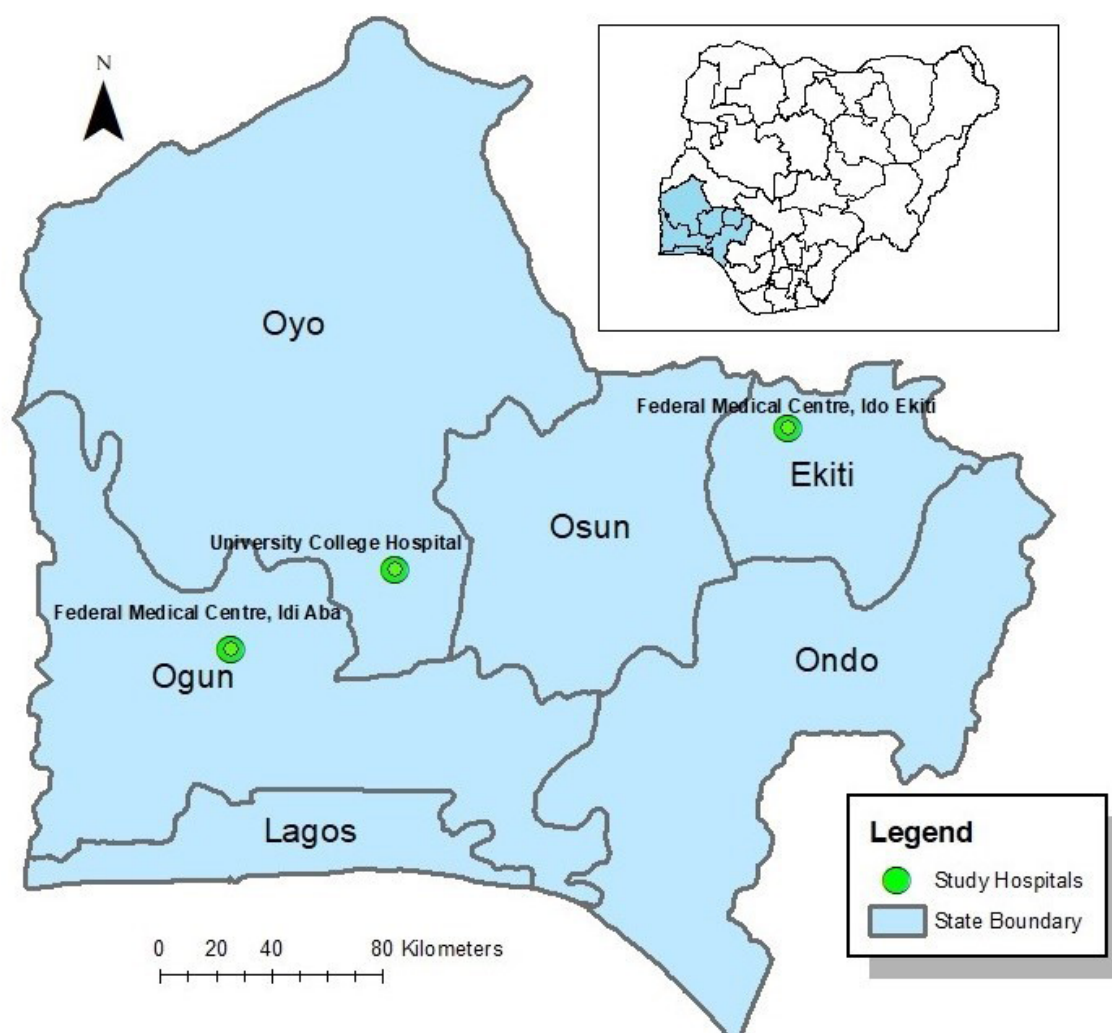
Stage 1: A simple random sampling technique was used to select three (Oyo, Ogun, and Ekiti) states out of the six (Lagos, Osun, Oyo, Ekiti, Ondo, and Ogun) states that have tertiary hospitals with oncology services in south-west Nigeria. A single random assignment sequence was generated by the researcher using a random number table; all six states had an equal chance of being selected, and possible biases in the selection process were avoided.

