# Development of the Opioid Self-Management Scale for Advanced Cancer Patients and Examination of its Validity and Reliability

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# Abstract

**Background:** Approximately 60% of outpatients with advanced cancer experience pain, and self-management with opioids according to lifestyle is important for appropriate pain relief. To date, there are no studies that clearly describe the concept of opioid self-management or that have assessed the factors involved, such as improving self-management abilities. This study developed the Opioid Self-Management Scale for Advanced Cancer Patients (OSSA), and examined its validity and reliability.

**Methods:** The scale was developed in three phases. In phase 1 the scale content was validated. In phase 2 surface validity was examined. The surface validity was examined using a draft scale that extracted qualitatively and deductively. Phase 3 validated and verified the reliability of the OSSA. The validity and reliability were examined using a factor analysis and re-testing.

**Results:** The OSSA consists of 33 items on six subscales. The structural equation modeling was such that the $\chi^2$ value was 709.8 ($p<.001$, df = 467), goodness-of-fit index 0.78, adjusted goodness-of-fit index 0.73, root mean squares of approximation 0.063, and comparative fit index 0.92. Cronbach's α was 0.93. The intraclass correlation coefficient was 0.59–0.90. The coefficient was -0.21 ($p<0.05$) for the total OSSA score and "Average pain over 24 hours," and 0.26 ($p<0.01$) for "Rate of pain relief over 24 hours."

**Conclusion:** We determined that the OSSA had tolerable validity and reliability, and the results indicated that a higher self-management ability leads to greater pain relief. The OSSA scales can be considered effective for use in research. A shortened version of the OSSA is required for realistic and practical clinical use.


# Background

Approximately 60% of outpatients with advanced cancer experience cancer pain, and approximately 20% experience moderate to severe cancer pain [1]. Cancer pain is complicated by tumor growth and metastasis, and is a factor that reduces patients' quality of life (QOL). It is presumed that patients have difficulties coping with the pain symptoms that they experience outside the hospital.

Although it is important to deal with total pain, approximately 90% of pain is relieved by pain treatment methods, according to the World Health Organization (WHO) Analgesic Ladder, which focuses on opioid use [2]. However, patients with strong concerns about opioids experience poor pain relief and a poor QOL due to inadequate medication [3, 4]. Patients should reduce their concerns about cancer pain and opioids and consult healthcare providers to receive appropriate opioids for effective cancer pain alleviation. If existential pain increases patient distress, patients need to develop problem-oriented coping mechanisms, such as consulting healthcare providers, family members, and friends.

In Japan, regular opioid administration, use of rescue medication for breakthrough pain, sufficient countermeasures against side effects, use of appropriate analgesic aids, and patient education, which constitute the WHO cancer pain treatment methods, are recommended for effective pain relief [5]. Such

support is implemented during patients' admission and includes support to increase self-efficacy [6], support to increase self-care abilities [7, 11], and support to reduce concerns about cancer pain and opioids [12, 13]. However, these kinds of support are intended to alleviate cancer pain. To date there no studies that clearly describe the concept of self-management with opioids or self-management abilities. In a previous study, the authors focused on opioids that are effective for cancer pain, such that patients are relieved from pain and can live in their own way, and concepts for enhancement of self-management with opioids for patients with cancer were indicated [14, 15]. In this study, a concept related to self-management of patients with advanced cancer using opioids and a scale with items were generated, based on the concepts from previous studies. The developed scale will help to clarify the self-management abilities of patients in a clinical context and determine the need for nursing care according to whether an intervention is required for patient cognitive function, whether a mental intervention is needed, whether an intervention by adjustment of medication is needed, or whether adjustments are needed for the patient's living environment, based on the evidence of cancer pain alleviation. This scale is expected to help patients understand their way of life through self-management. Patients' maintenance or improvement of their self-management abilities will help them live autonomously, even as their activities of daily living (ADL) decline with disease progression. In the context of research, using this scale as an evaluation index for the development of new care methods would enable the measurement of the effectiveness of the care provided for patient self-management.

# Methods

The scale was developed using a draft scale consisting of items extracted quantitatively [14] and inductively from 10 home-based patients with advanced cancer who were receiving opioids. These items were extracted deductively from previous studies [4,5,15,20]. We examined the Phase 1 content validity and Phase 2 surface validity. A refined draft scale for the validity and reliability of the Opioid Self-management Scale for Patients with Advanced Cancer (OSSA) in Phase 3 was considered.

