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Original research

International phase IV field study to validate the European Organisation for Research and Treatment of Cancer questionnaire for assessing the health-related quality of life of cancer survivors: The EORTC QLQ-SURV100

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ABSTRACT

Introduction: Cancer survivors face unique and persistent health-related quality of life (HRQoL) challenges. Existing HRQoL questionnaires for survivors lack content regarding chronic physical issues and have typically included limited cancer types and languages/cultures, affecting breadth of content and generalisability. We developed and validated the EORTC QLQ-SURV100, a questionnaire to assess HRQoL in disease-free survivors of diverse cancers. A conceptual framework of HRQoL in cancer survivors, developed in previous study phases and conceptualised as survivors' self-reported physical, mental and social functioning and well-being, formed the basis for questionnaire content.

Methods: The QLQ-SURV100 was administered to 1480 participants across 46 centres in 21 countries (31% breast cancer, 23% colorectal, 22% prostate, 24% other cancers), who had completed primary treatment 1–10 years earlier and had no evidence of active disease. Structural validity of the 21 multi-item questionnaire scales was assessed via confirmatory factor analysis; test-retest reliability via intraclass correlation coefficients (ICCs); construct validity through known-group comparisons; and cross-cultural validity and sex invariance through differential item functioning (DIF). Item response theory (IRT) analyses evaluated item redundancy and performance.

Results: The QLQ-SURV100 showed strong structural validity (Comparative Fit Index = 0.951; Tucker-Lewis Index = 0.944; Root Mean Square Error of Approximation = 0.046), with most standardised factor loadings > 0.7. Test-retest ICCs exceeded 0.7 for 27 of 35 scales and 0.6 for 34 scales. Known-groups analyses supported most hypotheses, confirming sensitivity to treatment, comorbidity, age, sex, and education. DIF analysis indicated minor cross-cultural item bias, but no sex-related DIF. IRT analysis found no redundant items.

Conclusions: The EORTC QLQ-SURV100 showed satisfactory structural validity, test-retest reliability and construct validity; limited item redundancy; and measurement invariance across the sex and language groups examined.

1. Introduction

Continuing improvement in early detection of cancer and cancer treatments and the ageing of the worldwide population have led to significant increases in cancer prevalence and cancer survivors [1,2]. Survivors experience a broad range of chronic and late effects of the disease and its treatment. As a result, there is a growing interest in evaluating health-related quality of life (HRQoL) of cancer survivors [3,4]. Clinical trials and comparative effectiveness studies are increasingly including long-term follow-up [5,6] and HRQoL assessments [7,8]. Integrating HRQoL measurements into longer-term cancer care requires robust, comprehensive tools reflecting the diverse, evolving experiences of survivors.

In this study (and for the purposes of the EORTC QLQ-SURV100 questionnaire) the term *cancer survivor* refers to those who *have completed anti-cancer treatment (with the exception of maintenance treatment settings) and have no current evidence of disease*, as per European expert consensus on the definition of a cancer survivor [9]. For brevity, here we use the term *disease-free* interchangeably with *no current evidence of disease*. We define *survivorship* as the physical, psychological, social, and existential experiences that may arise after treatment –

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including both challenges and positive adaptations.

Cancer survivors treated with curative intent may experience a wide range of physical and psychosocial effects that persist long after treatment ends. These include, but are not limited to, fear of recurrence, fatigue, pain, musculoskeletal problems, neurological symptoms, cognitive and sexual dysfunction, emotional distress, and social and financial challenges [10–12]. Surviving cancer can also be a catalyst for positive changes, including enhanced self-esteem, enhanced life appreciation and meaning, closer relationships, and heightened spirituality [13–15]. Such diverse outcomes necessitate a HRQoL questionnaire that captures a wide spectrum of survivorship experiences.

Many cancer-specific HRQoL questionnaires, such as the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30 (EORTC QLQ-C30) [16] and Functional Assessment of Cancer Therapy-General (FACT-G) [17], were developed for patients undergoing active treatment and are not entirely appropriate or sufficient for assessing experiences of cancer survivors. Existing questionnaires developed specifically for survivors tend to focus largely on psychological outcomes, with limited content regarding long-term physical effects and condition-specific issues – for example,

