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Original Article

Development and psychometric testing of the lymphedema self-management support scale for breast cancer survivors

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ABSTRACT

Objective: Effective self-management support should be tailored to the individual. To provide personalized and targeted self-management support, a rigorous assessment tool is needed to screen the actual degree of lymphedema self-management support received by breast cancer survivors. This study aims to develop and psychometrically test the Lymphedema Self-Management Support Scale for Breast Cancer Survivors (LSMS-BCs).

Methods: This study involves two phases: scale development and psychometric testing. In the scale development phase, preliminary items and domains were identified through a qualitative meta-synthesis, a quantitative systematic review, and reference to previous similar scales. Expert consultation and pilot study were conducted to refine the scale and evaluate the content validity. The psychometric characteristics were tested with 447 participants using item analysis, exploratory factor analysis (EFA), confirmatory factor analysis (CFA), reliability assessments, as well as measurement invariance.

Results: A preliminary 21-item scale with four domains, basic management support, management support for limb volume reduction, role management support, and emotional management support, was constructed in the scale development phase and well supported by EFA and CFA. The scale-level content validity index was 0.983. Cronbach's α coefficient for overall scale and subscales ranged from 0.732 to 0.949. McDonald's ω ranged from 0.848 to 0.955. Excellent known-groups validity, concurrent validity, predictive validity, and measurement invariance were demonstrated.

Conclusions: The LSMS-BCs is psychometrically valid and reliable. It can serve as a valuable tool for assessing and understanding the lymphedema self-management support received by breast cancer survivors.

Introduction

Breast cancer–related lymphedema (BCRL) is a prevalent and persistent complication that may arise after breast cancer treatment, affecting a significant portion of patients throughout their lifetimes.[1] Studies have revealed an incidence of approximately 21.9% (95% confidence interval [CI]: 19.8%–24.0%).[2] Without early prevention, self-management, and appropriate treatment, lymphedema can become a burdensome, chronic condition for affected individuals.[3] BCRL is often accompanied by distressing symptoms, such as limb pain, heaviness, and numbness, which can greatly impact patients' daily lives. Moreover, it can also lead to changes in body shape, restricted mobility, diminished function, evoking negative emotions, and significantly impact the overall quality of life.[4–6]

Currently, lymphedema remains incurable, but there is a consensus that patient self-management plays a pivotal role in its prevention and control.[7] Self-management is defined as "the intrinsically controlled ability of an active, responsible, informed, and autonomous individual to live with the medical, role, and emotional consequences of ones' chronic condition(s) in partnership with social network and the health care provider(s)".[8] However, poor adherence to lymphedema self-management has been reported.[9,10] Barriers to lymphedema self-management has been identified, including issues with the timing and volume of information provision, minimalization of BCRL education, and inaccurate information from health care providers. Additionally, feelings of marginalization, treatment burden, and lack of follow-up support have been reported as hindrances to effective self-management.[11]

Lymphedema self-management is a complex process.[12] During this process, patients require self-management education, instrumental support, and emotional support.[13] Self-management support (SMS) refers to comprehensive and continuous approaches aimed at improving outcomes for chronic illnesses.[14] However, the majority of patients with breast cancer face challenges in accessing timely and consistent effective support regarding lymphedema self-management.[13] Taylor et al. have pointed out that effective SMS encompasses various aspects, including the provision of information, psychological support strategies, practical assistance for tailored physical care, social support, and other potentially effective components.[15] Moreover, they emphasize that effective SMS should be personalized to the individual's culture, beliefs, and specific condition.[15] To offer adequate support to the patients with breast cancer dealing with lymphedema, it is essential to provide more individualized and targeted SMS interventions. Thus, the first step in this process is to comprehensively evaluate the actual condition of SMS received by patients.

Currently, there is a significant gap in the field as there is a lack of a specialized instrument to assess lymphedema SMS in patients with breast cancer. While several general support–related assessment instruments are widely used for patients with chronic diseases, such as the Chinese Mandarin Version of the Medical Outcomes Study Social Support Survey (MOS-SSS-CM), Social Support Revalued Scale, and Perceived Social Support Scale.[16–18] These scales primarily focus on assessing treatment and emotional support for patients with chronic conditions. However, they do not specifically target the unique challenges and complexities faced by patients with breast cancer managing lymphedema. Therefore, there is an urgent need to develop a specific scale that can accurately and comprehensively evaluate the lymphedema SMS for patients with breast cancer. By creating a specialized instrument, health care providers and researchers can gain valuable insights into the specific support requirements of these patients, enabling the implementation of personalized interventions and support strategies. The development of such a scale is an essential step toward improving the care and well-being of breast cancer survivors facing the challenges of lymphedema, ultimately leading to enhanced quality of life and better disease management outcomes.

Methods

Aims

The aim of this study is to develop the Lymphedema Self-Management Support Scale for Breast Cancer Survivors (LSMS-BCs) and evaluate its psychometric attributes.

Phases and procedure

This study followed DeVellis's scale development methodology[19] and adhered to consensus-based standards for the selection of health measurement instruments risk of bias (COSMIN-RoB).[20,21] This was a scale development and validation study comprised two phases: Phase I, the scale development phase, included items generation, expert consultation, and the pilot study; Phase II, the scale validation phase, involved a cross-sectional survey to evaluate the scale's psychometric properties, including reliability, validity, and measurement invariance. We reported this study following Strengthening the Reporting of Observational Studies in Epidemiology checklist for cross-sectional studies.

Phase I: scale development

(1) Construct clarification

The development of the scale requires a clear description of the concept being evaluated and the structure of the measurement. As there is currently no well-documented definition for lymphedema SMS among

patients with breast cancer, this study formed a concept by retrieving the concepts and concept analysis of SMS for chronic diseases. Based on the key components of SMS concepts, the lymphedema SMS for patients with breast cancer was evaluated.

