

Original Article

Linguistic Validation of the Functional Assessment of Chronic Illness Therapy-Spiritual-Well-being-Expanded Version 4 Tool into Malayalam Language and its Feasibility in Advanced Cancer Patients Receiving Palliative Care

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ABSTRACT

Objective: The objective of this study was to validate the 'Functional Assessment of Chronic Illness Therapy-Spiritual-Well-being-Expanded(FACIT-Sp-Ex) Version 4' tool in Malayalam and assess its feasibility among advanced cancer patients receiving palliative care.

Materials and Methods: The study was carried out at the outpatient Department of Cancer Palliative Medicine of Malabar Cancer Centre between November 2022 and June 2023. Initially, the FACIT-Sp-Ex version 4 tool with 23 items was translated into the Malayalam language with a forward-backward translation procedure. This was followed by pilot testing in 10 advanced adult cancer patients receiving palliative care who could read and comprehend the Malayalam language. After answering the draft version of the validated tool, patients responded to questions from a Malayalam-translated cognitive debriefing script.

Results: The process of translation and cross-cultural adaptation went on smoothly with very few hurdles. The Malayalam terms used in three items Sp⁷, Sp⁹ and Sp²³ when back translated were found to be different from the source. These issues were resolved with the use of the most suitable translations and closest equivalents available in Malayalam. In the pilot testing, the majority (70%) of the patients were female. The mean age of patients was 45.90 (standard deviation [SD] = 7.62) years. Carcinoma breast (50%) was the most common type of cancer. All the patients knew their diagnosis, while only 80% knew the prognosis. Almost 90% of the patients were receiving some form of palliative anticancer treatment. All patients completed the draft version of the validated tool. The mean spiritual well-being score measured using this validated tool was 71.20 (SD = 15.10). Analysis of the debriefing interviews revealed that the Malayalam version was easy to complete, relevant, and appropriate.

Conclusion: Linguistic validation and cognitive debriefing produced the Malayalam translated FACIT-Sp-Ex version 4 tool conceptually equivalent to the original FACIT-Sp-Ex version 4 tool, and it is feasible for its use.

Keywords: Functional assessment of chronic illness therapy-spiritual-well-being-expanded, Validation, Malayalam, Linguistic

INTRODUCTION

Cancer patients experience physical and psychological distress throughout their cancer trajectory. In addition to this, they may face deep existential challenges affecting their quality of life.^[1-3] Spirituality is recognised as one of the eight distinct domains within the National Consensus

Project for Quality Palliative Care guidelines.^[4] It is defined as the way people find meaning and purpose in life, and how they experience connectedness to self, others, the significant or sacred.^[5] Spirituality and religion have a role to play in the way patients cope with their cancer diagnosis and continue through treatment, survival, recurrence, and dying.^[6,7] Spirituality and religiosity are closely related

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though not the same.^[8] Religiosity refers to the beliefs and practices associated with a particular religious worldview and community while spirituality may be experienced in and/or outside of a specific religious context.^[9,10]

Multiple studies have been done among cancer patients and survivors to assess their spiritual well-being and these studies have used different tools to assess spiritual well-being.^[11-14] Levels of spiritual well-being have been reported to be different among cancer patients and survivors from different parts of the world. Although spirituality's role in health and medicine is important, there is a lack of literature and gaps in understanding its impact in the Indian context.^[15] Many more inpatients desire conversations about their religious and spiritual concerns than those who actually experience such conversations.^[16] Although there is a need for spiritual care for patients, especially at the end of life, routine provision of spiritual care is rare.^[17] The possible explanations include lack of time,^[18,19] concerns regarding the appropriateness of spiritual care^[20,21] and poor training.^[22] In India, offering spiritual care is challenging due to the wide variety of religions and cultures, along with the absence of reliable tools to measure spirituality.^[23] Most spirituality methods come from Western countries and need to be used carefully in India.^[24]

