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# Development of a Quality of Sexual Life Questionnaire for Breast Cancer Survivors in Mainland China

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**Background:** There is a great need for a quality of sexual life questionnaire (QVS) in breast cancer survivors (BCSs) based on the Chinese social culture since the imported tools lack localization verification.

To develop a QVS in BCSs and determine its validity and reliability.





**Material/Methods:** In the qualitative study, a total of 21 BCSs were interviewed by purposive sampling and snowball sampling; and in the quantitative study, a total of 249 BCSs, who were admitted and received outpatient follow-up, were investigated. Regarding construct validity, factor analysis was performed. The female sexual function index (FSFI), self-rating depression scale (SDS), and Locke-Wallace marital adjustment test (LWMAT) were used to evaluate criterion validity. Cronbach's alpha coefficient was used as an index of internal consistency. To evaluate test-retest reliability, 50 patients were re-evaluated after 1 week.

**Results:** We put 28 items in the factor analysis model: (1) 5 factors were extracted by exploratory factor analysis (EFA), with a cumulative contribution of 60.37%; (2) the confirmatory factor analysis (CFA) showed that the path coefficients among the factors were all above 0.5, and the standardized load coefficients of the most items were above 0.5; (3) the Cronbach's alpha coefficient was 0.929 for the overall questionnaire, and ranged from 0.571 to 0.869 for the 5 factors; (4) the correlation coefficients between the overall questionnaire and the FSFI, SDS, and LWMAT were 0.582, -0.456 and 0.515, respectively ( $P < 0.01$ ); and (5) the test-retest correlation coefficient was 0.816, and the split-half-reliability coefficient was 0.899.

**Conclusions:** The QVS in BCSs has good reliability and validity, and can be used to assess the quality of sexual life among BCSs in Mainland China.

**MeSH Keywords:** **Inflammatory Breast Neoplasms • Reproducibility of Results • Sexual Behavior • Survivors**

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## Background

Breast cancer is one of the most common malignant tumors among females. It has the highest incidence rate in some developed countries, such as Europe and the United States [1–3]. In China, the incidence rate has been relatively low [2] but has been steadily increasing [4]. At present, the most commonly used treatment for breast cancer is mastectomy, supplemented with chemoradiotherapy, endocrinotherapy, or targeted therapy. The 5-year survival rate of patients is 75.7–89.4% [5], which is similar in mainland China (80%) [6]. Compared to the comprehensive treatment of breast cancer, research on the quality of sexual life of BCSs is sparse. Therefore, with the increasing number of breast cancer survivors (BCSs), the quality of sexual life within the survival period has become the focus of medical researchers.

The adverse effects of breast cancer treatment, such as the damage to or absence of female breasts as the secondary sex organ, low or severe fluctuating estrogen levels, and negative body image issues like obesity and hair loss, can result in poor quality of sexual life in BCSs [7]. Bartula et al. [8] stated that the assessment and consultation of sexual problems are not regularly provided by health care workers during the diagnosis and treatment of tumors due to the concern about embarrassment or misunderstanding. Because traditional Chinese culture has traits of sexual conservatism, sexual shyness, and patriarchy, sexual topics are very sensitive [9], and it is difficult for health care workers to conduct objective, accurate, and comprehensive assessments of the quality of sexual life of BCSs in mainland China, and there is a lack of effective assessment tools.

As an important part of quality of life, a number of study tools, such as the Cancer Rehabilitation Evaluation System-Short Form (CARES-SF) [10] and the Menopause Rating Scale (MRS)-Urogenital Factor [11], incorporated quality of sexual life into assessment of overall quality of life as a subscale. The study of sexual quality of life in female breast cancer patients is still in the initial stage in mainland China. The evaluation of sexual quality of life mainly relies on the introduction of scales. Commonly used scales include the Female Sexual Function Index (FSFI) [12] and the Locke-Wallace Marriage Adjustment Test (LWMAT) [13]. Among them, FSFI and LWMAT mainly focus on 1 or more aspects of the sexual quality of life changes of BCSs, and failed to comprehensively consider the influence of social and cultural backgrounds and other factors on sexual function. In addition, due to the specific characteristics of social and sexual culture in mainland China, health care staffs evaluated the BCSs in mainland China with the assessment tools of sexual health problems developed by Western scholars, during which they met many obstacles and difficulties and even reached erroneous conclusions. Irwin Bloch, a

German physician, pointed out that the study of sex must be combined with studies on human beings and studies on the entire social and cultural development of human beings [14]. A general questionnaire on the quality of sexual life for mainland Chinese women was developed by Hulei et al. [15], but the questionnaire lacked pertinence and validity for the measurement of sexual health problems in BCSs, such as severe social psychological stress due to breast removal, changes in hormone levels, and disease diagnosis and treatment. Therefore, it is of great significance to develop tools for assessing the sexual quality of life of breast cancer patients that are suitable for the Chinese population.

