**ORIGINAL SCIENTIFIC REPORT** 



# Assessing the Quality of Life of Patients with Breast Cancer Treated in a Tertiary Hospital in a Resource-Poor Country

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#### Abstract

*Background* Very few studies have assessed the quality of life (QoL) of patients living with breast cancer in a resource-poor setting like Nigeria. The aim of our study was to comprehensively examine the measures of QoL in breast cancer patients using the Functional Assessment of Cancer Therapy-Breast (FACT-B) version 4 in order to deepen the literature on QoL among breast cancer patients to include non-Western/northern patient populations.

*Patients and methods* Purposive sampling of stable patients who attended general surgery clinics with histopathologically diagnosed breast cancer was done. Eligible patients were assessed using five domains of the FACT-B questionnaire including: the breast cancer-specific symptoms (BCS), emotional well-being (EWB), functional well-being (FWB), physical well-being (PWB), and social & family well-being (SWB). The questionnaire was administered in a face-to-face interview by trained research assistants. In addition, the five domains were compared among three different age categories, pre-menopausal and post-menopausal, and patients who have had surgery and chemotherapy alone. The SPSS (IBM Corp. Released in 2011. IBM SPSS Statistics for Windows, Version 20.0. Armonk, NY: IBM Corp.) and the Microsoft Excel (11. Corporation Microsoft, Redmond, WA, USA) were used for statistical analysis. Statistical significance was inferred when p < 0.05.

*Results* Among the 60 enrolled participants, total score of the five domains (n = 144) was 74.59  $\pm$  17.72, FACT-G score (n = 108) was 53.49  $\pm$  12.56, Trial outcome index (n = 112) was 49.20  $\pm$  13.13, PWB (n = 28) was 10.95  $\pm$  6.37, SWB (n = 28) was 18.41  $\pm$  6.48, EWB (n = 24) was 6.98  $\pm$  4.15, FWB (n = 28) was 17.15  $\pm$  7.12, and the BCS (n = 36) was 21.10  $\pm$  8.93. EWB was significantly less in post-mastectomy patients on adjuvant chemotherapy (p = 0.031) and pre-menopausal women (p = 0.041) as well as in patients less than 40 years when compared with patients more 50 years (p = 0.049).

*Conclusions* Breast cancer patients in resource-poor countries have a profoundly impaired quality of life. This study showed significantly lower emotional well-being domain scores in post-mastectomy patients on adjuvant chemotherapy, pre-menopausal women having breast cancer and in younger female patients. There is need to address this anomaly.

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# Introduction

Breast cancer is ranked second among cancers and the most common cancer among women worldwide [1]. There were an estimated 1.67 million new cases of breast cancer diagnosed in 2012 (25% of all cancers) with slightly more cases in low-income countries (883,000 cases) than in

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high-income countries (794,000 cases) [1]. Incidence rates vary across the world, with rates ranging from 27 per 100,000 in Africa and Eastern Asia to 92 per 100,000 in Northern America [1]. It is the most common cancer in women in Nigeria [2], where most new cases present late [3]. Recent improvement in the knowledge of breast cancer biology has led to better outcome [4]. But these survivors are confronted with barrage of side effects and adverse events comprising both psychological and emotional disabilities which stem from fear of having a potentially "incurable disease" [5]. Also the existing standard options of treatment are associated with various adverse effects or toxicities. The extent of these toxicities vary depending on the specific modalities that are used either alone or in combination. The question then is: whether these side effects have any impact on the quality of life of a woman undergoing breast cancer treatment?

