

**Title of measure:****Functional Assessment of Cancer Therapy-Prostate Version 4 (FACT-P)**

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**DISCLAIMER:**

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**Brief overview:**

The FACT-P is a multidimensional, self-report QoL instrument specifically designed for use with prostate cancer patients (1, 2, 3). It consists of 27 core items which assess patient function in four domains: Physical, Social/Family, Emotional, and Functional well-being, which is further supplemented by 12 site specific items to assess for prostate related symptoms. Each item is rated on a 0 to 4 Likert type scale, and then combined to produce subscale scores for each domain, as well as a global QoL score. Higher scores represent better QoL. Version 4 retains most items from Version 3, however some items have been reworded and adjustments will have to be made in comparing scores between versions.

**Validated (Yes/No):**

Yes (2, 3). The first FACT-G validation paper was published in 1993 by Cella et al, see references below. Developed as a disease-specific adjunct to the Functional Assessment of Cancer Therapy (FACT) measurement system, a 12-item prostate cancer subscale (PCS) was developed and tested in three independent samples: a subscale development sample (n = 43), validity sample 1 (n = 34), and validity sample 2 (n = 96). The 12 items ask about symptoms and problems specific to prostate cancer. These questions are added to the general (FACT-G) instrument. Internal consistency of the PCS ranged from 0.65 to 0.69, with coefficients for FACT-G subscales and aggregated scores ranging from 0.61 to 0.90. Concurrent validity was confirmed by the ability to discriminate patients by disease stage, performance status, and baseline prostate-specific antigen (PSA) level. Sensitivity to change in performance status and PSA score over a 2-month period suggested that some subscales of the FACT-Prostate (P) (including the PCS) are sensitive to meaningful clinical change. These findings support use of the FACT-P as a meaningful component of QOL evaluation in men undergoing therapy for prostate cancer.

**Psychometric properties and references:**

Internal consistency of the PCS ranged from 0.65 to 0.69, with coefficients for FACT-G subscales and aggregated scores ranging from 0.61 to 0.90.

**Normative data:**

Normative data is currently being developed with references.

**Clinically significant changes:**

Not specifically available for FACT-P.

**Website or how to register to use:**

Go to [www.facit.org](http://www.facit.org) and click on “registration permission” to use one or more of the Fact scales (in English), which can be obtained by agreeing to a user’s agreement and completing one collaborator’s project information form per project. This information can be found under the users agreement link on this website.

**List any fees for usage:**

Currently, there are no fees for use of any of the English versions of the Fact questionnaires.

**Languages available:**

The Fact questionnaires are now available in more than 45 different languages, permitting cross-cultural comparisons of people from diverse backgrounds. Please check the website for the specific languages available for FACT-G.

**Instructions for CRAs and or credentialing for administration:**

The FACT-P is designed for patient self-administration, but can also be administered by interview format. For self-administration, patients should be instructed to read the brief directions at the top of the page. After the patient's correct understanding has been confirmed, he/she should be encouraged to complete every item in order without skipping any. Some patients may feel that a given question is not applicable to them and will therefore skip the item altogether. **Patients should be encouraged to circle the response that is most applicable.** If, for example, a patient is not currently receiving any treatment, the patient should circle “not at all” to the question “I am bothered by side effects of treatment.”

During interview administration, it is helpful to have the patient hold a card on which the response options have been printed. Interview administration is considered appropriate given adequate training of interviewers so as to elicit non-biased patient responses. One of the aims of a large multicenter study of cancer and HIV patients (N=1227) 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 vs. interview). Technical equivalence across mode of administration was demonstrated in the high literacy patients; there were no differences in data quality or in mean QOL scores, after adjustment for performance status rating, socioeconomic status, gender and age. 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.

**Time to administer instrument:**

Five to ten minutes

**Quality assurance for administration (if needed):**

None.

### **Scoring of instrument:**

#### Scoring The Fact-G

The FACT-G scoring guide identifies those items which must be reversed before being added to obtain subscale totals. Negatively stated items are reversed by subtracting the response from “4”. After reversing proper items, all subscale items are summed to a total, which is the subscale score.

Handling missing items. If there are missing items, subscale scores can be prorated. This is done by multiplying the sum of subscale by the number of items in the subscale, then dividing by the number of items actually answered. This can be done on the scoring guide or by using the formula below:

Prorated subscale score = [Sum of item scores] x [N of items in subscale] ÷ [N of items answered]

When there are missing data, prorating by subscale in this way 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 score is then calculated as the sum of the unweighted subscale scores. The FACT scale is considered to be an acceptable indicator of patient quality of life as long as **overall item response rate** is greater than 80% (e.g., at least 22 of 27 FACT-G items completed). This is not to be confused with individual subscale item response rate, which allows a subscale score to be prorated for missing items if greater than 50% of items are answered

Multilingual versions can be scored on the English language scoring guides.

#### Scoring The Specific Scales & Symptom Indices

For the Prostate Cancer-specific subscale, the procedure for scoring is the same as described above for the FACT-G. Again, over 50% of the items (e.g., 5 of 9 items, 7 of 12 items) must be completed in order to consider each subscale score valid.

The total score consists of the sum of the FACT-G (the first 4 subscales common to almost all scales) plus the prostate-specific subscale.

### **References:**

Cella, D.F. Manual: Functional Assessment of Cancer Therapy (FACT) Scales and Functional Assessment of HIV Infection (FAHI) Scale. Chicago: Rush-Presbyterian-St. Luke's Medical Center (1994).

Cella, D.F., et al. The Functional Assessment of Cancer Therapy scale: development and validation of the general measure. J Clin Oncol 11, 570-9 (1993).

Esper P, Mo F, Chodak G etal Measuring QOL in men with prostate cancer using the FACT-P instrument. Urology 50(6), 920-8 (1997).