



Development and Content Validity of the Self-Care of Oral Anticancer Agents Index (SCOAAI)

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ABSTRACT

Objective: To develop and test the content validity of the Self-Care of Oral Anticancer Agents Index (SCOAAI). **Data Sources:** SCOAAI items were developed according to the CONsensus-based Standards for the selection of health Measurement INSTRuments (COSMIN) criteria. The Middle Range Theory of Self-Care of Chronic Illnesses informed item generation. A four-phase procedure was followed; Phase 1: items were created based on a previous systematic review and a qualitative study; Phase 2: the SCOAAI comprehensibility and comprehensiveness were established through qualitative interviews with clinical experts and with patients (Phase 3); and Phase 4: the SCOAAI was then administered through an online survey to a group of clinical experts for the Content Validity Index (CVI) calculation.

Conclusion: The first version of the SCOAAI included 27 items. Five clinical experts and 10 patients tested the comprehensiveness and comprehensibility of instructions, items, and response options. Fifty-three experts (71.7% female, mean experience with patients on oral anticancer agents 5.8 years [standard deviation \pm .2]; 66% nurses) participated in the online survey for content validity testing. The final version of the SCOAAI includes 32 items. Item CVI ranges between 0.79 and 1; the average Scale CVI is 0.95. Future studies will test the psychometric properties of the tool.

Implications for Nursing Practice: The SCOAAI showed excellent content validity, confirming its usefulness for assessing self-care behaviors for patients on oral anticancer agents. By implementing this instrument, nurses could define and implement targeted interventions for improving self-care and obtaining more positive outcomes (eg, better quality of life, reduced hospitalizations and emergency department visits).

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Introduction

In the last two decades, the use of oral anticancer agents (OAAs) has increased due to the growing number of patients diagnosed with cancer.¹ To date, OAAs are about a quarter of the currently available anticancer agents and include both cytotoxic and targeted drugs.²

Patients have many advantages when treated with OAAs, including better treatment satisfaction, less treatment burden,³ less of a

negative impact on daily life and relationships, greater treatment adaptability, and better autonomy.^{4,5} Moreover, patients generally prefer OAAs because they can manage their treatment at home.⁶

Although patients prefer OAAs, these medications can cause comparable problems to intravenous agents. In fact, patients treated with these drugs can have diarrhea, decreased white blood cell counts, fatigue, anemia, nausea, and musculoskeletal pain similar to patients treated with intravenous anticancer therapies.^{7,8} Also, because OAAs are autonomously managed by patients, with less contact with the cancer team, this regime is often associated with poorer adherence to treatment.⁹⁻¹¹

To prevent all of the aforementioned problems, patients treated with OAAs not only need to adhere to the pharmacological treatment

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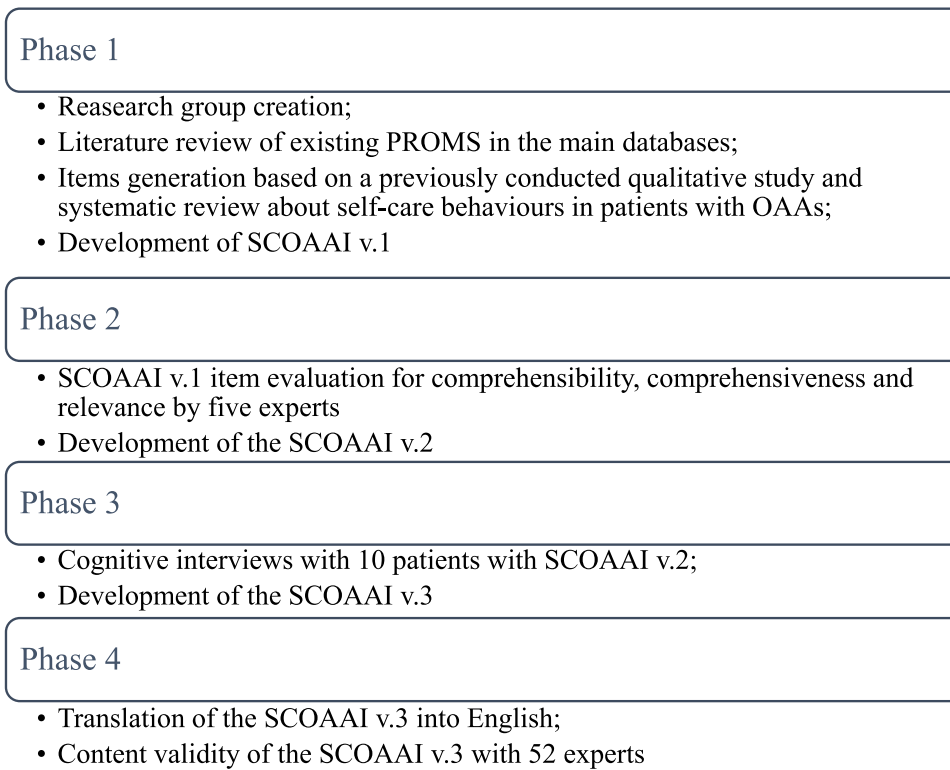


