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# Development and evaluation of a psychosocial adaptation questionnaire for women with breast cancer treated with adjuvant endocrine therapy: a single-centre, cross-sectional study in China

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## ABSTRACT

**Objective** To develop and evaluate a psychosocial adaptation (PSA) questionnaire of women with breast cancer treated with adjuvant endocrine therapy (AET).
**Design** Cross-sectional study.
**Setting** Conducted study in a tertiary care centre in China from March to June 2021.
**Participants** Women with breast cancer who have received AET.
**Methods** Item development and extraction were based on literature, qualitative interviews (n=16) and assessment of content validity. 300 participants were recruited to perform item analysis, internal consistency reliability and exploratory factor analysis by cross-sectional studies. Finally, test–retest, criterion validity and confirmatory factor analysis of the questionnaire were performed with 96 respondents.
**Results** An initial questionnaire was devised. The exploratory factor analysis demonstrated four factors: emotional response (six items), self-worth (five items), physical impacts (three items) and social communication (two items). The cumulative contribution of the factors was 65.057%. Cronbach's alpha coefficient of the questionnaire was 0.876. The correlation coefficient between the questionnaire and General Self-Efficacy Scale was 0.565 (p<0.01). A 16-item questionnaire and its factorial structure were confirmed.
**Conclusions** The 16-item questionnaire had good reliability and validity. This could be a useful tool to assess the PSA levels among women with breast cancer treated with AET and provide a basis for further research.

## INTRODUCTION

Breast cancer (BC) is the most diagnosed cancer globally, with 2.3 million new cases in 2020, accounting for 11.7% of all cancer cases in that year .[1] BC accounts for one in four cancer cases and one in six cancer deaths among women. Approximately two-thirds of women with BC test positive for the oestrogen receptor (ER) and/or progesterone receptor (PR).[2] Due to early diagnosis and aggressive adjuvant therapy, the 5-year survival rate for cancer is more than 91.2%, which is higher than that for other cancers.[3 4] Updated clinical practice guidelines recommend extending the use of adjuvant endocrine therapy (AET) from 5 to 10 years.[2 5]

Breast cancer has gradually become a chronic disease with higher survival rates. Breast cancer survivors (BCS) need to co-exist with cancer for a long time and learn to adapt to the disease.[6] While physical functioning in quality of life improves over time after completion of aggressive cancer treatment, emotional and social functioning as well as some breast cancer-specific symptoms significantly worsen, with all symptoms of distress (except pain) being higher in breast cancer patients than in the general population.[7] Compared with the general population, after AET, BCS experience physical symptoms and emotional issues as they enter remission.[8 9] Long period of AET brings immense pain to the patient's body and mind. They often worry about disease recurrence and metastasis, and

| Characteristics | n (%)/mean±SD |
|---|---|
| Age(year) | 50.628±9.024 |
| BMI | 24.112±2.903 |
| Education level | |
|    Junior high school or below | 108 (27.272) |
|    High school/college | 190 (47.980) |
|    Undergraduate college or above | 98 (24.748) |
| Marital status | |
|    Married | 339 (85.606) |
|    Unmarried | 9 (2.273) |
|    Divorced | 31 (7.828) |
|    Widowed | 17 (4.293) |
| Professional | |
|    Retired | 166 (41.920) |
|    Did not work | 99 (25.000) |
|    Temporary worked | 13 (3.283) |
|    Work as usual | 118 (29.798) |
| Years taking endocrine medications | 3.333±2.152 |

BMI, body mass index.

most have experienced hot flashes, night sweats, insomnia, stiff joints, weight gain, anxiety, depression, and a series of side effects.[10–14] In addition, BCS also suffer from a variety of psycho-social distress due to self-blame (negative perceptions of cancer) and social stigma.[8] Adaptation on a multi-dimensional level, such as social and sexual, while tolerating the symptoms of diagnosis and treatment is called psycho-social adaptation.[15] Psycho-social adaptation (PSA) in BCS is an important part of BCS evaluation.[16]

