



Original Article

Development and psychometric testing of a self-management scale for cancer survivors with radiotherapy/chemotherapy-induced oral mucositis in China

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ABSTRACT

Objective: This study aims to develop and validate a self-management scale for radiotherapy/chemotherapy-induced oral mucositis (SMS-RIOM/CIOM) in cancer survivors, addressing the need for a comprehensive tool to assess self-management capabilities.

Methods: This study employed a two-phase process: (1) initial scale development through literature review, semi-structured interviews, and expert consultations, and (2) psychometric testing with 420 cancer survivors from five wards of Zibo Hospital. The psychometric evaluation included item analysis, content validity testing, reliability assessments, exploratory factor analysis (EFA), and confirmatory factor analysis (CFA).

Results: The finalized SMS-RIOM/CIOM consists of 15 items across four dimensions: medication management, oral pain management, disease monitoring, and daily life management. EFA explained 77.322% of the total variance, while CFA demonstrated an excellent model fit ($\chi^2/df=1.909$, RMSEA=0.064, RMR=0.052, GFI=0.911, CFI=0.964, NFI=0.928, TLI=0.955, IFI=0.964). Reliability metrics were robust, including Cronbach's alpha of 0.902, split-half reliability of 0.849, test-retest reliability of 0.862, and a scale content validity index of 0.910.

Conclusions: The SMS-RIOM/CIOM is a reliable and valid tool for assessing self-management in cancer survivors with RIOM/CIOM. It provides valuable insights for clinical practice, enabling targeted interventions to improve self-management and enhance the quality of life for cancer survivors. Further research is recommended to validate its application across diverse populations and healthcare settings.

Introduction

In 2004, the National Cancer Institute (NCI) defined cancer survivors as individuals whose lives, from diagnosis to the end, are impacted by cancer and its treatment, affecting not only the patient but also the family and caregivers.¹ Radiotherapy/chemotherapy-induced oral mucositis (RIOM/CIOM) refers to the acute and chronic injury of oral mucosa in cancer survivors following radiotherapy and/or chemotherapy, primarily characterized by erosions and ulcers.² The administration of chemoradiotherapy disrupts the growth and differentiation of oral mucosal epithelial cells, leading to abnormal mucoepithelial cell cycles, apoptosis,

and subsequent acute and chronic mucosal inflammation. According to statistics, the incidence of oral mucositis is nearly 100% in survivors undergoing radiotherapy for head and neck tumors,³ ranging from 20% to 80% in patients receiving conventional chemotherapy,^{4,5} 40%–90% in survivors undergoing radiotherapy and chemotherapy,^{6,7} and approximately 80% in survivors pretreated with hematopoietic stem cell transplantation.^{8,9}

RIOM/CIOM causes discomfort in cancer survivors, including fatigue, pain, and dysphagia, while reducing their tolerance to antitumor therapy. This often leads to treatment delays or interruptions.^{10–13} Furthermore, oral mucositis-related pain and dysphagia can result in decreased

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nutrient intake, prolonged hospital stays, increased readmission rates, and added burden on both survivors and their families.^{11,14} The existent effective therapeutic and preventive interventions such as the use of honey, anti-inflammatory drugs, cryotherapy, mucosal protectors, traditional Chinese medicine, and lasers^{15–19} are unable to completely eliminate the occurrence of mucositis.^{11,20} Given the high incidence and long duration of RIOM/CIOM, its prevention and treatment must be integrated throughout the entire cancer treatment process.²¹

Nursing pertaining to RIOM/CIOM assumes a pivotal role throughout the radiotherapy/chemotherapy process, while the essentiality of self-care among cancer survivors remains unparalleled. Thus far, oncology teams have primarily focused on two aspects: prevention and treatment, which include essential oral care, health education, nutrition management, pain management, and medication management.^{22–25} Oncology nurses play a pivotal role in the prevention and management of oral mucositis. Currently, research focuses mainly on nurses' knowledge, attitudes, practical assessments, health education interventions tailored to individuals' needs, OM assessments, and remote guidance regarding OM.^{23–28} However, nurses face certain challenges, such as insufficient awareness of RIOM/CIOM, lack of standardized oral care protocols, and inadequate attention to OM prevention,^{23,26,27} resulting in ineffective management of OM in cancer survivors.

Self-management ability refers to the ability of patients to control their behavior according to their knowledge of the disease to delay and improve the progression of the disease.²⁹ It is a crucial skill that cancer survivors, like survivors with other chronic diseases, must acquire to effectively cope with their treatment, symptoms, physiological and psychosocial changes, and lifestyle adjustments. This ability is developed through the experience of managing traditional chronic illnesses.²⁹ According to Corbin and Strauss,³⁰ self-management encompasses three tasks: medication management, role management, and emotion management. Lorig and Holman³¹ proposed six self-management skills: problem-solving, decision-making, resource utilization, fostering partnerships between survivors and health care providers, action planning, and self-adjustment. Research has demonstrated that proficient self-management significantly alleviates physical symptoms such as cancer pain and nausea,³² improves the quality of life and self-efficacy,^{24,33,34} thereby addressing the long-term physical and mental health needs of survivors.^{25,35} Timely and accurate assessment plays a vital role in preventing OM and determining its prognosis and serves as an essential clinical intervention for managing this condition. However, due to the short hospital stays during radiotherapy or chemotherapy treatments, followed by long intervals between courses of treatment, discharge periods are challenging for nurses to promptly identify oral mucositis reactions in post-treatment survivors. Therefore, the survivors' ability to self-assess and self-manage becomes particularly significant in the timely detection of OM issues, along with prevention strategies for RIOM/CIOM.

