

Review

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## The Functional Assessment of Chronic Illness Therapy (FACIT) Measurement System: properties, applications, and interpretation

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Published: 16 December 2003

Received: 30 July 2003

*Health and Quality of Life Outcomes* 2003, 1:79

Accepted: 16 December 2003

This article is available from: <http://www.hqlo.com/content/1/1/79>

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### Abstract

The Functional Assessment of Chronic Illness Therapy (FACIT) Measurement System is a collection of health-related quality of life (HRQOL) questionnaires targeted to the management of chronic illness. The measurement system, under development since 1987, began with the creation of a generic CORE questionnaire called the Functional Assessment of Cancer Therapy-General (FACT-G). The FACT-G (now in Version 4) is a 27-item compilation of general questions divided into four primary QOL domains: Physical Well-Being, Social/Family Well-Being, Emotional Well-Being, and Functional Well-Being. It is appropriate for use with patients with any form of cancer, and extensions of it have been used and validated in other chronic illness condition (e.g., HIV/AIDS; multiple sclerosis; Parkinson's disease; rheumatoid arthritis), and in the general population. The FACIT Measurement System now includes over 400 questions, some of which have been translated into more than 45 languages. Assessment of any one patient is tailored so that the most-relevant questions are asked and administration time for any one assessment is usually less than 15 minutes. This is accomplished both by the use of specific subscales for relevant domains of HRQOL, or computerized adaptive testing (CAT) of selected symptoms and functional areas. FACIT questionnaires can be administered by self-report (paper or computer) or interview (face-to-face or telephone). Available scoring, normative data and information on meaningful change now allow one to interpret results in the context of a growing literature base.

### Review

#### What is the FACIT Measurement System?

The FACIT Measurement System is a collection of health-related quality of life (HRQOL) questionnaires targeted to the management of chronic illness. "FACIT" (Functional Assessment of Chronic Illness Therapy) was adopted as the formal name of the measurement system in 1997 to portray the expansion of the familiar "FACT" (Functional Assessment of Cancer Therapy) questionnaires into other chronic illnesses and conditions.

The measurement system, under development since 1987, began with the creation of a generic CORE questionnaire called the Functional Assessment of Cancer Therapy-General (FACT-G). The FACT-G (now in Version 4) is a 27-item compilation of general questions divided into four primary QOL domains: Physical Well-Being, Social/Family Well-Being, Emotional Well-Being, and Functional Well-Being. It is considered appropriate for use with patients with any form of cancer, and has also been used and validated in other chronic illness condition (e.g.,

HIV/AIDS and multiple sclerosis) and in the general population (using a slightly modified version).

Validation of a core measure allowed for the evolution of multiple disease, treatment, condition, and other targeted questionnaires. FACIT scales are constructed to complement the FACT-G, addressing relevant disease-, treatment-, or condition-related issues not already covered in the general questionnaire. Each is intended to be as specific as necessary to capture the clinically-relevant problems associated with a given condition or symptom, yet general enough to allow for comparison across diseases, and extension, as appropriate, to other chronic medical conditions. The latest version of the FACIT Measurement System, Version 4, was designed to enhance clarity and precision of measurement without threatening its established reliability and validity (from Version 3). Formatting simplification, item-reduction, and rewording (standardizing items across scales) constitute the major areas of change from version 3 to 4. To facilitate the clinical utility of the FACIT system, new methods for computer acquisition, scoring, and display of data will be available. These additions and improvements will likely ease patient burden, expedite data collection and scoring, and further guide the clinician or researcher in meaningful interpretation.

As of spring, 2003, there are over 40 different FACIT scales and nine disease-specific symptom indices. FACIT scales include 3 general, 14 disease-specific, 5 treatment-specific, 8 condition-specific, and 10 non-cancer specific measures.

#### **Why assess health-related quality of life with the FACIT Measurement System?**

The FACIT Measurement System offers several benefits to an investigator seeking to measure HRQOL in people with cancer, HIV disease, multiple sclerosis, arthritis and other conditions. First, item content was determined by combined expert and patient input, ensuring that clinically important issues relevant to patients are included. Second, there are several hundred publications detailing its performance, many of which are reports of formal validation studies. Thus, there is a deep reference literature to which one can compare results. A third advantage to FACIT is the availability of normative and cross-illness comparative scores to which one can relate results. Finally, a growing body of research has illustrated clinically significant differences and changes in scores in FACIT scales, aiding in study sample size determination and interpretation of study results.