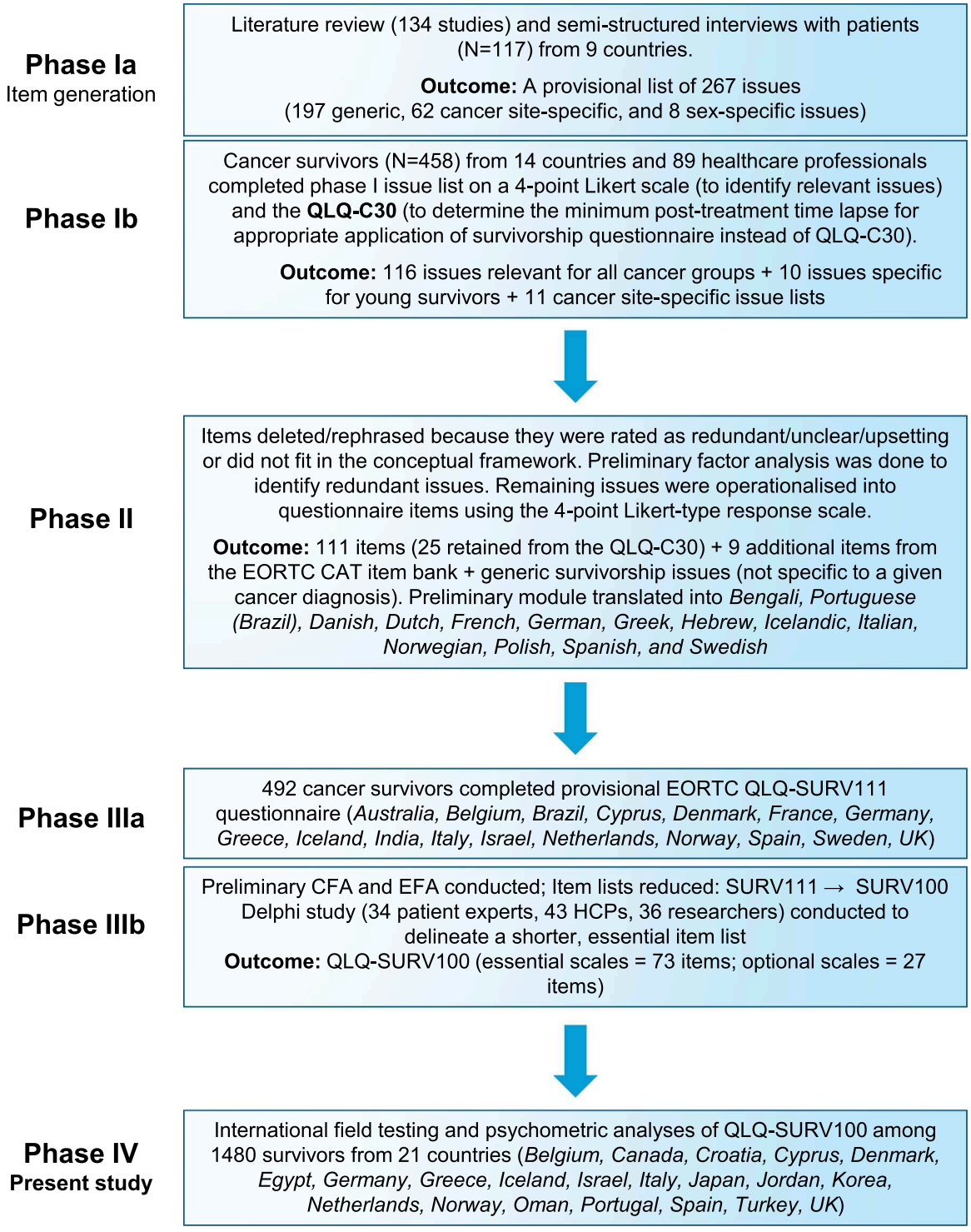


Fig. 1. Summary of EORTC QLQ-SURV100 development.

neuropathy or bowel issues. Most HRQoL questionnaires designed for cancer survivors are cancer type-specific, or lack broad cross-cultural validation and therefore may possess limited generalisability [18,19].

Aiming to address these issues, here we report the main results of the phase IV international validation of the EORTC QLQ-SURV100, evaluating its psychometric properties and applicability as a global standard for assessing HRQoL in disease-free adult survivors of cancer. The study reported here builds upon three previously reported study phases [20,21] conducted in accordance with the module development guidelines of the EORTC Quality of Life Group [22]. These guidelines represent a methodological framework for development of HRQoL measurement tools that is designed to ensure alignment with robust standards in patient-reported outcome measure (PROM) development (such as those outlined by the COSMIN framework [23]) while also aligning with the EORTC's modular-based approach to HRQoL measurement. Further detail on the methods used across all the study phases and their relevance to key principles of robust PROM development can be found in Supplementary Table S1.