The scales related to RIOM/CIOM primarily include the World Health Organization (WHO) Oral Mucositis Assessment Scale,³⁶ Oral Assessment Guide,³⁷ Oral Mucositis Daily Questionnaire,^{36,38} Group Standard for Prevention and Nursing of Oral Mucositis Associated with Chemoradiotherapy published in China,³⁹ and the Chinese Guidelines for the Management Practice of Cancer Symptoms (Oral Mucositis).⁴⁰ These scales are used to guide clinical nurses in preventing and managing RIOM/CIOM. However, the use of these scales has several limitations: (1) Medical staff typically assess the oral mucosa based on visual changes that occur after radio/chemotherapy, which cannot be discovered in advance. (2) Patients using self-rating scales can detect changes in their oral mucosa 1–3 days earlier than medical staff.⁴¹ While these scales can assess the level of OM, they do not evaluate patients' self-management ability. (3) The aforementioned scales encompass a multitude of items, potentially impeding targeted nursing staff management efforts. (4) The traditional self-management model involves a one-way indoctrination of knowledge while neglecting individual differences and survivor empowerment.^{31,42}

Cancer patients often undergo multiple cycles of radiotherapy and chemotherapy, but not all the time in the hospital during the entire treatment period. The self-evaluation of patients is not only important for the evaluation of OM but also has a positive role in its prevention. To realize the rapid and dynamic assessment of the self-management ability of oral mucositis in patients with radiotherapy and chemotherapy, nurses can use the least manpower and material resources to screen patients, accurately locate their disease cognitive blind spots, identify the internal mechanisms and core factors that affect their health behaviors and compliance behaviors, and then provide personalized guidance for patients, which is conducive to maximizing patients' disease cognition and optimizing self-management, and can also be used as an evaluation tool for the implementation of health education. Therefore, based on the self-management theory, relevant literature review, semi-structured interviews, and expert consultations, we developed a self-management scale for RIOM/CIOM (SMS-RIOM/CIOM), aiming to assess the self-management abilities of RIOM/CIOM survivors in China and provide targeted care for survivors.

Methods

This study had three phases: (1) item pool generation, (2) item improvement through expert consultation, (3) a pilot study, and (4) psychometric testing of the inventory.

Item pool generation

This study was based on the self-management theory proposed by Corbin and Lorig et al.^{30,31} A systematic literature search was performed using the PubMed, Medline, China Biomedical Literature Database, CNKI, VIP, and Wangfang databases. The search encompassed all available articles from the inception of each database up to June 2024. The following main keywords were used: "Chemotherapy," "Radiotherapy," "Oral Mucositis," "Self-management," and "management," etc. The WHO Oral Mucositis Assessment Scale, the North American Radiation Therapy Oncology Group, the Oral Assessment Guide, and the Chinese Nursing Association's group standard "Nursing Specifications for RIOM/CIOM" were also used as foundational references for the items.

In July 2024, five medical and nursing experts specializing in oncology from a Grade A general hospital in Zibo City, Shandong Province and Five survivors who experienced RIOM/CIOM were interviewed, with the obtained results serving as supplementary data for the scale items as follows: (1) What aspects do you think should be adopted to evaluate the self-management ability of RIOM/CIOM survivors? and (2) What knowledge do you have regarding the self-management of RIOM/CIOM survivors? (3) What do you think are the main problems in the self-management of RIOM/CIOM survivors? (4) What suggestions do you have regarding disease management for RIOM/CIOM survivors?

An objective sampling method was used to select patients undergoing radiotherapy and chemotherapy at the hospital. Inclusion criteria: (1) Cancer survivors diagnosed using pathological methods and those undergoing radiotherapy or chemotherapy for ≥ 1 year; (2) Age ≥ 18 years; (3) Survivors without any psychiatric illness and with an ability to read and understand; (4) Those with the ability to provide an informed consent form and cooperate with the researchers. The interview outline for RIOM/CIOM survivors was as follows: (1) How do you usually deliver your self-manage? (2) What do you know about disease management? and (3) What impact does oral mucositis have on daily life? The seven-step analysis method of Colaizzi phenomenology was used to analyze the interview data,⁴³ with three themes and seven subthemes acquired: insufficient self-management (weak medication compliance, insufficient disease cognition, and poor disease monitoring ability), the influence of RIOM/CIOM on daily life (affecting survivors' diet and mood), and weak coping ability for oral pain (difficulty in assessing the timing and degree of pain, and low degree of pain coping). Based on the study group interviews, we generated an original draft of 4 dimensions and 32 items.

