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# Re-validation and screening capacity of the 6-item version of the Cancer Worry Scale

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## Abstract

**Objective:** Fear of cancer recurrence (FCR) is one of the major existential unmet needs of cancer survivors. Due to growing availability of evidenced-based interventions for high FCR, valid and reliable brief measures of FCR are needed. This study aimed to validate the 6-item Cancer Worry Scale (CWS) and to establish a cut-off score for high FCR.

**Methods:** Participants in this study were 1033 cancer survivors and patients recruited as part of 5 existing studies on FCR involving patients and survivors with gastro-intestinal stromal tumors, colorectal, breast, and prostate cancer. De-identified data of the CWS, Fear of Cancer Recurrence Inventory (FCRI), Impact of Event Scale, Hospital Anxiety and Depression Scale, and EORTC-QLQ-C30 were amalgamated for the analyses.

Confirmatory factor analysis of the CWS was performed. Sensitivity and specificity were tested with the FCRI as gold standard.

**Results:** Results confirmed that the 6-item version of the CWS maintained good construct validity, convergent and divergent validity, and high internal consistency (α 0.90). The optimal cut-off for the 6-item CWS was 9 versus 10 using the 12 vs 13 FCRI-SF score (sensitivity 82%, specificity 83%) and the 15 vs 16 FCRI-SF score (sensitivity 88%, specificity 73%). Using the highest FCRI-SF cut-off (21 vs 22), the optimal CWS cut-off was 11 vs 12 (sensitivity 88%, specificity 81%).

**Conclusions:** The present results provide researchers and clinicians with a brief valid and reliable measure of FCR which is suitable for measuring FCR in cancer patients and survivors.

KEYWORDS

cancer, Cancer Worry Scale, fear of cancer recurrence, oncology

## 1 | BACKGROUND

Fear of cancer recurrence (FCR) is a prevalent concern amongst cancer survivors.[1,2] High levels of fear are characterized amongst others by a long duration and greater severity of the problem, impact on daily life, having cancer-related thoughts and imagery that are difficult to control, and coinciding psychological distress.[3] Evidence-based interventions to address high FCR have recently been developed and proven effective,[4-6] yet there are currently few well-validated brief (≤10 item) measures of FCR which are suitable to screen for inclusion in clinical trials and to facilitate new areas of FCR research like the impact of personalized medicine on FCR.[7-9]

The 6-item Cancer Worry Scale (CWS) was originally developed in English to assess fear of developing cancer in women at risk of

  

hereditary cancer.[10] Two items were later added to the Dutch version of the CWS[11] (*How often do you worry about the chance of family members developing cancer?*, *How concerned are you about the possibility that you will ever need surgery (again)?*). Due to the lack of Dutch validated brief measures of FCR, the CWS was adapted in 2010 to assess FCR in curatively treated breast,[12] prostate,[13] and colorectal cancer patients.[14,15] FCR prevalence rates are reported in these validation samples[12-14] and newly diagnosed head and neck cancer patients,[16] sarcoma patients,[17] and adolescent and young adult cancer survivors.[18] The studies suggest that 31% to 62% experience high FCR.

Despite the CWS 8 item version already being well utilized in research, previous studies have highlighted concerns about validity of the final 2 items due to sub-optimal item-total correlations (0.34-0.45 for item 7; 0.59-0.63 for item 8) in the validation studies.[12-14]

There is a current debate in the FCR literature concerning the point at which FCR becomes "clinically significant". The Fear of Cancer Recurrence Inventory[19] severity subscale (FCRI-SF) is to date the only measure that has a cut-off established compared with a "gold standard" clinical interview. The authors of the FCRI reported an initial cut-off score of ≥13 on the 9-item severity subscale (FCRI-SF) as having optimal sensitivity (88%) and specificity (75%) to screen for high FCR determined by clinical interview. The same authors subsequently reported a score of ≥16 with increased specificity (97%), but decreased sensitivity (67%), and was suggested as a means for detecting severe FCR or identify patients that may be in need of immediate specialist referral.[20] However, based on a study which combined the results of 2 independent studies of 167 Australian and 40 Canadian cancer survivors,[21] it has recently been suggested that a higher cut-off (≥22) might be required to the most severe and clinically significant forms of FCR.

