

Face Validity of the Functional Assessment of Cancer Therapy-Breast Symptom Index (FACT- B) into Formal Arabic

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Abstract

Background: Breast cancer affects over one million women annually and is the most common global malignancy among women. Extensive improvements have taken place in the management of breast cancer in recent years and a higher percentage of women are cured from this disease. A proper assessment of the quality of life of women with breast cancer is an essential component in disease management. The Functional Assessment of Cancer Therapy- Breast Symptom Index has been commonly used and well-validated among English speaking populations as well as other populations. To date, no formal translation and evaluation of the Functional Assessment of Cancer Therapy-Breast System Index exists in Arabic. Therefore, this study intends to translate, adapt and face-validate the Functional Assessment of Cancer Therapy-Breast System Index into Arabic, specifically in the context of the Lebanese culture.

Methods: We conducted forward and backward translation in Arabic, combined with face validity by clinicians. This was followed by pre-testing to ensure the instrument's adequacy and cultural sensitivity conducted by the administration of face-to-face interviews with individual breast cancer patients (n=33) and two focus groups (4 women/group) to evaluate the relevance and appropriateness of each item and words used in the questionnaire.

Results: Study results reinforced the value of the Arabic translated version of the Functional Assessment of Cancer Therapy-Breast System Index in capturing the quality of life of women with breast cancer in Lebanon.

Conclusion: The instrument was perceived to be adequate, appropriate for use, culturally sensitive, simple as well as exhaustive. Suggestions have been made to enrich the instruments' ability to incorporate other quality of life dimensions not captured, as well to enhance the cultural specificity of the Functional Assessment of Cancer Therapy-Breast System Index, when administered among Lebanese women diagnosed with breast cancer who are specifically beyond therapy.

Keywords: Breast cancer, Quality of life, FACT-B, Arabic, Face validity

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Introduction

Breast cancer affects over one million women annually. It is the most common malignancy among women globally, including Lebanon. Extensive improvements have taken place in the management of breast cancer in recent years and a higher percentage of women are cured from this disease. A proper assessment of the quality of life (QOL) of women with breast cancer is an essential component in disease management. The availability of standardized instruments to assess the QOL of women with breast cancer is lacking among Arabic speaking nations. Given the current burden of breast cancer in the world as well as in the Middle East, the need for such tools becomes extremely crucial.

In Lebanon, breast cancer constitutes more than one-third of all female cancers. It is the second leading cause of cancer mortality among Lebanese women. According to the Lebanese Ministry of Public Health (MoPH), the crude breast cancer incidence rate in 2013 was 86.9 per 100,000 females and the overall age standardized rate (ASR) by using the total world population as a reference was 78.8 per 100,000.¹

Given this high breast cancer burden in Lebanon, the operationalization and assessment of QOL among women post-diagnosis with the disease becomes essential. It also requires well-validated instruments that are short and easy to both score and interpret, as well culturally relevant and disease-specific.^{2,3}

It has been well noted that the availability of valid QOL instruments that are culturally and linguistically sensitive improves doctor-patient communication.⁴⁻⁷ According to a randomized clinical trial by Detmar et al. in 2002, the intervention physicians because of their ability to assess QOL were able to identify more problems with patients that pertained to concerns with daily living, feelings, social activities, pain, and fatigue compared to the control group physicians who were only able to identify problems related to daily activities and pain.⁸ This better communication resulted in higher satisfaction among patients in relation to their overall mental

health (reduction of anxiety), role functioning, and quality of care that resulted in fewer complaint visits as a result of the perceived emotional support obtained during communication with the physician.

The availability of standardized QOL tools allows for the evaluation of clinical interventions designed to enhance clinical and mental health outcomes among women who suffer from breast cancer.⁷⁻¹¹

In Middle Eastern communities including Lebanon, many social, cultural and religious factors interplay to either improve or aggravate breast cancer morbidity. Such factors can lead to poorer prognosis as well as poorer QOL. They may also hinder women from taking advantage of screening opportunities and early disease detection, and also quite likely hinder women's compliance with treatment regimens which can lead to reduced coping and adjustment abilities among those affected with breast cancer.¹² These poor outcomes can be attributed to fear from both a positive diagnosis as well as a possible stigma based on the assumption that the disease is a punishment for some life transgression that may accompany such diagnosis.¹³ These religious / cultural / ethnic practices specific to this region¹⁴ can also improve, as already indicated, the QOL of women with breast cancer. It has been suggested that religion and culture affect the way groups reflect their perceptions of reality and the world around them.¹⁵ Religion usually plays a conducive role in the management of illness because it gives meaning to the maintenance of health and care practices.^{14,15}

It remains unclear how social, economic, cultural, and religious factors, among others, interplay differently to affect QOL of women diagnosed with breast cancer, particularly when comparing Western to Middle Eastern societies. One main reason attributed to the lack of such understanding is the lack of availability of standardized, adequately validated instruments to document these differences.

