



## Translation and validation of the Dutch version of the Fear of Cancer Recurrence Inventory (FCRI-NL)

Sanne Jasperine van Helmond<sup>a</sup>, Marije Liesbeth van der Lee<sup>b, \*</sup>, Jolanda de Vries<sup>c, d</sup>

<sup>a</sup> Helen Dowling Instituut, Scientific Research Department, Bilthoven, The Netherlands

<sup>b</sup> Helen Dowling Instituut, Scientific Research Department, P.O. Box 80, 3723 MB Bilthoven, The Netherlands

<sup>c</sup> Center of Research on Psychology in Somatic diseases (CoRPS), Department of Medical and Clinical Psychology, Tilburg University, Tilburg, The Netherlands

<sup>d</sup> Department of Medical Psychology, St Elisabeth Hospital, Tilburg, The Netherlands

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### ABSTRACT

**Objective:** The study objectives are to translate the FCRI in Dutch, and to explore the factor structure and the psychometric qualities of the Dutch translation of the Fear of Cancer Recurrence Inventory (FCRI-NL).

**Method:** The original French-Canadian FCRI had been forward-backward translated into English by the developers, and this method was also used to translate the English version of the FCRI into Dutch.

Patients were recruited via patient organizations between July 2011 and October 2013. To replicate the original 7-factor structure of the FCRI, confirmatory factor analysis (CFA) was performed. To examine the psychometric qualities, reliability (Cronbach's alpha), test-retest reliability (intra-class correlations; ICC), and convergent and divergent validity (Spearman's correlations) were calculated.

**Results:** From 290 cancer patients, 255 (88%) were eligible for analysis (aged  $51.0 \pm 9.8$  years, 88.6% women). CFA showed a reasonable yet suboptimal fit of the hypothesized model to the data. The FCRI-NL has good reliability (Cronbach's  $\alpha = 0.93$  for the total scale and  $\alpha = 0.75-0.92$  for the subscales) and test-retest reliability (ICC = 0.84 for the total scale and ICC = 0.56–0.87 for the subscales). Convergent ( $r = 0.53-0.66$  for the FCRI-NL and  $r = 0.48-0.57$  for the FCRI-SF-NL) and divergent ( $r = -0.20-0.07$  for the FCRI-NL and  $r = -0.28-0.17$  for the FCRI-SF-NL) validity was demonstrated.

**Conclusion:** The FCRI-NL seems to have sufficient psychometric properties. However, the FCRI-NL total score should be interpreted with caution. The Severity subscale (FCRI-SF-NL) may be a valuable screening tool for fear of cancer recurrence severity in clinical care.

### 1. Introduction

Fear of cancer recurrence (FCR) is one of the most reported long-term consequences of surviving cancer [1]. Elevated levels of FCR represent a continuing problem in cancer patients, for ten years or more after diagnosis [2–4]. In 2015, the International Expert Special Interest Group on FCR (FORwaRdS) redefined FCR as “fear, worry, or concern about cancer returning or progressing”, which is broader than previous definitions and more suitable for all types and stages of cancer [5]. This definition also shows that FCR ranges from normal or healthy levels of concerns about cancer recurrence to clinical levels of FCR [5]. Across different cancer types, 39–97% of cancer survivors reported some degree of FCR, 22–87% reported moderate to high degree of FCR

and 0–15% reported a high degree of FCR [6]. A growing body of research recognizes FCR as a multi-dimensional construct, including intrusive thoughts, physical sensations, psychological distress, coping strategies, and functioning impairments [7–9].

Currently, at least 32 assessment instruments for FCR have been developed [6,10]. Of these, 11 are subscales of comprehensive measures, 17 are brief questionnaires (2–10 items), and four are longer (multi-dimensional) questionnaires (10 + items) [6,10]. However, many of these scales have limited generalizability due to limited psychometric data and/or have been used in few studies [6,10]. Other limitations are that measures are only available in one language and/or are cancer site specific, which impedes comparison across cancer populations [6,10]. Currently, the Fear of Cancer Recurrence Inventory (FCRI) is one of the best measures available [10].

\* Corresponding author.

Email addresses: svanelmond@hdi.nl (S.J. van Helmond); mvanderlee@hdi.nl (M.L. van der Lee); J.deVries@uvt.nl (J. de Vries)

The FCRI was developed by a committee of experts in psycho-oncology, based on their definition of FCR, on DSM-IV diagnostic criteria of anxiety and somatoform disorders and on a cognitive-behavioral conceptualization of FCR inspired by the model developed by Lee-Jones et al. [8,11]. The original version of the FCRI was developed in French-Canadian and contains 42 items measuring seven factors (Triggers, Severity, Psychological Distress, Coping Strategies, Functioning Impairments, Insight, and Reassurance) [8]. In the initial article it was stated that a higher score on the total scale indicates higher levels of FCR [8]. The FCRI was validated in a sample of 600 participants who had been treated for breast, prostate, lung, or colorectal cancer, and it demonstrated good reliability and validity (reliability Cronbach's  $\alpha = 0.95$ ; test-retest reliability  $r(287) = 0.89, p < 0.001$ ) [8]. The psychometric properties of the English version of the FCRI were similar to those of the original French-Canadian version (reliability Cronbach's  $\alpha = 0.96$ ; test-retest reliability  $r(135) = 0.88, p < 0.001$ ; ICC = 0.94,  $p < 0.001$ ) [7]. Simard and Savard recommend more validation studies in other cultures and languages [8]. Recently, an empirically validated cut-off score was determined for the Severity subscale of the FCRI, making it usable as a short form of the FCRI (FCRI-SF) to screen for clinical levels of FCR [12]. The Severity subscale is strongly associated with the FCRI total score and seems the most accurate representation of FCR severity, the other subscales represent related aspects, such as antecedents (e.g., Triggers), modifiers (e.g., Coping Strategies), or consequences (e.g. Functioning Impairments), which give important clinical information about FCR [12,13]. There is some disagreement about the interpretation of the FCRI. While the authors of the original version of the FCRI recommend to measure FCR with the total FCRI scale or use the Severity subscale for screening purposes, Costa and colleagues recommend separate interpretation of the subscale scores [8,14].

FORwaRdS recently reported a lack of translations of FCR measures and stated that we need cross-culturally validated measures [15]. To make the FCRI available in Dutch speaking countries, the FCRI was translated into Dutch (FCRI-NL). We will refer to the Dutch translation of the FCRI-SF as FCRI-SF-NL. The present study describes the translation and validation of the FCRI-NL (i) by performing a confirmatory factor analysis (CFA) to investigate whether the multidimensional seven factor structure of the original FCRI could be confirmed and (ii) by assessing internal consistency, test-retest reliability, and convergent and divergent validity of the FCRI-NL and its subscales. We hypothesized that confirmatory analysis would show a good fit and that the FCRI-NL would demonstrate good psychometric qualities.