### Phase 1: Content Validity

*Participants and Procedures*

The inclusion criteria were 1) researchers with experience in cancer pain research and 2) physicians, pharmacists, specialists, and certified oncology nurses with direct involvement in cancer pain care. The exclusion criteria were 1) researchers with no experience in cancer pain research and 2) physicians, pharmacists, specialists, and certified cancer care nurses with no direct involvement in cancer pain care. The minimum calculated sample size was five [21]; therefore, we aimed to recruit at least five professionals from each category for a total of 30 researchers, physicians, pharmacists, and nurses as subjects.

Study information and questionnaire forms were given to the participants between August and October 2018. The variables of interest included occupation, specialist's qualifications, years of experience in cancer pain research or care, and draft scale 1. The scale consisted of 15 items on "Understanding pain

and opioids," 12 items on "Coping with pain by taking opioids," 3 items on "Coping with side effects of opioids," 5 items on "Having someone that can provide support," and 5 items on "Living in your own way while coexisting with the disease" for a total of 40 items in five subscales. The evaluation was conducted using the content validity ratio (CVR), and the subjects were asked to choose one of the following fitting responses: "Very appropriate," "Very appropriate but expression needs to be corrected," "There is a problem with the appropriateness," and "Inappropriate." The CVR was calculated using the formula:

$$\frac{ne - \frac{N}{2}}{\frac{N}{2}}$$

ne indicates the number of subjects who chose "Very appropriate" and "Very appropriate but expression needs to be corrected".  indicates the total number of subjects [22].

Furthermore, the subjects who chose "Very appropriate but expression needs to be corrected," "There is a problem with the appropriateness," and "Inappropriate" were asked to propose corrections, additions, and provide feedback.

*Data Analyses*

Using a CVR of 0.62 as the standard, items that did not meet the standard were deleted [23]. The participants' recommendations were discussed by two nursing researchers with experience in developing scales and five graduate students in nursing research. The items were then refined to create draft scale 2.

## Phase 2: Surface Validity

*Participants and Procedures*

The inclusion criteria were: 1) patients with advanced cancer, 2) administration of opioids for cancer pain alleviation, 3) over 20 years old, and 4) aware of the name of their disease. The exclusion criteria were: 1) patients without advanced cancer, 2) administration of opioids for other purposes apart from cancer pain alleviation, 3) younger than 20 years old, 4) aware of the disease name, and 5) having physical, mental, and cognitive disorders according to their responses. The sample size was 10 [19].

The information document of the study and questionnaire forms were given to the participants, who were outpatients in a designated cancer hospital in October 2018 and patients receiving home-based care. Subjects' submission of the questionnaire forms was considered consent provision. The assessed variables in the questionnaire were age, sex, performance status (PS), duration of opioid use, and draft scale 2. Draft scale 2 assessed the appropriateness of the responses, proposals for improvement, and participants' feedback: they were asked to comment freely.

*Data Analyses*

Two nursing researchers with experience in developing scales and five graduate students in cancer nursing research discussed the choice of expressions for the items, refined the items, and created draft scale 3.

## Phase 3: The Validity and Reliability of the OSSA

*Participants and Procedures*

The inclusion and exclusion criteria for Phase 3 were the same as those for surface validity. The calculated sample size was 130. Based on an α coefficient of 0.90, confidence interval of 0.05, and estimated response rate of 60% [19], 210 subjects were recruited.

The information document of the study and questionnaire forms were given to the participants, who were outpatients at three designated cancer hospitals. The questionnaires were self-administered and returned on site or via mail. Submission of questionnaire forms by patients was considered consent provision. Patients were re-tested one week later, and the forms were mailed back.

*Measures*

*Participant Characteristics*

Patient characteristics included age, sex, PS, presence or absence of a caregiver, employment form, patient history, disease evolution, treatment history, types of opioids, opioid doses used, duration of opioid use, type of pain and extent of pain (was assessed using the numeric rating scale [NRS]: most intense pain, average pain, and pain that interferes with daily life activities; and the rate of pain relief over a 24-hour period).

*OSSA*

Draft scale 3 was used. Each score is a Likert scale score ranging from 1 point for “No” to 5 points for “Yes.” Higher scores indicate greater self-management ability.