(2) Items generation

The first authors consist of one master's student and one PhD candidate in nursing. Both authors have received comprehensive methodology training through courses such as "scale development and validation" and have completed the JBI Systematic Review Training Program. In addition, they possess experience in the development of lymphedema self-management behavior scale for patients with breast cancer within the research team.[22] The framework of the scale was constructed based on the key components of SMS. To create a comprehensive item pool, systematic searches were conducted for qualitative studies and intervention studies related to lymphedema self-management in breast cancer survivors, gathering valuable insights from both patients and medical staffs. In addition, several established support scales were consulted during the development process.[16–18] The scale developers sorted and merged the items from the pool to create the initial version of the scale.

First, we conducted a meta-synthesis of qualitative studies on breast cancer survivors' experiences of lymphedema self-management[13]: Following JBI methodology guidance for meta-synthesis, we developed a Participants, Intervention, Comparison, Outcomes, Study design (PICOS) framework to guide the study inclusion. Comprehensive searches were conducted in databases, including Cochrane Library, Embase, PubMed, Web of Science, CINAHL, and PsycINFO, from inception to March 9, 2022, using free keywords and Medical Subject Headings (MeSH) terms. Only English papers with full-text available were included. Two reviewers independently performed study selection, extraction, and quality assessment. JBI meta-aggregative approach was followed during data synthesis. Further details are available in our prior publication.[13]

Then, a systematic review of interventional studies on lymphedema self-management for breast cancer survivors was conducted with the guidance of JBI methodology. A PICOS framework was developed to guide the study eligibility. Three sets of MeSH terms and free keywords, including "breast cancer," "breast cancer-related lymphedema," and "self-management" were used to search Cochrane Library, Embase, PubMed, Web of Science, CNKI, and WanFang data, from inception to September 16, 2022. Two independent reviewers conducted study selection, data extraction, and quality assessment using Cochrane risk of bias tool for randomized controlled trial and quasi-experimental studies. Meta-analysis and narrative synthesis were performed where suitable.

Finally, we searched databases using terms "self-management", "support", "scale" to identify relevant SMS scales, which could provide reference for item pool development.

(3) Item design and measurement method selection

Based on the initial compilation of the original item pool, the principles for scale item development are as follows: (1) ensure alignment with the scale's purpose. (2) Prioritize clarity, simplicity, and avoidance of redundancy when crafting specific items. Avoid ambiguity, vagueness, and unclear references using language familiar to survey respondents and maintaining readability at a primary school level. Statement formats, response formats, and the number of alternative options for scale items were determined through literature review and team discussions.

(4) Expert consultation

The suggested number of experts for a Delphi expert consultation can vary depending on the specific research context but typically ranges between 10 and 20 experts.[23] We invited experts with at least 5 years of experience in clinical nursing of lymphedema management, nursing education, nursing management, or scale development. In addition, experts

were required to hold a bachelor's degree or above to evaluate the preliminary scale and propose revisions. Expert consultation was conducted via email. The experts were invited to assess the relevance, importance, and provide modification suggestions for the preliminary scale. They evaluated the content's relevance on a 4-point Likert scale from 1 (not relevant) to 4 (highly relevant) and the importance on a 5-point Likert scale from 1 (not important) to 5 (highly important). After the initial consultation, the responses from the experts were summarized and statistically analyzed. The scale was then modified based on the experts' suggestions and in-depth discussions with the scale developers. Subsequently, the experts re-evaluated the modified scale. The consultation process continued until a consensus was reached among the experts. Finally, to assess the content validity, the content validity indices (CVIs) were calculated, providing an objective measure of the scale's content validity.[24]

(5) Pilot study

After the expert content validity verification, a pilot study was conducted to test the feasibility and comprehensibility of the preliminary scale. According to Johanson and Brooks' suggestion, a sample size of 24–36 is a reasonable recommendation.[25] We planned to recruit 30 patients for pilot test. The eligibility included women aged 18 years or older, diagnosed with breast cancer, and who had undergone breast cancer surgery for at least 1 month. Incomplete and invalid questionnaires were excluded. Participants independently completed the scale and evaluated its format, content, comprehensibility, ease of reading, and answer options.

Phase II: scale validation

Participants and data collection. From September to December 2022, we performed convenience sampling at a tertiary hospital in China, recruiting patients with breast cancer from both the wards and outpatient services. The inclusion and exclusion criteria were the same as in the pilot study. The sample size of 445 was calculated based on the recommended guidelines of 5–10 respondents per item and the structural equation model's requirement of a sample size over 200,[26] while accounting for a 10% loss rate. In addition, the recommended sample size for test–retest reliability was 40–480 or at least 105 of the total estimated participants.[27,28] We aimed for a sample size of at least 40 participants for the test–retest reliability assessment, which is considered sufficient for reliable results.[29] Finally, 40 patients were invited to complete the scale again after a 2-week interval to assess its test–retest reliability.

Measures and instruments. This study used paper questionnaires and telephone surveys. The questionnaire consisted of five parts:

(1) The self-designed general information questionnaire: It was used to collect information about patient's age, education level, time after breast cancer surgery, type of operation, treatments received, lymphoedema health education, and lymphedema diagnosis.
(2) The beta version of Lymphedema Self-Management Support Scale for breast cancer patients: It consisted of three dimensions and 21 items, including informational support (items 1–8), behavioral support (items 9–17), and emotional support (items 18–21).
(3) Lymphedema self-management behavior questionnaire for patients with breast cancer: Developed and validated by Wei et al.,[22] this scale consisted of 22 items and six dimensions: disease information management, diet and exercise management, affected limb protection management, promotion of lymph reflux management, emotional management, and role management. Cronbach's α coefficients for the overall scale and subscales ranged from 0.747 to 0.910.
(4) The Chinese Version of the Breast Cancer Survivor Self-Efficacy Scale: Originally developed by Champion et al.,[30] the Chinese

version was created by Yuan et al.[31] and consisted of two dimensions: self-acceptance and self-development.[31] Cronbach's α coefficients of total scale and two dimensions were 0.82, 0.88, and 0.79.[31]
(5) MOS-SSS-CM: Developed by Sherbourne and Stewart and adapted by Li,[16,32] this scale included 20 items and four dimensions: tangible dimension, emotional/informational dimension, positive social interaction dimension, and affectionate dimension. The Cronbach's α coefficient for the overall scale was 0.889.