In our study, the research was conducted under the guidance of the conceptual framework of the quality of life in breast cancer patients [16] and the scope of sex study [17], and the quality of sexual life was defined as the assessment of the objective states and subjective feelings of BCSs after the comprehensive treatment for breast cancer, including sexual physiology, sexual psychology, and social culture related to sex.

To effectively carry out the nursing assessment and intervention on the quality of sexual life for BCSs in mainland China, a questionnaire based on the Chinese social-cultural environment is needed to assist the health care workers, so as to improve the quality of sexual life of the BCSs in the survival period.

## Material and Methods

### Ethical approval

This study was approved by the Ethics Committee of the First Affiliated Hospital of China Medical University (No. 2016 145).

### Subjects

In the qualitative study, patients who were pathologically diagnosed with breast cancer, received the comprehensive treatment, and were married or had regular sex partners were selected after obtaining their permission by the following sampling methods. (1) Purposive sampling: The potential participants were identified through checking the medical records of those patients who were admitted to the Department of Breast Surgery of the First Affiliated Hospital of China Medical University, underwent comprehensive treatment, and were married or had regular sex partners. The physicians in charge of the patients also played an important role in the identification of potential participants. (2) Snowball sampling: Both the physicians and interviewees were encouraged to recommend appropriate patients to participate in the study. (3) Maximum variation sampling: According to the results derived from some of the BCSs who were previously interviewed, a number

of factors (such as age, ethnic group, education, occupation, residence, marital status, number of children, family income, months since surgery, and type of surgery) that might have great impact on the quality of sexual life were identified. All of the above factors were then taken into consideration in the subsequent sampling [18–20].

In the quantitative study, BCSs were selected by convenience sampling. The inclusion criteria were as follows: (1) older than 21 years; (2) first onset and diagnosed with breast cancer (0-IIIa); (3) in a pre-menopausal period (including the pseudo-menopausal patients due to endocrine therapy and chemotherapy), patients who were younger than 55 years or self-reported to be not yet naturally experiencing menopause during hospitalization were defined as pre-menopausal [21–23]; (4) at least 3 months after receiving the mastectomy-oriented comprehensive treatment; and (5) with normal sexual life and complete cognitive and behavioral abilities before diagnosis. The exclusion criteria were as follows: (1) dying patients with breast cancer; (2) patients complicated with other severe acute or chronic diseases; and (3) patients without sex partners.

All participants signed the written informed consent forms.

## Qualitative study

### *Development of interview outline*

The interview outline was developed based on the literature review and pre-interview results, which mainly enumerated the changes in sexual life before and after diagnosis of breast cancer and their influences on life, such as effects on physical being, psychology, marital relationship, and perceptions.

### *Interview*

To establish a trusting relationship with the interviewees, the interviewer (JLW) conducted a 6-month clinical practice at the Department of Breast Surgery of the First Affiliated Hospital of China Medical University. Before interview, a self-introduction, the purpose and significance of the study, and the benefits to and possible influence on the interviewees were presented by the interviewer to the interviewees. As sensitive information was involved in the interview contents, the interview environment was strictly controlled and a commitment to confidentiality was given by the interviewer. Semi-structured, in-depth interviews were conducted until data saturation. Each pilot interview lasted 16–72 min and was recorded. The interviewer encouraged the interviewees to express their thoughts, deliberately collected verbal and non-verbal information, and took detailed notes during the process. All data were numbered, stored, and transcribed within 24–72 hours.

## Quantitative study

### *Formation of initial questionnaire*

A pool of 80 questionnaire items was created by literature review and qualitative interview. The initial questionnaire of 46 items was generated by expert enquires based on the content validation rate (CVR=the number of breast cancer experts who agreed with the questionnaire item/the total number of experts who took part in evaluating the questionnaire) [24], including a lie-detecting item. The lie-detecting item in the present study was item 37: “If you need guidance from health care workers because of difficulties in sexual life, you will turn to the female health care workers rather than male health care workers”.

Since there are many sensitive questions involved in the questionnaire, the patient may lie, resulting in untrustworthy results. Therefore, the lie-detecting item is essential. In the current study, once the patient answered that “I will absolutely not turn to female health care workers for help”, the questionnaires was excluded. Because it is usually more acceptable for BCSs to seek help from female health care workers in Chinese culture, the choice of the “strongly disagree” option indicated that the questionnaire was not seriously completed and could not be used in the subsequent analysis [25,26].

