



## Original Article

## Development of the quality of life of family caregivers of advanced cancer patients scale in Japan: Psychometric properties

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## ABSTRACT

**Objective:** We aimed to develop a new scale for use in Japan, called the “Quality of Life of Family Caregivers of Advanced Cancer Patients Scale (QFCS)” and to examine its psychometric properties.

**Methods:** A draft scale was extracted based on qualitative inductive and deductive analyses, and its content validity and surface validity were investigated. Its psychometric properties were examined.

**Results:** The QFCS consists of 30 items comprising four factors. Cronbach's  $\alpha$  was 0.92 and the intraclass correlation coefficient was 0.90. Correlation coefficients between the total QFCS score and eight subscale scores of the revised Medical Outcomes Study 12-Item Short Form Survey Instrument were  $r_s = 0.22\text{--}0.65$  ( $P < 0.01\text{--}0.05$ ). The Physical Component Summary was  $r = 0.29$  ( $P < 0.01$ ), and the Mental Component Summary was  $r = 0.67$  ( $P < 0.01$ ). Correlation coefficients between the QFCS total score and four subscale scores of the Caregiver Quality of Life Index-Cancer (CQOLC) were  $r = 0.27\text{--}0.59$  ( $P < 0.01$ ) and the CQOLC total score was  $r = 0.65$  ( $P < 0.01$ ).

**Conclusions:** Our results suggest that the QFCS exhibited acceptable psychometric properties in measuring the quality of life of family caregivers of patients with advanced cancer. Future research is needed to evaluate the effectiveness and quality of family support using the QFCS.

## Introduction

Cancer is a major cause of death in Japan, with the number of patients with cancer estimated to be 980,856 out of the total population of 126.44 million in 2018,<sup>1</sup> and this number is expected to increase.

In recent years, the medical care system has shifted from inpatient care to early discharge and outpatient visits. The family of a patient with cancer often faces challenges in daily life, both during hospitalization and after hospital discharge. Therefore, appropriate support should be made available to patients and their families. Qualitative studies in Japan have reported on family caregivers' experiences<sup>2,3</sup> and highlighted difficulties in supporting patients with cancer. Studies in Europe and America indicate that the needs and responsibilities of family caregivers increase over time,<sup>4,5</sup> which affects their physical and mental health and leads to problems such as sleep disorders or psychological pain.

However, few studies have evaluated the current situation of family caregivers in Japan, where no established family support system is yet in

place. A possible reason is the lack of any established outcome standard for appropriately evaluating the quality of life (QOL) of family caregivers of patients with cancer. Effectiveness of family support needs to be demonstrated and its quality evaluated to develop the family support of patients with cancer in Japan.

Western countries, on the other hand, have recognized the concept of family caregiver support. Given the importance of family caregivers' individual needs, several instruments have been developed to evaluate the individual QOL of family caregivers. Instruments developed for family caregivers of patients with cancer have specifically included the Caregiver Quality of Life Index<sup>6</sup> and the Quality of Life in Life-Threatening Illness: Family Carer Version,<sup>7</sup> which were developed specifically for family caregivers of patients with cancer in palliative and hospice care. Thus, it asks about the family's condition within the past 24–48 h to account for changes in the patient's condition. We consider 1 month to be suitable for family members of patients with cancer undergoing treatment. The Caregiver QOL Index-Cancer (CQOLC),<sup>8</sup> Quality of Life-Family

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Version (QOL-FV),<sup>9</sup> and Caregiver Oncology Quality of Life (CarGO-QoL)<sup>10</sup> were developed for family caregivers of patients with cancer in general. These existing instruments were developed in Western countries. The cultural backgrounds of Asian and Western societies differ in terms of family relationships, religion, and sexuality. Thus it follows that the concept of QOL will be different in Asian countries.<sup>11</sup>

In Japan, outcome instruments are needed to address cultural differences between Western countries and Japan, especially in terms of spiritual health, family roles and responsibilities, economic background based on the social security system, and religion. Cultural background has complex effects particularly on spiritual health.<sup>11</sup> Currently, no instrument has been originally developed in Asia. Although the CQOLC has been translated into Japanese and validated in Japan,<sup>12</sup> it is characterized by the care burden and does not evaluate physical health. The physical condition of family caregivers is closely related to the patient's illness and represents their own physical condition. Thus, family caregivers' physical health is important in the QOL of family caregivers of patients with advanced cancer. A QOL instrument is needed that considers the family of patients with cancer, reflects the Japanese cultural background, and combines aspects of the family as caregivers and as individual persons who are not just caregivers to demonstrate the future effects of support for families.