*Self-Care Agency Questionnaire（SCAQ）* [24]

There are 29 items in four subscales, including 10 items on “Ability to perform self-care operations,” 7 items on “Ability to adjust one’s own physical condition based on personal weaknesses,” 7 items on “Ability to concentrate one’s attention on self-care,” and 5 items on “Ability to receive valid support.” The scores range from 1 point for “No” to 5 points for “Yes.” A higher score indicates greater self-care ability.

*Medication Adherence Scale* [25]

There are 12 items in 5 subscales, including “Medical compliance,” “Collaboration with healthcare providers,” “Willingness to access and use information about medication,” and “Acceptance to take medication and how taking medication fits patient’s lifestyle”; each has 3 items. The scores range from 1

point for “Never” to 5 points for “Always,” including two reverse items, with a higher score indicating greater medication adherence.

*Data Analyses*

All analyses were performed with SPSS version 24.0 for Windows (Japan IBM, Tokyo) and SPSS AMOS ver 26.0 (Japan IBM, Tokyo). The analyses included item analysis, exploratory factor analysis (maximum-likelihood estimation, promax rotation, factor loading of 0.45 or more), reliability (Cronbach’s α coefficient, intra-class correlation coefficient [ICC] by re-testing), coexistense validity (Pearson’s correlation coefficient between the OSSA, SCAQ and medication adherence scale), multitrait scaling analysis, confirmatory factor analysis (analysis of covariance), and probability of use (Pearson’s correlation coefficient) by testing the hypothesis—“Patients with high opioid self-management scale scores have a low intensity of pain.”

# Results

## Phase 1: Content Validity

*Sample Characteristics*

Questionnaires were sent to 67 individuals. Forty-four persons (9 physicians [20.5%], 32 nurses [72.7%], and 3 pharmacists [6.8%] ) responded and were included. The response rate was 65.7%.

*Content Validity*

The CVR for “Understanding pain and opioids” was 0.71–0.95. Of these sub-concepts, four respondents had similar answers to the two items: "Can you remember the date you took the painlillers" and "Can you remember the time you took the painlillers." Therefore, they were combined into one. The CVR for “Coping with pain by taking opioids” was 0.55–1.00. Two items with a CVR of 0.55 (“A generous quantity of painlillers can be prepared” and “How the painlillers are used can be adjusted according to the pain intensity”) were deleted. The CVR for “Coping with side effects of opioids” was 0.86–0.95. The CVR for “Having someone that can provide support” was 0.72–0.95. The CVR for “Living in your own way while coexisting with the disease” was 0.76–0.81. After the discussion on the changes of expressions used in the items, the data of a woman in her 30s, a woman in her 50s, and a man in his 60s, were used to create draft scale 2 that was made of 37 items.

## Phase 2: Surface Validity

*Sample Characteristics*

Ten persons were invited to participate, and they all responded. There were 4 men (40.0%). The average age of the participants was 56.5 (standard deviation [SD] = 10.1) years. The duration of opioid use was 21 (SD = 32.8) months. The most intense pain was 7.5 (SD = 2.1), and average pain was 4.5 (SD = 1.2).

*Surface Validity*

The subjects responded that 2 out of 37 items needed to have their expressions corrected. One of these was “I can keep as-needed painkillers in an easily accessible place” and the comments provided included “The expression ‘as-needed’ is difficult to understand. ‘Painkillers to take when pain is felt’ is better”. However, we decided to keep “as-needed painkillers” unchanged as it is a commonly used expression in clinical practice. The second item was “Can preventively use ‘use-as-needed’ painkillers before pain emerges,” and subjects commented “There are times when you don’t know when pain will emerge, so ‘predictable pain’ would be better”. We decided to replace with “For predictable pain, I can take as-needed painkillers preventively”.

Draft scale 3 was created after the discussions on the changes of the expressions.

## Phase 3: The Validity and Reliability of the OSSA

The questionnaires were distributed to 234 individuals, and responses were provided by 154 individuals (response rate of 65.8%). Of these, we excluded 20 inadequate responses and analyzed the responses from 134 forms (effective response rate of 87.0%).

*Sample Characteristics*

Table 1 lists the characteristics of the samples. Men accounted for 54.5% of the responses, and 63.2% had a PS of 1. Digestive cancer accounted for 56.5% of the cases, and around-the-clock opioid analgesic used was oxycodone at 76.5%.