FIG 1. Study phases.

(ie, taking the medications as prescribed) but also to perform several self-care behaviors to maintain good health and avoid complications.

According to Riegel et al,¹² self-care is the process used by the patient to ensure physiological and emotional stability (self-care maintenance), detect the occurrence of signs and symptoms of a condition (self-care monitoring), and put in place adequate behaviors when they recognize elements of exacerbation (self-care management). These theoretical principles also fit OAA treatment because patients taking these medications need to perform those behaviors aimed at maintaining good clinical stability (eg, eating healthy food or getting enough sleep), monitoring their health condition (eg, specific side effects), and managing eventual complications caused by the treatment (eg, contacting the health care provider in the case of unmanageable symptoms). Good self-care in patients with cancer was found to be associated with many positive outcomes, such as fewer rehospitalizations, fewer emergency attendances,^{13,14} and a better quality of life.¹⁵

There are literature reports of two instruments to measure self-care in patients on OAAs: the Leuven Questionnaire for Patient Self-care during Chemotherapy (L-PaSC) and the Oral Chemotherapy Self-Management Scale (OCSMS). The L-PaSC¹⁶ is composed of 22 items that are grouped into two factors (adhering to treatment recommendations and managing treatment-related events and relieving symptoms). This instrument evaluates self-care but was not specifically designed for patients taking OAAs, with only three items focused on OAAs. Also the L-PaSC mainly focuses on the management of physical symptoms and does not consider psychological symptoms that could be present in this population.

The OCSMS¹⁷ includes 36 items that are divided into five factors (daily life management, symptom management, medication management, emotional cognitive management, and social support). Although this instrument is specific for patients taking OAAs, the OCSMS mainly focuses on the management of complications related to oral chemotherapy and does not consider self-care maintenance and self-care monitoring behaviors, which are also important for patients taking OAAs.

Indeed, a recent systematic review¹⁸ and a qualitative study¹⁹ identified several self-care behaviors that patients on OAA treatment

need to perform, which are not considered in the existing instruments. Beyond adherence to pharmacological treatment, the two studies emphasized that patients taking OAAs should perform several self-care behaviors, for example, related to eating habits, physical activity (self-care maintenance), symptom monitoring, early detection of side effects related to OAAs (self-care monitoring), and for managing the side effect of OAAs, such as alerting the health care provider or taking specific medicines (self-care management). Because all of these self-care behaviors are essential but not considered in the existing instruments, a new tool is needed to measure self-care in the three dimensions of self-care maintenance, monitoring, and management. This instrument would be helpful for health care professionals to ensure the effectiveness and safety of OAA regimens and encourage, as much as possible, the possibility for the patient to continue taking medicines at home while promoting their lifestyle.²⁰ Therefore, this study aimed to develop the Self-Care of Oral Anticancer Agents Index (SCOAAI) and test its content validity.

Methods

The development and the content validation of the SCOAAI were performed in four phases in line with the Consensus-based Standards for the selection of health Measurement INstruments (COSMIN) methodology.²¹ Fig 1 shows the study phases.