Therefore, in this study, we aimed to develop the Quality of Life of Family Caregivers of Advanced Cancer Patients Scale (QFCS) and examine its psychometric properties.

In this study, "family" indicates primary caregivers who are blood relatives of the patient with whom they have a personal relationship, and who provide physical, emotional, or practical assistance and support to the patient, with mutual recognition. "QOL of family caregivers" refers to important concepts related to the family caregiver's life with the cancer patient.

## Methods

This study has two phases<sup>1</sup>: scale development, content validity, and surface validity of the draft scale; and<sup>2</sup> evaluation of the psychometric properties of the QFCS.

### *Phase I: scale development, content validity, and surface validity of the draft scale*

Twenty-one family caregivers of patients with advanced cancer were interviewed in a semi-structured format.<sup>13</sup> The interviewer asked about feelings considered important for the family caregiver's life and how their QOL was affected by the cancer diagnosis. The interview guide was developed based on a literature review.<sup>11</sup> The interview focused on physical, psycho-emotional, social, financial,<sup>6-10</sup> spiritual,<sup>8,9</sup> and daily life<sup>7-10</sup> factors. Components of 41 items were revealed by qualitative inductive analysis.<sup>13</sup> A comprehensive systematic review of the existing literature<sup>6-11</sup> allowed the researchers to discuss their opinions on what should be integrated or modified. As result, a draft scale of 41 items was prepared.

Next, the content validity of the draft scale was evaluated by sending experts an information sheet and 41-item questionnaire. The inclusion criteria for the experts were (1) researchers whose length of cancer research experience was 5 years or more, (2) doctors, certified nurse specialists, or certified nurses whose length of clinical experience in cancer care was 10 years or more. Exclusion criteria were (1) researchers with no cancer research experience and (2) doctors, certified specialist nurses, or certified nurses who were not engaged in cancer care. A sample size of at least five experts was required,<sup>14</sup> with a target total of 10 that included four researchers, one doctor, and four nurses. A 41-item questionnaire was evaluated using the content validity ratio (CVR),<sup>15</sup> with respondents asked to evaluate each item as "very appropriate," "very appropriate but the expression should be changed," "some problems with appropriateness," or "not appropriate." Participants who rated any item

anything other than "very appropriate" were asked to suggest changes or additions and to describe their impressions in their own words. Each item's rating was considered based on the CVR and experts' free-response comments.

Next, surface validity of the draft scale was evaluated to determine whether an item's expression required correction by family caregivers of patients with advanced cancer (grade IV, stage IV, or metastases as per World Health Organization classification) from our university hospital's outpatient and inpatient departments between May 2018 and November 2018. Inclusion criteria were (1) primary caregivers who were blood relatives of the patient with whom they have a personal relationship and who provide physical, emotional, or practical assistance and support to the advanced cancer patient; (2) both patient and family caregivers who were aware of the cancer diagnosis for over 2 weeks; (3) primary caregivers who were aged 20 years or older; and (4) primary caregivers who were willing to participate. Exclusion criteria were primary caregivers who (1) had difficulty with and were unable to understand explanations of the study due to a mental disorder or cognitive impairment, (2) were unable to respond to interviews in Japanese, and/or (3) were in bereavement. Sample size was set at 10 individuals. Consent was obtained after a researcher verbally explained the study to the patient orally and then had the patient introduce their family caregiver. The family caregiver was provided the study aims in writing and then invited to participate in the study. Data collection involved providing participants an information sheet and a 45-item questionnaire. Each item was rated on a scale of 0 ("not at all") to 4 ("completely"). In addition, participants were asked to rate the questionnaire in terms of required response time for each item and appropriateness of the scale and to suggest improvements and describe their impressions in their own words.

### *Phase II: psychometric properties of the QFCS*

#### *Participants and procedures*

Inclusion and exclusion criteria were the same as those for surface validity. The target sample size was set at 133, calculated from  $\alpha = 0.90$  and retest (twice), and 95% confidence interval (CI). Assuming a return rate of 60%,<sup>7,12</sup> 222 questionnaires were sent.

