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Validity and Reliability of Turkish Version of the Functional Assessment of Cancer Therapy–Brain Questionnaire

Background: Assessing the quality of life (QOL) of patients with brain tumors is ever more important, given increasing survivorship and the higher likelihood of developing potential morbidities associated with new therapies. **Objective:** The aim of this study was to adapt the Functional Assessment of Cancer Therapy–Brain (FACT-Br) Questionnaire for Turkish populations and test its validity and reliability. **Methods:** The questionnaire was first translated into Turkish and back-translated, adapting it to the Turkish culture. This Turkish version of the FACT-Br was administered to 500 patients. Confirmatory factor analysis was conducted to examine the scale's construct validity. Test-retest and Cronbach's α reliability coefficients were calculated to determine reliability of the total questionnaire and all subdimensions. **Results:** The questionnaire's factor structure demonstrated good fit, implying that it could be applied to the Turkish population. Interclass correlation coefficients were between 0.93 and 0.99. The 5 subscales demonstrated good internal consistency, with Cronbach's α ranging from .72 to .87. Overall, the reliability estimate for the total scale was 0.93. There was no difference between a 15-day test and retest coefficients for subscale and total scores, indicating stability. **Conclusions:** The Turkish version of the FACT-Br is a valid and reliable instrument that can be used to measure the QOL of patients with a brain tumor in Turkey. **Implications for Practice:** This assessment tool can be used in treatment evaluations and to evaluate other measures of QOL.

Primary tumors of the central nervous system (CNS) are rare. They are a heterogeneous group of tumors, constituting approximately 3% of cancers. Incidence peaks at 50 to 70 years of age and is 1.5 times higher in men.[1] Incidence of CNS tumors is 6.1 and 4.4 in 100 000 men and women, respectively. Furthermore, it is the eighth most frequent cancer

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in Turkey. Annually, nearly 4000 patients receive a diagnosis of primary brain tumors, more than 800 of whom are younger than 20 years.[2] These tumors vary in malignancy; some benign tumors can have high morbidity and mortality rates, depending on their location, and some histological benign tumors may develop into malignant tumors.[3–5]

Brain tumors differ considerably in their diagnosis, treatment, and threat to life.[6] Survivability and complications vary according to patients' age, performance status, and cognitive ability, as well as the magnitude and type of tumor.[7] Brain tumors and their treatment can shorten the life span and contribute to poorer quality of life (QOL) in affected patients.[8] Patients have difficulties with general symptoms such as headache, anorexia, nausea, seizures, and insomnia.[5,9,10] Symptoms secondary to focal neurologic deterioration, including motor deficits, personality changes, cognitive deficits, and aphasia/visual-field defects, are common and considerably affect patients' QOL.[4,5,11–13] In addition, treatments such as surgery, radiotherapy, chemotherapy, antiepileptic drugs, and corticosteroids can have a negative effect on QOL.[5,14] Despite the magnitude of these challenges, there are only a few clinical guidelines and well-tested interventions to manage symptoms and improve QOL.[12]

■ Theoretical Framework

According to the World Health Organization, health is not merely the absence of disease, but rather the individual perception of complete physical, mental, and social well-being (http://www.who.int/about/definition, 2015). By assessing treatment effectiveness, changes in the frequency and intensity of the sickness, as well as patient wellness, can be determined. One way to assess well-being is to convert subjective experiences to measurable objective data through QOL questionnaires.[5,15]

A well-validated QOL questionnaire designed for patients with brain tumors is the Functional Assessment of Cancer Therapy–Brain (FACT-Br), composed of subscales that address physical, social/family, emotional, and functional well-being as well as additional concerns. The FACT-Br is a simple, short, self-report questionnaire, originally developed in English by Weitzner et al[16] in 1995.

A valid and reliable tool that measures the QOL of patients with brain cancer is important, especially because QOL has prognostic value; QOL improvement may indicate better overall survival.[12] However, because no such questionnaires have been developed or translated into Turkish, systematic evaluations of Turkish patients' QOL and functionality are lacking. Although psychometric properties of the FACT-Br have been established in other countries,[5,16] scale validation has not been conducted with Turkish patients.