Stage 2: The researcher used purposive sampling to select three tertiary hospitals: UCH, Ibadan, Oyo State;

**Table 1. A  $3 \times 2 \times 3$  factorial matrix distribution of the participants**

Group	Treatment (1st level)						Group total
	PD (2nd level)						
	Low			High			
	RoM (3 <sup>rd</sup> level)			RoM (3 <sup>rd</sup> level)			
	Low	Moderate	High	Low	Moderate	High	
CBT (Group 1)	6	4	4	9	5	4	32
NC (Group 2)	1	3	7	10	7	2	30
Control (Group 3)	2	3	3	14	6	2	30
Total	9	10	14	33	18	8	92

Abbreviations: CBT: Cognitive-behavioral therapy; NC: Nutritional counseling; PD: Psychological distress; RoM: Risk of malnutrition.



**Figure 2.** Map of south-western Nigeria showing the study locations. Reprinted from Ref.<sup>21</sup>

FMC, Idi Aba, Abeokuta, Ogun State; and FMC, Ido-Ekiti, Ekiti State, based on the high number of breast cancer patients. UCH Ibadan is Nigeria's leading federal tertiary hospital, attracting breast cancer patients from across the country for its specialized oncology services and facilities. This referral pattern may have broadened the geographic scope of the sample. The inclusion of the other two hospitals may have increased the diversity of patients' urban-rural backgrounds and socioeconomic and ethnic characteristics.

Stage 3: The selected three hospitals were randomly assigned to three groups using a single sequence of random assignment with the aid of a random number table: Two experimental and one control group, as follows: UCH (Group 1), FMC, Idi-Aba (Group 2), and FMC, Ido-Ekiti (control group).

Stage 4: Screening tests were administered to 200 women with breast cancer receiving treatment at the selected hospitals, using the Functional Assessment of Cancer Therapy—Breast (FACT-B). The purpose of the screening test was to ascertain their QoL score. The total scores ranged from 0 to 148, and the norm (cut-off score) was set at 74.

## 2.5. Sample size determination

Sample size estimation with two proportions was used to determine the sample size. According to the literature, the method is used in research whose results depend on the proportions of occurrences across two or more populations (groups), such as complication rates, reductions in mortality, improvements in QoL, and surgical or medical outcomes.<sup>22</sup> Based on the percentage of outcomes reported in the literature, the sample size estimate provided adequate

power to detect statistically significant variations in QoL. The prior study yielded an overall QoL score of 75%.<sup>23</sup> With a Type I error rate of 5% ( $\alpha = 0.05$ ) and a study power of 95%, the required sample size was calculated using **Equation 1**, yielding approximately 26 samples per group.

$$n = \frac{2(Z_{\alpha} + Z_{1-\beta})^2 pq}{d^2} \quad (1)$$

where  $n$  is the required sample size per group,  $Z_{\alpha}$  is the standard normal deviate for the Type I error,  $Z_{1-\beta}$  is the standard normal deviate corresponding to the desired power,  $p$  and  $q$  are the estimated proportions of the outcome, and  $d$  is the minimum detectable difference between groups.

We recruited 32 participants who met the inclusion criteria into each group to compensate for potential dropouts, using **Equation 2**:

$$N_1 = \frac{n}{1-d} \quad (2)$$

where  $N_1$  is the adjusted sample size,  $n$  is the calculated sample size, and  $d$  is the estimated dropout rate.

Of the 200 patients screened across the three selected hospitals, 96 consenting ambulatory breast cancer patients who scored below 74 in FACT-B and met the inclusion criteria were recruited, with 32 participants in each of the two experimental and control groups. However, 4 participants (2 in Group 2 and 2 in the control group) dropped out of the study due to insufficient funds for chemotherapy. Therefore, hospital 1 (Group 1) had 32 participants, hospital 2 (Group 2) and hospital 3 (control group) had 30 each. The final sample size for the study comprised 92 breast cancer participants.

## 2.6. Inclusion criteria

The inclusion criteria for the study included women of ages 21 and above irrespective of her marital status, women with a diagnosed case of breast cancer, irrespective of the stage and treatment, who scored below 74 in FACT-B, who did not have any other medical conditions such as diabetes mellitus, hypertension, or psychotic disorders, who were not on any anti-depressant or anxiolytic medications, and those who signed a consent form to participate in the study.

## 2.7. Instrumentation

Four adopted and validated instruments were used to collect data for this study. These include the FACT-B, the European Organisation for Research and Treatment of Cancer QoL Questionnaire-30 (EORTC QLQ-30 and QLQ-BR23) ([Appendix](#)), the Hospital Anxiety and

Depression Scale (HADS), and the Malnutrition Universal Screening Tool (MUST).