*Validity and Reliability of the OSSA*

Table 2 shows the results of the item analysis of the 37-item opioid self-management scale for advanced cancer patients. In terms of skewness, 36 items showed negative values, and seven items had a kurtosis ≥3. There were no items with a floor effect, but there were 27 items with a ceiling effect. There were no items with an I-T correlation ≦ 0.2. We considered removing items with a ceiling effect. Since the participants were from a specialized cancer treatment center, they had coping mechanisms for intense pain. Since excluding these items at this stage could prevent proper measurement of the contents of interest, rather than deleting the items, they were reviewed using an exploratory factor analysis, and their validity and reliability were examined.

In the exploratory factor analysis of the 37-item OSSA, the Kaiser-Meyer-Olkin (KMO) value was 0.851 and p was <0.001 using Bartlett’s sphericity test. Based on the results of the scree plot, the eigenvalue was set at 6. Four items with a loading factor <0.45 were deleted, and 33 items were left. With this 33-item OSSA, the KMO value was 0.848, and p was <0.001 with Bartlett’s sphericity test. Table 3 shows the results of the factor analysis of the 33-item OSSA. As a result, it was 6 subscales.

Table 4 shows the Cronbach’s α. The α coefficient was 0.93, and the subfactors ranged from 0.78 to 0.93.

Table 5 shows the results of the coexistence validity of the OSSA and SCAQ. The total OSSA score was 0.59–0.75 for the total score of the SCAQ and the 4 subscales, showing a strongly significant correlation. The OSSA subscales "Recording pain and opioid use" and " Understanding the characteristics of pain" were uncorrelated with the SCAQ subscales "Ability to adjust one's own physical condition based on personal weaknesses" and "Ability to concentrate one's attention on self-care," respectively. Table 6 shows the results of the coexistence validity of the OSSA and medication adherence scale. The total OSSA score was 0.32–0.62 for the total score of the medication adherence scale and the score of the 4 subscales, showing a weak-to-strongly significant correlation. The OSSA subscale "Recording pain and opioid use" was uncorrelated with the Medication Adherence Scale subscale "Medical compliance" and "Collaboration with healthcare providers." The OSSA subscale "Living with the disease" was uncorrelated with the Medication Adherence Scale subscale "Medical compliance." The OSSA subscale "Understanding the characteristics of pain" was uncorrelated with the Medication Adherence Scale subscale "Medical compliance" and "Acceptance to take medication and how taking medication fits patient's lifestyle".

For the re-test, we analyzed responses from 107/133 responses (80.5%). Table 7 shows the results of the repeat reliability assessment. The intraclass correlation coefficient (ICC) was 0.62–0.86.

Table 8 shows the results of the multitrait scaling analysis. The discriminant correlation coefficient was -0.02–0.64. The convergent correlation coefficient was 0.54–0.96, and the scaling success rate was 100% for all items.

Figure 1 shows the results of the confirmatory analysis. The values were $\chi^2 = 709.8$ ($p<0.001$, $df = 467$), goodness-of-fit index (GFI) = 0.78, adjusted goodness-of-fit index (AGFI) = 0.73, root mean squares of approximation (RMSEA) = 0.063, and comparative fit index (CFI) = 0.92.

Table 9 shows the relationship between the OSSA and pain. There was a significant negative correlation ($r = -0.21$) between the total OSSA score and "Average pain in 24 hours," and a significant positive correlation ($r = 0.26$) between the total OSSA score and the "Pain relief rate in 24 hours" There were no significant differences in pain association between the subscales "Recording pain and opioid use" and "Understanding the characteristics of pain."

# Discussion

After examining the validity and reliability of the OSSA, we found that the OSSA consisted of six sub-concepts consisting of 33 items. The sub-concepts included " Managing opioids and coping with pain," "Talking to a healthcare provider," "Talking to friends and family," "Recording pain and opioid use," "Living with the disease," and "Understanding the characteristics of pain." In this study, we extracted concepts similar to OTSES-CA developed by Liang et al. [17], as well as the new concept of living with the disease. Pain is "an unpleasant sensory and emotional experience that occurs when some tissue damage actually occurs, when tissue damage is likely to occur, or when such tissue damage occurs" [26]. It has both psychological and physical aspects. Breivik reported that 32% of patients with cancer pain reported that

the pain makes them want to die [27]. Twycross mentioned that total pain is consisted of physical, mental, social, and spiritual aspects, and that relief of patient tension and diminished anxiety alleviates the perception of pain [28]. Factors that lead to refusal of opioid medication include the idea that pain is a sign that the cancer is getting worse, and the idea of gradual development of tolerance to opioids [29, 30]. Therefore, it is important to recognize that opioids are essential for patients with advanced cancer to help them adapt and live with disease.