### *Face validity and content validity test*

The face validity was evaluated by 10 BCSs and 2 nursing undergraduates who did not participate in the study. The content validity was evaluated by 6 experts, including 2 oncologists, 2 psychologists, 1 nursing specialist, and 1 sexologist, and the average scale-level content validity index (S-CVI/ave) was calculated.

## Investigation methods

The investigation tools and contents included: (1) baseline data of the patients; (2) the initial questionnaire on the quality of sexual life in BCSs (the 5-point Likert scale was used to quantify the results, 1 point=strongly agree, 2 point=agree, 3 point=general, 4 point=disagree, 5 point=strongly disagree); (3) self-rating depression scale (SDS) [27] used for measuring the criterion-related validity of the sexual psychology in the QVS in BCSs; (4) Locke-Wollance marriage adjustment test (LWMAT) [28] used for measuring the criterion-related validity of the sexual relationship in the QVS in BCSs; and (5) female sexual function index (FSFI) [29,30] used for measuring the criterion-related validity of the sexual physiology in the QVS in BCSs. After 1 week, 50 BCSs who had answered the questionnaire were randomly selected to take the survey again for determining test-retest reliability.

The questionnaires were filled out anonymously. The researchers promised that the questionnaire contents were kept by specially-assigned staff, were kept strictly confidential, and were used for research purpose only. The data were collected using paper-based questionnaires on-site, web-based electronic questionnaires, and postal questionnaires.

### Data processing and analysis

The steps of qualitative data analysis were as follows: reading the primary material, logging on to a computer system, looking for native concepts, establishing a code and filing system, and carrying out a category analysis [31].

Statistical analysis was performed using SPSS version 19.0 and AMOS 19.0. Data are expressed as number (percentage) and mean  $\pm$  standard deviation (SD) for categorical and continuous variables, respectively. Item screening was performed using item discrimination (ID) and item-total correlation (ITC) analysis. The construct validity was tested by exploratory factor analysis (EFA) and confirmatory factor analysis (CFA). The criterion-related validity and the test-retest reliability reflecting the stability of the scale were assessed by Pearson correlation coefficient. The internal consistency reliability was measured with Cronbach's alpha coefficient. The split-half-reliability was measured with Guttman Split-Half coefficient.

## Results

### Demographic data of qualitative study

A total of 19 participants were interviewed from May to Dec, 2016. The interviewees were between 26 and 53 years old, with an average age of  $39.47 \pm 7.58$  years old, and most were of Han or Manchu ethnicity. Among them, 14 were married, 2 were living together after divorce, 2 were remarried, and 1 was divorced. The time after breast cancer surgery was from 4 to 78 months, with an average of  $18.05 \pm 16.81$  months. Among the interviewees, 14 underwent mastectomy, 3 received breast-conserving therapy, and 2 received prosthetics; 13 received chemotherapy, 13 received endocrine therapy, and 8 received radiotherapy. Most of the interviewees came from cities (15/19), and had certificates of junior school, high school, or technical secondary school (10/19), and the monthly family income was less than 6000 yuan (14/19). All interviewees were not allowed to participate in the second phase of the survey, because after the patients were interviewed the first time, they were familiar with the interview questions in the survey, which may affect the accuracy of the results.

### Demographic data of quantitative study

A total of 252 subjects participated in the investigation from October 2016 to January 2017, and 16 subjects were removed by the lie-detecting item (6%). Their ages ranged from 26 to 55 years, with a mean age of  $42.61 \pm 6.62$  years. The postoperative time varied from 3 to 108 months, with an average time of  $25.44 \pm 20.19$  months. The general demographic characteristics are shown in Table 1.

### Validity

#### Face validity and content validity

The items with CVR less than 0.8 were removed, and the initial questionnaire included 46 items. The face validity showed that the subject was consistent with the purpose of the test, and on the surface, no errors were found. The content validity was tested by expert enquiry, and the initial questionnaire showed that S-CVI/ave was 0.98, and the overall questionnaire and all the items met the criterion indicating a good logical relationship between the content and objective of the questionnaire and the overall content.

Eighteen items with the coefficients less than 0.3 were deleted after ITC analysis, and 10 items with no significant results ( $P > 0.05$ ) were removed after ID analysis. By applying the 2 methods, a total of 18 items were deleted, and the questionnaire consisted of the remaining 28 items.