The FACT-B<sup>24</sup> was used to measure QoL in breast cancer patients. It has been validated in two groups of patients. It was initially tested twice over a two-month span to determine its sensitivity to change. Additional data on validity and reliability were also collected from a larger sample. The subscale alpha coefficients ranged from 0.63 to 0.86. Test-retest reliability coefficients were 0.88 for the breast cancer-specific and 0.85 for the FACT-B total score, indicating stability over time. Evidence also supported the validity of the convergent, divergent, and known-group methods.<sup>25</sup> The FACT-B total score ranges from 0 to 148, with higher scores indicating better overall QoL. In this study, a score below 74 was used as an eligibility cut-off.

The HADS is a self-report instrument comprising 14 items<sup>26</sup> that was used to measure and categorize PD at the pre-intervention stage. The 14 items were divided equally between anxiety and depression (seven items each), with 4-point rating scales (0–3) for each item, with a higher score indicating higher symptom frequencies. The score for each subscale (anxiety and depression) ranged from 0 to 21; therefore, the total score for PD (anxiety + depression) ranged from 0 to 42, with higher scores indicating more distress. PD was classified into two levels (high and low), and a cut-off value of the total score of HADS (depression score plus anxiety score) greater than or equal to 14 indicated patients with a high level of PD, whereas scores of 8–13 were indicative of low PD. Participants scoring 0–7 were considered not to have PD; no participants in this category were identified in the present study. HADS has been used in non-psychiatric hospital settings and in hospital outpatient departments, including oncology units.<sup>26–28</sup> Cronbach's alpha coefficients of 0.77 and 0.83 (anxiety subscale) and 0.74 and 0.82 (depression subscale) were reported by Zigmond and Snaith<sup>26</sup> and Annunziata *et al.*,<sup>28</sup> respectively. The current study used all items.

The MUST was used to screen for and categorize malnutrition risk among study participants at the pre-intervention stage. It was developed by the British Association for Parenteral and Enteral Nutrition. It is a five-step screening tool to identify adults who are malnourished, at RoM (under-nutrition), or obese. It also includes management guidelines, which can be used to develop a care plan. It was designed for use in hospitals, the community, and other care settings, and can be used by all health care workers. The five steps were as follows:

- (i) Step 1: Height and weight were measured using standard tools to calculate body mass index.
- (ii) Step 2: The percentage of unplanned weight loss and score were obtained from the participants.



- (iii) Step 3: The acute disease effect and score were established based on information provided by the participants.
- (iv) Step 4: The scores from steps 1, 2, and 3 were added to assess participants' RoM, and overall risk was categorized into three groups: low risk (score 0), moderate risk (score 1), and high risk (score 2 or more).
- (v) Step 5: NC was given as the first line of the nutrition care plan, as recommended.

In terms of validity and reliability, MUST was found to detect patients at RoM with a sensitivity of 0.80, specificity of 0.89, positive predictive value of 0.87, and negative predictive value of 1.0.<sup>29</sup> MUST, when compared against Patient-Generated Subjective Global Assessment (PG-SGA), resulted in 86.7% sensitivity and 94.5% specificity, indicating perfect agreement with PG-SGA (Kappa = 0.81;  $p < 0.05$ ) and the highest area under the receiver operating characteristic curve (0.91). In addition, it showed high agreement with PG-SGA in identifying chemotherapy outpatients at RoM.<sup>30</sup>

The general EORTC QLQ-C30 and the specific QLQ-BR23<sup>31,32</sup> were used to assess participants' QoL before and after the intervention. The scoring of the EORTC QLQ-C30 and QLQ-BR23 was conducted according to the EORTC scoring manual. Reliability was assessed using Cronbach's alpha, which indicated good internal consistency ( $\alpha = 0.80$ ), within the acceptable range of 0.72 to 0.95.<sup>24,33,34</sup> All items correlated well with the total scale (lowest  $r = 0.40$ ), and all items were retained.

## 2.8. Data collection procedure

The study was designed and conducted in four stages: pre-session activities, pre-test, treatment, and post-test. The pre-session activities included recruiting participants based on the previously mentioned inclusion criteria and administering the screening test. The instruments, HADS, MUST, EORTC QLQ-30, and QLQ-BR23, were administered at the pre-test to participants in both experimental groups and the control group.