For the development of the QLQ-SURV100, HRQoL was conceptualised as cancer survivors' *self-reported physical, mental and social functioning and well-being, including symptoms and the perceived impact of health on daily life*. During the earlier development phases [20,21], issues identified through literature review and interviews with cancer survivors and healthcare professionals were organised within these three broad domains, drawing on the WHO's broad conceptualisation of health [24], and the Medical Outcomes Study framework [25]. This framework informed item generation, content selection and the mapping of the 35 questionnaire scales [26].

2. Methods

2.1. Study design and participants

We conducted an international, observational field study to evaluate the psychometric properties of the QLQ-SURV100 as per the EORTC Quality of Life Group's module development guidelines [22]. The study was cross-sectional, with a repeated measures component for evaluating test-retest reliability. Data were collected from 46 research sites across 21 countries (see Fig. 1), using 16 translated versions of the questionnaire generated by the dedicated Translation Unit of the EORTC Quality of Life Department.

Eligibility criteria were: 1) aged $\geq$ 18 years at diagnosis; 2) only one primary cancer; 3) between one and ten years post-primary treatment, or treatment for recurrence (with the exception of maintenance therapies), with curative intent (except glioma patients, whose treatment is never considered curative); 4) no evidence of active disease (except glioma patients); 5) able to complete the questionnaire in one of the available language; and 6) provided written informed consent. Low-grade glioma patients were included in the study because, although they are not treated with curative intent and are not disease-free, they have a median survival of between 4.7 and 9.8 years [27].

A sampling matrix based on cancer type was used. For breast, colorectal, and prostate cancer, we had minimum sample requirements because we were concurrently developing cancer site-specific survivorship modules for these populations (we will report on these modules in future publications). Hence, breast, colorectal and prostate cancer patients each comprised approximately 25% of the total sample; and lymphoma, bladder, gynaecological, head and neck, lung, testicular, melanoma, and glioma patients together comprised the remaining 25% of the sample. We targeted a sample-wide 2:1 ratio of participants who were 1–5 years and 5–10 years post-treatment.

Ethical approval was obtained from the Institutional Review Board of the Netherlands Cancer Institute, Amsterdam (2 February 2022; reference IRBd21–295) and from the local ethics committees of all participating organisations according to national or local requirements.

2.2. EORTC QLQ-SURV100

In 2014, the EORTC Quality of Life Group (QLG) initiated a four-phase project to develop a comprehensive HRQoL assessment strategy for adult cancer survivors who are disease-free. The resulting questionnaire, the EORTC QLQ-SURV100, is the product of comprehensive, rigorous EORTC QLG development processes conducted in three earlier phases which have been previously reported (see Fig. 1) [20,21]. The QLQ-SURV100 is intended to be used for survivors who have completed curative treatment at least 12 months prior (excluding maintenance therapy) and have no evidence of active disease. It contains 75 essential items (for shorter administration) and 25 optional items (for full administration). It includes cancer-generic scales directly translated from the EORTC QLQ-C30 [16] (adapted for relevance to cancer survivors) as well as new, survivorship-specific scales (see Table 1).

2.3. Procedures

Upon enrolment, participants completed the full 100-item QLQ-SURV100; and sociodemographic and clinical questions including sex, marital status, living arrangements, employment status, educational level, and comorbid conditions. Participants also completed some additional questionnaires related to their health behaviours and care received (in service of additional research questions outside the scope of this manuscript). In addition, breast, colorectal, and prostate cancer survivors completed condition-specific survivorship modules (BR-SURV40, CR-SURV33, and PR-SURV19, respectively). Questionnaires were administered via an online data collection portal (CHES version 5.27.1, Evaluation Software Development, Innsbruck, Austria) or via pen/paper.

Background information was collected from participants' electronic health records by local investigators to document disease- and treatment-related information (including disease stage, disease subtype, treatment(s) received, and time since treatment), and comorbidity information. Participants also completed a short debriefing questionnaire.

In addition to the above, for the purposes of examining test-retest reliability, 25% of breast, colorectal, and prostate cancer participants were asked to complete the QLQ-SURV100 a second time, between 10 and 21 days after the first.

2.4. Statistical analysis

We evaluated the psychometric properties of the QLQ-SURV100 in terms of structural validity, test-retest reliability, construct validity, and measurement invariance (including cross-cultural validity), using statistical packages in R (version 4.3.3).