#### *Survey methods*

We provided information sheets and questionnaires to family caregivers of our university hospital's outpatient and inpatient departments between June 2019 and December 2019. Consent was obtained after a researcher explained the study to the patient orally and then had the patient introduce their family caregiver. Returning the questionnaire indicated informed consent. Data collection involved repeating the questionnaire 1 week later and returning it by mail.

#### *Participant characteristics*

Data on family caregivers included age, sex, relationship with the patient (spouse, child, parent, or sibling), marital status, employment status, living arrangement (living with the patient or not), care experience, and religion. Patient data included age, gender, marital status, employment status, religion, cancer location (brain, head and neck, lung, breast or uterus, ovary, gastrointestinal tract, digestive organ, or urinary organ), treatment modality (surgery, chemotherapy, radiotherapy, or combination), and treatment environment (inpatient or outpatient).

#### *Measures*

##### *QFCS*

The draft scale consisted of 45 items, with each item rated on a scale from 0 ("not all") to 4 ("completely"). The higher the score, the better the family caregiver's QOL.

### Japanese version of the 12-item short form survey instrument

We measured concurrent validity using the Japanese version of the revised Medical Outcomes Study 12-Item Short Form Survey Instrument (SF-12v2),<sup>16</sup> which was developed from the widely used SF-36v2.<sup>17,18</sup> The SF-12v2 has eight subscales as follows: physical functioning; role limitation due to physical health problems, bodily pain, general health, vitality, social functioning; and role limitation due to emotional problems and mental health. We calculated two summary scores from this measure:<sup>1</sup> the Physical Component Summary (PCS), which is an index of overall physical functioning, and<sup>2</sup> the Mental Component Summary (MCS), which is an index of mental and emotional health. The higher the score, the better the family caregiver's QOL.

### Japanese version of the CQOLC

The CQOLC<sup>8</sup> is one of the more widely used instruments for measuring holistic QOL of caregivers of patients with cancer and has been translated into Japanese.<sup>12</sup> The Japanese version of the CQOLC has 21-items within four domains: psychological burden (8 items), positive emotions (5 items), financial burden (3 items), and disruption of daily living (5 items). This self-report measure of caregivers' QOL uses a six-point Likert-type scale from 6 (*not at all*) to 1 (*very much*). This score is obtained by summing the item scores, with higher scores denoting better QOL of caregivers.

### Data analysis

Normality was confirmed by the normal probability plot, skewness, and kurtosis. We performed item analysis (ie, rate of missing data, ceiling, or floor effects). For each item, the deletion criterion for the missing data rate was greater than 5%. The rate of missing data was less than 2% for all items. For ceiling and floor effects of each item, the deletion criterion was a mean  $\pm$  standard deviation of 4.1 or more and 0 or less, respectively. Next, exploratory factor analysis (ie, maximum likelihood method, promax rotation, factor loading  $\geq 0.40$ ), the Kaiser-Meyer-Olkin measure for 36 items, and Bartlett's test of sphericity were performed. Total scale scores and scores within each item were calculated from the total score of the items. In addition, missing values were complemented by the average score. This scale shows that the higher the total score for the whole scale and each item, the higher the QOL of the family. In addition, we performed measures of reliability (ie, Cronbach's  $\alpha$ , intraclass correlation coefficient [ICC] calculated by test-retest method). Cronbach's  $\alpha$  should be  $\geq 0.7$  for research use and  $\geq 0.9$  for clinical use.<sup>19</sup> In test-retest analysis, ICCs of 0.41–0.60 are considered moderate, 0.60–0.80 substantial, and 0.81–1.00 almost perfect.<sup>20</sup> Concurrent validity (Pearson's correlation coefficient between the QFCS and Japanese versions of both SF-12v2 and CQOLC) and multitrait scaling analysis<sup>21</sup> were also performed. SPSS version 24.0 for Windows (IBM Japan, Tokyo) was used for statistical analysis. *P* values  $< 0.05$  were considered statistically significant.

### Ethical considerations

This study was conducted with approval from the ethics committee of our institution on January 12, 2018 (Approval No. 2018-1-12). A researcher explained the purpose and content of the study to each family caregiver in writing. The researcher then explained that for those who consented, their participation was voluntary, they did not have to answer questions if they preferred not to, and they could decline participation at any time, and that those who declined participation would not face any disadvantage in medical care. All obtained data were secured under lock and key. Additionally, the researcher explained to the family caregivers that the data would not be used for purposes other than the present study and that all data would be erased 5 years after the study was completed.

