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## The World Health Organization Quality of Life Instrument-Short Form (WHOQOL-BREF) in women with breast problems<sup>1</sup>

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**ABSTRACT.** The aim of this instrumental study was to compare the psychometric properties between World Health Organization Quality of Life instrument, short form (WHOQOL-BREF), data derived from the WHOQOL-100 and data directly from the WHOQOL-BREF and to assess additional psychometric properties of the WHOQOL-BREF in women with breast problems. One group ( $n = 607$ ) completed the WHOQOL-100 four times, another group ( $n = 549$ ) completed the WHOQOL-BREF once. The groups consisted of women with a palpable lump in the breast or an abnormality on a screening mammography. All participants completed measures of anxiety (STAI), depressive symptoms (CES-D), and fatigue (FAS). Women with breast cancer completed a health status measure (EORTC QLQ-BR23). Confirmatory analyses of the WHOQOL-BREF-data of both groups showed a reasonably good fit. Cronbach's alphas of the domains exceeded .70 in both groups, except for Social Relationships. Convergent validity was shown by the moderate to high correlations between scores on the FAS, STAI-State, EORTC QLQ-BR23 and the WHOQOL-BREF domains of physical and psychological health. Good test-retest reliability was found. In conclusion, WHOQOL-BREF-data derived from the WHOQOL-100 or obtained from the WHOQOL-BREF are directly comparable, and the WHOQOL-BREF has good psychometric properties in women with breast problems.

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**KEYWORDS.** WHOQOL-BREF. Quality of life. Breast cancer. Benign breast problems. Instrumental study.

**RESUMEN.** El objetivo de este estudio instrumental fue comparar las propiedades psicométricas entre el Cuestionario de Calidad de Vida de la Organización Mundial de la Salud, Forma Breve (WHOQOL-BREF), datos derivado de WHOQOL-100 y datos directamente del WHOQOL-BREF y evaluar las propiedades psicométricas adicionales del WHOQOL-BREF en mujeres con problemas de pecho. Un grupo ( $n = 607$ ) completó el WHOQOL-100 cuatro veces, otro grupo ( $n = 549$ ) completó el WHOQOL-BREF una vez. Los grupos fueron formados por mujeres con un nódulo palpable en el pecho o una anomalía en la mamografía de cribado. Todas las participantes cumplieron medidas de ansiedad (STAI), síntomas depresivos (CES-D) y fatiga (FAS); las mujeres con cáncer de pecho completaron además una medida del estado de salud (EORTC QLQ-BR23). El Análisis confirmatorio del WHOQOL-BREF tomando los datos de ambos grupos mostró un ajuste razonablemente bueno. Los alfas de Cronbach superaron el 0,70 en ambos grupos, excepto en el área de relaciones sociales. La validez convergente fue demostrada por correlaciones de moderadas a altas entre las puntuaciones del FAS, STAI-Estado, EORTC QLQ-BR23, y las áreas física y psicológica del WHOQOL-BREF. La fiabilidad test-retest medida por la correlación fue buena. En resumen, los datos del WHOQOL-BREF derivado de WHOQOL-100 y datos directamente del WHOQOL-BREF son comparables, y el WHOQOL-BREF tiene buenas propiedades psicométricas en mujeres con problemas de pecho.

**PALABRAS CLAVE.** WHOQOL-BREF. Calidad de vida. Cáncer de pecho. Problemas benignos de pecho. Estudio instrumental.

Breast cancer (BC) is the most common malignancy in women in Europe (Ferlay *et al.*, 2007). Nowadays, one in every eight women in the Netherlands will receive the diagnosis of BC in her life (Kiemeneij *et al.*, 2008). In general, women with a lump or pain in their nipple or breast or an abnormality on a screening mammography are referred to an outpatient clinic or hospital to get a thorough examination of a mammography, ultrasound and/or tissue. Afterwards women receive a diagnosis of either BC or a benign breast problem (BBP). The prognosis of women with BC has improved due to, for instance, better treatment and earlier detection. As a consequence, the number of BC survivors has increased (Courtillot *et al.*, 2005; Ferlay *et al.*, 2007; Jatoi and Miller, 2003; Jemal *et al.*, 2009; Louwman *et al.*, 2008;). Furthermore, there are even more women that receive a diagnosis of BBP (Pearlman and Griffin, 2010). These women were also in the distressing phase of waiting for a diagnosis (Liao, Chen, Chen, and Chen, 2008) and might even have heightened levels of stress afterwards even though they received a benign diagnosis (Meechan, Collins, Moss-Morris, and Petrie, 2005).

Therefore, it has become increasingly important to focus on patient-centred outcomes (Pérez-San-Gregorio, Martín-Rodríguez, Galán-Rodríguez, and Borda-Más, 2009; Schmid-Buchi, Halfens, Dassen and Van Den Borne, 2008; Verdugo, Arias, Gómez, and Schallock, 2010), such as quality of life (QOL). There is still debate on how to conceptualize QOL, illustrated by the amount of literature concerning QOL in which there are major differences in the definition of the concept (Van der Steeg, De Vries, and Roukema, 2007). Nevertheless,

there are some communalities in the definitions of QOL, namely multidimensionality, which refers to QOL comprising of at least the psychological, physical and social facets of life, and subjectivity, which means that QOL is evaluated from the perspective of the individual.

