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ORIGINAL RESEARCH

Development and Preliminary Validation of the Chinese Version of the Totally Implantable Venous Access Port Self-Management Behavior Scale (CPTSMBS) for Patients with Cancer

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Objective: This study aimed to develop the Chinese version of the totally implantable venous access port (TIVAP) self-management behavior scale for patients with cancer to provide a reliable tool for medical staff to judge patients with TIVAP self-management behavior.

Methods: This study employed a mixed-method exploratory design. The initial scale was developed through a literature review, expert meetings, and two-round Delphi expert consultation. The reliability indicators included retest reliability and Cronbach's alpha coefficients. The validity indicators included content, construct, convergent, discriminant, and criterion validity. Exploratory factor analysis (EFA) and confirmatory factor analysis (CFA) were employed for the validity analysis; 22 venous therapy experts participated in the Delphi expert consultation. A total of 500 patients were recruited from two third-class A hospitals in Guangdong Province, China, between July 2020 and January 2021 to test reliability and validity. A convenience sampling method was adopted.

Results: The final scale comprised seven dimensions and 29 items. The content validity index (S-CVI) was 0.990. Cronbach's alpha coefficient and retest reliability of the scale were 0.931 and 0.900, respectively. The EFA results indicated a seven-factor structure, accounting for 65.68% of the total data variance. The results of the CFA showed that the CMIN/DF value was 2.348; the root mean square error of approximation value was 0.06; and the values of comparative fit index, incremental fit index, and Tucker–Lewis index were all >0.90. The factor loadings for all the items were >0.50, the composite reliability value was >0.70, and the average variance extracted (AVE) value was >0.50. Moreover, all absolute values of the correlation coefficients were less than the square root of the AVE for the seven dimensions. The total scores between the health promoting lifestyle profile-II revise (HPLP-IIR) and CPTSMBS were positively correlated (r = 0.465, p < 0.01).

Conclusion: The scale demonstrated good reliability and validity and can be applied in clinical practice to evaluate self-management behavior among patients using a TIVAP.

Keywords: totally implantable venous access port, TIVAP, reliability, validity, scale, self-management

Background

A totally implantable venous access port (TIVAP) is a closed intravenous infusion system that is completely implanted under the skin. This use of TIVAP was first reported in 1982.[1] Compared with peripherally inserted central catheters (PICC) and nontunneled central venous catheters, TIVAP has fewer complications, higher levels of patient satisfaction,

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and ensures a higher quality of life for the patient.[2] However, several unavoidable TIVAP-related complications remain and include catheter rupture, infection, and thrombosis, which can increase the financial and health burdens on patients.[3]

The TIVAP is completely implanted under the skin and has a minimal impact on the daily lives and work of the patients, which could cause a lack of observation of complications and the protection of the TIVAP. Multiple studies have shown port-related complications are closely associated with self-management behaviors, and poor compliance with TIVAP maintenance, lack of knowledge regarding TIVAP-related maintenance, and inadequate self-management behaviors, which can cause complications such as catheter occlusion and infection.[4–7] Therefore, a reliable assessment tool is needed for TIVAP self-management behaviors. Researchers have developed a self-management ability assessment scale for PICCs, which has been widely used in clinical practice. However, a comprehensive and reliable evaluation tool for the self-management behavior of TIVAP remains lacking. This study aimed to develop a self-management behavior assessment scale for TIVAP and to provide an effective assessment instrument for evaluating and monitoring self-management behaviors in patients with cancer who used TIVAP.

Methods
Study Design
This study used a mixed-method exploratory design comprising two phases: initial scale generation and reliability and validity analyses of the initial scale. A flowchart of scale formation is shown in Figure 1. We followed the eight-step scale development guidelines proposed by DeVellis and Thorpe to develop this scale and verified the reliability and validity through a questionnaire survey.[8] All participants signed an informed consent form. This study was reviewed and approved by the Ethics Committee of the First Affiliated Hospital of Shantou University Medical College (Approval Number: 035). Our study complied with Declaration of Helsinki.

## Phase 1: Initial Scale Formation
Conceptual Framework
The development of the TIVAP self-management behavior assessment scale was based on self-efficacy,[9] which was reflected as "I can do it, or I will do it" in the specific description of the scale. Self-management refers to the ability to effectively manage symptoms, treatments, physical and psychosocial changes, and lifestyle adjustments.[10] The scale was designed using three self-management tasks proposed by Corbin et al.[11] These tasks included role, medical, and abnormal-emotion management. Although emotional management is one of the three major tasks of self-management, the scale developed in this study was mainly used for the self-management behavior of the TIVAP, emphasizing the management of the catheter rather than the management of the disease. Hence, no emotional management was present under the preset framework. The conceptual framework of this scale is illustrated in Figure 2. The predesigned dimension represented medical management, including observation of complications, treatment of complications, maintenance compliance, and confidence in the self-management of TIVAP. The predesigned dimension represented role management, including the acquisition of maintenance knowledge, protection of TIVAP in daily life, protection of TIVAP during exercise, and protection during the period with the TIVAP needle.

Item Pool Generation
We reviewed the self-management-related scale, TIVAP-related guidelines, industry standards, and analyzed the causes of TIVAP complications. The Chinese and English databases searched included CNKI, VIP, Wan Fang, PubMed, Cochrane Library, Web of Science, EMBASE, CINAHL, and OVID. The 67 initial items were formulated from the retrieved literature. We then conducted an expert meeting with 30 specialist nurses in intravenous therapy at the First Affiliated Hospital of Shantou University Medical College to assess, revise, and delete redundant items. Finally, 49 preliminary items were selected for the Delphi experts.