The intervention was single-blinded; participants in the three groups were not aware of which treatment they would receive. At this stage, Group 1 was exposed to eight weeks of CBT delivered by a clinical psychologist, with each session lasting about 60 to 90 min. Simultaneously, Group 2 was exposed to four sessions of NC, each lasting 60 to 90 min, delivered by a Nigerian registered nutritionist-dietitian. The four sessions were delivered fortnightly and completed within eight weeks. Both interventions were administered concurrently, starting and finishing simultaneously. Participants in the control group received only standard

medical care and a health talk covering the overview of COVID-19 infection, its causes, preventive measures, and control measures. Refreshments were provided after each session to support participant retention. At the post-intervention stage, only the EORTC QLQ-30 and QLQ-BR23 were administered.

## 2.9. Treatment package

### 2.9.1. Group 1 (cognitive behavioral therapy)

Participants in this group were exposed to eight sessions of CBT as stated below:

- (i) Session 1: General introduction and discussion on the overview of breast cancer and QoL.
- (ii) Session 2: Introduction to CBT (introducing the rationale for CBT and its process).
- (iii) Session 3: Introduction to the ABC (A = Activating event, B = Beliefs, C = Consequences) connection, identification of dysfunctional thoughts and beliefs, and progressive muscle relaxation technique.
- (iv) Session 4: Cognitive distortion, challenging dysfunctional thoughts and beliefs, cognitive restructuring, and progressive muscle relaxation at the end of the session.
- (v) Session 5: Use of the ABCDEF (D = Disputation, E = New positive emotions, F = Functional feelings and behaviors) journaling process to explain how to develop new positive emotions and functional feelings and behaviors, followed by deep breathing exercises.
- (vi) Session 6: Introduction to behavioral activation and activity scheduling, overcoming inaction through the 5-second rule, and engagement in deep breathing exercises.
- (vii) Session 7: Further explanation of the use of the ABCDEF journaling model and review of the activity scheduling sheet.
- (viii) Session 8: General review of the sessions and termination.

### 2.9.2. Group 2 (nutritional counseling)

The counseling sessions are intended to help participants gain better knowledge of what and how to eat while receiving treatment, and thereafter to prevent or reduce the RoM, maintain a fair or good nutritional status, and enhance QoL. The summary of the sessions was as follows:

- (i) Session 1: General introduction and overview of breast cancer, QoL, and causes of malnutrition.
- (ii) Session 2: Food groups and their benefits, as well as tips on healthy ways of cooking and food preparation.
- (iii) Session 3: Tips on how to ameliorate treatment side effects that can influence nutritional well-being and

how to facilitate optimal control.

- (iv) Session 4: General review. Provision of sample meal plans and advice on recipes, correction of non-scientific or evidence-based dietary information and misconceptions, reinforcement of all the topics, questions, and answers, and termination of the sessions.

### 3. Results

Table 2 shows a significant three-way interaction effect of treatment (CBT or NC), PD, and RoM on the QoL of women with breast cancer ( $F_{(4,73)} = 3.44$ , Partial  $\eta^2 = 0.16$ ). This implies that the combination of the therapies (CBT and NC), PD, and RoM has significant interaction effects on the QoL of breast cancer patients, suggesting a strong need for a multidisciplinary approach to breast cancer care.

Table 3 shows information on the extent of the interaction based on the estimated marginal means. It was revealed that after controlling for the effects of pre-test QoL, both CBT and NC experimental groups were similarly moderated by PD and RoM. They had similar PD

and RoM, far from the moderation of the control group. Group 2 was more moderated by PD and RoM than Group 1 and the control. The participants, however, demonstrated varying levels of QoL across the three-way interaction of treatment, PD, and RoM. In the NC group, the highest mean QoL score was observed among participants with low PD and low RoM (131.52), whereas in the CBT group, the highest mean QoL score was observed among participants with low PD and moderate RoM (107.93). These findings suggest that the effect of treatment on QoL differed according to participants' levels of PD and RoM.