One of the instruments that is regularly used to measure QOL, is the World Health Organization Quality of Life instrument – 100 items (WHOQOL-100; WHOQOL Group, 1998b), a cross-culturally developed generic instrument. It was created by the World Health Organization Quality of Life Group (WHOQOL Group), that defined QOL as «an individual's perception of his/her position in life in the context of the culture and value systems in which he/she lives and in relation to his/her goals, expectations, standards and concerns» (WHOQOL group, 1995).

Following the development of the WHOQOL-100, the WHOQOL Group developed an abbreviated form of the WHOQOL-100, the WHOQOL-BREF (WHOQOL Group, 1998a). The WHOQOL-BREF has been proposed as an alternative instrument to measure QOL, since the WHOQOL-100 may be too lengthy for some users, for instance, where burden of the participants should be minimized. In addition, it has been shown that response rates tend to be higher when short measures are employed (WHOQOL Group, 1998a). The WHOQOL-BREF contains 26 items; one item from each of the 24 facets contained in the original WHOQOL-100 and two items were retrieved from the '*Overall QOL* and *General health*' facet. The WHOQOL-BREF covers four domains: *Physical health*, *Psychological health*, *Social relationships*, and *Environment*.

The WHOQOL-100 has been validated in different patient groups, for example, women with BC (Den Oudsten, Van Heck, Van der Steeg, Roukema, and De Vries, 2009), in sarcoma patients (Paredes, Simões, and Canavarro, 2010), and in psychiatric outpatients (Masthoff, Trompenaars, Van Heck, Hodiament, and De Vries, 2005). Also the WHOQOL-BREF was previously validated in multiple countries and languages (Nedjat, Montazeri, Holakouie, Mohammad, and Majdzadeh, 2008; Rocha and Fleck, 2009), and different patient groups, such as patients with HIV/AIDS (Sakthong, Schommer, Gross, Sakulbumrungsil, and Prasithsirikul, 2007), spinal cord injury (Hill, Noonan, Sakakibara, and Miller, 2010), sickle cell disease (Asnani, Lipps, and Reid, 2009), postnatal women (Webster, Nicholas, Velacott, Cridland, and Fawcett, 2010), and adult psychiatric outpatients (Trompenaars, Masthoff, Van Heck, Hodiament, and De Vries, 2005), but never in women with breast problems.

Therefore, the aim of the present instrumental study (Montero and León, 2007; Servera and Cardo, 2006) in women with breast problems was twofold. First, to compare the psychometric properties of WHOQOL-BREF scores obtained by deriving them from scores on the WHOQOL-100 (Study group 1 - SG1) with the WHOQOL-BREF scores obtained by completing the WHOQOL-BREF directly (Study group 2 - SG2). Second, to examine additional convergent validity and test-retest reliability, and obtain an indication of the sensitivity to change of the WHOQOL-BREF for use in women with breast problems.

With regard to the first aim, we hypothesized that reliability and validity for the two methods of obtaining scores on the WHOQOL-BREF would be good and comparable between SG1 and SG2. We also expected the earlier mentioned four-domain model (WHOQOL Group, 1998a) to fit well in women with breast problems, in SG1 and SG2.

Furthermore, based on previous studies (Carter, Lewin, Rashid, Adams, and Clover, 2008; Najafi, Sheikhvatan, Montazeri, and Sheikhfathollahi, 2009; Skevington, Lotfy, and O'Connell, 2004; Webster *et al.*, 2010), our expectation was that the internal consistency would be good for the domains of the WHOQOL-BREF, with a Cronbach's alpha exceeding .70.

We expected the construct validity to be good. To explore the convergent and divergent validity we correlated scores on the WHOQOL-BREF with measures of anxiety, depression, and fatigue since these symptoms are common in women with breast problems (Schmid-Buchi *et al.*, 2008). We expected that Pearson's correlation coefficients would be moderate ( $r = .30 - .49$ ) to high ( $r > .49$ ) between specific domains of the WHOQOL-BREF and the related questionnaires, for example, between the *Psychological health* domain and the Center for Epidemiological Studies-Depression Scale (CES-D) (Chiu *et al.*, 2006). Low correlations ( $r = .10 - .29$ ) were expected between WHOQOL-BREF domains and non-related questionnaires, for example, between the *Social relationships* domain and the State-Trait Anxiety Inventory - State scale (STAI-State; Marteau and Bekker, 1992).

Regarding the second aim, the hypothesis was that Pearson's correlation coefficients would be moderate to high between the *Physical health* domain and the *Symptom* scales of the European Organization for Research and Treatment of Cancer Breast Cancer-Specific Quality of Life Questionnaire (EORTC QLQ-BR23; Sprangers *et al.*, 1996) in SG1, expressing good convergent validity (Den Oudsten *et al.*, 2009). Based on the results of previous research, test-retest reliability of the WHOQOL-BREF was expected to be good in SG1 (Nedjat *et al.*, 2008; Ohaeri and Awadalla, 2009). We expected the WHOQOL-BREF to have good sensitivity to change in the BC group.

## Method

### *Participants*

SG1 consisted of women visiting the department of surgery of the St. Elisabeth hospital (Tilburg), Jeroen Bosch hospital (Den Bosch), or Maasland hospital (Sittard) in The Netherlands for the first time with a palpable lump in the breast or an abnormality on screening mammography between September 2002 and September 2006. SG1 consisted of 607 women. Of this group, 225 women later received the diagnosis breast cancer (BC group) and 382 women had a benign breast problem (BBP group).