The aim of the present study is to validate a shorter 6-item version of the CWS. A secondary aim is to establish a cut-off for high FCR of the 6-item CWS that can be used for inclusion in clinical trials and research settings. Given the current debate concerning optimal cut-offs for high FCR, 3 previously published FCRI-SF cut-offs (≥13, ≥16, ≥22) are used as the gold standard.[19-21]

## 2 | METHODS

### 2.1 | Sample and procedure

Participants in this study were 1033 cancer survivors and patients recruited as part of 5 existing studies of FCR involving colorectal cancer (CRC) survivors and patients[14,15] sarcoma patients with gastro-intestinal stromal tumors (GIST),[17] breast cancer survivors,[12] and prostate cancer survivors.[13] Participants were identified by searching hospital databases for consecutive patients meeting the eligibility criteria. Eligible CRC survivors were treated with curative intent and disease-free 1 to 9 years after surgery. Eligible CRC patients were awaiting their curatively intended surgery. Sarcoma patients with GIST were eligible if they had undergone surgery and/or had received imatinib (Glivec)/sunitinib (Sutent) as part of their treatment. Breast cancer survivors were eligible if they were disease-free, 0 to 5 years after surgery and treated with curative intent. Prostate cancer survivors were eligible if diagnosed with localized prostate adenocarcinoma and treated with curative radical prostatectomy with or without additional radiotherapy. Questionnaires were completed either online or in paper and pencil form. Further details of the procedure are published elsewhere.[12-15,17] Only participants with complete data on all 6 CWS items were included in the current analyses (52 participants were excluded due to 1 or more missing CWS items). Excluded patients were more likely to have had prostate cancer ($n$ = 35; $\chi^2(4) = 44.3$, $P < .001$), be male ($n$ = 41; $\chi^2(1) = 26.3$, $P < .001$), older (M = 69.7; $t(61.9) = 6.0$, $P < .001$), and increased time since diagnosis (M = 7.9; $t(49.3) = 4.4$, $P < .001$) than included patients.

#### 2.1.1 | Measures

***Original 6-item Cancer Worry Scale (CWS)*** assesses concerns about cancer recurrence and the impact of these concerns on daily functioning.[10] Items are rated on a 4-point Likert scale ranging from 1 ("*never*") to 4 ("*almost always*"). Possible scores range from 6 to 24 with higher scores indicating more worry. Cronbach's α = 0.90.

***Fear of Cancer Recurrence Inventory (FCRI)*** is a valid and reliable theoretically derived 42-item multi-dimensional measure of FCR.[20] The total score of the FCRI ranges between 0 and 168 with higher scores indicating higher levels of FCR. Cronbach's α = 0.95.

The subscale *severity*, also referred to as *FCRI-short form*, consists of 9 items. Scores range from 0 to 36. Cronbach's α = 0.84.

***Impact of Event Scale (IES)*** assesses the frequency of intrusive and avoidant phenomena during or after the traumatic experience of cancer.[22] Fifteen items are divided into 2 dimensions: *Intrusion* (7 items) and *Avoidance* (8 items). Scores range from 0 to 75 with higher scores reflecting higher frequency of symptoms.
Cronbach's α = 0.92.

***Hospital Anxiety and Depression Scale (HADS)*** assesses psychological distress.[23] This questionnaire includes 14 items divided into 2 subscales, *Anxiety* and *Depression*, both consisting of 7 items. Subscale scores can range from 0 to 21. Higher scores indicate more anxiety or depressive symptoms. The HADS was validated for cancer survivors.[24] Cronbach's α = 0.89.

***EORTC Quality of Life Questionnaire Core 30 (EORTC QLQ-C30)*** assesses health-related quality of life (QOL) in cancer patients.[25] The questionnaire consists of 5 functional scales (physical, role, cognitive, emotional, and social functioning), 3 symptom scales (fatigue, pain, nausea/vomiting), 6 single symptom items (dyspnea, insomnia, appetite loss, constipation, diarrhea, financial difficulties), and a global QOL scale. Scores are transformed linearly and range from 0 to 100 for the overall total score, with a higher score indicating better functioning or QOL.[25] Cronbach's α = 0.85.