Evaluation of the quality of life (QoL) of patients on breast cancer therapy has gained increasing attention within the oncology community over the past two decades and is now considered an important outcome in cancer clinical trials [6]. Besides contributing to improvement in treatment, it may also have prognostic value like other clinic-pathologic factors [6, 7]. Although the term "quality of life" is used widely used, defining it is challenging due to the subjective nature of the interpretation of the term. It is multi-dimensional, and in accordance with the definition given by the World Health Organization (WHO), it is generally believed to include physical, mental and social health, cognitive and sexual functions, working ability and lifelong pleasure, and reflects patients' perceptions of the impact of breast cancer diagnosis and treatment on their daily living [8]. Thus determining the quality of life of patients who are being managed for breast cancer may provide insights on the level of function of these patients as well as helping to form the basis for further studies to determine the factors responsible for good or impaired QoL. Our extensive review of the psycho-oncology literature as it pertains to QoL at the time this study was conducted revealed paucity of studies on the QoL of patients living with breast cancers in Nigerian population with only a single published study in Nigeria which encompasses QoL of breast cancer patients receiving radiotherapy [9]. These two populations vary significantly on the areas of: life expectancy, social support and healthcare payment mechanisms (social health insurance, out-of-pocket spending [OOPs]) and gross domestic product (GDP). For instance, 53.5% of Nigerian population live below 1.9 dollars per day and the life expectancy at birth is 53 years and 3.6% of GDP spent on health [10, 11] (for context, The life expectancy at birth in the USA is 79 years with 1.3% of the population living below 1.9 dollars per day and 16.8% of GDP spent on health) [11, 12]. Compromised by the challenges of late presentation, lack of supportive care groups as well as the shortcomings of out-of-pocket payment in the face of widespread poverty due to lack of universal health insurance, the hope of survival of patients diagnosed of breast cancer seems bleak in our environment. Therefore, findings in the Western literature on the QoL of breast cancer patients cannot be directly applied to breast cancer patients in a low-income country such as Nigeria that has distinct economic, social, cultural differences and a different pattern of presentation from Western societies.

To explore these questions, we comprehensively examined the measures of QoL under five domains: breast cancer-specific symptoms (BCS), emotional well-being (EWB), functional well-being (FWB), physical well-being (PWB), and social & family well-being (SWB) using the Functional Assessment of Cancer Therapy-Breast (FACT-B) version four among patients being treated for breast cancer in our hospital. It was also compared among three different age categories: pre-menopausal and post-menopausal, and patients who have had surgery and chemotherapy alone. This will help to deepen the literature on the QoL among breast cancer patients to include non-Western/northern patient populations.

## Materials and methods

#### The study area

The Nnamdi Azikiwe University Teaching Hospital (NAUTH), Nnewi Nigeria is a tertiary hospital in Southeastern Nigeria. The Igbos are the indigenous ethnic group in the town with the majority of the populace being traders, artisans and few civil servants. The hospital has three general surgery units that manage breast oncology patients. It has a Breast tumour board that provides an oversight function which was formed during the course of this study. The surgical units administer chemotherapy for the breast cancer patients because of the absence of an oncologist in our hospital. The outpatient clinic, where the study took place, is run in rotation by six surgical consultants and six senior registrars. The hospital is government owned and units generate cost for their services. It is National Health Insurance Scheme (NHIS) accredited but this does not cover cancer treatment.

# Subjects

This study was a prospective study that involved 60 participants managed for breast cancer from May 2015 to 30 April 2018. The participants were selected by purposive sampling from outpatient clinic attendees who fulfilled the study's inclusion criteria. To be included in the study, the participants must be formally diagnosed with breast cancer and on treatment with chemotherapy. Participants who were on chemotherapy had surgery within the 3 months of enrolment into the study. Secondly, the participants must be in stable clinical condition at the time of the interview. Unstable patients (Karnofsky scores below 70) and patients with stage 4 diseases were excluded. Some of the participants have had surgery. The definitive surgery offered to our patients was total mastectomy and axillary dissection. None of the participants had breast reconstruction. The study was carried out at no extra cost to the eligible participants who gave their informed consent. There was strict observation of the participants' confidentialities by using codes in place of names for reference, analysis and presentation of the results of this study. This study adhered to the tenets of the Declaration of Helsinki for medical research in humans [13]. Written consent was obtained from all the participants.

#### **Study instruments**

The QoL of breast cancer patients was assessed using the Functional Assessment of Cancer Therapy-Breast (FACT-B) version 4. The Functional Assessment of Chronic Illness Therapy (FACIT) Measurement System is a collection of health-related quality-of-life (HRQoL) questionnaires for various chronic diseases [14].