■ Objective

This study assessed the psychometric properties of the FACT-Br in a Turkish sample. Thus, the research questions were as follows:

1. Is the Turkish version of the FACT-Br valid?
2. Is the Turkish version of the FACT-Br reliable?

■ Methods

Design

An instrument methodological study was conducted.

■ Participants

Participants were 500 clinically stable patients who received a diagnosis of brain tumors at the brain surgery unit at Marmara University Institute of Neurological Sciences. Data were collected between February 18, 2012, and January 30, 2013.

There are different approaches to determine the appropriate sample size for cross-cultural adaption of a questionnaire. Comfrey and Lee[17] suggest that "the adequacy of sample size might be evaluated very roughly on the following scale: 50 = very poor, 100 = poor, 200 = fair, 300 = good, 500 = very good, 1000 or more = excellent."[18] Some authors state that the number of patients in a sample should be equal to 5 to 10 times the number of items.[19,20] Considering that the FACT-Br comprises 50 items, a sample size of 500 was deemed appropriate.

Inclusion criteria were being older than 18 years, having a histologically diagnosed brain tumor, and undergoing single or combined surgery/gamma knife/stereotactic surgery/radiotherapy/ chemotherapy treatment. Patients with cognitive impairment and/or speech disorders and those who were unconscious during the evaluation process were excluded from this study to avoid confounding variables when evaluating health status and symptoms. Approval for the study was granted by the institutional ethics committee and the hospital's chief executive. All participants provided written consent.

Measures

Data were collected using the Patient Introduction Form, FACT-Br Turkish version, and Karnofsky Performance Scale (KPS). Although the FACT-Br measures general QOL, it reflects symptoms or problems associated with brain malignancies. The FACT-General version, which measures QOL specific to cancer patients, was modified for patients with brain tumors (FACT-Br).[16] The FACT-Br contains 50 items, assessing 5 aspects of QOL: physical well-being (7 items), social/family well-being (7 items), emotional well-being (6 items), functional well-being (7 items), and any additional concerns (23 items, but according to the original FACT-Br questionnaire with the last 4 items not currently scored), scored on a 5-point scale ranging from 0 "not at all" to 4 "very much." (http://www.facit.org/FACITOrg/Questionnaires, 2015). Total scores can range from 0 to 184, with higher scores implying higher QOL The questionnaire is based on the 7 days prior to test administration.[16] The FACT-Br is written at the fourth-grade reading level, such that patients can complete it in 5 to 10 minutes. Furthermore, this self-report questionnaire can be completed by the patient or with the examiner's assistance (http://www.facit.org/FACITOrg/Questionnaires, 2015).

The KPS was developed in 1949 by Joseph Burchenal and David Karnofsky. It is widely used in clinical neuro-oncology

to diagnose the individual's functional state. A scaled point between 0 and 100 represents the individual's functional state, where 100 refers to normalcy and 0 represents death. Each functional state is differentiated by a 10-point interval.[21] According to the National Comprehensive Cancer Network guidelines, a score between 80 and 100 indicates patients based on their functional status in performing normal activities without assistance. Score between 50 and 70 indicates that one can care for oneself but cannot carry out certain activities of daily living such as working. Score between 0 and 40 indicates that one cannot care for oneself and requires hospital care ("Brain Tumor Staging," American Society of Clinical Oncology. www.cancer.net/patient/Cancer+Types/Brain+Tumor?sectionTitle=Staging, 2015). The KPS in this study was used to test the validity of the FACT-Br questionnaire.[22] A single researcher made the assessment based on observations.

Translation Into Turkish and Assessing the Forward Translation

Translation and cultural adaptation were performed in accordance with the Functional Assessment of Chronic Illness Therapy (FACIT) measurement system in the United States, which owns the overall rights to the FACT-Br. We used the FACIT translation methodology for translation and back translation (http://www.facit.org/FACITOrg/FAQ, 2015).

In the first phase, the translation of the FACT-Br from English to Turkish was performed by 3 bilingual academics. In the second phase, another native Turkish-speaker fluent in English evaluated the 3 translated versions and consolidated them into a single version. In the third phase, this version was back translated into English by another bilingual specialist living in the United States who had not seen the original form of the questionnaire. In the fourth phase, another specialist reviewed the assessment of the backward-translated version. This process focused on the conceptual equivalence to the original FACT-Br. Subsequently, the Turkish questionnaire form was sent by e-mail to 12 specialists—nursing lecturers from 10 universities in Turkey—to determine content validity. Items were scored as follows: 1 = item is not appropriate, 2 = item needs to be changed, 3 = item is appropriate but need minor corrections, and 4 = item is well suited. After obtaining their feedback, the Turkish form was evaluated by determining the content validity index (CVI) developed by Waltz and Bausell.[23,24] In this study, CVI was 96%, implying high content validity.