#### **How was the FACIT developed and validated?**

Most FACIT measures have undergone a standard scale development and validation methodology, which takes

place in four phases: item generation, item-reduction, scale construction, and psychometric evaluation [1-22]. The scale development process involves considerable input from patients and expert health care providers, using a semi-structured interview designed to elicit personal experiences and educated opinions about how a disease, treatment, or condition may affect physical status, emotional well-being, functional well-being, family / social issues, sexuality/intimacy, work status, and future orientation. This process yields an exhaustive list of candidate items, which then undergo a series of reviews and reductions based on patient and expert ratings and item quality. A finite set of targeted concerns are then derived. Final candidate items are formatted with response choices compatible with a 5-point Likert-type scale, and appended to the FACT-G.

Newly constructed FACIT subscales then undergo an initial assessment of reliability and validity using a sample of at least 50 patients. The validation design typically involves patient completion of a baseline assessment, a test-retest assessment 3–7 days later, and a third assessment 2–3 months later to demonstrate sensitivity to change over time. Relevant sociodemographic and treatment data is also collected and a battery of other measures administered at the baseline and 2–3 month retest to help determine convergent and divergent validity. A comprehensive analysis of the data gathered (including item response theory modeling when sample size allows) yields useful psychometric information and establishes initial reliability and validity of the scale.

#### **Which language translations are available?**

Equivalent foreign language versions of the FACIT questionnaires are now available in more than 45 different languages (for some scales), permitting cross-cultural comparisons of people from diverse backgrounds (see <http://www.facit.org> for details). FACIT language translations include the following: Afrikaans, Arabic, Bulgarian, Chinese-Simplified, Chinese-Traditional, Croatian, Czech, Danish, Dutch, English, Estonian, Farsi, Finnish, French, Georgian, German, Greek, Hebrew, Hindi, Hungarian, Indonesian, Italian, Japanese, Korean, Latvian, Lithuanian, Malay, Marathi, Norwegian, Pedi, Polish, Portuguese, Romanian, Russian, Serbian, Slovak, Slovene, Spanish, Swahili, Swedish, Tagalog, Tamil, Telugu, Thai, Tswana, Turkish, Vietnamese, and Zulu.

The FACIT Translation Project team has developed a scientific approach to translating patient reported outcomes measures, which includes a rigorous forward-backward-forward methodology, psychometric testing, and cognitive interviewing. This process was developed to ensure that the resulting measures are both conceptually equivalent as well as cross-culturally valid, thus enabling data

pooling in multinational clinical trials that enroll patients who speak various languages.

The FACIT Translation Project was initiated to fulfill a need for valid and reliable HRQOL assessment instruments in languages other than English as part of the FACIT Measurement System. The translation methodology developed for the FACIT project has proven to be successful in adapting questionnaires into European, Asian and African languages. The list of available languages has grown, keeping pace with the globalization of medical outcomes research.

#### **Why are the FACIT questionnaires good instruments to consider using?**

There are many questionnaires available to measure HRQOL of people with chronic illnesses. The FACIT questionnaires are some of the more commonly used questionnaires in national and international research settings. Selecting an appropriate outcome measure is often driven by many considerations including the purpose of the study, the patient-reported endpoint required to address the study purpose, the content of the items in the questionnaire with regard to the study purpose, and the validity of the questionnaire. Although no single questionnaire is right for all studies, the FACIT Measurement System provides an array of generic and targeted measures with multiple benefits regarding validity, ease of administration, global application, and interpretation.