## Results

### Phase I: scale development, content validity, and surface validity of the draft scale

#### Content validity

As a result, 10 individuals (4 researchers, 1 doctor, 5 nurses) received and responded to the questionnaire, forming the analysis population. The length of research experience was 5–14 years, and length of clinical experience was 10–21 years. Among 41 draft items, 33 satisfied a CVR of 0.62 whereas 8 items did not. However, 6 of the 8 items satisfied a CVR of 0.60, which is approximately equal to CVR 0.62. At this stage, we retained the 8 items after reconsideration and revision based on free-response comments on their improvement. As a result, there were 41 items. Opinions on how the changes were made were discussed by researchers. After discussion, 4 items were added to the draft scale, for a total of 45 items.

#### Surface validity

We obtained consent from a total of 10 eligible family caregivers who were approached to participate in the study. Questionnaires were sent to and received from 10 individuals, comprised of three men and seven women, among whom three were over 61 years of age, seven were spouses, and six were employed. As for answer time required, three participants provided no response and seven participants answered for 5–10 min. One of the 10 participants noted in the free response that a draft item needed correction. Out of 45 items, one was noted to require correction. After modifying the item, the revised draft scale comprised 45 items.

### Phase II: psychometric properties of the QFCS

#### Sample characteristics

The questionnaire was distributed to 216 individuals, and responses were received from 131 (response rate: 60%). Of these, one was excluded for response deficiencies and 130 were used for analysis.

Table 1 shows the characteristics of participants and patients. Among participants, 80 participants were women (61.1%), average age was 60.8 years, and 95 (72.5%) were a patient's spouse. Among patients, 70 were women (53.4%), average age was 64.4 years, and 65 (49.6%) had an ECOG PS of 1.

#### Item analysis

No item exhibited a 5% rate of missing data. Skewness was present for nine items, and kurtosis was present for nine items. No item exhibited a floor effect, but a ceiling effect was observed in nine items. Nine common items were deleted.

#### Factor analysis

The exploratory factor analysis of 36 items revealed a Kaiser-Meyer-Olkin measure of 0.845 and a Bartlett's test of sphericity of  $P < 0.001$ . The eigenvalue was set at 4 based on screen plotting results. Six items with a factor loading  $< 0.40$  were deleted, leaving 30 items. Table 2 shows factor analysis results of the 30-item four-factor QFCS. The four factors were "social and personal connections with trusted persons and taking care of oneself," "condition when supporting the patient," "maintaining one's physical health," and "relationship with the patient and autonomy" (Table 2).

#### Evaluation of reliability

Table 3 shows Cronbach's  $\alpha$ . The  $\alpha$  coefficient of 30 items was 0.92, and subscale factors were in the range of 0.86–0.90. In addition, Table 3 shows results of reliability analysis by the test-retest method, in which 130 of 131 participants returned questionnaires. ICCs were 0.90 (95% CI: 0.86–0.93). The ICC of Factor 1 was 0.88 (95% CI: 0.84–0.92), Factor 2 was 0.82 (95% CI: 0.75–0.87), Factor 3 was 0.87 (95% CI: 0.82–0.90), and Factor 4 was 0.82 (95% CI: 0.75–0.87) (Table 3).

**Table 1**  
Characteristics of family caregivers and patients ( $n = 131$ ).

Characteristics	Data
<b>Family caregivers</b>	
Age, years, mean (SD)	60.8 (11.8)
Gender, $n$ (%)	
Male	51 (38.9)
Female	80 (61.1)
Relationship to patient, $n$ (%)	
Spouse	95 (72.5)
Parent	9 (6.9)
Brother/sister	4 (3.1)
Child	23 (17.6)
Married, $n$ (%)	122 (93.1)
Employed, $n$ (%)	74 (56.5)
Caregiver, $n$ (%)	28 (21.4)
Living together, $n$ (%)	113 (86.3)
Religion, $n$ (%)	15 (11.5)
<b>Patients</b>	
Age, years, mean (SD)	64.4 (11.8)
Gender, $n$ (%)	
Male	61 (46.6)
Female	70 (53.4)
Performance status (ECOG), $n$ (%)	
0	32 (24.4)
1	65 (49.6)
2	20 (15.3)
3	14 (10.7)
4	0 (0)
Cancer type (multiple answers allowed), $n$ (%)	
Brain	14 (9.7)
Head and neck	7 (4.8)
Lung	15 (10.3)
Breast/reproductive organ	39 (26.9)
Digestive system	64 (44.1)
Urinary system	4 (2.8)
Other	2 (1.4)
Treatment type (multiple answers allowed), $n$ (%)	
Chemotherapy	107 (81.7)
Radiotherapy	8 (6.1)
Surgery	7 (5.3)
Other	9 (6.9)
Inpatient or outpatient, $n$ (%)	
Inpatient	3 (2.3)
Outpatient	128 (97.7)
Employed, $n$ (%)	29 (22.1)
Religion, $n$ (%)	12 (9.2)