Tools to measure spiritual well-being

Several tools are available to measure spiritual well-being. There is no validated tool in local vernacular form to use in our population. One commonly used tool is the Functional Assessment of Chronic Illness Therapy–Spiritual Well-being (FACIT-Sp) tool. FACIT-Sp is a 12-item self-administered questionnaire that explores the three sub-domains of spiritual well-being: peace, meaning, and faith. It is not limited to any one religion or spiritual tradition. FACIT-Sp-expanded (FACIT-Sp-Ex) is the expanded version of FACIT-Sp. In addition to the original 12 items in FACIT-Sp, this tool has 11

other items that address other aspects of spiritual well-being, namely, connectedness, love, gratitude, and forgiveness, grouped as the fourth sub-domain – the relational subscale [Table 1].^[25] We chose to use the FACIT-Sp-Ex version 4 tool as the relational content of the items is very relevant to Indian culture. In India, the family is centrally involved in most decision-making.^[26] This may also provide additional depth of information regarding spiritual well-being and health outcomes in our population. Administration of this tool in a regional language will help us in capturing spiritual well-being in our population and compare the level of spiritual well-being among our patients against the international data. This may help us to identify patients who may need interventions. The objective of the present study was to translate the FACIT-Sp-Ex version 4 tool into the Malayalam language and to linguistically validate the tool among advanced cancer patients receiving palliative care with or without their cancer treatment.

Tool translation and cross-cultural adaptation

Tools used in research need to be translated and cross-culturally adapted into the language of the research^[27] and the process needs to be systematic.^[28] One of the different methods available for this process is the functional assessment of chronic illness therapy (FACIT) translation methodology with a double-back translation. The FACIT translation methodology consists of several steps, including pilot testing of the tool with ten patients in the target language. The aim of the FACIT translation methodology is to produce translations of the original source instrument that have conceptual and semantic equivalence with the source version.^[29,30] Conceptual equivalence refers to the theoretical constructs as the source, while semantic equivalence refers to the translated items expressing the same meaning as the source.^[28] Linguistic validation is the entire process for the

Table 1: Relational subscale measures in FACIT-Sp-Ex questionnaire (version 4).

		Not at all	A little bit	Some-what	Quite a bit	Very much
Sp ¹³	I feel connected to a higher power (or God)	0	1	2	3	4
Sp ¹⁴	I feel connected to other people	0	1	2	3	4
Sp ¹⁵	I feel loved	0	1	2	3	4
Sp ¹⁶	I feel love for others	0	1	2	3	4
Sp ¹⁷	I am able to forgive others for any harm they have ever caused me	0	1	2	3	4
Sp ¹⁸	I feel forgiven for any harm I may have ever caused	0	1	2	3	4
Sp ¹⁹	Throughout the course of my day, I feel a sense of thankfulness for my life	0	1	2	3	4
Sp ²⁰	Throughout the course of my day, I feel a sense of thankfulness for what others bring to my life	0	1	2	3	4
Sp ²¹	I feel hopeful	0	1	2	3	4
Sp ²²	I feel a sense of appreciation for the beauty of nature	0	1	2	3	4
Sp ²³	I feel compassion for others in the difficulties they are facing	0	1	2	3	4

FACIT-Sp-Ex: Functional Assessment of Chronic Illness Therapy-Spiritual-Well-being-Expanded

translation and cross-cultural adaptation of the instrument into the target language maintaining the conceptual and semantic equivalence with the source version.^[31]

MATERIALS AND METHODS

The FACIT-Sp-Ex version 4

FACIT-Sp-Ex [Figure 1] is a 23-item questionnaire published in 1999 as a brief measure to assess spiritual well-being which assesses meaning (items 2, 3, 5 and 8 reverse-coded), peace (items 1, 4 reverse-coded, 6 and 7), faith (items 9, 10, 11 and 12) and relational aspects of spirituality (13, 14, 15, 16, 17, 18, 19, 20, 21, 22 and 23) on a 5-point Likert-type scale (0 = Not at all, 1 = Little bit, 2 = Some-what, 3 = Quite a bit and 4 = Very much). The FACIT-Sp-Ex is scored by summing the item scores in each subscale and then summing the subscale scores to yield the total score. The score ranges from 0 to 92, with a higher score indicating greater overall spiritual well-being.^[32]