- *Approximately 50 different generic and targeted questionnaires and symptom indices*
- *Range of questionnaires allow for greater disease, treatment or condition specificity*
- *Easy to complete (most in 5–10 minutes)*
- *Demonstrated reliability, validity and sensitivity to change*
- *Some questionnaires translated and pre-tested in over 45 languages*
- *Special consideration for spiritual well-being, palliative care, and treatment satisfaction*
- *More social well-being coverage than most other commonly-used instruments*
- *Written at the 4th Grade reading level (9–10 years old) or below*
- *Demonstrated equivalence in mode of administration (interview vs. self-administration)*

- *Validated for use with special populations such as with the elderly and those living in rural areas*
- *Appropriate for use in patients with a variety of chronic health conditions, and in the general population*
- *Multiple scoring options: subscale scores, total score, and a Trial Outcome Index (TOI)*
- *Used by major cooperative clinical trial groups, international-industry sponsored research, other government/military funded research, and health practice self studies*
- *No charge for use of the English versions*

#### **What are the applications of the FACIT?**

Current implementation of the FACIT questionnaires range in use from Phase I, II, and III clinical trials and other treatment evaluations, as an intervention tool in the clinical management of symptoms (both physical and psychological), and as an outcomes measure in health practice studies.

#### **What areas of health does it measure?**

Four primary quality of life domains are covered in the general measure: Physical Well-Being (PWB; 7-items), Social/Family Well-Being (SWB; 7-items), Emotional Well-Being (EWB; 6-items); and Functional Well-Being (FWB; 7-items). Disease-, treatment-, and condition-specific scales, and the non-cancer specific scales (e.g., spiritual well-being, treatment satisfaction) cover additional physical, functional, social, emotional and/or treatment-related concerns.

#### **How long does it take to complete?**

Respondent burden is typically minimal given that the questionnaire is written at the 4<sup>th</sup> grade-reading level, and is specifically formatted for ease of self-administration. Average time to complete the 27-item FACT-G is 5–10 minutes, and even less for the stand-alone scales and symptom indices. As a rule of thumb, it takes 2–3 minutes to complete 10 questions, so administration length can be estimated after one selects the subscales to be combined in one's assessment plan. The option to complete the questionnaire by interview decreases burden for patients whose condition (e.g. fatigue; poor eyesight) or mood preclude them from completing the questionnaire by self-administration, but may increase completion time.

#### **How is the FACIT administered?**

The FACIT scales are designed for patient self-administration, either on paper or direct to computer. They can also be administered using face-to-face or telephone interview. Interview administration is appropriate with adequate training of interviewers to minimize bias to patient

responses. One of the aims of a large multicenter study of cancer and HIV patients (N = 1615) was to test the psychometric properties and statistical equivalence of the English and Spanish language versions of the FACT subscales across literacy level (low vs. high) and mode of administration (self report vs. interview). Technical equivalence across mode of administration was demonstrated in the high literacy patients; there were few differences in data quality or psychometric measurement properties of the FACT-G. Technical equivalence between modes of administration with the FACT permits unbiased assessment of the impact of chronic illnesses and their treatments on patients from diverse backgrounds [23].

We have additional data to support the appropriateness of computer-administered versions of the questionnaire, including a multimedia touchscreen program [24]. We are currently developing other novel administration methods such as computer-assisted telephony and web-based administration. Across these modes of administration, our preliminary data suggest that while there are small differences in the way people respond based on mode of administration, these alternate formats are essentially equivalent.

#### **How is the FACIT scored?**

All FACIT scales are scored so that a high score is good. To achieve this, we reverse response scores on negatively-phrased questions, then sum item responses. In cases where individual questions are skipped, scores are prorated using the average of the other answers in the scale. The total FACT-G score is obtained by summing individual subscale scores (PWB + EWB + SWB + FWB). Total scores for the disease-, treatment-, and condition-specific subscales are obtained by summing all subscale scores (PWB + EWB + SWB + FWB + additional concerns subscale). For these scales there is also the option to calculate a Trial Outcome Index (TOI). The TOI can be computed for any FACIT disease-, treatment-, or condition-specific scale. It is the sum of the Physical Well-Being (PWB), Functional Well-Being (FWB), and "additional concerns" subscales. Our experience with this TOI endpoint is that it is an efficient summary index of physical/functional outcomes. It is therefore a common endpoint used in clinical trials, because it is responsive to change in physical/functional outcomes, sometimes more than a total (overall) multidimensional aggregated score, which includes social and emotional well-being. While social and emotional well-being are very important to quality of life, they are not as likely to change as quickly or dramatically over time or in response to physical health interventions such as pharmaceutical treatments in clinical trials.