Structural validity of the multi-item scales was assessed using confirmatory factor analysis (CFA) with a diagonally weighted least-squares estimator in the *lavaan* package. The prespecified first-order factor structure was established during phase III and was informed by the conceptual framework developed in the earlier study phases [20,21,26]. The physical, mental and social domains were used to organise the questionnaire content but were not modelled as higher-order latent factors, as fitting this model would have required a much larger sample size [28]. Goodness-of-fit was assessed using the comparative fit index (CFI), Tucker-Lewis Index (TLI), and Root Mean Square Error of Approximation (RMSEA). For the CFA modelling, multiple imputation using predictive mean matching was used to manage missing data [29], generating pooled statistics from ten imputed datasets. All hypothesised latent factors (i.e. all hypothesised scales comprising two items or more) (21 scales, comprising 69 of the 100 items), were used to assess structural validity (see Table 1). Inclusion of the conditional scales for *work* or *sexual problems* in the CFA model drastically reduced the number of observations (n) and thus these scales were omitted from the primary CFA model, which hence comprised 19 scales (63 items). Two further CFA models were examined to assess whether inclusion of these two

Table 1
Scales of the QLQ-SURV100. Information is included on which scales were used in each analysis. 'X' indicates that the scale was included in the analysis.

Scale	Items (n)	QLQ-C30 scale / new survivorship scale	Essential (e) / Optional (o)	Functional / Symptom	Item numbers	CFA	Test-retest	DIF	IRT
Cognitive functioning	4	QLQ-C30	e	Functional	17, 22, 45, 46	x	x	x	x
Emotional functioning	7	QLQ-C30	e	Functional	18–21, 47–49	x	x	x	x
Fatigue	4	QLQ-C30	e	Symptom	12, 14, 15, 41	x	x	x	x
Financial difficulties	1	QLQ-C30	e	Symptom	25		x		
Global health status	2	QLQ-C30	e	Functional	99, 100		x	x	
Loss of income	1	QLQ-C30	e	Symptom	73		x		
Pain	2	QLQ-C30	e	Symptom	11, 16	x	x	x	
Physical functioning	7	QLQ-C30	e	Functional	1–7	x	x	x	x
Role functioning	3	QLQ-C30	e	Functional	8, 9, 50	x	x	x	x
Sleep problems (*insomnia* in the C30)	4	QLQ-C30	e	Symptom	13, 42–44	x	x	x	x
Social interference (*social functioning* in the C30)	2	QLQ-C30	e	Symptom	23, 24	x	x	x	
Symptom checklist (incl. *dyspnoea* from the C30)	17	New	e	Symptom	10, 26–40, 62		x		
Body image	2	New	e	Functional	51, 52	x	x	x	
Health distress	3	New	e	Symptom	53–55	x	x	x	x
Negative health outlook	7	New	e	Symptom	56–60, 63, 64	x	x	x	x
Problems insurances loans mortgages	1	New	e	Symptom	86		x		
Social isolation	2	New	e	Symptom	67, 68	x	x	x	
Symptom awareness	2	New	e	Functional	65, 66	x	x	x	
Work	4	New	e	Functional	69–72	x	x	x	x
Deeper meaning	1	New	o	Functional	89		x		
Fertility	1	New	o	Symptom	88		x		
Partner relation stronger	1	New	o	Functional	79		x		
Positive life outlook	4	New	o	Functional	80–83	x	x	x	x
Positive health behaviour change	2	New	o	Functional	74, 87	x	x	x	
Positive impact on behaviour towards others	2	New	o	Functional	84, 85	x	x	x	
Positive social functioning	2	New	o	Functional	77, 78	x	x	x	
Sexual functioning	2	New	o	Functional	92, 93	x	x	x	
Sexual pleasure	1	New	o	Functional	97		x		
Sexual problems	2	New	o	Symptom	90, 91	x	x	x	
Sexual problems female	1	New	o	Symptom	98		x		
Sexual problems when sexually active	2	New	o	Symptom	95, 96	x	x	x	
Sexual problems male	1	New	o	Symptom	94		x		
Treated differently	1	New	o	Symptom	76		x		
Worry cancer risk family	1	New	o	Symptom	61		x		
Worry impact of cancer on children	1	New	o	Symptom	75		x		

Note. n = number of items; CFA = confirmatory factor analysis; DIF = differential item functioning; IRT = item response theory.

conditional scales affected model fit. Model fit was assessed using the Comparative Fit Index (CFI) and the Tucker-Lewis Index (TLI) (with values >0.95 indicating acceptable fit); and the Root Mean Square Error of Approximation (RMSEA) (with a value <0.08 indicating acceptable fit).

