Development and Psychometric Properties of a Tuberculosis-Specific Multidimensional Health-Related Quality-of-Life Measure for Patients with Pulmonary Tuberculosis

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A B S T R A C T

Background: Various generic instruments exist to assess health-related quality of life (HRQOL) in patients with tuberculosis (TB), but a psychometrically sound disease-specific instrument is lacking. **Objectives:** The present study aimed to develop and psychometrically validate a multidimensional TB-specific HRQOL instrument relevant to the value of patients with pulmonary TB in Iraq with an eye toward cross-cultural application. **Methods:** The core general HRQOL questionnaire is composed of the Functional Assessment of Cancer Therapy-General items. A modular approach was followed for the development of the Functional Assessment of Chronic Illness Therapy-Tuberculosis (FACIT-TB) questionnaire in which a set of items assessing quality-of-life (QOL) issues not sufficiently covered by the core Functional Assessment of Cancer Therapy-General items, but considered to be relevant to the target population, was added. Moreover, principal-component analysis was used to determine the new subscale structure of the questionnaire. **Results:** In addition to the 27 items of the core questionnaire, a set of 20 items referring to disease symptoms related to the site of infection, adverse effects, and additional QOL dimensions such as fatigue, social stigma, and economic burden of the illness was included. Factor analysis demonstrated that the FACIT-TB construct comprised five domains. **Conclusions:** A rigorous method was applied in the development of the FACIT-TB measure to fully understand the impact of TB on patients' QOL. The instrument is psychometrically sound and portrays multiple important dimensions of HRQOL. FACIT-TB is relatively brief, is easy to administer and score, and is appropriate for use in clinical trials and practice.
Keywords: disease-specific instrument, FACT-G, health-related quality of life, pulmonary tuberculosis, social stigma.

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Introduction

For decades, health-related quality of life (HRQOL) has been introduced in medical practices and assessed in many diseases including tuberculosis (TB). The prevention of morbidity and the maintenance of quality of life (QOL) experienced by individuals treated for TB have become the goals of management [1]. Various generic instruments exist to assess HRQOL in patients with TB, but a psychometrically sound disease-specific instrument is sorely lacking. The present study aimed to develop and psychometrically validate an HRQOL instrument that is multidimensional in scope, including physical well-being (PWB), functional well-being (FWB), social well-being (SWB), and emotional well-being (EWB) as well as symptoms and disease-specific concerns.

Several disease-specific HRQOL instruments were derived from the Functional Assessment of Chronic Illness Therapy (FACIT) Measurement System. The FACIT Measurement System provides an array of generic and targeted measures with multiple benefits in terms of validity, ease of administration, global application, and interpretation. Although the Functional Assessment of Chronic Illness Therapy-General (FACT-G) was developed for use in patients with cancer, its extensions have been used and validated in other chronic illnesses including HIV/AIDS, multiple sclerosis, Parkinson's disease, and rheumatoid arthritis, as well as in the general population [2,3].

Methods

The study comprised two parts: 1) development of the Functional Assessment of Chronic Illness Therapy-Tuberculosis (FACIT-TB) instrument and 2) psychometric validation of the scale.

Development of the FACIT-TB Instrument

A modular approach was followed for the development of the FACIT-TB questionnaire in which a set of items assessing QOL issues not sufficiently covered by the core FACT-G items, but considered to be relevant to the target population, was added. This set of items refers to disease symptoms related to the site of infection (pulmonary region), adverse effects, other issues related to treatment, and additional QOL dimensions such as fatigue, fear of disease transmission, and economic burden of the illness. The development process of an additional concerns subscale of the new FACIT-TB instrument involved several stages: 1) concept clarification, 2) item pool generation, 3) item reduction, and 4) refinement. Table 1 presents a summary of the stages in the development of the additional concerns subscale of the FACIT-TB questionnaire.

All questions asked about the last week before the administration of the questionnaire. The supplementary questions were grouped in a separate section titled "Additional-Concerns Items." Feedback on any problem with wording, comprehension, instruction, relevance of items, and the overall impression of the measure was provided by all investigators and the measure was further refined accordingly. The response choices of the additional subscale were similar to those of the core questionnaire, ranging from "not at all" to "very much." Moreover, the final format was sent to the FACIT (the developers of FACT-G and related instruments) for review and was further refined.