## 2. Method

### 2.1. Translation process

The original FCRI had been forward-backward translated into English by the developers, and this method was also used to translate the English version of the FCRI into Dutch (FCRI-NL) [7,8]. Forward translations were done by two independent native Dutch translators (AV, CV). Semantics of these two versions were evaluated by an expert panel consisting of the two translators and a researcher/psychologist expert in psycho-oncology (all bilingual; two of them had clinical experience in psycho-oncology) (AV, CV, JL). Discrepancies ( $N = 45$ ) between the two translations were discussed and resolved (best translation was selected ( $N = 18$ ) or an alternative translation was proposed ( $N = 27$ )). Mostly minor modifications were made. One difficult issue and important modification was the Dutch translation of "cancer recurrence". This term occurs a lot in the questionnaire, therefore many items needed modification. The focus was on clinical meaningfulness rather than literal equivalence. At the end of the expert meeting, a single translation of the FCRI-NL was agreed upon. After the translation of

the FCRI-NL was agreed upon, backward translations were made by two independent native English translators blind to the original version (SD, MY). The expert team evaluated the backward translations and four important points were discussed. The first two concerned the lack of backward translation of the word "anxiety". A possible explanation could be, that there are more words for anxiety in the English language than in the Dutch language. Consensus was reached about this point, all experts agreed that the initial Dutch translation was the best choice. Concerning the third point of discussion, the experts considered a slightly different translation for the word "disrupt", but eventually they decided the initial translation was better. Regarding the fourth discussion point they proposed a better translation of item 34 and agreed to use the new translation. Consensus was reached on the final version of the FCRI-NL.

### 2.2. Pilot-testing

The FCRI-NL was pilot-tested in ten patients with different types of cancer receiving therapy at the Helen Dowling Institute for cancer-related psychological distress. Participants were recruited by therapists after their treatment session, they assessed if filling out the questionnaire would not be too stressful for the patients. Written informed consent was obtained from all participants. All participants stated that the questions were clear and understandable. Nine participants had clinical levels of FCR. Participants filled out the questionnaires in a clinical setting, therefore detailed demographic and medical information was not assessed to minimize patient burden. Additionally, two independent members of the Dutch Lymphoma Patients Society (LVN) were asked to provide comments on the questionnaire. They did not report ambiguities either and made some valuable suggestions for adjustments, which were discussed by the expert panel. The expert panel decided to stay as close as possible to the original FCRI. Finally, therapists indicated that the FCRI-NL provided them with valuable information for clinical practice.

### 2.3. Participants

For testing the psychometric properties of the FCRI-NL and the FCRI-SF-NL, patients were recruited with an opt-in recruitment method through an email newsletter from the Dutch Federation for Cancer Patients Organizations, and through websites of the Dutch Lymphoma Patients Society and the Lung Cancer Information Center between July 2011 and October 2013. Inclusion criteria were: 1) any type of cancer diagnoses in the past 10 years; 2) cancer was successfully treated; 3) end of treatment  $\geq 1$  years ago; 4)  $\geq 18$  years old; and 5) sufficient command of the Dutch language. Exclusion criterion was cancer recurrence.

### 2.4. Materials

At the time of data collection there was no validated measure for FCR available yet. Therefore, we used questionnaires measuring constructs related to FCR, namely several forms of anxiety, for determining convergent validity. Divergent validity was examined using subscales from a measure for personality traits (i.e., extraversion, openness to experience, conscientiousness, and agreeableness), which are presumed to be distinct from FCR.

#### 2.4.1. Fear of Cancer Recurrence Inventory-Dutch version (FCRI-NL) [8]

The 42 items are rated on a 5-point Likert scale ranging from 0 (not at all or never) to 4 (a great deal or all the time) [8]. The score of item 13 "I believe that I am cured and the cancer will not come back" must be reversed before summation [8]. A total score can be obtained for each subscale and for the total scale by summing the items [12]. In the

original version a score of 13 or higher on the Severity subscale (FCRI-short form; FCRI-SF) is an optimal cutoff for detecting the presence of clinically significant FCR (with high sensitivity), which makes it a brief and rapid screening instrument [12]. A cutoff score of 16 or higher is an optimal cutoff for the purpose of differentiating between clinical and nonclinical levels FCR (higher specificity) [12]. The FCRI-SF has a strong correlation with the total score of the FCRI ( $r = 0.84$ ) and it demonstrated good reliability and validity (reliability Cronbach's  $\alpha = 0.89$ ; test-retest reliability  $r(287) = 0.80, p < 0.001$ ) [8].

#### 2.4.2. The state trait anxiety inventory, version Dutch Y (STAI-DY) [16,17]

The STAI-DY measures state anxiety and trait anxiety and consists of two 20-item subscales. Each item is rated on a 4-point Likert scale ranging from 0 (not at all/almost never) to 3 (very much so/almost always). The psychometric properties of the STAI-DY are satisfactory. Both subscales of the STAI-DY were used for examining convergent validity.

#### 2.4.3. Profile of moods states (POMS)-Dutch (shortened version) [18]

The POMS-Dutch (shortened version) measures affective mood-states (depression, anger, fatigue, vigor, and tension) and consists of 32 items with a 5-point Likert scale ranging from 0 (not at all) to 4 (extremely). The POMS-Dutch (shortened version) has been found to be a reliable and valid instrument. The tension subscale of the POMS was used for examining convergent validity.

#### 2.4.4. Agoraphobic cognition questionnaire (ACQ)-Dutch version [19,20]

The ACQ measures the frequency of certain thoughts concerning negative consequences of experiencing anxiety, and it consists of 14 statements which are rated on a 5-point Likert scale ranging from 1 (thought never occurs) to 5 (thought always occurs). The total score was computed by averaging responses across the individual items. The original ACQ has been found to be reliable. The ACQ was used for examining convergent validity.

#### 2.4.5. The Big Five inventory (BFI)-Dutch version [21]

The BFI measures the Big Five personality factors and consists of 44 items with a 5-point scale ranging from 1 (strongly disagree) to 5 (strongly agree). The BFI consists of 5 subscales: Extraversion, Neuroticism, Conscientiousness, Agreeableness, and Openness to Experience. The Dutch version of the BFI has been found to be of sufficient psychometric quality. The Neuroticism subscale of the BFI was used for examining convergent validity, and the remaining subscales of the BFI were used for examining divergent validity.

### 2.5. Procedure

Via the e-mail newsletter described in the Participants section, patients could access the questionnaire through a link to the online questionnaire, developed using Qualtrics software. Informed consent was obtained from all individual participants. The questionnaire consisted of demographic information, the FCRI-NL, and measures for validity assessment. To minimize patient burden, and at the same time have enough different questionnaires to assess both convergent and divergent validity, we randomly selected two (out of six) measures for each participant. For exploring test-retest reliability, participants recruited until 4 October 2011 were invited to complete the FCRI-NL again after two weeks.