To date around 21 QOL instruments have been used in various research assessments of the breast

cancer population, among which is the Functional Assessment of Cancer Therapy-Breast Symptom Index (FACT-B). None of these QOL instruments serve as a gold standard for the assessment of QOL among breast cancer patients⁷ and none have been validated into Arabic.

The FACT-B questionnaire is a multi-dimensional tool for the assessment of QOL. It is made up of the Fact-General (FACT-G) and supplemented by a Breast Cancer Subscale (BCS). It consists of 44 self-reported items¹⁶ distributed among approximately four general subscales: physical well-being (PWB), social/family well-being (SWB), emotional well-being (EWB), and functional well-being (FWB) as well as a fifth BCS. The BCS specifically measures breast cancer related symptoms and concerns such as arm swelling and tenderness.¹⁷

The FACT-B questionnaire is characterized by its emphasis on patients' values as well as brevity. It has been translated into 17 different languages: English, French (appropriate for use in Canada, France, and Belgium), German (appropriate for use in Germany, Austria, and Switzerland), Italian, Norwegian, Dutch, Swedish, Spanish, Japanese, Hebrew, Czech, Hungarian, Danish, Slovak, Chinese-Taiwan/Hong Kong, Indian and Korean.¹⁷⁻²⁰ It is also known to have adequate psychometric properties in terms of reliability, validity, and sensitivity to change in clinical status over time. FACT-B has been shown to depict QOL differences among different disease stages as well as different treatment protocols. The internal consistency of FACT-B has been reported in the order a total alpha coefficient (α) of 0.90, accompanied with subscale α coefficients that ranged from 0.63 to 0.86. The test re-test reliability correlation coefficient score was reported in the order of $r = 0.85$.¹⁷⁻²¹

The current study aimed to translate, adapt and face-validate FACT-B into formal Arabic in the Lebanese context. This adaptation/translation process combined both quantitative interviews as well as focus groups with women diagnosed with breast cancer. In this paper, we described the results observed from both assessments and

highlighted the strengths and weakness that pertained to FACT-B when administered among Lebanese women with breast cancer.

Materials and Methods

Study design

The study consisted of three phases: translation, quantitative pilot testing and focus groups.

The first phase of the study involved both forward and backward translation of the FACT-B questionnaire from English to Arabic and vice versa. This was done by a clinical psychologist, a social worker and a nurse. All had previous experiences with translation and were bilingual. Of note, translation and back translation were checked by the research team that consisted of an oncologist, an epidemiologist, and a nurse for accuracy. All terminology used by the translation team were accepted.

The second phase of this study involved pre-testing the Arabic translated FACT-B by conducting a series of hospital-based face-to-face interviews with female survivors of breast cancer who attended private clinics and outpatient department (OPD) clinics of the Oncology / Hematology Clinic at American University of Beirut-Medical Center (AUB-MC). Both the private clinics and OPD were intentionally chosen to balance socio-economic status differences.

Following pre-testing, the third phase of study included conducting two focus group discussions with a total of four women in each focus group. These focus groups aimed to cross-validate the results obtained during the interviews and to create the final FACT-B format in Arabic.

Participants

For this pilot study a convenient sample of 33 breast cancer women performed the face-to-face interviews and 8 additional women participated in the focus groups. Only women who were aware of their breast cancer status and willing to talk about it were selected. The target population for both approaches (face-to-face interview and focus group) were Lebanese females who met the following inclusion criteria: breast cancer

Table 1. Overall Distribution of FACT- B responses (n=33).

	Mean \pm SD, Median, Mode (Min-Max)
Fact-B total score¹	57.6 \pm 15.7, 54.5, 41 (33-92)
Physical well-being (PWB) subscale²	8.7 \pm 4.5, 9, 9 (1-18)
Lack of energy	
Nausea	
Difficulty in meeting family needs	
Pain	
Bothered by treatment side effects	
Feeling ill	
Forced to spend time in bed	
Social well-being (SWB) subscale³	9.3 \pm 4.7, 10, 12 (5-10)
Feel close to my friends	
Get enough emotional support from family	
Get enough support from friends	
Family accepted my illness	
Satisfied with family communication about my illness	
Feel close to my partner	
Satisfied with my sexual life	
Emotional well-being (EWB) subscale⁴	7.2 \pm 4.5, 6, 4 (0-18)
Feel sad	
Satisfied with the way I am coping with my illness	
I am losing hope in the fight against my illness	
I feel nervous	
I worry about dying	
I worry that my condition will get worse	
Functional well-being subscale (FWB)⁵	12 \pm 4.6, 11, 7 (4-23)
I am able to work (including work at home)	
My work (including work at home) is fulfilling	
I am able to enjoy life	
I have accepted my illness	
I am sleeping well	
I am enjoying the things I usually do for fun	
I am content with the quality of life right now	
Additional concerns subscale⁶	23.3 \pm 6.2, 24, 15 (15-35)
I have been short of breath	
I am self-conscious about the way I dress	
One or both of my arms are swollen or tender	
I feel sexually attractive	
I am bothered by my hair loss	
I worry that other members of my family will get the disease	
I worry about the effect of stress on my illness	
I am bothered by the change in my weight	
I am able to feel like a woman	
I have certain parts of my body where I experience pain	