#### Construct validity

The construct validity was evaluated using EFA, and the results showed that the Kaiser-Meyer-Olkin (KMO) measure of sampling adequacy was 0.854, and the Bartlett's test of sphericity was statistically significant ( $\chi^2 = 5263.100$ ,  $P < 0.001$ ), indicating that the questionnaire was suitable for factor analysis. Five factors with Eigen values greater than 1.0 were extracted by using varimax rotation, and the extraction was also supported by the examination of the screen plots. The cumulative contribution was 60.37%. The 5 factors renamed based on the contents were as follows: Factor 1 (sexual physiology) including 8 items; Factor 2 (sexual psychology) including 7 items; Factor 3 (sexual relationship) including 5 items; Factor 4 (sexual body image) including 5 items; and Factor 5 (sexual cognition) including 3 items (Table 2). The factor loading of most items in the 5 factors was greater than 0.4. However, there was instability of factor analysis since the factor loadings of 4 items including the 22<sup>th</sup>, 30<sup>th</sup>, 35<sup>th</sup>, and 43<sup>th</sup> items were both larger than 0.40 in 2 major factors. After literature review and expert enquiry, the new classification of the 4 items is shown in Table 3.

**Table 1.** Demographic characteristics of Quantitative Study (N=246).

Items	Contents	Cases	Percentage (%)	Cumulative percentage (%)
Education	Junior high school or below	71	28.9	28.4
	High school/Secondary school	66	26.8	55.7
	Junior college	64	26.0	81.7
	Undergraduate college or above	45	18.3	100.0
Marital status	Married	237	96.3	96.3
	Unmarried	9	3.7	100.0
Occupational status	Occupation	107	43.5	43.5
	No occupation	139	56.5	100.0
Payment	Medical insurance for urban worker	147	59.8	59.8
	Medical insurance for urban residents	39	15.9	75.7
	New rural co-operative care	44	17.8	93.5
	Others	16	6.5	100.0
Monthly income(family)	3000Yuan or below	82	33.3	33.3
	3000~6000 Yuan	100	40.7	74
	6000~10000 Yuan	45	18.2	92.2
	10000Yuan or above	19	7.8	100.0
Menstruation	Regular menstruation	60	24.4	24.4
	Not menopause,but not regular	96	39.0	63.4
	Non natural menopause*	90	36.6	100.0
Having children	Yes	220	89.4	89.4
	No	26	10.6	100.0
Operation mode	Conservative	43	17.5	17.5
	Mastectomy	203	82.5	100.0
Pathological types	Cancer <i>in situ</i>	97	39.4	39.4
	Early invasive carcinoma	79	32.1	71.5
	Special types of infiltrating cancer	39	15.9	87.4
	Others	31	12.6	100.0
Pathological staging	I	40	16.3	16.3
	II	152	61.8	78.1
	III	54	21.9	100.0
Endocrine therapy	Yes	192	78.0	78.0
	No	54	22.0	100.0
Chemotherapy	Yes	215	87.4	87.4
	No	31	12.6	100.0
Radiotherapy	Yes	83	33.7	33.7
	No	163	66.3	100.0
Family history	Yes	18	7.3	7.3
	No	228	92.7	100.0

\* The patient has been in the status of unnatural menopause due to the comprehensive treatment of breast cancer.