Table 4 presents the mean score rankings of the efficacy of CBT and NC in enhancing the QoL of breast cancer patients with different levels of PD and RoM. Participants with low PD and low RoM who underwent NC had the highest mean score (131.52). The trend continued hierarchically, as shown in Table 4. Participants with high PD and a high RoM who received NC had the lowest mean score (88.11). However, the mean score (103.39) of participants with high PD and a high RoM who underwent CBT ranked sixth on the table and was higher

**Table 2. Analysis of covariance ( $3 \times 2 \times 3$ ) of pretest-posttest interactive effects on the quality of life, psychological distress, and the risk of malnutrition in breast cancer patients in the treatment groups**

Source	Type III sum of squares	Degree of freedom	Mean square	<i>F</i>	<i>p</i> -value	Partial $\eta^2$
Corrected model	24,559.258 <sup>a</sup>	18	1,364.403	14.909	<0.001	0.786
Intercept	2,820.774	1	2,820.774	30.824	<0.001	0.297
Pre-test	2,632.522	1	2,632.522	28.767	<0.001	0.283
Three-way interaction						
Treatment, psychological distress, and risk of malnutrition	1,260.720	4	315.180	3.444	0.012	0.159
Error	6,680.481	73	91.513			
Total	874,510.000	92				
Corrected total	31,239.739	91				

Notes: <sup>a</sup> $R^2 = 0.786$  (Adjusted  $R^2 = 0.733$ ); significant at  $p < 0.05$ .



**Table 3. Estimated marginal means of the interaction effect between treatment, psychological distress, and risk of malnutrition on the quality of life**

Treatment	Psychological distress	Risk of malnutrition	Mean	Standard error	95% CI	
					Lower bound	Upper bound
CBT	Low	Low	96.972 <sup>a</sup>	3.905	89.188	104.755
		Moderate	107.934 <sup>a</sup>	4.786	98.395	117.473
		High	99.197 <sup>a</sup>	4.331	90.567	107.828
	High	Low	97.192 <sup>a</sup>	3.381	90.453	103.931
		Moderate	93.486 <sup>a</sup>	4.303	84.910	102.063
		High	103.387 <sup>a</sup>	5.566	92.293	114.481
NC	Low	Low	131.516 <sup>a</sup>	9.603	112.377	150.655
		Moderate	131.149 <sup>a</sup>	5.534	120.120	142.178
		High	110.969 <sup>a</sup>	3.616	103.762	118.175
	High	Low	102.052 <sup>a</sup>	3.036	96.002	108.102
		Moderate	113.058 <sup>a</sup>	3.620	105.844	120.273
		High	88.113 <sup>a</sup>	6.831	74.499	101.728
CG	Low	Low	79.256 <sup>a</sup>	6.791	65.720	92.791
		Moderate	73.924 <sup>a</sup>	5.550	62.863	84.985
		High	89.730 <sup>a</sup>	5.533	78.704	100.757
	High	Low	77.715 <sup>a</sup>	2.584	72.565	82.864
		Moderate	81.574 <sup>a</sup>	3.906	73.790	89.358
		High	64.651 <sup>a</sup>	6.779	51.141	78.161

Note: <sup>a</sup>Covariates were evaluated at the following values: pre-test = 79.5652.

Abbreviations: CBT: Cognitive behavioral therapy; CG: Control group; CI: Confidence interval; NC: Nutritional counseling.

**Table 4. Mean score ranking of the efficacy of CBT and NC in enhancing the quality of life of breast cancer patients with different levels of PD and RoM**

Ranking	Moderating variables		Treatment	Mean score
	PD (2 levels)	RoM (3 levels)		
1	Low	Low	NC	131.52
2	Low	Moderate	NC	131.15
3	High	Moderate	NC	113.06
4	Low	High	NC	110.97
5	Low	Moderate	CBT	107.93
6	High	High	CBT	103.39
7	High	Low	NC	102.05
8	Low	High	CBT	99.20
9	High	Low	CBT	97.19
10	Low	Low	CBT	96.97
11	High	Moderate	CBT	93.47
12	High	High	NC	88.11

Abbreviations: CBT: Cognitive-behavioral therapy; NC: Nutritional counseling; PD: Psychological distress; RoM: Risk of malnutrition.

than the mean score (88.11) of participants with similar characteristics who received NC.

#### 4. Discussion

There was a significant interaction among treatments, PD, and the RoM on the QoL in breast cancer patients. This indicates that PD, RoM, and their interaction with the combined interventions significantly affect QoL, emphasizing the importance of a multidisciplinary approach in breast cancer care.

After adjusting for pre-test QoL, PD, and RoM, they exerted similar effects in both experimental groups compared to the control group. However, Group 2 (NC group) was more strongly moderated by PD than RoM, compared to Group 1 (CBT group) and the control group.