### 2.6. Statistical analyses

Descriptive statistics were calculated to describe the sample. Prior to data analysis, all relevant data was screened for normality by look-

ing at skewness and kurtosis values. Z-scores (skewness and kurtosis values divided by standard error) were evaluated to test whether skewness and kurtosis were larger than expected by chance. Z-values of  $> 2$  or  $< -2$  were considered a violation of the normality assumption [22,23]. Furthermore, the data was screened for floor and ceiling effects, which are present if  $> 15\%$  of the respondents achieved the lowest or highest possible score [24]. Significance level was set at 5%.

In order to replicate the original 7-factor structure of the FCRI [8], CFA was performed. As already stated by Lebel et al. [7], the tested model is "a second-order CFA model with three levels: items (42), primary factors (7 subscales), and one secondary factor (FCR)". Goodness of fit was evaluated using the following fit indices: the adjusted goodness of fit index (AGFI); the normed fit index (NFI); the parsimonious normed fit index (PNFI); and the standardized root-mean-squared residual (SRMR) [25]. The goodness of fit criteria for each fit index are:  $AGFI \geq 0.90$ ;  $NFI \geq 0.95$ ;  $SRMR \leq 0.05$  [25]. The PNFI is difficult to interpret, because there are no threshold levels reported yet [25–27]. However, the use of a parsimony fit index (such as the PNFI) next to other goodness-of-fit measures is strongly recommended [25]. By default, AMOS uses maximum likelihood estimation to estimate model parameters. This method assumes multivariate normality of the item scores, yet this assumption is likely to be violated given the characteristics of our data. To handle any non-normal item score distributions, we used the scale-free least squares estimation method (also included in AMOS). Although this procedure is robust against violations of multivariate normality, it does not provide some well-known fit indices such as the root mean square error of approximation (RMSEA); the comparative fit index (CFI); and the non-normed fit index (NNFI). Furthermore, it was not possible to improve model fit by freeing parameters in the error covariance matrix, because modification indices were not given by the scale-free least squares estimation method.

Concerning reliability, Cronbach's coefficient alpha's (including confidence intervals) and test-retest reliability were calculated for the FCRI-NL and the subscales. An alpha of  $\geq 0.70$  was considered acceptable and an alpha of  $\geq 0.80$  was considered preferable [28]. For assessing test-retest reliability, intra-class correlations coefficients (ICC) were computed between the scores on two different occasions, separated by an interval of two weeks. High correlation coefficients of ( $ICC \geq 0.70$ ) were considered sufficient [29]. Construct validity was evaluated by assessing convergent and divergent validity (Spearman's rank-order correlation coefficient). Convergent validity was examined by calculating Spearman's correlations between the FCRI-NL and FCRI-SF-NL scores and related constructs: the tension subscale of the POMS; the ACQ; the neuroticism subscale of the BFI; and the state and trait anxiety subscales of the STAI-DY. Divergent validity was evaluated by calculating Spearman's correlations between the FCRI-NL and FCRI-SF-NL scores and the extraversion, openness, conscientiousness, and agreeableness subscales of the BFI. Moderate ( $r = 0.30-0.49$ ) and high ( $r \geq 0.50$ ) correlations indicate convergent validity, while small correlations ( $r = 0.10-0.29$ ) indicate divergent validity [30].

Analyses were conducted using IBM SPSS 23 for Windows [31]. CFA was conducted using IBM SPSS AMOS 22 [32].

## 3. Results

### 3.1. Patient characteristics

Patient characteristics are presented in Table 1. 546 potential participants clicked on the link to the questionnaire. Subsequently, 290 participants completed the FCRI-NL and two randomly assigned questionnaires at baseline (Time-1). Thirty-five participants (12%) reported a recurrence, leaving 255 (88%) participants eligible for analysis. To explore the test-retest reliability, the first 213 participants were invited

**Table 1**  
Patient characteristics at baseline.<sup>a</sup>

	n = 255
Age (years)	51.0 ± 9.8
Age (min-max)	26-77
Gender (%)	
Female	226 (88.6)
Male	29 (11.4)
Education (%)	
Primary education	9 (3.5)
Lower general secondary education	29 (11.4)
High school, higher general secondary education, pre-university education	21 (8.2)
Community college	75 (29.4)
College	92 (36.1)
University	28 (11.0)
Other	1 (0.4)

<sup>a</sup> Cancer characteristics were not collected.

to fill out the FCRI-NL again after an interval of two weeks (Time-2). Of them, 95 participants (45%) completed the questionnaire within 7–21 days and were eligible for test-retest analysis. Questionnaires that were filled out < 7 or > 21 days after baseline, were excluded for analysis. Mean time between Time-1 and Time 2 was 16.2 ± 2.0 days (range 13–21). Cancer characteristics were not collected.

### 3.2. Score distribution

Skewness and kurtosis values and z-scores, mean scores and standard deviations (for normally distributed subscales), medians and interquartile ranges (for non-normally distributed subscales), and floor and ceiling effects of the FCRI-NL and its subscales are shown in Table 2. The skewness and kurtosis values, z-scores, and floor and ceiling effects of the items are presented in Appendix A. The assumption for normality was violated for 34 items and for the Psychological Distress, Functioning Impairments, Insight, Reassurance, and Coping Strategies subscales of the FCRI-NL. Floor scores were achieved by 45.9% of the participants on the Insight subscale and by 20.8% of the patients on the Reassurance subscale. More specifically, 45.9% of the participants answered “not at all” on all three items of the Insight subscale, indicating that their self-criticism towards FCR intensity is low. Furthermore, 20.8% of the participants answered “never” on all three items of the Reassurance subscale, indicating that they do not seek reassurance through self-examination or repeated medical consultations. There were no ceiling scores larger than 15% for the subscales. Furthermore, floor scores were achieved by 21 items and ceiling scores were achieved by 5 items (for details see Appendix A). Correlations between the FCRI-NL subscales will not be discussed in the context of this paper, the correlation matrix will be attached for all who are interested (see Appendix B).

### 3.3. Confirmatory factor analysis

The goodness of fit of the original second-order model was not convincingly confirmed. The model ( $X^2(812) = 1752.6$ ,  $p < 0.001$ ,  $X^2/df = 2.16$ ) showed an AGFI (0.93) that meets the criteria for model fit. The NFI (0.93) was smaller than the recommended criterion, and the SRMR index (0.08) was greater than the recommended criterion, which indicates some misfit in the model. However, when applying older and less strict guidelines (i.e.  $NFI \geq 0.90$ ;  $SRMR \leq 0.08$ ), the criteria for model fit would be met [25]. The PNFI (0.87) points towards an acceptable model fit. However, this goodness of fit index should be interpreted with caution because there are no strict guidelines reported [26,27]. Altogether, these mixed results suggest a reasonable yet sub-

optimal fit of the second-order model to the data.<sup>1</sup> The standardized parameter estimates (standardized regression weights and squared multiple correlations) associated with the model structure obtained with AMOS are presented in Fig. 1.