Subsequently, the FACIT-TB instrument was translated and linguistically validated in Arabic. The linguistic validation process is composed of general procedures derived from internationally accepted guidelines for linguistic validation and cultural adaptation of the FACIT Measurement System [4]. The translated

questionnaire was pretested among seven patients with pulmonary TB (PTB) at the Thoracic and Respiratory Diseases Specialist Center in Baghdad, Iraq. Patients were then interviewed to ascertain whether they had any difficulty comprehending any questions and to label any questions not relevant to their QOL. Furthermore, they were requested to identify QOL issues not currently covered by the questionnaire. A permission to develop FACIT-TB in collaboration with the FACIT and all related subscales and to translate the measurement into Arabic for the study under the guidance of the FACIT system was granted. Moreover, the study protocol, informed consent, and other relevant documents were reviewed and approved by the Research and Teaching Aids Division, Training and Development Center, Ministry of Health, Iraq.

The FACIT-TB questionnaire is suitable for self-administration or face-to-face interview by a trained interviewer. For self-administration, patients are instructed to read the brief direction on the top of the page. Patients' correct understanding was ensured, and they were encouraged to complete every question in chronological order without skipping any items. During interview administration, patients were given a copy of the questionnaire as a reference for the response options. Administration via interview was deemed appropriate by giving adequate training to the interviewer so as to elicit nonbiased patient responses. The health concepts described by the scale range in score from 0 to 188 (for the 47-item FACIT-TB), with higher scores indicating higher levels of function and/or better health. The subjects' responses are presented as a profile of scores calculated for each subscale. Total score can be calculated by the sum of subscales scores.

Psychometric Validation of the FACIT-TB Instrument

This phase of the study was conducted between September 1, 2012, and July 31, 2013, among consecutive patients with PTB treated at the Thoracic and Respiratory Disease Specialist Center, the largest center for the diagnosis, treatment, and recording of all new and previously treated TB cases in Baghdad, Iraq. Patients with PTB aged 18 years or older who completed at least 2 weeks of TB treatment were included in the study. Moreover, patients with

Table 1 – Stages in the development of the FACIT-TB questionnaire.			
Stage	**Objective**	**Method**	**Result**
1. Concept clarification	To establish an approach for HRQOL assessment in patients with PTB	It involved extensive literature review, opinion of investigators, and input from patients, consultants, and experts (defined as credentialed MD)	The key aspects of domains contribute to QOL in patients with PTB
2. Item pool generation	To supply sufficient and informative items that are of greatest interest to patients with PTB in Iraq	The FACIT Measurement System was the main source of items for the additional concerns subscale for PTB infection. In addition, input from four expert physicians with at least 4 years' experience in treating patients with TB in Iraq	Fifty candidate question for the additional concerns subscale of PTB infection
3. Item reduction	To consider the most elevant questions	Item pools were then carefully reviewed and were examined to discern their relevance for the population with PTB in Iraq	Twenty additional concern items
4. Refinement	To refine the structure of the scale	The format of the instrument was standardized with respect to instructions, header, and order of the questions	A 47-item instrument to assess the HRQOL for patients with PTB in Iraq

FACIT, Functional Assessment of Chronic Illness Therapy; FACIT-TB, Functional Assessment of Chronic Illness Therapy-Tuberculosis; HRQOL, health-related quality of life; PTB, pulmonary tuberculosis; QOL, quality of life.

any associated pulmonary disease such as lung cancer, chronic obstructive pulmonary disease, asthma, and other chronic diseases likely to affect HRQOL, namely, diabetes mellitus and cardiovascular disease, and hospitalized patients were excluded from the validation study. Patients with underlying immune suppression such as renal failure and cancer, subjects receiving immunosuppressive drug treatment, individuals unable to read the questionnaire who were also suffering from hearing impairment, and mentally handicapped patients were also excluded.

Statistical Analyses

Psychometric and other analyses were conducted using Statistical Package for Social Science 18 for Windows. The responses of the total sample (n = 305) were subjected to factor analysis to examine the underlying structure of the 47 items of the FACIT-TB scale using principal-component analysis (PCA) with orthogonal rotations. To obtain the largest possible sample for the factor analysis, subjects with missing data, totaling 22.62% of the entire sample (n = 69), had missing items imputed using the mean item value for the sample. The remainders of the analyses, however, were run using only subjects' raw or nonimputed data. The adequacy of fit of each item in the scale was evaluated using the following criteria:

1. Is the factor loading of the item greater than a cutoff point of 0.4?
2. How good is the conceptual fit of the item with QOL domains identified in factor analysis?