Breast cancer patients with low PD and low RoM benefited the most from NC, while those with high PD and high RoM benefited the least. However, among patients with high PD and high RoM, those who underwent CBT showed greater improvements. While NC demonstrated better overall performance than CBT, its benefits were not uniform across subgroups. This implies that people with breast cancer who have a high RoM and PD may benefit more from CBT.

These results are consistent with the principles of the bio-psycho-social model,<sup>19,20</sup> particularly its emphasis on the biological and psychological dimensions of human health and illness. The paradigm helps clinicians understand how social actions and subjective experiences affect health outcomes, including QoL. According to Claudiu-Cristian and Anamaria-Gabriela,<sup>35</sup> the model includes biological factors (e.g., breast cancer as a cellular disease, RoM due to altered nutrition), psychological factors (e.g., cancer-related stress, depression, anxiety), behavioral factors (e.g., treatment adherence), and social factors (e.g., sex, ethnicity).

The QoL for cancer patients is influenced by a complex interaction of biological, psychological, and social factors. Key players include pro-inflammatory cytokines such as interleukin (IL)-1, IL-6, tumor necrosis factor- $\alpha$ , and interferon- $\gamma$ , which play a significant mechanistic role.<sup>36</sup> These cytokines rise due to tumor burden, treatment side effects, and malnutrition, causing chronic inflammation that promotes cancer progression. This process likely involves pathways such as signal transducer and activator of transcription 3 and nuclear factor- $\kappa$ B, which support tumor growth, epithelial-mesenchymal transition, immune suppression, and metastasis. Additionally, malnutrition exacerbates cytokine release by impairing gut barrier function and antioxidant defenses, creating

a vicious cycle that increases inflammation and muscle wasting (cachexia), oxidative stress, and DNA damage. These effects accelerate tumor growth and reduce treatment tolerability, potentially leading to poorer survival and diminished QoL for cancer patients.<sup>36</sup>

In addition, chronic psychological stress, including anxiety and maladaptive illness perceptions, has the tendency to activate the hypothalamic-pituitary-adrenal axis and the sympathetic nervous system, increasing levels of glucocorticoids and catecholamines. These hormones promote the production of pro-inflammatory cytokines and inhibit anti-tumor immunity. This association could also lead to loss of appetite, behavioral changes, and anxiety.<sup>36</sup> Moreover, both malnutrition and PD independently predict lower QoL in cancer patients, with overlapping symptoms.<sup>7,29,35,36</sup>

These results also support the study by Gordon *et al.*,<sup>37</sup> who found that multifaceted interventions (education, counseling, environmental changes) outperform medical care alone in improving QoL. It also affirms Engel's<sup>18</sup> call to broaden clinical perspectives beyond biology to include psychological and social dimensions, addressing patients' ultimate psychosocial needs.

The findings also guide therapy choices; NC appears suitable for breast cancer patients with low PD and low RoM, while CBT is preferable when conditions worsen to high PD, high malnutrition risk, and poor QoL. Furthermore, literature confirms that low dietary and psychological status are independent risk factors for severe cancer treatment side effects, and both hinder post-treatment physical recovery.<sup>36,38,39</sup> Therefore, psychologists and dietitians should be integrated into cancer care teams to address the varying PD and malnutrition risk in screened patients.

In addition, CBT could help patients challenge faulty beliefs, reduce distress, and build coping skills, thereby improving emotional adjustment. NC, on the other hand, could provide targeted dietary guidance to mitigate the RoM and further improve QoL.<sup>40</sup> These outcomes affirm George's<sup>41</sup> endorsement of the bio-psycho-social paradigm's interdisciplinary approach to cancer care, including breast cancer, to optimize QoL.

#### 5. Conclusion

In this study, a significant three-way interaction was observed between treatment, PD, and RoM on breast cancer patients' QoL in south-western Nigeria. NC seems to be more efficacious overall than CBT, particularly benefiting those with low PD and low RoM. However, CBT was observed to be more potent for patients with high

PD and high RoM, highlighting the value of screening at baseline and throughout cancer treatment, followed by tailored psychological and nutritional interventions.

Addressing these initial findings requires targeted interventions, such as nutritional support (e.g., omega-3 food-to-food fortification or supplementation to reduce inflammation) and stress reduction (e.g., CBT), to break cytokine-mediated loops and thus improve QoL and outcomes across treatment phases. Although our study emphasizes these associations, mechanistic validation through longitudinal cohorts and biomarker trials is crucial to establish causality.