SG2 consisted of women visiting the department of surgery of the St. Elisabeth hospital (Tilburg), Jeroen Bosch hospital (Den Bosch), VieCuri medical centre (Venlo), Medical Center Alkmaar (Alkmaar), or Catharina hospital (Eindhoven) in The Netherlands for the first time with a palpable lump in the breast or an abnormality on screening mammography between June 2007 and August 2009. SG2 consisted of 549 women, of whom 121 women later received the diagnosis BC and 428 had a BBP.

The exclusion criteria in both studies were recurrence of disease at baseline, poor expression in the Dutch language, dementia, and a history of psychiatric illness. Women with a history of psychiatric illness were excluded to obtain the QOL information about

women with breast problems without interference of psychiatric illness, which is related to a range of psychosocial problems and a decreased QOL (Baumeister, Balke, and Harter, 2005). The studies were approved by the medical ethics committee, and patients were only included after giving informed consent. The inclusion of patients in both studies occurred before diagnosis was known.

### *Measures*

The WHOQOL-100, Dutch version (De Vries and Van Heck, 1995) was used in SG1. The structure of the WHOQOL-100 covers six domains: *Physical, Psychological, level of independence, Social relationships, Environment, and Spirituality*. Within the domains there are 24 facets and there is one *Overall QOL* and *General health* facet. Each facet is assessed by four items, which score on a five-point Likert scale, ranging from 1 (*not at all/never/very dissatisfied/very unhappy/very poor*) to 5 (*extremely/always/very satisfied/very happy/very good*). The time frame of the items is the previous two weeks. High facet scores indicate good QOL; except for the facets *Pain and discomfort, Negative feelings, and Dependence on medication or treatments*, which are negatively framed. The time frame of reference is the previous 2 weeks. The instrument is reliable and valid (O'Carroll, Smith, Couston, Cossar, and Hayes, 2000) and the sensitivity of the instrument is also high (De Vries and Van Heck, 1997).

SG2 completed the WHOQOL-BREF, the short form of the WHOQOL-100 (WHOQOL Group, 1998b). The WHOQOL-BREF consists of four domains (*Physical health, Psychological health, Social relationships, and Environment*) and two items concerning *Overall QOL* and *General health*. These two items are not included in the calculation of domain scores. The response scales, all five-point Likert type ranging from 1 (*not at all/never/very dissatisfied/very poor*) to 5 (*extremely/always/very satisfied/very good*), and the time frame, *i.e.* the previous two weeks, are similar as in the WHOQOL-100. Higher scores indicate a better subjective QOL. Reliability and validity are reported to be good (WHOQOL Group, 1998a), and sensitivity to change was found to be high in patient with a liver transplantation, except for the *Social relationships* domain (O'Carroll *et al.*, 2000).

The CES-D (Radloff, 1977) is a 20-item self-report scale measuring the presence and degree of depressive symptoms over the past week. The CES-D has been established as a valid and reliable measure of depressive symptoms in BC patients (Hann, Winter, and Jacobsen, 1999). Reliability and criterion validity are good (Beekman *et al.*, 1997; De Rijk, Schreurs, and Bensing, 1999). The rating scale ranges from 0 (*seldom or never*) to 3 (*almost always*). Scores can range from 0 to 60.

State anxiety was measured by the STAI-State. State anxiety is defined as anxiety at the present moment. The version completed by SG1 consists of 20 items (Spielberger, Gorsuch, and Lushene, 1970; Van der Ploeg, Defares, and Spielberger, 1980). Validity and reliability of this version appear to be good (Spielberger, Gorsuch, and Lushene, 1968). The version completed by SG2 consists of 6 items (Marteau and Bekker, 1992). This short form also has shown to have good reliability and validity (Marteau and Bekker, 1992; Van der Bij, De Weerd, Cikot, Steegers, and Braspenning, 2003).

The Fatigue Assessment Scale (FAS; Michielsen, De Vries, and Van Heck, 2003) is a 10-item questionnaire to assess fatigue. The response scale is a 5-point scale from 1 (*never*) to 5 (*always*); scores on the FAS can range from 10 to 50. The reliability and validity of the FAS appeared to be good in persons working at least 20 hours per week (Michielsen *et al.*, 2003; Michielsen, De Vries, Van Heck, Van de Vijver, and Sijtsma, 2004), sarcoidosis patients (De Vries, Michielsen, Van Heck, and Drent, 2004; Michielsen, De Vries, Drent, and Peros-Golubicic, 2005), and women with breast problems (Michielsen, Van der Steeg, Roukema, and De Vries, 2007; De Vries, Van der Steeg, and Roukema, 2010).

The EORTC QLQ-BR23 (Montazeri *et al.*, 2000; Sprangers *et al.*, 1996) is a health status measure containing 23 items. It measures the functional scales *Body image*, *Sexual functioning*, *Sexual enjoyment*, and *Future perspective* and the disease symptom scales *Systemic therapy side-effects*, *Breast symptoms*, *Arm symptoms*, and *Upset by hair loss*. Answers vary from 1 (*not at all*) to 4 (*very much*). Higher scores on the functional scales represent a higher level of functioning, while higher scores on the symptom scales represent more symptomatology.