Internal consistency reliability analysis was performed by calculating Cronbach alpha coefficient. Moreover, the FACIT-TB questionnaire was administered at two occasions for each patient separated by an interval of 1 week to examine test-retest reliability.

Results

During the development process of the FACIT-TB instrument, several broad domains that were assumed to contribute to the QOL of patients with PTB in Iraq were proposed. Table 2 represents the domains of QOL affected by TB disease. Each domain was further divided into a series of specific areas summarizing each particular domain. In addition, nine scales represent the patrimony of the additional concerns subscale for PTB disease. Table 3 displays the additional concerns items and items' code and origin. As a result, 47 items were included in the final structure of the FACIT-TB questionnaire before conducting the PCA. Moreover, information derived from the pretesting did not require additional domains of QOL. Respondents found that the questionnaire covered a broad spectrum of QOL in patients with TB disease and better characterized their HRQOL.

The 305 subjects who were subjected to the validation study ranged in age from 18 to 91 years, with a mean age of 41.59 years; 64.6% of them were men, and 28.2% were illiterate. The average completion time of the questionnaire was 16.3 ± 3.1 minutes. Moreover, our results found no significant effects for the mode of administration of the FACIT-TB questionnaire (self-administration vs. face-to-face interview) on the reporting of HRQOL data.

Before performing the PCA, the suitability of the data for factor analysis was assessed. Inspection of the correlation matrix revealed the presence of many coefficients of 0.3 or more. The Kaiser-Meyer-Olkin value was 0.791, exceeding the recommended value of 0.6, and Bartlett's Test of Sphericity was statistically significant (P < 0.001), supporting the factorability of the correlation matrix.

PCA revealed the presence of 12 components with eigenvalues exceeding 1, explaining 72.6% of the total cumulative variance. An inspection of the scree plot revealed that a clear cutoff fell

Table 2 – Proposed domains that were assumed to contribute to the QOL in patients with PTB in Iraq.

Domain I: Physical Well-Being

- Somatic sensation of physical symptoms
- Adverse side effects of anti-TB drugs
- Energy and fatigue

Domain II: Psychological Well-Being
- Psychological reaction of TB diagnosis
- Distress about spreading the disease to others
- Social stigma

Domain III: Function Well-Being
- Effect on the activity of daily living
- Effect on work capacity

Domain IV: Social Well-Being
- Impact on the personal relationship
- Impact of social support
- Impact on sexual relationship

Domain VI: Spiritual Well-Being
- Impact on religion and relationship with God
- Impact on personal belief

Domain V: Environment
- Economic burden of TB disease
- Clinic environment
- Physical environment including pollution and climate

Domain VII: Perception
- General health perception and overall QOL
- Perspective changes

PTB, pulmonary tuberculosis; QOL, quality of life; TB, tuberculosis.

after the fifth factor (Fig. 1). Therefore, five factors were retained for further investigation according to Catell's scree test recommendation. In fact, a five-factor solution produced a readily interpretable structure and collectively explained 53% of the total variance. The structure was quite similar to that of the FACT-G and the names of the factors were chosen to be as consistent as possible with those of the core instrument, while still allowing for modifications based on the TB-specific content of the subscales. Because there were two items with very low factor loading, including GS7 cross-loaded on the first and second factors (0.23 and 0.16; respectively) and TB1 with factor loading of 0.22 on the first factor and 0.18 on the third factor, they were not considered in the further reliability and validity analysis. The PCA was performed again after the omission of these items.

The first factor explained 25.56% of the variance and contained 17 items, of which 7 were the original FACT-G PWB items and 10 came from the expanded TB-specific concerns subscale. As a result, this first factor was named PWB. Table 4 contains the result of factor analysis. The second factor (11.98% of the total variance) contained seven items, of which six were the original FACT-G SWB items and one was from the TB-specific concerns subscale. This second factor was named social and economic well-being, reflecting the item content related to subjects' social life as well as the economic burden of the disease.