Londono and McMillan used literature analysis to form the intermediate domain theory of the concept of PSA, showing its multidisciplinary characteristics and properties of variability, process, persistence, interactivity and individuality.[17 18] PSA involves the integration of illness or disability into an individual's life, identity, self-concept and self-image.[19] Based on the perspective of positive psychology, PSA refers to the transition process of the person with disability from a state of disability to an enabling state, which is characterised by the transition from negative to positive happiness.[20] PSA has both relation and difference with self-efficacy and health-related quality of life. BCS with an optimistic disposition, and with a positive perception of illness have better health-related quality of life.[21] Self-efficacy is important for better PSA.[22] Based on previous theories and studies, when women have BC treated with AET, they will adopt either a positive or negative attitude and behaviour to face it, which results in the changes of emotional dimension, self-cognition, self-image and social dimension. After an extensive literature review, no effective questionnaire was found that revealed the PSA of women with BC undergoing AET among the few studies available regarding the psychosocial adjustment of patients with BC. For instance, the Self-Reported version of the Psycho-social Adjustment to Illness Scale (PAIS-SR) was designed by Derogatis[23] in 1986 to measure psychosocial adjustment in Greek patients with BC with heterogeneous cancer, and their close family members, with Cronbach's alpha coefficients >0.620.[24] When we used the Chinese version of the PAIS-SR to measure the PSA of women with BC treated with AET, patients felt that many contents of the questionnaire were not applicable, and the internal consistency coefficient was only 0.129. Therefore, shorter questionnaires needed to be devised, which can be quickly answered and easily managed in busy clinical centres.

To measure the PSA of patients with BC more accurately and provide better targeted intervention measures, our team constructed a questionnaire that evaluated PSA levels among BC women who have received AET, tested the questionnaire and subscales on women with BC treated with AET, and examined the reliability and validity of the new assessment tool.

## METHODS
Based on this preliminary concept, the development of the questionnaire included item development, questionnaire development and evaluation.[25 26] This mixed research was conducted from March to June 2021 in China. Recruitment information was posted through the WeChat follow-up group of women with BC treated with AET at the Affiliated Hospital of China Medical University. According to the inclusion and exclusion criteria, participants were recruited online and voluntarily included.

Inclusion criteria were as follows: diagnosed with BC, positive ER and/or PR, received AET, women over the age of 18 years having BC and volunteering to participate in the study.

Exclusion criteria were as follows: women with other critical diseases (such as, severe infection, malignant tumours, malignant hypertension, myocardial infarction, severe cerebrovascular accident and heart failure).

### Item development
The related literature on PSA levels in women with BC treated with AET was reviewed. This qualitative study was conducted through interviews and participatory observation.[27] The literature reviewed and the information obtained from the participants (n=16) provided abundant data for the development of the item pool and the initial questionnaire. The PSA of women with BC treated with AET was closely related to emotional response, self-cognition, self-image and social situation.

### Questionnaire development
Five experts (two BC specialists, two psychologists and one nursing specialist) assessed the questionnaire's