Phase 1. First, a research group including seven experts was set up. The research group included two clinical nurses, one oncologist with OAA expertise, and four researchers. In particular, one researcher was an expert in the theory of self-care, one in qualitative analysis, and one in quantitative analysis. Patient-reported outcomes measurement (PROM) databases, including Patient-Reported Outcomes Measurement Information System (PROMIS), Core Outcome Measures in Effectiveness Trials (COMET), and COSMIN, were analyzed to identify existing self-care instruments for patients on OAAs. Then a systematic literature review and qualitative study,^{18,19} which were previously conducted by the research group, were taken into consideration during this phase for the item generation. Furthermore,

the guidelines of the main oncological scientific societies were consulted (ie, European Society for Medical Oncology, Oncology Nursing Society) to identify the main side effects of OAA and how to prevent and manage them. All of these sources were used to create a first draft of the SCOAAI (V.1) consisting of 27 items. Items were then grouped into the three theoretical dimensions of self-care maintenance, self-care monitoring, and self-care management. A 5-point Likert scale of frequency ranging from 1 (never) to 5 (always) was chosen for the response format of the items in the self-care maintenance and self-care monitoring dimensions. A 5-point Likert scale of likelihood ranging from 1 (not at all likely) to 5 (totally likely) was chosen for the response format of the items in the self-care management dimension. Higher scores indicate more adequate self-care.

Phase 2. In the second phase, SCOAAI V.1 items were revised by a group of five experts. These experts had a degree in medicine or nursing; a specialization in oncology, hematology, or palliative care; and had been working in an oncological setting with patients on OAA for at least 6 months. The meetings with the experts were conducted online because of coronavirus disease 2019 (COVID-19) restrictions and had the objectives of assessing the comprehensibility, comprehensiveness, and relevance of each SCOAAI V.1 item or modifying, eliminating, or adding new items. Thus, the SCOAAI V.2 was created with 42 items.

Phase 3. SCOAAI V.2 was then administered to a group of 10 patients taking OAA for at least 3 months, through cognitive interviews, to verify, also with them, the comprehensiveness and comprehensibility of the instrument. These patients were six females and four males, with an average age of 67.2 (standard deviation 9.7), had used OAA for a mean of 5.7 months (standard deviation 3.8), and had lung cancer (n = 6), renal cell carcinoma (n = 2), colorectal cancer (n = 1), or prostate cancer (n = 1). The OAA taken by these patients were Afatinib (n = 3), Sunitinib (n = 3), Alectinib (n = 1), Bevacizumab (n = 1), Gefitinib (n = 1), and Pazopanib (n = 1). For these purposes, the think-aloud technique²² was used. Specifically, each patient was asked to read aloud each item and then report what the item meant. Minimal revisions were made after the cognitive interviews as suggested by patients to improve comprehensibility. After the completion of this phase, the SCOAAI V.3 was created, with 32 items.

Phase 4. The Italian version of SCOAAI V.3 was then translated into English by a researcher who is fluent in both in Italian and English. The English translation was evaluated by two nurses with PhDs and who are native English speakers, with long expertise in oncology or self-care. Thus, the Italian and English versions of the SCOAAI V.3 underwent content validity with another group of national and international experts. These experts were recruited using convenience criteria and included clinicians caring for patients on OAA and working in several fields (oncological, hematological, and palliative care). From these experts, we also collected sociodemographic and professional data (role and professional background, years of work experience, years of experience in oncology, gender, and degree).

Data Analysis

Sociodemographic and professional data of the experts who participated in the content validity phase (Phase 4) were analyzed with descriptive statistics. For the calculation of the Content Validity Index (CVI), the experts had to evaluate each item relevance by using a 4-point Likert scale ranging from "Totally irrelevant" (score 1), to "Irrelevant" (score 2), "Relevant" (score 3), and "Totally relevant" (score 4). This approach was chosen to avoid neutral answers. After collecting all experts' responses, the score 1-4 was dichotomized into two categories: scores 1 and 2, indicating irrelevant items, became 0 and scores 3 and 4, indicating relevant items, became 1. Then the CVI was calculated for each SCOAAI item by summing all the relevant scores (categorized as 1) attributed by each expert to the item (I-CVI) divided by the number of experts interviewed. We also computed

TABLE 1
Sociodemographics Characteristics of Experts Involved in the Online Survey (n = 53).