ECOG, Eastern Cooperative Oncology Group; SD, standard deviation.

#### Concurrent validity

Table 4 shows concurrent validity results for the QFCS and SF-12v2 and CQOLC. Correlation coefficients between the total QFCS score and eight subscale scores of the SF-12v2 were  $r_s = 0.22$ – $0.65$  ( $P < 0.01$ – $0.05$ ). The PCS was  $r = 0.29$  ( $P < 0.01$ ), demonstrating weak positive correlations, and the MCS was  $r = 0.67$  ( $P < 0.01$ ), demonstrating strong positive correlations (Table 4). Correlation coefficients between the QFCS total score and four CQOLC subscale scores were  $r = 0.27$ – $0.59$  ( $P < 0.01$ ) and the CQOLC total score was  $r = 0.65$  ( $P < 0.01$ ), demonstrating strong positive correlations.

Table 5 shows the results of multitrait scaling analysis. Distinctive correlation coefficients were 0.27–0.83, convergent correlation coefficients were 0.00–0.68, and scaling success rate was 90%–100% for all items.

#### Discussion

In this study, we developed the QFCS to measure the QOL of family caregivers of patients with advanced cancer and examined its psychometric properties. Based on our results, the scale consists of “social and personal connections with trusted persons and taking care of oneself” (10 items), “condition when supporting the patient” (7 items), “maintaining one’s physical health” (7 items), and “relationship with the patient and autonomy” (6 items).

#### Psychometric properties of the developed scale

For reliability, research indicates that Cronbach’s  $\alpha$  should be  $\geq 0.7$  for research use.<sup>19</sup> The QFCS had an overall Cronbach’s  $\alpha$  of 0.92, and its subscale factors were in the range of 0.86–0.90, values that assured adequate consistency. As for test-retest analysis, ICCs of 0.61–0.80 were considered substantial<sup>20</sup> and the lower limit of the 95% CI of the ICC should be  $\geq 0.7$ .<sup>22</sup> The QFCS had an overall ICC of 0.90 and subscale factors in the range of 0.82–0.88. The 95% CI was  $\geq 0.75$ , confirming high reproducibility. As for concurrent validity results for the QFCS and SF-12v2, the correlation coefficient between the QFCS total score and PCS of the SF-12v2 was  $r = 0.29$  ( $P < 0.01$ ), demonstrating a weak positive correlation. The correlation coefficient between the total QFCS score and MCS of the SF-12v2 was  $r = 0.67$  ( $P < 0.01$ ), demonstrating a strong positive correlation. The correlation coefficient between the QFCS and CQOLC total score was  $r = 0.65$  ( $P < 0.01$ ), demonstrating a strong positive correlation. Thus, the QFCS had adequate concurrent validity. This scale of convergent and divergent validity in multitrait scaling analysis and the scaling success rate also confirmed that the QFCS possesses construct validity. As these evaluations suggest that the QFCS has acceptable reliability and validity, the QFCS is ready for use.

The first factor, “social and personal connections with trusted persons and taking care of oneself” concerns social support that the family of a patient with cancer receives from others and its own members as well as being able to lead one’s daily life while taking care of oneself. Family members seek out others with whom they can discuss the patient’s disease and share their worries. A study reported that 26.5% of caregivers screened positive for depression and 34.9% for anxiety, with higher anxiety scores in caregivers associated with unmet caregiver needs in the domains of emotional and psychological needs and communication and family needs.<sup>23</sup> Thus, family support systems are needed to help family members cope with medical issues and caregiving burdens. Also, religion describing the existence of God has taken root among people of Western culture. Therefore, existing instruments have included spiritual support through religion.<sup>9</sup> In general, the Japanese people have no specific religion, with only about 10% of family caregivers and patients in this study having a religion. However, some Japanese people worship ancestors at the family Buddhist altar and hold memorial services to thank their ancestors. Both practices reflect the culture or customs of Shintoism. Although there are differences in manners and customs in both religions, the life existence of ancestors is recognized as continuing into the present day. Against this background, having peace of mind is reflected in a culture that values non-physical existence.