Delphi Expert Consultation
The criteria for the inclusion of experts in this study were as follows: (1) specialist nurses in intravenous therapy from the provincial nursing association or Chinese Nursing Association; (2) professional title of supervisor or above; and (3) >5 years of
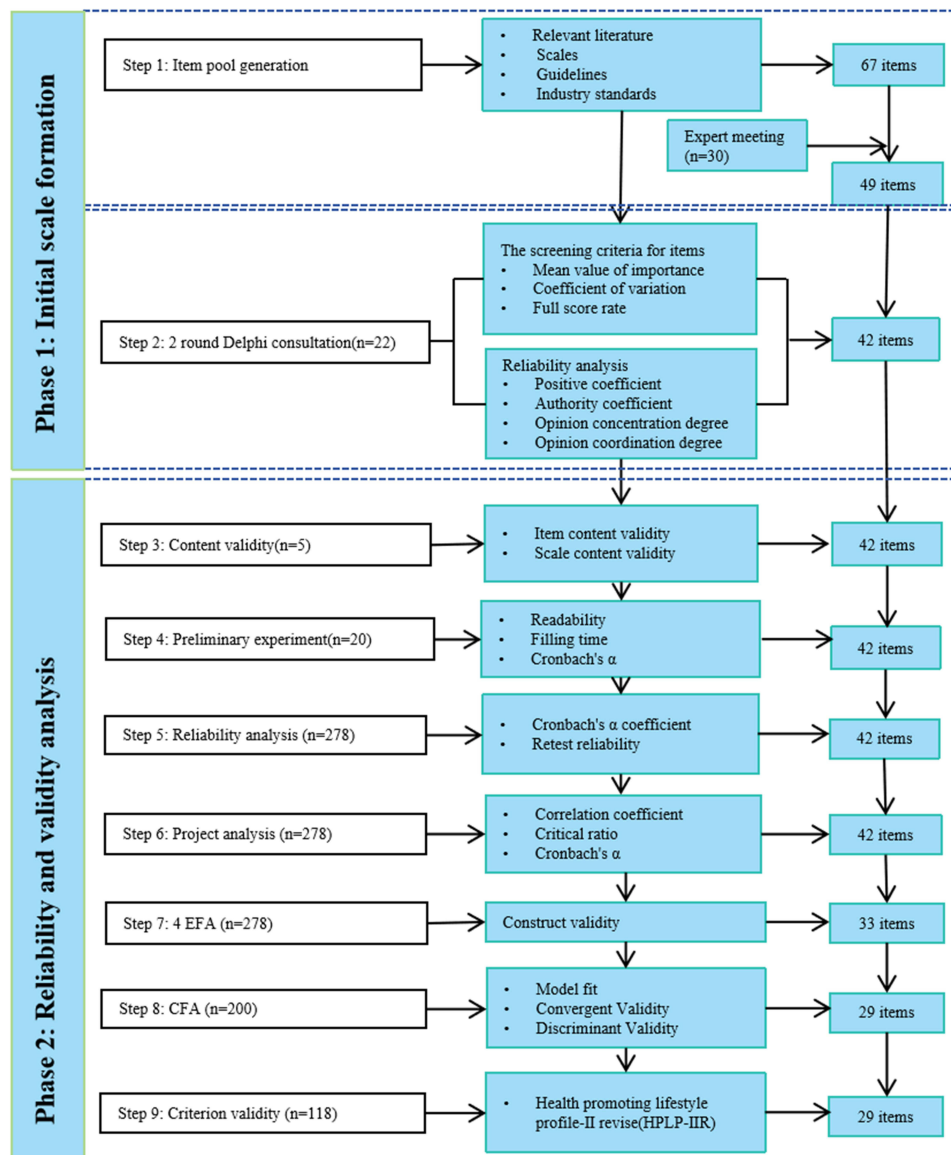
Figure 1 Scale development process.

experience in intravenous therapy. We recruited 26 experts based on their published recommendations.[12] The expert consultation questionnaire comprised four parts. (1) Introduction: Explain the background, purpose, method, and significance of the research and questionnaire filling requirements; (2) General information of Delphi experts, including age, educational background, professional title, and working years. (3) The assessment of scale indicators consisted of eight first-level indicators and 49 second-level indicators, and the Likert five-level method was used to assess the importance of the indicators (1 = very unimportant to 5 = very important). Each item establishes a modified opinion column, and experts can put forward suggestions for modifying, deleting, and adding items to enrich the scale. (4) Familiarity with expert indicators and the basis of judgment. Questionnaires were distributed to experts via email. The second round of the questionnaire, which was formed according to the importance score and revised opinions from the first round of expert consultation, was fed back to the experts until they gradually agreed.
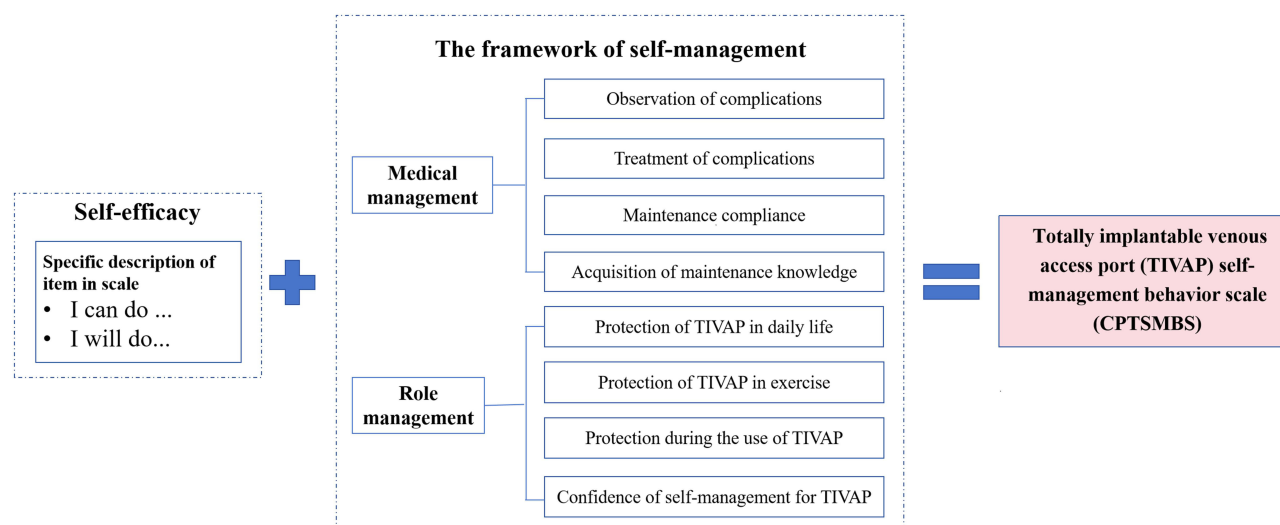
Figure 2 Conceptual framework of scale.

Phase 2: Reliability and Validity Analysis

Sample Size

DeVellis and Thorpe recommended that, in exploratory factor analysis (EFA), the sample size should be at least five- to ten-fold the number of items to obtain reliable factors for tool development.[8] Hair et al suggested that a minimum sample size of 100–150 is required for confirmatory factor analysis (CFA).[13] The initial scale comprised 42 items after two rounds of expert consultation in Phase 1. Hence, the required theoretical sample size ranged from 310 to 570 patients. In addition, a 10% invalid questionnaire response rate was considered. The final sample size was 500.

Questionnaire Distribution

After two rounds of expert consultation in Phase 1, the initial scale consisted of seven dimensions and 42 items. The initial scale, which is commonly used to measure attitudes, was scored on a Likert scale ranging from 1 (never) to 5 (always).[14] All questionnaires were distributed by the researchers and immediately collected to ensure that real data could be obtained. Convenience sampling was also used. In total, 500 patients were recruited from two third-class A hospitals in Guangdong Province, China, between July 2020 and February 2021.

Inclusion and Exclusion Criteria

The inclusion criteria for this study were: (1) implantation of TIVAP for at least 1 month, (2) age range of 18–80, (3) ability to read and comprehend the questionnaire, (4) completion of the questionnaire independently or with the assistance of the researcher, and (5) willingness to sign informed consent. The exclusion criteria were as follows: (1) patients with serious illnesses or complications related to their disease, and (2) patients with cognitive, psychiatric, speech, or hearing impairments.

Preliminary Experiment

Before distributing questionnaires, we conducted a preliminary experiment with 20 patients in the First Affiliated Hospital of Shantou University Medical College to test whether the questions are easy to understand, measure the required time for completing the entire questionnaire, and calculate the Cronbach's α coefficient of scale. The result of preliminary experiment showed that the questionnaire completion time was 7–9 min, and the Cronbach's α coefficient was 9.458.