In the confirmatory factor analysis, although the GFI of the model was ≥ AGFI, GFI was 0.78, and AGFI was 0.73, which were low. We believe that this is due to the large number of variables. The CFI (the closer to 1, the better the model) was 0.92, and RMSEA (0.05–0.08 is a reasonable fit) [31] was 0.06, which meant that there was a certain level of fitness.

The coexistence validity analysis confirmed the expected correlation and non-correlation between the OSSA and SCAQ and the medication adherence scale. Regarding the relationship between the OSSA and SCAQ, there was no correlation between the OSSA's "Recording pain and opioid use" and "Understanding the characteristics of pain" and SCAQ's " Ability to adjust one's own physical condition based on personal weaknesses" and " Ability to concentrate one's attention on self-care." This result indicates that the OSSA is the self-management of opioid medications to relieve pain. Regarding the relationship between OSSA and the medication adherence scale, there was no correlation between the OSSA's "Recording pain and opioid use," "Living with the disease," and "Understanding the characteristics of pain," and "Medical compliance" on the medication adherence scale. This result shows that since the medication adherence scale is specialized for adherence, it does not contain items related to specific coping measures associated with opioids, which can help improve the understanding of disease characteristics and measure the psychological adaptation to advanced cancer. As such, the OSSA showed a high coexistence validity. Furthermore, from the results of the examination of the discriminant validity, convergence validity and scaling success rate in a multitrait scaling analysis, we confirmed that the OSSA has a constructive validity.

In the reliability analysis, the α coefficient, which is ideally ≥ 0.7 for use in research and ≥ 0.9 for clinical use [31], was 0.93 for the OSSA, which suggests that the OSSA is sufficiently consistent. In re-testing, an ICC of 0.61–0.80 is considered substantial [31]. The ICC in this study was 0.62–0.86, confirming the high reproducibility of the OSSA. The aforementioned tests confirmed the acceptable validity and reliability of the OSSA, suggesting its readiness for practical use.

The results of the hypothesis testing were in line with the hypothesis that patients with a high opioid self-management had a significantly lower 24-hour average pain and a higher rate of pain relief. Furthermore, subscales such as Managing opioids and coping with pain, Talking to healthcare provider, and Talking to friends and family were shown to alleviate persistent pain. Our study supports the importance of compliance to medication [17], symptom-coping efficacy [32], and reception of help from those around [21] in alleviating pain.

In addition, living with the disease showed a significant increase in pain-relief rates. Patients with advanced cancer experience anxiety about an uncertain future and death. Anxiety about death exacerbates depression, mental distress, existential distress, social distress, etc. [33]. Pain is an unpleasant sensory and emotional experience [2], and since emotions are also involved, relief of psychiatric symptoms is effective for pain relief. Therefore, cognitive behavioral therapy and relaxation are recommended [34]. It has also been reported that having a positive mentality even in advanced cancer stages can reduce anxiety and depression, leading to a high QOL [35]. These suggest that care for mental and existential distress is important in treatment using opioids.

Our study had three limitations. First, our data had a ceiling effect. This can be explained by the fact that the study subjects were patients from dedicated cancer hospitals and had high pain-coping abilities. Going forward, we need to carry out further tests by accumulating data, including those from non-cancer-specialized hospitals. Second, we need to establish a cut-off value in future for the practical application of OSSA. Third, although 33 items are effective for use in research, it is not realistic for patients to answer 33 questions in a real-world clinical setting. In future, it will be necessary to develop a shortened version that can be used by many patients in clinical settings.

# Conclusions

In this study, we constructed an opioid self-management scale for advanced cancer patients and examined its validity and reliability. Based on the above, the OSSA, which consists of 33 items in 6 subscales, is a scale with acceptable validity and reliability and is fit for use.