Translation of FACIT-Sp-Ex version 4

The FACIT-Sp-Ex Version 4 tool was translated into Malayalam following the FACIT translation methodology.^[29,30] A document called the Malayalam Item History (MAL IH) was used to track each step of the translation and cultural adaptation process, along with the results. A flowchart of the FACIT translation methodology is outlined in Figure 2

The translation process involved translating the English version of the FACIT-Sp-Ex Version 4 into Malayalam using a forward-backward translation method. First, two independent translators fluent in both English and Malayalam translated the tool into Malayalam, ensuring they captured the meaning of each item. Their translations were then compared and merged by a third translator. Next, a fourth translator backtranslated the Malayalam version into English to ensure accuracy of the translation. In the next step, the MAL IH document, consisting of the forward translations, the reconciled, and the back translations, was sent to the FACIT team. This back-translation was compared with the original English version by the FACIT team, and any discrepancies were noted. A fifth translator reviewed all translations and comments, created a draft version, and corrected any grammatical, spelling, or formatting errors. Finally, the draft was pilot-tested with ten patients with advanced cancer who completed the questionnaire and provided feedback through a cognitive debriefing script translated into Malayalam.

Pilot testing

The pilot testing was carried out at the outpatient Department of Cancer Palliative Medicine of Malabar Cancer Centre, a tertiary Cancer Centre in Thalassery in the State of Kerala in South India, between November 2022 and June 2023.

As per the FACIT validation methodology, ten patients were recruited from the outpatient Department of Cancer Palliative

Medicine at Malabar Cancer Centre. The participant's inclusion criteria included: (1) Diagnosis of advanced cancer (defined as metastatic disease or recurrence or progressive disease) and receiving palliative care; (2) 18 years and above; (3) able to read and comprehend Malayalam language and (4) willing to provide informed consent to participate in this study. Exclusion criteria included: (1) Patients with cognitive dysfunction (psychiatric illness and neurological disorders) precluding administration of tool; (2) patients deemed unwell as per the investigator's clinical assessment, defined as instability in vital signs requiring hospitalisation and/or intensive care unit care.

Procedure

All eligible patients diagnosed with advanced cancer were enrolled in the study after providing the information sheet and getting informed consent. The demographic details such as age, gender, diagnosis, performance status, socioeconomic status, and treatment details were recorded from their case records. The Malayalam translated 'FACIT Sp-Ex version 4 tool was then administered by the Medical Social Worker who supervised the process. Later, each patient underwent the cognitive debriefing interview, where they were asked questions on an item-by-item basis to restate the item in their own words and to provide interpretations for particular items that were problematic in translation. This process ensured that the meaning intended by the developer was retained in translation and was also understood by the patient in the same way.^[30] The interviewer recorded any issues with the understanding or word changes suggested by the patient on the patient information form provided by the FACIT secretariat. The duration of the interviews ranged from 30 to 45 min, of which <10 min were required for most patients to complete the Malayalam version of FACIT-Sp-Ex.

Data analysis

The cognitive debriefing interviews were analysed by the reviewer/language coordinator and FACIT experts. There were multiple harmonised translations of problematic words/sentences as mentioned by the participants. The updated back translations of these harmonised translations were reviewed by the FACIT experts and, in some cases, investigated further until a consensus was reached for each item.

Quantitative variables are presented as mean (\pm standard deviation [SD]), and qualitative variables as absolute and relative frequencies.

All statistical analyses were conducted using the Statistical Package for the Social Sciences for Windows statistical software version 29.