Data analysis

SPSS Statistics Version 27.0, SPSS Amos Version 24.0, and Mplus Version 8.3 were adopted for data analysis.

Item analysis

Classical test theory points out that items should be evaluated from multiple perspectives.[19] We used the coefficient of variation method, the high-low grouping comparison method and item total correlations to achieve a comprehensive assessment of the items.[26,33]

Validity

We assessed construct validity, known-groups validity, concurrent validity, and predictive validity.

(1) Construct validity refers to the extent to which a test actually measures the theoretical structure (concept) and characteristics that it aims to measure. To evaluate construct validity, both exploratory factor analysis (EFA) and confirmatory factor analysis (CFA) were conducted.[34,35] EFA was used to identify the underlying construct of the items using principal components analysis with varimax rotation. Several criteria were used to determine the meaningful factors: (1) eigenvalues greater than 1.0, (2) Cattell scree plot, (3) the percentage of total explained variance accounting for more than 50%, and (4) item loadings greater than 0.45 in absolute value.[26] Subsequently, CFA was performed to confirm the identified factor structure. Acceptable model fit was determined by meeting the following criteria:[35] χ^2/df (NC) < 3, Tucker–Lewis index > 0.90, the comparative fit index (CFI) > 0.90, standardized root mean square residual (SRMR) < 0.08, root mean square error of approximation residual (RMSEA) < 0.08.[27]

Convergent validity suggests that measures of the same construct should be highly intercorrelated among themselves and uniform in the pattern of intercorrelations. Fornell and Larcker suggested that for optimal convergent validity, the Average Variance Extracted (AVE) should exceed 0.5, and the Construct Reliability (CR) should be > 0.7. In addition, AVE values between 0.36 and 0.50 are considered acceptable.[34] Discriminant validity measures how distinct a measurement indicator is from other factors.[27,34] It is deemed high when the AVE for each indicator exceeds the shared variance with any other factor. That is, if the square root of the factor's AVE is greater than its correlation with other factors, discriminant validity is established.

(2) Known-groups validity was used to assess the scale's ability to differentiate between known different groups of people. We tested the hypothesis that patients receiving lymphedema health education or diagnosed with lymphedema would receive better SMS.[19] The scores of lymphedema SMS between two groups (received lymphedema health education vs. not, diagnosed with lymphedema vs. not) of patients were compared using the rank sum test.
(3) Concurrent validity was assessed by examining the correlation coefficient (r) between scores on LSMS-BCs and scores on other measures assessing similar constructs administered at the same
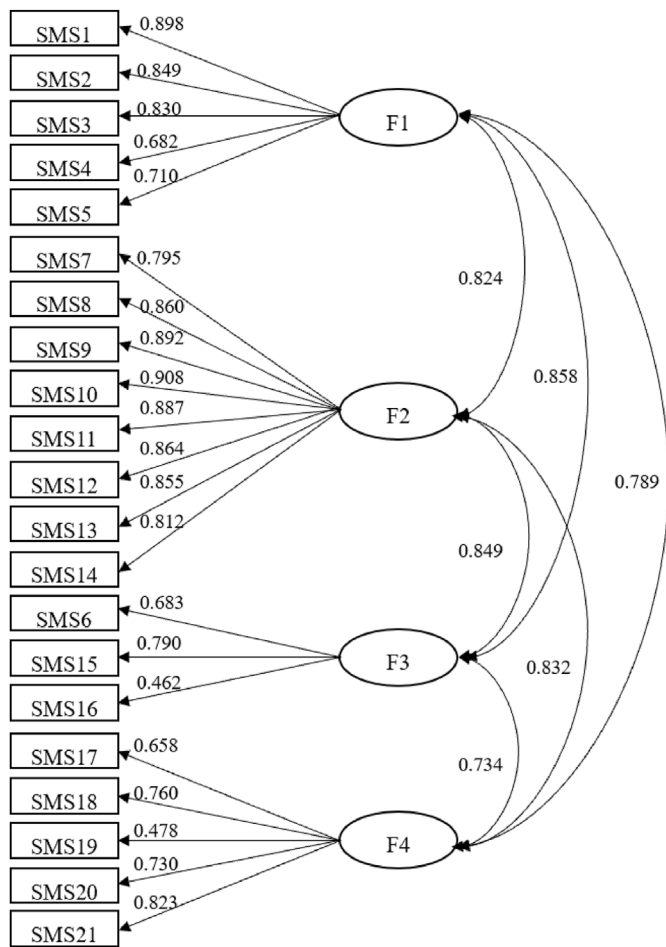
Fig. 1. A 4-factor model for confirmatory factor analysis. Note: F1 (Factor 1: basic management support), F2 (Factor 2: treatment management support), F3 (Factor 3: role management support), and F4 (Factor 4: emotional management support). SMS, self-management support.

time point. We chose the Medical Social Support Scale as the reference scale.

(4) Predictive validity refers to the ability of a scale to predict a particular outcome. Based on the Self-efficacy Theory, support can enhance patients' self-efficacy through indirect experiences and verbal persuasion. Based on a previous report, self-efficacy and SMS facilitated self-management behaviors. Hence, we constructed a hypothesis model among self-efficacy, SMS and self-management behaviors (Fig. 2A). Predictive validity was assessed by constructing a structural equation model to examine the relationship between self-efficacy, SMS, and lymphedema self-management behavior.[19]

Reliability

Cronbach's *a* and McDonald's ω were both used to evaluate the internal consistency reliability (> 0.7), the retest reliability was used to evaluate the external consistency reliability.[19]

Measurement invariance

In this study, the participants' education level ranged from primary school to postgraduate level. While we initially designed for readability at a primary school level, to ensure consistency in understanding across diverse educational levels, we evaluated the measurement invariance between low education: high school and below, and high education: college and above, using Brown's method with a stepwise procedure.[35]

This allowed us to ensure the scale's validity and reliability were consistent across groups.

Ethical consideration

Ethical approval was obtained from the Biomedical Research Institutional Review Board of Peking University (IRB No. 00001052-22123). This study was conducted in accordance with the ethical principles of the Declaration of Helsinki. Before the survey, written or oral informed consent was obtained from all participants to ensure their voluntary participation and protection of their rights and privacy.