Criterion Validity

We used the health promoting lifestyle profile-II revise (HPLP-IIR) suitable for Chinese people to assess the criterion validity of the scale developed in this study.[15] The scale was revised by Cao et al based on the health-promoting lifestyle

profile II (HPLP-II) developed by Walker et al.[16] The HPLP-IIR includes six dimensions and 40 items, including interpersonal relationships (5 items), nutrition (6 items), health responsibility (11 items), physical exercise (8 items), stress management (5 items), and spiritual growth (5 items). The Cronbach's α coefficient of the scale measured in the preliminary experiment was 0.952 in this study. A total of 118 patients with TIVAP completed both the CPTSMBS and the HPLP-IIR.

Data Analysis
SPSS 23.0 and AMOS 23.0 were used for statistical analysis.

Delphi Expert Consultation
The screening criteria for items in Delphi are a mean value of importance assignment ≥3.5, coefficient of variation ≤0.25, and full score rate ≥20%. When items do not meet any of the above criteria, the research team discussed whether to retain or delete the item.[17] The indicators to evaluate the reliability of Delphi expert consultation included expert positive coefficient, expert authority coefficient (Cr), expert opinion concentration degree, and expert opinion coordination degree (Kendall coefficient W).[18,19]

Content Validity
Five experts were invited to evaluate the content validity. The relevance of the items was scored using a Likert four-level method (1 = very irrelevant to 4 = very relevant). The calculation method of content validity was as follows: I-CVI = Ne / N (Ne: the number of experts who selected "3" and "4"; N: the total number of experts); S-CVI = (sum of I-CVI scores) / (number of items). The I-CVI was 0.78 or above, indicating that the content validity of the item was good. The S-CVI was 0.90, indicating very good content validity of the scale.[20,21]

Reliability Analysis
(1) Internal consistency: Cronbach's α coefficient was used to evaluate the internal consistency of the scale.[22] Cronbach's α coefficient >0.7 was generally considered to indicate good internal consistency.[23] (2) External stability: Fourteen patients completed the scale again after a one-month interval to assess its retest reliability.[24] ICC ≥ 0.7 was considered good retest reliability.[25]

Project Analysis
Before exploring the factor analysis, a project analysis was performed to filter the items. Items that met the following criteria were retained: (1) items with an item-total correlation coefficient of >0.4, and a correlation coefficient between items of less than 0.8;[8,26] (2) items with a critical ratio > 4.00, with significant differences ($P < 0.05$); and (3) items did not lead to a decrease in the total Cronbach's α coefficient.[27]

EFA
The Kaiser–Meyer–Olkin (KMO) value >0.8, and Bartlett's spherical test ($p < 0.05$) indicated that the items were suitable for EFA.[28] A cumulative variation rate >60% and a factor loading of each item >0.4 indicated good construct validity for the scale.[26] The deletion methods of the items and common factors in the EFA were as follows: (1) Items appeared under two common factors simultaneously, (2) items with only two or one common factors, (3) common factors without any items, and (4) items with factor loadings of <0.4.[29]

Confirmatory Factor Analysis
(1) Model fit: The indicator goodness of fit which checks the fitting degree of scale theoretical framework formed by EFA, was tested by analyzing the chi-square (χ^2)/degrees of freedom (df) (CMIN/DF), standardized residual mean root (SRMR), root mean square error of approximation (RMSEA), comparative fit index (CFI), incremental fit index (IFI) and Tucker–Lewis index (TLI).[30,31] (2) Convergent Validity(CV): Convergent validity was used to distinguish the degree of item aggregation in each dimension. Factor loading values >0.5, average variance extraction (AVE) >0.5, and composite reliability (CR)>0.7 indicated good convergent validity.[32] (3) Discriminant Validity (DV): DV was used to check whether the factors measured the different concepts. An AVE > r^2 indicates good DV of the scale.[33] If the fitting degree,

convergent validity, and DV were unsatisfactory, the model could be modified by removing items with low factor loading values or by establishing covariance relationships between the residuals of the variables.[26]

Criterion Validity

Pearson correlation coefficient method was used to analyze the correlation between the total scores of the two scales to assess criterion validity.

Results
Phase 1: Initial Scale Formation
Characteristics of Delphi Experts

Twenty-two experts from Guangdong, Shanghai, Tianjin, and Xinjiang provinces were invited to participate in expert consultation for this study. These experts were specialist intravenous therapy nurses with an average age of 46.18 ± 5.61 years and had 6–33 years of experience in intravenous therapy. The current occupations of these experts included nursing education (nine experts), nursing management (17 experts), clinical nursing (22 experts), and nursing scientific research (nine experts) (Table 1).

The Results of Delphi Expert Consultation

The positive coefficient of experts in the two rounds was 84.62% (22/26) and 86.36% (19/22) respectively, exceeding 70%, which indicated the experts showed a high level of knowledge. The authority coefficient of the experts in the two rounds was 0.94 and 0.98 respectively, exceeding 0.7, which indicated the experts had a high level of authority and the results of their consultation were reliable.[19] The mean value of importance assignment in the second round was higher than the first round [(4.69 ± 0.28) vs (4.81 ± 0.20)], the coefficient of variation and the rate of expert opinion presentation in the second round was lower than the first round [Coefficient of

Table 1 The General Characteristics of Consult Expert (n=22)

Project		N	Ratio (%)
Age (years)	35–40	4	18.18%
	41–50	13	59.09%
	51–60	5	22.73%
Position	Head of nursing	3	13.64%
	Head nurse of the department	3	13.64%
	Head nurse	16	72.72%
The title of a professional post	Chief nurse	9	40.91%
	Deputy chief nurse	7	31.82%
	Supervisor nurse	6	27.27%
Work (years)	10–20	6	27.27%
	21–30	10	45.45%
	31–40	6	27.27%
Experience work in intravenous therapy (years)	5–10	2	9.09%
	11–20	9	40.91%
	21–30	9	40.91%
	31–40	2	9.09%

variation: (0.13 ± 0.08) vs (0.09 0.08); Opinion: 68.18% (15/22) and 47.37% (9/19)], indicating that expert opinions were gradually consistent.[34] The Kendall coordination coefficient W in the two rounds was 0.26 and 0.50, respectively, showing an improvement in the coordination of expert opinions.[35,36] After two rounds of consultation with a Delphi expert, an initial scale with seven preset dimensions and 42 items was developed (Table 2). The 42 items were shown in Table 3. The detailed information regarding the modification of the initial item pool has been presented in the previously published master's thesis by Xiao-Hong Wu.[37]

