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Research Paper

Development and validation of a self-management behavior questionnaire for Chinese enterostomy patients



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ABSTRACT

Objectives: This study aimed to develop a self-management behavior questionnaire for Chinese enterostomy patients and examine its reliability and validity.

Methods: Guided by the theory of self-management, an initial questionnaire was generated through literature review, group meetings, and two rounds of an expert consultation. Finally, the reliability and validity of the questionnaire were validated through a questionnaire survey of 200 enterostomy patients were selected from the Affiliated Hospital of Medical University from June 2016 to March 2017.

Results: The content validity index was 0.80–1.00. The exploratory factor analysis yielded a five-factor (dietary behavior, psychosocial behavior, symptom management behavior, medical compliance behavior, information management behavior), consisting of 40 items. The cumulative variance contribution rate was 65.42%. The Cronbach's α coefficient for the total questionnaire was 0.972, and for the five factors ranged from 0.797 to 0.939, indicating a good internal consistency. The test-retest reliability was 0.867 (P < 0.01). The self-management behavior questionnaire score was negatively related to the Ostomy Skin Tool score (r = -0.800, P < 0.01).

Conclusions: The self-management behavior questionnaire developed in this study showed good reliability and validity and can be used to assess the self-management behavior of Chinese enterostomy patients.

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What is known?

- Complications such as edema, bleeding, and prolapse are prone to occur after enterostomy, seriously affecting patients' quality of life.
- Good self-management ability can reduce or even avoid complications after enterostomy.

What is new?

• This study developed a self-management behavior questionnaire for Chinese enterostomy patients, tested with good reliability and validity.

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• The questionnaire developed in this study can be used to evaluate the self-management level of the patients with enterostomy and assist the medical staff in making a targeted nursing plan for the patients with enterostomy.

1. Introduction

Due to the development of the social economy and changes in peoples' eating habits and living environments, colorectal cancer is rising worldwide, and it has become one of the most common gastrointestinal malignancies [1–4]. The WHO's International Center for Research on Cancer predicted 1,931,590 new cases of colorectal cancer worldwide in 2020 and 935,173 related deaths [5]. Additionally, the incidence of colorectal cancer in China is also increasing every year [6]. In 2018, data from China's cancer center showed that the incidence of colorectal cancer ranked fifth among male cancers and fourth among female cancers, with approximately 130,000 new cases each year [7]. At present, the treatment of colorectal cancer is still based on low enterostomy surgery.

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With the continuous improvement of the postoperative survival rate, an increasing number of patients accept and choose enterostomy surgery, with nearly 100,000 people choosing enterostomy surgery every year in China [8]. Although colostomy surgery saves the lives of most patients with colorectal cancer, due to changes in the patient's normal bowel movement, it affects their normal life and social activities [9–11]. Additionally, patients are prone to complications after surgery, such as edema, bleeding, or prolapse, which may bring great harm to the patient's physical and mental health and seriously affect their quality of life [12,13].

Self-management of patients with enterostomy refers to patients to respond to their daily life, physical symptoms, emotions, and coping [14]. Enterostomy patients enter a long-term chronic disease stage after hospital treatment and gradually realize the importance of self-management. Good self-management behavior can monitor and manage patients' disease changes, improve their symptoms, prevent complications, and reduce the re-hospitalization rate, which enhances patients' quality of life [15–19].

The self-management assessment tool is the basis for evaluating patients' self-management behavior and ability with enterostomy. For patients, appropriate assessment tools can help them correctly understand the problems existing in self-management and avoid misunderstanding self-management. Similarly, scientific assessment tools can also provide theoretical guidance for medical staff to implement self-management education. However, most of the current clinical assessment tools for enterostomy patients' selfmanagement ability are self-compiled questionnaires, lacking reliability and validity tests, and the accuracy of the assessment results cannot be guaranteed [20,21]. On the other hand, although some regional self-management behavior scales and questionnaires have been proposed [22–24], these scales or questionnaires do not reflect the differences in culture, diet, and level of care in different countries and regions. These differences play an important role in the compilation of the scale and questionnaire and must be considered. Therefore, this study aimed to develop a tool that measured the self-management behavior of Chinese enterostomy patients, hoping to provide a reference basis for an accurate evaluation of the self-management behavior of Chinese enterostomy patients.