RESULTS

Translation and cross-cultural adaptation

The process of translation and cross cultural adaptation went on smoothly with very few hurdles. For most items,

FACIT-Sp-Ex (Version 4)						
Below is a list of statements that other people with your illness have said are important. Please circle or mark one number per line to indicate your response as it applies to the past 7 days.						
		Not at all	A little bit	Some- what	Quite a bit	Very much
Sp1	I feel peaceful.....	0	1	2	3	4
Sp2	I have a reason for living.....	0	1	2	3	4
Sp3	My life has been productive.....	0	1	2	3	4
Sp4	I have trouble feeling peace of mind.....	0	1	2	3	4
Sp5	I feel a sense of purpose in my life	0	1	2	3	4
Sp6	I am able to reach down deep into myself for comfort	0	1	2	3	4
Sp7	I feel a sense of harmony within myself	0	1	2	3	4
Sp8	My life lacks meaning and purpose.....	0	1	2	3	4
Sp9	I find comfort in my faith or spiritual beliefs.....	0	1	2	3	4
Sp10	I find strength in my faith or spiritual beliefs	0	1	2	3	4
Sp11	My illness has strengthened my faith or spiritual beliefs....	0	1	2	3	4
Sp12	I know that whatever happens with my illness, things will be okay.....	0	1	2	3	4
Sp13	I feel connected to a higher power (or God)	0	1	2	3	4
Sp14	I feel connected to other people	0	1	2	3	4
Sp15	I feel loved.....	0	1	2	3	4
Sp16	I feel love for others	0	1	2	3	4
Sp17	I am able to forgive others for any harm they have ever caused me	0	1	2	3	4
Sp18	I feel forgiven for any harm I may have ever caused.....	0	1	2	3	4
Sp19	Throughout the course of my day, I feel a sense of thankfulness for my life	0	1	2	3	4
Sp20	Throughout the course of my day, I feel a sense of thankfulness for what others bring to my life	0	1	2	3	4
Sp21	I feel hopeful	0	1	2	3	4
Sp22	I feel a sense of appreciation for the beauty of nature	0	1	2	3	4
Sp23	I feel compassion for others in the difficulties they are facing.....	0	1	2	3	4

English (Universal)
Copyright 1987, 1997

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Figure 1: The Functional Assessment of Chronic Illness Therapy-Spiritual-Well-being-Expanded.

the reconciled Malayalam translation was acceptable by the reviewer/language coordinator and the FACIT team. The Malayalam terms used in three items Sp⁷, Sp⁹ and Sp²³ when back translated were found to be different from the source. The terms 'harmony', 'faith', 'compassion' and 'difficulties' in the original source items when back translated from the Malayalam version became 'unity', 'belief', 'empathy' and 'trouble' respectively. These issues were discussed between the language coordinator/reviewer and the FACIT team. Following this, the most suitable translation and closest

equivalent available in Malayalam was used, and the updated back translation matched the original source term. One other issue solved by the language coordinator was the use of the present continuous tense in the back translation instead of the simple present tense used in the source item.

Pilot testing

A total of ten patients (seven females and three males) participated in the study. The mean age of the participants was 45.90 ± 7.62 years. Eighty per cent of the participants