**Table 2.** Results of exploratory factor analysis (28 items).

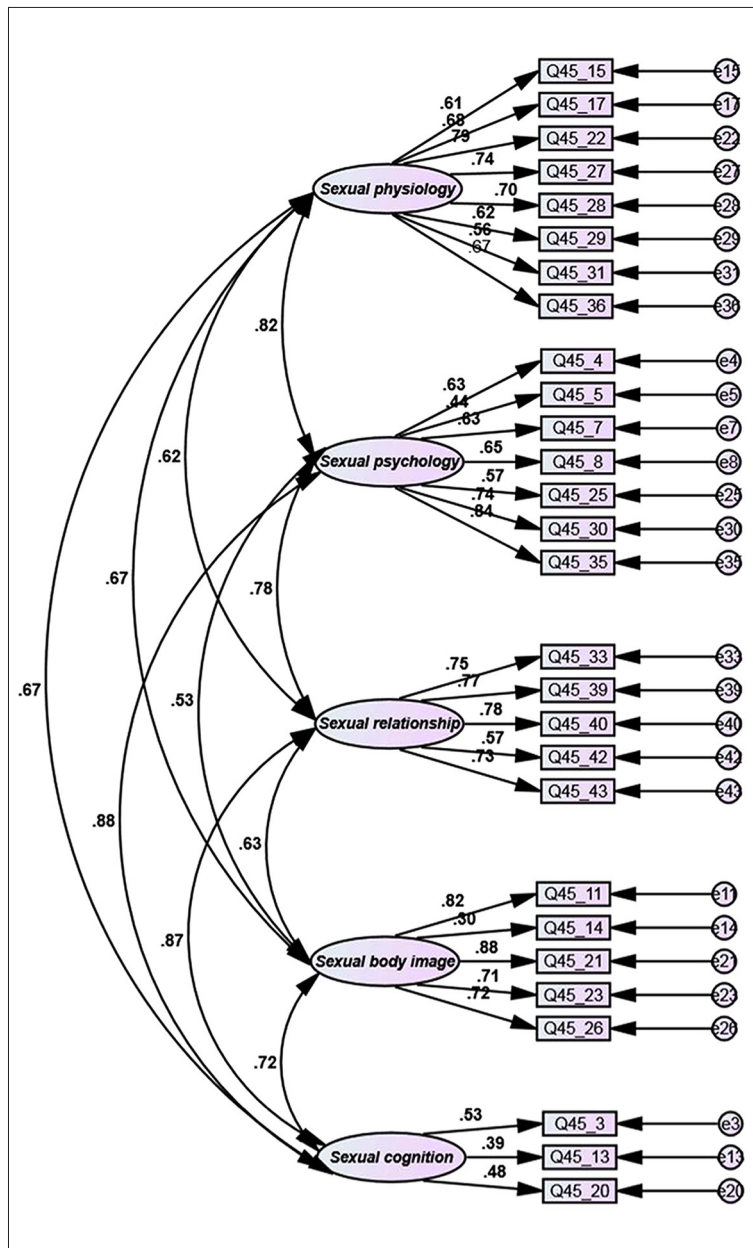
Item	Common factor				
	Factor1	Factor2	Factor3	Factor4	Factor5
29. Compared with pre-illness, vagina has decreased secretion and is dry	<b>.825</b>	.096	.060	-.008	.077
31. Compared to pre-illness, I feel vaginal pain during sex	<b>.794</b>	.114	.189	-.082	.028
28. Compared with pre-illness, I feel lack of physical strength during sex and tired after sex	<b>.643</b>	.099	.236	.311	-.064
17. The demand for sexual life is less than before	<b>.638</b>	.275	-.179	.202	.119
22. I feel the physiological response is out of sync with the thinking during sexual life	<b>.553</b>	.261	.285	.423	.156
15. It is difficult to achieve orgasm during sexual life compared to pre-illness	<b>.532</b>	.238	.064	.231	.192
36. The desire for sexual life is lower than before	<b>.484</b>	.351	.086	.424	-.103
27. Sexual arousal is more difficult than before	<b>.614</b>	.003	.125	-.010	-.042
7. Even guidance from medical staff, I am still afraid to go into sex	.165	<b>.750</b>	.248	-.039	.093
8. I would like to prefer hug, kiss and other intimacy, rather than sexual intercourse	.287	<b>.717</b>	.114	.058	.139
5. I think sexual life may lead to breast cancer recurrence or metastasis	.012	<b>.615</b>	.367	.024	-.106
30. In my life, I intentionally avoid sexual behavior and try my best to avoid the environment or conditions for sexual activity	.525	<b>.569</b>	.090	.138	.036
4. Now I am psychologically sensitive to sex	.322	<b>.559</b>	-.035	.215	.329
35. I am afraid of asking for sex from my partner	.511	<b>.537</b>	.317	.302	.033
25. I think sexual activity is now done to meet the needs of my husband	.384	<b>.509</b>	.090	.254	.209
33. The complains from the partner on the current sexual status become more	.177	.264	<b>.724</b>	.225	.093
39. The worse marital relationship after the illness affects sexual life	.130	.317	<b>.688</b>	.162	.262
42. For sexual life and partner relationship, I had to change the treatment plan, such as stopping taking endocrine drugs, taking estrogen, etc.	-.113	.351	<b>.667</b>	.018	.170
40. I think I do not know my partner as before	.208	.310	<b>.598</b>	.268	.305
43. The current state of sexual life with my partner makes me feel depressed	.338	.376	<b>.405</b>	.402	-.040
21. I feel that I have no female charm without breast	.266	.090	.147	<b>.731</b>	.264
11. I believe I am not a complete woman without breast	.306	.005	.162	<b>.707</b>	.278
14. I have less interest in sexual life without breast	-.166	.098	-.092	<b>.672</b>	-.170
26. I feel no female charm due to hair loss caused by chemotherapy	.298	-.116	.291	<b>.626</b>	.274
23. I feel reduced or loss of female charm due to the obesity caused by the treatment	.258	.192	.255	<b>.542</b>	.278
13. I feel awkward to receive guidance for sexual life	-.061	.231	.133	.037	<b>.759</b>
3. I think I cannot take the initiative to ask for sex as a woman	.257	.091	.083	.264	<b>.567</b>
20. I feel embarrassed when sex fails or does not go on	.333	.039	.137	.251	<b>.527</b>
Contribution rate	16.570	13.422	12.094	11.835	6.449
Cumulative contribution rate	16.570	29.992	42.086	53.921	60.370