Variables	N	Mean ± SD
Gender		
Male	15	
Female	38	
Professional background		
Nursing	35	
Medicine	18	
Country		
Italy	51	
Australia	1	
US	1	
Highest degree held		
Degree in Medicine and Surgery	16	
Bachelor's Degree in Nursing	32	
Master's Degree in Nursing Science	3	
PhD	2	
Years of Experience With Patients on OAA		5.8 ± 0.16

OAA = oral anticancer agent; SD = standard deviation.

the scale content validity (S-CVI) by combining all I-CVI scores divided by the total number of items (S-CVI average). An I-CVI >0.78 is considered excellent, a score between 0.70 and 0.79 implies that the item needs revision, while a score <0.70 indicates that the item should be deleted. For S-CVI, a score >0.90 is considered to show excellent content validity.^{23,24}

Results

Sociodemographic characteristics of clinical experts who participated in the content validity (Phase 4) of the study are reported in Table 1. In total, there were 53 clinical experts; they were mostly female (n = 38), with a nursing degree (n = 35), from Italy (n = 51), and with an average of 5.8 years of expertise with patients treated with OAA.

Results of the content validity analysis are reported in Table 2. We found excellent agreement among participants with the I-CVI ranging from 0.79 for item 30, related to the use of stress reduction practices, to 1 for seven out of 32 items (eg, item 32 related to telling the health care provider about symptoms). None of the items fell below the acceptable cutoff of <0.78²³ and only four items scored <0.90. Also, the S-CVI for the total SCOAAI was very high, with a value of 0.95.

Discussion

Considering the increasing use of OAA and the importance of self-care behaviors in patients with cancer,¹³ we developed the SCOAAI, a self-care PROM for patients taking OAA and tested its content validity. To the best of our knowledge, this is the first theoretically driven instrument to measure self-care behaviors in this population in a comprehensive manner, considering behaviors that can help to maintain the stability of patient conditions, monitoring the occurrence of treatment complications, and dealing with these complications at their onset.

In line with other instruments that evaluate self-care in chronic conditions, the application of the SCOAAI can investigate all of the aspects that need to be managed by a patient living with cancer, which is considered a chronic condition, in a broader way.²⁵ Moreover, because OAA are quite novel treatments that can lead to novel problems, the early identification of physical and psychosocial issues related to these anticancer agents is fundamental for enhancing patients' quality of life.²⁶ Thus, the SCOAAI can be considered an innovative and advantageous tool that could improve existing approaches to self-care assessment, helping to identify all of the above physical and psychological issues.