Moreover, 11 items were contained in the third factor, which accounted for 7.01% of the variance. Six of the original FACT-G EWB items loaded highly on this factor, as did five additional concerns subscale items. The later items mainly reflected concerns about the social stigma of TB, such as HI10, HI2, and HI4. Therefore, this factor was named emotional well-being/stigma of having TB (EWB/TB). The fourth factor accounted for 6.05% of the

| Table 3 – Additional concerns items and their origin.		
Code	Items	Origin
HI7	I feel fatigued	Functional Assessment of HIV Infection (FAHI) scale for HIV co-infected patients
HI12	I feel weak all over	FAHI scale for HIV co-infected patients
BMT 6	I get tired easily	Functional Assessment of Cancer Therapy-Bone Marrow Transplantation (FACT-BMT) scale for patients undergoing bone marrow transplantation
L2	I have been coughing	Functional Assessment of Cancer Therapy-Lung (FACT-L) scale for patients with lung cancer
B1	I have been short of breath	Functional Assessment of Cancer Therapy-Breast (FACT-B) for patients with breast cancer
TB1	I am worried about coughing up blood	Nil
BRM3	I am bothered by fever (episode of high body temperature)	Functional Assessment of Cancer Therapy-Biologic Response Modifier (FACT-BRM) scale for patients receiving biologic response modifiers
B8	I am bothered by change in weight	FACT-B for patients with breast cancer
HI2	It is hard to tell other people about my infection	FAHI scale for HIV co-infected patients
HI4	I worry about spreading my infection	FAHI scale for HIV co-infected patients
HI5	I am concerned about what the future holds for me	FAHI scale for HIV co-infected patients
HI10	I am embarrassed by my illness	FAHI scale for HIV co-infected patients
TB2	My physical condition and/or medical treatment cause me financial difficulties	European Organization for Research and Treatment of Cancer (EORTC) scale for patients with cancer
Ga1	I have a loss of appetite	Functional Assessment of Cancer Therapy-Gastric (FACT-Ga) scale for patients with gastric cancer
Hep4	I have had itching	Functional Assessment of Cancer Therapy-Hepatobiliary (FACT-Hep) scale for patients with hepatobiliary cancer
Hep8	I have discomfort or pain in my stomach area	FACT-Hep scale for patients with hepatobiliary cancer

continued on next page

Table 3 – *continued*		
Code	Items	Origin
TB3	Dust worsens my symptoms	Nil
Sp10	I find strength in my faith or spiritual belief	Functional Assessment of Chronic Illness Therapy-Spiritual Well-Being (FACIT-Sp) scale to assess spiritual well-being in chronic illness
Sp11	My illness has strengthened my faith or spiritual belief	FACIT-Sp scale to assess spiritual well-being in chronic illness
Sp3	My life has been productive	FACIT-Sp scale to assess spiritual well-being in chronic illness

variance and contained seven items. All these items were FACT-G FWB items; accordingly, this factor was named FWB. Three items loaded most highly on the fifth factor, which accounted for 4.36% of the variance. These items reflected spirituality. This factor was confidently named spiritual well-being.

The internal consistency estimate for the FACIT-TB total score was 0.92. The Cronbach alpha coefficients for the FACIT-TB subscales were uniformly high across all the subscales, ranging from 0.81 to 0.93. Table 5 contains the mean ± SD and Cronbach alpha coefficients for the FACIT-TB total score and for each subscale score. Test-retest reliability analysis was performed by calculating items' intraclass correlation coefficients within a recall period of 1 week. Out of 305 subjects, 267 patients with PTB agreed to participate in test-retest reliability study. Intraclass correlation coefficients ranged from 0.72 to 0.92.

Discussion

There is considerable evidence that the somatic sensation of physical symptoms and the adverse effects of TB therapy negatively affect the QOL of patients with TB [5,6]. In addition, a study carried out in China using the Medical Outcomes Study short-form 36 health survey (SF-36) questionnaire demonstrated
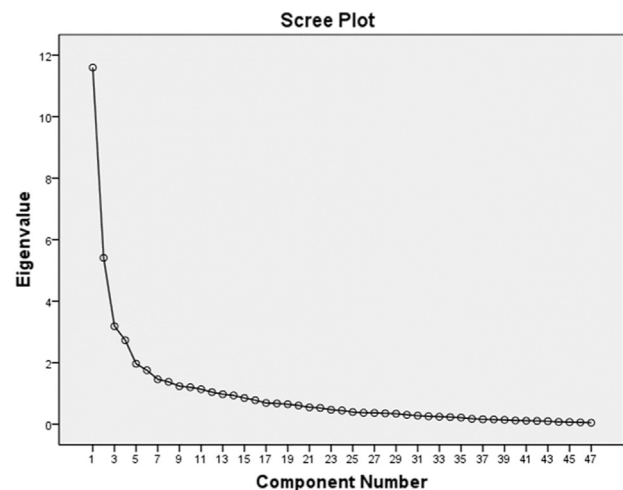
Fig. 1 – The scree plot for 47-item FACIT-TB. FACIT-TB, Functional Assessment of Chronic Illness Therapy-Tuberculosis.