**Table 2** Results of reliability and validity analysis for the PSA questionnaire among BC women with AET

| Factor | Item | Factor loading | Eigenvalue | Explanatory variation (%) | Cumulative explanatory variation (%) | Cronbach's alpha coefficient | Correlation coefficient |
|---|---|---|---|---|---|---|---|
| 1 | Q1. I am worried about metastasis or recurrence | 0.845 | 5.920 | 36.997 | 36.997 | 0.899 | 0.857* |
| | Q2. Breast problems make me feel nervous | 0.802 | | | | | |
| | Q3. I am worried that breast disease will get worse | 0.800 | | | | | |
| | Q4. Breast problems make me feel scared | 0.795 | | | | | |
| | Q5. I am worried about the side effects of the drug | 0.705 | | | | | |
| | Q6. Breast problems make me very depressed | 0.670 | | | | | |
| 2 | #Q7. I still think of myself as an attractive person | 0.784 | 1.954 | 12.211 | 49.208 | 0.790 | 0.685* |
| | #Q8. Overall, I am satisfied with myself | 0.761 | | | | | |
| | #Q9. I think I am still a valuable person | 0.738 | | | | | |
| | #Q10. I can share happiness and sadness with friends and colleagues | 0.660 | | | | | |
| | #Q11. I am still interested in things I was interested in before | 0.649 | | | | | |
| 3 | Q12. Breast problems affect my sex life | 0.795 | 1.468 | 9.174 | 58.382 | 0.664 | 0.698* |
| | Q13. I can not face the weight gain | 0.681 | | | | | |
| | Q14. Disease affects my appearance and makes me unhappy | 0.638 | | | | | |
| 4 | Q15. I am not willing to discuss breast problems with others | 0.861 | 1.068 | 6.675 | 65.057 | 0.730 | 0.573* |
| | Q16. I do not like others asking about my condition | 0.839 | | | | | |

Confirmatory factor analysis.
*At level 0.01 (double tail), the correlation is significant. # is the reverse scoring item.
AET, adjuvant endocrine therapy; BC, breast cancer; PSA, psychosocial adaptation.
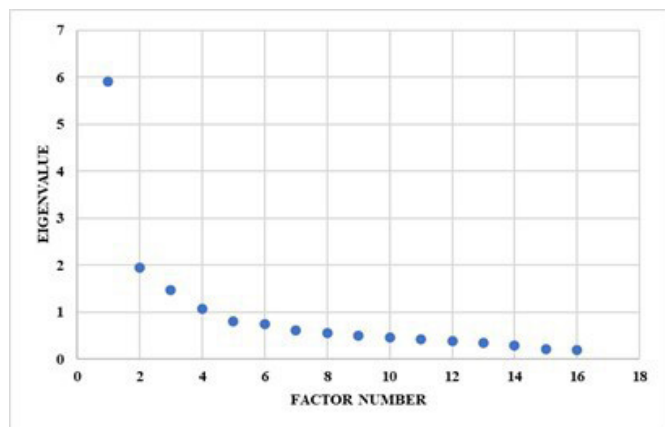
**Figure 1** Scree plot.

content validity through two rounds of panel discussions. In preparation for the formal survey, participants who met the criteria were chosen prior to the survey, and the difficulty, suitability and complexity of the items were assessed.

## Investigation

There are two parts to the investigation. The sample size was determined by the item number, which met the requirement of 5–10 times the item number. In the first part, the initial questionnaire contained 56 items (56×5=280). A total of 300 participants (>280) were included to perform item analysis, internal consistency reliability and exploratory factor analysis (EFA). In the second part, the final questionnaire contained 16 items (16×5=80). Test–retest, criterion validity and confirmatory factor analysis (CFA) of the questionnaire were performed with 96 respondents (>80).

Sociodemographic characteristics of the participants were obtained in the survey, which included population-related and disease-related variables. The PSA questionnaire was developed for women with BC who have received AET. The answers were scored on a five-point Likert scale: all the time, often, sometimes, rarely and never. The higher the score, the better was the PSA level. The 10-item General Self-Efficacy Scale (GSES), developed by Schwarzer in 1981, has been widely used to measure self-efficacy and has been shown to have good reliability and validity.

The items were analysed using the critical ratio, discriminative index (DI) and item-total correlation (ITC). Items with values below the standard value were deleted. Construct validity was assessed using EFA and CFA. The internal consistency of the questionnaire was evaluated using Cronbach's alpha coefficient. Test–retest reflects the stability and consistency of the test over time. After 10–18 days, 31 patients completed the questionnaire again, and the correlation coefficients of the two measures were used to assess the reliability of the retest. The Spearman correlation coefficient test was used to assess the validity of scale stability. The GSES was used to assess criterion validity.[28]

## Statistical analysis

If an item was not answered, the score was replaced with the average. If two or more questions were not answered, the questionnaire was excluded from analysis. In the qualitative part, all data were managed and analysed using NVivo V.11.0. In the quantitative stage, IBM SPSS Statistics 25.0 and AMOS 23.0, were used for statistical analysis.