These results support the bio-psycho-social paradigm's emphasis on interdisciplinary cancer management. In this context, psychologists and dietitians should be integrated into cancer care teams to better address psychosocial and nutritional needs, thereby advancing the Lisbon Declaration's vision of psychosocial cancer care as a universal human right, especially in low- and middle-income countries.

Despite its contributions, this study has numerous limitations, including the use of self-report measures of PD, RoM, and QoL, which may be subject to social desirability and recall biases. Furthermore, the short-term post-test design was unable to evaluate the maintenance of long-term QoL beyond the intervention period. Thus, studies with long-term follow-up are suggested for future research.

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## Conflict of interest

The authors declare that they have no competing interests.

## Author contributions

*Conceptualization:* All authors

*Data curation:* Bosede O. Adebayo-Oke

*Formal analysis:* Bosede O. Adebayo-Oke

*Investigation:* Bosede O. Adebayo-Oke

*Methodology:* All authors

*Supervision:* Chioma C. Asuzu

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## Ethics approval and consent to participate

Ethical approvals were obtained from the University College Hospital, Ibadan (UI/EC/21/0620), the Federal Medical Centre, Idi-Aba, Abeokuta (FMCA/470/HREC/01/2022/07), and the Federal Medical Centre, Ido-Ekiti (ERC/2022/02/21/734B). In addition, written informed consent to participate in the study was obtained from all participants.

## Consent for publication

The study was conducted in accordance with ethical guidelines, and the researcher obtained written informed consent from all participants to publish the study's findings after providing information on the study's objectives and nature.

## Availability of data

The data sets used and/or analyzed during the current study are available from the corresponding authors upon reasonable request.

## Further disclosure

Part of Table 2 has been published in Ref.<sup>21</sup>

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## Appendix

### QUESTIONNAIRE

Department of Counseling and Human Development Studies, Faculty of Education, University of Ibadan

Dear Respondent,

This questionnaire is designed for research purposes. It seeks to know your reaction/opinion to the statements listed in the questionnaire. Confidentiality of all information provided is assured. Please be as honest as possible with your responses.

### SECTION A: DEMOGRAPHIC AND MEDICAL INFORMATION

**Please tick ( ) the appropriate option and fill in the gap where necessary**

1 Age: Below 30 ( ) 31-50 ( ) 51-70 ( ) Above 70 ( )

2. Religion: Christianity ( ) Islam ( ) Others ( )

3. Ethnicity: Hausa ( ) Igbo ( ) Yoruba ( ) Others----- (Specify)

4. Level of Education: None ( ) Primary Six ( ) SSCE ( ) BSc, HND and above ( )

5. Marital Status: Married ( ) Single ( ) Divorced ( ) Widow ( )

6. Parity: Non-gravida ( ) Primi-para ( ) Para 1-3 ( ) Multi-para ( )

Social Economic Status:

7 Are you gainfully employed? Yes( ) No ( )

8. Occupation: ----- (specify)

9. Monthly earnings ----- (specify the estimated amount)

10. Source (s) of income ----- (specify)

11. When did you first notice the sickness in your body? -----

12. When were you diagnosed of breast cancer? ----- (Specify)

13. Cancer stage on diagnosis: Stage 1 ( ) Stage 2 ( ) Stage 3 ( ) Stage 4 ( )

14. Type of Treatment currently (Tick as applicable): Surgery ( ) Chemotherapy ( ) Radiotherapy ( )

### SECTION B (1): MEASUREMENT OF QUALITY OF LIFE (GENERAL)

**Please answer all of the questions yourself by ticking the option that best applies to you. There is no "right" or "wrong" answers. The information that you provide will remain strictly confidential.**

S/N		Not At All	A Little	Quite A Bit	Very Much
1	Do you have any trouble doing strenuous activities, like carrying a heavy shopping bag or a suitcase?				
2	Do you have any trouble taking a long walk?				
3	Do you have any trouble taking a short walk outside of the house?				
4	Do you need to stay in bed or a chair during the day?				
5	Do you need help with eating, dressing, washing yourself or using the toilet?				