The prefinal version of the Turkish form was sent to FACIT with an explanation of the translation process; FACIT approved the process. Then, a pilot study using the Turkish prefinal version of the FACT-Br was conducted through interviews with 50 follow-up patients at the brain surgery policlinics. None of the patients declined participation in the pilot study. After a 15-day interval, the researcher administered the questionnaire to the same 50 patients in order to determine test-retest reliability when they returned to policlinic control. These patients were clinically stable, and their treatment had not changed during this period.

The interviews were aimed at assessing difficulties in understanding the questionnaire and patients' interpretations of all subscales. The wording of the Turkish FACT-Br was generally well understood by all patients, although some patients found it difficult to understand item 9 of the additional concerns subscale, "I am able to find the right words to say what I mean." After revising it to "I am able to find the right words to express what I mean," it was better understood.

The Turkish version of the FACT-Br (final version) was administered to 500 patients to evaluate its validity and reliability. The entire questionnaire (including the items) in the present study was read aloud by a single researcher through face-to-face interviews to ensure consistency in data collection. All items were completed by the patients and took 10 to 15 minutes. Five patients declined participation.

Construct validity, sensitivity to change, and scale item validity of the Turkish version of the FACT-Br were assessed. Furthermore, to examine the test-retest and internal reliability of the Turkish version of the FACT-Br, interclass correlation coefficients (ICCs) and internal consistency reliability were calculated.

Data Analyses

Descriptive analyses were performed on patients' demographic and clinical characteristics. Structural analysis of the FACT-Br was conducted using confirmatory factor analysis. Student t tests were performed to compare high- and low-scoring groups based on cutoffs, as well as test and retest results for total and subscale FACT-Br scores. Interclass correlation coefficients were used to measure reliability, and 95% confidence intervals were determined. Cronbach's α was used to determine internal consistency. Significance was set at $P < .05$.

■ Results

Participants' Characteristics

The 50 patients who participated in the translation and cultural adaptation phase were included in final sample of 500 patients. Participants comprised 278 women and 222 men (mean age, 50.2 [SD, 15.2] years; range, 18–90 years); 45% had cancer diagnosed in the previous 6 months, and overall 35.2% had undergone surgical treatment. According to the KPS, 44.2% of the participants scored 100 points, 36.6% scored 90, 9.2% scored 80, 2.6% scored 70, 2.4% scored 60, and 5% scored 50. Most patients (79%) were married, and a majority had graduated from primary school (52%).

Validity

Confirmatory factor analysis aims at discovering factors using correlations between variables based on a predetermined structure.[25] Independent evaluation criteria were goodness-of-fit indices for the model's suitability for the data. However, there is no clear agreement about which goodness-of-fit indices can be used to determine construct validity.[25,26] It is desirable that χ^2, used to assess the fit index, should not be significant for the acceptability of the model; however, it is usually significant in large samples.[26] In our study, χ^2 was significant (Table 1). According

Table 1 • Goodness-of-Fit Indices of the Functional Assessment of Cancer Therapy–Brain (FACT-Br) Turkish Version (N = 500, df = 979)

Fit Measure	Good Fit	Acceptable Fit	FACT-Br Turkish Version Goodness-of-Fit Indices
χ^2	$0 \leq \chi^2 \leq 2\ df$	$2\ df < \chi^2 \leq 3\ df$	5738.52
P	$.05 < P \leq 1.00$	$.01 \leq P \leq .05$	.001
χ^2/df	$0 \leq \chi^2/df \leq 2$	$2 < \chi^2/df \leq 3$	5.86
SRMR	$0 \leq$ SRMR ≤ 0.05	$0.05 <$ SRMR ≤ 0.10	0.091
RMSEA	$0 \leq$ RMSEA ≤ 0.05	$0.05 <$ RMSEA ≤ 0.10	0.099
CFI	$0.95 \leq$ CFI ≤ 1.00	$0.90 \leq$ CFI < 0.95	0.62
TLI	$0.95 \leq$ TLI ≤ 1.00	$0.90 \leq$ TLI ≤ 0.95	0.93
AIC	< AIC for comparison model		5942
CAIC	< CAIC for comparison model		6474
ECVI	< ECVI for comparison model		11.91