## Patient and public involvement

No patient or public involvement.

## RESULTS

### Participant characteristics

A total of 409 women with BC treated with AET were selected between May and June 2021, of which 396 patients agreed to participate (response rate=96.82%). The sociodemographic and clinical characteristics of the study participants are presented in table 1.

### Development and analysis of items

#### Item pool

The initial questionnaire included items related to the literature, qualitative research and group discussion.
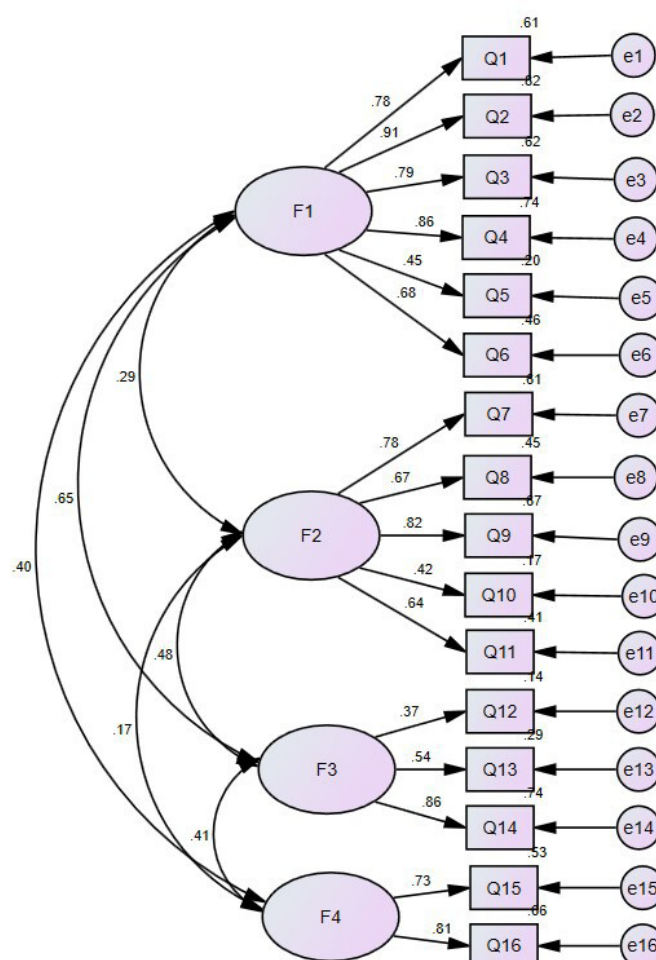


**Figure 2** The standardised estimate of each coefficient in the confirmatory factor analysis model.

**Table 3** Confirmatory factor analysis of PSA in BC women with AET

| Items | | | Estimate | SE | Z | P value | Estimate | CR | AVE |
|---|---|---|---|---|---|---|---|---|---|
| Q1 | <--- | F1 | 1 | | | | 0.781 | 0.887 | 0.577 |
| Q2 | <--- | F1 | 1.076 | 0.109 | 9.869 | *** | 0.908 | | |
| Q3 | <--- | F1 | 1 | 0.12 | 8.309 | *** | 0.79 | | |
| Q4 | <--- | F1 | 1.088 | 0.118 | 9.243 | *** | 0.86 | | |
| Q5 | <--- | F1 | 0.575 | 0.131 | 4.392 | *** | 0.452 | | |
| Q6 | <--- | F1 | 0.806 | 0.117 | 6.904 | *** | 0.678 | | |
| Q7 | <--- | F2 | 1 | | | | 0.779 | 0.803 | 0.461 |
| Q8 | <--- | F2 | 0.781 | 0.126 | 6.216 | *** | 0.669 | | |
| Q9 | <--- | F2 | 0.91 | 0.123 | 7.42 | *** | 0.819 | | |
| Q10 | <--- | F2 | 0.494 | 0.13 | 3.791 | *** | 0.416 | | |
| Q11 | <--- | F2 | 0.78 | 0.132 | 5.921 | *** | 0.639 | | |
| Q12 | <--- | F3 | 1 | | | | 0.371 | 0.632 | 0.390 |
| Q13 | <--- | F3 | 0.973 | 0.329 | 2.953 | 0.003 | 0.542 | | |
| Q14 | <--- | F3 | 1.891 | 0.598 | 3.164 | 0.002 | 0.86 | | |
| Q15 | <--- | F4 | 1 | | | | 0.727 | 0.747 | 0.596 |
| Q16 | <--- | F4 | 1.308 | 0.378 | 3.463 | *** | 0.815 | | |