2. Methods

2.1. Theoretical framework

This study was guided by the self-management theory, which refers to the ability of individuals to cope with diseases by gradually developing symptoms management, treatment, physiological and psychosocial changes, and lifestyle changes. This theory emphasizes that patients are the subjects of self-management behavior. Patients should not only assume important responsibilities in disease management and rehabilitation but also take the initiative to make behavioral changes within their power to deal with the disease. For patients with chronic diseases, it refers to the behaviors taken to prevent complications and improve health, that is, the management of complications, the management of daily activities, the monitoring of symptoms and signs, the management of selfimage, role function, and interpersonal relationship induced by disease and treatment, and the coping with psychological problems caused by disease and treatment. Based on this theory, this study explored the self-management behavior of enterostomy patients from the aspects of patient information management, symptom management, daily activity management, psychological management, and nursing management.

2.2. Development of the first item pool

The concept and theoretical framework of self-management behavior were determined through a literature review. Based on the concept definition of self-management behavior of enterostomy patients, the influencing factors of self-management behavior of enterostomy patients were analyzed through a literature review. Self-management behavior questionnaire was designed, and four dimensions were determined as follows: dietary behavior management (11 items), daily life behavior management (13 items), psychosocial behavior management (9 items), and treatmentrelated behavior management (10 items).

2.3. Primary questionnaire development

The initial questionnaire was prepared as follows. 1) After a group discussion, we conducted semi-structured interviews with ten patients with enterostomy. Considering the questions and suggestions raised by the interviewed patients on each item in the revised draft, we made revisions on the complex items in the revised draft that contain specialized vocabulary that patients cannot understand. 2) A model of two rounds of expert consultation was adopted: first, five experts were invited to evaluate the following contents of the questionnaire, including a) whether the questionnaire could objectively, accurately, and comprehensively measure the self-management behavior of colostomy patients; b) whether the presentation of the questionnaire is appropriate; c) whether the entries in each dimension appropriately reflect the meaning of that dimension; d) whether there is confusion among the items and whether the language expression is accurate and easy to understand. The items were screened, modified, or added to form an initialization questionnaire according to the evaluation results. The expert group consisted of three stoma treatment experts and two nursing experts, who had more than ten years of work experience in the field of ostomy treatment and nursing. According to the 5-point Likert scoring system, experts rated the importance of each item on a scale of 1-5, indicating very important, important, somewhat important, unimportant, and very unimportant. In addition, experts were encouraged to comment and justify these items. The revised text was formed after two reiterated feedback and discussions by the experts.

Afterward, ten enterostomy patients were pre-tested, and comments were recorded to delete or modify items. After pretesting, four items were removed due to similar meanings. In addition, eight items were revised according to the opinions and grades of the two rounds of expert consultation. Two items were added to form an initial questionnaire with 41 items. Finally, the item content validity index (I-CVI) and scale-level CVI (S-CVI) were calculated [25].

2.4. Formal investigation

2.4.1. Participants

Using a convenience sampling method, participants had undergone colorectal cancer surgery with stoma retention in the anorectal surgery, gastrointestinal surgery, and gastrointestinal oncology surgery ward of the First Affiliated Hospital of China Medical University from June 2016 to March 2017. The inclusion criteria were: 1) age \geq 18 years; 2) enterostomy retention time >6 months, and the radiotherapy and chemotherapy were completed; 3) provided informed consent and voluntarily participated in this study; and 4) had the complete cognitive ability. The exclusion criteria were: 1) had a recurrence or metastasis of cancer; 2) had complications of heart, kidney, liver, and other diseases that seriously affected their quality of life.

2.4.2. Ethical considerations

The Ethics Committee approved this study of the First Affiliated Hospital of China Medical University (Project No. 20130102). All participants were informed of the details of the research content, and participants can voluntarily agree or refuse to participate in the research at any time. Signed informed consent was obtained from each participant and kept it confidential by the researcher.