Item improvement through expert consultation

The purposeful sampling method was employed to select 15 reputable oncology specialists affiliated with Grade A hospitals from Guangzhou, Changcun, Beijing, Tianjin, Zibo, Weifang and Jinan as consulting experts. The selection criteria: (1) Oncology medical and nursing professionals with intermediate or higher professional titles; (2) Those engaged in clinical practice of oncology medical treatment or nursing for more than 10 years; and (3) Those possessing extensive theoretical knowledge and clinical experience related to RIOM/CIOM.

The selection criteria for the items in the expert correspondence consultations were as follows: mean value of item importance assignment > 3.5, variation coefficient < 0.25, and expert authority coefficient > 0.7 were deemed acceptable.⁴⁴

Pilot study

After verifying expert content validity, a pilot study was conducted to test the feasibility and comprehensibility of the preliminary scale, and a convenience sampling method was used in a pilot study to select 30 survivors from a tumor ward of Zibo Hospital in July 2024. The inclusion criteria were the same as those used in Phase 1. The exclusion criterion encompassed survivors with impaired consciousness or an inability to communicate effectively. Based on feedback received from the survivors, improvements were made to aspects such as scale expression, layout, and wording.

Psychometric tests

Recruitment

A convenience sampling method was employed to select survivors undergoing radiotherapy and/or chemotherapy from five wards of a Grade A general hospital in Zibo, China, from July to August 2024. The specific inclusion and exclusion criteria were the same as those used in Phase 2. A sample size of 432 was calculated based on the recommended guidelines of 5–10 respondents per item and the structural equation model's requirement of a sample size of over 200,⁴⁵ considering that 5% of the samples may be invalid questionnaires. A total of 432 questionnaires were distributed, of which 420 were returned. SPSS software was used to randomly select cases and divide the data into two groups: sample 1 ($n = 200$) was used for exploratory factor analysis (EFA), and sample 2 ($n = 220$) was used for confirmatory factor analysis (CFA).

Data collection

During the data collection process, we initially reached out to the hospital managers and obtained permission to conduct the surveys in 5 wards. Prior to commencing the investigation, we first established contact with the head nurse and then facilitated communication with the survivors through the assistance of responsible nurses. We effectively conveyed the research purpose to each survivor to get cooperation, obtained signed informed consent forms, and then filled in the questionnaire. The investigator will confirm the information again after the survivor fills in to avoid Errors and omissions.

Data analysis

SPSS 25.0 and AMOS version 26.0 (IBM Corp., Armonk, NY, US) software were used to analyze the data. Descriptive statistics, including means, standard deviations, frequencies, and percentages, were generated to summarize the demographic characteristics, and $P < 0.05$ was considered statistically significant.

Item analysis: Classical test theory points out that items should be evaluated from multiple perspectives.⁴⁶ The discrete trend testing, critical ratio (CR), and item-to-total correlation were conducted to assess the items. (1) Discrete trend testing: Items with a standard deviation less than 0.75 were excluded. (2) The total scale scores were

ranked in ascending order, and an independent samples t test was employed to analyze the high subgroups in the top 27% compared to the low subgroups in the bottom 27%. Items with a CR value below 3 or those not reaching the significance level were excluded. (3) Items with an item-to-total correlation value of 0.3 or lower were deleted. **Content validity:** The item content validity index (I-CVI), the scale CVI (S-CVI).⁴⁶ A panel of 15 experienced medical and nursing experts who have worked in the oncology department for over a decade were selected to assign scores using Lynn's 4-level scoring method. The scoring system ranged from "not relevant" to "very relevant," with points assigned on a scale of 1–4 respectively.

Construct validity: EFA and CFA were conducted.⁴⁶ EFA was used to identify the underlying construct of the items using principal components analysis with varimax rotation. Several criteria were used: (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 0.40 in absolute value. CFA was performed to confirm the identified factor structure.⁴⁷ Acceptable model fit was determined based on the following criteria: χ^2/df (NC) < 3, Tucker–Lewis index (TLI), normed fit index (NFI), goodness of fit index (GFI), incremental fit index (IFI), and comparative fit index (CFI) > 0.90, root mean square residual (RMR) and root mean square error of approximation residual (RMSEA) < 0.08.⁴⁸

Test reliability: The internal consistency reliability was assessed using both Cronbach's α and split-half reliability measures (> 0.7).⁴⁶ The retest reliability was used to assess the external consistency reliability in a cohort of 50 participants at two-week intervals.

Measurement invariance: In this study, the participants' education levels ranged from high school level to postgraduate level. While we initially designed the scale for readability at the high school level, to ensure consistency in understanding across diverse educational levels, we evaluated measurement invariance between low education (high school and below) and high education (college and above) using Brown's method with a stepwise procedure. This ensured that the scale's validity and reliability were consistent across the groups.

Ethical considerations

The study was approved by the Medical Ethics Committee of Zibo Central Hospital (IRB No.20240149) in accordance with the principles outlined in the Declaration of Helsinki, and written informed consent was obtained prior to conducting the survey. They can opt out at any time without punishment.