### 3.4. Reliability

The reliability (Cronbach's alpha) of both the FCRI-NL, the FCRI-SF-NL and most of the remaining FCRI-NL subscales exceeded 0.80 (except for Reassurance and Coping Strategies, internal consistency of these scales exceeded 0.70). The lower bound of the Cronbach's alpha confidence intervals was > 0.70 for the FCRI-NL and all subscales, which indicates with certainty that reliability is sufficient. Test-retest reliability (ICC) of the FCRI-NL, the FCRI-SF-NL and most of the remaining FCRI-NL subscales exceeded 0.70 (except for Reassurance and Coping Strategies, test-retest reliability of these subscales exceeded 0.50). The ICC confidence intervals show that the FCRI—NL, the FCRI-SF-NL and most of the remaining FCRI-NL subscales have good test-retest reliability, except for Reassurance and Coping Strategies subscales. For these two subscales, test-retest reliability is weaker. Results are shown in Table 3.

### 3.5. Construct validity

Evidence of convergent validity was provided by high associations between the FCRI-NL and the tension subscale of the POMS, agoraphobic cognitions measured by the ACQ, the neuroticism subscale of the BFI, and the state and trait anxiety subscales of the STAI-DY. Convergent validity was also supported for the FCRI-SF, with a moderate association between the FCRI-SF-NL and the trait anxiety subscale of the STAI-DY, and by high associations between the FCRI-SF-NL and the tension subscale of the POMS, agoraphobic cognitions measured by the ACQ, the neuroticism subscale of the BFI, and the state anxiety subscale of the STAI-DY. Furthermore, weak associations were found between the FCRI-NL and the extraversion, openness, conscientiousness, and agreeableness subscales of the BFI, demonstrating divergent validity. The same was found for the FCRI-SF-NL. Results are shown in Table 4.

## 4. Discussion

This is the first study that investigated the psychometric properties of the FCRI-NL and its subscales by performing a CFA to investigate whether the multidimensional 7-factor structure of the original FCRI could be confirmed in the FCRI-NL and by assessing reliability, test-retest reliability, and convergent and divergent validity.

Results indicate that the FCRI-NL has acceptable psychometric properties. The FCRI-NL, the FCRI-SF-NL, and the other subscales have sufficient to good reliability and test-retest reliability, except for a lower test-retest reliability on the Reassurance and Coping Strategies subscales. Convergent and divergent validity of both the FCRI-NL and FCRI-SF-NL are demonstrated in the current study. However, the hypothesized multi-dimensional structure of the FCRI-NL was not convincingly replicated in the present sample. CFA showed a reasonable

<sup>1</sup> We were not able to improve model fit by freeing parameters in the error covariance matrix ourselves. However, because we were curious what would happen when we added some error covariances to the model, we also did confirmatory factor analysis using the exact models (including error covariances) of the French version (covariances between E2-E3, E9-E10, E15-E16, E22-E23, E39-E40) and the English version (covariances between E2-E3, E5-E6, E13-E14, E22-E23, E29-E30, E31-E32, E34-E35, E39-E40, E41-E42) [S. Simard, personal communication, 8 July 2010] [7]. Results were very similar to the results of our model (French version:  $X^2(812) = 1634.9$ , AGFI = 0.94, NFI = 0.93, SRMR = 0.08, PNFI = 0.87; English version:  $X^2(812) = 1533.6$ , AGFI = 0.94, NFI = 0.94, SRMR = 0.08, PNFI = 0.87).

**Table 2**  
Descriptive statistics, normality tests, and floor and ceiling scores.<sup>a</sup>

FCRI-NL factors	Number of items	Score range		Normality test			Mean (SD) <sup>c</sup>		Median (IQR) <sup>c</sup>		Floor score <sup>d</sup>	Ceiling score <sup>d</sup>
				Time-1	Time-2	z-score <sup>b</sup>	Time-1	Time-2	Time-1	Time-2	Time-1 (%)	Time-1 (%)
Triggers	8	0–32	Skewness	– 0.112	0.153	– 0.732	17.2 (6.3)	16.4 (6.4)	–	–	0.4	0.8
			Kurtosis	– 0.168	0.304	– 0.553						
Severity/FCRI-SF-NL	9	0–36	Skewness	– 0.257	0.153	– 1.680	19.5 (6.3)	18.5 (6.7)	–	–	0	0
			Kurtosis	– 0.226	0.304	– 0.743						
Psychological distress	4	0–16	Skewness	0.318	0.153	2.078	–	–	7.0 (6.0)	7.0 (5.0)	1.2	2.7
			Kurtosis	– 0.560	0.304	– 1.842						
Functioning impairments	6	0–24	Skewness	0.989	0.153	6.464	–	–	5.0 (7.0)	4.0 (7.0)	12.9	0
			Kurtosis	0.437	0.304	1.438						
Insight	3	0–12	Skewness	1.632	0.153	10.667	–	–	1.0 (3.0)	0.0 (1.0)	45.9	0.8
			Kurtosis	2.527	0.304	8.313						
Reassurance	3	0–12	Skewness	1.153	0.153	7.536	–	–	2.0 (3.0)	2.0 (2.0)	20.8	0.4
			Kurtosis	0.830	0.304	2.730						
Coping strategies	9	0–36	Skewness	– 0.420	0.153	– 2.745	–	–	18.0 (7.0)	18.0 (9)	1.2	0
			Kurtosis	0.113	0.304	0.372						
Total score	42	0–168	Skewness	0.070	0.153	0.458	71.6 (22.7)	67.7 (23.0)	–	–	0	0
			Kurtosis	– 0.045	0.304	– 0.148						

<sup>a</sup>  $n = 255$ . <sup>b</sup> Z-scores of  $> 2$  or  $< -2$  are considered a violation of the normality assumption. <sup>c</sup> Means and standard deviations (SD) were reported for normally distributed subscales, medians and interquartile ranges (IQR) were reported for not-normally distributed subscales. <sup>d</sup> Percentages of  $> 15\%$  indicate floor or ceiling effects.