TABLE 2
I-CVI Scores of the SCOAAI V. 3.0

Scales	Item n°	Item text	I-CVI
Instructions: In reference to the cancer medication that you take, how often do you do the following? (tick the corresponding number)*			
Self-care Maintenance	1	Follow the recommendations of healthcare providers	0,98
	2	Take the cancer medication as prescribed	0,96
	3	Attend all medical visits as scheduled	0,98
	4	Use a system/method that helps you to remember to take your medications (e.g., calendar, writing on medication boxes, etc.)	0,92
	5	Only take medication recommended by your healthcare providers	0,98
	6	Do physical activity (e.g., walking, cycling, etc.) within the limits of your possibilities	0,98
	7	Eat sufficiently and with healthy food	0,96
	8	Take liquids adequately (e.g. 1-1.5 litres of water per day)	0,96
	9	Get enough sleep to feel rested	0,94
	10	Refrain from tobacco	0,90
	11	Limit drinking alcohol	0,84
	12	Asking healthcare providers about your cancer medications	0,92
	13	Maintain good oral hygiene	1
	14	Preventing infections (e.g., by washing your hands often, getting vaccinated against the flu, etc.)	0,96
	15	Limit situations that can bring to physical and/or emotional stress	0,90
Instructions: Regarding the cancer medications you take, how often do you monitor the following? (tick the corresponding number)*			
Self-care monitoring	16	Cancer medication side effects	0,94
	17	New symptoms	1
	18	Decrease or increase in appetite	1
	19	If you have constipation or diarrhoea	0,98
	20	Whether you tire more than usual doing normal activities	1
	21	Skin and nail changes	0,96
	22	Your pain level	0,96
	23	The colour and the quantity of your urine	0,90
	24	Your mouth, teeth and eyes	1
	25	Any measurement your healthcare provider recommends (e.g., blood pressure, heart rate, etc.)	0,94
	26	Your weight	0,94
Instructions: When you have symptoms attributable to the cancer medication(s) (e.g., nausea, vomit, constipation, diarrhoea, fatigue, etc.), how likely are you to do the followings? (tick the corresponding number) [†]			
Self-care management	27	Modify your daily routine (e.g., modifying the diet, the time of daily life activities, etc.)	0,84
	28	Implement home remedies that help you reduce symptoms (e.g., hot/cold packs, drink cola, etc.)	0,88
	29	Take prescribed medication to reduce symptoms	0,98
	30	Use stress reduction practices (e.g., yoga, outdoor activities etc.)	0,79
	31	Contact your doctor or nurse to ask what to do if you have symptoms that you are unable to manage	1
	32	Tell your healthcare provider about the symptom at the next oncological visit	1

I-CVI = item-content validity index; SCOAAI = Self-Care of Oral Anticancer Agents Index.

* For the scales of Self-care maintenance and self-care monitoring, items are scored with a Likert scale from 1 to 5, where 1 = Never, 2 = Hardly ever, 3 = Sometimes, 4 = Often, 5 = Always.

[†] For the self-care management scale, items are scored with a Likert scale from 1 to 5, where 1 = Not at all likely, 2 = Not very likely, 3 = Quite likely, 4 = Very likely, 5 = Totally likely.

The SCOAAI items were created considering all the dimensions of self-care according to Riegel's theory of self-care in chronic conditions (ie, self-care maintenance, monitoring, and management)¹² and tailored to patients taking OAs. The self-care maintenance dimension includes all of the behaviors that allow patients to keep their condition stable. Adequate pharmacological adherence is certainly included in these behaviors. Literature supporting such adherence for patients with cancer is growing and its measurement is crucial to improve the disease course of patients. However, the SCOAAI not only measures pharmacological adherence but also several other aspects, such as a healthy lifestyle,²⁷ psychological aspects,²⁶ and infection prevention,²⁸ which may enhance patients' quality of life. Moreover, all these self-care maintenance behaviors can contribute to better OAA therapeutic effects and, thus, the longer stability of oncological disease.⁶ As a result, compared with other instruments measuring adherence in the literature, the SCOAAI may allow a more in-depth assessment of those behaviors that patients put in place to improve the control of their disease.

The dimension of self-care monitoring refers to all behaviors that patients should put in place to monitor the occurrence of signs and symptoms related to the use of OAs. Monitoring whether adverse events occur is essential for patients using OAs to ensure an excellent clinical course. However, these events are often underestimated,¹⁹ potentially leading to patient hospitalization,²⁹ increased distress, a worse quality of life, more frequent visits to the emergency department, and an increase in public health costs. Measuring self-

care monitoring can prevent numerous adverse outcomes, providing the possibility for health care providers and patients, if educated, to intervene as soon as a sign or a symptom of worsening condition appears. Indeed, Dürr et al⁷ have already demonstrated that counseling interventions to encourage the recognition of adverse events related to taking OAs effectively reduce unplanned hospitalizations. Thus, based on the SCOAAI score for self-care monitoring, health care professionals can carry out tailored interventions to educate patients to self-monitor specific parameters, allowing them to continue to manage their disease at home.