Results

Delphi results

The consultation process involved two rounds of correspondence. In July 2024, 15 experts were invited for consultation, comprising 2 chief physicians, 3 head nurses, 2 professors, 1 associate professor, 7 tumor nurse specialists, as well as 1 with doctor degree, 9 master degree, 5 undergraduate degree. The participants had an average age of (45.53 ± 5.60) years. The recovery rates achieved in the two rounds of expert consultation questionnaires were 88.24% and 100.00%, respectively, indicating a high level of engagement. Fifteen experts proposed 31 modifications, mostly overlapping and focusing on language or word revisions. The authority coefficients obtained in both rounds were 0.91 and 0.92, respectively, highlighting the experts' significant expertise. The Kendall harmony coefficients for the two rounds were 0.228 and 0.151, respectively ($P < 0.01$), indicating a high level of consistency in the correspondence results and a strong concentration of expert opinions. After two rounds of expert consultation, 7 items were eliminated, 15 items were merged, 5 items were modified, and 1 new item was added. When faced with health threats, based on environmental and individual differences, radiotherapy and chemotherapy patients form their awareness of the seriousness of the

threat (judging the degree of harm of complicated oral mucositis), susceptibility (thinking about the possibility and risk of complications of oral mucositis), response efficacy of self-management (awareness of the benefits of self-management), self-efficacy (confidence in successful self-management), and response cost (awareness of the possible cost of self-management). Based on this, we added an item 'Before chemoradiotherapy, I deal with my oral problems in advance.'

Details of the modification are described in Table 1.

Consequently, an initial scale comprising four dimensions and 15 items was developed using the Likert five-point scoring method, in which scores ranged from "none" (1 point) to "always" (5 points).

Pilot study results

During the pre-survey process, the survivors said that the items were clearly formulated and the language was easy to understand. The scale was retained with only a modification of the language description, which retained its four dimensions and consisted of 15 items.

Item analysis results

The dispersion coefficients ranged from 0.972 to 1.244. The CR values ranged from 8.131 to 13.218 ($P < 0.05$). The item-to-total correlation coefficients ranged from 0.562 to 0.713.

Reliability and validity analysis

General characteristics of participants

The sociodemographic and disease-related information of 420 cancer survivors is presented in Table 2. The average age of the research participants was 54.27 ± 14.94 years.

Table 1
SMS-RIOM/CIOM item modification.

Items	Pre-modification	Modified
Excluded items	①I can stick to the medication according to the doctor's advice until the end of the treatment. ②I can stick to the medication according to the doctor's advice until the end of the treatment. ③I will accurately judge the severity and grade of oral mucositis. ④I can master my own examination results and take the initiative to consult the medical staff about the significance of the examination results. ⑤I know my overall health in the past 24 hours. ⑥I will take the initiative to rest and avoid overwork. ⑦I often pay attention to TV programs, WeChat official account, books and so on related to radiotherapy and chemotherapy for oral mucositis.	
Modified items	①I can evaluate the oral mucosa once a day before, during and after radiotherapy and chemotherapy. ②I know the common causes (such as infection) that lead to the recurrence or aggravation of oral mucositis and prevent it. ③I can make a reasonable diet and ensure nutrition. ④I can avoid bad emotions and take the initiative to adjust.	I Can check my oral pain at least once a day before, during, and after chemoradiotherapy. I Could avoid risk factors for recurrence or exacerbation of oral mucositis. I Could keep a pretty diet habit. I Can deal with unhealthy emotions effectively. I Would not smoke and drink alcohol.
Merged items	⑤Do not smoke or drink during the treatment. ①When I feel uncomfortable after taking the medicine, the accountant sees a doctor to adjust the medicine. ②I won't add or subtract drugs according to my feelings. ③I know that once I stop taking medicine, my condition will get worse. ①I can correctly evaluate the effect of oral pain on drinking water. ②I can correctly assess the effect of oral pain on eating. ③I can correctly evaluate the influence of oral pain on the degree of speech. ④I can correctly evaluate the effect of oral pain on sleep. ①I can master and do the correct gargle method. ②I can master and do the correct oral cleaning method. ③I will avoid eating foods that are easy to damage or irritate the oral mucosa. ④During the treatment, dental floss and toothpicks are forbidden, and people should drink plenty of water, and drink many times in small sips. ①I know the main manifestations of oral mucositis: Erythema, pain, ulcer, etc., and I can identify them. ②When the oral mucosa has symptoms such as erythema, pain and ulcer, I will take the initiative to seek medical treatment.	I Will seek medical advice in time if I feel unwell after taking a medicine. I Can correctly assess the degree to which the oral pain may affect drinking, eating, speaking, and sleeping. I Can maintain good oral hygiene habits. I Can recognize oral mucositis.
New item	①Before chemoradiotherapy, I deal with my oral problems in advance.	

SMS-RIOM/CIOM, self-management scale for radiotherapy/chemotherapy induced oral mucositis.

Validity analysis

(1) Content validity

The I-CVI of this scale ranged from 0.800 to 1.00, and the S-CVI was 0.910.