### *Procedure*

All patients (SG1 and SG2) were asked to report a number of socio-demographic aspects (age, sex, marital status, educational level) and completed a questionnaire set before they received a diagnosis (Time 0). Patients in SG1 completed the following questionnaires at Time 0: WHOQOL-100, CES-D, STAI-State, and FAS. The WHOQOL-100 was completed again one (Time 1), three (Time 2) and twelve (Time 3) months later. Women with BC additionally completed the disease-specific EORTC QLQ-BR23 at Time 3. Patients in SG2 completed the following questionnaires at Time 0: WHOQOL-BREF, CES-D, STAI-State, and FAS.

### *Statistical analysis*

Student *t*-tests, Chi-square tests, and analyses of variance (ANOVAs) were used to compare the BBP and the BC groups of both SG1 and SG2 on socio-demographic aspects, scores on state anxiety, depressive symptoms, fatigue, and QOL. A confirmatory factor analysis (CFA) was conducted to test the four-domain structure in SG1 and SG2. Goodness of fit was verified by the following fit indices: the Comparative Fit Index (CFI) and the Root Mean Square Error of Approximation (RMSEA). The models have a satisfactory to good fit when  $CFI > .90$  and  $RMSEA < .06$  (Hu and Bentler, 1999). The internal consistency for each domain was estimated using Cronbach's alpha. Depending on the number of questions in a domain, values should be at least .70 (Cohen, 1988). In order to provide information on construct validity, Pearson's correlation coefficients were calculated between the WHOQOL-BREF domains and the STAI-State, CES-D, FAS at Time0 for both SG1 and SG2, and the EORTC QLQ-BR23 scores at Time 3 for SG1. Since the EORTC QLQ-BR23 is a disease-specific questionnaire for BC patients, in this analysis only BC patients were included. Moderate ( $r = .30-.49$ ) and high ( $r > .49$ ) correlations are indicative for convergent validity, whereas small correlations ( $r = .10-.29$ ) are indicative for divergent validity (Cohen, 1988). To measure the test-retest

reliability of the WHOQOL-BREF, Pearson's correlation coefficients of the *Overall QOL* and *General health* facet and the WHOQOL-BREF domains were calculated between Time 1 and Time 2, Time 1 and Time 3, and Time 2 and Time 3 in the BBP group of SG1. These correlations were also computed for the BC group of SG1, to get information on the sensitivity to change of the WHOQOL-BREF. With a Fisher r-to-z transformation we calculated the significance of the differences between the correlations of the BBP group and the BC group. To compare the predictive value of the domain scores of the WHOQOL-100 and the WHOQOL-BREF on scores on the CES-D, FAS, STAI-State and EORTC 12 months after baseline, regression analyses (enter method) were performed on SG1. Significant different variables between the BC and BBP group were entered in the first block, domain scores in the second block.

The data were processed by means of the Statistical Package for the Social Sciences (version 17.0 for Windows), except for the CFA (AMOS 17.0).

## Results

Patient characteristics of SG1 and SG2 are presented in Table 1. Extensive descriptive statistics for SG1 and SG2 on the four domains and *Overall QOL* and *General health* of the WHOQOL-BREF are provided in Table 2.

**TABLE 1.** Patient characteristics and questionnaire scores at baseline of the total groups SG1 and SG2, and separately for the breast cancer group, and benign breast problems group.

	<i>Total group</i>		<i>BC group</i>		<i>BBP group</i>		<i>BC vs. BBP group</i> ( <i>p-value</i> )	
	SG1	SG2	SG1	SG2	SG1	SG2	SG1	SG2
Age ( <i>M</i> ± <i>SD</i> )	55 ± 10.40	53.10± 11.70	58.60± 9.40	60.30± 9.50	52.90± 10.40	51.90± 11.50	<.001*	<.001*
Age (min-max)	19-87	19-94	34-87	39-94	19-83	19-83		
Living with partner (%) <sup>1</sup>	83	81.80	80	76.90	84.80	83.20	.112	.055
Children (%) <sup>1</sup>	84.20	86.20	84.90	86	83.80	86.20	.300	.535
Educational level (l/m/h) <sup>1</sup>	206/267/110	188/250/97	83/95/38	52/52/16	123/171/72	136/198/81	.264	.023*
Paid work (%) <sup>1</sup>	47	57	38.20	37.20	52.10	62.20	.001*	<.001*
Scores CES-D ( <i>M</i> ± <i>SD</i> )	14.39± 10.20	7.80 ± 8	14.54± 9.40	8.92± 8.10	14.31± 10.60	7.48 ± 7.90	.800	.086
Scores FAS ( <i>M</i> ± <i>SD</i> )	20.41 ± 7	19.34± 6.60	19.74± 6.80	19.04± 6.90	20.82± 7.10	19.42± 6.40	.076	.584
Scores STAI-State ( <i>M</i> ± <i>SD</i> ) <sup>2</sup>	42.79± 13.80	13.38± 3.90	47.80± 13.80	14.51± 3.90	39.94± 13.10	13.06± 3.80	<.001*	<.001*

*Note.* <sup>1</sup> missing values range from 0-25, <sup>2</sup> the difference in scores between SG1 and SG2 was caused by different versions of the STAI-State (20-item version and 6-item version).

\* significant at  $\alpha = .05$  level SG1 = Study group 1; SG2 = Study group 2; *M* = mean; *SD* = standard deviation; BC = breast cancer; BBP = benign breast problems; CES-D = Center for Epidemiological Studies-Depression Scale; FAS = Fatigue Assessment Scale; STAI - State = State-Trait Anxiety Inventory - State scale. Educational level: l = low = up to 10 years of education; m = middle = 10-14 years of education; h = high = more than 14 years of education.