2.4.3. Instruments

2.4.3.1. General data questionnaire. Demographic data (age, weight, education, occupation, lived alone, marital status, lifestyle, monthly family income, medical payment method, etc.) and disease-related data (with other diseases, type of stoma, and stoma complications) were included.

2.4.3.2. Self-management behavior questionnaire. Designed by the researcher, it contains five dimensions and 41 items. To measure the self-management ability of enterostomy patients. Designed by the researcher, it contains five dimensions and 41 items. According to the 5-point Likert scoring system:"1 = never, 2 = hardly, 3 = sometimes, 4 = often, 5 = always." The score ranged from 41 to 205, and the higher the score, the better the patient's self-management ability.

2.4.3.3. Ostomy Skin Tool. Ostomy Skin Tool contains three domains of abnormal peristomal skin (D - Discolouration, E - Erosion, T - Tissue overgrowth) [26]. Within each domain, both the area of peristomal skin affected (the percentage of the area under the adhesive barrier) and the severity of the skin changes is taken into account. The area within is assigned a score between 0 and 3, and the severity a score between 0 and 2. Therefore, each of the three domains contributes with a score between 0 and 5 and consequently, the total DET score is defined to be on a scale from 0 to 15. This study used the DET score as calibration to measure calibration correlation validity.

2.5. Data collection

The researchers distributed questionnaires. Before the survey, the researchers explained the study's purpose, significance, and requirements to the patients and promised to keep the data confidential. The items that the patients did not understand during the filling process were explained on time. For patients with poor vision or for whom it was inconvenient to fill in the questionnaire themselves, the researchers read the items one by one. The patients answered the questions orally, and the researchers recorded the answers. All the questionnaires were checked on the spot to ensure the accuracy and authenticity of the results.

2.6. Data analysis

SPSS version 20.0 was used for data processing and statistical analysis. The main statistical analysis methods included descriptive statistics such as frequency, mean, and standard deviation, and inferential statistics such as *t*-test, factor analysis, Pearson correlation analysis, etc. Statistical significance was set at P < 0.05.

2.6.1. Item analysis

Differentiation analysis, correlation analysis, and factor analysis were used for the joint screening of the items [27]. 1) The scale's total score was ranked from high to low, and 27% of the patients with the highest and lowest scores were selected to form the high

and low groups, respectively. An independent sample *t*-test of the two groups was conducted to compare the scores of each item between the groups, and the items with no statistically significant difference (P > 0.05) were deleted. 2) We calculated the correlation coefficient between each item and the total questionnaire. The larger the correlation coefficient, the more the item represented the content of the evaluation tool. We deleted the items with a correlation coefficient of less than 0.4. 3) After factor analysis, we deleted items with factor loads less than 0.4 on the corresponding factors.

2.6.2. The reliability and validity tests

Expert validity was used to reflect content validity, represented by the content validity index (CVI). A factor analysis was used to test the structural validity of the questionnaire. The Ostomy Skin Tool DET scores were used as criterion validity of the questionnaire. Cronbach's α coefficient was used to assess the internal consistency reliability. We conducted a second questionnaire survey among 50 patients two weeks later, and the Pearson correlation coefficient between the two measurements was calculated to verify the testretest reliability of the questionnaire.

3. Results

3.1. Patients characteristics

A total of 250 questionnaires were sent out, and 200 were received with an effective recovery rate of 80.0%. The patients' age ranged from 39 to 79 years old (average age of 61.93 ± 81.4 years old). Among them, 132 (66.0%) were males, 68 (34.0%) were females, 175 (87.5%) had a colostomy, and 25 (12.5%) had an ileostomy, as shown in Table 1.

3.2. Item analysis

The mean difference test was conducted to compare the highest 27% group with the lowest 27% of the total scores. The results showed statistically significant differences in the scores of the high and low groups (P < 0.05). The correlation coefficient between each item and the total score was 0.457–0.789. The correlation coefficient and load value of item 26 were both below 0.4 (one item in total). So, this item was deleted, and 40 items remained.