(2) Construct validity

Firstly, the suitability of data for factor analysis was confirmed through a Kaiser-Meyer-Olkin (KMO) value of 0.852 and Bartlett's sphericity test χ^2 of 2035.223 ($P < 0.001$). Orthogonal rotation was performed using principal component analysis and the variance maximum method. The Scree Plot shows that the slope tended to be flat after the fourth factor, so four factors were extracted for principal component analysis. The cumulative variance contribution rate of these four factors reached 77.322%, where all items exhibited factor loadings exceeding 0.40 (Table 3).

(3) Confirmatory factor analysis

The hypothesized models (Figs. 1–3) yielded the following fit indices: $\chi^2/df = 1.909$, RMSEA = 0.064, RMR = 0.052, GFI = 0.911, CFI = 0.964, NFI = 0.928, TLI = 0.955, and IFI = 0.964, all of which closely approximated the ideal standard.

(4) Reliability analysis

The Cronbach's α coefficient for the overall scale was 0.902, while the coefficients for medication management, oral pain management, disease monitoring and management, and daily life management were 0.890, 0.856, 0.910, and 0.881, respectively (> 0.7). The split-half reliability

Table 2
General characteristics of participants (N = 420).

Variable		n (%)
Gender	Male	227 (54.0)
	Female	193 (46.0)
Education	High school	66 (15.7)
	Junior college	187 (44.5)
	Undergraduate	142 (33.8)
	Graduate	25 (6.0)
Marriage	Unmarried	56 (13.3)
	Married	289 (68.8)
	Divorced or widowed	75 (17.9)
Monthly household (yuan)	≤ 3000	110 (26.2)
	3001–5000	51 (12.1)
	≥ 5001	259 (61.7)
Residence	Rural	67 (16.0)
	Town	226 (53.8)
	City	127 (30.2)
Type of tumor	Lung tumors	91 (21.7)
	Oral tumors	61 (14.5)
	Intestinal tumors	61 (14.5)
	Breast tumors	52 (12.4)
	Esophageal tumors	51 (12.1)
	Nasopharyngeal tumors	35 (8.3)
	Laryngeal tumors	34 (8.1)
	Stomach tumors	24 (5.7)
	Malignant lymphoma	11 (2.6)
Tumor stage	II	145 (34.5)
	III	169 (40.2)
	IV	106 (25.2)
Surgery	Yes	297 (70.7)
	No	123 (29.3)
Smoking history	Yes	151 (36.0)
	No	269 (64.0)
Drinking history	Yes	110 (26.2)
	No	310 (73.8)
Complicated with hypertension	Yes	131 (31.2)
	No	289 (68.8)
Complicated with diabetes	Yes	81 (19.3)
	No	339 (80.7)
Treatment	Radiotherapy	195 (46.4)
	Chemotherapy	193 (46.0)
	Chemoradiotherapy	32 (7.6)
Work status	Unemployed	87 (20.7)
	Retired	142 (33.8)
	On leave	118 (28.1)
	On-the-job	73 (17.4)

Table 3
Factor load matrix of the self-management scale for RIOM/CIOM.

Item	Factor load			
	Disease monitoring and management	Daily life management	Medication management	Oral pain management
Q1 I know the name, dosage, reasons, effects, and side effects of my medication.	0.259	0.144	0.859	0.084
Q2 I can follow my doctor's instructions to take my medication on time and in the right amount every day.	0.251	0.122	0.827	0.212
Q3 I will seek medical advice in time if I feel unwell after taking a medicine.	0.232	0.151	0.842	0.089
Q4 I can check my oral pain at least once a day before, during, and after chemoradiotherapy.	0.159	0.287	0.132	0.811
Q5 I can correctly assess the degree to which the oral pain may affect drinking, eating, speaking, and sleeping.	0.235	0.29	0.14	0.815
Q6 When I have pain, I can deal with it properly.	0.11	0.201	0.11	0.838
Q7 I can assess the cleanliness and comfort of my mouth correctly.	0.803	0.039	0.132	0.216
Q8 I can check my oral mucosa at least once a day before, during, and after chemoradiotherapy.	0.79	0.145	0.154	0.065
Q9 I can recognize oral mucositis.	0.829	0.068	0.185	0.079
Q10 I could avoid risk factors for recurrence or exacerbation of oral mucositis.	0.801	0.127	0.177	0.172
Q11 Before chemoradiotherapy, I deal with my oral problems in advance.	0.856	0.062	0.247	0.082
Q12 I can maintain good oral hygiene habits.	0.153	0.839	0.168	0.201
Q13 I could keep a pretty diet habit.	0.104	0.852	0.161	0.149
Q14 I can deal with unhealthy emotions effectively.	0.03	0.809	0.087	0.241
Q15 I would not smoke and drink alcohol.	0.104	0.893	0.054	0.213

Bold numbers indicate factor loads greater than 0.40. RIOM/CIOM, radiotherapy/chemotherapy induced oral mucositis.

coefficient for the total scale was 0.849, whereas for the four dimensions, it was determined as 0.875, 0.866, 0.946, and 0.889, respectively. The test-retest reliability coefficient of the total scale was 0.862, while for the four dimensions, it yielded coefficients of 0.935, 0.714, 0.720, and 0.929, respectively, providing further evidence supporting the scale's strong internal consistency reliability.