Abbreviations: AIC, Akaike information criterion; CAIC, consistent AIC; CFI, comparative fit index; ECVI, expected cross-validation index; RMSEA, root mean square error of approximation; SRMR, standardized root mean square residual; TLI, Tucker Lewis index.

to additional indices, including the standardized root mean square residual, root mean square error of approximation, and Tucker-Lewis index values, the fit of the Turkish version was acceptable. Furthermore, the Akaike information criterion, consistent Akaike information criterion, and expected cross-validation index values showed good fit.[27] According to these values, the 5-factor model of the FACT-Br demonstrated good fit to Turkish culture.

The Turkish FACT-Br's sensitivity to change was determined by KPS scores of 80 or greater (n = 450) ("can engage in normal activity + disease symptoms are rare or absent") and KPS scores of 70 or less (n = 50) ("need help + cannot engage in normal activities").[21,22] A KPS score of 80 or greater was equivalent to the total mean score of 127.3 (SD, 25.2) on the FACT-Br Turkish form, whereas KPS score of 70 or less was equivalent to a total mean score of 92.6 (SD, 17.3). A statistically significant difference between these 2 groups was observed (P < .001; Table 2).

Total scores were listed in ascending order to determine discriminative and predictive power of the items in relation to total scores.[23,25] The mean score was significantly lower among the participants who comprised the lowest 27% of the sample than among participants who comprised the highest 27% of the sample (90.7 [SD, 10.3] vs 157.5 [SD, 10.1], respectively; P < .001). Thus, the questionnaire items were able to predict the total score and distinguishability was good (Table 3).

Reliability

Cronbach's α coefficients for subscales ranged from .72 to .87, demonstrating good internal consistency. The reliability esti-

mate for the total scale was 0.93. The ICCs between the total FACT-Br and subscale scores were between 0.93 and 0.99 (Table 4), indicating very good internal consistency. Regarding reproducibility or temporal consistency, the mean scores differed on the 5 subscales at the 2 administrations; with a 15-day interval, they did not differ significantly (Table 5).

■ Discussion

The lack of Turkish QOL instruments for patients with brain tumors limits studies in this area. Moreover, studies on the psychometric features of the FACT-Br in relation to the Turkish population have not been conducted. We assessed the psychometric properties of the FACT-Br in Turkish because this questionnaire specifically assesses the impact of brain tumors on QOL.

The translation and cultural adaptation of the questionnaire were performed in collaboration with FACIT and were comparable to other translation processes. In terms of content validity, the Turkish questionnaire form had very high CVI values. Based on the present study, the FACT-Br Turkish version was deemed simple and easy to understand by participants. Nevertheless, there was a problem with 1 item, "I am able to find the right words to say what I mean." This may be attributable to the loss of meaning resulting from cross-cultural translation. After revising it, the item was better understood. Chen et al[28] conducted a study in Canada on 37 healthcare professionals and 50 patients with brain metastases to assess the content validity of the FACT-Br. Participants evaluating item appropriateness reported that none of the

Table 2 • Sensitivity to Change of the Functional Assessment of Cancer Therapy–Brain (FACT-Br) Turkish Version

KPS Score	n	FACT-Br Turkish Version Total Scores, Mean (SD)	P^a
KPS 50–70	50	92.6 (17.3)	<.001
KPS 80–100	450	127.3 (25.2)	

Abbreviation: KPS, Karnofsky Performance Scale.
[a]Student t test.

Table 3 • Item Validity of the Functional Assessment of Cancer Therapy–Brain (FACT-Br) Turkish Version

Cutoff Groups	n	FACT-Br Turkish Version Total Scores, Mean (SD)	P^a
Lower-27% group	135	90.7 (10.3)	<.001
Upper-27% group	135	157.3 (10.1)	

[a]Student t test; P < .001.

items were difficult, off-topic, or disruptive. However, some patients found it difficult to respond to the emotional content of the questionnaire.