3.3. Validity test

3.3.1. Content validity

I-CVI of each item was in the range of 0.80–1.00, and S-CVI of the total questionnaire was 0.966.

3.3.2. Construct validity

Factor analysis was used to evaluate the construct validity of the questionnaire, and the KMO value of 40 items in the selfmanagement behavior questionnaire of enterostomy patients was 0.955. The Bartlett spherical test statistic was 6356.521 (df = 780, P < 0.001), suitable for factor analysis. Application of the principal component analysis, the maximum variance orthogonal rotation, choose characteristic value > 1, and the final draw five common factors according to the corresponding content of each factor, named dietary behavior (13 items), psychosocial behavior (11 items), symptom management behavior (nine items), medical compliance behavior (four items), information management behavior (three items). The cumulative contribution rate was 65.421%, the items on the corresponding factor of load were all above 0.4, and items 5, 12, 14, 16, 17, 29, 33 attributed to multiple factors at the same time, after expert review decision to these items belonging to the high factor loading factor. A questionnaire of five

Table 1

Characteristics	of	the	partici	pants	(n	=	200)).
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Characteristics	Group	n	%
Age (years)	≤50	18	9.0
	51-60	62	31.0
	61-69	85	42.5
	≥70	35	17.5
Gender	Male	132	66.0
	Female	68	34.0
BMI(kg/m ²)	≤18.50	14	7.0
	18.51-24.99	80	40.0
	25.00-29.99	87	43.5
	30.00-34.99	19	9.5
National	Han	178	89.0
	Others	22	11.0
Marital status	Married/cohabiting	177	88.5
	Unmarried	1	0.5
	Divorced	3	1.5
	Separated	12	6.0
	Death of a spouse	7	3.5
Education level	Primary school and below	108	54.0
	Junior high school	57	28.5
	College or above	35	17.5
Whether lived alone	Yes	19	9.5
	No	181	90.5
Employment	Yes	68	34.0
	No	132	66.0
Monthly household income (CNY)	≤2000	74	37.0
5	2,001-4,000	75	37.5
	4,001-6,000	40	20.0
	6,000-8,000	11	5.5
Medical payment method	At public expense	15	7.5
	Medical insurance	139	69.5
	At their own expense	46	23.0
Smoking	No	158	79.0
C C	Yes	42	21.0
Drinking	No	163	81.5
	Yes	37	18.5
With other diseases	Yes	53	26.5
	No	147	73.5
Enterostomy type	Ileum colostomy	25	12.5
	Colon colostomy	175	87.5
Enterostomy complications	Incision hernia	71	35.5
	Irritant dermatitis	49	24.5
	Edema	27	13.5
	Bleeding	26	13.0
	Enterostomy retraction	21	10.5
	Allergic dermatitis	16	8.0
	Enterostomy stenosis	13	6.5
	Incision infection	7	3.5
	Radioactive dermatitis	3	1.5
	Skin mucosal separation	2	1.0
	Ischemic necrosis	1	0.5
	None	36	18.0

factors and 40 items were finally formed, as shown in Table 2. The Chinese version of the questionnaire is provided in Appendix A.

The correlation coefficients between the factors and questionnaire ranged from 0.768 to 0.918 (P < 0.01), and the correlation coefficients among the factors ranged from 0.594 to 0.777 (P < 0.01), as shown in Table 3.

3.3.3. Criterion validity

The correlation coefficient between the self-management behavior questionnaire and the Ostomy Skin Tool DET scores of enterostomy patients was -0.800 (P < 0.01).

3.4. Reliability test

3.4.1. Internal consistency reliability

The Cronbach's α coefficient of the self-management behavior questionnaire of enterostomy patients was 0.972. The internal

consistency estimates for five dimensions ranged from 0.797 to 0.939, as shown in Table 4.

3.4.2. Test-retest reliability

We randomly invited 50 patients to complete the questionnaire again two weeks after the first time. The intraclass correlation coefficient of the total questionnaire was 0.867, and the five dimensions ranged from 0.777 to 0.949 (P < 0.01), as shown in Table 4.