Table 2 The Results of Delphi Expert Consultation

Indicator of Results	First Round	Second Round
Positive coefficient of the experts	84.62% (22/26)	86.36% (19/22)
Authority coefficient of the experts	0.94	0.94
Degree of concentration of expert opinions		
Mean value of importance assignment	4.69±0.28(3.64–5.00)	4.69±0.28(4.32–5)
Coefficient of variation	0.13±0.08(0–0.29)	0.09±0.08(0–0.29)
Rate of expert opinion presentation	68.18% (15/22)	47.37% (9/19)
Degree of coordination of expert opinions		
The Kendall coordination coefficient	0.26	0.50
Number of issued indicators		
1-level indicator	8	8
2-level indicator	49	52
Number of revised indicators		
1-level indicator	1	0
2-level indicator	17	10
Number of deleted indicators		
1-level indicator	0	1
2-level indicator	7	6
Number of combined indicators		
1-level indicator	0	0
2-level indicator	2	8
Number of increased indicators		
1-level indicator	0	0
2-level indicator	11	0
Number of final indicators		
1-level indicator	8	7
2-level indicator	52	42

Table 3 The Project Analysis of Initial Scale with 42 Items(n=278)

Item and Preset Dimensions Before EFA		IS	II	CR	Cronbach's α
Dimension a: Observation of complications (six items)					
a1	I will observe if there is redness, swelling, heat, pain and other manifestations in arm, shoulder, or neck at the side of the TIVAP and the skin around the TIVAP every day	0.523**	0.072–0.641	−9.811**	0.930
a2	I will observe every day if there is curling, loosening, moisture, or contamination of the TIVAP dressing during the period with the TIVAP needle.	0.629**	0.057–0.770	−12.999**	0.928
a3	I will observe if there is itching, redness, or blisters around the dressing every day during the period with the TIVAP needle.	0.663**	0.122–0.770	−13.212**	0.928
a4	I will observe if the infusion speed is slow during the period of using TIVAP for infusion, especially after severe vomiting, sneezing, coughing, or changing position.	0.589**	0.071–0.670	−11.122**	0.929
a5	I will observe if there is blood returning in the extension tube of the needle of TIVAP during the period with the TIVAP needle.	0.479**	0.023–0.730	−8.662**	0.930
a6	I will observe if blood or fluid is oozing or if there is any redness, swelling, pain, prolapse of the TIVAP needle, or other manifestations during the period with the TIVAP needle.	0.609**	0.089–0.730	−12.279**	0.928
Dimension b: Treatment of complications (five items)					
b1	If there is redness, swelling, heat, pain, or other symptoms in the arm, shoulder, or neck at the side of the TIVAP and the skin around the TIVAP, I will promptly seek medical attention at the hospital or a qualified TIVAP maintenance station for appropriate treatment.	0.592**	0.165–0.592	−9.864**	0.928
b2	If there is any curling, loosening, moisture, or contamination for the dressing of TIVAP during the period with the TIVAP needle, I will promptly inform the doctors or nurses.	0.578**	0.102–0.692	−8.752**	0.929
b3	If there is any itching, redness, or blisters around the TIVAP dressing during the period with the TIVAP needle, I will promptly inform the doctors or nurses.	0.533**	0.090–0.692	−8.087**	0.929
b4	If there is any blood oozing, fluid leakage, needle prolapse, or any other manifestations during the period with the TIVAP needle, I will promptly inform the doctors or nurses.	0.537**	0.103–0.680	−7.133**	0.929
b5	If the infusion speed is slow during the period with the TIVAP needle, I will promptly inform the doctors or nurses.	0.459**	0.077–0.604	−6.194**	0.930

Dimension c: Maintenance compliance (four items)					
c1	I can return to the hospital or a qualified TIVAP maintenance station for the TIVAP maintenance according to the specified maintenance time instructed by the doctors or nurses.	0.553**	0.092–0.543	−7.362**	0.929
c2	I will not fail to perform TIVAP maintenance on time for any reason (such as traffic, economy).	0.467**	0.023–0.543	−7.089**	0.930
c3	I can find professionals to perform TIVAP maintenance.	0.421**	0.054–0.648	−6.672**	0.930
c4	I will seek professional assistance if I encounter any TIVAP complications.	0.524**	0.120–0.648	−8.650**	0.929
Dimension d: Acquisition of maintenance knowledge (three items)					
d1	I can access information related to TIVAP maintenance through the internet.	0.487**	0.069–0.694	−9.220**	0.931
d2	I can obtain information on TIVAP maintenance through manuals, posters, or lectures.	0.574**	0.122–0.694	−11.337**	0.929
d3	I can obtain information on TIVAP maintenance from healthcare professionals such as doctors or nurses.	0.586**	0.076–0.387	−10.269**	0.929
Dimension e: Protection in exercise and daily life (10 items)					
e1	I will avoid using the arm with TIVAP for strenuous activities such as pull-ups, basketball, etc.	0.525**	0.058–0.639	−6.789**	0.929
e2	I will avoid any violent abduction movement, arm swing, or large bosom movement during the period with the TIVAP needle.	0.549**	0.071–0.639	−7.222**	0.929
e3	I will avoid being in a lateral position on the side of TIVAP for long periods of time.	0.545**	0.101–0.514	−8.912**	0.929
e4	I will not apply any medication to the skin around the TIVAP without obtaining permission from doctors or nurses.	0.438**	0.079–0.471	−5.698**	0.93
e5	I will promptly remove any remaining adhesive residue around the TIVAP and ensure that the skin remains clean and dry.	0.525**	0.136–0.436	−7.404**	0.929
e6	I will avoid friction between the skin around TIVAP with safety belts, backpack straps, bra straps, and others clothing items.	0.536**	0.136–0.571	−7.917**	0.929
e7	I will choose to wear loose-fitting, cotton clothing to minimize irritation to the skin around the TIVAP.	0.605**	0.143–0.647	−7.886**	0.929
e8	I will avoid rubbing or pressing vigorously on the TIVAP to prevent any damage to TIVAP.	0.482**	0.028–0.647	−6.717**	0.930
e9	I will avoid holding a baby in arms with TIVAP during the period with the TIVAP needle.	0.520**	0.102–0.581	−6.341**	0.929
e10	I will observe if the dressing of TIVAP is damp after taking a bath during the period with the TIVAP needle.	0.634**	0.139–0.532	−7.924**	0.928

(*Continued*)

Table 3 (Continued).

Item and Preset Dimensions Before EFA		IS	II	CR	Cronbach's α
Dimension f: Protection during the period with the TIVAP needle (nine items)					
f1	I will proactively change the clothes that easily expose the skin of TIVAP area before the maintenance of the TIVAP.	0.555**	0.145–0.522	−7.219**	0.929
f2	When performing maintenance TIVAP, I will turn my head to the opposite side or wear a mask.	0.497**	0.108–0.495	−6.331**	0.929
f3	After removing the TIVAP needle, I will apply pressure to the puncture site for at least 5 minutes and remove the dressing after 24 hours.	0.423**	0.093–0.458	−6.329**	0.930
f4	After removing the TIVAP needle, I will avoid getting the puncture site wet for 24 hours.	0.549**	0.098–0.459	−6.476**	0.929
f5	I will not leave the hospital with the needle of TIVAP without the permission of the doctors or nurses.	0.404**	0.005–0.686	−4.700**	0.930
f6	I will not use the TIVAP needle for more than 7 days.	0.401**	0.054–0.647	−4.409**	0.930
f7	I will keep the dressing of TIVAP clean and dry and not remove the dressing during the period with the TIVAP needle.	0.493**	0.087–0.686	−5.694**	0.930
f8	I will proactively inform the doctors or nurses about the presence of a TIVAP implanted in my body during an MRI examination.	0.407**	0.078–0.585	−5.127**	0.930
f9	I will not use the TIVAP for a high-pressure contrast injection without obtaining permission from the doctors or nurses.	0.437**	0.115–0.585	−7.129**	0.930
Dimension g: Confidence of self-management for TIVAP (five items)					
g1	I think I can observe the TIVAP every day and find out the abnormal situation of TIVAP in a timely manner.	0.608**	0.091–0.489	−11.325**	0.928
g2	When I notice the abnormal situation of TIVAP, I think I can contact doctors or nurses to deal with this in a timely manner.	0.542**	0.122–0.568	−8.383**	0.929
g3	I think I can find professionals to maintain the TIVAP in a timely manner.	0.501**	0.102–0.568	−8.901**	0.929
g4	I think I can proactively acquire the related knowledge of TIVAP maintenance.	0.532**	0.066–0.497	−10.108**	0.929
g5	I think I can manage the TIVAP correctly in daily work, life, or sports.	0.584**	0.141–0.497	−9.380**	0.929