Results for all scores are the non-weighted sums of the individual questions for the total score, and for each individual subscale. For the total result and all subscale results, the higher scores reflect worse reported quality of life (QOL).

1: 37 questions (lowest score = 0; highest score = 148).

2: 7 questions (lowest score = 0; highest score = 28).

3: 7 questions (lowest score = 0; highest score = 28).

4: 6 questions (lowest score = 0; highest score = 24).

5: 7 questions (lowest score = 0; highest score = 28).

6: 10 questions (lowest score = 0; highest score = 40).

Table 2. Descriptive characteristics of participants (n=33).

A	Socio-economic status (SES)	Mean ± SD (range)
	Age (years)	47.2 ± 11.8 (20-71)
	Age categories (years)	N (%)
	20-39	4 (12.1)
	40-49	17 (81.8)
	50-71	2 (6.1)
	Marital status	N (%)
	Single	4 (12.1)
	Married	17 (81.8)
	Widowed	2 (6.1)
	Educational status	N (%)
	Intermediate or below	8 (25)
	High school/vocational	12 (37.5)
	University	12 (37.5)
	Occupational background	N (%)
	Teacher/accountant/secretary	10 (32.3)
	Nurse/physical therapist/social worker	3 (9.7)
	Shopkeeper/other	6 (19.4)
	Never worked	12 (38.7)
	Monthly salary (US\$)	N (%)
	<900	9 (28.1)
	1000-3000	11 (34.4)
	>3000	3 (9.4)
	Don't know/no answer	9 (28.1)
	Smoking status	N (%)
	Cigarettes	
	Current	8 (24.2)
	Previously	7 (21.2)
	Never	18 (54.5)
	Water pipe smoking	
	Current	3 (9.1)
	Previously	7 (21.2)
	Never	23 (69.7)
B	Reproductive history	Mean ± SD (range)
	Age (years) at first marriage	20.12 ± 9.37 (0-36)
	Age (years) at first pregnancy	18.8 ± 11.6 (0-41)
	Total number of pregnancies	3.33 ± 2.5 (0-10)
		Yes- N (%)
	History of lactation	21 (63.6)
	Use of oral contraceptive pill (OCP)	7 (21.2)
	Use of Hormone Replacement Therapy (HRT)	4 (12.5)
C	Family history	Yes- N (%)
	Mother had breast cancer	4 (12.1)
	Sister had breast cancer	3 (9.1)
	Daughter had breast cancer	0 (0)
	Father had breast cancer	0 (0)
	Grandmother on the mother's side had breast cancer	0 (0)
	Aunt on the mother's side had breast cancer	2 (6.1)
	Grandmother on the father's side had breast cancer	0 (0)
	Aunt on the father's side had breast cancer	2 (6.1)
D	Diagnosis and disease management	N (%)
	Disease TNM stage at diagnosis	
	Stage I	7 (21.2)
	Stage II	10 (30.3)
	Stage III	6 (18.2)
	Stage IV	5 (15.2)
	Don't know	5 (15.2)
	Therapy status	N (%)
	Ongoing	28 (87.5)
	Finished	4 (12.5)
	Disease management	Yes- N (%)
	Surgery	26 (81.3)
	Chemotherapy	31 (93.9)
	Radiotherapy	24 (72.7)
	Hormonal therapy	15 (45.5)

diagnosis, patients followed by the AUB-MC oncology clinics, were aware of their diagnosis, were willing to share their experiences, and signed an informed consent to participate in the study.

Recruitment strategies and techniques

After securing the approval of the Institutional Review Board of the American University of Beirut, ethical approval of the AUB-MC and consent of the treating physicians, we recruited women from either the private clinics or outpatient department clinics of the Oncology/Hematology Clinics.

Recruitment employed advertisements were displayed on the bulletin boards of the Hematology/Oncology Clinics. Women were approached by a trained research assistant who explained the purpose of the study and presented a request to join the study.

Only women providing consent were selected for the interviews and the focus groups.

Two types of informed consent were used, as the study involved two phases of data collection: pilot test interviews and focus groups. The informed consents for both the interviews and the focus groups were obtained from each woman in a private separate room prior to their study participation. The consent forms were administered in Arabic and explained the purpose of the study (pre-testing of FACT-B in Arabic). In seeking consent, it was ensured that the woman felt at ease to refuse or to accept to take part in this study, as well as to ask questions or clarifications. Issues of confidentiality and willingness to stop the interview at any time, even after giving consent, as well as the risks and the benefits were all clearly highlighted.