Test-retest reliability of each of the 35 scales was assessed using intraclass correlation coefficients (ICCs) between assessment timepoints [30], with values ≥ 0.7 indicating good test-retest reliability, and values between 0.6 and 0.7 indicating satisfactory test-retest reliability.

We assessed construct validity via known-groups analyses, using hypothesis-driven comparisons across clinical and demographic groups (e.g., treatment type, comorbidities, age, sex, education) with analysis of variance or independent *t*-tests. We hypothesised statistically significant and clinically meaningful HRQoL differences, based on known survivorship patterns or findings from our prior phase III work (see Table 2). In the absence of known minimally important differences (MIDs) for the QLQ-SURV100, we applied the criterion of a Cohen's *d* effect size of ≥ 0.2 to indicate clinically meaningful difference, based on insights from previous literature [31,32].

We assessed measurement invariability using ordinal logistic regression models to examine: 1) cross-cultural validity (i.e., differences by linguistic group); and 2) sex differences. We conducted differential item functioning (DIF) analyses for six linguistic/regional groupings – West-Germanic (Dutch, Flemish, German); Scandinavian (Danish, Icelandic, Norwegian); Semitic (Arabic, Hebrew); Romance (Italian, Portuguese, Spanish); Japanese/Korean; and Turkish – comparing each with English as a reference category; and for females, with males as the reference category. All models were adjusted for cancer type, and overall scale score (i.e. the matching criterion). We judged DIF to be present for a given item and group based on numerical thresholds previously recommended [33]; and prior experience of members of the EORTC Quality of Life Group using these thresholds in computerised adaptive testing (CAT) settings [34,35]. DIF with statistical and practical significance was hence deemed present where the 95% confidence interval of the odds ratio was outside the range of 0.53–1.89, with such values indicative of a tendency in that linguistic/regional group to score higher/lower than the reference group (English) on that item, when controlling for overall scale score.

Previous cross-sectional analyses conducted in phases I and III indicated that time since treatment (in years) was not associated with HRQoL at the sample level [20,21]. Hence, we did not have a good rationale for undertaking responsiveness to change analysis with change

Table 2
A priori hypotheses for known-groups analyses produced from prior work in phases I-III. Scale-level information related to the presence or absence of support for these hypotheses can be found in Tables 5 and 6 (treatment type and co-morbidity); and Supplementary Tables S2, S3 and S4 (age, sex and education level).

H_i	Hypothesis
H_1	Survivors **treated with radiotherapy and chemotherapy** are expected to report lower health-related quality of life on most scales of the QLQ-SURV100 (with the exception of emotional functioning, sleep problems, and sexual problems) than those treated with surgery or radiotherapy only.
H_2	Survivors **with fewer comorbid conditions** will report in general better health-related quality of life than survivors with more comorbid conditions, but not on the scales assessing body image, health distress, symptom awareness, negative health outlook, positive health behaviour change, and social isolation.
H_3	**Younger survivors** will report better physical and sexual functioning but will report more psychosocial problems as assessed by emotional functioning and the survivorship scales compared to older survivors.
H_4	**Female survivors** are expected to score lower on physical functioning and to report more symptoms, and to report a higher impact of cancer on the survivorship-specific scales (i.e. they will report both stronger positive and negative effects of having had cancer in the past) than male survivors, but will not report more emotional problems.
H_5	Survivors **with higher socioeconomic status** (i.e. educational attainment) will report higher physical functioning compared to survivors with lower socioeconomic status and will report higher impact of cancer on symptom awareness and positive health behaviour change than survivors with a lower socioeconomic status.

defined as time posttreatment, as in the survivorship context we would not have expected to observe HRQoL differences over time at the sample level. Rather, we reproduced the cross-sectional analysis in this larger sample by: i) comparing scale scores between dichotomised groups (1–5 years posttreatment vs. >5 years posttreatment) using independent *t*-tests; ii) comparing scores between three groups (1–2 years posttreatment vs. 2–5 years posttreatment vs. >5 years posttreatment) using one-way ANOVA; and iii) examining Pearson correlations between scale scores and time since treatment as a continuous variable (in days). We adjusted for multiple comparisons using the Benjamini-Hochberg method.

To check for poorly performing items, redundant items in a scale, or items not fitting well in the hypothesised scales we conducted Item Response Theory (IRT) analysis, using the *mirt* package, with partial credit models for all scales with more than two items (10 scales), producing item characteristic curves and item information function plots.