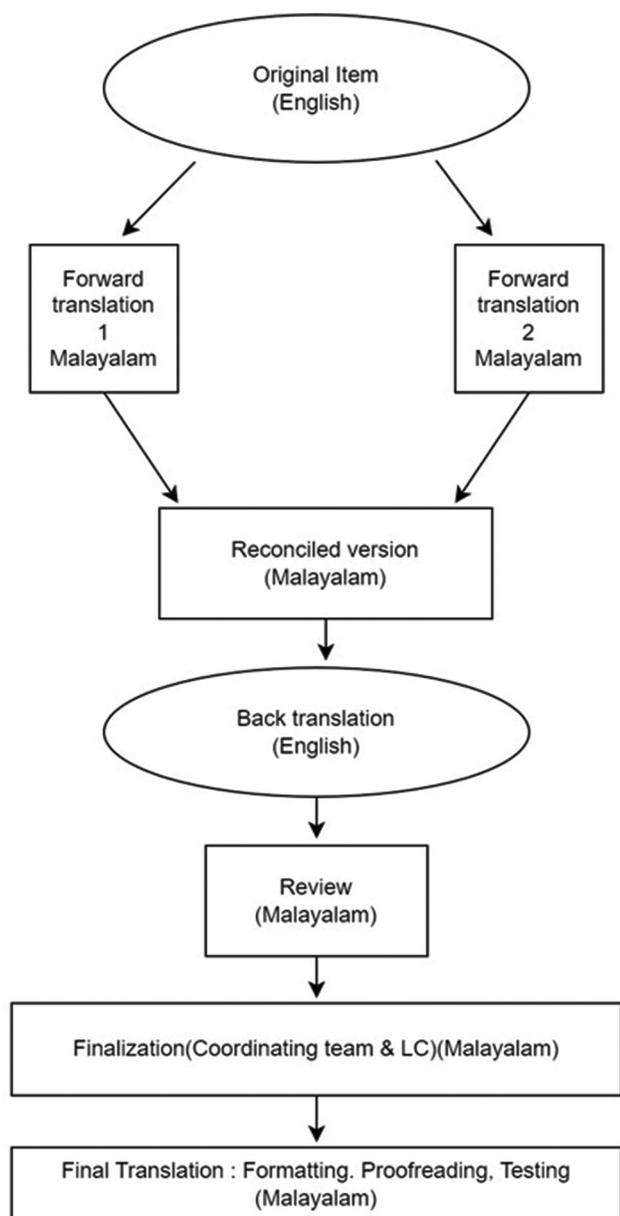


Figure 2: Flow chart of the Functional Assessment of Chronic Illness Therapy translational methodology.

were married, and 50% of them belonged to the upper lower socioeconomic status. Sixty per cent of them lived in a nuclear family, and 70% of them were taken care of primarily by their spouses. Among the patients studied, 50% ($n = 5$) had breast cancer as their primary diagnosis. Sixty per cent of them were diagnosed as having recurrence, and the remaining were diagnosed as having *de novo* metastatic disease at the time of their participation in this study. Ninety per cent of the

participants were on some form of active palliative anticancer treatment. All patients were aware of the cancer diagnosis, but only 80% of them were aware of the prognosis [Table 2]. The mean spiritual well-being score assessed by the FACIT Sp-Ex version 4 tool was 71.20 (SD = 15.10).

Cognitive debriefing interviews

Nine out of the ten participants showed a good understanding of items as the responses they selected corresponded with the reasons they provided for choosing those answers. One participant had difficulty in understanding item Sp²⁰ ('Throughout the course of my day, I feel a sense of thankfulness for what others bring to my life') and suggested it be phrased as 'The happiness I get from the people who talk to me in a day'. After discussion with the other members of the team and with the FACIT team, it was decided to retain the item as the other nine participants had no issues understanding this item.

Other than this all the participants found the items in the Malayalam tool relevant, easy to complete with unambiguous and comprehensive response categories. Once all the issues were resolved, a final validated version of the translated tool was created [Figure 3]. This final version was proofread for grammatical, spelling and formatting errors by the reviewer/language coordinator and the entire team.

Finally, the results of the translation and cross-cultural adaptation suggest that the Malayalam translated 'FACIT-SP-Ex version 4' tool is conceptually and semantically equivalent to the English version and is linguistically valid.

DISCUSSION

The aim of our study was to translate and cross-culturally adapt the FACIT-Sp-Ex version 4 tool into Malayalam and evaluate its linguistic validity. To the best of our knowledge, the FACIT-Sp-Ex version 4 is the first linguistically validated tool to assess spiritual well-being in Malayalam speaking people.

A poor translation can result in a tool that does not match the original questionnaire, making it unsuitable for different languages or cultures.^[27] To adapt a tool for a new culture, it must be both semantically and conceptually equivalent^[33] and this requires careful translation and cultural adaptation.^[27] We used the FACIT method, which includes double-back-translation as it is more effective than single translation or translation by committee,^[34] followed by the cognitive debriefing in the target population.^[30]

In our study, the process of translation and cross-cultural adaptation was conducted smoothly, with only the items such as 'difficulty', 'faith' and 'harmony' having back translation problems. These were resolved with discussion within our team and with the FACIT team.

Table 2: Sociodemographic and clinical profile of the study participants (n=10).