The core component of the FACIT system is the Functional Assessment of Cancer Therapy-General (FACT-G) for patients with any cancer type. This 27-item instrument, when added to a 9-item breast cancer-specific module becomes the FACT-B. The FACT-B questionnaire has been translated into 17 different languages including French, German, Italian, Norwegian, Dutch, Swedish, and has been shown to demonstrate QoL differences among different disease stages as well as different treatment protocols. The internal consistency (alpha coefficient) of FACT-B has been reported to be 0.90, accompanied with subscale  $\alpha$  coefficients that ranged from 0.63 to 0.86. The test and retest reliability correlation coefficient scores were reported in the order of r = 0.85 [15–18]. The FACT-B questionnaire contains 36 items, comprising four general subscales(27 items), including physical well-being (PWB), social well-being/family well-being (SWB), emotional well-being (EWB) and Functional well-being (FWB) and The fifth subscale (nine items) that contains the specific problems for breast cancer (BSS). In 2001, a four-question subscale was added to the FACT-B questionnaire to assess arm morbidity in patients who underwent breast surgery [19]. The instrument has multiple scoring options: subscale scores, total score (FACT-B and FACT-G) and Trial outcome index (TOI). FACT-G focuses more on social and emotional aspects, while TOI which is the sum of PWB, FWB and BCS is an efficient summary of the index of physical/functional aspects.

## **Data collection**

The questionnaires were administered face to face by trained research assistants. In the preliminary stage of the study, the research assistants were trained in the use of the questionnaires using patients who did not participate in the main study. The data collection started when the research team was satisfied that the research assistants could reliably administer the questionnaires to the participants. All the participants in the study were verbally instructed on how to complete the consent form. They were given a form where they signed consent on confidentiality as well as the option to refuse participation in the study at any time, without any explanation with no effect to their management. Participants were given the choice to ignore the question on the sexual activity if they were uncomfortable to disclose it. The participants were interviewed during their routine outpatients visits to avoid additional expenses. Other relevant patients' information was collected from their medical records. Nature of treatment already received including types of surgery, menopausal status and chemotherapy was recorded.

#### Statistical analysis

The items were graded according to a Likert scale of five levels, ranging from 0 (not at all) to 4 (very much). Higher number of points denoted poor functioning or a higher number of symptoms. The values for some questions (GP1-GP 7, GE1, GE3-GE6, B1-B3, B5-B8) were inverted in the calculation of the final score. In the presence of unanswered questions, the mean of the answered questions was considered for that scale. The results were summed up to obtain the final total score ranging from 0 to 144. The higher the score is, the better the QoL of the participant. The subscales were analysed with descriptive statistics including frequency, percentage, means (average), median, standard deviation (CI) and range. The SPSS (IBM Corp. Released in 2011. IBM SPSS Statistics for Windows, Version 20.0. Armonk, NY: IBM Corp.) and the Microsoft Excel (11. Corporation Microsoft, Redmond, WA, USA) were used for statistical analysis. Continuous variables were expressed as the mean  $\pm$  standard deviation (SD), while categorical variables were shown as frequencies and percentages. FACT-B subscales were compared among post-menopausal and pre-menopausal participants; participants who had mastectomy and those with no surgical treatment, and across the three age groups. Menopause was defined as permanent cessation of menses due to prior bilateral oophorectomy, or Age  $\geq 60$  years, or age < 60 years and amenorrheic for 12 or more months in the absence of chemotherapy, hormonal therapy or ovarian suppression and follicle-stimulating hormone (FSH) and estradiol in the post-menopausal range.

The mean differences in the three groups were determined using ANOVA. Post hoc Tukey HSD test was done for significant variables. Statistical significance was inferred when p < 0.05.

#### Results

The mean age of the participants was 48.5 years (median  $50.0 \text{ SD} \pm 11.92$ ) with an age-range of 27–77 years. All of them had locally advanced breast cancer (stage IIIA-C). Forty-seven (78.0%) participants were pre-menopausal while thirteen (22.0%) were post-menopausal. Twentyseven participants had total mastectomy with axillary dissection after neoadjuvant chemotherapy, while 33 participants were receiving/received neoadjuvant chemotherapy during the period of the study. All the participants in this study received cyclophosphamide, doxorubicin and 5-fluorouracil as first-line therapy. None of them had breastconserving surgery nor breast reconstructive surgery. The physical well-being (PWB), social well-being/family wellbeing (SWB), emotional well-being (EWB), Functional well-being (FWB), breast cancer-specific questions (BCS), total score (FACT-B and FACT-G) and Trial outcome index (TOI) scores for the participants, based on menopausal status, and surgery are shown in Table 1, 2 and 3, respectively. Table 4 shows the different scores based on three age categories, while Table 5 shows the results of the post hoc test for variables with significant mean differences in Table 4 Table 4 also shows that EWB score of subjects less than 40 years (younger adults) was significantly worse than that of subjects more than 50 years (older adults). However, there was no difference in the EWB score when younger adults were compared with subjects within the 41-50 age group.