For all scales, we examined skewness and kurtosis; and, for all items, response distributions for floor or ceiling effects.

3. Results

The QLQ-SURV100 was completed by 1480 cancer survivors (see Table 3 for a summary and Supplementary Table S3 for additional detail). Of these, 264 survivors of breast, colorectal, or prostate cancer completed the questionnaire again 10–21 days later for test-retest analysis. The sample was 51.1% female and had a mean age of 62.3 years. The mean time since curative treatment completion was 4.4 years, with 38.6% of the sample being > 5 years since curative treatment completion. The sample included 31.2% survivors of breast cancer; 22.9% colorectal cancer; 22.3% prostate cancer; and 23.6% other cancers. Median time to complete the baseline questionnaire was 7.8 min (interquartile range: 4.1–13.1 min).

Responses across the 35 scales were well-distributed, with no floor or ceiling effects (Fig. 2). Skewness (median: 0.35; range: −1.43–1.94) and kurtosis (median: 2.75; range: 1.44–5.94) were within acceptable bounds, indicating that the items captured a broad range of survivor experiences.

Table 3
Sociodemographic and clinical patient characteristics (N = 1480).

	M	SD
Age (M, SD)	62.3	12.9
Time since curative treatment completion (in years)	4.4	2.6
Sex	**n**	**%**
Male	721	48.7
Female	756	51.1
Missing	3	0.2
Time since treatment	**n**	**%**
< 5 years since curative treatment	908	61.4
> 5 years since curative treatment	572	38.6
Cancer type	**n**	**%**
Breast	462	31.2
Colorectal	339	22.9
Prostate	330	22.3
Head & Neck	61	4.1
Melanoma	53	3.6
Testicular	48	3.2
Lymphoma	46	3.1
Bladder	40	2.7
Gynaecological	36	2.4
Lung	33	2.2
Glioma	32	2.2
Treatment(s) previously received (either first or second line)[a]	**n**	**%**
Surgery (any)	1132	76.5
Surgery only	299	20.2
Radiotherapy (any)	715	48.3
Radiotherapy only[b]	123	8.3
Chemotherapy and radiotherapy[b]	195	13.2
Chemotherapy (any)	671	45.3
Hormone therapy (any)	427	28.9
Targeted therapy and/or immunotherapy (any)	95	6.4
Stem cell transplantation	4	0.3
Watchful waiting or active surveillance (current or previous)	39	2.6
Maintenance therapy (current)	144	9.7
Other	54	3.6
Language groupings	**n**	**%**
Croatian	23	1.6
English	436	29.5
Greek	39	2.6
Japanese/Korean	132	8.9
Romance (Italian, Portuguese, Spanish)	230	15.5
Scandinavian (Danish, Icelandic, Norwegian)	149	10.1
Semitic (Arabic, Hebrew)	99	11.4
Turkish	60	4.1
West-Germanic (Dutch, Flemish, German)	312	21.1

Note. [a]multiple answers possible; [b]surgery possible; M = mean; SD = standard deviation.

3.1. Scale structure based on CFA

Using the primary model comprising 63 items (i.e. omitting the two conditional scales), CFA supported the hypothesised scale structure of the QLQ-SURV100, with strong item-factor associations: 61 of 63 items had standardised factor loadings of > 0.7 (median: 0.86) with their hypothesised scale. Two items (one on sexual functioning and one on symptom awareness) fell just below this threshold (item 93, *"Have you been sexually active?"*, 0.66; and item 66, *"Are you more likely to contact your doctor when you experience symptoms?"*, 0.64) (Table 4). The other *sexual functioning* item, item 93 (*"Have you been sexually active?"*), produced a negative error variance estimate (i.e. a Heywood case) in some, but not all imputed datasets. This did not affect overall pooled model fit, or parameter estimates, so the item was retained. Overall model fit was satisfactory (Comparative Fit Index=0.951; Tucker-Lewis Index=0.944; Root Mean Square Error of Approximation=0.046 [95% CI 0.045–0.047]), supporting the proposed structure of the multi-item scales. Additional CFA models that included the two conditional