# Abbreviations

ADL: activities of daily living; AGFI: Adjusted Goodness of Fit Index; CFI: comparative fit index CVR: content validity ratio; GFI: goodness of fit index; ICC: intraclass correlation coefficients; KMO: Kaiser-Meyer-Olkin; NRS: Numeric Rating Scale; OSSA: Opioid Self-management Scale for Patients with Advanced Cancer; PS: performance status; QOL: quality of life; RMSEA: root mean squares of approximation; SCAQ: Self-care Agency Questionnaire; SD: standard deviation; WHO: World Health Organization

# Declarations

**Ethics approval and consent to participate:** This study was approved by the Tohoku University Graduate School of Medicine Ethics Committee (2018-1-292). All methods were carried out in accordance with the ethical guidelines and regulations stipulated by this ethics boards. A participation request form and an anonymous questionnaire were given to identified patients who met the inclusion criteria. Patients who submitted completed questionnaires were considered to have consented to participate in the study.

**Consent for publication:** Not applicable

**Availability of data and materials:** The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

**Competing interests:** The authors declare that they have no competing interests.

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**Authors' contributions:** SY and FS designed the study. SY, KT, RS, and ST were responsible for participant recruitment. SY was responsible for data generation and analysis. SY, CT, and KS interpreted the data. All authors contributed to the manuscript preparation and approved the final version of the manuscript.

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# References

1. Yamagishi A, Morita T, Miyashita M, Igarashi A, Akiyama M, Akizuki N, et al. Pain intensity, quality of life, quality of palliative care, and satisfaction in outpatients with metastatic or recurrent cancer: a Japanese, nationwide, region-based, multicenter survey. J Pain Symptom Manage. 2012;43:503-14.
2. Takeda F. Japan: status of cancer pain and palliative care. J Pain Symptom Manage. 1993;8:425-6.
3. Ward SE, Carlson-Dakes K, Hughes SH, Kwekkeboom KL, Donovan HS. The impact on quality of life of patient-related barriers to pain management. Res Nurs Health. 1998;21:405-13.
4. Kondo Y, Shibuya S. Studies on concerns about morphine use and medication behavior in painful outpatients with cancer. J Jpn Soc Cancer Nurs. 2002;16:5-16(text in Japanese)
5. Japanese Society for Palliative Medicine, Palliative Medicine Guidelines Preparation Committee. Guidelines related to pharmacotherapy for cancer pain. Tokyo: Kanehara Publishing; 2014. p. 12-5, 18-83, 89-101, 122-6, 169-80, 212-9(text in Japanese)
6. Foster C, Breckons M, Cotterell P, Barbosa D, Calman L, Corner J, et al. Cancer survivors' self-efficacy to self-manage in the year following primary treatment. J Cancer Surviv. 2015;9:11-9
7. Rustøen T, Valeberg BT, Kolstad E, Wist E, Paul S, Miaskowski C. A randomized clinical trial of the efficacy of a self-care intervention to improve cancer pain management. Cancer Nurs. 2014;37:34-43.
8. Koller A, Miaskowski C, De Geest S, Opitz O, Spichiger E. Results of a randomized controlled pilot study of a self-management intervention for cancer pain. Eur J Oncol Nurs. 2013;17:284-91.
9. Rustøen T, Valeberg BT, Kolstad E, Wist E, Paul S, Miaskowski C. The PRO-SELF(©) Pain Control Program improves patients' knowledge of cancer pain management. J Pain Symptom Manage. 2012;44:321-30.
10. Miaskowski C, Dodd M, West C, Paul SM, Schumacher K, Tripathy D, et al. The use of a responder analysis to identify differences in patient outcomes following a self-care intervention to improve cancer pain management. Pain. 2007;129:55-63.