Although χ^2 test results cannot be significant for goodness of fit, in practice it is very sensitive to sample size, often yielding significant values.[25–27] The Turkish questionnaire's significant χ^2 value may be attributable to sample size. Tanaka et al[29] suggest that for normally distributed data 100 to 200 participants are preferable limits. Despite the limitations of goodness-of-fit indices, the factor structure of the Turkish version demonstrated good fit.

A patient's QOL is directly related to his/her KPS score; patients with high functional performance have the highest QOL.[12,22] In the current study, a statistically significant difference was observed between upper and lower cutoff groups for both the KPS and FACT-Br, demonstrating discriminative validity. This suggests that the questionnaire content was suited to the patients' conditions and was able to distinguish between them, allowing for effective decision making. According to the KPS scores, 90% of the patients had good health status. Weitzner et al[16] have reported that high functionality could constrain the applicability of the scale in patients with low functionality.

The difference in each subscale and total scores between the 2 test administrations (15-day interval) was not statistically significant, implying that the questionnaire is consistent, with sufficient replicability. Furthermore, ICC values for all subscales and overall scores were between 0.93 and 0.99. These values were higher than a Portuguese translation and validation study of the FACT-Br (0.87–0.95).[5] Moreover, in the present study, the 5 subscales of the Turkish version demonstrated acceptable to good internal consistency, with higher Cronbach's α values than the original questionnaire. Similar to Weitzner and colleagues'[16] study, the additional concerns subscale yielded the highest values, followed by functional well-being (α = .83–.84).

The participants' demographic characteristics in the present study were similar to Weitzner and colleagues'[16] study. A single researcher collected data to avoid confounding factors resulting from inconsistent collection methods. In this study, 15% of the patients were illiterate, and 52% had a lower level of education. Although the FACT-Br is a self-report questionnaire, this issue in administering the questionnaire should be considered because of the prevalence of lower education levels in Turkey.[30]

Table 5 • Test-Retest Subscale and Total Scores of the Functional Assessment of Cancer Therapy–Brain Turkish Version (n = 50)

	Test, Mean (SD)	Retest, Mean (SD)	P^a
Physical well-being	19.4 (6.1)	19.1 (5.8)	.245
Social/family well-being	23.7 (4.7)	23.6 (4.9)	.755
Emotional well-being	17.8 (5.5)	17.3 (5.9)	.256
Functional well-being	19.0 (6.1)	19.2 (6.1)	.262
Additional concerns	51.9 (12.8)	51.9 (13.1)	.932
Total score	132 (29.04)	131.4 (29.5)	.566

[a]Student t test.

Conclusion and Implications for Clinical Practice and Research

Evaluation of the QOL can give a clearer view on how to evaluate patient complaints in the case of worsening QOL, especially in patients with brain tumor disease. Assessment of QOL of patients is not easy for clinicians and healthcare providers because of the poor health status or well-being of the patient. Clinicians and healthcare providers should be aware of factors associated with patients' QOL in order to choose the most effective interventions in the framework of treatment. The Turkish version of the FACT-Br was found to be reliable and valid in assessing the QOL of Turkish patients with brain tumors. The Turkish form of the FACT-Br may now be used to investigate the QOL of patients with brain tumors.

Future research could examine the contribution of certain demographic variables and comorbidities linked to QOL of patients with brain tumors or correlations between the FACT-Br and other measures of QOL adapted for Turkish populations. Quality of life is an important aspect of clinical practice with patients receiving treatment for a brain tumor or who are survivors of such treatment, and the FACT-Br Turkish version can assist in identifying such patients with concerning QOL scores.

Table 4 • Cronbach's α Values and Interclass Correlation Coefficient of the Functional Assessment of Cancer Therapy–Brain Turkish Version Subscales and Total Score

	Cronbach's α	ICC (95% CI)	P
Physical well-being	0.728	0.97 (0.95–0.98)	<.001
Social/family well-being	0.847	0.99 (0.98–0.99)	<.001
Emotional well-being	0.834	0.93 (0.88–0.96)	<.001
Functional well-being	0.873	0.99 (0.98–0.99)	<.001
Additional concerns	0.867	0.98 (0.97–0.99)	<.001
Total score	0.933	0.98 (0.97–0.99)	<.001

Abbreviations: CI, confidence interval; ICC, interclass correlation coefficient.

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