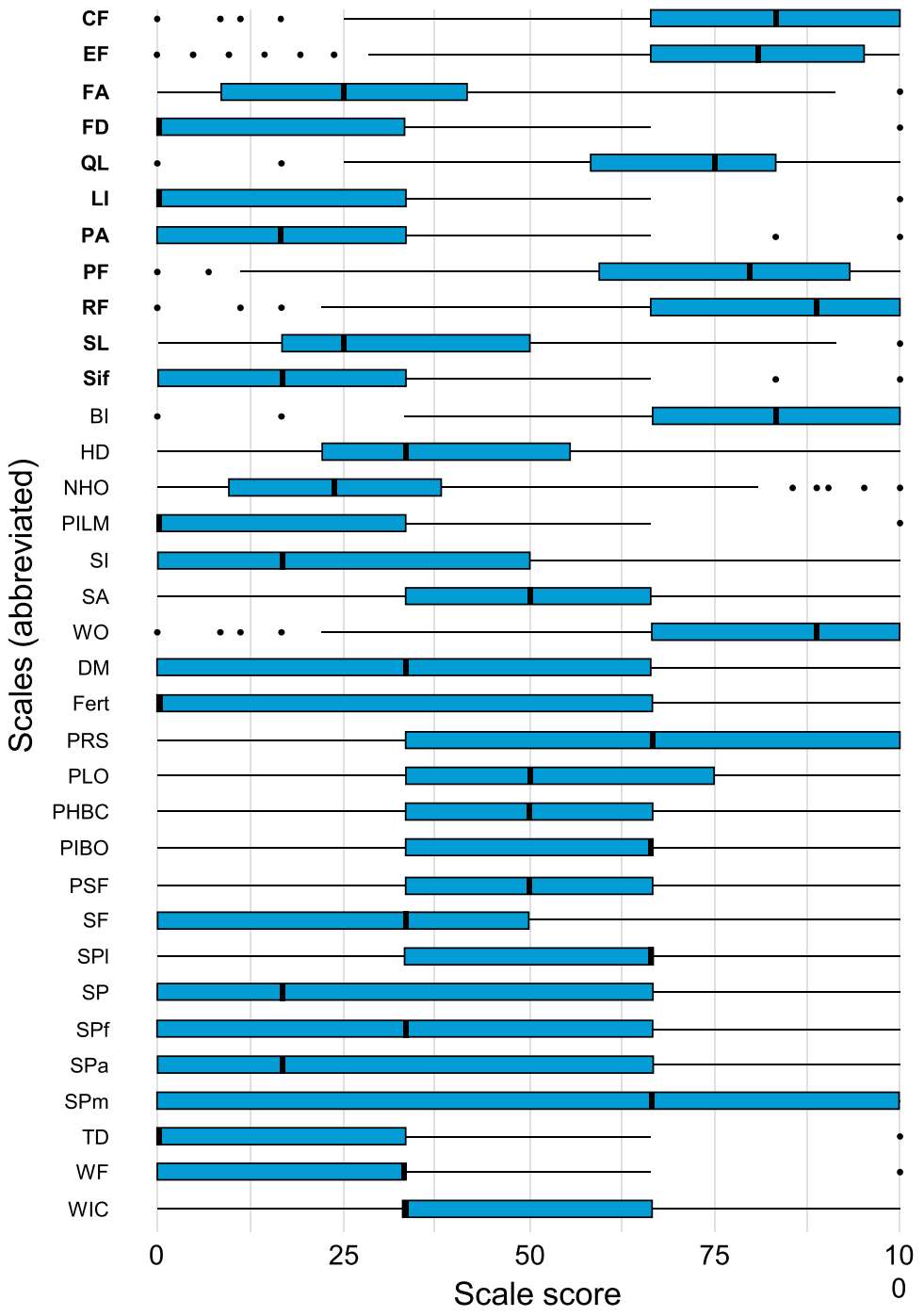


Fig. 2. Boxplot displaying the scale score distributions for 34 scales contained in the EORTC QLQ-SURV100 (i.e. with the symptom checklist excluded). Scales are ordered with scales derived from the EORTC QLQ-C30 first (in bold), then new survivorship scales. CF, cognitive functioning; EF, emotional functioning; FA, fatigue; FD, financial difficulties; QL, global health status; LI, loss of income; PA, pain; PF, physical functioning; RF, role functioning; SL, sleep problems; Sif, social interference; BI, body image; HD, health distress; NHO, negative health outlook; PILM, problems insurance loans mortgages; SI, social isolation; SA, symptom awareness; WO, work; DM, deeper meaning; Fert, fertility; PRS, partner relation stronger; PLO, positive life outlook; PHBC, positive health behaviour change; PIBO, positive impact on behaviour toward others; PSF, positive social functioning; SF, sexual functioning; SPl, sexual pleasure; SP, sexual problems; SPf, sexual problems female; SPa, sexual problems when sexually active; SPm, sexual problems male; TD, treated differently; WF, worry cancer risk family; WIC, worry impact of cancer on children.

scales, *work* (n = 460) and *sexual problems when sexually active* (n = 685), also showed robust fit and loadings (>0.7 for all included items; range: 0.73–0.88).