Results

Phase I: scale development

Definition of the scale construct

Drawing from the literature on SMS for chronic diseases, "self-management support" was characterized as a continuous process aimed at empowering patients with chronic conditions to manage their health effectively. This involves providing them with the necessary motivation, confidence, knowledge, and skills to navigate their condition independently, thereby fostering long-term engagement in self-care and enhancing health outcomes. Key components of SMS include informational, material, emotional, and decision support.[8] Given that lymphedema shares characteristics with chronic diseases, this study defined lymphedema SMS for patients with breast cancer as an ongoing process involving health care professionals, family members, friends, and peers, all providing supportive measures to aid patients in managing lymphedema. The goal is to equip patients with the motivation, confidence, knowledge, and skills required for effective lymphedema management, thus promoting sustained engagement in self-care and improving lymphedema care outcomes. These dimensions align with the essential components of SMS concept.
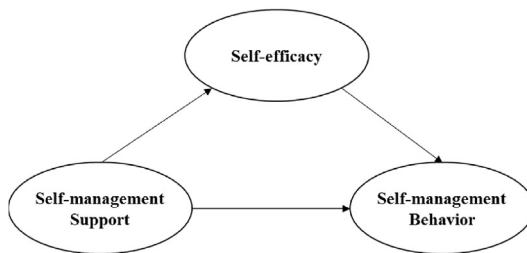
Development of the initial scale

Based on the components of the SMS concept, the scale's dimensions were categorized into information support, instrumental support, emotional support, and decision support. The items pool was formed by extracting supporting items from 24 qualitative studies[13] and 30 quantitative studies.[36] Initially, we obtained 183 items for the item pool. After careful analysis and several discussions, the research team developed the initial version of the scale comprising 21 items and four dimensions. The scale used a 5-point Likert score (no $= 0$, rarely $= 1$, sometimes $= 2$, often $= 3$, always $= 4$).

Expert consultation for content validity verification and item revision

Sixteen experts, including eight in clinical nursing specializing in lymphedema management, three nursing education professors with research experience in lymphedema, four in nursing management, and one in scale development, participated in two rounds of expert consultation. Their age ranged from 30 to 59 (42.94 ± 8.52) years, and their years of research experience varied from 6 to 27 (15.56 ± 7.23) years. The overall authority coefficient and positive coefficients of the experts were 0.960 and 100.0%, respectively, indicating that experts were authoritative and highly interested in the study.

In the first round, 14 experts proposed 88 modificati on suggestions, mostly overlapped and focused on language or words revision (importance value Kendall's *W* between four dimensions $= 0.091$, $P = 0.223$; importance value Kendall's *W* between 21 items $= 0.078$, $P = 0.205$), reflecting differences in the importance they attributed to each dimension and item. Based on the expert advice and discussions among the scale developers, the scale underwent revisions. Specifically, "instrumental support" and "decision support" were merged into "behavioral
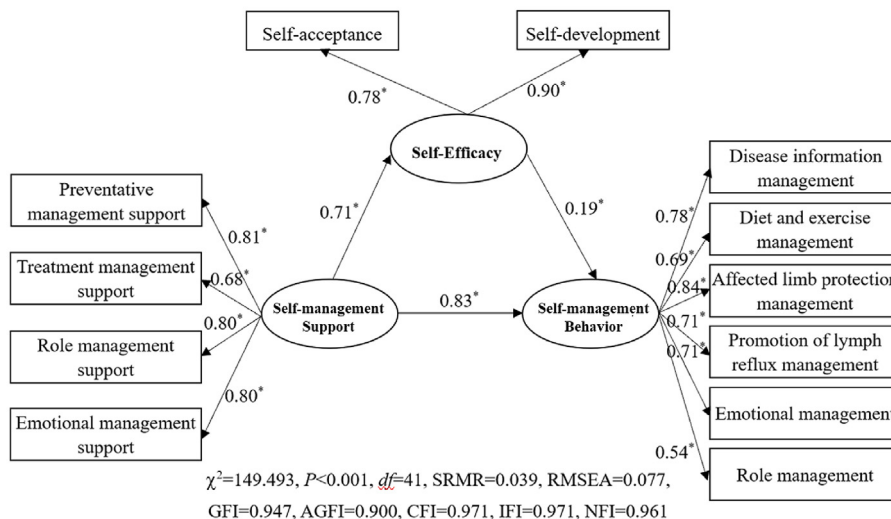
(A) Hypothesized Model

(B) Estimated Model

χ^2=149.493, *P*<0.001, *df*=41, SRMR=0.039, RMSEA=0.077,
GFI=0.947, AGFI=0.900, CFI=0.971, IFI=0.971, NFI=0.961

Fig. 2. Hypothesized model and estimated model of predictive validity: (A) Hypothesized model of self-efficacy, self-management support, and lymphedema self-management behavior; (B) Structural equation model of self-efficacy, self-management support, and lymphedema self-management behavior. SRMR, standardized root mean square residual; RMSEA, root mean square error of approximation residual; CFI, comparative fit index.

support", 13 items were modified, two items were deleted, five items were added, and four items were merged. Consequently, the revised scale used in the second round of expert consultation consisted of three dimensions and 22 items.

In the second round of expert consultation, 12 experts provided 47 modification suggestions (importance value Kendall's *W* between 22 items = 0.111, *P* = 0.015), indicating that a consensus was reached among the experts. Based on expert opinions and discussions among the scale developers, the "emotional support" dimension was revised, 10 items were modified by refining language and wording, and one item was deleted. As a result, the modified scale consisted of 21 items and three dimensions: informational support, behavioral support, and emotional support.

The content validity was assessed, with the scale-level CVI of 0.983 ($\geq$ 0.90) and the item-level CVI ranging from 0.88 to 1.00 ($\geq$ 0.78),[37] indicating a high level of content validity.