***$p<0.001$.
AET, adjuvant endocrine therapy; BC, breast cancer; CR, critical ratio; PSA, psychosocial adaptation.

Content validity was evaluated by five specialists (three breast specialists and two psychologists) through two rounds of panel discussions. The content validity index (CVI) of 76 questionnaires ranged from 0.769 to 0.893, and the average of the first round was 0.832. The content validity after deleting the 19 items was 0.930. A pre-experiment was conducted with 37 women with BC receiving AET to test the reliability of the questionnaire contents, of which 31 completed questionnaires were returned (recovery rate: 83.78%). Women with BC receiving AET judged the content of the questionnaire for appropriateness and accuracy. Cronbach's alpha coefficient of the questionnaire was 0.934 ($p<0.05$).

### Item analysis
After an independent sample t-test, item 2, which proved that the discrimination was poor, was deleted. Items with DI and ITC <0.3 were deleted at the same time. Consequently, a total of 17 items were deleted.

### Exploratory factor analysis
Twenty-three items were deleted in 21 rounds of EFA. From the perspective of factor load and content, the first subscale was 'emotional response' consisting of six items. The second subscale was 'self-worth', which consisted of five items. The third subscale was 'physical impacts', consisting of three items, and the fourth subscale was social communication', consisting of two items (table 2, online supplemental file 1). The Kaiser-Meyer-Olkin (KMO) index of the 16-item questionnaire was 0.880, and the result of Bartlett's spherical test was 2129.914 ($p=0.000$), which was suitable for factor analysis. When the eigenvalue was >1.0 (figure 1), four factors were extracted through principal factor analysis and varimax rotation, and the cumulative contribution rate of the factors was 65.057%.

CFA was used to further evaluate the construct validity, and the results are shown in figure 2. Except for Item 10, the load coefficient of the standardised factor obtained was >0.50. The path coefficients of the four subscales were highly correlated ($p<0.001$, table 3). The discrimination degree of the questionnaire and common fitting indices of the CFA model are listed in table 4, and the Pearson correlation coefficient between subscales is 0.165–0.760 ($p<0.001$).

**Table 4** Discrimination and model fit of confirmatory factor analysis for the questionnaire

| Items | Emotional response | Self-worth | Physical impacts | Social communication | CMIN/DF | RMSEA | CFI | PNFI | AIC |
|---|---|---|---|---|---|---|---|---|---|
| Emotional response | 0.760 | | | | 1.366* | 0.062 | 0.941 | 0.667 | 209.819 |
| Self-worth | 0.290 | 0.679 | | | | | | | |
| Physical impacts | 0.655 | 0.478 | 0.625 | | | | | | |
| Social communication | 0.399 | 0.165 | 0.405 | 0.772 | | | | | |

*$p<0.05$.

## Psychometric properties

### Internal consistency

The Cronbach's alpha coefficient of the PSA questionnaire among women with BC treated with AET and the four subscales were 0.876, 0.899, 0.790, 0.664 and 0.730, respectively (table 2). Correlation analysis showed that the correlation coefficients between each dimension and the total questionnaire ranged from 0.573 to 0.857 (p<0.01; table 2).