The formal scale

The formal scale included 4 dimensions: medication management, oral pain management, disease monitoring and management, and daily life management, with 15 items. To facilitate the use by patients, we adopted the Likert five-point scale for evaluation, in which scores ranged from "none" (1 point) to "always" (5 points). The total possible score was 75 points, and the higher the score, the stronger the survivor's self-management abilities.

Discussion

SMS-RIOM/CIOM has a standardized compiling process and good reliability and validity

Self-management ability and prevention of exacerbation and recurrence of related symptoms play crucial roles in alleviating the suffering experienced by cancer survivors during chemotherapy/radiotherapy and enhancing their overall quality of life. Choosing appropriate measurement tools to evaluate patients' self-management levels is the premise for developing personalized health education and nursing guidance. By integrating qualitative and quantitative methodologies, the SMS-RIOM/CIOM tool was developed to help health care professionals and patients identify factors associated with self-management defects related to OM. The formulation of this scale is based on widely adopted self-management theory,^{30,31} and relevant literature retrieval, ensuring a scientifically grounded theoretical foundation for the scale. In addition, qualitative interviews were conducted with oncology experts and cancer survivors to supplement the initial item pool of the scale, thereby enhancing its clinical relevance. The results of EFA demonstrated a consistent extraction of four common factors, aligning with the intended dimensions in the scale. This shows that the scale can fully reflect the self-management ability of patients with OM before and after radiotherapy and chemotherapy and can accurately explain and predict their self-management behavior, ensuring the practicability of the scale, and compensating for the shortcomings of existing research.

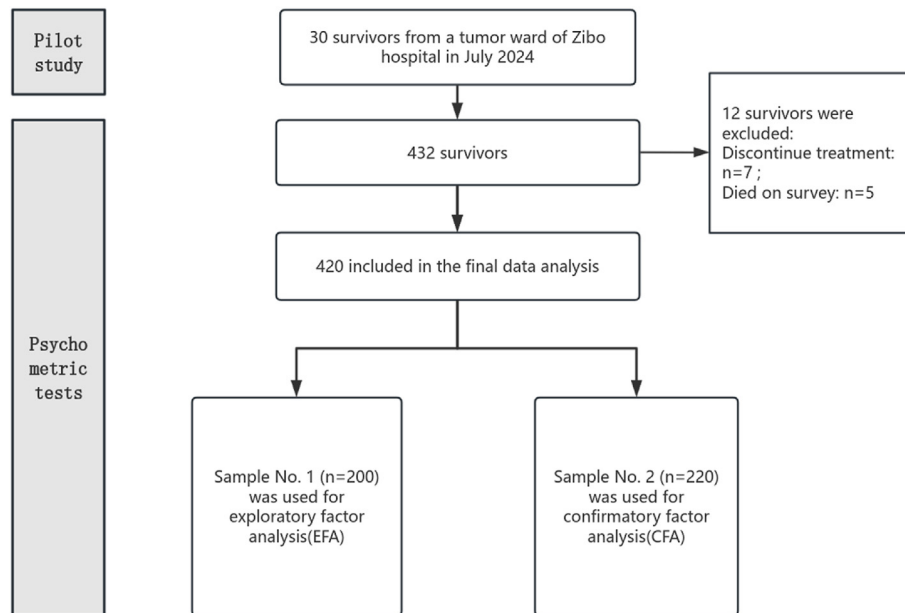


Fig. 1. Survivors flow chart.

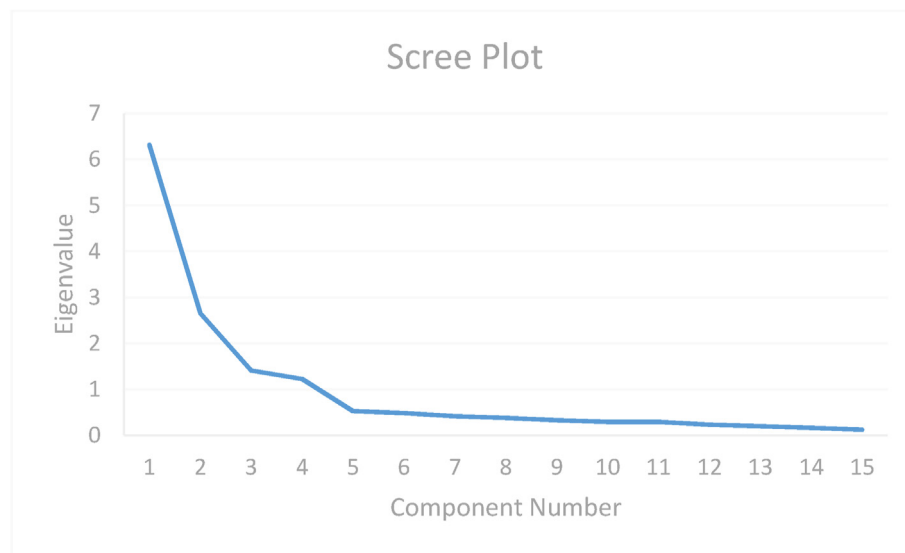


Fig. 2. The gravel diagram.