11. Miaskowski C, Dodd M, West C, Schumacher K, Paul SM, Tripathy D, et al. Randomized clinical trial of the effectiveness of a self-care intervention to improve cancer pain management. J Clin Oncol. 2004;22:1713-20.
12. Jahn P, Kitzmantel M, Renz P, Kukk E, Kuss O, Thoke-Colberg A, et al. Improvement of pain related self management for oncologic patients through a trans institutional modular nursing intervention: protocol of a cluster randomized multicenter trial. Trials. 2010;11:29.
13. Jahn P, Kuss O, Schmidt H, Bauer A, Kitzmantel M, Jordan K, et al. Improvement of pain-related self-management for cancer patients through a modular transitional nursing intervention: a cluster-randomized multicenter trial. Pain. 2014;155:746-54.
14. Yoshida S, Sato F, Takahashi C, Inoue m, Tomizawa A. Self-management of opioid analgesics for cancer pain relief by patients with advanced. J Jpn Soc Cancer Nurs. March 2021 Accept(text in Japanese).
15. Chiba S, Sato F, Sato N. Relationship between cancer pain self-management and pain in outpatients with advanced cancer taking opioid analgesics Palliat Care Res. 2019;14(2):113–26 (abstract in English, text in Japanese).
16. Liang SY, Yates P, Edwards H, Tsay SL. Opioid-taking tasks and behaviours in Taiwanese outpatients with cancer. J Clin Nurs. 2008;17:2079-88.
17. Liang SY, Yates P, Edwards H, Tsay S. Development and initial evaluation of reliability and validity of the opioid-taking self-efficacy scale. Oncol Nurs Forum. 2008;35:E62–9.
18. Liang SY, Yates P, Edwards H, Tsay SL. Factors influencing opioid-taking self-efficacy and analgesic adherence in Taiwanese outpatients with cancer. Psychooncology. 2008;17:1100–7
19. Arao H. Development of a Patient Self-Care Capacity Scale for Cancer Pain Management Doctoral Dissertation, Graduate School of Nursing. University of Hyogo. p. 1-122; 2008. (abstract in English, text in Japanese).
20. Japanese Society for Palliative Medicine. Pain treatment guide for patients and family. Tokyo: Kanehara Publishing; 2014. p. 26-59, 86-111. (text in Japanese).
21. Lynn MR. Determination and quantification of content validity. Nurs Res. 1986;35(6):382-5.
22. Kihara M, Kaji M, Kihara M. Theory and application of medical measurement scales 2016 Medical Science. International:23-5, 82-8, 284-6. (text in Japanese).
23. Clark LACD, Watson D. Constructing validity: basic issues in objective scale development. Psychol Assess. 1995;7(3):309-19.
24. Honjo K. Revision of the self-care agency questionnaire for patients with chronic illness. Journal of Japan Academy of Nursing Science. 2001;21(1):29-39. (abstract in English, text in Japanese).
25. Ueno H, Yamazaki Y, Yonekura Y, Park MJ, Ishikawa H, Kiuchi T. Reliability and validity of a 12-item medication adherence scale for patients with chronic disease in Japan. BMC Health Serv Res. 2018;18(1):592.

26. Merskey H. Pain terms: a list with definitions and notes on usage. Recommended by the IASP Subcommittee on Taxonomy. Pain. 1979;6:249.
27. Breivik H, Cherny N, Collett B, de Conno F, Filbet M, Foubert AJ, et al. Cancer-related pain: a pan-European survey of prevalence, treatment, and patient attitudes. Ann Oncol. 2009;20:1420-33.
28. Supervised and translated by Fumikazu Takeda: Symptom management of cancer patients by Dr. Twycross. Tokyo: Igaku Shoin; 2003. p. 17-75. (text in Japanese).
29. Gunnarsdottir S, Donovan HS, Serlin RC, Voge C, Ward S. Patient-related barriers to pain management: the Barriers Questionnaire II (BQ-II). Pain. 2002;99:385-96.
30. Sakakibara N, Komatsu H, Takahashi M, Yamauchi H, Yamauchi T, Doorenbos AZ. Validation of the Japanese version of the barriers questionnaire II in cancer pain management: a cross-sectional study. BMC Palliat Care. 2020;19:102.
31. Landis JR, Koch GG. The measurement of observer agreement for categorical data. Biometrics. 1977;33:159-74.
32. Kimura R, Hashiguchi S, Kawa M, Miyashita M, Sasahara T, Shirai Y, et al. Pain management and related factors in advanced cancer patients who initiated opioid therapy in an outpatient setting. Palliat Support Care. 2005;3:301-9.
33. Lo C, Hales S, Zimmermann C, Gagliese L, Rydall A, Rodin G. Measuring death-related anxiety in advanced cancer: preliminary psychometrics of the Death and Dying Distress Scale. J Pediatr Hematol Oncol. 2011;33:S140–5.
34. Syrjala KL, Jensen MP, Mendoza ME, Yi JC, Fisher HM, Keefe FJ. Psychological and behavioral approaches to cancer pain management. J Clin Oncol. 2014;32:1703-11.
35. Applebaum AJ, Stein EM, Lord-Bessen J, Pessin H, Rosenfeld B, Breitbart W. Optimism, social support, and mental health outcomes in patients with advanced cancer. Psychooncology. 2014;23:299-306.