### 2.2 | Statistical analyses

Descriptive statistics were computed to characterize the sample. Incomplete data were recorded as missing and handled as such in the analyses. Inter-item correlations and corrected item-total correlations were calculated for each item and the CWS total score. Confirmatory factor analysis (CFA) was performed to confirm the single-factor structure of the CWS, using the weighted least squares estimator with a diagonal weight matrix, robust standard errors, and

a mean-adjusted and variance-adjusted chi-square statistic with delta parameterization in MPlus.[26] Model fit was assessed with the chi-square test, the Tucker-Lewis Index (TLI),[27] the Comparative Fit Index (CFI),[28] and the Root Mean Square Error of Approximation (RMSEA).[29] Because the chi-square test is highly sensitive to sample size and can lead to the rejection of well-fitting models,[30] the TLI, CFI, and RMSEA fit indices were emphasized. Good fitting models are indicated by a TLI and CFI $\geq$ 0.95 and RMSEA $\leq$0.06.[31]

Cronbach's alpha was calculated to estimate internal consistency. Floor and ceiling effects were defined as $\geq$15% of participants having the lowest or highest possible score, respectively.[32]

To assess the optimal cut-off for screening with the CWS, sensitivity, specificity, and positive and negative predictive values were assessed at each cut-off point of the CWS against the 3 proposed cut-offs of the FCRI, and the area under the ROC curve and its 95% confidence interval were examined. For a scale to be useful as a screening instrument, the proposed cut-off point should maximize the proportion of high fearful patients scoring positive (sensitivity) and maximize the proportion of negative test results corresponding to low fearful (negative predictive value). To be used for diagnostic purposes, it should maximize the proportion of low fearful patients scoring negative (specificity) and maximize the proportion of positive test results corresponding to being high fearful (positive predictive value). To be useful as an instrument to differentiate high fearful from low fearful individuals, it should have high sensitivity and specificity (around. 80), which maximizes the proportion of patients whose test results are accurate.[33] The area under the curve (AUC) gives an indication of the ability of the CWS to differentiate between high and low fearful individuals according to being a case or non-case on the gold standard (FCRI-SF).

Pearson's correlations were calculated between CWS and another scale of fear of cancer recurrence (FCRI),[20] anxiety and depression scores (HADS),[23] intrusion and avoidance scores (IES),[22,34] and a cancer-related QOL measure (EORTC QLQ-C30).[25] To categorize the results, Cohen's effect size categories were used: small ($|r| \leq 0.3$), moderate ($0.3 < |r| < 0.5$), or large ($|r| \geq 0.5$).[35] It was hypothesized that the CWS total score would be highly positively correlated with the FCRI[20] and moderately to highly positively correlated with IES[22,34] and HADS[23] total scores. Small to moderate negative correlations were hypothesized for the correlation between the CWS and EORTC-QLQ-C30[25] (Table 2).

## 3 | RESULTS

### 3.1 | Descriptive statistics

Complete CWS data were available for 981 patients, including 418 men and 563 women. Demographic and disease characteristics are shown in Table 1. The mean age of the total sample was 62.7 years, 57% were female, and the mean time since diagnosis was 4.7 years.

### 3.2 | Validity and reliability of the CWS

The mean ± SD CWS score was 10.2 ± 3.5 with a range of 6 to 24. Mean item scores ranged from 1.2 for Item 3 to 2.1 for Item 4. Correlations between items ranged from $r = 0.41$ ($P < 0.001$, Items 1 and 3) to $r = 0.77$ ($P < 0.001$, Items 4 and 5). Corrected item-total correlations ranged from $r = 0.53$ (item 3) to $r = 0.81$ (item 5). Cronbach's alpha was 0.90. There were 149 patients (15.2%) who had the lowest possible score (6) on the scale and 4 (0.4%) with the highest possible score (24), suggesting that there was a floor effect.

In the initial confirmatory factor analysis, in which measurement errors between all items were specified as uncorrelated, model fit for the hypothesized single-factor model was suboptimal ($\chi^{29} = 122.4$, $P < 0.001$, TLI = 0.99, CFI = 0.99, RMSEA = 0.11). Inspection of the modification indices indicated that model fit would be improved if the error terms of Items 2 and 3 were freed to covary. Items 2 ("How often have these thoughts affected your mood?) and 3 ("How often have these thoughts interfered with your ability to do daily activities") both evaluate the *impact* of worry thoughts, whereas other CWS items refer to frequency and severity. Therefore, the model was refitted to the data, allowing the error terms of these items to covary. These changes resulted in a model with a good fit to the data ($\chi^{28} = 53.8$, $P < 0.001$, TLI = 1.00, CFI = 1.00, RMSEA = 0.08).