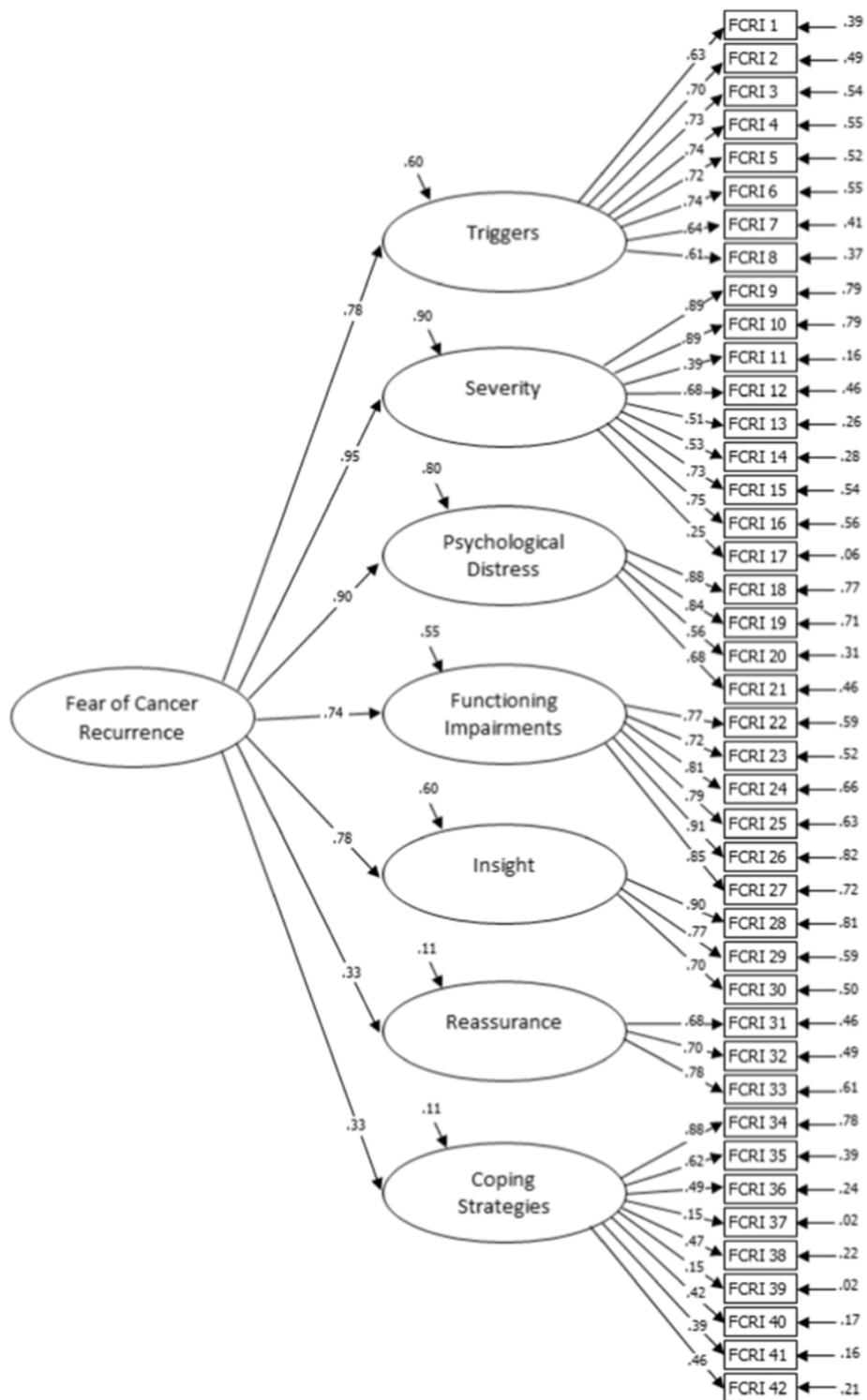


Fig. 1. Path diagram with standardized parameter estimates of the tested model.

yet suboptimal fit of the second-order model to the data. Because of this result, we strongly suggest that a FCRI-NL total score should not be used. It is unclear what a total score of the FCRI represents, but the individual items and some of the subscales scores capture important information and “may be useful indicators of when FCR levels are clinically significant” [13]. We recommend to use the FCRI-SF-NL for research and screening purposes. For clinical practice the remaining subscales can be used and discussed by clinicians or clinical psychologists at item level for tailoring interventions to the patients' needs.

These results are largely comparable to the results of the validation studies of the original French and the English version, with the exception of the Insight, Reassurance, and Coping Strategies subscales that have lower scores on (test-retest) reliability [7,8]. For a detailed comparison table see Appendix C. These differences could be attributed to either the small number of items in some subscales, the translation, the sample, or cultural differences. Concerning the CFA, results are difficult to compare because it is unclear which estimation methods were used

**Table 3**  
Reliability and test–retest reliability (including confidence intervals).

	Cronbach's alpha <sup>a</sup>	95% CI	ICC <sup>a</sup>	95% CI
	Time-1		(2 weeks)	
	n = 255		n = 95	
Triggers	0.88	0.86–0.90	0.81*	0.72–0.87
Severity/FCRI-SF-NL	0.85	0.82–0.88	0.87*	0.80–0.91
Psychological distress	0.84	0.80–0.87	0.74*	0.63–0.82
Functioning impairments	0.92	0.91–0.94	0.78*	0.68–0.84
Insight	0.84	0.80–0.87	0.74*	0.64–0.82
Reassurance	0.76	0.70–0.80	0.56*	0.40–0.68
Coping strategies	0.75	0.71–0.80	0.59*	0.44–0.70
FCRI-NL	0.93	0.92–0.94	0.84*	0.77–0.89

<sup>a</sup> High correlation coefficients of ( $r \geq 0.70$ ) were considered sufficient.

\*  $p < 0.001$ .

**Table 4**  
Spearman's correlations obtained between the FCRI-NL, the FCRI-SF-NL and other measures.<sup>a</sup>

Measures	N	Spearman	
		FCRI-NL (rho)	FCRI-SF-NL (rho)
Convergent validity <sup>a</sup>			
Tension (POMS)	81	0.66**	0.50**
Agoraphobic cognitions (ACQ)	85	0.65**	0.57**
Neuroticism (BFI)	86	0.53**	0.50**
State anxiety (STAI-DY)	79	0.63**	0.53**
Trait anxiety (STAI-DY)	78	0.63**	0.48**
Divergent validity <sup>b</sup>			
Extraversion (BFI)	86	– 0.20	– 0.28**
Openness (BFI)	83	– 0.20	– 0.25*
Conscientiousness (BFI)	83	– 0.07	– 0.18
Agreeableness (BFI)	86	– 0.17	– 0.17

<sup>a</sup> Moderate and high correlations ( $r \geq 0.30$ ) indicate convergent validity.

<sup>b</sup> Small correlations ( $r = 0.10$ – $0.29$ ) indicate divergent validity.

\*  $p < 0.05$ .