**TABLE 2.** Descriptive statistics for SG1 and SG2 at baseline on the WHOQOL-BREF domains and the Overall QOL and General Health facet (in SG1 derived from WHOQOL-100 scores) in a population of women with breast problems.

		<i>Mean</i>	<i>Median</i>	<i>SD</i>	<i>Min</i>	<i>Max</i>	<i>Av. inter-corr.</i>
Overall QOL and General health	SG1 BC	7.46	8	1.44	2	10	.51
	SG1 BBP	7.58	8	1.48	3	10	.61
	SG2 BC	7.82	8	1.47	3	10	.54
	SG2 BBP	7.85	8	1.45	3	10	.58
Physical domain	SG1 BC	15.93	15.43	2.38	8	20	.56
	SG1 BBP	15.17	15.43	2.50	6.29	20	.56
	SG2 BC	15.75	16.57	2.82	7.43	20	.58
	SG2 BBP	15.73	16	2.54	6.86	20	.59
Psychological domain	SG1 BC	14.81	14.67	2.10	8.67	19.33	.56
	SG1 BBP	14.54	14.67	2.14	8	20	.60
	SG2 BC	15.35	15.33	2.28	8.67	20	.58
	SG2 BBP	15.13	15.33	2.19	7.33	20	.62
Social relationships	SG1 BC	16.60*	16	2.26	10.67	20	.45
	SG1 BBP	16.09*	16	2.54	4	20	.49
	SG2 BC	16.35	16	2.55	9.33	20	.34
	SG2 BBP	15.84	16	2.60	6.67	20	.48
Environment	SG1 BC	16.34*	16.50	2.11	10	20	.59
	SG1 BBP	15.93*	16	2.12	9.50	20	.58
	SG2 BC	16.59	16.75	2.18	9.50	20	.54
	SG2 BBP	16.15	16	2.18	7	20	.58

*Note.* \* Means differ significantly ( $p = .014$  in *Social relationships*;  $p = .026$  in *Environment*). SG1 = Study group 1; SG2 = Study group 2; WHOQOL-BREF = World Health Organization Quality of Life instrument-short version; QOL = quality of life; WHOQOL-100 = World Health Organization Quality of Life instrument - 100 items; BC = breast cancer; BBP = benign breast problems; SD = standard deviation; Min = minimum; Max = Maximum; Av. inter-corr. = average of the inter-correlations between facet and domains of the WHOQOL-BREF.

### *Confirmatory factor analysis*

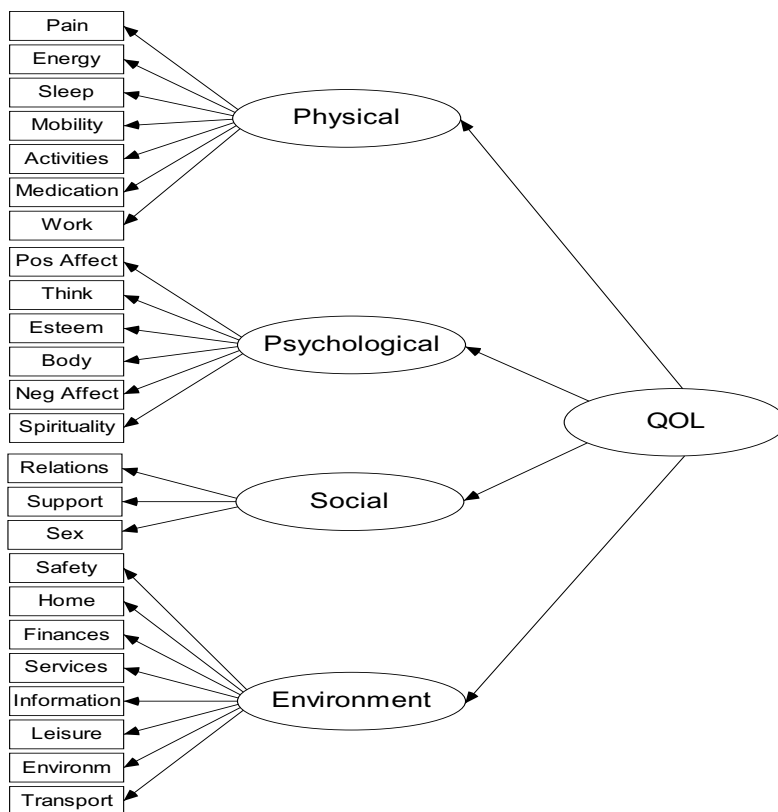
Careful inspection of the modification indices suggested a number of modifications to improve the four-domain models. Without correlated errors, the model for did not meet our criteria for an acceptable fit in SG1 (CFI = .85; RMSEA = .07) and in SG2 (CFI = .86; RMSEA = .07) (see Figure 1).

The model fit for SG1 improved significantly (CFI = .88; RMSEA = .06) when three pairs of error variances were allowed to covary (*i.e.*, item 10 (*Physical health*) and item 11 (*Psychological health*); *Psychological health* domain and item 22 (*Environment*); item 12 (*Environment*) and item 13 (*Environment*)). In SG2 the model fit improved significantly (CFI = .90; RMSEA = .06) when five pairs of error variances were allowed to covary (*i.e.*, *Social relationships* domain and *Environment* domain; *Social relationships* domain and item 22 (*Environment*); *Environment* domain and item 25 (*Physical health*); *Psychological health* domain and item 8 (*Environment*); item 7 (*Psychological health*) and *Psychological health* domain).