As hypothesized, there were moderate to large correlations between the CWS and measures of FCR, intrusion, avoidance, anxiety, depression, and emotional functioning. There were small to moderate correlations with physical functioning, role functioning, cognitive functioning, social functioning, and global QoL (Table 2).

#### 3.2.1 | Receiver operating curve

The mean of the FCRI-SF was 13.8 (SD 7.29). Five hundred and twenty-nine survivors (53.9%) were classified as having high FCR using the 12 vs 13 FCRI-SF cut-off. At a FCRI-SF cut-off of 15 vs 16, 398 survivors (40.6%) were classified as having high levels, and at 21 vs 22, 148 survivors (15.1%) reported high FCR. AUC of the ROC analysis at FCRI-SF cut-off of 12 vs 13 was 0.90 (95% CI 0.89-0.92, $P < 0.001$) suggesting a 90% probability that a randomly selected patient defined as a case by the FCRI-SF would score higher on the CWS than a randomly selected patient defined as a non-case. Using a cut-off of 15 vs 16 yielded an AUC of 0.90 (95% CI 0.88-0.92, $P < 0.001$), and AUC of the ROC analysis at FCRI-SF cut-off of 21 vs 22 was 0.93 (95% CI 0.91-0.95, $P < 0.001$) (Figure 1).

On the basis of ROC analysis, when using the 12 vs 13 FCRI-SF score as the gold standard optimal screening cut-off for the 6-item CWS was 9 versus 10 (sensitivity 82%, specificity 83%, a positive predictive value (PPV) 86%, and a negative predictive value (NPV) 79%. Using the more stringent standard of 15 vs 16 FCRI-SF resulted in the same CWS cut-off score of 9 vs 10 (sensitivity of 88%, specificity of 73%, PPV 70%, NPV 90%). Finally, when the highest FCRI-SF cut-off proposed to date for severe FCR (ie, 21 vs 22) was used as a gold standard, the optimal CWS cut-off score was 11 vs 12, (sensitivity of 88%, specificity of 81%, PPV 46%, NPV 97%) (Table 3).

## 4 | DISCUSSION AND CONCLUSIONS

There are currently very few validated brief measures of FCR suitable for screening for inclusion in clinical trials. The present study confirms that the 6-item version of the CWS maintains good construct validity,

**TABLE 1** Participant clinical and demographic characteristics

| | Prostate (*n* = 253) *N* (%) | GIST (*n* = 54) *N* (%) | Breast (*n* = 451) *N* (%) | Colorectal (*n* = 146)[a] *N* (%) | Colorectal (*n* = 77)[b] *N* (%) |
|---|---|---|---|---|---|
| Age in years. Mean (SD) | 69.6 (7.1) | 61.7 (11.0) | 56.6 (9.7) | 67.1 (10.4) | 67.4 (12.1) |
| Years since diagnosis. Mean (SD) | 8.0 (5.0) | 4.8 (3.7) | 2.8 (1.3) | N.A. | 4.8 (2.3) |
| Gender | | | | | |
| % female | 0 (0) | 25 (46.3) | 451 (100) | 52 (35.6) | 35 (45.5) |
| % male | 283 (100) | 29 (53.7) | 0 (0) | 94 (64.4) | 42 (54.5) |
| Partnered (%) | | | | | |
| Yes | 232 (91.7) | 47 (87.0) | 361 (80.0) | 128 (87.7) | 61 (79.2) |
| No | 19 (7.5) | 7 (13.0) | 79 (17.5) | 14 (9.6) | 10 (13.0) |
| Unknown | 2 (0.8) | - | 11 (2.5) | 4 (2.7) | 6 (7.8) |
| Children (%) | | | | | |
| Yes | 231 (91.3) | 46 (85.2) | 375 (83.1) | 128 (87.7) | 65 (84.4) |
| No | 21 (8.3) | 8 (14.8) | 73 (16.2) | 18 (12.3) | 10 (13.0) |
| Unknown | 1 (0.4) | - | 3 (0.7) | | 2 (2.6) |
| Education (%) | | | | | |
| Primary | 33 (13.0) | 13 (24.1) | 88 (19.5) | 34 (23.3) | 20 (26.0) |
| Secondary/vocational | 94 (37.2) | 21 (38.9) | 220 (48.8) | 69 (47.3) | 28 (36.4) |
| Tertiary | 109 (43.1) | 19 (35.2) | 135 (29.9) | 41 (28.1) | 24 (31.2) |
| Other | 15 (5.9) | 1 (1.9) | 3 (0.7) | 0 (0) | 5 (6.5) |
| Unknown | 2 (0.8) | - | 5 (1.1) | 2 (1.4) | - |
| Paid employment (%) | | | | | |
| Yes | 50 (19.8) | 15 (27.8) | 211 (46.8) | 31 (21.2) | 20 (26.0) |
| No | 203 (80.2) | 39 (72.2) | 240 (53.2) | 115 (78.8) | 57 (74.0) |
| Cancer treatments (%) | | | | | |
| Surgery | 253 (100) | 42 (77.8) | 451 (100) | N.A. | 77 (100) |
| Radiotherapy (RT) | 67 (26.5) | N.A. | 341 (75.6) | N.A. | 9 (11.7) |
| Chemotherapy (CT) | N.A. | N.A. | 324 (71.8) | N.A. | 24 (31.2) |
| CWS total score. Mean (SD) | 9.0 (3.0) | 10.8 (4.3) | 11.2 (3.4) | 9.7 (3.2) | 9.0 (3.1) |