Data collection

Face-to-face interviews

Data collected consisted of both close ended face-to-face interviews as well as focus groups. The face-to-face interviews ranged between 15-20 minutes. They were undertaken by the research assistant on this project following informed consent and administered in form of a questionnaire. The questionnaire consisted of 44

questions, divided over six different sections. The first five sections consisted of questions that cover the following QOL dimensions of FACT-B: PWB, SWB, EWB, FWB and additional concerns pertaining to breast cancer. Table 1 shows the description and distribution of each of the subscales along with the overall total instrument score.

The last section inquired about various socio-economic characteristics of the women and disease-related questions. These included: age, marital status, education, occupation, smoking history, reproductive history and disease-specific questions such as stage of diagnosis, therapy status, and type of therapy (Table 2). At the end of the interview, the women were also asked to indicate which questions they considered most relevant and whether or not any additional questions or concerns needed to be incorporated. They were also asked to rate the overall degree of complexity of the FACT-B.

Focus groups

Two focus groups were conducted with women who were breast cancer survivors, from the same clinics who did not participate in the interviews. Women selected in each of the focus groups were asked to come for only one visit to conduct the focus group. The scheduling of the focus groups was ensured to be at a time of convenience to the participating women. The focus groups were run by a moderator with extensive experience in qualitative methodology.

The two focus groups took place on two different days. For each group, 8 to 10 women were invited but only four from each group responded and attended the meeting. At the beginning of each meeting, the moderator explained the purpose of the study. To prevent socially pleasing answers, the moderator emphasized that there were no right or wrong answers, and that all answers were important for eliciting feedback on the tool. The language used in the focus groups was the native language of the participants, which was Arabic. Of note, during the focus groups the Arabic translated Fact-B version was used (see translation process earlier).

Table 3. Performance of FACT-B with disease-related management.

FACT-B Categories	Therapy Status (Finished vs Ongoing)	Surgery	Radiotherapy	Chemotherapy	Hormonal therapy	Willing to take part in an intervention to improve quality of life
	Mean±SD	Mean±SD	Mean±SD	Mean±SD	Mean±SD	Mean±SD
Total score¹						
Yes	75.2± 14.9	72.8±14.8	74±13.3	73.1± 13.3	76.7±16.1	73.6± 13.1
No	72.7± 13.9	76.2± 10.2	71.8± 15.9	78.5±27.6	72.1± 10.9	72.3±18.0
Physical well-being (PWB) subscore²						
Yes	10.7±54.3	7.9± 3.9	8.8± 4.9	8.7±4.7	7.8±5.2	8.4± 4.4
No	8.2± 4.6	12.8± 4.5	8.3± 3.7	9± 0.0	10.1±3.5	7.67±5.0
Social well-being (SWB) subscore³						
Yes	23± 4.2	21.1± 4.2	21.4± 4.7	20.9± 4.5	22.2± 4.6	20.5±4.4
No	20.9± 4.6	20.8±6.1	20.7± 4.0	25.0±1.41	20.6± 4.4	21.8±3.6
Emotional well-being (EWB) subscore⁴						
Yes	7± 2.9	6.4± 3.3	6.5± 4.0	6.4± 3.6	7.5±4.5	6.7±3.3
No	6.4± 3.7	7.8±3.6	6.5±1.9	8.0± 1.4	5.7±2.2	6.3±4.8
Functional well- being (FWB) subscore⁵						
Yes	18.7± 4.8	18.8± 4.2	18.6± 4.3	18.4±4.3	19.8± 3.3	18.4± 3.4
No	18.4± 4.3	15.8± 3.9	17.8± 4.2	18.0± 1.4	16.6± 4.3	20.7± 3.7
Additional concerns subscore⁶						
Yes	26±9.9	24.1±6.8	23.9±5.9	24.3±6.04	27.3± 5.7	24.8±6.4
No	24.5± 6.5	29.6± 1.1	28.4± 7.7	37±0	22.4± 6.7	25.6± 4.9

Results for all scores are the non-weighted sums of the individual questions for the total score, and for each individual subscale. For the total result and all subscale results, the higher scores reflect worse reported quality of life (QOL).

1: 37 questions (lowest score = 0; highest score = 148).

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6: 10 questions (lowest score = 0; highest score = 40).

When evaluating the performance of FACT-B, women who completed therapy tended to have better scores. FACT-B scores were better for women who did not have surgery compared with those who did. Similar trends were observed among women who received radiotherapy and hormonal therapy. FACT-B scores were lower for women who were administered chemotherapy (Table 3). None of these observed differences reached statistical significance.