The second factor, “condition when supporting the patient,” consists of family caregivers’ conviction that helping others is an important value. In a study on experiences of family caregivers of people with cancer in an Asian country, Kristanti et al.<sup>24</sup> found that caregivers believed in giving up something to focus on or meet a patient’s needs, reflecting their conviction that providing care was an important value from which arises will power and the source of their strength. In this scale, items in the second factor indicate the importance of caregiving on the QOL of family caregivers of patients with advanced cancer.

The third factor, “maintaining one’s physical health,” relates to the family’s health condition. Palos et al.<sup>25</sup> reported that family caregiving over time increasingly affects physical and mental health leading to problems such as sleep disorders or psychological pain. Gooden and White<sup>26</sup> reported that family concerns about managing a patient’s diet and symptoms were linked to increased carer burden and significant distress. Family caregivers’ physical condition was closely related to the patient’s illness and indicative of their own physical condition.<sup>26</sup> Therefore, caregivers practiced emotional coping skills to support the patient and maintain their own mental tranquility. Although the CQOLC has been translated into Japanese and validated in Japan,<sup>12</sup> it

**Table 2**  
Exploratory factor analysis of the QFCS (n = 131).

Scale item	Factor 1	Factor 2	Factor 3	Factor 4	Communality
<b>Factor 1: Social and personal connections with trusted persons and taking care of oneself (10 items)</b>					
Item 20: Having a safe place to talk about this problem	<b>0.86</b>	0.11	-0.18	-0.07	6.4
Item 44: Having a doctor to consult about one's own health/physical condition	<b>0.85</b>	-0.15	0.06	0.08	0.70
Item 19: Being supported to talk about patient's illness at one's workplace and in society	<b>0.75</b>	-0.02	-0.28	-0.07	0.38
Item 17: Having other family members or friends to discuss patient's illness	<b>0.72</b>	-0.06	-0.01	0.01	0.48
Item 18: Having friends or other family members to spend time with	<b>0.69</b>	-0.13	0.10	0.08	0.51
Item 42: Having time for oneself	<b>0.56</b>	0.23	0.03	-0.13	4.9
Item 40: Having peace of mind	<b>0.48</b>	-0.14	0.01	0.43	0.45
Item 45: Having daily life unchanged since before patient's cancer diagnosis	<b>0.46</b>	0.23	0.13	-0.13	0.47
Item 22: Communicating effectively with healthcare staff	<b>0.43</b>	-0.07	-0.22	0.23	0.20
Item 43: Taking care of one's own health	<b>0.43</b>	0.01	0.33	0.07	0.48
<b>Factor 2: Condition when supporting the patient (7 items)</b>					
Item 12: Feeling mentally burdened by caring for the patient	0.08	<b>-0.93</b>	0.14	-0.12	0.70
Item 8: Feeling physically burdened by caring for the patient	0.27	<b>-0.89</b>	0.07	-0.12	0.62
Item 11: Feeling stress due to patient's cancer diagnosis	-0.02	<b>-0.77</b>	0.03	0.07	0.56
Item 13: Feeling calm	0.18	<b>0.54</b>	0.13	-0.12	0.54
Item 7: Feeling fatigue	0.00	<b>-0.50</b>	-0.03	0.10	0.27
Item 10: Feeling helpless no matter what I do	-0.05	<b>-0.47</b>	-0.19	-0.06	0.43
Item 14: Feeling positive	0.12	<b>0.47</b>	0.30	0.01	0.59
<b>Factor 3: Maintaining one's physical health (7 items)</b>					
Item 4: Enjoying meals	-0.31	-0.15	<b>1.12</b>	-0.02	0.78
Item 3: Having an appetite	-0.24	-0.03	<b>0.99</b>	-0.05	0.72
Item 5: Feeling healthy	-0.02	0.23	<b>0.60</b>	0.08	0.59
Item 16: Switching one's emotion	0.22	-0.02	<b>0.58</b>	0.16	0.57
Item 15: Controlling one's emotions to ease stress (eg, not overdoing it, taking rest)	0.30	0.00	<b>0.56</b>	-0.02	0.61
Item 1: Feeling satisfied with one's sleep	0.11	0.22	<b>0.52</b>	-0.06	0.56
Item 2: Getting enough sleep	0.22	0.23	<b>0.43</b>	-0.08	0.56
<b>Factor 4: Relationship with the patient and autonomy (6 items)</b>					
Item 26: Cherishing the time spent with the patient	-0.13	0.01	0.00	<b>0.94</b>	0.86
Item 27: Considering it important to communicate with the patient	-0.07	0.07	-0.14	<b>0.93</b>	0.86
Item 29: Feeling relieved when patient is cheerful	-0.10	0.02	0.09	<b>0.81</b>	0.65
Item 35: Feeling confident about helping the patient	0.16	-0.13	-0.02	<b>0.62</b>	0.42
Item 28: Feeling peaceful when spending time with patient	0.10	0.31	0.01	<b>0.49</b>	0.45
Item 41: Continuing to fulfill my roles and duties at work, school, home, etc.	0.18	0.04	0.17	<b>0.47</b>	0.39
Eigenvalue	9.91	4.05	2.72	<b>1.54</b>	
Inter-factor correlations					
Factor 1		0.48	0.59	0.21	
Factor 2			0.66	0.17	
Factor 3				0.06	
Factor 4					