[a]Colorectal cancer patients awaiting surgery.

[b]Colorectal cancer survivors 1 to 9 years after surgery.

**TABLE 2** Correlations between CWS total score and other measures

| Hypotheses | Pearson's Correlation | *P* | Confirmed |
|---|---|---|---|
| Large positive correlation | | | |
| Measures of FCR (FCRI total) | 0.80 | <0.001 | Yes |
| Measures of FCR (FCRI severity) | 0.81 | <0.001 | Yes |
| Moderate to large positive correlation | | | |
| Intrusive thoughts (IES-intrusion) | 0.66 | <0.001 | Yes |
| Avoidant thoughts (IES-avoidance) | 0.55 | <0.001 | Yes |
| Anxiety (HADS-anxiety) | 0.64 | <0.001 | Yes |
| Depression (HADS-depression) | 0.44 | <0.001 | Yes |
| Moderate to large negative correlation | | | |
| Emotional functioning (EORTC-QLQ-C30) | −0.59 | <0.001 | Yes |
| Small to moderate negative correlation | | | |
| Physical functioning (EORTC-QLQ-C30) | −0.23 | <0.001 | Yes |
| Role functioning (EORTC-QLQ-C30) | −0.30 | <0.001 | Yes |
| Cognitive functioning (EORTC-QLQ-C30) | −0.32 | <0.001 | Yes |
| Social functioning (EORTC-QLQ-C30) | −0.36 | <0.001 | Yes |
| Global quality of life (EORTC-QLQ-C30) | −0.39 | <0.001 | Yes |

Abbreviations: CWS, Cancer Worry Scale; EORTC QLQ-30, Quality of Life Questionnaire; HADS, Hospital Anxiety and Depression Scale; IES, Impact of Event Scale.