The focus groups began by asking each participant to choose a pseudo name and sign an informed consent. Surprisingly, all participants decided to keep their original names, stating that they were happy to share their experiences and feedback with others and that they were not ashamed of what they were doing. The patients all emphasized that their primary aim behind

participating in these focus groups was to share their experiences to help other women with breast cancer.

The focus group framework centered on evaluating the subcomponents of FACT-B including the individual questions. The participants were asked to give their feedback on the pertinence of the questions posed across their experiences with breast cancer. They were also requested to give feedback about the terminology used and the level of comprehensibility of the questions.

Data analysis

Two types of analyses were made. The first was the interviews' analysis which included descriptive and bivariate analyses. The descriptive analysis included the mean, standard deviation (SD) and ranges for continuous variables and frequency as

Table 4. Performance of FACT-B with disease TNM stage at initial diagnosis.

FACT-B categories	Do not know Mean±SD	Stage I Mean±SD	Stage II Mean±SD	Stage III Mean±SD	Stage IV Mean±SD
Total score ¹	74.6±11.34	73.8±15.9	74.2±16.9	70.7±11.7	66.8±7.2
Physical well-being (PWB) subscore ²	8.2±6	10.1±5.1	7.4±3.6	9.7±2.5	7.6±6.3
Social well-being (SWB) subscore ³	20.2±3.9	20.3±3.3	22.7±4.8	20.7±3.3	18.0±5.6
Emotional well-being (EWB) subscore ⁴	5.8±1.6	7.6±4.9	6.3±3.8	5±1.7	7±3.9
Functional well-being (FWB) subscore ⁵	19.2±3.9	18.7±4.3	19.7±3.9	14.2±4.9	18.5±4.4
Additional concerns subscore ⁶	23.0±4.9	26.6±5.0	27.1±6.0	19.7±6.7	21.7±6.4

Results for all scores are the non-weighted sums of the individual questions for the total score, and for each individual subscale. For the total result and all subscale results, the higher scores reflect worse reported quality of life (QOL).

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well as the percentage distribution for categorical variables. The bivariate analysis used the chi-square test of association, set at a 5% type I error as well as the independent sample t-test and ANOVA, also set at a 5% type I error. The purpose of the bivariate analysis was to check if the instrument could depict differences for stage of diagnosis, therapy status, type of therapy, and socioeconomic background. This analysis was conducted using the Statistical Package for Social Sciences (SPSS) version 19.

The second type was the focus groups' analysis, which involved transcribing, analyzing, and assimilating obtained data from the focus groups. To ensure validity and reliability, the researchers made sure to maintain stability, equivalence and internal consistency of the data.²² These three criteria were guaranteed respectively through the following approaches: consistency of issues discussed over time, breast cancer as the common trait for all group members, and one moderator who led the discussion with both groups and played a dominant role in data analysis. The moderator played the role of the group facilitator and did not interfere in the participants' discussions. Moreover, the moderator incited participants to give more in depth feedback through probing techniques.

Results

Quantitative assessment

A total of 33 women were administered the

FACT-B for pilot-testing purposes. The average age of the women was 47.2±11.8 years, with 12.1% in the 30-39 year age group. This was similar to the Lebanese national mean age of 50 years at the time of diagnosis with breast cancer. The majority of the women were married. The sample consisted of fairly educated, currently employed women. The average monthly income for the majority of these women was below 1000 US dollars. A total of 44.5 % of the women were current or past cigarette smokers and 30.3% were current or past smokers of the water pipe.

As far as the participants' reproductive and family history, the average age of the first marriage was 20±9.4 years, average age of first pregnancy was 18±11.6 years, and average number of pregnancies was 3.3. Of participants, 63.6% indicated that they have breastfed, 21.2% used oral contraceptive pills (OCPs) and 12.5% indicated that they were on hormone replacement therapy (HRT) prior to breast cancer diagnosis. Participants whose mothers had breast cancer comprised 12.1% of the women, 9.1% had a sister with breast cancer, 6.1% had an aunt from the mother's side and 6.1% stated they had an aunt from the father's side with breast cancer. In terms of immediate family members, 15% indicated they had one immediate family member with breast cancer and 9% stated they had two immediate family members with breast cancer.

As far as disease diagnosis and management, the sample was fairly balanced across the different

Table 5. Performance of FACT-B with socio-economic background characteristics.