# Tables

Due to technical limitations, tables are only available as a download in the Supplemental Files section.

# Figures

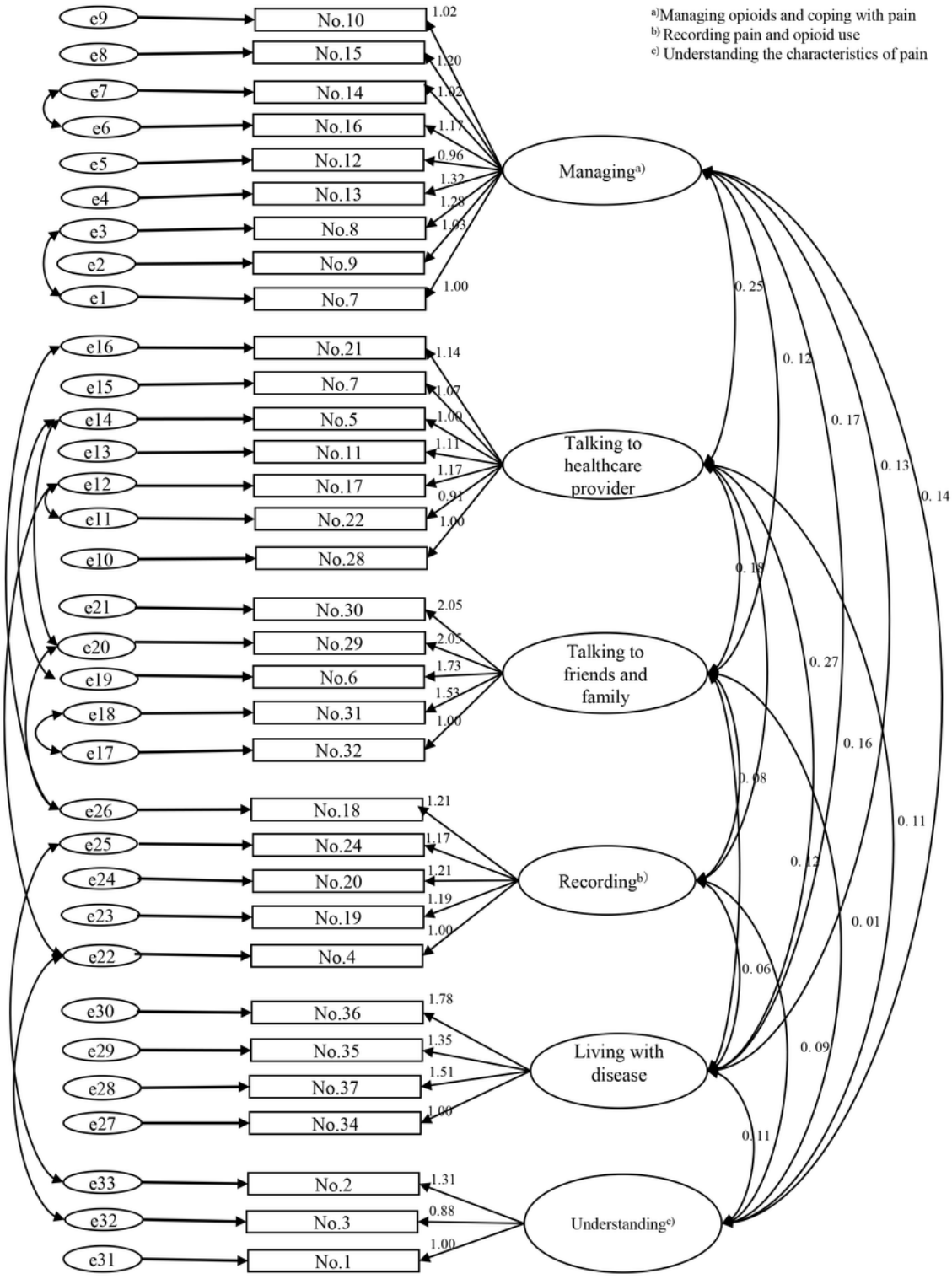


**Figure 1**

Standardized path diagram of the OSSA's confirmatory factor analysis

# Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- OSSATable.xlsx