Sociodemographic and clinical details	n (%)
Age	
Mean±S.D	45.90±7.62
Min-Max	33-57
Gender	
Male	3 (30)
Female	7 (70)
Marital status	
Married	8 (80)
Unmarried	2 (20)
Religion	
Hindu	7 (70)
Muslim	1 (10)
Christian	2 (20)
Family type	
Nuclear family	6 (60)
Joint family	4 (40)
Socioeconomic status (Kuppuswamy scale)	
Upper middle	1 (10)
Lower middle	4 (40)
Upper lower	5 (50)
Primary caretaker	
Spouse	7 (70)
Children	1 (10)
Other relatives	2 (20)
Site of cancer	
Head and neck	2 (20)
Gastrointestinal tract	1 (10)
Sarcoma	1 (10)
Breast	5 (50)
Lung	1 (10)
Nature of the advanced disease at the time of study	
Metastatic at diagnosis	4 (40)
Recurrent	6 (60)
Aware about the diagnosis	
Yes	10 (100)
No	0 (0)
Aware about the prognosis	
Yes	8 (80)
No	2 (20)
Education level	
Middle school certificate	1 (10)
High school certificate	4 (40)
Intermediate or diploma	4 (40)
Graduate	1 (10)
Performance status	
1	1 (10)
2	6 (60)
3	3 (30)
Currently on any palliative anticancer treatment	
Yes	9 (90)
No	1 (10)

S.D: Standard deviation

FACIT-Sp-Ex (Version 4)

നിങ്ങളുടെ മാതിരി അസുഖമുള്ള മറ്റു ചിലർ പറഞ്ഞ വളരെ പ്രധാനമായ ചില പ്രസ്താവനകളാണ് താഴെ കൊടുത്തിരിക്കുന്നത്. കഴിഞ്ഞ 7 ദിവസങ്ങളിൽ അനുഭവമായ നിങ്ങളുടെ പ്രതികരണത്തെ സൂചിപ്പിക്കാൻ ഓരോ വരിയിലേയും ഒരു സംഖ്യയിൽ ദയവായി വൃത്തം വരയ്ക്കുകയോ അടയാളപ്പെടുത്തുകയോ ചെയ്യുക.