Pilot study to verify the feasibility of the scale

Twenty-six breast cancer survivors participated in the pilot study. The patients' age ranged from 35 to 77 (56.27 $\pm$ 12.40) years. Their education level varied from primary school to graduate school. The postoperative period was 3–130 (20.46 $\pm$ 34.99) months. Three patients (11.5%) self-reported having limb edema, and 24 patients (92.3%) mentioned receiving health education related to lymphedema during their treatment. All participants found the scale's content easy to understand without any ambiguity and had no suggestions for modifications. The filling time for the scale ranged from 3 to 9 (5.23 $\pm$ 1.51) minutes.

Phase II: scale validation

General characteristics of participants

The sociodemographic and disease-related information of 447 patients was presented in Table 1.

Item analysis

The item analysis results revealed that the coefficient of variation range was 0.30–1.61 (> 0.25),[26] indicating acceptable variability. In addition, there was a statistically significant difference in scores between the high and low groupings for all 21 items (*P* < 0.001). The mean interitem correlation was 0.403 (0.142–0.945) (between 0.15 and 0.50).[38] The item total correlation ranged from 0.46 to 0.84 (> 0.20).[33] The ceiling effect was 0.67% (3/447), and the floor effect was 0.33% (1/447), both below 15%. The total score was approximately normally distributed (Skewness = 0.602, *Z*-score = 5.23; Kurtosis = 0.106, *Z*-score = 0.460). Therefore, all 21 items were retained.

Validity

(1) Construct validity, convergent validity, and discriminant validity

Based on the chronological order of survey sequence, the 447 samples were divided into two sets: the first 224 sample data for EFA and the last 223 sample data for CFA. First, a Kaiser-Meyer-Olkin (KMO) value of 0.921 and Bartlett's sphericity test χ^2 of 4024.476 (*P* < 0.001) indicated that data were suitable for factor analysis. The

Table 1
Sociodemographic and clinical characteristics of the sample.

Variable	Total number of patients ($n = 447$)	Number of retest patients ($n = 41$)
	n (%)	n (%)
Education level		
Primary school	18 (4.0)	4 (9.8)
Junior high school	96 (21.5)	7 (17.1)
Senior high school	124 (27.7)	13 (31.7)
Junior college	89 (19.9)	8 (19.5)
Undergraduate	106 (23.7)	8 (19.5)
Graduate student	14 (3.1)	1 (2.4)
Employment status		
Unemployed	93 (20.8)	8 (19.5)
Employed	157 (35.1)	13 (31.7)
Retired	197 (44.1)	20 (48.8)
Operation type		
Modified radical mastectomy	20 (4.5)	4 (9.8)
Mastectomy	214 (47.9)	19 (46.3)
Breast conserving surgery	213 (47.7)	18 (43.9)
Sentinel lymph node biopsy		
Applied	447 (100.0)	41 (100.0)
Axillary lymph node dissection		
Applied	263 (58.8)	26 (63.4)
Not applied	184 (41.2)	15 (36.6)
Preoperative neoadjuvant chemotherapy		
Applied	83 (18.6)	16 (39.0)
Not applied	364 (81.4)	25 (61.0)
Postoperative chemotherapy		
Applied	360 (80.5)	27 (65.9)
Not applied	87 (19.5)	14 (34.1)
Radiotherapy		
Applied	238 (53.2)	18 (43.9)
Not applied	209 (46.8)	23 (56.1)
Targeted treatment		
Applied	213 (47.7)	16 (39.0)
Not applied	234 (52.3)	25 (61.0)
Hormonotherapy		
Applied	272 (60.9)	13 (31.7)
Not applied	175 (39.1)	28 (68.3)
Lymphedema health education		
Yes	408 (91.3)	38 (92.7)
No	39 (8.7)	3 (7.3)
Lymphedema diagnosis		
Yes	26 (5.8)	7 (17.1)
No	421 (94.2)	34 (82.9)

EFA results showed that four factors were extracted, explaining 71.70% of the variance (see Table 2). All items exhibited factor loadings exceeding 0.45. Items 4, 5, and 11 displayed dual loadings on two factors. The load difference between items 4 and 5 on the two factors (Factor 1 and Factor 3) was less than 0.2. Therefore, we categorized these two items under Factor 1 (Basic Management Support) due to their conceptual relevance. Specifically, item 4 (Limb Protection Instruction) and item 5 (Lymph Reflux Promotion Instruction) pertained to basic management support.[39,40] However, item 11 demonstrated a load difference greater than 0.2 between Factor 1 (0.464) and Factor 2 (0.785), resulting in its classification with the factor exhibiting higher load (Factor 2 Role Management Support).[39,40] Considering both the factor loadings and the substantive meaning of the items, the scale was divided into four dimensions: basic management support, management support for limb volume reduction, role management support, and emotional management support. For the 4-factor model of EFA (see Fig. 1), 223 samples were used for CFA. The fit indices were as follows: χ^2/df (NC) = 1.533, SRMR = 0.044, RMSEA = 0.049, GFI = 0.901, CFI = 0.979, IFI = 0.979, NFI = 0.942, demonstrating a good fit.

Regarding convergent validity, which ensures that observed variables measuring the same underlying trait align with the same factor,[27,34] the AVE for the four factors exceeded 0.36 (AVE for Factor 1 to Factor 4 was 0.637, 0.739, 0.435, and 0.490, respectively), and the CRs for Factor 1 (0.897), Factor 2 (0.958), and Factor 4 (0.823) were greater than 0.7, except for Factor 3 (CR = 0.688), indicating relatively ideal convergent

validity. As for discriminant validity, which indicates the extent to which a factor does not correlate with other factors,[27,34] the correlation coefficient between factors F1 and F4 was less than the square root of the AVE of F1. In addition, the correlation coefficients between F2 and F1, F3 and F4 were less than the square root of the AVE of F2, whereas the other correlation coefficients were greater than the corresponding AVE square root values. These results suggest that the discriminant validity was not ideal for some factor pairs.

(2) Known-groups validity: The groups were distinguished based on whether they received lymphedema health education and whether they had been diagnosed with lymphedema.[19] The results indicated that there was a statistically significant difference in the scores of lymphedema SMS between the two groups ($P < 0.05$), confirming the scale's known-groups validity.