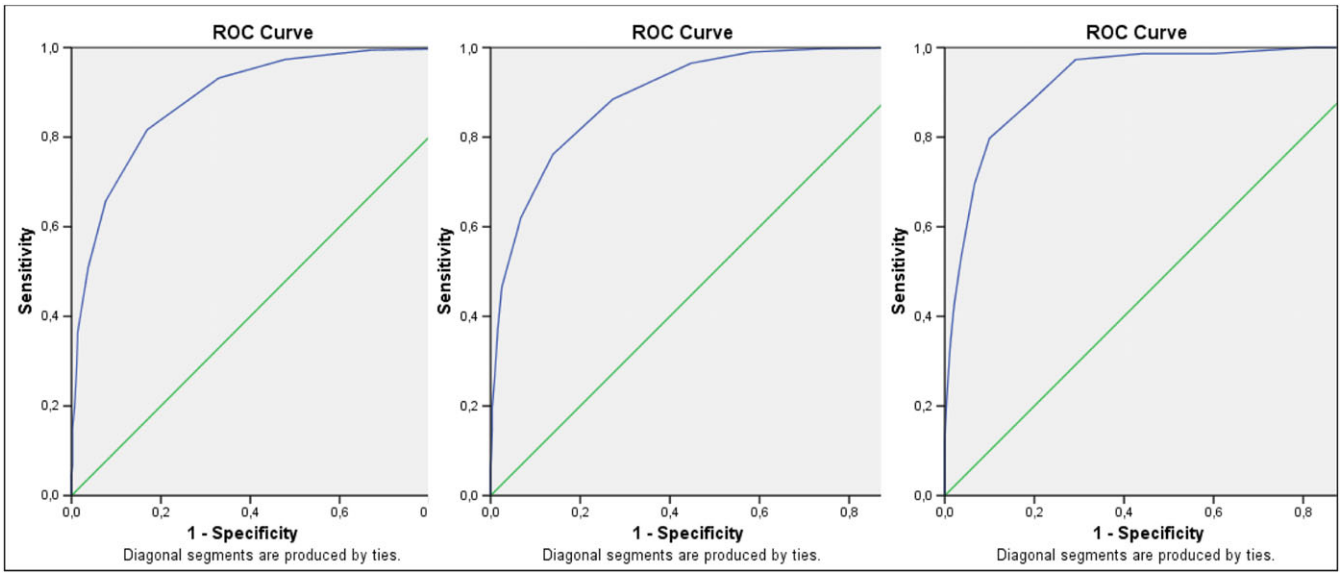


**FIGURE 1** Receiver operating curve (ROC) analyses of the 6-time CWS using varying cut-offs of the FCRI-SF as a gold standard

**TABLE 3** Accuracy measures for 6-item Cancer Worry Scale (CWS) scores using varying cut-offs of the FCRI-SF as a gold standard

| Gold Standard CWS cut-off | FCRI-SF 12 vs 13 | | | | FCRI-SF 15 vs 16 | | | | FCRI-SF 21 vs 22 | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Sensitivity (%) | Specificity (%) | PPV (%) | NPV (%) | Sensitivity (%) | Specificity (%) | PPV (%) | NPV (%) | Sensitivity (%) | Specificity (%) | PPV (%) | NPV (%) |
| 6 vs 7 | 99.4 | 33.2 | 64.6 | 97.9 | 99.7 | 25.8 | 51.2 | 99.3 | 100.0 | 18.0 | 18.2 | 100.0 |
| 7 vs 8 | 97.4 | 52.2 | 71.4 | 94.1 | 99.0 | 41.8 | 54.6 | 98.3 | 99.3 | 29.3 | 20.4 | 99.6 |
| 8 vs 9 | 93.2 | 67.1 | 77.6 | 88.9 | 96.5 | 55.3 | 60.5 | 95.7 | 98.6 | 39.8 | 23.0 | 99.4 |
| 9 vs 10 | 81.7 | 83.1 | 85.5 | 78.7 | 88.4 | 72.8 | 69.7 | 89.9 | 98.6 | 55.8 | 28.9 | 99.6 |
| 10 vs 11 | 65.8 | 92.3 | 91.3 | 68.7 | 76.1 | 86.1 | 79.5 | 83.6 | 97.3 | 70.8 | 37.8 | 99.3 |
| 11 vs 12 | 50.9 | 96.3 | 94.4 | 61.5 | 62.1 | 93.2 | 86.7 | 77.6 | 87.8 | 80.9 | 45.6 | 97.3 |
| 12 vs 13 | 36.5 | 98.6 | 96.9 | 55.8 | 46.5 | 97.5 | 93.0 | 72.0 | 79.7 | 90.0 | 59.3 | 96.1 |
| 13 vs 14 | 28.7 | 98.8 | 96.8 | 53.1 | 37.2 | 98.4 | 94.3 | 68.9 | 69.6 | 93.3 | 65.6 | 94.4 |
| 14 vs 15 | 20.0 | 99.3 | 97.2 | 50.3 | 26.1 | 99.1 | 95.4 | 65.5 | 53.4 | 96.3 | 72.5 | 91.9 |
| 15 vs 16 | 14.9 | 99.8 | 98.8 | 48.9 | 19.6 | 99.6 | 97.5 | 63.6 | 42.6 | 97.9 | 78.8 | 90.3 |
| 16 vs 17 | 11.2 | 99.8 | 98.3 | 47.8 | 14.6 | 99.6 | 96.7 | 62.2 | 33.8 | 98.8 | 83.3 | 89.1 |
| 17 vs 18 | 6.8 | 99.8 | 97.3 | 46.6 | 9.0 | 99.8 | 97.3 | 60.8 | 22.3 | 99.5 | 89.2 | 87.5 |
| 18 vs 19 | 4.5 | 100.0 | 100.0 | 46.0 | 6.0 | 100.0 | 100.00 | 60.0 | 15.5 | 99.9 | 95.8 | 86.6 |
| 20 vs 21 | 3.2 | 100.0 | 100.0 | 45.4 | 4.3 | 100.0 | 100.00 | 59.2 | 11.5 | 100.0 | 100.0 | 85.6 |
| 21 vs 22 | 2.1 | 100.0 | 100.0 | 45.2 | 2.8 | 100.0 | 100.00 | 58.9 | 7.4 | 100.0 | 100.0 | 85.2 |
| 22 vs 23 | 1.3 | 100.0 | 100.0 | 45.1 | 1.8 | 100.0 | 100.00 | 58.8 | 4.7 | 100.0 | 100.0 | 84.9 |
| 23 vs 24 | 0.8 | 100.0 | 100.0 | 45.1 | 0.1 | 100.0 | 100.00 | 58.8 | 2.7 | 100.0 | 100.0 | 84.9 |