During the past week:					
6	Were you limited in doing either your work or other daily activities?				
7	Were you limited in pursuing your hobbies or other leisure time activities?				
8	Were you short of breath?				
9	Have you had pain?				
10	Did you need to rest?				
11	Have you had trouble sleeping?				
12	Have you felt weak?				
13	Have you lacked appetite?				
14	Have you felt nauseated?				
15	Have you vomited?				
16	Have you been constipated?				
17	Have you had diarrhea?				
18	Were you tired?				
19	Did pain interfere with your daily activities?				
20	Have you had difficulty concentrating on things, like reading a newspaper or watching television?				
21	Did you feel tense?				
22	Did you worry?				
23	Did you feel irritable?				
24	Did you feel depressed?				
25	Have you had difficulty remembering things?				
26	Has your physical condition or medical treatment interfered with your family life?				
27	Has your physical condition or medical treatment interfered with your social activities?				
28	Has your physical condition or medical treatment caused you financial difficulties?				

**For the following questions, please circle the number between 1 and 7 that best applies to you**

29. How would you rate your overall health during the past week?

1      2      3      4      5      6      7

Very poor

Excellent

30. How would you rate your overall quality of life during the past week?

1      2      3      4      5      6      7

Very poor

Excellent

**SECTION B (2): MEASUREMENT OF QUALITY OF LIFE (BREAST CANCER SPECIFIC)**

***Please indicate the extent to which you have experienced these symptoms or problems during the past week.***

During the past week:					
S/N		Not At All	A Little	Quite A Bit	Very Much
31	Did you have a dry mouth?				
32	Did food and drink taste different than usual?				
33	Were your eyes painful, irritated or watery?				
34	Have you lost any hair?				
35	Answer this question only if you have had any hair loss: Were you upset by the loss of your hair?				
36	Did you feel ill or unwell?				
37	Did you have hot flushes?				
38	Did you have headaches?				
39	Have you felt physically less attractive as a result of your disease or treatment?				
40	Have you been feeling less feminine as a result of your disease or treatment?				
41	Did you find it difficult to look at yourself naked?				
42	Have you been dissatisfied with your body?				
43	Were you worried about your health in the future?				
During the past four weeks:					
S/N		Not At All	A Little	Quite A Bit	Very Much
44	To what extent were you interested in sex?				
45	To what extent were you sexually active? (with or without intercourse)				
46	Answer this question only if you have been sexually active: To what extent was sex enjoyable for you?				
During the past week:					
S/N		Not At All	A Little	Quite A Bit	Very Much
47	Did you have any pain in your arm or shoulder?				
48	Did you have a swollen arm or hand?				
49	Was it difficult to raise your arm or to move it sideways?				
50	Have you had any pain in the area of your affected breast?				
51	Have you had any swelling in the area of your affected breast?				
52	Was the area of your affected breast oversensitive?				
53	Have you had skin problems on or in the area of your affected breast (e.g., itchy, dry, flaky)?				

### SECTION C: MEASUREMENT OF PSYCHOLOGICAL DISTRESS USING HOSPITAL ANXIETY AND DEPRESSION SCALE (HADS)

S/N	A	Most of the time	A lot of the time	Occasionally	Not at all
1.	I feel tense or wound up				
2.	I get a sort of frightened feeling as if something awful is about to happen				
3	Worrying thoughts go through my mind				
4	I can sit at ease and feel relaxed				
5	I get a sort of frightened feeling like 'butterflies' in the stomach				
6	I feel restless as I have to be on the move				
7	I get sudden feelings of panic				
	D				
1	I still enjoy the things I used to enjoy				
2	I can laugh and see the funny side of things				
3	I feel cheerful				
4	I feel as if I am slowed down				
5	I have lost interest in my appearance				
6	I look forward to things with enjoyment				
7	I can enjoy a good book, radio, or TV program				

### SECTION D: MEASUREMENT OF RISK FOR MALNUTRITION USING MALNUTRITION UNIVERSAL SCREENING TOOL (MUST)

#### STEP 1: BMI SCORE

BMI (kg/m <sup>2</sup> )	Score
>20.0 (>30.0 Obese)	0
18.5–20.0	1
<18.5	2

#### STEP 2: WEIGHT LOSS SCORE

Unplanned weight loss in the past 3–6 months

%	Score
<5	0
5–10	1
>10	2

**STEP 3: ACUTE DISEASE EFFECT SCORE**

Condition	Score
If the patient is acutely ill and there has been or is likely to be no nutritional intake for >5 days	2
However, the acute disease effect is not likely to apply outside the hospital.	0

**STEP 4: OVERALL RISK OF MALNUTRITION**

Risk	Score
Low risk	0
Moderate risk	1
High risk	$\geq 2$

**STEP 5: INTERVENTION (NUTRITIONAL COUNSELING)**