	Total score¹	Physical well-being (PWB) subscore²	Social well-being (SWB) subscore³	Emotional well-being (EWB) subscore⁴	Functional well-being (FWB) subscore⁵	Additional concerns subscore⁶
Age (years)	Mean±SD	Mean±SD	Mean±SD	Mean±SD	Mean±SD	Mean±SD
20-39	75±17.8	8.1± 3.3	19.1± 5.7	7.3± 3.6	19.1± 5.1	25.7± 7.6
40-49	76.1±15.1	8.5±4.8	21.8± 3.4	6.4± 3.2	17.3± 4.5	25.4± 7.1
50-71	69.2±10.8	9.5± 4.9	22.1± 4.5	7.1± 3.7	18.9± 3.6	23.0± 5.9
Education						
Intermediate or below	75± 12.3	11±4.4	19.4± 3.1	7.1±2.9	17.7± 3	26.2±7
Vocational/high school	73.8 ±16.9	6.9± 4.2	21.7± 3.5	6.4± 4	19±3.6	25.1± 6.7
University	72.3 ± 12.9	8.8±4.7	22.8± 5.2	6.2±3.8	18.8± 5.4	23.1± 6.5
Salary (monthly- US\$)						
<1000	75.7±17.4	7.5 ±3.4	22± 3.4	6.5±2.6	18.8± 3.2	26.1± 8.2
1000-3000	69.8 ± 12	8.3±4.3	21.3± 5.6	5.3± 3.9	17.4± 4.4	22.4± 6.8
>3000	89.7±7.1	10±6.9	23.3 ±2.3	8.7± 5.7	19.7± 4.9	28.0±3.6

Results for all scores are the non-weighted sums of the individual questions for the total score, and for each individual subscale. For the total result and all subscale results, the higher scores reflect worse reported quality of life (QOL).

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disease stages at initial diagnosis - approximately 50% had stages I or II and the other half had stages III or IV (Table 4). The majority of women were undergoing therapy at the time of the interview. Most underwent surgery to manage the disease as well as radiotherapy and chemotherapy. Hormone therapy for disease management was administered to 45.5% of the total population (Table 2).

In terms of the performance of the instrument according to disease stage results revealed that, generally, FACT-B had better scores for women with stages I/II cancer compared to those with stages III/IV. Possibly the tool could depict differences in QOL according to disease extent (Table 4). The same trend was generally observed for the different subscales of FACT-B. There was no statistical significance, which could be mainly attributed to the limited sample size.

Younger women had better FACT-B scores

than older women. Women with higher educational level had lower FACT-B scores which means better quality of life. Women with an average salary income >3000 US\$ also had better FACT-B scores (Table 5). Again, there was no statistical significance observed.

When evaluating responses to individual questions by respondents, the following items were rated as inapplicable for PWB: nausea and bothered by treatment side effects; SWB: sex life, feeling sad; FWB: my work (including work at home is fulfilling, I enjoy the things I do in life); and additional concerns: shortness of breath, self-consciousness about the way to dress, having swollen or tender arms, feeling sexually attractive, hair loss and feeling like a woman.

When inquired of whether or not the women had any comprehension difficulty pertaining to the questions and the associated complexity of FACT-B, all respondents indicated that the questions

Table 6. Consensus on the different FACT-B items pertaining to the different sub-components: Summary of the quantitative & qualitative results.

FACT-B Sub-categories	Most relevant/ important	Not relevant/ indifferent/not applicable	To be added
Physical well-being (PWB) subscore	-Ability to meet the needs of my family Pain	-Staying in bed (only relevant during treatment) -Side effects post treatment -Nausea	-Social visits during treatment - Changes in taste during treatment
Social well-being (SWB) subscore	-Emotional support from family	-Informing friends or other family members -Sex life	-Being close to partner to be split into: - Spouse - Significant other
Emotional well-being (EWB) subscore	-Worry that my condition will get worse	-Feeling sad -Feeling Nervous	- Timing of when to administer the interview
Functional well-being (FWB) subscore	-Sleeping well	- Shortness of breath	-Pity
Additional concerns subscore	-Worry that other family members will get the disease -Change in weight -Pain in different body parts	- Self-conscious about the way to dress - Hands swollen or tender -Feeling sexually attractive -Hair loss	-Financial aspect of the disease - Doctor-patient interaction - Feeling like a woman

used were fairly simple, linguistically appropriate and culturally sensitive.

Qualitative assessment

Demographics of women who participated in the focus groups paralleled those who participated in the face-to face interviews. Findings from both focus groups showed concordance in terms of the obtained feedback between groups on all categories and questions of FACT-B.

Physical well-being (PWB)

All participants agreed that the questions were well formulated and clear. When asked to rank the questions in priority order, the items related to “pain” and “meeting the needs of my family” were ranked first. Participants dwelt on the item related to “spending time in bed” and mentioned that it was only natural to be in bed if one took pain medication. Therefore, it was not considered to be an important question. When asked if the questions were satisfactory or if they wanted to add a new question, some participants mentioned that they would like to add an item related to social visits after the treatment. Some emphasized the above

point by stating that they do not like to receive visits after treatment because of the noise and need to rest. On the contrary, others mentioned that they would like to be surrounded by people and receive visits at all times. Another suggested a question related to the change in taste because of treatment. Participants felt that this section was more pertinent to the period during which they were receiving chemotherapy. They also agreed that during post-treatment, the most important question for them was related to side effects, which might continue even after the treatment was finished.