Abbreviations: NPV, negative predictive value; PPV, positive predictive value.

convergent and divergent validity, and high internal consistency. These results provide preliminary support for use of the 6-item CWS as a brief measure of FCR in research settings.

An advantage of the CWS over many other brief measures is that it has an established cut-off which has been validated with a range of cancers including breast,[12] prostate,[13] and CRC.[14] The screening capacity of the 6-item CWS was explored against 3 published cut-off scores for high FCR. Results showed that a cut-off 9 vs 10 on the CWS-6 is optimal for detecting high levels. However, if one is interested in identifying only those with severe levels of FCR, who might for example be candidates for an intensive or costly face-to face FCR intervention, then a cut-off of 11 vs 12 might be preferable. To date, many researchers use the severity subscale of the FCRI in observational and intervention studies, which was also used as gold standard in this study. Although the correlation between the CWS and FCRI measures was quite high ($r$ = .81), the percentages of patients experiencing high FCR differ between the measures. At a cut-off score of 9 vs 10 on the CWS, 52.4% of patients experience high FCR, which is comparable to a percentage of 53.9% at a cut-off score of 12 vs 13 on the FCRI and to 40.6% at a cut-off score of 15 vs 16 on the FCRI. However, comparing the measures at higher cut-off scores reveals differences because 29.7% of patients score

high on the CWS cut-off of 11 vs 12 whereas only 15.1% of patients score high on the FCRI cut-off score of 21 vs 22. Thus, the CWS seems less stringent compared with the FCRI-SF. This underlines the need for consensus on a definition of clinical FCR, based on which a diagnostic interview could be designed. This would be the ultimate gold standard to use in research on validation and cut-off scores for FCR measurements.

### 4.1 | Study limitations

A strength of this study is the large and heterogeneous sample, resulting in a generic cut-off score which is applicable to different types of cancers and both genders. However, this approach did not permit determination of cut-offs for specific populations (eg, breast cancer) or genders. Previous research has already investigated CWS cut-offs in homogeneous samples that were amalgamated for this research.[12-14] Future research might focus on establishing cut-offs in different samples.

A limitation is that the CWS has been mostly used in Dutch samples. Cross-cultural validation in other common languages is therefore required to encourage its uptake in research and the clinic. A further limitation of this study is that as it was a secondary analysis of existing data, it was not possible to determine test-retest reliability and future studies should investigate this.

Work on developing an expert consensus definition of clinical FCR is currently underway (*Personal Communication, Sophie Lebel, 12 December, 2017*). When completed, it will be of interest to compare how this 6-item CWS aligns with the clinical definition and what the cut-off score is using an interview of consensus criteria of clinical FCR as a gold standard. Therewith, it also might be possible to interpret the floor effect we encountered because it is not clear to what degree this reflects a true floor in which the measure does not capture the full spectrum of symptoms or if there is a proportion of patients that does not experience FCR at all.

### 4.2 | Clinical implications

The present results provide researchers and clinicians with a brief valid and reliable measure of FCR which is suitable for measuring FCR in cancer patients. By using this instrument in clinical practice, it is possible to provide support and assistance for patients with high FCR in accessing the appropriate and available support.

## ETHICS APPROVAL

The 5 studies from which the de-identified data for this secondary analysis were amalgamated received approval by a regional human research ethics committee (CMO Nijmegen-Arnhem Nos.# 2011/404; 2011/562; 2012/101; 2012/227; 2013/184) and local hospital management committees.

All procedures performed in this study involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

## INFORMED CONSENT

Written informed consent was obtained from all individual participants included in the study.

## CONFLICT OF INTEREST

None declared.

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