4. Discussion

4.1. The validity of the questionnaire

Validity is used to evaluate the validity and accuracy of research tools. When S-CVI > 0.90 and I-CVI > 0.78, the content validity of the questionnaire was better. The S-CVI and I-CVI of the selfmanagement questionnaire were 0.966 and 0.80-1.00, respectively, indicating good validity of the questionnaire [28,29]. Structural validity reflects the degree of conformity between the research tool and the theoretical or conceptual framework it is based on. When the exploratory factor analysis was used to evaluate the questionnaire structure validity, the load value of each item on its attribution factor was required to be > 0.4, if the cumulative variance contribution rate of extracted common factor > 60%, indicating that the questionnaire structure validity is ideal [30,31]. In this study, five common factors were extracted by exploratory factor analysis. The load values of each factor were > 0.4: the cumulative variance contribution rate is 65.42%, indicating that the questionnaire has good structural validity.

4.2. The reliability of the questionnaire

Reliability refers to the consistency and stability of the results measured by the measurement tool. The internal consistency reliability is a widely adopted reliability evaluation method, which can reflect the degree of correlation between items. The larger Cronbach's α coefficient is, the better the internal consistency is [32]. The ideal measurement questionnaire requires the Cronbach's α coefficient of the total questionnaire > 0.80, Cronbach's α coefficient of the questionnaire developed in this study is 0.972, and the Cronbach's α coefficient of each dimension is 0.797–0.939, indicating that the questionnaire has good internal consistency. The test-retest reliability of this questionnaire is 0.867, and the test-retest reliability of each dimension is 0.777–0.949, indicating that the questionnaire has good stability.

4.3. The practicality and scientificity of the questionnaire

Based on the literature review, questionnaires were compiled according to guidelines and relevant literature. The questionnaires covered the core contents of postoperative enterostomy management, such as diet management, life management, symptom management, drug use, and information acquisition, ensuring the scientificity and practicability of the questionnaires [34]. In this study, experts in related fields were invited to evaluate and guide the content of the questionnaire, including clinical enterostomy doctors and specialized nurses, which are represented in the professional field, and ensure the authority and standardization of the questionnaire. In addition, item analysis, factor analysis, and other methods were used to revise and screen the items in this study. Reliability and validity tests were carried out through a questionnaire survey to ensure the scientific and rigorous content of the questionnaire. The research team also modified the language

X. Du, H. Jiang, L. Fu et al.

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Exploratory factor analysis of the questionnaire (n = 200).

Dimensions and items	Factor 1	Factor 2	Factor 3	Factor 4	Factor 5
Dietary behavior					
Q8	0.741	0.261	0.199	0.114	0.348
Q11	0.721	0.234	0.306	0.058	0.243
Q27	0.717	0.165	0.225	0.283	0.192
Q7	0.704	0.351	0.113	0.104	0.249
Q20	0.679	0.262	0.207	0.205	0.309
Q38	0.651	0.201	0.237	0.372	0.043
Q1	0.639	0.072	_	0.161	0.151
Q13	0.632	0.339	0.263	0.170	0.043
Q21	0.610	0.390	0.284	0.217	0.049
Q4	0.563	0.196	0.426	-	0.004
Q10	0.546	0.159	0.398	0.221	0.142
Q39	0.520	0.211	0.319	0.335	—
Q30	0.491	0.393	0.244	0.261	0.170
Psychosocial behavior					
Q35	0.242	0.727	0.203	0.226	0.273
Q19	0.223	0.698	0.289	0.171	-
Q9	0.219	0.640	0.321	0.059	0.363
Q31	0.380	0.633	0.150	0.332	0.071
Q2	0.166	0.618	0.358	0.136	0.395
Q18	0.306	0.579	0.368	0.129	-
Q15	0.200	0.575	0.271	0.261	0.201
Q28	0.361	0.545	0.253	0.355	0.161
Q6	0.272	0.530	0.199	0.230	0.264
Q5	0.304	0.503	0.024	0.154	0.448
Q33	0.337	0.466	0.265	0.425	0.051
Symptom management behavior					
Q41	0.231	0.304	0.791	0.130	0.156
Q22	0.214	0.257	0.758	0.185	0.211
Q32	0.250	0.212	0.739	0.163	0.218
Q23	0.220	0.342	0.704	0.187	0.232
Q16	0.196	0.166	0.659	0.152	0.494
Q29	0.178	.301	0.598	0.226	0.438
Q34	0.196	0.467	0.581	0.310	0.100
Q24	0.292	0.469	0.511	0.336	0.108
Q12	0.413	0.221	0.493	0.418	0.018
Medical compliance behavior					
Q36	0.381	0.289	0.156	0.704	0.177
Q40	0.296	0.211	0.211	0.667	0.299
Q37	0.281	0.389	0.209	0.613	0.107
Q25	0.101	0.275	0.258	0.486	0.212
Information management behavior					
Q14	0.192	0.105	0.442	0.285	0.587
Q17	0.334	0.122	0.261	0.127	0.580
Q3	0.254	0.231	0.389	0.191	0.556
Cumulative variance contribution rate (%)	18.124	33.626	49.079	57.972	65.421