\*\*  $p < 0.01$ .

for the CFA of the French and English version. By all odds, the default estimation method (maximum likelihood) was used, and therefore different fit indices were reported, which makes it impossible to compare properly. However, their results also show some fit indices that only meet the criteria for model fit when older and less strict guidelines are applied [25], which could indicate some misfit in these models too. One separate study on melanoma survivors in Australia reported a CFA in which they used the mean-adjusted and variance-adjusted weighted least squares estimation procedure, which is a more similar estimation technique compared to the scale-free least squares estimation method [14]. This study of Costa and colleagues [14] showed a good model fit, which is better than the suboptimal fit we found in the current study. Despite the difficulty with comparing results, we believe using the scale-free least squares estimation method, which handles any non-normal item score distributions, was the most appropriate way to perform the CFA.

When considering the findings of the current study, some limitations should be noted. First, the study sample may not be representative for the general population of cancer patients, because the online opt-in recruitment method may have resulted in response bias. For example, cancer patients with a high level of FCR may be preoccupied and may tend to participate in research on FCR. Also, this study sample consists of patients who are successfully treated for cancer, while in other studies patients with cancer recurrence or metastatic disease were included [7,8]. However, compared to other studies, our study sample seems to be quite normal with respect to their FCRI scores. As

already explained by Lebel and colleagues [7], the items of the FCRI were inspired by literature on anxiety disorders and DSM diagnostic criteria, and were included to discriminate between healthy levels of concerns about cancer recurrence and clinical levels of FCR, [6–8,11]. Previous research showed that in most studies, FCR mean scores were below the mid-points of the FCR measures, indicating low to moderate levels of FCR [6]. Also, approximately 15% of cancer survivors report a high degree of FCR [6,7]. This is largely in line with our results: our study sample is normally distributed and few participants have high scores on FCR. However, the mean score of the FCR Severity subscale is slightly higher than the subscale midpoint, which may indicate some response bias. A second limitation of this study is that the cancer characteristics were not assessed. This makes it difficult to compare between cancer types and to compare to earlier studies. However, in previous research no differences were found in FCR severity between different cancer types [33]. Since the results are largely comparable to previous research, it is likely that these limitations of our study sample are not insurmountable. Moreover, these limitations of the sample have limited impact on validation studies. A further limitation is the small sample size for the CFA analysis. This may have resulted in unstable parameter estimates, especially because there are factors with fewer items [34]. Finally, translation of an already translated questionnaire might cause some problems, yet we have decided to use the English version for practical reasons (bilingual French-Dutch translators and experts are scarce in the Netherlands). More recently, this English translation also demonstrated good reliability and validity, therefore we do not foresee any problems [7].

A strength of this study was the large amount of different measures that were used for validation, compared to previous validation studies of the FCRI. Also, this study adds to the knowledge on FCR measures in the Netherlands. The added value of the FCRI-NL compared to the only known other validated Dutch measure for FCR, the Cancer Worry Scale (CSW) [35], is the extensiveness of the FCRI-NL, which gives a lot of important additional information compared to the CSW.

Future studies are needed to replicate the results of the current study. When consensus about a golden standard for FCR is reached, a study assessing the screening potential of the FCRI-SF-NL for detecting clinical levels of FCR as assessed with the golden standard would be highly relevant. The clinical face-to-face interview (SIFCR) developed by Simard and colleagues, using specific criteria to define clinical levels of FCR, may serve as a starting point for discussion on the golden standard [12]. Moreover, future studies should further explore the factor structure of the FCRI-NL, preferably in larger samples. Also, in future research, the FCRI-NL should be studied using large heterogeneous inpatient and outpatient samples of cancer patients, to determine norm scores. Lastly, since there is a growing number of interventions for FCR in the Netherlands (for example a CBT-based online self-help training

[36], and a combined online and face-to-face CBT [37]), there is a need for future research that establishes the sensitivity to change of the FCRI-NL.

4.1. Conclusion

Overall, this study showed that the FCRI-NL has sufficient psychometric properties. However, the results of this study also show that caution is recommended with using and interpreting the FCRI-NL total score. Nevertheless, the FCRI-SF-NL may be a valuable screening tool for FCR severity in clinical care.

Ethical approval

All procedures performed in studies 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 [38].

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Conflict of interest

The authors declare that they have no conflict of interest.

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Appendix A

Skewness and kurtosis values, z-scores, and floor and ceiling scores of all FCRI-NL items.

FCRI-NL	Subscale		Normality test
Items		Time-1	SE
1	Triggers	Skewness	- 0.026 0.153
		Kurtosis	- 0.227 0.304
2		Skewness	- 0.252 0.153
		Kurtosis	- 0.419 0.304
3		Skewness	- 0.542 0.153
		Kurtosis	- 0.324 0.304
4		Skewness	0.000 0.153
		Kurtosis	- 0.308 0.304

5		Skewness	- 0.003 0.153
		Kurtosis	- 0.702 0.304
6		Skewness	- 0.075 0.153
		Kurtosis	- 0.482 0.304
7		Skewness	- 0.195 0.153
		Kurtosis	- 0.265 0.304
8		Skewness	0.536 0.153
		Kurtosis	- 0.641 0.304
9	Severity	Skewness	0.165 0.153
		Kurtosis	- 0.688 0.304
10		Skewness	0.155 0.153
		Kurtosis	- 0.862 0.304
11		Skewness	- 0.362 0.153
		Kurtosis	- 0.199 0.304
12		Skewness	- 0.538 0.153
		Kurtosis	- 0.285 0.304
13		Skewness	- 0.231 0.153
		Kurtosis	- 0.790 0.304
14		Skewness	0.245 0.153
		Kurtosis	- 0.390 0.304
15		Skewness	0.606 0.153
		Kurtosis	0.043 0.304
16		Skewness	0.143 0.153
		Kurtosis	- 0.129 0.304
17		Skewness	- 0.616 0.153
		Kurtosis	- 0.643 0.304
18	Psychological distress	Skewness	0.090 0.153
		Kurtosis	- 0.924 0.304
19		Skewness	0.080 0.153
		Kurtosis	- 1.062 0.304
20		Skewness	0.396 0.153
		Kurtosis	- 0.798 0.304
21		Skewness	0.345 0.153
		Kurtosis	- 0.784 0.304
22	Functioning impairments	Skewness	1.399 0.153
		Kurtosis	1.269 0.304
23		Skewness	1.178 0.153
		Kurtosis	0.498 0.304
24		Skewness	1.073 0.153