Table 4 – Factor loading of 45-item FACIT-TB subscale items.	
Subscale and items	Factor loading with identified subscale
Physical well-being	
I feel ill	0.827
I get tired easily	0.794
I have a lack of energy	0.784
I have pain	0.782
I feel weak all over	0.771
I feel fatigued	0.735
I have been short of breath	0.730
I have nausea "a sense of vomiting outbreak"	0.700
Because of my physical condition, I have trouble meeting the needs of my family	0.688
I am bothered by fever (episode of high body temperature)	0.650
I am forced to spend time in bed	0.645
I have discomfort or pain in my stomach area	0.628
I have had itching	0.626
I have a loss of appetite	0.615
I have been coughing	0.579
I am bothered by side effects of treatment	0.520
Dusts worsen my symptoms	0.394
Social and economic well-being	
I feel close to my friends	0.902
I get emotional support from my family	0.886
I am satisfied with family communication about my illness	0.844
My family has accepted my illness	0.843
I feel close to my partner (or the person who is my main support)	0.826
I get support from my friends	0.827
My physical condition and/or medical treatment cause me financial difficulties	0.320
Emotional well-being/Stigma of having TB	
I worry that my condition will get worse	0.785
I worry about dying	0.712
I am concerned about what the future holds for me	0.654
I am embarrassed by my illness	0.583
It is hard to tell other people about my infection	0.574
I am losing hope in the fight against my illness	0.501
I am bothered by change in weight	0.484
I worry about spreading my infection	0.481
I feel nervous	0.427
I feel sad	0.376
I am satisfied with how I am coping with my illness	0.344
Functional well-being	
I am content with the quality of my life right now	0.770
My work (include work at home) is fulfilling	0.693

Table 4 – continued	
Subscale and items	Factor loading with identified subscale
I am able to work (include work at home)	0.691
I am able to enjoy life	0.667
I am enjoying the things I usually do for fun	0.616
I have accepted my illness	0.507
I am sleeping well	0.498
Spiritual well-being	
I find strength in my faith or spiritual belief	0.886
My illness has strengthened my faith or spiritual belief	0.869
My life is still productive	0.663

FACIT-TB, Functional Assessment of Chronic Illness Therapy-Tuberculosis.

that physical scales are the most affected scales among patients treated for TB compared with the general population [7]. Moreover, prolonged cough, fatigue, and weight loss are most concerning for patients with TB and the reason patients seek medical care [5,6,8,9]. Thus, items with respect to these symptoms were considered. Patients also reported other classic symptoms of PTB as key features of the disease including fever, hemoptysis, decrease appetite, and shortness of breath [10].

Guo et al. [11] first reported the impact of adverse drug reaction (ADR) induced by first-line anti-TB drugs on patients' HRQOL using the SF-36 questionnaire. The finding showed that ADRs resulted in more decrement in HRQOL. In addition, patients with lower baseline SF-36 scores had a higher risk of developing ADRs during the first 3 months of TB treatment [11]. ADRs due to anti-TB medications such as epigastric distress, pruritus, itching, hepatotoxicity, visual disturbances, and arthralgia are common [12]. In view of this, items regarding the impact of the most common ADRs on patients' HRQOL were supplemented.

A large proportion of patients perceive stigma of TB including fear of disease transmission, values and attitudes associated with shame, blame, and the adverse social judgment about a patient identified with TB, as well as disclosure of disease status [13–16]. Such perception might have a great impact on the SWB and the EWB of patients with TB and their families [17]. Therefore, questions to capture the social stigma linked with TB were included.