Furthermore, all 15 items exhibited factor load values exceeding 0.4,⁴⁷ and the cumulative rate of total variance interpretation (77.322%) surpassed 50%,⁴⁷ indicating that the scale effectively captures the level of self-management ability among RIOM/CIOM cancer survivors. SMS-RIOM/CIOM encompasses medication management, oral pain management, disease monitoring and management, and daily life management, effectively covering the essential components of self-management for RIOM/CIOM. The scale has been designed to closely resemble clinical practice. Medication and daily life management are essential components of daily patient care, serving as the foundation for effective treatment and recovery of cancer survivors. The patients frequently emphasized in the interviews that pain management poses a significant challenge for OM. They may be always troubled by the occurrence of pain, even in the absence of its manifestation. The fear of experiencing pain has led some individuals to abandon their treatment altogether. Consequently, pain management has been regarded as a research dimension. The early detection and prevention of RIOM/CIOM are crucial in mitigating their occurrence.

Therefore, researchers consider disease monitoring and management as a distinct dimension. The SMS-RIOM/CIOM developed in this study enables the evaluation of patients' self-management capacity and facilitates ongoing monitoring, thereby facilitating the formulation of an appropriate self-management plan.

To assess the feasibility of implementing this scale with patients, we developed it into a concise instrument. The 15-item scale also demonstrates practical applicability. During the evaluation process, the majority of survivors stated that the number of items was appropriate and that they encountered no difficulties while completing it within 5 minutes. With clear and easily comprehensible content, the items effectively articulated patients' self-management requirements. Its succinct items are well-suited for patient self-assessment; they are straightforward to use and have significant clinical applicability.

The scale was developed using two rounds of the Delphi method. Clinical oncologists and professors were selected to ensure the integration of clinical care experience and teaching expertise, thereby providing

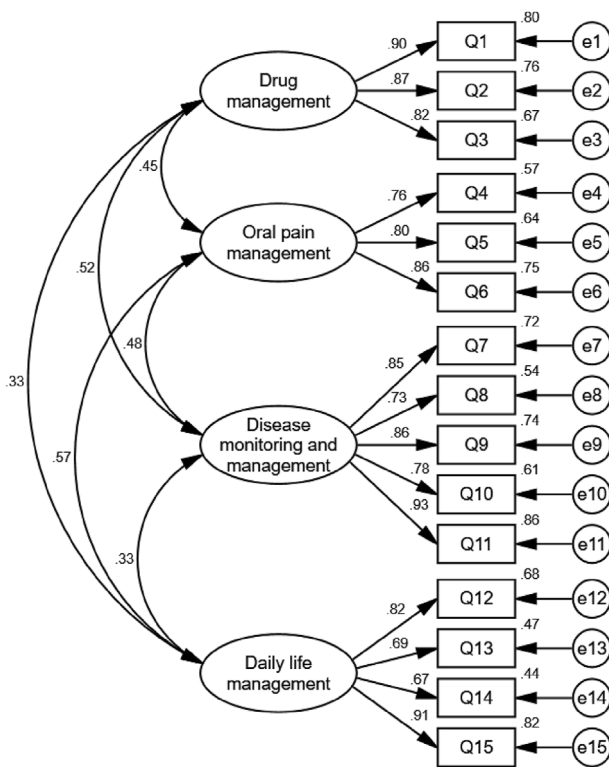


Fig. 3. Results of confirmatory factor analysis.

constructive opinions and suggestions for this study. All requirements regarding the expert authority coefficient, importance score assignment, variation coefficient, and Kendall coordination coefficient were met. Furthermore, the expert opinions exhibited a relatively high level of concentration. The items underwent rigorous screening, and group discussions were organized to ensure the scale's representativeness and differentiation. In conclusion, the scale developed in this study was highly scientific.

The results of the content validity analysis revealed that the S-CVI (0.91) exceeded the threshold of 0.800, while the I-CVI ranged from 0.80 to 1.000, surpassing the minimum requirement of 0.700, thus indicating satisfactory content validity.⁴⁶ The model was tested using CFA, which showed a good fit between the model and the data. An RMSEA less than 0.08 is considered a close fit; the GFI, CFI, NFI, IFI, and TLI of the obtained model are all greater than 0.90, and the values of χ^2/df and RMSEA also supported the acceptable fit of the model.⁴⁸ The results of the CFA analysis showed that the relevant indicators meet the established standards, thereby indicating a high level of congruence and strong structural validity for the scale. The results of the reliability analysis revealed that Cronbach's α coefficient for the overall scale was 0.902, with each dimension ranging from 0.856 to 0.910, indicating a high level of internal consistency and reliability within the scale.⁴⁶ The split-half reliability coefficient for the total scale was determined to be 0.849, while dimensions exhibited split-half reliabilities ranging from 0.866 to 0.946, suggesting strong homogeneity among items.⁴⁶ Furthermore, a test-retest reliability coefficient of 0.862 was obtained after a two-week interval, demonstrating excellent stability in the measurement.