(3) Concurrent validity: The SMS score showed a strong correlation with the Medical Outcomes Study Social Support Survey score ($r = 0.597$, $P < 0.001$). This correlation verifies the scale's good concurrent validity.[19]

(4) Predictive validity: The correlations between variables in the structural equation model are presented in Table 3. The results supported the hypothesized models (Fig. 2B), and the fit indices were as follows: $\chi^2 = 76.090$, $P = 0.005$, χ^2/df (NC) = 3.646, SRMR = 0.039, RMSEA = 0.077, GFI = 0.947, AGFI = 0.900, CFI = 0.971, IFI = 0.971, NFI = 0.961. The total predictive effect of SMS on self-management behavior was strong ($\beta = 0.961$, $P < 0.001$). SMS directly predicted BCRL self-management behavior ($\beta = 0.827$, $P < 0.001$), explaining 86.1% of the variance. It can also indirectly predict BCRL's self-management behavior through self-efficacy ($\beta = 0.134$, $P < 0.001$), accounting for 13.9% of the variance.

Reliability

Cronbach's α coefficient of the overall scale was 0.949, and Cronbach's α coefficients of basic management support, management support for limb volume reduction, role management support, and emotional management support were 0.889, 0.958, 0.732, and 0.795, respectively (all > 0.7). McDonald's ω coefficient of the total scale was 0.955, and for the four dimensions, it was 0.922, 0.966, 0.848, and 0.862, further confirming the scale's good internal consistency reliability.

In terms of external consistency reliability, a total of 41 patients completed the retest 2 weeks later, and the intragroup correlation coefficient (ICC) of the total scale and four dimensions were 0.921 (95% CI: 0.857–0.957), 0.797 (95% CI: 0.651–0.887), 0.815 (95% CI: 0.679–0.897), 0.921 (95% CI: 0.857–0.957), and 0.951 (95% CI: 0.846–0.954), respectively. These findings indicated that the scale had good external consistency reliability, as the ICC values exceeded the acceptable threshold of 0.7, confirming the stability and consistency of the measurements over time.

Measurement invariance

The measurement invariance results for the low education group and the high education group were presented in Table 4. (1) Configural Invariance: Model 0 showed a good fit with CFI = 0.940 (≥ 0.90) and RMSEA = 0.078 (≤ 0.08). (2) Metric Invariance: Model 1 also exhibited a good fit with CFI = 0.937 and RMSEA = 0.078. The comparison with Model 0 revealed a very small change in CFI ($\Delta CFI = 0.003$, ≤ 0.01), suggesting that adding constraints for metric invariance did not substantially affect the model fit. (3) Strong invariance: Model 2 showed a good fit with CFI = 0.937, RMSEA = 0.078. The comparison with Model 1 yielded a negligible change in CFI ($\Delta CFI = 0.003$, ≤ 0.01). (4) Strict Invariance: Model 3 exhibited a good fit with CFI = 0.924 and RMSEA = 0.082. The comparison with Model 2 showed a change in CFI of 0.010 (≤ 0.01). The above results demonstrated that the scale had measurement invariance among patient groups with different education levels.

Table 2
Exploratory factor analysis exploratory factor analysis results (*N* = 224).

Items	Item factor loading			
	1	2	3	4
Factor 1: Basic management support				
1. Someone gave me the knowledge about lymphedema as a complication of breast cancer treatment, such as the meaning, performance, harm, and impact of lymphedema.	**0.674**	0.274	0.365	0.225
2. Someone informed me of the risk level and causes of lymphedema.	**0.746**	0.356	0.113	0.160
3. Someone told me how to self-monitor lymphedema (such as early symptom monitoring, arm circumference measurement, etc.) and proactively report to a professional.	**0.535**	0.415	0.411	0.207
4. Someone told me how to protect the affected limb, such as avoiding blood injection, wearing gloves to protect the affected limb while doing housework, etc.	**0.530**	0.146	**0.643**	0.074
5. Someone told me how to promote lymph reflux, such as functional exercises for affected limbs, simple self-drainage, etc.	**0.550**	0.278	**0.609**	0.100
Factor 2: Treatment management support				
7. Someone informed me about the treatment of lymphedema, such as surgical treatment, complete decongestive therapy, etc.	0.440	**0.648**	0.150	0.174
8. Someone provided me with information on medical resources related to lymphedema, such as rehabilitation clinics for lymphedema, related mobile applications, and websites.	0.430	**0.682**	0.254	0.167
9. Someone assisted me in developing personalized goals and plans for lymphedema self-management.	0.416	**0.799**	0.009	0.140
10. Someone guided and help me with self-monitoring of lymphedema.	0.273	**0.870**	0.118	0.200
11. Someone guided and helps me promote lymph reflux.	**0.464**	**0.785**	−0.05	0.097
12. Someone regularly reminded and encouraged me to stick to lymphedema self-management.	0.141	**0.899**	0.171	0.164
13. Someone regularly evaluated my affected arm or lymphedema.	0.036	**0.912**	0.230	0.164
14. Someone helped me adjust the goals and plans for lymphedema self-management based on my own situation regularly.	−0.005	**0.874**	0.243	0.184
Factor 3: Role management support				
6. Someone told me the necessity and methods of maintaining a healthy weight.	0.264	0.109	**0.746**	0.291
15. Someone provides timely guidance and assistance when I encounter issues related to lymphedema management or abnormal situations.	0.271	0.319	**0.599**	0.406
16. Someone helps me do things that may cause or worsen lymphedema in my daily life, such as lifting heavy objects, mopping the floor, cleaning windows, etc.	−0.032	0.074	**0.727**	0.201
Factor 4: Emotional management support				
17. Someone shared with me successful experiences and skills in preventing and managing lymphedema in daily life.	0.406	0.127	0.009	**0.696**
18. Someone guided me to manage my emotions, such as relaxing, listening to music, meditating, etc.	0.176	0.237	0.219	**0.508**
19. Someone provided me with appropriate emotional support, such as listening, comforting, encouraging, accompanying, etc.	0.004	0.200	0.284	**0.592**
20. Someone shared with me the psychological process of lymphedema self-management.	0.076	0.055	0.065	**0.824**
21. Someone provided me with professional psychological counseling when I encountered emotional problems.	0.032	0.177	0.340	**0.699**

Bold numbers indicate factor loads greater than 0.45.