When there are missing data, prorating subscale scores is acceptable as long as *more than* 50% of the items were

answered (e.g., a minimum of 4 of 7 items, 4 of 6 items, etc). The total (FACT-G) score is considered appropriate to score as long as *overall item response rate* is greater than 80% (e.g., at least 22 of 27 FACT-G items completed).

#### **Is there automated administration or scoring software?**

Raw score scoring templates and computer scoring programs written for use with both SAS and SPSS statistical software packages are available for all FACIT measures. We are currently developing computer-administered programs for various FACIT questionnaires. Packages will include a patient-friendly computer-administered questionnaire, with automatic scoring and the ability to plot individual patient scores longitudinally on a reader-friendly graph. Some programs may also offer plotted graphs with patient and normative reference data. We expect to have these programs available by the end of 2003. See <http://www.facit.org> for updates.

#### **How are FACIT scores interpreted?**

Higher scores for the scales and subscales indicate better quality of life. Average FACT-G scores for a group of patients can be compared to normative data to determine the HRQOL of the patients relative to the general U.S. population. These comparisons facilitate meaningful interpretation of HRQOL in patient populations.

Normative data for the FACT-G and the 13-item fatigue subscale have been collected on 1,075 men and women drawn from the general U.S. population. The range of ages in the sample was 18 to 91 years with a mean (s.d.) of 45.9 (16.6), 50.6% were female, 75.9% were white, and 87.8% had at least a high school education. Means (s.d.) for FACT-G and fatigue subscale scores were 80.1 (18.1) for total FACT-G; 22.7 (5.4) for PWB; 19.1 (6.8) for SWB; 19.9 (4.8) for EWB; 18.5 (6.8) for FWB, and 40.1 (10.4) for the fatigue subscale. Normative data have also been established separately for males and females and for 10-year age groups. For more information on U.S. population norms for the FACT-G visit our website at <http://www.facit.org>.

#### **Are the FACIT questionnaires responsive to change? What is a meaningful change in a FACIT score?**

The FACIT instruments have been shown to be responsive to change in both clinical and observational studies. Considerable work has been done in recent years to identify minimally important differences (MIDs) for scores of scales and subscales from several FACIT instruments. An MID is the "smallest difference in score in the domain of interest that patients perceive as important, either beneficial or harmful, and that would lead the clinician to consider a change in the patient's management" (p 377) [25]. MIDs were identified using both anchor- and distribution-based methods [26]. MID estimates may vary across

**Table 1: Minimally important differences for select FACIT scales**

Instrument	Scale/Subscale	MID (points)	Reference
FACT-G	PWB	2-3	[28]
	SWB	NA	
	EWB	2*	[28,29]
	FWB	2-3	[28]
	Total FACT-G	3-7	[27,28,30,31]
FACT-Anemia	Fatigue Subscale	3-4	[27,31]
	TOI-Fatigue	5	[27]
	TOI-Anemia	6	
	Total FACT-Anemia	7	
FACT-Breast	Breast cancer subscale	2-3	[30]
	TOI-Breast	5-6	
	Total FACT-Breast	7-8	
FACT-Colorectal	Colorectal cancer subscale	2-3	[32]
	TOI-Colorectal	4-6	
	Total FACT-Colorectal	5-8	
FACT-Head & Neck	Total FACT-Head & Neck	6-12	[33]
FACT-Lung	Lung cancer subscale	2-3	[34]
	TOI-Lung	5-6	

\*This MID should be considered tentative as it may be revised based on future research.

patients and possibly across patient groups; thus, ranges of MIDs were identified for some scales. As TOIs are frequently used measures of QoL, MIDs have been established for the TOIs for several FACIT instruments. Table 1 provides a list of established MIDs:

These MIDs can be used to aid the interpretation of group differences and changes in HRQOL over time, and they can be useful in sample size calculations.

**Has the FACIT been used in individual patient assessment?**

Yes. The FACT-G has been used extensively in clinic-based evaluations of individual patients. Instruments like the FACT-G, relatively brief, multidimensional questionnaires, are designed primarily for group comparisons, lacking precision needed for individual diagnosis. Nevertheless, individual assessment using the FACT-G has been helpful to patients and clinicians attempting to estimate change over time. It can also be a useful "springboard" for discussion. We have developed more accurate assessment from our item response theory (IRT)-derived item-banks that are indeed sufficiently precise for individual diagnosis. Each of our IRT-derived item banks (pain, fatigue, physical function, emotional distress, etc.) can be administered to patients using a computerized assessment algorithm, which selects only those questions that will add to the precision of the measurement estimate. This procedure, called computerized adaptive testing (CAT), results in brief, accurate assessment of the selected HRQOL domains.