Extraction method: principal component; Rotation method: Orthogonal rotation method with Kaiser standardization; a. The rotation converges after 8 iterations.

**Table 3.** The commonly used fit indices in confirmatory factor analysis model.

Fit index	$\chi^2$ (df)	$\chi^2/df$	RMR	GFI	AGFI	NFI	TLI	CFI
Results	967.557 (340)	2.846	0.094	0.744	0.695	0.722	0.775	0.797

RMR – Root Mean Square Residual; GFI – goodness of fit index; AGFI – adjusted GFI; NFI – Normed Fit Index; TLI – Tucker-Lewis Index; CFI – Comparative Fit Index.



**Figure 1.** The standardized estimate of each coefficient in the confirmatory factor analysis model. The model coefficient is estimated by maximum likelihood method.

The construct validity was further evaluated by CFA, and the results are shown in Figure 1. Most of the standardized factor loading coefficients obtained were greater than 0.50 (23/28). All the path coefficients in the 5 factors were above 0.5, showing a high degree of correlation among the factors. In addition,

the results of the critical ratio test showed that all the coefficients were statistically significant (all  $P < 0.001$ ). The common fit indices in the CFA model are shown in Table 3.

**Table 4.** The correlation coefficients between factors and between factor and overall questionnaire.

Overall questionnaire and sub-questionnaires	Sexual physiology	Sexual psychology	Sexual relationship	Sexual body image	Sexual cognition	Overall questionnaire
Sexual physiology	1					
Sexual psychology	0.590**	1				
Sexual relationship	0.392**	0.612**	1			
Sexual body image	0.554**	0.418**	0.489**	1		
Sexual cognition	0.337**	0.473**	0.401**	0.438**	1	
Total questionnaire	0.746**	0.759**	0.693**	0.735**	0.547**	1

\*\*  $P < 0.01$  (two tailed).

**Table 5.** Cronbach's alpha coefficient of overall questionnaire and 5 sub-questionnaires.

Factors	Total questionnaire and sub-questionnaires	Numbers of items	Cronbach's $\alpha$ coefficient
	The quality of sexual life questionnaire	28	0.929
1	Sexual physiology	8	0.869
2	Sexual psychology	7	0.836
3	Sexual relationship	5	0.845
4	Sexual body image	5	0.816
5	Sexual cognition	3	0.571

**Table 6.** The correlation coefficients of the overall questionnaire and 5 sub-questionnaires of two measurements.

Total questionnaire and sub-questionnaires	Numbers of items	correlation coefficient
The quality of sexual life	28	0.816**
Sexual physiology	8	0.847**
Sexual psychology	7	0.767**
Sexual relationship	5	0.767**
Sexual body image	5	0.710**
Sexual cognition	3	0.685**

The correlation analysis between the factors, as well as between the factors and the overall questionnaire, showed that the correlation coefficients ranged from 0.401 to 0.759 ( $P < 0.01$ ) (Table 4).

**Criterion-related validity**

The correlation coefficients between the overall questionnaire and FSFI, SDS, and LWMAT were 0.582, -0.456, and 0.515, respectively (all  $P < 0.01$ ).

**Reliability**

*Internal consistency reliability*

The Cronbach's alpha coefficient for the overall questionnaire on sexual quality of life in BCSs was 0.929, and for the 5 factors were 0.869, 0.836, 0.845, 0.816, and 0.571, respectively (Table 5).

*Test-retest reliability*

Fifty subjects were selected randomly for the test-retest reliability after 1 week. The Pearson correlation coefficients for the overall questionnaire and the 5 factors were 0.816, 0.847, 0.767, 0.767, 0.710, and 0.685, respectively ( $P < 0.01$ ) (Table 6).



### Split-half-reliability

The 28 items were classified into 2 parts according to the parity of the item number, and the Guttman split-half-reliability coefficient of 2 parts was 0.879.