Maximum likelihood method, promax rotation, and factor loading are  $\geq 0.40$ . QFCS, Quality of life of family caregivers of advanced cancer patients scale.

is characterized by care burden and does not evaluate physical health. In the QFCS, the third factor, "maintaining one's physical health," might represent both physical and mental aspects as they are closely related to each other. Thus, this factor is important to the QOL of family caregivers of patients with advanced cancer.

**Table 3**  
Reliability of the QFCS.

Factor	Mean	SD	Cronbach's $\alpha$	ICC	95% CI
Factor 1 (10 items)	25.69	7.14	0.87	0.88	0.84–0.92
Factor 2 (7 items)	15.07	5.45	0.86	0.82	0.75–0.87
Factor 3 (7 items)	18.83	4.75	0.90	0.87	0.82–0.90
Factor 4 (6 items)	17.84	4.11	0.87	0.82	0.75–0.87
30 items	77.47	15.82	0.92	0.90	0.86–0.93

Factor 2 (item nos. 12, 8, 11, 7, 10) treated as reverse scoring. CI, confidence interval; ICC, intraclass correlation coefficient; QFCS, quality of life of family caregivers of advanced cancer patients scale.

The fourth factor, "relationship with the patient and autonomy," concerns the spiritual dimension likely due to the serious situation faced by the family of patient with advanced cancer. This factor also relates to a sense of values and faith that expresses the strong ties of Japanese family relationships in terms of "cherishing time spent with the patient," "considering it important to communicate with the patient," and "being confident in helping the patient." This study found cultural differences when compared with existing instruments, and the differences are remarkable. In existing instruments, the patient-family relationship is simply assessed as good or bad. In this study, this highly sensitive relationship appears as a strong bond, which largely reflects the spiritual aspects of family caregiving. No existing instruments have as delicate an approach to patient-family relationships as this study, which represents Japanese family relationships and the specific circumstances of families of patients with cancer. There are two aspects to family caregiving: the aspect of the person as a caregiver and the person as an individual, not just as a caregiver. In this scale, the QOL of family caregivers of patients with advanced cancer was based on these two aspects.

**Table 4**  
Correlation coefficients between total QFCS score and SF-12v2 and CQOLC (n = 131).

Scale item	Factor 1	Factor 2	Factor 3	Factor 4	30 items
SF-12v2					
PF	0.27**	0.16	0.20*	-0.07	0.22**
RP	0.39**	0.44**	0.46**	0.13	0.48**
BP	0.17	0.21*	0.14	0.08	0.22*
GH	0.42**	0.56**	0.54**	0.11	0.54**
VT	0.35**	0.57**	0.60**	0.36**	0.61**
SF	0.36**	0.48**	0.44**	0.04	0.46**
RE	0.27**	0.54**	0.44**	0.14	0.47**
MH	0.40**	0.69**	0.57**	0.23*	0.65**
PCS	0.29**	0.26**	0.26**	-0.04	0.29**
MCS	0.39**	0.69**	0.62**	0.32**	0.67**
CQOLC					
Psychological burden	0.22*	0.08	0.12	0.45**	0.27**
Positive emotions	0.33**	0.54**	0.35**	0.17*	0.48**
Financial burden	0.31**	0.56**	0.45**	-0.06	0.45**
Disruption of daily living	0.43**	0.63**	0.58**	0.03	0.59**
CQOLC total score	0.50**	0.62**	0.53**	0.26**	0.65**