**Is there Item Banking of the FACIT Questionnaires?**

Yes. Our item-banking program is very active. There are two types of item banks. The first is a simple compilation of all items (questions) available in our database. We have over 400 questions in this "general" item bank, and most of them have been translated into several languages.

A second kind of item bank is one that can be created from large sample datasets using IRT modeling techniques. We have this item bank as well. Our current item banks include the following HRQOL domains: fatigue (72 items); pain (43 items); physical functioning (43 items); general emotional distress (48 items); cognitive complaints (35 items); and illness-specific concerns (46 items). We have several other IRT-derived item banks in development.

**In which populations has the FACIT been used?**

The FACIT Measurement System has questionnaires targeted to:

- Cancer
- HIV Disease
- Multiple Sclerosis
- Arthritis
- Parkinson's Disease

- Stroke
- Other non-life-threatening chronic illnesses or conditions
- General medical practice

**How may we obtain a copy of the questionnaires, permission for use, or more information about the FACIT Measurement System?**

You may obtain user-ready copies of all available English language FACIT measures, permission for use of a FACIT measure, and a variety of other information regarding the FACIT Measurement System on our website at <http://www.facit.org>.

**How much does it cost to purchase the FACIT itself?**

License for use of any English version of a FACIT measure is granted free of charge. Collaborators are asked to agree to a simple user agreement and to register their use of a FACIT questionnaire by completing a Collaborators' Project Information Form. License for use of a translated questionnaire may require a fee. This decision is made on an individual project basis according to the nature of the trial, the questionnaires and translations to be used, the sponsor, and existing contractual arrangements.

**How can we obtain scientific support during our study?**

Consultation services are available. Please contact [http://information@facit.org](mailto:information@facit.org) with a description of your research project or clinical trial and support needs.

**Conclusion**

The Functional Assessment of Chronic Illness Therapy (FACIT) Measurement System is a collection of health-related quality of life (HRQOL) questionnaires that assess multidimensional health status in people with various chronic illnesses, including cancer. The measurement system, under development since 1987, began with the creation of a generic CORE questionnaire called the Functional Assessment of Cancer Therapy-General (FACT-G). The FACT-G (now in Version 4) is a 27-item compilation of general questions divided into four primary QOL domains: Physical Well-Being, Social/Family Well-Being, Emotional Well-Being, and Functional Well-Being. It is appropriate for use with patients with any form of cancer, and extensions of it have been used and validated in other chronic illness condition (e.g., HIV/AIDS; multiple sclerosis; Parkinson's disease; rheumatoid arthritis), and in the general population. The FACIT Measurement System now includes over 400 questions, some of which have been translated into more than 45 languages. Assessment of any one patient is tailored so that the most-relevant questions are asked and administration time for any one assessment is usually less than 15 minutes. This is accom-

plished both by the use of specific subscales for relevant domains of HRQOL, or computerized adaptive testing (CAT) of selected symptoms and functional areas. FACIT questionnaires can be administered by self-report (paper or computer) or interview (face-to-face or telephone). Available scoring, normative data and information on meaningful change now allow one to interpret results in the context of a growing literature base.

**Authors' contributions**

Ms. Webster contributed to the conception of much of the original research, the conduct of many of the studies, and to the writing of the manuscript. Dr. Cella contributed to the conception of all original research, the conduct of all of the referenced studies, and the writing of the manuscript. Dr. Yost contributed to the analysis of the data and to the writing of the manuscript.

**Acknowledgements**

Over the past 15 years, more than 10,000 people have agreed to participate in research projects that have collectively contributed to the writing of this manuscript. We are grateful to those people for agreeing to help advance health status assessment with no motive other than to give something back. We are also grateful to so many of our colleagues who have contributed to the accumulated knowledge captured by the FACIT Measurement System research program, including Elizabeth Hahn, Chih-Hung Chang, Amy Peterman, Lauren Lent, Sonya Eremenco, Susan Yount, David Eton, Jin-Shei-Lai, and Marianne Brady.

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