## Discussion

### Social and cultural background and BCSs in mainland China

In mainland China, sexual shame, sexual conservatism, and male authority have a great impact, and sexual health problems are easily overlooked or deliberately avoided. Therefore, studying this issue has certain challenges and difficulties. According to the point of view of German physician Irwin Bloch [14], the sexual dysfunction in BCSs is related to physiological factors, as well as sex-related social and cultural background, such as the understanding of sex and breast awareness in BCSs and women's social status. To carry out clinical and psychological counseling, as well as therapeutic intervention and guidance on the sexual dysfunction in BCSs, the development of a localized, comprehensive, high-reliability sexual life quality assessment tool is important.

### General condition of questionnaire

We developed a questionnaire consisting of 28 items and 5 factors. The cumulative contribution rate of the 5 major factors (*sexual physiology, sexual psychology, sexual relationship, sexual body image, and sexual cognition*) reached 60.37%. However, there are differences between the 5 factors extracted from factor analysis and the concept of quality of life, except for the sexual physiology and sexual psychology. The in-depth analysis showed that sexual social factors were mainly reflected in the change of conjugal relationship, which can be reflected through sexual relations. Sexual culture mainly reflected from the somatotype resulted from the absence of breasts and the cognition of the traditional sexual thoughts. According to indices of CFAs values, the compatibility of the scale was considered good in terms of the CFI, NFI, and GFI values [32].

### Validity

In practice, the 5-factor structure can be clearer and more refined to show the connotation of the quality of sexual life in BCSs. After analysis of the factors, it can be found that the physiological factor mainly reflects the physiological aspect of the quality of sexual life in BCSs; the sexual psychological factor mainly reflects the psychological aspect of the quality of sexual life; the sexual relationship factor mainly reflects the marital relationship in the quality of sexual life; the sexual body

image mainly reflects the impact of breast defect on sexual function, and is also the characteristic measurement dimension for breast cancer patients; and the sexual cognition mainly reflects the impact of Chinese traditional conservative sexual culture on the cognition of BCSs. In summary, these statistical dependencies and structural relationships can all be reasonably explained by logical relationships [33]. Therefore, it can be considered that the structure of the questionnaire basically conforms to the expected content framework and has good structural validity.

The correlation coefficients between the factors and between the factors and the overall questionnaire ranged from 0.401 to 0.759 ( $P < 0.01$ ). The correlation coefficient between each factor was less than the correlation coefficient between each factor and the overall questionnaire, indicating a significant correlation between the factors and between each factor and the overall questionnaire [34,35].

The criterion-related validity reflected the degree between the research tool and other measurement criteria. The results showed that the quality of sexual life questionnaire in BCSs was negatively correlated with the Self-Rating Depression Scale (SDS) [36,37], ( $r = -0.356, P < 0.01$ ), showing that worse depression is associated with lower quality of sexual life in BCSs. The SDS can reflect the health status of BCSs in aspects such as psychology, sexual cognition, and sexual body image. The SDS scale includes 20 items, which reflect 4 sets of specific symptoms: psychogenic-emotional symptoms, physical disorders, mental motor disorders, and depression mental disorders. Higher FSFI and LWMAT scores indicate better quality of sexual life in BCSs. The FSFI is well correlated to the aspect of sexual physiology in the sexual life quality questionnaire. The FSFI score was developed by Rosen et al. [38] in 2000 and includes 19 items, with Cronbach's  $\alpha = 0.76-0.87$  [39,40], test-retest reliability = 0.82-0.92, and content validity = 0.95. It has a strong psychological attribute in addition to sexual function, and can be used for detecting the sexual function and assessing the sexual dysfunction in cancer patients. The LWMAT score [41] is well correlated to the aspect of sexual correlation in the sexual life quality questionnaire (all  $P < 0.01$ ), and includes 15 items, with Cronbach's  $\alpha = 0.90$ , half-reliability coefficient = 0.90, and test-retest reliability = 0.59. Generally, if the LWMAT score is less than 100 points, it is considered poor marital adjustment [13].

The correlation coefficient of the criterion-related validity ranging from 0.4 to 0.8 was associated with a good degree of correlation [42]. The correlation coefficients between the questionnaire on the quality of sexual life in BCSs and each questionnaire satisfied the above criteria.