		Kurtosis	0.417	0.304
25		Skewness	0.604	0.153
		Kurtosis	- 0.707	0.304
26		Skewness	0.623	0.153
		Kurtosis	- 0.060	0.304
27		Skewness	0.675	0.153
		Kurtosis	- 0.275	0.304
28	Insight	Skewness	1.198	0.153
		Kurtosis	0.560	0.304
29		Skewness	1.920	0.153
		Kurtosis	3.054	0.304
30		Skewness	1.757	0.153
		Kurtosis	2.429	0.304
31	Reassurance	Skewness	1.509	0.153
		Kurtosis	1.242	0.304
32		Skewness	1.300	0.153
		Kurtosis	0.799	0.304
33		Skewness	0.383	0.153
		Kurtosis	- 0.831	0.304
34	Coping strategies	Skewness	- 0.309	0.153
		Kurtosis	- 0.880	0.304
35		Skewness	- 0.031	0.153
		Kurtosis	- 0.917	0.304
36		Skewness	0.708	0.153
		Kurtosis	- 0.639	0.304
37		Skewness	- 0.495	0.153
		Kurtosis	- 0.404	0.304
38		Skewness	0.100	0.153
		Kurtosis	- 0.915	0.304
39		Skewness	- 0.191	0.153
		Kurtosis	- 0.138	0.304
40		Skewness	- 0.274	0.153
		Kurtosis	- 0.878	0.304
41		Skewness	- 0.423	0.153
		Kurtosis	- 0.230	0.304
42		Skewness	- 0.162	0.153
		Kurtosis	- 1.020	0.304

**Appendix B**  
FCRI-NL subscales correlation matrix<sup>a,b</sup>.

	Triggers	Severity (FCRI-SF-NL)	Psychological distress	Functioning impairments
FCRI-NL	0.81**	0.85**	0.81**	0.78**
Triggers		0.73**	0.61**	0.54**
Severity (FCRI-SF-NL)			0.68**	0.58**
Psychological distress				0.62**
Functioning impairments				
Insight				
Reassurance				

<sup>a</sup> Spearman's correlations.

<sup>b</sup>  $n = 255$ .

\*  $p < 0.05$ .

\*\*  $p < 0.001$ .

**Appendix C**

Reliability and test-retest reliability for the original French, the English, and the Dutch version of the FCRI.

	Reliability <sup>a</sup>			Test-retest (1 month)
	French	English	Dutch	
Triggers	0.90*	0.93	0.88	0.83
Severity/FCRI-SF-NL	0.89	0.88	0.85	0.80
Psychological distress	0.86	0.88	0.84	0.76
Functioning impairments	0.91	0.94	0.92	0.70
Insight	0.80	0.85	0.84	0.58
Reassurance	0.75	0.71	0.76	0.73
Coping strategies	0.89	0.91	0.75	0.75
FCRI-NL	0.95	0.96	0.93	0.89

<sup>a</sup> High correlation coefficients of ( $r \geq 0.70$ ) were considered sufficient.

\*  $p < 0.001$ .

**References**

[1] F. Baker, M. Denniston, T. Smith, M.M. West, Adult cancer survivors: how are they faring?, *Cancer* 104 (S11) (2005) 2565-2576, <https://doi.org/10.1002/cncr.21488>.