Discussion

The scale development process was guided by both theoretical principles and clinical practice using DeVellis's scale development methodology and COSMIN-RoB.[19,20,41] This combined approach ensured the high quality of the scale. By integrating established theoretical frameworks, the scale's conceptual foundation was robust and aligned with the current understanding of SMS in patients with breast cancer. Moreover, following the rigorous COSMIN-RoB guidelines helped to enhance the methodological rigor and reliability of the scale development process. By adopting a comprehensive and evidence-based approach, the scale's validity, reliability, and applicability were strengthened, making it a valuable tool for assessing lymphedema SMS in patients with breast cancer.

The final scale was composed of four dimensions: basic management support, treatment management support, role management support, and emotional management support, which was in line with the definition of SMS.[8,14,42] In the process of defining the construct, we characterized SMS for BCRL according to the broader definition of SMS for chronic diseases.[14] This entailed an ongoing empowerment process aimed at enabling breast cancer survivors to effectively manage their lymphedema, providing them with the motivation, confidence, knowledge, and skills required to independently manage their condition. Based on this definition, the scale was first categorized into four dimensions: informational, material, emotional, and decision support, reflecting the multifaceted nature of SMS in the context of BCRL. With the feedback of expert consultation, "material support" and "decision support" were combined into the "behavioral support". However, the EFA and CFA supported four-dimension construct, and the items were reallocated with role management support, and emotional management support remained, and the "behavioral support" being divided into "basic management support" and "treatment management support". The fluctuations in the number of dimensions during the scale development process reflected the iterative nature of psychometric testing and the challenges

inherent in capturing complex constructs. The items were sourced from various perspectives, including breast cancer survivors, health care professionals, and existing scale developers. Qualitative studies revealed diverse challenges faced by patients with breast cancer in lymphedema self-management, highlighting their need for varied support.[13] The provision of SMS also requires collaboration among multidisciplinary teams.[42,43] Exploration of SMS measures from current intervention studies further enriched insights from medical professionals. In addition, mature scales related to support were considered, providing a rational and evidence-based approach to item generation. This comprehensive approach ensures the scale's validity and applicability in assessing lymphedema SMS in breast cancer survivors. However, we did not consider including noninterventional quantitative studies, which might potentially offer additional information on the construct of SMS into systematic reviews.

The scale development underwent rigorous evaluation, including expert consultation and pilot study. In two rounds of expert consultation, 16 experts provided 135 specific and valuable modification suggestions, laying a strong foundation for scale refinement. The scale's validity was further established through psychometric testing. EFA revealed four distinct dimensions: basic management support, management support for limb volume reduction, role management support, and emotional management support. Remarkably, these four dimensions aligned with the three aspects of self-management identified by Van de Velde et al. through conceptual analysis,[44] which include treatment management, role management, and emotional management. Basic management support and management support for limb volume reduction corresponded to treatment management, role management support aligned with role management, and emotional management support reflected emotional management. This correspondence validates the scale's comprehensive assessment of lymphedema SMS in breast cancer survivors.

However, the discriminant validity fell short of expectations. One possible reason could be the lack of a clear definition of SMS. Initially, we attempted to define the construct of SMS across four aspects:

Table 3
Correlation between variables in the structural equation model.

	Variables	1 Basic management support	2 Treatment management support	3 Role management support	4 Emotional management support	5 Disease information management	6 Diet and exercise management	7 Affected limb protection management	8 Promotion of lymph reflux management	9 Emotional management	10 Role management	11 Self-acceptance	12 Self-development
1	Basic management support	1											
2	Treatment management support	0.715**	1										
3	Role management support	0.675**	0.540**	1									
4	Emotional management support	0.610**	0.555**	0.630**	1								
5	Disease information management	0.620**	0.557**	0.578**	0.735**	1							
6	Diet and exercise management	0.517**	0.419**	0.568**	0.526**	0.512**	1						
7	Affected limb protection management	0.716**	0.574**	0.776**	0.655**	0.634**	0.611**	1					
8	Promotion of lymph reflux management	0.672**	0.767**	0.514**	0.537**	0.641**	0.431**	0.621**	1				
9	Emotional management	0.514**	0.472**	0.460**	0.638**	0.605**	0.453**	0.551**	0.556**	1			
10	Role management	0.388**	0.296**	0.322**	0.437**	0.436**	0.411**	0.409**	0.396**	0.601**	1		
11	Self-acceptance	0.370**	0.290**	0.447**	0.494**	0.467**	0.462**	0.480**	0.371**	0.518**	0.547**	1	
12	Self-development	0.459**	0.339**	0.512**	0.552**	0.563**	0.508**	0.545**	0.429**	0.602**	0.590**	0.697**	1

*$P < 0.05$, **$P < 0.01$.

8

Table 4
Measurement invariance.

Model	χ^2	df	χ^2/df	CFI	RMSEA	ΔCFI	ΔRMSEA
M0	820.887	346	2.373	0.940	0.078	–	–
M1	862.667	363	2.376	0.937	0.078	0.003	0.000
M2	899.433	380	2.367	0.934	0.078	0.003	0.000
M3	1003.206	401	2.502	0.924	0.082	0.010	−0.004

CFI, comparative fit index; RMSEA, root mean square error of approximation residual.