For the associations between the latent variable QOL and the four domains the following standardized regression weights were obtained in SG1: 1.00 (*Physical health*), .70 (*Psychological health*), .77 (*Social relationships*), and .76 (*Environment*) and in

SG2: .64 (*Physical health*), .11 (*Psychological health*), .76 (*Social relationships*), and .84 (*Environment*).

**FIGURE 1.** Four-domain confirmatory factor analysis model.



*Note.* QOL = Quality of life.

*Reliability*

Cronbach’s alpha coefficients were calculated separately for the total group, the BBP group, and the BC group in both studies. In general, the internal consistency of the domains exceeded .70, except in the *Overall QOL* and *General health* facet (2 items) of SG1, and in the *Social relationships* domain (3 items) of SG1 and SG2, where Cronbach’s alpha fell below this criterion in the total group (SG1:  $\alpha = .67$ ; SG2:  $\alpha = .68$ ), the BC group (SG1:  $\alpha = .66$ ; SG2:  $\alpha = .61$ ), and the BBP group (SG1:  $\alpha = .67$ ; SG2:  $\alpha = .69$ ) (see Table 3).

**TABLE 3.** Internal consistency of the WHOQOL-BREF at baseline: Cronbach's alpha for the total groups SG1 and SG2, and for the breast cancer and benign breast problems groups separately.

	<i>Total group</i>		<i>BC group</i>		<i>BBP group</i>	
	SG1	SG2	SG1	SG2	SG1	SG2
Overall QOL and General health	.64	.71	.58	.70	.67	.72
Physical health	.77	.82	.75	.83	.78	.82
Psychological health	.72	.78	.71	.78	.72	.79
Social relationships	.67	.68	.66	.61	.67	.69
Environment	.80	.82	.80	.78	.80	.83

*Note.* SG1 = Study group 1; SG2 = Study group 2; WHOQOL-BREF = World Health Organization Quality of Life instrument-short version; QOL = quality of life; BC = breast cancer; BBP = benign breast problems.

### *Construct validity*

To measure construct validity, the scores of the FAS, STAI-State, and CES-D at Time 0 were correlated with the four domains and the *Overall QOL* and *General health* facet of the WHOQOL-BREF in all patients in SG1 and SG2 (see Table 4). Pearson's correlations between scores on the FAS, STAI-State, CES-D, and the related domains of the WHOQOL-BREF were moderate or high (Table 4). Lower correlations were found between *Social relationships* and the STAI-State (SG1 and SG2), *Social relationships* and the CES-D (SG2), and *Environment* and the STAI-State (SG2), indicating divergent validity.

**TABLE 4.** Construct validity of the WHOQOL-BREF at baseline: Pearson's correlation coefficients for SG1 and SG2.

	<i>FAS</i>		<i>STAI</i>		<i>CES-D</i>	
	SG1	SG2	SG1	SG2	SG1	SG2
Overall QOL and General health	-.56	-.63	-.47	-.28	-.49	-.42
Physical health	-.69	-.73	-.44	-.31	-.55	-.46
Psychological health	-.62	-.63	-.51	-.43	-.60	-.52
Social relationships	-.39	-.41	-.26	-.15	-.31	-.20
Environment	-.44	-.50	-.34	-.27	-.35	-.33

*Note.* WHOQOL-BREF = World Health Organization Quality of Life instrument-short version; SG1 = Study group 1; SG2 = Study group 2; QOL = quality of life; FAS = Fatigue Assessment Scale; STAI = State-Trait Anxiety Inventory - State scale; CES-D = Center of Epidemiological Studies - Depression scale. All correlations are significant at  $p < .01$ , except for the correlation between *Social relationships* and STAI-State, which was significant at  $p < .05$ .

Construct validity was also measured in SG1 by correlating the scores at Time 4 on the four domains and the *Overall QOL* and *General health* facet of the WHOQOL-BREF with the scores at Time 4 of the different facets of the EORTC QLQ-BR23 (see

Table 5). The *Physical health* domain of the WHOQOL-BREF were associated moderately ( $p < .01$ ) with the symptom scales of the EORTC QLQ-BR23. The *Psychological health* domain of the WHOQOL-BREF was respectively moderately and highly associated ( $p < .01$ ) with the facets *Body image* and *Future perspective* of the EORTC QLQ-BR23. Correlations between the *Social relationships* domain of the WHOQOL-BREF and the facets *Sexual functioning* and *Sexual enjoyment* were respectively moderate and low (Table 5).

**TABLE 5.** Construct validity in women with breast cancer of SG1 at 12 months after surgery: Pearson's correlation coefficients between the WHOQOL-BREF and the EORTC QLQ-BR23.