#### Discussion

The key finding of this study is the widespread low scores across the studied domains of quality of life in patients being managed for breast cancer in our centre when compared with scores from the high-income countries [20, 21]. Additionally, post-mastectomy and pre-menopausal participants had a significantly lower emotional well-being domain score when compared with participants who did not have surgery and post-menopausal participants, respectively. The general low QoL scores in this study mirror the results from less developed countries as shown in Table 6.

All the participants in the present study had locally advanced breast cancer (stages IIIA, IIIB, and IIIC). In our environment, late presentation of breast cancer patients is a common finding. A similar observation was reported by other investigators from the African subcontinent [22, 23]. Early breast cancers including screening-detected breast cancers are uncommon finding in our setting. Some of the suggested reasons for the delayed presentation include ignorance, aggressive diseases, superstition, self-denial, fear of mastectomy and inadequate treatment facilities [3, 24].

In the present study, participants who have had surgery in addition to chemotherapy had a significantly lower emotional score when compared with participants who were on chemotherapy alone (Table 2). Cancer treatments, particularly chemotherapy create changes in the female body that may have an effect on emotional relations and psychological status. These changes are worsened when breast surgeries particularly mastectomy were added to the treatment. Newell [25] reported that mutilation caused by mastectomy may put women at risk of considerable

Table 1 Scores of QoL questionnaires and scales used in the study in mean and standard deviations

Observed scores	Mean	SD	Minimum	Q1	Median	Q3	Max	Lower	Upper
Total score(0-144)	74.59	17.72	33.00	62.00	79.00	82.00	114.00	56.87	92.32
FACT-G score(0-108)	53.49	12.56	26.00	47.00	56.00	62.00	83.00	40.94	66.05
Trial outcome index(0–112)	49.20	13.13	20.00	40.00	50.00	60.00	78.00	36.07	62.33
Physical well-being(0-28)	10.95	6.37	0	5.00	11.00	17.00	23.00	4.58	17.32
Social well-being(0-28)	18.41	6.48	1.00	15.00	20.00	23.00	28.00	11.92	24.89
Emotional well-being (0-24)	6.98	4.15	0	4.00	7.00	9.00	23.00	2.83	11.14
Functional well-being (0-28)	17.15	7.12	3.00	12.00	18.00	23.00	28.00	10.03	24.27
Breast cancer symptoms(0-36)	21.10	8.93	0	17.00	23.00	27.00	38.00	12.17	30.04

Q1 first quartile, Q3 third interquartile, CI confidence interval

Observed scores	Mastectomy + chemotherapy	Chemotherapy	p value*		
Total score (0-144)	$72.85 \pm 16.67$	$76.06 \pm 18.70$	0.048		
FACT-G score (0-108)	$52.56 \pm 11.74$	$54.28 \pm 13.34$	0.603		
Trial outcome index (0-112)	$48.22 \pm 10.57$	$50.03 \pm 15.08$	0.602		
Physical well-being (0-28)	$10.07 \pm 5.61$	$11.69 \pm 6.94$	0.337		
Social well-being (0-28)	$17.78 \pm 7.52$	$18.94 \pm 5.54$	0.498		
Emotional well-being (0-24)	$6.86 \pm 4.09$	$7.09 \pm 4.27$	0.031		
Functional well-being (0-28)	$17.85 \pm 6.92$	$16.56 \pm 7.34$	0.493		
Breast cancer symptoms (0-36)	$20.30 \pm 8.84$	$21.78\pm9.1$	0.529		

Table 2 Different scales of QoL questionnaire compared patients who had mastectomy with chemotherapy and only chemotherapy

\*T test

Table 3 Different scales of QoL questionnaire compared between post-menopausal patients and pre-menopausal patients