informational, material, emotional, and decision support. However, experts suggested revising it to informational support, behavioral support, and emotional support. Nevertheless, EFA suggested a four-factor structure, revealing that items 4, 5, and 11 exhibited cross-loadings on different factors. Although we assigned dual-loading items to corresponding factors according to methodology guidance,[40] potential overlaps among factors persisted, contributing to the unsatisfactory discriminant validity. In addition, the iterative process of scale development presented challenges in maintaining distinct dimensions. Modifications made based on expert feedback and EFA results may inadvertently reintroduce elements of overlap or ambiguity if distinctions between dimensions were not adequately delineated. Addressing these challenges may necessitate further refinement of scale items and validation studies involving diverse samples. In addition, standardized coefficient of some items, e.g., item 16, was considerably low. Item 16 was related to instrumental support for participants, which could be regarded as role management. After examining the item and its alignment with the Factor 3 "Role Management Support", possible reasons for the low coefficient could include ambiguity in the item's wording, lack of relevance to the construct being measured, or issues with respondent interpretation. Bandura emphasized that self-efficacy was a significant predictor of individuals' behavior.[45] Studies by Jiang et al. demonstrated that self-efficacy and social support played essential roles in lymphedema self-management among patients with breast cancer.[46] However, many patients lacked self-efficacy for effectively lymphedema self-managing.[13] Providing social support had the potential to enhance patients' self-efficacy and self-management capabilities.[47] Our results indicated that the scale had good predictive validity, as the total predictive effect of SMS on self-management behavior was 0.961 ($P < 0.001$). Moreover, SMS directly predicted self-management behavior ($\beta = 0.827$, $P < 0.001$), accounting for 86.1%, and also indirectly influenced self-management behavior through self-efficacy ($\beta = 0.134$, $P < 0.001$), accounting for 13.9%. This demonstrated that the scale effectively predicted lymphedema self-management behavior among patients with breast cancer. In addition, Tong Yang et al. verified the mediating effect of self-efficacy between social support and self-care ability in patients with upper limb lymphedema after breast cancer surgery.[48] Social support could predict the total effect of patients' self-care ability ($\beta = 0.799$, $P < 0.01$), the direct effect ($\beta = 0.112$, $P < 0.05$), and indirect effect value through self-efficacy ($\beta = 0.054$, $P < 0.01$), accounting for 14.02% and 6.76%, respectively.[48] In contrast, SMS had a stronger predictive effect on self-management behavior compared with social support on self-care ability, with a higher proportion of direct predictive effects, indicating that consistent and effective SMS may more effectively improve lymphedema self-management behaviors in breast cancer survivors.

The results of reliability analysis showed that Cronbach's α and McDonald's ω coefficients of the total scale and each dimension ranged from 0.795 to 0.958 and from 0.848 to 0.955, indicating that the scale demonstrated high internal consistency and reliability. Although the Cronbach's α coefficient for the "management support for limb volume reduction" dimension was 0.955, which exceeded the recommended threshold of 0.95,[49] this dimension contained eight items that reflected different aspects and stages of treatment focus. These items provided valuable information for formulating specific support interventions after

evaluation, and therefore, it was decided not to delete any of the eight items.

Implications for nursing practice and research

The development of the LSMS-BCs offers health care providers a comprehensive tool to assess and address the lymphedema SMS needs of breast cancer survivors. With its ability to identify areas of insufficient support, the scale allows for tailored interventions, empowering patients to effectively manage their condition and improve their overall well-being. The scale's multidimensional approach emphasizes the importance of multidisciplinary teamwork in providing comprehensive care. Moreover, its predictive value offers insights into future self-management needs, enabling proactive support. The scale's implications extend to enhancing patient empowerment, advancing research in SMS, and ultimately promoting more effective and patient-centered care in clinical practice.

Limitations

Despite adhering to the guidelines of scale development and validation, this study has several limitations. First, the item pool was constructed based on literature analysis of qualitative studies and interventional studies with a deliberate exclusion of noninterventional quantitative studies, which could be restricted by the scope of the literature search and potentially missed some items. Second, we divided the sample based on the chronological order of recruitment instead of randomly, which might limit the robustness and generalizability of the findings. Third, while we implemented measures for quality control during data collection, discrepancies in responses might arise between self-administered questionnaires and telephone interviews due to factors, such as respondent interpretation, social desirability bias, and communication dynamics. Fourth, the use of convenience sampling from a single hospital may limit the generalizability of the findings, making it challenging to apply the scale to a broader population of patients with breast cancer managing lymphedema. Further research is needed to test the reliability and validity of the scale in various patient groups and health care settings. Conducting larger, more diverse studies across multiple hospitals or clinics would enhance the scale's generalizability. Longitudinal studies could evaluate the scale's ability to detect changes in SMS over time and its predictive validity for long-term self-management behaviors. In addition, investigating the scale's sensitivity to interventions would provide valuable insights. Overall, these further studies would enhance the scale's utility and broaden its application in clinical practice and research.

Conclusions

In conclusion, this study successfully developed and validated the LSMS-BCs. Through a rigorous scale development and validation methodology, the scale was refined to include 21 items with four dimensions: informational support, behavioral support, and emotional support. The scale demonstrated good psychometric properties, with high reliability and validity, and can be a valuable tool for health care providers in clinical practice. However, further research is needed to validate its applicability in diverse patient groups and settings. Overall, the scale holds great promise in enhancing the support and care provided to breast cancer survivors managing lymphedema.

Ethics statement

The study was approved by the Biomedical Research Institutional Review Board of Peking University (IRB No. 00001052-22123). All participants provided oral or written informed consent.

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CRediT authorship contribution statement

Xin Fu: Conceptualization, Methodology, Formal analysis, Data curation, Writing – original draft, Writing – review and editing, Visualization. Aomei Shen: Data curation, Writing – review and editing. Lichuan Zhang: Validation, Data curation, Formal analysis. Yujie Wang: Validation, Data curation, Formal analysis. Qian Lu: Conceptualization, Methodology, Writing – review and editing, Supervision, Project administration, Funding acquisition. Authors Xin Fu and Aomei Shen contributed equally to this work and should be considered joint first authors. The corresponding author attests that all listed authors meet authorship criteria and that no others meeting the criteria have been omitted.

Declaration of competing interest

The authors declare no conflict of interest. The corresponding author, Professor Qian Lu, serves as a member of the editorial board of the *Asia-Pacific Journal of Oncology Nursing*. The article has undergone the journal's standard publication procedures.

Data availability statement

The data sets generated and analyzed in this study cannot be publicly shared due to ethical considerations. However, they can be obtained from the corresponding author upon reasonable request.

Declaration of Generative AI and AI-assisted technologies in the writing process

No AI tools/services were used during the preparation of this work.

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