## Reliability

Cronbach's alpha coefficient is generally considered to be very reliable at 0.50–0.70, followed by 0.7–0.9 [43]. The Cronbach's alpha coefficient was 0.929 in the present study. The Cronbach's alpha coefficient ranged from 0.816 to 0.869 among sexual physiology, sexual psychology, sexual relationship, and sexual body image, while the Cronbach's alpha coefficient of sexual cognition was 0.571, which was lower than the other 4 factors. This may be due to the lack of items related to this aspect, suggesting that further studies are needed. Cronbach's alpha coefficient as a whole showed that the homogeneity or intrinsic correlation between the factors that made up the questionnaire was consistent and that the items focused on the same point.

Test-retest reliability can reflect the stability of the questionnaire, which was used to test the degree of consistency of the same evaluation tool by assessing the same subject 2 or more times [43]. The correlation coefficient of the overall questionnaire was 0.816, and the correlation coefficient of each factor ranged from 0.685 to 0.847, which confirmed that the questionnaire was stable. The degree of consistency is also known as the degree of consistency within the questionnaire. In the present study, the coefficient of the Guttman Split-Half was 0.879, which proved that the questionnaire had good reliability.

## Characteristics

Through investigation in 28 countries, Laumann et al. [44] found that the incidence of sexual health problems in East Asia and Northeast Asia was higher than in other regions. In the United States, compared with other ethnic groups, Chinese Americans believe that sexual life is less important [45]. The social and cultural backgrounds such as sexual conservatism and sexual shyness have influences on the interracial sexual function [46]. The SQOL-F scale [47] developed by Symonds et al. in 2005 mainly evaluated women's self-esteem, emotions, and partnership in sexual life, with a focus on social and psychological assessment. However, questionnaires developed outside of China were based on the psychological characteristics of their own countries, and are not directly applicable for the Chinese population [48]. In 2008, based on the SQOL-F scale and the social and cultural background of China, Lei Hu [49], a scholar in mainland China, developed the Sexual Quality of Life Questionnaire for Women, which is universally used to assess the quality of sexual life of Chinese women, but it lacks a focus on breast cancer, such as the effect of breast defect on patient psychology and marital relationship, endocrine therapy, chemotherapy-induced senescence, chemotherapy-induced hair loss, and symptoms of obesity and nausea. Our questionnaire was designed based on the BCSs in mainland China and was verified for reliability and validity. The 5-factor scale structure

obtained was based on the physiological, psychological, social, and cultural factors affecting the sexual life of BCSs, and reflects most aspects of the Sexual Quality of Life Questionnaire for Women developed by Lei Hu [49]. In addition, in the questionnaire developed in the present study, sexual body image can reflect the effects arising from breast defect and related treatment in BCSs, and the sexual cognition reflects the impacts arising from traditional Chinese sexual culture on BCSs. Therefore, the assessment of sexual life in BCSs is more targeted, and consistent with the content framework of the quality of life [50], which is clearer in terms of the structure. As the mode of communication, sexual cognition is related to the social and cultural background, and most of the items of sexual cognition, sexual body image, and sexual relationship in the study came from interviews with married (or having regular sex partners) BCSs (who underwent comprehensive treatment for breast cancer, mainly surgery) in mainland China. By sorting out the interviews, the questions that conformed to the questionnaire concept were extracted. Therefore, some of the items in the present study are more in line with the current sex-related social and cultural background in mainland China in terms of the contents and expression.

## Strengths and Limitations

### Strengths

The study on the quality of sexual life in BCSs is currently still a challenge in China. With the combined qualitative and quantitative method and the comprehensive consideration of the influence of social and cultural backgrounds on the quality of sexual life, the study developed an original tool for assessment of and intervention in the quality of sexual life in BCSs in mainland China from the perspective of the patients.

### Limitations

There are 2 shortcomings in this study. Firstly, to obtain understanding and support from the study subjects, only the BCSs who received outpatient follow-up in the Department of Breast Surgery of the hospital where the authors work were selected for participation in the questionnaire survey, and the sources and the size of samples should be expanded in the future. Secondly, the study design only considered the BCSs affected by the sexual, social, and cultural backgrounds of mainland China, and but did not consider populations affected by other sexual, social, and cultural settings in addition to the traditional Chinese ones, such as BCSs from Hong Kong and Taiwan as well as ethnic Chinese BCSs. Further studies involving different populations and cultural backgrounds are needed to validate our questionnaire.

## Conclusions

The questionnaire on the quality of sexual life in BCSs has good reliability and validity, and is a simple and convenient tool for the evaluation of the quality of sexual life in BCSs in mainland China. However, it is necessary to further verify the reliability and validity of the questionnaire in other research groups.

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## Conflict of interest

The authors declare that they have no competing interests.

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