Observed scores	Pre-menopausal	Post-menopausal	p value*	
Total score (0–144)	$75.46 \pm 18.55$	$71.54 \pm 14.66$	0.486	
FACT-G score (0-108)	$53.33 \pm 13.45$	$54.08 \pm 9.11$	0.851	
Trial outcome index (0-112)	$50.33 \pm 13.52$	$45.23 \pm 11.29$	0.220	
Physical well-being (0-28)	$11.09 \pm 6.61$	$10.46 \pm 5.64$	0.758	
Social well-being (0-28)	$18.11 \pm 6.79$	$19.46 \pm 5.34814$	0.511	
Emotional well-being (0-24)	$6.85 \pm 2.73$	$7.02 \pm 450$	0.041	
Functional well-being (0-28)	$17.11 \pm 7.68$	$17.31 \pm 4.89$	0.911	
Breast cancer symptoms (0-36)	$22.13 \pm 9.00$	$17.46 \pm 7.96$	0.096	

\*T test

Table 4 Scores different scales of QoL compared across three age categories

Age categories	Fact-G	Total score	TOI	FWB	PWB	SWB	EWB	BCS
<40 years	55.39 ± 13.28	$81.28 \pm 14.30$	47.33 ± 10.11	$19.28\pm7.87$	$11.17\pm7.50$	$19.78\pm 6.89$	$5.17\pm3.43$	$25.89\pm 6.12$
41-50 years	$48.00\pm13.69$	$65.43\pm20.59$	$43.21\pm13.94$	$17.14\pm7.40$	$8.64\pm4.97$	$15.50\pm7.20$	$6.71 \pm 4.27$	$17.43 \pm 8.71$
>50 years	$54.88 \pm 11.19$	$74.38\pm16.81$	$47.35  \pm  12.99$	$16.12\pm 6.14$	$11.73\pm6.06$	$18.96\pm5.63$	$8.08\pm4.04$	$19.50\pm9.58$
F value	1.241	2.468	3.29	1.582	1.302	1.311	3.379	2.941
p value	0.304	0.072	0.027	0.204	0.283	0.280	0.025	0.311

F ANOVA, TOI trial outcome score, FWB functional well-being, PWB physical well-being, SWB social well-being, EWB emotional well-being, BCS breast cancer-specific symptoms

emotional distress. In contrast to our study, Pandey et al. [17] found that women who had surgery had a lower score in the physical well-being domain during the 30-day post-operative period, and there was no difference in the emotional well-being score between participants who had surgery and those who did not. They posited that this was due to the increased amount of physical discomfort and pain immediately after surgery. It must be noted that most of the patients studied by Pandey et al. [17] had breast-conserving

surgeries and breast reconstruction, unlike in our studied subjects where the concern of the image appearance of the participants who had mastectomy may explain the reason for the significant lower EWB score. Also the index study did not show any significant differences in the outcomes of other domains (FWB, PWB, and SWB) among postmenopausal and pre-menopausal participants, participants who had mastectomy and those who did not and across the three age groups. This was unsurprising because of the

Studied domain	Age category (I)	Age category (II)	p value*	95% Confidence Interval		
				Lower bound	Upper bound	
EWB	<40 years	41–50	0.513	- 4.9125	1.8172	
	<40 years	>50	0.049	- 5.8056	0149	
	41-50 years	>50	0.550	- 4.4928	1.7676	
TOI	<40 years	41–50	0.012	2.46	23.77	
	<40 years	>50	0.056	18	18.16	
	41-50 years	>50	0.577	- 14.04	5.78	

Table 5 Mean scores of EWB and TOI scores compared across three age categories

EWB emotional well-being, TOI trial outcome Index

\*Post hoc Tukey HSD test

Table 6 Mean scores of QoL scales and standard deviations of index study compared other studies