	<i>Body image</i>	<i>Sexual functioning</i>	<i>Sexual enjoyment</i>	<i>Future perspective</i>	<i>Side effects</i>	<i>Breast symptoms</i>	<i>Arm symptoms</i>	<i>Upset by hair loss</i>
Overall QOL and General health	.18*	.19*	.35**	.51**	-.31**	-.37**	-.33**	.09
Physical health	.15	.29**	.31**	.42**	-.32**	-.43**	-.37**	.20
Psychological health	.45**	.24**	.21	.57**	-.24**	-.34**	-.27**	.04
Social relationships	.13	.36**	.27*	.31**	-.13	-.34**	-.12	.16
Environment	.06	.24**	.21	.35**	-.12	-.32**	-.15	.13

*Note.* SG1 = Study group 1; WHOQOL-BREF = World Health Organization Quality of Life instrument-short version; QOL = quality of life; FAS = Fatigue Assessment Scale; STAI = State-Trait Anxiety Inventory - State scale; CES-D = Center of Epidemiological Studies - Depression scale. \* correlations are significant at  $p < .05$ . \*\* correlations are significant at  $p < .01$ .

#### *Test-retest reliability and sensitivity to change*

Pearson's correlations between all time points of the *Overall QOL* and *General health* facet and the four domains of the WHOQOL-BREF in patients with a BBP were ranging from .73 to .86. In the BC group the correlations ranged from .58 to .84, with the lowest correlations between Time 1 and Time 3. Differences between the correlations of the BBP group and the BC group were significant at Time 1-Time 2 and Time 1-Time 3, except for the *Environment* domain (Table 6).

**TABLE 6.** Pearson's correlation coefficients of the WHOQOL-BREF in the BBP group and BC group of SG1 and *p*-values of the difference between two correlations (BBP and BC group).

	T1-T2			T1-T3			T2-T3		
	BBP	BC	<i>p</i>	BBP	BC	<i>p</i>	BBP	BC	<i>p</i>
Overall QOL and GH	.84	.65	<.001	.75	.58	<.001	.73	.66	.107
Physical health	.86	.74	<.001	.78	.69	.019	.79	.72	.052
Psychological health	.85	.79	.029	.82	.67	<.001	.82	.76	.057
Social relationships	.79	.71	.029	.79	.60	<.001	.74	.69	.226
Environment	.80	.84	.147	.81	.84	.267	.83	.84	.679

*Note.* WHOQOL-BREF = World Health Organization Quality of Life instrument-short version; T1 = measurement one month after diagnosis/surgery; T2 = measurement three months after diagnosis/surgery; T3 = measurement twelve months after diagnosis/surgery; BBP = benign breast problem; BC = breast cancer; SG1 = Study group 1; QOL = quality of life; GH = General Health. All correlations are significant at  $p < .01$

#### *Predictive value of domain scores*

Adjusted R-squares were slightly higher for the WHOQOL-100 compared with the WHOQOL-BREF. The differences between adjusted R-squares of the WHOQOL-100 and the WHOQOL-BREF range from .001 to .042 (see Table 7).

**TABLE 7.** Prognostic value (adjusted R-squares) of the WHOQOL-100 and the WHOQOL-BREF for scores on the CES-D, STAI-State, FAS and scales of the EORTC QLQ-BR23 at 12 months after baseline.

	WHOQOL-100*	WHOQOL-BREF*	Difference between WHOQOL-100 and WHOQOL-BREF
CES-D	.177	.145	.032
STAI-State	.122	.120	.002
FAS	.254	.212	.042
EORTC-body image	.039	.038	.001
EORTC-sexual functioning	.154	.149	.005
EORTC-future perspective	.070	.052	.018
EORTC-breast symptoms	.130	.116	.014

*Note.* Four scale scores of the EORTC QLQ-BR23 are not shown due to low *n*. WHOQOL-100 = World Health Organization Quality of Life instrument – 100 items; WHOQOL-BREF = World Health Organization Quality of Life instrument-short version; CES-D = Center of Epidemiological Studies – Depression scale; STAI = State-Trait Anxiety Inventory - State scale; FAS = Fatigue Assessment Scale; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Breast Cancer-Specific Quality of Life Questionnaire. \* scores corrected for Age, Working status, and score on STAI-State.

## Discussion

The aim of this study was to examine the psychometric properties of the WHOQOL-BREF in a population of women with breast problems (benign or malignant) and examine whether these properties are different when completing only the WHOQOL-BREF or deriving the scores of this questionnaire from the larger WHOQOL-100.

Overall, the four-domain model fitted reasonably well in both SG1 and SG2, although respectively three and five covariances had to be allowed between error terms to determine a model that better represented the sample data. The finding that a four-factor structure is not only present in a general population (WHOQOL Group, 1998b) but also in a population of women with breast problems, demonstrates that the WHOQOL-BREF is a generic instrument. Furthermore, the four-factor structure was present when WHOQOL-BREF scores were derived from scores on the WHOQOL-100, and also when WHOQOL-BREF scores were obtained directly from the WHOQOL-BREF questionnaire. This result shows that the WHOQOL-BREF derived from WHOQOL-100 data, produces a four-factor solution comparable to the four-factor model on WHOQOL-BREF data (Skevington *et al.*, 2004).