Social/family well-being (SWB/FWB)

All participants agreed that the questions were very clear. They also mentioned that none were embarrassing, including those related to sexual life. Participants suggested splitting the question G86 related to “being close to the partner” into “partner and significant other”, because some of them were widowed or not married. To them “partner” meant “husband”. The most important question for them was GS2, “I get emotional support from my family”. The family support was emphasized

as a very important aspect to be able to cope with the disease. While discussing friend support, some participants stated that they did not tell their friends about their disease. Some did not inform their extended family members and only the members of their nuclear family were aware of their diagnosis. Therefore, it was suggested to add an item that asks whether they have revealed the information to their friends/extended family members.

Emotional well being (EWB)

Again, participants reported that all words and ideas were clear. When asked to identify the most important question, most women alluded to GE6, "I worry that my condition will get worse". When asked to highlight the least important question they mentioned that GE1 and GE4, which talked about "being sad and being nervous" were the same. In fact, they considered that each of the questions triggered or led to the other. Hence, the women did not see the need for having both. However, they stressed that some surrounding environmental factors could trigger those feelings of sadness and nervousness like hearing nice music during sunset or in the afternoon or at night. So the timing of administering this section of the questionnaire was an important factor to consider. Most participants mentioned that all questions in this section were equally important. All concepts in the section seemed to be important for women's EWB.

Functional well-being (FWB)

All words and ideas were reported as clear in this section. Participants again mentioned that all questions adequately reflected their FWB. The most important item with the greatest impact on their FWB was GF5, "I am sleeping well". Sleep was highlighted as an important factor. All participants debated the importance of sleep on the well-being of the individual. Some reported lack of sleep because of pain and others as a result of some haunting ideas that prevented them from sleep.

Additional concerns

Participants reported that all questions were comprehensible. The most important items in this section was "the worry about the family members from getting the disease", "the change in weight" and "pain" in the different parts of the body. When asked whether or not they perceived that this tool covered all aspects of their life in relation to their disease, the participants mentioned two items not available in the tool that seemed to be vital for them. They all talked about the way others looked at them, or dealt with them and they specifically mentioned "pity". Another emphasized item was related to the financial aspect of treatment.

Convergence of quantitative and qualitative assessments

The results of the quantitative assessment (interviews) converged with many of those observed during the qualitative assessment (focus groups), in terms of the perceived: important questions, irrelevant/unimportant questions and questions that needed to be added.

In general, the following questions were perceived to be most important: ability to meet the needs of my family, pain, emotional support, worry that my condition will get worse, sleep, worry that other family members will get the disease, change in weight, and pain in different areas of the body. Irrelevant or inapplicable questions included: staying in bed (only relevant during treatment), informing friends or other family members about their disease, feeling sad, feeling nervous, shortness of breath, self-conscious about the way to dress, hands swollen or tender, feeling sexually attractive, hair loss, and feeling like a woman. Questions suggested to be added included: nuisance of repeated social visits during treatment, changes in taste during treatment, being close to partner which should be divided into partner or significant other, timing of when to administer the interview, pity, financial aspect of the disease, and doctor-patient interaction (Table 6).

Discussion

Results from this face-validity study of the

Arabic translation of the FACT-B questionnaire indicated that for most of its subcategories, the instrument adequately tackled the different aspects that could possibly affect QOL of women with breast cancer. In both the qualitative and quantitative assessments, the instrument was considered easy to follow, short, simple, culturally appropriate and pertinent to the women's experience with the disease.

The interview questionnaire revealed that FACT-B, when delivered in Arabic, had a good ability to distinguish QOL status with respect to whether or not the women were undertaking or finished treatment, disease stage at initial screening, and disease management (surgery, radiotherapy, hormonal therapy and chemotherapy). Women had better QOL outcomes when their disease management was surgery, radiotherapy and hormonal therapy compared to chemotherapy. The instrument was also able to depict that younger women and those with higher monthly incomes had better QOL outcomes.