Note: **P<0.001.
Abbreviations: IS, Item-scale, Correlation coefficient between items and total scale scores; II, Item-Item, Correlation coefficient between items; CR, Critical Ratio; Cronbach's α, Cronbach's α coefficient of the scale after deleting items one by one.

Phase 2: Reliability and Validity Analysis
The Characteristics of Patients

A total of 500 questionnaires were distributed to patients with cancer who used TIVAP. A total of 478 cases were available for analysis, with a questionnaire recovery rate of 95.60%. Among the 478 cases, 278 were randomly selected for EFA and 200 were used for CFA. The mean age of the study subjects was (48.38 ± 11.35) years. In 299 cases, the use of TIVAP exceeded 90 days (Table 4).

Table 4 Demographic Characteristics of the Participants (n=478)

Characteristic	N (%)/M ± SD
Sex	
Male	157(32.85)
Female	321(67.15)
Age (years)	(48.38±11.35)
≤40	125(26.15)
40–60	270(56.49)
>60	83(17.36)
Education level	
Primary school and below	49(10.25)
Middle school	111(23.22)
High school	123(25.73)
University or above	195(40.79)
Marital status	
Unmarried	26(5.44)
Married	430(89.96)
Death of a spouse	9(1.88)
Divorce	13(2.72)
Current working status	
Working in home	30(6.28)
Rest at home with illness	277(57.95)
Work in units	63(13.18)
Retired	108(22.59)
Payment method	
Medical insurance	150(31.38)
The social security	249(52.09)
Own expense	79(16.53)
Family Residence	
Rural area	164(34.31)
Urban areas	314(65.69)
The days with TIVAP(days)	
30–60	132(27.6)
60–90	47(9.83)
>90	299(62.55)

Content Validity

Five experts were invited to evaluate the content validity. Only the I-CVI of item D1 was 0.8, and the I-CVI values of the other items were 1. The mean S-CVI/AVE scale score was 0.995. Five experts were both specialist nurses in intravenous therapy, and the characteristics of experts was shown in Table 5.

Reliability Analysis

The Cronbach's α coefficient of the scale in this study was 0.931. Each dimension ranged from 0.733 to 0.877. The retest reliability of the scale was 0.900, and each dimension ranged from 0.515 to 0.911. Therefore, the scale has good reliability (Table 6).

Project Analysis

The items with item-total correlation coefficients ranged from 0.401 to 0.663, and the items with item-total correlation coefficients ranged from 0.005 to 0.770. The critical ratio was 9.864–10.108, with a significant difference ($P < 0.05$). The Cronbach's α of the initial scale was 0.931. After deleting items individually, Cronbach's α of the scale was 0.928–0.931. All items were retained after the project analysis in this study. The results of the project analyses are presented in Table 3.

Construct Validity by EFA

We conducted four EFAs with the 42 items to test construct validity. In the first three EFAs, we deleted nine items for the following reasons: six items that did not appear in any common factors (f2, f3, f4, e10, f8, and f9), one item that appeared in two common factors simultaneously (f1), and only two items that had the same common factor (c3 and c4). The results of four EFAs were shown in Table 7. In the fourth EFA, the KMO value was 0.881, and the Bartlett's spherical test was statistically significant ($X^2 = 4732.439$, $P < 0.001$), indicating that data were suitable for EFA. The results of the fourth EFA showed that seven common factors with eigenvalues >1 accounted for 65.68% of the total variance. The factor loading of remaining 33 items were >0.50 (Table 7). All items were successfully classified into the seven common

Table 5 The Characteristics of Five Experts

Expert	Age (Years)	Educational Background	The Title of a Professional Post	Experience Work in Intravenous Therapy (Years)	Engage in Work
Expert 1	40	Master	Deputy Chief Nurse	6	3,4
Expert 2	50	Bachelor	Chief Nurse	25	1,2,3,4
Expert 3	45	Bachelor	Deputy Chief Nurse	17	3
Expert 4	44	Master	Chief Nurse	12	1,2,3,4
Expert 5	36	Master	Supervisor Nurse	13	1,2,3,4

Notes: 1=Nursing education; 2=Nursing management; 3=Clinical nursing; 4=Nursing scientific research.

Table 6 The Results of Reliability

Dimension	Cronbach's α	Retest Reliability
Total scale	0.931	0.900**
Each dimension		
Observation of complications	0.887	0.911**
Treatment of complications	0.850	0.799**
Maintenance compliance	0.754	0.625*
Acquisition of maintenance knowledge	0.733	0.569*
Protection in exercise and daily life	0.862	0.824**
Protection during the period with the TIVAP needle	0.793	0.825**
Confidence of self-management for TIVAP	0.798	0.515*

Notes: **P<0.01, *P<0.05.

Table 7 The Results of Four EFA

| EFA	KMO	BST	CF	FL	CVVR	Deleting items	Deleting reason
First	0.885	P<0.001	8	>0.4	63.43%	f3, f4, e10, f8, f9	A
Second	0.888	P<0.001	8	>0.4	65.27%	f2, f1	f1(B)/f2(A)
Third	0.883	P<0.001	8	>0.4	66.54%	c3, c4	C
Fourth	0.881	P<0.001	7	>0.4	65.68%	No	/

Notes: A: Not included in common factor; B: Included in two common factors simultaneously; C: A common factor contained two items.
Abbreviations: BST, Bartlett's spherical test; CF, Common factor; FL, Factor loading; CVVR, Cumulative variance variation rate.

factors, and each common factor had three or more items. The scree plot also supported the seven-factor structure (Figure 3). Based on the results of the fourth EFA, the dimensions of the scale were renamed and redivided. After the fourth exploring factor analysis, the scale consisted of seven dimensions and 33 items, and the renamed dimensions and items are shown in Table 8.