Name of study	Total score	TOI	BWB	PWB	SWB	EWB	FWB
Beaulac et al. [20] (with lymphedema)	$109.10 \pm 2.90$		22.40 ± 1.10	$23.10 \pm 0.70$	23.70 ± 1.00	18.80 ± 0.70	$21.20 \pm 0.80$
Beaulac et al. [20] (without lymphedema)	$122.70 \pm 1.40$		$27.20\pm0.50$	$26.00 \pm 0.30$	$24.60 \pm 0.50$	$20.60\pm0.30$	$24.40 \pm 0.40$
Yan et al. [21]	$94.99 \pm 18.48$		$24.97\pm4.21$	$22.19\pm4.79$	$16.78\pm5.84$	$16.48\pm4.20$	$13.56\pm6.21$
Pandey et al. [17]	$85.5\pm13.20$	$54.90\pm8.80$	$24.20\pm3.70$	$19.80\pm4.20$	$18.20\pm4.90$	$12.50\pm9.10$	$11.20\pm4.10$
Oliveira et al. [19]	$101.20 \pm 17.60$		$22.30\pm5.70$	$21.00\pm7.20$	$22.00\pm7.20$	$20.00\pm 6.00$	$17.80\pm5.70$
Kobeissi et al. [28]*	$70.70 \pm 11.70$		$19.70\pm6.70$	$9.70\pm2.50$	$20.70\pm3.30$	$5.00\pm1.70$	$14.20\pm4.90$
Current study	$74.59 \pm 17.72$	$49.20 \pm 13.13$	$21.10\pm8.93$	$10.95\pm 6.37$	$18.41\pm4.10$	$6.98 \pm 4.15$	$17.15\pm7.12$
Maximum expected score	144.00	112.0	36.00	28.00	28.00	24.00	28.00

TOI trial outcome score, FWB functional well-being, PWB physical well-being, SWB social well-being, EWB emotional well-being, BCS breast cancer-specific symptoms

\*Studies done in low-income countries

social and cultural aspects of our environment where social and family support are very well provided when someone is in distress particularly affect surgery.

The index study also showed that older women performed better in the EWB subscale compared with younger women (Tables 4, 5). These differences may be due to the psychological distress caused by the malignant breast condition and the fear of death. Social and family supports have been found to be an essential coping mechanism in patients that have breast cancer in other studies [26, 27]. Although we did not assess it specifically, clinical experience shows that in our environment with a well-established extended family system, the older patients were generally well supported by their relatives. Furthermore, the generally low scores may also be a reflection of the financial burden of cancer treatment. Awadalla et al. [26] reported high QoL scores for cancer survivors in Sudan who had active financial support. The cost of cancer care of our participants was totally borne by the participants and their caregivers. This study also showed that younger adults had better TOI scores than the other age categories, with the subjects between 41 and 50 years having the worst score. This showed that subjects less than 40 years were able to cope with most of their physical and functional activities. We could not explain while older women (age > 50 years) had better scores than women between 41 and 50 years. Though, because of the extended family system in Nigeria, the societal demands on older women in terms of everyday physical activities are less.

In socially conservative societies, such as Nigeria where public discussion of sexuality and women's health issues tied to sexuality in particular often go unvoiced, assessment of sexuality-related QoL criteria is difficult. The fact that sexuality and feminine-related issues were left unanswered could indirectly suggest that women could be possibly worried about these aspects yet, at the same time, not comfortable enough to disclose them in front of the investigators. In this study, a substantial number of participants (30.0% of the respondents including all the participants under 40 years) did not respond to the sexuality and body image related items in the FACT-B tool. A similar finding was reported by other authors from conservative societies like Nigeria [28].

## **Study limitations**

The present study has some limitations including that it was cross-sectional, from a single centre, with a relatively small sample size. Thus, this finding may not be generalized for this population of patients in the country. Also, we were unable to state the effects of radiotherapy, number cycles of chemotherapy on QoL as well as the baseline QoL prior to the commencement of the treatment of these patients. Radiotherapy services were not available at our centre during the period of this study. Patients in need of radiation treatment were referred to centres with active radio-oncology services after surgery and chemotherapy. In addition, we could not compare the QoL of patients with early and advanced breast cancer patients because all the participants presented with advanced breast cancer. In spite of the above limitations, we were able to demonstrate that patients living with breast cancer in our patients have a greatly impaired QoL.

## Conclusion

Our study has added to the body of evidence that breast cancer patients in our resource-poor setting as in Nigeria have a profoundly impaired quality of life, thus, the need for psychosocial intervention and financial support amongst these patients cannot be understated. This study also showed significantly lower emotional well-being domain scores in post-mastectomy patients on adjuvant chemotherapy and pre-menopausal women as well as in younger females with breast cancer.

This study suggests that existing supports for breast cancer patients are inadequate; thus there is need to assist women and their families in developing coping strategies.

The researchers recommend further researches on this subject using a larger sample size and involving multiple centres in Nigeria.

#### Compliance with ethical standards

**Conflict of interest** No conflict of interest was declared by the authors.

**Informed consent** Written informed consent was obtained from patients who participated in this study.

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