A review of English language literature demonstrates the impact of TB on patients' spiritual and financial well-being [18]. In many cultures, TB is considered a God-given punishment for sins and patients may ask God for forgiveness to attain cure [19,20]. Furthermore, it is difficult to separate spirituality, religion, and culture because patients' acceptance of their illness may stem from cultural acceptability of the disease [18]. A qualitative research in a culturally diverse setting reported that TB enhanced patients' spirituality and faith in God was a considerable support for them while they were ill [5]. Moreover, patients reported that being sick was considered a "wake-up call" to adopt a productive and healthier lifestyle and that recovering from a serious illness made one want to thank God for a chance to get better [5,21]. Items related to personal belief, religion, and relationship with God were added to the additional concerns subscale.

Although TB treatment in Iraq is sponsored by the government, the additional nonmedication costs such as consultation

Table 5 – Mean, SD, and Cronbach α coefficient of FACIT-TB and of each subscale.

Scale/subscale (no. of items)	Mean ± SD	Possible score range	Observed score range	Cronbach α
Physical well-being (17)	31.25 ± 17.26	0–68	2–67	0.93
Social and economic well-being (7)	22.54 ± 5.37	0–28	1–28	0.84
Emotional well-being/Stigma of having TB (11)	20.17 ± 9.82	0–44	1–43	0.81
Functional well-being (7)	13.28 ± 7.31	0–28	0–28	0.84
Spiritual well-being (3)	9.74 ± 2.63	0–12	0–12	0.82
FACIT-TB (45)	96.99 ± 29.80	0–180	17–165	0.92

FACIT-TB, Functional Assessment of Chronic Illness Therapy-Tuberculosis; TB, tuberculosis.

fees, money spent on diagnostic and other investigations, expenditure incurred for travel, lodging, special food, and persons accompanying patients, loss of wages due to illness, and decreased earning ability due to TB affect the financial state of individuals and families [22–25]. Studies reported that the low case detection and treatment completion rate of TB may partly be due to economic consequences of the diagnosis and treatment of the disease [25]. Thus, a question on the economic burden of TB was considered in constructing the subscale. According to patients' opinion, environmental factors including pollution and large amount of dust in the air in Iraq markedly influence their well-being; therefore, an item to assess the impact of environmental effect was supplemented.

There are a number of reasons that items were selected from previous inventories. First, the selected items have gone through a repeated testing process and have proven themselves to be advantageous and psychometrically sound. Second, it saves time and work and the need for constructing new ones [2,26]. Third, there are only a limited number of ways to ask about a specific problem. If the scale is trying to tap symptoms of TB disease, for instance, it is difficult to ask about cough in a way that has not been used previously [27].

This study is to our knowledge the first to develop and assess psychometric properties and reliability of TB-specific instruments for patients with PTB in Iraq. In terms of the mode of administration, our findings demonstrated technical equivalence in the sample of patients with PTB in Iraq [28]. Flexibility is important in selecting methods and modes of questionnaire administration to accommodate the needs of patients with diverse social, educational, and functional skills [29]. Moreover, the result of PCA demonstrated a five-factor structure that corresponded mostly to the FACT-G subscales [2]. Several items, however, did not pass at least one of the two criteria described for the evaluation of the adequacy of fit for each item. These included four items with factor loadings of less than 0.4 on all factors.

Item GE1 loaded on both the first and the third factors (0.443 and 0.380, respectively). This item was retained in the third factor because it did have a reasonably good fit with the items in this factor. The decision to retain item GE1 in the third factor was consistent with the FACT-G core questionnaire [3], and to produce a subscale that is empirically sound and has a sense of conceptual coherence. Similarly, item B8 was evaluated with both PWB and EWB/TB (factor loading of 0.368 and 0.496, respectively). From Iraqi people's perspectives, someone bothered by change in weight reflects the mental image of the body figure, in other words, someone's feelings about his or her body. Furthermore, the item loaded most highly on the EWB/TB factor and there is considerable evidence of the association between weight changes and EWB [30,31]. Spontaneously, factor 3 was considered a more attractive location for this item.

Because Iraqi people, particularly women, tend to regard sex as a private and sensitive topic, a relatively low item response rate was demonstrated for the sex-related item. All Arab cultures, however, share the same traditional conservative view

of sexuality [32]. Furthermore, a study conducted in Mainland China to assess the reliability and validity of the Chinese version of the FACT-Cervix in women with cervical cancer also revealed that the Chinese culture retains conservative values regarding sexual topics, which was confirmed by the low item response rate for item GS7 [33]. The tendency of Iraqi people to be less sexually outspoken does not mean that sexual problems are not experienced or that such problems may not be detrimental to the HRQOL of patients with PTB in Iraq. Although the Iraqi culture's traditional conservative view obscures understanding of the true sexual concerns for patients, health care providers are expected to clarify this issue and to find more proficient solutions. Thus, this challenging task may improve the patients' acceptability of the sex-related item within the instrument.