- [2] A. Mehnert, U. Koch, C. Sundermann, A. Dinkel, Predictors of fear of recurrence in patients one year after cancer rehabilitation: a prospective study, *Acta Oncol.* 52 (6) (2013) 1102–1109, <https://doi.org/10.3109/0284186X.2013.765063>.
- [3] A.J. Mitchell, D.W. Ferguson, J. Gill, J. Paul, P. Symonds, Depression and anxiety in long-term cancer survivors compared with spouses and healthy controls: a systematic review and meta-analysis, *Lancet Oncol.* 14 (8) (2013) 721–732, [https://doi.org/10.1016/S1470-2045\(13\)70244-4](https://doi.org/10.1016/S1470-2045(13)70244-4).
- [4] L. Koch, L. Jansen, H. Brenner, V. Arndt, Fear of recurrence and disease progression in long-term ( $\geq 5$  years) cancer survivors - a systematic review of quantitative studies, *Psycho-Oncol.* 22 (2013) 1–11, <https://doi.org/10.1002/pon.3022>.
- [5] S. Lebel, G. Ozakinci, G. Humphris, B. Mutsaers, B. Thewes, J. Prins, A. Dinkel, P. Butow, From normal response to clinical problem: definition and clinical features of fear of cancer recurrence, *Support Care Cancer* 24 (2016) 3265–3268, <https://doi.org/10.1007/s00520-016-3272-5>.
- [6] S. Simard, B. Thewes, G. Humphris, M. Dixon, C. Hayden, S. Mireskandari, G. Ozakinci, Fear of cancer recurrence in adult cancer survivors: a systematic review of quantitative studies, *J. Cancer Surviv.* 7 (3) (2013) 300–322, <https://doi.org/10.1007/s11764-013-0272-z>.
- [7] S. Lebel, S. Simard, C. Harris, A. Feldstain, S. Beattie, M. McCallum, M. Lefebvre, J. Savard, G.M. Devins, Empirical validation of the English version of the Fear of Cancer Recurrence Inventory, *Qual. Life Res.* 25 (2) (2015) 311–321, <https://doi.org/10.1007/s11136-015-1088-2>.
- [8] S. Simard, J. Savard, Fear of Cancer Recurrence Inventory: development and initial validation of a multidimensional measure of fear of cancer recurrence, *Support Care Cancer* 17 (3) (2009) 241–251, <https://doi.org/10.1007/s00520-008-0444-y>.
- [9] C. Lee-Jones, G. Humphris, R. Dixon, M.B. Hatcher, Fear of cancer recurrence - a literature review and proposed cognitive formulation to explain exacerbation of recurrence fears, *Psycho-Oncol.* 6 (1997) 95–105, [https://doi.org/10.1002/\(SICI\)1099-1611\(199706\)6:2<95::AID-PON250>3.0.CO;2-B](https://doi.org/10.1002/(SICI)1099-1611(199706)6:2<95::AID-PON250>3.0.CO;2-B).
- [10] B. Thewes, P. Butow, R. Zachariae, S. Christensen, S. Simard, C. Gotay, Fear of cancer recurrence: a systematic literature review of self-report measures, *Psycho-Oncol.* 21 (2012) 571–587, <https://doi.org/10.1002/pon.2070>.
- [11] American Psychiatric Association, *Diagnostic and Statistical Manual of Mental Disorders*, American Psychiatric Association, Washington, DC, 1994.
- [12] S. Simard, J. Savard, Screening and comorbidity of clinical levels of fear of cancer recurrence, *J. Cancer Surviv.* 9 (2015) 481–491, <https://doi.org/10.1007/s11764-015-0424-4>.
- [13] D.S.J. Costa, A. Ben Smith, J.E. Fardell, The sum of all fears: conceptual challenges with measuring fear of cancer recurrence, *Support Care Cancer* 24 (1) (2016) 1–3, <https://doi.org/10.1007/s00520-015-2943-y>.
- [14] D.S.J. Costa, M. Dieng, A.E. Cust, P.N. Butow, N.A. Kasparian, Psychometric properties of the Fear of Cancer Recurrence Inventory: an item response theory approach, *Psycho-Oncol.* 25 (7) (2016) 832–838, <https://doi.org/10.1002/pon.4018>.
- [15] S. Lebel, G. Ozakinci, G. Humphris, B. Thewes, J. Prins, A. Dinkel, P. Butow, Current state and future prospects of research on fear of cancer recurrence, *Psycho-Onc.* 26 (2017) 424–427, <https://doi.org/10.1002/pon.4103>.
- [16] H.M. Van der Ploeg, The development and validation of the Dutch state-trait anxiety inventory, in: C.M. Spielberger, I.G. Sarason, P.B. Defares (Eds.), *Stress and Anxiety*, vol. 9, Hemisphere Pub. Corp, Washington, 1985, pp. 129–139.
- [17] H. Van der Ploeg, P. Defares, C. Spielberger, Handleiding bij de Zelf-Beoordelings Vragenlijst (ZBV): Een Nederlandse bewerking van de State-Trait Anxiety Inventory [Manual of the Dutch State-Trait Anxiety Inventory], Swets & Zeitlinger, Lisse, 1980.
- [18] F. Wald, G. Mellenbergh, The abbreviated version of the Dutch adaptation of the profile of mood states (POMS), *Nederlands Tijdschrift Voor de Psychologie* 45 (1990) 86–90.
- [19] D.L. Chambless, G.C. Caputo, P. Bright, R. Gallagher, Assessment of fear of fear in agoraphobics: the body sensations questionnaire and the agoraphobic cognitions questionnaire, *J. Consult. Clin. Psychol.* 52 (6) (1984) 1090–1097, <https://doi.org/10.1037/0022-006X.52.6.1090>.
- [20] T. Bouman, The agoraphobic cognitions questionnaire (ACQ), *Gedragstherapie.* 27 (1995) 69–72.
- [21] J.J. a Denissen, R. Geenen, M. a G. van Aken, S.D. Gosling, J. Potter, Development and validation of a Dutch translation of the Big Five Inventory (BFI), *J. Pers. Assess.* 90 (2) (2008) 152–157, <https://doi.org/10.1080/00223890701845229>.
- [22] A. Field, *Discovering Statistics Using SPSS*, Third edition, SAGE Publications, London, 2009.
- [23] B. Tabachnik, L. Fidell, *Using Multivariate Statistics*, Harper Collins, New York, 2001.
- [24] C.B. Terwee, S.D.M. Bot, M.R. de Boer, D.A.W.M. van der Windt, D.L. Knol, J. Dekker, L.M. Bouter, H.C.W. de Vet, Quality criteria were proposed for measurement properties of health status questionnaires, *J. Clin. Epidemiol.* 60 (2007) 34–42, <https://doi.org/10.1016/j.jclinepi.2006.03.012>.
- [25] D. Hooper, J. Coughlan, M.R. Mullen, Structural equation modelling: guidelines for determining model fit, *EJBRM* 6 (2008) 53–60.
- [26] S.A. Sivo, X. Fan, E.L. Witta, J.T. Willse, The search for “optimal” cutoff properties: fit index criteria in structural equation modeling, *J. Exp. Educ.* 74 (2006) 267–288, <https://doi.org/10.3200/JEXE.74.3.267-288>.
- [27] S.A. Mulaik, L.R. James, J. Van Alstine, N. Bennett, S. Lind, C.D. Stilwell, Evaluation of goodness-of-fit indices for structural equation models, *Psychol. Bull.* 105 (1989) 430–445, <https://doi.org/10.1037/0033-2909.105.3.430>.
- [28] J. Pallant, *SPSS Survival Manual: A Step by Step Guide to Data Analysis Using SPSS*, Third edition, Open University Press McGraw-Hill, Maidenhead, 2007.
- [29] H.a. DeVon, M.E. Block, P. Moyle-Wright, D.M. Ernst, S.J. Hayden, D.J. Lazzara, S.M. Savoy, E. Kostas-Polston, A psychometric toolbox for testing validity and reliability, *J. Nurs. Scholarsh.* 39 (2) (2007) 155–164, <https://doi.org/10.1111/j.1547-5069.2007.00161.x>.
- [30] J. Cohen, *Statistical Power Analysis for the Behavioral Sciences*, Second edition, Lawrence Erlbaum Associates, Inc., Hillsdale, 1988.
- [31] I.B.M. Corp, *IBM SPSS Statistics for Windows*, Version 23.0, 2014.
- [32] J. Arbuckle, Amos (Version 22.0), 2013.
- [33] M. van de Wal, L. van de Poll-Franse, J. Prins, M. Gielissen, Does fear of cancer recurrence differ between cancer types? A study from the population-based PROFILES registry, *Psycho-Oncology* (2015) <https://doi.org/10.1002/pon.4002>.
- [34] H.W. Marsh, K. Hau, J.R. Balla, D. Grayson, Is more ever too much? The number of indicators per factor in confirmatory factor analysis, *Multivar. Behav. Res.* 33 (1998) 181–220, [https://doi.org/10.1207/s15327906mbr3302\\_1](https://doi.org/10.1207/s15327906mbr3302_1).
- [35] J.A.E. Custers, S.W. van den Berg, H.W.M. van Laarhoven, E.M.A. Bleiker, M.F.M. Gielissen, J.B. Prins, The cancer worry scale: detecting fear of recurrence in breast cancer survivors, *Cancer Nurs.* 37 (1) (2013) E44–50, <https://doi.org/10.1097/NCC.0b013e3182813a17>.
- [36] S.J. van Helmondt, M.L. van der Lee, J. de Vries, Study protocol of the CAREST-trial: a randomised controlled trial on the (cost-) effectiveness of a CBT-based online self-help training for fear of cancer recurrence in women with curatively treated breast cancer, *BMC Cancer* 16 (1) (2016) 527, <https://doi.org/10.1186/s12885-016-2562-0>.
- [37] M.A. van de Wal, M.F. Gielissen, P. Servaes, H. Knoop, A.E. Speckens, J.B. Prins, Study protocol of the SWORD-study: a randomised controlled trial comparing combined online and face-to-face cognitive behaviour therapy versus treatment as usual in managing fear of cancer recurrence, *BMC Psychol.* 3 (2015) 12, <https://doi.org/10.1186/s40359-015-0068-1>.
- [38] World Medical Association, World medical association declaration of Helsinki: ethical principles for medical research involving human subjects, *JAMA* 310 (2013) 2191–2194, <https://doi.org/10.1001/jama.2013.281053>.