As indicated above, the results of the quantitative assessment (interviews) paralleled many of those observed during the qualitative assessment (focus groups) in terms of perceived important questions, irrelevant/unimportant questions and questions that needed to be added. Respondents agreed that the FACT-B questionnaire was more reflective of QOL during disease management/therapy as opposed to post-treatment. This agreed with a number of available literatures on FACT-B as it was specifically designed to assess QOL of breast cancer patients during disease management/therapy.^{16,17}

Our findings were comparable to literature published elsewhere regarding FACT-B translation in other languages/settings. Husband's support was a relevant theme observed in the current study as well as other studies.²³

The fact that sexuality and feminine-related issues were perceived by the women as unimportant or 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 others. A study has estimated that 25%-33% of women experience problems with femininity and sexuality after a year following mastectomy.²⁴ One woman in our study during one of the focus groups actually noted that she had feelings of guilt towards her husband. Mastectomy and hair loss, as it seems, were the main sources for this fear. Not only the husband, but the society at large has imposed a certain stigmatization on women who have undergone mastectomy and lost their hair.^{25,26}

In general, society places heavy pressures on women's overall physical appearance. Many women try to hide their condition to prevent stigma and preserve their identity.²⁷ For example, one woman in our study explained that in spite of the fact that she wore a head cover to hide her hair loss, people were still bothered and commented on her pale color. Also, the majority of the women in the focus groups indicated being bothered by people's looks. The fact that many women left the femininity and sexuality questions in our study unanswered reflected the cultural influence as reported in other cultures.^{23,28} In a very few other cultures, however, women acted indifferent to their appearance to teach society to accept their condition.²⁹

Family, friends and neighbors was a relevant theme in this study and in other studies cited in the literature.^{24,30} The women worried about their immediate surroundings at many levels: emotional, psychological, physical as well as social in terms of meeting certain obligations. In our study, "meeting the needs of my family" was one of the highest priority items in FACT-B according to the women in the focus groups. Women were also concerned about hiding their distress and agony about the disease from their family, which was supported by another study conducted in Lebanon by Doumit et al.²⁶ on Lebanese cancer patients who received palliative care.

Breast cancer patients, according to the literature, often feel the pressure from their surroundings to pretend optimism when they are not actually optimistic.^{23,25,26,30} The role of the husband in helping to disclose disease status to

children and immediate family was perceived as very important.³¹

On another note, allowing personal space and time to rest (especially after therapy) was also noted to be very significant for women of this study. Repeated visits by family or friends were noted to be a cause of nuisance. The same was perceived true for offering assistance with the performance of certain chores that the women could do by themselves. This introduced feelings of incapability and reminded women of their disease.^{26,31}

The role of spirituality in dealing with the disease was significantly emphasized in our study. Adding a spirituality component to FACT-B was noted by the women. One of the women shared that she continued to wear a veil even after her hair grew because she felt that God helped her to cope with her agony. Another woman explained how praying and reading verses from the Quran provided her with immediate relief. Women did not deny that it was their fear that drove them more towards God, but they also explained that they had strong beliefs even before diagnosis. Other studies shared similar results.^{24,31-33} This contrasted results of a Canadian study where some women viewed God as harsh and punitive, and decided not to pray to Him anymore.³⁴

Fear of disease recurrence was commonly cited by the women in our study as having an effect on their overall QOL. This item was not present in FACT-B. This finding, moreover, has been commonly shared by studies of women with breast cancer.^{26,35,36}

When women were asked if whether or not taking part in a psychosocial intervention could be conducive to their QOL the majority in the quantitative assessment answered positively. However, participants in the qualitative assessment explained that this could only be conducive if the intervention did not tackle/speak of their disease or if they had to share painful details or agonies experienced by other women. This was also highlighted in the literature by Simpson, 2005. Finally, two important aspects per the women in our study that were perceived to affect

QOL and presumed missing in FACT-B were the role of the doctor-patient relationship and finances.

A good relationship with physicians is often perceived as instrumental for patients and an important source for psychological comfort.^{32,35} In our study, the women have stated that they were not satisfied by the way their physicians disclosed their disease status with them or the ways physicians explained disease management options and associated side effects. They also noted that little time was given to them to interact with their physician and comprehend the repercussions of their disease. This contrasted the women's documented experiences with nurses. The women explained that the kindness of nurses and their reinforcing messages significantly helped them to overcome many of their anxieties.

In summary, our study results reinforced the value of the Arabic translated version of FACT-B in capturing the QOL of women with breast cancer in Lebanon. The instrument was perceived to be adequate, appropriate for use, culturally sensitive and simple, as well as exhaustive. Suggestions were made to enrich the instruments' ability to capture QOL in breast cancer patients after therapy.

This study is characterized by several strengths which include combining qualitative and quantitative assessments to ensure a holistic face-validity exercise, forward and backward translations by experts with significant experience in the field, data management and analysis that have been conducted independently from the translation process.

Limitations associated with our study included the limited sample size, sample selection comprised of volunteers (hence, more cooperative women could have participated), and the need to conduct content and construct validity as well as reliability assessments. These could have played a role in affecting the generalizability of the findings observed in our study. Regional assessment with other women whose native language is Arabic and are residents of other countries in the Middle East and North African region is also recommended to strengthen the

conclusions of the findings observed in this study.

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Conflict of Interest

No conflict of interest is declared.

Ethical Approval

This trial received ethical approval by the Institutional Review Board of the American University of Beirut.

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