The SCOAAI also offers the ability to assess self-care management, defined as the patient's ability to implement the proper behavior when recognizing elements of any symptom exacerbation. These include behaviors to manage treatment-related side effects (actions the individual put in place in case of the OAs side effects). It is essential to consider the dimension of self-management in a tool that evaluates self-care because patients can recognize the side effects of OAs early and activate strategies to manage them. Inadequate patient symptom management can result in neglected and untreated symptoms that hamper an individual's ability to continue their activities of daily living,³⁰ thereby worsening the quality of life. Systematic evaluation of patients' ability to manage adverse events is therefore necessary to ensure medication safety and identify problems in managing these events even when patients do not report them directly. The ability to manage issues arising during the disease course is also important because patients with cancer may experience signs or

symptoms related to the worsening of the disease or interaction of OAs with other drugs.³¹ Furthermore, improving self-care behaviors in symptom management could prevent the negative consequences of neglecting exacerbation of the disease and increase the quality of life in patients taking cancer medications.^{32,33}

This study tested SCOAAI content validity, which is considered one of the most important steps of a PROM.²¹ All content validity steps followed the COSMIN methodology to ensure the highest quality of the measurement tool. We generated SCOAAI items by performing a systematic review¹⁸ and a qualitative study¹⁹ and by consulting PROM databases and OAA guidelines. Furthermore, we consulted experts in the field, performed cognitive interviews with patients, and established the content validity of the SCOAAI with an adequate number of clinical experts. In other words, we adopted the most comprehensive approach to develop the SCOAAI and test its content validity, one of the most important steps of a PROM, in line with the COSMIN recommendations. On average, the S-CVI was 0.95, which is a very high coefficient, and only item 30 “Use stress reduction practices (e.g., yoga, outdoor activities, etc.)” in the self-care management scale did not achieve an excellent score (0.79). However, this score remains higher than the threshold of acceptability, which is 0.78. Considering that no comments regarding comprehensibility were left for this item, the low score could be due to the lower importance given by patients to stress-reduction activities compared to taking medications to manage the side effects of OAs. From the results obtained from this content validity process, the tool captured all of the relevant aspects describing self-care in patients with cancer using OAs.

Limitations

This study has some limitations. The first limitation concerns the study design because we only developed the instrument and tested its content validity. For these reasons, the instrument cannot yet be used in clinical practice and research because we still have to test SCOAAI psychometric properties by testing its factorial structure, construct validity, and reliability. However, the development phases and content validity testing are two essential steps to obtain a psychometrically sound instrument. Another limitation can be found in the sampling method that we adopted for content validity, which was based on a “convenience approach” with only two international experts. Moreover, the patients recruited to test comprehensiveness and comprehensibility of the instrument were all on targeted therapy. However, the aim of phase 3 of this study was to assess the patients’ understanding of the instrument; thus, the comments obtained can be considered reliable.

Implications for Nursing Practice

The SCOAAI has proven to have good content validity and is ready for subsequent validation steps. Once implemented, it can have a significant impact on the nursing care of patients taking OAs; first, because the use of a scale assessing patient self-care provides information on what behaviors can be implemented or supported with tailored nursing interventions, aimed at obtaining positive outcomes on patients (eg, better quality of life, reduced hospitalizations and emergency department visits) and second, because it can be a useful tool in the research on the effectiveness of the nursing interventions where the expected outcome is self-care.

Conclusion

In conclusion, in this study, we have developed a new instrument to measure the self-care maintenance, monitoring, and management of patients treated with OAs and have tested its content validity with excellent results. Considering the lack of validated and theory-based tools in the literature to evaluate self-care in patients taking

OAs, the SCOAAI can become an essential and valuable instrument to support oncology clinical practice. Also, the SCOAAI, once fully tested, can be used in research to identify predictors and outcomes of self-care in patients taking OAs and could be used to tailor interventions aimed at improving self-care in this population. Following the same procedures adopted in other self-care instruments guided by the middle range theory of self-care in chronic illness, we will test the self-care maintenance, self-care monitoring, and self-care management dimensions as three separate scales because it is important to have a score for each dimension rather than an SCOAAI total score.

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Supplementary materials

Supplementary material associated with this article can be found in the online version at doi:[10.1016/j.soncn.2023.151402](https://doi.org/10.1016/j.soncn.2023.151402).

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