Model Fit Degree in the CFA

A total of 200 samples was used for the CFA, excluding those used in the EFA. The model fit was CMIN/DF = 2.909, RMSEA = 0.072, GFI = 0.809, CF I =0.854, and IFI = 0.855. The model fit was acceptable but could be improved. Hence, the model was modified by removing items B7, C1, D2, and F4 because of their low factor loadings after discussion by the research group and establishing covariance relationships between the variable residuals of items D4 and G1, A4 and A5, A5 and A6, and A4 and A6. The results of the CFA after model modification showed that the CMIN/DF value was 2.348, the RMSEA value was 0.06, and the CFI, IFI, and TLI values were all >0.90. The modified model fit was sufficient for acceptance (Table 9).
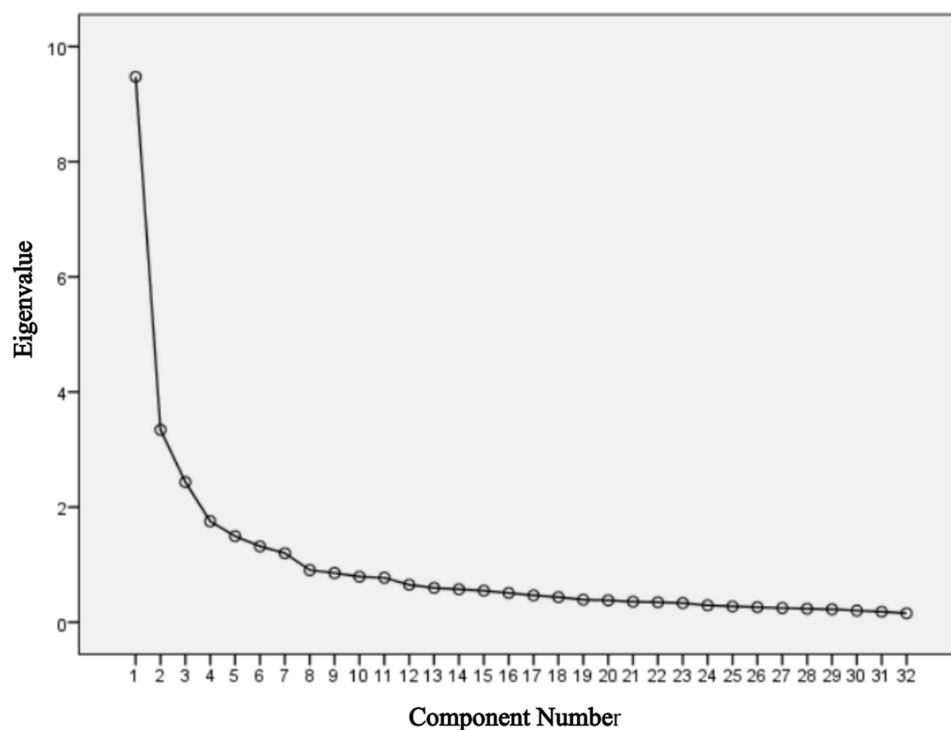
Figure 3 The scree plot in the fourth EFA.

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Table 8 The Results of Fourth EFA

The Reserved Item and Rename Dimension After the Fourth EFA		Common Factor							Rename Item
		1	2	3	4	5	6	7	
Rename dimension A—Observation of complications (six items)									
a6	I will observe if blood or fluid is oozing or if there is any redness, swelling, pain, prolapse of the TIVAP needle, or other manifestations during the period with the TIVAP needle.	0.833							A1
a5	I will observe if there is blood returning in the extension tube of the needle of TIVAP during the period with the TIVAP needle.	0.789							A2
a2	I will observe every day if there is curling, loosening, moisture, or contamination of the TIVAP dressing during the period with the TIVAP needle.	0.775							A3
a4	I will observe if the infusion speed is slow during the period of using TIVAP for infusion, especially after severe vomiting, sneezing, coughing, or changing position.	0.759							A4
a3	I will observe if there is itching, redness, or blisters around the dressing every day during the period with the TIVAP needle.	0.757							A5
a1	I will observe if there is redness, swelling, heat, pain and other manifestations in arm, shoulder, or neck at the side of the TIVAP and the skin around the TIVAP every day	0.641							A6
Rename dimension B——Treatment of complications and maintenance compliance (seven items)									
b3	If there is any itching, redness, or blisters around the TIVAP dressing during the period with the TIVAP needle, I will promptly inform the doctors or nurses.		0.800						B1
b4	If there is any blood oozing, fluid leakage, needle prolapse, or any other manifestations during the period with the TIVAP needle, I will promptly inform the doctors or nurses.		0.789						B2
b5	If the infusion speed is slow during the period with the TIVAP needle, I will promptly inform the doctors or nurses.		0.752						B3
b2	If there is any curling, loosening, moisture, or contamination for the dressing of TIVAP during the period with the TIVAP needle, I will promptly inform the doctors or nurses.		0.707						B4
b1	If there is redness, swelling, heat, pain, or other symptoms in the arm, shoulder, or neck at the side of the TIVAP and the skin around the TIVAP, I will promptly seek medical attention at the hospital or a qualified TIVAP maintenance station for appropriate treatment.		0.698						B5
c1	I can return to the hospital or a qualified TIVAP maintenance station for the TIVAP maintenance according to the specified maintenance time instructed by the doctors or nurses.		0.604						B6
c2	I will not fail to perform TIVAP maintenance on time for any reason (such as traffic, economy).		0.592						B7

	Rename dimension C——Protection of skin around TIVAP (five items)							
e4	I will not apply any medication to the skin around the TIVAP without obtaining permission from doctors or nurses.			0.734				C1
e5	I will promptly remove any remaining adhesive residue around the TIVAP and ensure that the skin remains clean and dry.			0.692				C2
e6	I will avoid friction between the skin around TIVAP with safety belts, backpack straps, bra straps, and others clothing items.			0.652				C3
e7	I will choose to wear loose-fitting, cotton clothing to minimize irritation to the skin around the TIVAP.			0.624				C4
e8	I will avoid rubbing or pressing vigorously on the TIVAP to prevent any damage to TIVAP.			0.563				C5
	Rename dimension D——Confidence of self-management for TIVAP (five items)							
g3	I think I can find professionals to maintain the TIVAP in a timely manner.				0.756			D1
g2	When I notice the abnormal situation of TIVAP, I think I can contact doctors or nurses to deal with this in a timely manner.				0.734			D2
g5	I think I can manage the TIVAP correctly in daily work, life, or sports.				0.686			D3
g4	I think I can proactively acquire the related knowledge of TIVAP maintenance.				0.609			D4
g1	I think I can observe the TIVAP every day and find out the abnormal situation of TIVAP in a timely manner.				0.505			D5
	Rename dimension E——Protection during the period with the TIVAP needle (three items)							
f5	I will not leave the hospital with the needle of TIVAP without the permission of the doctors or nurses.					0.814		E1
f6	I will not use the TIVAP needle for more than 7 days.					0.813		E2
f7	I will keep the dressing of TIVAP clean and dry and not remove the dressing during the period with the TIVAP needle.					0.767		E3
	Rename dimension F——Protection in exercise and daily life (four items)							
e2	I will avoid any violent abduction movement, arm swing, or large bosom movement during the period with the TIVAP needle.						0.775	F1
e9	I will avoid holding a baby in arms with TIVAP during the period with the TIVAP needle.						0.731	F2
e9	I will avoid holding a baby in arms with TIVAP during the period with the TIVAP needle.						0.662	F3
e3	I will avoid being in a lateral position on the side of TIVAP for long periods of time.						0.610	F4

(Continued)

Table 8 (Continued).