Pearson's correlation coefficient. \*P < 0.05, \*\*P < 0.01. Factor 2 (items nos. 12, 8, 11, 7, 10) treated as reverse scoring. SF-12v2, medical outcomes study 12-item short form survey instrument; PF, physical functioning; RP, role-physical; BP, bodily pain; GH, general health perception; VT, vitality; SF, social functioning; RE, role-emotional; MH, mental health; PCS, physical component summary; MCS, mental component summary; CQOLC, caregiver quality of life index-cancer.

**Table 5**  
Distinctive validity and convergent validity of the QFCS.

Factor	No. of items	Convergent validity (range of correlation coefficients) <sup>a</sup>	Distinctive validity (range of correlation coefficients) <sup>b</sup>	Scaling success (%) <sup>c</sup>	
Factor 1: Social and personal connections with trusted persons and taking care of oneself	10	0.27–0.83	0.03–0.53	27/30	90
Factor 2: Condition when supporting the patient	7	0.49–0.74	0.05–0.68	20/21	95
Factor 3: Maintaining one's physical health	7	0.67–0.76	0.00–0.61	21/21	100
Factor 4: Relationship with the patient and autonomy	6	0.54–0.79	0.00–0.41	18/18	100

Factor 2 (items nos. 12, 8, 11, 7, 10) treated as reverse scoring.  
<sup>a</sup> Pearson's correlation coefficient between each item's score and scores for the domains to which that item does not belong.  
<sup>b</sup> Pearson's correlation coefficient between each item's score and the score for each domain that excludes that item.  
<sup>c</sup> Number of correlation coefficients in which convergent correlation is higher than distinctive correlation/total number of correlation coefficients.

**Limitations**

There are limitations in the current study. First, the sample was obtained from a single hospital. Second, this scale was not limited by cancer type. Thus, a patient's particular cancer type could conceivably affect the family's QOL. The application of the scale to all cancer types represents both a limitation and an advantage. Third, only three men participated in the evaluation of surface validity, which might indicate bias toward a female viewpoint. However, we collected interview data on various background factors (relationship with the patient, employment status, living arrangement, care experience) of the family caregivers by heterogeneous sampling. Therefore, this does not seem to be a problem. Fourth, this study did not emphasize aspects of sexuality to the degree that existing Western instruments have. Asians seem to avoid discussions of sexuality,<sup>11</sup> which appeared to be the case for the Japanese participants in the present study. Thus, our study was unable to ascertain the importance of sexuality for family caregivers or whether there exists a Japanese social construct to avoid discussion on this topic. Although this is a study limitation, the QFCS showed reliability and validity. Future research is needed to evaluate the effectiveness and quality of family support using the QFCS.

**Conclusions**

In this study, we developed the QFCS and then examined its psychometric properties. The QFCS is a 30-item measure with four factors (each factor title reflects its constitutive items) as follows: "social and personal connections with trusted persons and taking care of oneself,"

"condition when supporting the patient," "maintaining one's physical health," and "relationship with the patient and autonomy."

The QFCS exhibited acceptable reliability and validity for measuring the QOL of family caregivers of patients with advanced cancer.

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**Authors' contributions**

Designed the study: Chikako Takahashi, Fumiko Sato. Methodology: Chikako Takahashi, Fumiko Sato. Participant recruitment: Chikako Takahashi. Collected the data: Chikako Takahashi. Performed the analysis: Chikako Takahashi. Interpreted the data: Chikako Takahashi, Fumiko Sato, Shiori Yoshida. Wrote the paper: Chikako Takahashi. Approved the final version of the manuscript: Chikako Takahashi, Fumiko Sato, Shiori Yoshida.

**Declaration of competing interest**

None declared.

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Nil.

## Ethics statement

This study was approved by the Ethics Committee of the Research Department at the Tohoku University Graduate School of Medicine on January 12, 2018 (Approval No. 2018-1-12).

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