Note: Factor loads less than 0.10 are not shown. Factor 1 = dietary behavior. Factor 2 = psychosocial behavior. Factor 3 = symptom management behavior. Factor 4 = medical compliance behavior. Factor 5 = information management behavior.

Table 3

The correlation coefficients between the factors and questionnaire.

Dimensions	Dietary behavior	Psychosocial behavior	Symptom management behavior	Medical compliance behavior	Information management behavior
Dietary behavior	1				
Psychosocial behavior	0.770	1			
Symptom management behaviour	0.722	0.777	1		
Medical compliance behaviour	0.704	0.745	0.692	1	
Information management	0.637	0.625	0.716	0.594	1
behaviour					
Total questionnaire	0.908	0.918	0.900	0.834	0.768

Note: All *P* < 0.01.

expression of the questionnaire several times. The length of the questionnaire is suitable and easy to understand, which is convenient for clinical application. Clinical nurses and managers of enterostomy can evaluate the self-management ability of enterostomy patients according to the evaluation content, fully understand the personal situation and self-management ability of patients, further formulate clear improvement focus of nursing quality, and analyze the shortcomings of individual self-management. To provide a comprehensive, reliable, and detailed data basis for the realization of follow-up accurate nursing intervention measures and evaluation of intervention effects.

X. Du, H. Jiang, L. Fu et al.

Table 4

The reliability of the questionnaire and each dimension.

Dimensions	Number of items	Cronbach's α coefficient ($n = 200$)	The test-retest coefficient $(n = 50)$
Dietary behavior	13	0.938	0.847
Psychosocial behavior	11	0.921	0.777
Symptom management behavior	9	0.939	0.914
Medical compliance behavior	4	0.823	0.865
Information management behavior	3	0.797	0.949
Total questionnaire	40	0.972	0.867

4.4. Limitations

The current study has some limitations. The sample size selected in this study is limited, and the sample sources are relatively concentrated. It is recommended to increase the total number of samples and expand the range of sample selection in further research to verify the reliability and validity of the questionnaire again. In addition, the questionnaire was developed in Chinese, and the author translated the English version of the questionnaire without a rigorous translation process.

5. Conclusion

This study developed a self-management behavior questionnaire for enterostomy patients with five dimensions and 40 items, including dietary behavior, psychosocial behavior, symptom management behavior, medical compliance behavior, and information management behavior. The results show that the questionnaire has good reliability and validity and can be used to evaluate the selfmanagement behavior of Chinese enterostomy patients by health-care professionals.

CRediT authorship contribution statement

Xiaoyan Du: Conceptualization, Methodology, Software, Writing-original draft. **Haoran Jiang**: Methodology, Formal analysis, Writing-original draft. **Luxia Fu**: Writing-original draft, Writing-review & editing, Visualization. **Aiping Wang**: Conceptualization, Validation, Writing - Review & Editing, Supervision.

Data availability statement

The datasets used and analyzed during the current study are available from the corresponding author on reasonable request.

Declaration of competing interest

The authors have declared no conflict of interest.

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Appendices. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ijnss.2022.03.007.

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