The Reserved Item and Rename Dimension After the Fourth EFA		Common Factor							Rename Item
		1	2	3	4	5	6	7	
Rename dimension G——Acquisition of maintenance knowledge (three items)									
d1	I can access information related to TIVAP maintenance through the internet.							0.892	G1
d3	I can obtain information on TIVAP maintenance from healthcare professionals such as doctors or nurses.							0.888	G2
d2	I can obtain information on TIVAP maintenance through manuals, posters, or lectures.							0.789	G3

Table 9 The Fitness Results in CFA

	CMIN/DF	RMSEA	GFI	CFI	IFI
Results	2.909	0.072	0.809	0.854	0.855
Modified	2.348	0.06	0.913	0.914	0.901
Good	≤2.00	≤0.08	≥0. 90	≥0. 90	≥0. 90
Acceptable	≤5.00	≤0.10	≥0.80	≥0.80	≥0.80

Convergent Validity in the CFA

The AVE values of dimensions B (0.498), C (0.481), D (0.480), and F (0.491) were all <0.5, and the convergent validity was unideal (Table 10). After model modification, all factor loadings ranged from 0.552 to 0.896 and were >0.50 (Figure 4), the AVE value ranged from 0.5231 to 0.6258, and the CR value ranged from 0.763 to 0.885, which met the criteria of AVE>0.50 and CR values >0.7. This scale had good convergent validity (Table 10).

Discriminant Validity (DV) in the CFA

The absolute value of the correlation coefficients between the dimensions was smaller than the square root of the AVE for each dimension in both the premodification and postmodification models (Table 11).

Criterion Validity

The total scores between the HPLP-IIR and CPTSMBS were positively correlated (r = 0.465, <0.01), with a moderate-strength association, and the difference was statistically significant.

Discussion

The CPTSMBS comprising seven dimensions and 29 items was developed in this study to evaluate TIVAP self-management behaviors among patients with cancer. The scale is scored on a Likert five-level, with a total score ranging from 29 to 145. Higher scores indicate better self-management ability. The scale was divided into three levels: <87, low; 87–116, medium; and >116, good. The scale structure included two stages of TIVAP self-management in hospitals and at home, covering various aspects of the self-management of TIVAP by patients with cancer, such as complication observation, treatment, protection, and maintenance compliance. This scale can help medical staff identify patients with poor TIVAP self-management behavior and formulate targeted intervention measures to reduce TIVAP-related complications. The development of the scale followed the methodology proposed by Rattray and Jones to ensure scientific rigor.[38]

Table 10 Convergent Validity

Dimension	Before Modification		After Modification	
	AVE	CR	AVE	CR
Dimension A: Observation of complications (6 items)	0.599	0.898	0.568	0.885
Dimension B: Treatment of complications and maintenance compliance (7 items)	0.498	0.871	0.539	0.873
Dimension C: Protection of skin around port (5 items)	0.481	0.820	0.532	0.818
Dimension D: Confidence of self-management for port (5 items)	0.480	0.821	0.507	0.803
Dimension E: Protection during the period with the TIVAP needle (3 items)	0.626	0.834	0.626	0.834
Dimension F: Protection in exercise and daily life (4 items)	0.491	0.791	0.546	0.780
Dimension G: Acquisition of maintenance knowledge (3 items)	0.537	0.772	0.523	0.763

Notes: Discriminant Validity. The absolute value of the correlation coefficient between each dimension were less than the square root of the AVE value.
Abbreviations: AVE, Average variance extracted; CR, composite reliability.
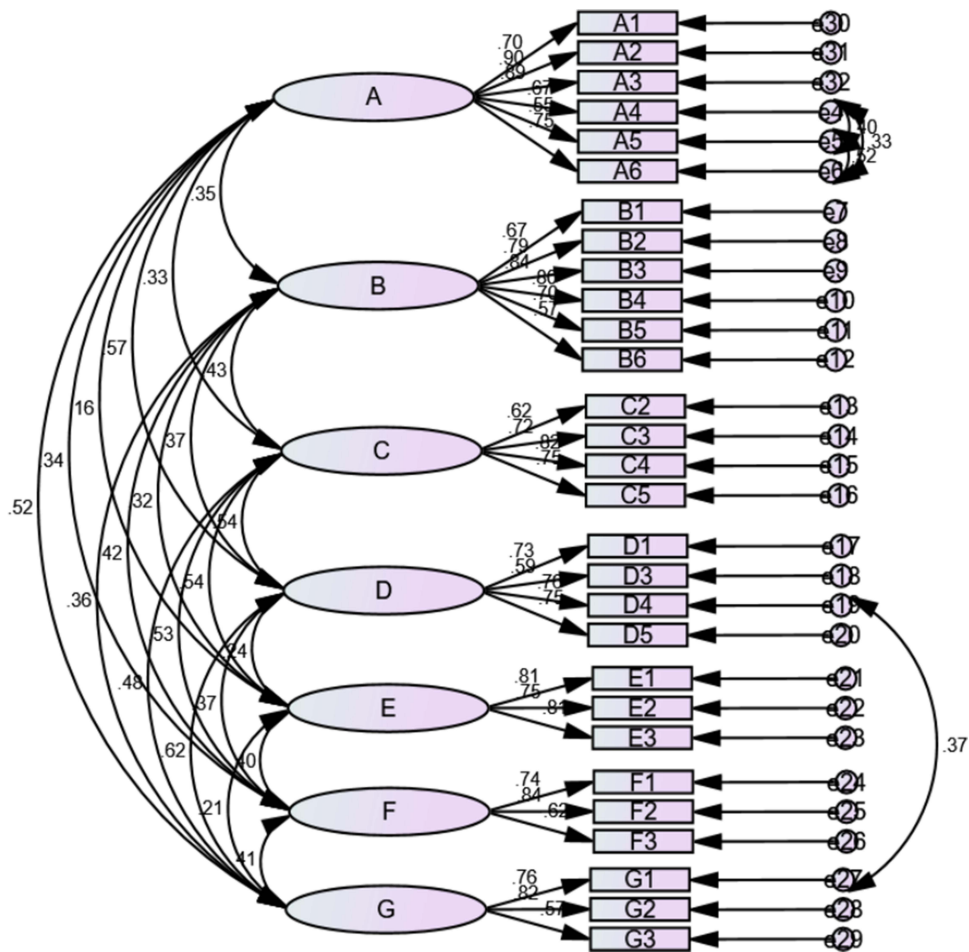
Figure 4 The results of CFA after model modification.