FACIT-TB had excellent internal consistency reliability, whereas the reliability of the subscales ranged from good to excellent according to the commonly accepted rule of thumb for describing internal consistency reliability using Cronbach alpha [34]. In comparison, the internal consistency estimate for the original FACT-G total score and the subscales was also uniformly high. The Cronbach alpha coefficient for the FACT-G total score was 0.872 and for all subscales ranged from 0.736 to 0.817 [3].

FACIT-TB is the first measure specifically designed to assess the HRQOL of patients with TB disease. The measure will benefit from ongoing enhancements. Specifically, research should further develop the psychometric properties of the FACIT-TB. In addition, given the cross-sectional nature of this initial validation study, future longitudinal research should examine the responsiveness of the measure to longitudinal clinical change. Future research using FACIT-TB in samples with greater sociodemographic and clinical heterogeneity will also advance the generalizability of the measure.

Conclusions

A rigorous method was applied in the development of the FACIT-TB scale to better characterize QOL in patients with TB. The 45-item FACIT-TB is a psychometrically sound instrument that portrays multiple important dimensions of HRQOL, and it is a part of the FACIT Measurement System. The development of the TB-specific HRQOL measure will provide an additional parameter to fully evaluate the effectiveness of treatment and treatment strategies, as well as help health care planners focus on the nonmedication aspects of TB management and allow them to allocate funds where these are most needed.

Acknowledgments

REFERENCES

[1] Blumberg HM, Burman WJ, Chaisson RE, et al. American Thoracic Society/Centers for Disease Control and Prevention/Infectious Diseases Society of America: treatment of tuberculosis. Am J Respir Crit Care Med 2003;167:603–62.

[2] Webster K, Cella D, Yost K. The Functional Assessment of Chronic Illness Therapy (FACIT) Measurement System: properties, applications, and interpretation. Health Qual Life Outcomes 2003;1:79.

[3] Cella DF, Tulsky DS, Gray G, et al. The Functional Assessment of Cancer Therapy scale: development and validation of the general measure. J Clin Oncol 1993;11:570–9.

[4] Bonomi AE, Cella DF, Hahn EA, et al. Multilingual translation of the Functional Assessment of Cancer Therapy (FACT) quality of life measurement system. Qual Life Res 1996;5:309–20.

[5] Hansel NN, Wu AW, Chang B, et al. Quality of life in tuberculosis: patient and provider perspectives. Qual Life Res 2004;13:639–52.

[6] Marra CA, Marra F, Cox VC, et al. Factors influencing quality of life in patients with active tuberculosis. Health Qual Life Outcomes 2004;2:58–68.

[7] Chamla D. The assessment of patients' health-related quality of life during tuberculosis treatment in Wuhan, China. Int J Tuberc Lung Dis 2004;8:1100–6.

[8] Ayisi J, van't Hoog A, Agaya J, et al. Care seeking and attitudes towards treatment compliance by newly enrolled tuberculosis patients in the district treatment programme in rural western Kenya: a qualitative study. BMC Public Health 2011;11:515.

[9] Yimer S, Holm-Hansen C, Yimaldu T, et al. Health care seeking among pulmonary tuberculosis suspects and patients in rural Ethiopia: a community-based study. BMC Public Health 2009;9:454.

[10] World Health Organization. Global Tuberculosis Control: WHO Report 2011. Geneva, Switzerland, 2011.

[11] Guo N, Marra F, Fitzgerald JM, et al. Impact of adverse drug reaction and predictivity of quality of life status in tuberculosis. Eur Respir J 2010;36:206–8.

[12] Yee D, Valiquette C, Pelletier M, et al. Incidence of serious side effects from first-line antituberculosis drugs among patients treated for active tuberculosis. Am J Respir Crit Care Med 2003;167:1472–7.

[13] Baral S, Karki D, Newell J. Causes of stigma and discrimination associated with tuberculosis in Nepal: a qualitative study. BMC Public Health 2007;7:211.