The WHOQOL-BREF appears to be a reliable instrument for the use in a breast problem population, both when scores are derived from the WHOQOL-100 and from the WHOQOL-BREF itself. Cronbach's alpha coefficients were .70 or more for the total scale and separate domains. The internal consistency for Social Relationships, however, fell below the threshold in the BC group, the BBP group and the total group in both SG1 and SG2. This finding could at least be partly attributed to the small number of items within this domain (3 items), whereas at least four items are recommended to obtain a Cronbach's alpha of at least .70 (Cohen, 1988). Another possible reason for the slightly lowered Cronbach's alpha in the *Social relationships* domain could be that one of the three items in this domain is about sexuality. However, excluding the item on sexuality resulted in a Cronbach's alpha of .64 instead of .67 in SG1 and .62 instead of .68 in SG2 in the total group, and the correlation between the sexuality item and the other two items (which are about personal relationships and support from friends) within the domain was .46 and .31 in SG1, and .49 and .32 in SG2. Therefore, no indication was found that the content of this item was related to the lowered Cronbach's alpha. In other validation studies this domain also showed a lowered Cronbach's alpha (Najafi *et al.*, 2009; Nedjat *et al.*, 2008; Skevington *et al.*, 2004).

Concerning convergent validity, the *Physical* and *Psychological health* domains of the WHOQOL-BREF were associated moderately or highly with the FAS, the STAI, and the CES-D in SG1 and SG2, as expected. Divergent validity was shown by lower correlations between *Social relationships* (WHOQOL-BREF) and the STAI-State and CES-D (SG2), and between *Environment* (WHOQOL-BREF) and the STAI-State (SG2). Results regarding construct validity, and especially convergent validity, were rather comparable between the two study groups and also to other studies that examined the correlations between the WHOQOL-BREF domains and depression scales (Chachamovich, Trentini, and Fleck, 2007; Chiu *et al.*, 2006; Rabin, Heldt, Hirakata, and Fleck, 2008; Trompenaars *et al.*, 2005). Engin and colleagues (Engin, Uguz, Yilmaz, Ozdemir, and Mevlitoglu, 2008) compared the WHOQOL-BREF with the Beck Depression Inventory (BDI; Beck, Steer and Garbin, 1988) and the Beck Anxiety Inventory (BAI; Beck, Epstein, Brown, and Steer, 1988) in idiopathic urticaria patients. Both scores on the BDI and the BAI correlated moderately or highly negative with scores on the WHOQOL-BREF domains *Physical health* and *Psychological health*. Regarding fatigue, there is one study that correlated the FAS with the WHOQOL-100, and it emerged that the FAS was

highly correlated with the WHOQOL-100 facet of *Energy* and *Fatigue* (De Vries *et al.*, 2004).

The *Physical health* domain of the WHOQOL-BREF correlated moderate and significant with the functional scales of the EORTC QLQ-BR23, as measured in SG1. The *Psychological health* domain was moderately associated with the facets *Body image* and *Breast symptoms* scales and highly with the facet about *Future perspective* of the EORTC QLQ-BR23. Recently, Den Oudsten *et al.* (2009) showed comparable results regarding correlations between the WHOQOL-100 and the EORTC QLQ-BR23.

A test-retest analysis was done in the BBP and the BC group of SG1, between all time points. Although the shortest time span between two succeeding measurements was quite long (two months), correlations were still high, indicating that the test-retest reliability of the WHOQOL-BREF was good. This result was in line with our expectations based on previous research on the WHOQOL-BREF (Nedjat *et al.*, 2008; Ohaeri and Awadalla, 2009) and the WHOQOL-100 (Den Oudsten *et al.*, 2009), but has to be interpreted with caution, because of the time span of two months. Furthermore, correlations between Time 1 and Time 2, and Time 1 and Time 3 were significantly lower in the BC group than in the BBP group (except for the *Environment* domain), indicating a good sensitivity to change of the WHOQOL-BREF. This difference can be attributed to the diagnosis and treatment that women with BC receive and women with BBP do not receive. The lowest correlations were found between Time 1 and Time 3 in the BC group. The results imply that one should administer QOL at three and 12 months after surgery, because correlations are significantly lower in the BC group than in the BBP group at those time points.

When we compared the predictive value of the WHOQOL-100 domain scores with the WHOQOL-BREF domain scores, the WHOQOL-100 predicted depression, anxiety, fatigue, and health status 12 months after baseline slightly better. Our opinion was that this difference was too small to overcome the benefit of the much shorter WHOQOL-BREF version. The advantage of the WHOQOL-100 however, is that it has facet-scores in addition to domain scores, which can describe QOL more comprehensively.

Some limitations of this study should be pointed out. Firstly, some analyses could not be performed in some of the groups or at a specific time point, for example we could not perform a test-retest analysis on the data of SG2, since we did not administer the WHOQOL-BREF at all time points in that group. The reasons for this limitation are twofold: a) the set of completed questionnaires did not match at all measure moments; b) the first measurement took place while all participating women were in a stressful situation, since women were awaiting diagnosis for their breast problem. Only in the next measurements, women were aware of their diagnosis, and patients were then divided in the two groups: BC patients and patients with a BBP. This diagnostic event between the first and second measurement, for example, made a test-retest analysis between the two measurements unreliable. In future research, questionnaires and measure moments should be matched better with each other, when working with two samples. And to analyze test-retest reliability, the time span between two measure moments should be shortened.

Secondly, because the study was aimed at patients with breast problems, there were only female respondents. The results may, therefore, not be applicable to other cancer patient groups and to the small group of male patients with BC or BBP, since these patients were not represented in this study.

In conclusion, scores on the WHOQOL-BREF derived from WHOQOL-100 data and scores obtained directly from the WHOQOL-BREF are comparable. This implies that they can be used interchangeably, without affecting the results. Furthermore, the WHOQOL-BREF appears to be a reliable and valid instrument to measure QOL in women with breast problems.

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