The reliability of the scale was assessed by Cronbach's α coefficient and retest reliability. Overall, the scale demonstrates excellent reliability. The Cronbach's α coefficient of the scale and each dimension exceed 0.7, indicating a good internal consistency.[23,39,40] Additionally, the retest reliability of the scale was 0.900, which exceeded 0.7, suggesting good stability over time.[25] The retest reliability of each dimension ranges ranged from 0.515 to 0.911. However, the retest reliabilities of the dimensions of maintenance compliance, acquisition of maintenance knowledge, and confidence in self-management were <0.7. This indicates that these dimensions had poor stability, which may be

Table 11 Discriminant Validity

Dimension		A	B	C	D	E	F	G
Before model modification	A	0.599						
	B	0.368**	0.498					
	C	0.344**	0.439**	0.481				
	D	0.565**	0.384**	0.548**	0.480			
	E	0.158**	0.336**	0.569**	0.256**	0.620		
	F	0.339**	0.441**	0.590**	0.388**	0.413**	0.491	
	G	0.497**	0.351**	0.438**	0.627**	0.198**	0.391**	0.537
	AVE^2	0.774	0.705	0.693	0.693	0.791	0.701	0.733

(Continued)

Table 11 (Continued).

Dimension		A	B	C	D	E	F	G
After model modification	A	0.568						
	B	0.350**	0.539					
	C	0.326**	0.432**	0.532				
	D	0.568**	0.373**	0.538**	0.507			
	E	0.155**	0.321**	0.537**	0.236**	0.626		
	F	0.342**	0.417**	0.529**	0.375**	0.403**	0.546	
	G	0.519**	0.363**	0.477**	0.624**	0.214**	0.409**	0.523
	AVE²	0.754**	0.734**	0.729**	0.712**	0.791**	0.739**	0.723**

Notes: The diagonal is the AVE value, **P<0.01.
Abbreviation: AVE², AVE square root.

attributed to the four-week interval between the retests.[25] The best time interval for retest reliability was 10–14 days.[41] Since our scale is issued on-site and the TIVAP maintenance interval in China is one month, most patients return to the hospital after a month. Hence, our retest interval was 1 month. Therefore, we suggest that the retest reliability of the scale used in this study was acceptable.

Woo suggested that in EFA, highly statistically correlated variables can be grouped together.[42] In the fourth EFA, the five items under the dimension b all described "seeking medical help timely for different abnormal situations" and the items c1 and c2 both described "seeking medical help timely for maintenance." A close relationship is present between items b1 to b5 and between c1 and c2. Hence, these items were classified under the same common factors as in the fourth EFA. The dimension E describes "The protection of TIVAP under different circumstances in the daily routine of exercise and life." The items e4 to e8 all describes "protection of skin around TIVAP." Hence, these items were classified into the same common factors. The fourth EFA identified seven common factors with eigenvalues >1, explaining 65.68% of the total variance, indicating that the scale had good construct validity.[26]

The model fit was checked using CMIN/DF, GFI, CFI, and IFI, all of which had values within acceptable ranges (Table 9). We used a minimum sample size of 100–150 for CFA, following the criteria of Hair et al.[13] However, the small sample size might have affected model fit. Therefore, future studies using this scale should include a sufficient sample size to perform a CFA. For a model fit that may have problems because of a small sample size, the RMSEA, which is less affected by sample size, should be checked.[42] Therefore, we also calculated the RMSEA value, which was 0.072 (< 0.08) and within the excellent range.[43] Although a better model fit is desirable, building a research model based solely on a good model-fitting criterion is undesirable.[42] Therefore, based on the RMSEA values and the small sample size in the CFA, the fit of scale of the model was considered to be acceptable Moreover, the fit indicator in the revised model was better than before, and the GFI, CFI, and IFI of the model fit indicators had ideal values.

Convergent validity refers to the correlation of items within the same dimension, which is evaluated using composite reliability and average variance extraction (AVE).[32] Composite reliability reflects the consistency of items in the same dimension. A higher composite reliability value indicates a stronger association between the items and dimensions. A value >0.70 indicates better composite reliability.[44] In this study, the composite reliability values for all dimensions were >0.7, indicating a good combination reliability. The AVE represents the comprehensive interpretation ability of the items under the dimension. The greater the AVE value, the stronger the ability of the dimension to explain items, and the better the convergence validity. Generally, the AVE value was >0.5 indicating good convergent validity.[45] In this study, The AVE values of dimensions B, C, D, and F were all <0.5, indicating that convergence validity was not ideal. The factor load reflects the standardized regression coefficient from the dimension to item; the larger the factor load, the higher the AVE value. When the degree of fit, convergent validity, and DV were unsatisfactory, a common method is to delete items with low factor-loading values and establish covariance relationships between the residuals of mutually explainable variables.[26] Based on the clinical importance of the items, those with the smallest factor loads in dimensions B(B7), C(C1), D(D2), and F(F4) for model modification were deleted. Moreover, since items A4, A5 and A6 all describe

"observed complications", and items D4 and G1 all describe "acquisition of TIVAP information", these variables can be interpreted by each other. Hence, we established covariance relationships between the variable residuals of A4 and A5, A5 and A6, A4 and A6, and D4, and G1 (Figure 4). Chen et al adopted the same model modification method in their study.[46] All factor loadings of all items were >0.50 (Figure 4), the CR value of all dimensions was >0.70, and the AVE value of all dimensions >0.50 after model modification, indicating good convergent validity.

Discriminant validity emphasizes the degree of differentiation among different dimensions.[33] The correlation coefficient between latent variables (ie, dimensions) was smaller than the square root of the AVE, suggesting that all dimensions had a certain degree of differentiation and that the scale had good discriminant validity.

The Chinese version of the Health Promotion Lifestyle Scale II Revision (HPLP-IR) is widely used clinically in China, with good reliability and validity.[15] A health-promoting lifestyle refers to the adoption of spontaneous, multi-layered behaviors to maintain or have better health.[47] Self-management behavior refers to the initiative to perform preventive or therapeutic healthcare activities related to one's own diseases under the guidance or assistance of medical personnel.[48] These two scales are closely related and exhibit synergistic effects. Due to the lack of an existing validated scale for the CPTSMBS, we used the HPLP-IIR to measure the criterion validity of this scale. This tool has also been used in other studies on health behaviors.[49] In this study, the total scores of both instruments were positively correlated ($r = 0.465$, $P < 0.01$), with a moderate-strength association.[50]

Limitations

This study had some limitations. First, data collection took place during the COVID-19 pandemic when China was in a critical situation, which caused difficulties in the distribution of the questionnaire. Hence, we only included 500 patients with TIVAP from two hospitals in China, which may have led to regional bias and limited the promotion of the scale. Second, patients with cancer are physically weak. The scale is completed at an intravenous catheter clinic, and their schedule is very busy, which may have affected their answers to the questions. Finally, the scale was developed in China, and its items might have been influenced by Chinese culture. Hence, it is necessary to examine different cultural backgrounds in the future to improve the applicability of the scale.

Conclusions

The CPTSMBS developed in this study, comprising seven dimensions and 29 items, demonstrated good reliability and validity. The scale provides an effective evaluation tool for the prevention, monitoring, and intervention of TIVAP self-management in patients with cancer. Nevertheless, further validation and adjustments using multicenter and large-sample studies are necessary.

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Disclosure

All authors declare that they have no conflicts of interest. Data acquisition was approved by the hospital ethics committee.

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