[14] Gerrish K, Naisby A, Ismail M. The meaning and consequences of tuberculosis among Somali people in the United Kingdom. J Adv Nurs 2012:2654–63.

[15] Jittimanee SX, Nateniyom S, Kittikraisak W, et al. Social stigma and knowledge of tuberculosis and HIV among patients with both diseases in Thailand. PLoS One 2009;4:e6360.

[16] Van Rie A, Sengupta S, Pungrassami P, et al. Measuring stigma associated with tuberculosis and HIV/AIDS in southern Thailand: exploratory and confirmatory factor analyses of two new scales. Trop Med Int Health 2008;13:21–30.

[17] Abebe G, Deribew A, Apers L, et al. Knowledge, health seeking behavior and perceived stigma towards tuberculosis among tuberculosis suspects in a rural community in Southwest Ethiopia. PLoS One 2010;5:e13339.

[18] Chang B, Wu AW, Hansel NN, et al. Quality of life in tuberculosis: a review of the English language literature. Qual Life Res 2004;13:1633–42.

[19] Khan A, Walley J, Newell J, et al. Tuberculosis in Pakistan: socio-cultural constraints and opportunities in treatment. Soc Sci Med 2000;50:247–54.

[20] Liefooghe R, Michiels N, Habib S, et al. Perception and social consequences of tuberculosis: a focus group study of tuberculosis patients in Sialkot, Pakistan. Soc Sci Med 1995;41:1685–92.

[21] Rajeswari R, Muniyandi M, Balasubramanian R, et al. Perceptions of tuberculosis patients about their physical, mental and social well-being: a field report from south India. Soc Sci Med 2005;60:1845–53.

[22] Mauch V, Woods N, Kirubi B, et al. Assessing access barriers to tuberculosis care with the Tool to Estimate Patients' Costs: pilot results from two districts in Kenya. BMC Public Health 2011;43.

[23] Pocock D, Khare A, Harries AD. Case holding for tuberculosis in Africa: the patients' perspective. Lancet 1996;347:1258.

[24] Rajeswari R, Balasubramanian R, Muniyandi M, et al. Socio-economic impact of tuberculosis on patients and family in India. Int J Tuberc Lung Dis 1999;3:869–77.

[25] Steffen R, Menzies D, Oxlade O, et al. Patients' costs and cost-effectiveness of tuberculosis treatment in DOTS and non-DOTS facilities in Rio de Janeiro, Brazil. PLoS One 2010;5:e14014.

[26] Sprangers MA, Cull A, Bjordal K, et al. The European Organization for Research and Treatment of Cancer. Approach to quality of life assessment: guidelines for developing questionnaire modules. EORTC Study Group on Quality of Life. Qual Life Res 1993;2:287–95.

[27] Streiner DL, Norman GR. Health Measurement Scales: A Practical Guide to Their Development and Use. (4th ed.). New York, NY: Oxford University Press, 2008.

[28] Dujaili JA, Syed SSA, Hassali MA, et al. Comparability of interview and self-administration of the Functional Assessment of Chronic Illness Therapy-Tuberculosis (FACIT-TB) instrument in Iraqi pulmonary tuberculosis patients. Value Health;17:A573.

[29] Hahn EA, Rao D, Cella D, et al. Comparability of interview- and self-administration of the Functional Assessment of Cancer Therapy-General (FACT-G) in English- and Spanish-Speaking ambulatory cancer patients. Med Care 2008;46:423–31.

[30] Wright FE, Boyle S, Baxter K, et al. Understanding the relationship between weight loss, emotional well-being and health-related quality of life in patients attending a specialist obesity weight management service. J Health Psychol 2012;18:574–86.

[31] Loth KA, Mond J, Wall M, et al. Weight status and emotional well-being: longitudinal findings from Project EAT. J Pediatr Psychol 2011;36:216–25.

[32] Oz S. Teaching sex education in the Arab sector in Israel: an approach for working with a traditional population. J Sex Marital Ther 1996;22:54–62.

[33] Ding Y, Hu Y, Hallberg I. Psychometric properties of the Chinese version of the Functional Assessment of Cancer Therapy-Cervix (FACT-Cx) measuring health-related quality of life. Health Qual Life Outcomes 2012;10:124.

[34] George D, Mallery P. SPSS for Windows Step by Step: A Simple Guide and Reference 11.0 Update (4th ed.). Boston, MA: Allyn & Bacon, 2003.