	ഒട്ടും തന്നെ ഇല്ല	ഒരല്പം കുറച്ച്	വളരെക്കുറച്ച്	കുറച്ചുകൂടി	വളരെ അധികം
Sp1 എനിക്ക് സമാധാനം തോന്നുന്നു.....	0	1	2	3	4
Sp2 എനിക്ക് ജീവിക്കാൻ ഒരു കാരണമുണ്ട്	0	1	2	3	4
Sp3 എന്റെ ജീവിതം ഫലപ്രദമാണ്.....	0	1	2	3	4
Sp4 എനിക്ക് മനസമാധാനം അനുഭവിക്കുന്നതിൽ പ്രശ്നമുണ്ട്.....	0	1	2	3	4
Sp5 എന്റെ ജീവിതത്തിൽ ഒരു ലക്ഷ്യബോധം എനിക്ക് അനുഭവപ്പെടുന്നു.....	0	1	2	3	4
Sp6 ആശ്വാസത്തിനായി എന്നിലേക്ക് ആഴത്തിൽ എത്താൻ എനിക്ക് കഴിയുന്നു.....	0	1	2	3	4
Sp7 എനിക്ക് ഉള്ളിൽ ഒരു ഐക്യം തോന്നുന്നു.....	0	1	2	3	4
Sp8 എന്റെ ജീവിതത്തിന് അർത്ഥത്തിന്റെയും ലക്ഷ്യത്തിന്റെയും അഭാവം ഉണ്ട്.....	0	1	2	3	4
Sp9 എന്റെ വിശ്വാസത്തിലോ, ആത്മീയ വിശ്വാസങ്ങളിലോ എനിക്ക് ആശ്വാസം തോന്നുന്നു.....	0	1	2	3	4
Sp10 എന്റെ വിശ്വാസത്തിലോ, ആത്മീയ വിശ്വാസങ്ങളിലോ ഞാൻ ശക്തി കണ്ടെത്തുന്നു.....	0	1	2	3	4
Sp11 എന്റെ അസുഖം എന്റെ വിശ്വാസത്തെയോ, ആത്മീയ വിശ്വാസങ്ങളെയോ ശക്തിപ്പെടുത്തിയിട്ടുണ്ട്.....	0	1	2	3	4
Sp12 എന്റെ അസുഖത്തിൽ എന്ത് സംഭവിച്ചാലും, കാര്യങ്ങൾ ശരിയാകുമെന്ന് എനിക്കറിയാം	0	1	2	3	4
Sp13 ഉയർന്ന ശക്തിയുമായി (അല്ലെങ്കിൽ ദൈവവുമായി) ബന്ധപ്പെട്ടിരിക്കുന്നുവെന്ന് എനിക്ക് തോന്നുന്നു.....	0	1	2	3	4
Sp14 മറ്റുള്ളവരുമായി ബന്ധപ്പെട്ടിരിക്കുന്നുവെന്ന് എനിക്ക് തോന്നുന്നു.....	0	1	2	3	4
Sp15 എനിക്ക് സ്നേഹിക്കപ്പെട്ടതായി തോന്നുന്നു.....	0	1	2	3	4
Sp16 എനിക്ക് മറ്റുള്ളവരോട് സ്നേഹം തോന്നുന്നു.....	0	1	2	3	4
Sp17 മറ്റുള്ളവർ എനിക്കു വരുത്തിയ ഏതെങ്കിലും ദ്രോഹത്തിന് എനിക്ക് ക്ഷമിക്കാൻ കഴിയുന്നുണ്ട്.....	0	1	2	3	4
Sp18 ഞാൻ ഇതുവരെ വരുത്തിയേക്കാവുന്ന ഏതെങ്കിലും ഉപദ്രവത്തിന് ക്ഷമിക്കപ്പെട്ടതായി എനിക്ക് തോന്നുന്നു.....	0	1	2	3	4
Sp19 എന്റെ ദിവസത്തിലുടനീളം, എന്റെ ജീവിതത്തോട് എനിക്ക് നന്ദി തോന്നുന്നു	0	1	2	3	4
Sp20 എന്റെ ദിവസത്തിലുടനീളം മറ്റുള്ളവർ എന്റെ ജീവിതത്തിലേക്ക് കൊണ്ടുവരുന്നതിന് നന്ദി തോന്നുന്നു	0	1	2	3	4
Sp21 എനിക്ക് പ്രതീക്ഷ തോന്നുന്നുണ്ട്.....	0	1	2	3	4
Sp22 പ്രകൃതിയുടെ സൗന്ദര്യത്തോടുള്ള വിലമതിപ്പ് എനിക്ക് തോന്നുന്നു	0	1	2	3	4
Sp23 മറ്റുള്ളവർ നേരിടുന്ന ബുദ്ധിമുട്ടുകളിൽ എനിക്ക് അനുകമ്പ തോന്നുന്നു	0	1	2	3	4

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Figure 3: The Functional Assessment of Chronic Illness Therapy-Spiritual-Well-being-Expanded Malayalam Version.

The results of our study indicated that the Malayalam version of FACIT-Sp-Ex version 4 is conceptually and semantically equivalent to the English version and linguistically valid.

Limitations of the study

Our study was consistent with FACIT recommendations for pilot testing of a validated tool. A larger sample size of 15-30 patients would provide greater reliability for our results.

Implications for practice

Spiritual care is an important component of quality palliative care and should be incorporated into the routine care of cancer patients. Our study introduces the Malayalam version of FACIT-Sp-Ex as a valid tool to assess spiritual well-being in advanced cancer patients.

CONCLUSION

Linguistic validation and cognitive debriefing produced the Malayalam translated FACIT-Sp-Ex version 4 tool conceptually equivalent to the original FACIT Sp Ex version 4 tool, and it is feasible for its use.

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Ethical approval

The research/study was approved by the Institutional Review Board at Malabar Cancer Centre, number 1617/IRB-IEC/13/MCC/October 18, 2022/6, dated 31st October 2022.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent.

Conflicts of interest

There are no conflicts of interest.

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Use of artificial intelligence (AI)-assisted technology for manuscript preparation

The authors confirm that there was no use of artificial intelligence (AI)-assisted technology for assisting in the writing or editing of the manuscript and no images were manipulated using AI.

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