### Test–retest reliability

After 10–18 days, 30 patients answered the questionnaire again, with a correlation coefficient of 0.846 for both measures (p<0.01).

### Convergent validity

The correlation coefficient between the PSA questionnaire among women with BC treated with AET and the GSES was 0.565 (p<0.01).

## DISCUSSION

According to the adaptive model theory proposed by Roy, an American nursing theorist, individuals determine the best coping strategies based on objective analysis and thinking of various stress stimuli based on self-cognition and emotional state evaluation, so as to adopt adaptive response behaviours.[29] Based on Roy's adaptation theory and the PSA defined by Londono and McMillan, a literature review found that PSA is associated with psychological, social and other factors.[17 30] Qualitative analysis found that the self-cognition of women with BC treated with AET played a crucial role in the process of PSA. Based on this, a questionnaire for women with BC treated with AET was developed, which consisted of sixteen items and four subscales (emotional response, self-worth, physical impacts and social communication). According to the indicators of the CFA value, the questionnaire was considered to have good compatibility from three aspects: Goodness of Fit Index (GFI), adjusted GFI and contracted GFI.[31]

The item pool was derived from reviews, qualitative research and two rounds of panel discussions. The DI and ITC among the 16 items of the PSA questionnaire among women with BC treated with AET was >0.30, which confirms that the entries are sufficiently differentiated and relevant.[32 33]

In practice, the four-factor structure can display the connotation of PSA in patients with BC with AET more finely and intuitively. In short, these statistical correlations and structural relationships can be reasonably explained by logical relationships.[34] The KMO of the 16 questionnaires was 0.880, which was considered suitable for factor analysis.[35] Four subscales were extracted, and the factor load of each item of the questionnaire was >0.60.[36]

The correlation coefficient between each subscale was smaller than that between each subscale and the overall questionnaire, indicating that the correlation coefficient between each subscale and the overall questionnaire was significant.[37]

Standard correlation validity reflects the level of consistency between the research tools and other measurement criteria. The 16-item questionnaire was positively correlated with GSES,[38] indicating that the lower the PSA level of psychosocial patients with BC assisted by endocrine therapy is, the lower is their self-efficacy. The correlation coefficient of standard correlation validity was 0.4–0.8, indicating a good level of correlation.[39 40] The correlation coefficient between the 16-item questionnaire and the GSES met this.

By convention, an alpha of 0.60 or higher, is needed to keep an item on a 'sufficient' scale.[41 42] Therefore, the 16-item questionnaire was considered to have good internal consistency. Test–retest reliability could reflect the stability of the questionnaire, which was used to test the consistency of the same tool, and the same participants were evaluated twice or more.[43] The test–retest reliability of 16-item questionnaire was high.[41] To sum up, this questionnaire had good reliability.

From a clinical perspective, the 16-item questionnaire can be answered quickly; that is, it can effectively and pertinently evaluate the PSA of women with BC treated with AET, and is easy to administer in busy centres practicing treatment for BC. Women with BC treated with AET will be completed directly, and their PSA will be assessed by their healthcare provider based on the scoring method listed below. The questionnaire can be used as a comprehensive and cost-effective clinical assessment tool and overall PSA level of patients with BC with AET.

The use of a self-report may have influenced the answers of the participants to show their intentions as more 'morally acceptable'. The 16-item questionnaire mainly focused on the subjective feelings of patients, which can easily produce measurement bias, and there may be differences between subjective and objective indicators. Further evaluation of external validity is required. Therefore, we encourage action to acculturate, translate and validate the psychosocial adjustment questionnaire for women with BC receiving AET and to refine the normative component by adding descriptive and ethical norms.[35 41]

The reliability and validity of the 16-item questionnaire, which can be used as a tool for clinical evaluation and further study, were verified in this study. This will help healthcare providers to evaluate PSA in women with AET for BC and provide an appropriate basis for women with AET to adapt to it and improve their quality of life.

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