Self-management refers to a health-promoting behavior that changes lifestyles by managing disease symptoms, treatments, and physical and psychological conditions, to reduce the impact of disease on the quality of life; it is a promising strategy for curing chronic diseases—Forward education, which teaches individuals to actively identify challenges and address disease-related problems.⁴⁹ This study adheres strictly to the scale production process under the context of China, taking into account of the specific characteristics of RIOM/CIOM

cancer patients, to provide a more scientifically rigorous and targeted evaluation tool. In summary, the overall content of the scale is comprehensive and scientifically sound, thereby exemplifying its specialized characteristics.

Implications for nursing practice and research

The SMS-RIOM/CIOM is suitable for the rapid and dynamic evaluation of the self-management ability of patients undergoing radiotherapy and chemotherapy in different clinical periods. Compared to previously common scales, such as the WHO Oral Mucositis Assessment Scale,³⁶ Oral Assessment Guide,³⁷ and Oral Mucositis Daily Questionnaire,^{36,38} the novelty of this scale lies in focusing on self-management related to oral mucositis in survivors. It uses positive and effective self-management behaviors to reduce the side effects and risks of cancer treatment, thus presenting a new perspective for improving the quality of life of survivors undergoing radiotherapy and chemotherapy. Questionnaires were conducted among cancer survivors when they were admitted to the hospital, the nurses can screen patients with the least manpower and material resources, accurately locate their cognitive blind spots, identify the internal mechanism and core factors that affect their health behavior and compliance behavior, and then provide personalized guidance for patients, which is conducive to maximizing patients' disease cognition and optimizing self-management, and can also be used as an evaluation tool for the implementation effect of health education. The findings of this study can serve as a reference for the implementation of preventive measures against oral mucositis in survivors. However, the specificity of each survivor, including their individual risk factors for developing oral mucositis and current primary care concerns, should be noted.

Limitations

This study has several limitations. First, the use of convenience sampling from a single hospital may restrict the generalizability of the findings, thereby posing challenges when applying the scale to a broader population of cancer survivors. In future research, a more scientific sampling method could be used to randomly select representative research objects from different hospital levels for multicenter and large-sample research to further verify and improve the scale. Second, cultural differences, language translation, time changes, and other factors should be considered when using the SMS-RIOM/CIOM in different countries. For example, cultural differences greatly influence the cognition, emotion, and behavior of things, and these differences may limit the applicability of existing scales to different cultural backgrounds. For example, differences in diet may affect people's understanding of and answers to the questions on the scale. Our research did not test criterion validity, which might have caused deviations in the results. We will select appropriate criterion to conduct the test of criterion validity in future research. Further investigation is warranted to assess the scale's reliability and validity across various patient cohorts and health care contexts. This cross-sectional study identified the characteristics and factors influencing the self-management abilities of RIOM/CIOM cancer survivors. Moreover, longitudinal studies can assess the scale's capacity to detect changes in SMS-RIOM/CIOM over time and its predictive validity for long-term self-management behaviors. Additionally, exploring the scale's sensitivity to interventions would yield valuable insights and further investigation is warranted to ascertain its applicability across diverse patient populations and settings, particularly among elderly patients. Overall, these subsequent investigations will enhance the scale's utility and expand its application in clinical practice and research.

Conclusions

This study successfully developed and validated the SMS-RIOM/CIOM through a rigorous scale development and validation methodology, the scale was refined to include four dimensions with 15 items. The scale demonstrated good psychometric properties, characterized by high

levels of reliability and validity, rendering it a valuable instrument in clinical practice. The assessment results of this tool can help medical staff and patients themselves understand the deficiencies in self-management of oral mucositis during radiotherapy and chemotherapy, facilitate targeted education and prevention provided by medical staff, and strengthen the self-management ability of survivors. Advancing interventions to reduce the occurrence of oral mucositis will significantly impact the clinical outcomes for survivors. However, further research is required to validate its applicability to diverse patient groups and settings. Overall, the scale has significant potential to enhance the support and care offered to RIOM/CIOM cancer survivors.

CRedit authorship contribution statement

Hanfei Cui: Writing – Original draft, Validation, Methodology, Investigation, Formal analysis. **Qingkun Han:** Writing – Original draft, Validation, Methodology, Investigation, Formal analysis. **Yulian Wei:** Validation, Methodology, Investigation, Formal analysis. **Juan Qiao:** Supervision, Resources, Methodology, Conceptualization. **Xiaohong Ji:** Writing – review & editing, Validation, Supervision, Resources, Methodology. **Yuanyuan Li:** Investigation, Formal analysis, Resources. **Xuebing Jing:** Writing – review & editing, Visualization, Validation, Supervision, Resources, Methodology, Conceptualization. **Xiaojie Fang:** Writing – review & editing, Visualization, Validation, Supervision, Resources, Methodology, Conceptualization. All authors had full access to all the data in the study, and the corresponding author had final responsibility for the decision to submit for publication. The corresponding author attests that all listed authors meet authorship criteria and that no others meeting the criteria have been omitted.

Ethics statement

The study was approved by the Medical Ethics Committee of Zibo Central Hospital (IRB No. 20240149) in accordance with the principles outlined in the Declaration of Helsinki, and written informed consent was obtained prior to conducting the survey.

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Declaration of competing interest

The authors declare no conflict of interest.

Data availability statement

The data that support the findings of this study are available from the corresponding author, X. Fang, 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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