3.2. Test-retest reliability

Test-retest reliability of all 35 scales was assessed using intraclass correlation coefficients (ICCs) (Table 5). Twenty-seven scales had ICCs > 0.7; and 34 of 35 scales had an ICC > 0.6 (95% CIs covered or exceeded 0.7 in all such cases); indicating relatively strong reliability over repeated administration. The *sexual pleasure* scale (ICC=0.53) was the exception, with sex differences contributing to lower stability (women were more likely to report declines over time than men). Post hoc investigation of the other seven scales with ICCs < 0.7 indicated that

Table 4
Standardised factor loadings and estimated error variances for all items comprising multi-item scales of the QLQ-SURV100.

Item	Standardised factor loadings	Estimated error variance	Latent variable
Scales adapted from the EORTC QLQ-C30			
17	0.926	0.14	Cognitive functioning
22	0.904	0.18	
45	0.851	0.27	
46	0.789	0.38	
18	0.874	0.24	Emotional functioning
19	0.874	0.24	
20	0.859	0.26	
21	0.852	0.27	
47	0.835	0.30	
48	0.834	0.31	
49	0.793	0.37	
12	0.884	0.22	Fatigue
14	0.877	0.23	
15	0.857	0.27	
41	0.849	0.28	
11	0.984	0.04	Pain
16	0.888	0.22	
1	0.906	0.18	Physical functioning
2	0.900	0.19	
3	0.877	0.23	
4	0.875	0.23	
5	0.833	0.31	
6	0.832	0.31	
7	0.793	0.37	
8	0.928	0.13	Role functioning
9	0.926	0.14	
50	0.800	0.36	
13	0.882	0.22	Sleep problems
42	0.846	0.28	
43	0.796	0.37	
44	0.713	0.49	
23	0.949	0.10	Social interference
24	0.838	0.30	
New survivorship scales			
51	0.895	0.20	Body image
52	0.754	0.43	
53	0.963	0.07	Health distress
54	0.923	0.15	
55	0.907	0.18	
56	0.905	0.18	Negative health outlook
57	0.869	0.24	
58	0.827	0.31	
59	0.825	0.32	
60	0.798	0.36	
63	0.714	0.49	
64	0.711	0.49	
84	0.918	0.16	Positive behaviour
85	0.874	0.24	toward others
74	0.824	0.33	Positive health behaviour
87	0.742	0.46	
80	0.874	0.24	Positive outlook
81	0.873	0.24	
82	0.811	0.34	
83	0.783	0.39	
77	0.898	0.19	Positive social
78	0.788	0.38	functioning
92	0.970	0.04	Sexual functioning
93	0.661	0.55	
90	0.927	0.13	Sexual problems
91	0.855	0.26	
95	0.883	0.22	Sexual problems when
96	0.843	0.29	sexually active[a]
67	0.956	0.08	Social isolation
68	0.932	0.12	
65	0.915	0.17	Symptom awareness
66	0.637	0.60	
69	0.834	0.31	Work[b]
70	0.785	0.38	
71	0.863	0.26	
72	0.732	0.46	

Note. [a]tested in a separate model (n = 685); [b]tested in a separate model (n = 460).

Table 5
Intraclass correlation coefficients produced from test-retest reliability analysis.

Scale	No. of items	Subsample *n*	ICC	95% CI
Scales adapted from the EORTC QLQ-C30				
Cognitive functioning	4	261	0.81	[0.77–0.85]
Emotional functioning	7	261	0.82	[0.77–0.85]
Fatigue	4	261	0.78	[0.73–0.83]
Financial difficulties	1	260	0.73	[0.66–0.78]
Global health status	2	262	0.70	[0.63–0.75]
Pain	2	262	0.75	[0.69–0.80]
Physical functioning	5	262	0.86	[0.82–0.89]
Role functioning	3	262	0.76	[0.71–0.81]
Sleep problems	4	261	0.77	[0.72–0.82]
Social interference	2	261	0.70	[0.63–0.77]
New survivorship scales				
Body image	2	261	0.79	[0.73–0.83]
Deeper meaning	1	257	0.64	[0.57–0.71]
Fertility	1	24	0.84	[0.66–0.93]
Health distress	3	261	0.77	[0.71–0.82]
Loss of income	1	122	0.77	[0.68–0.83]
Negative health outlook	7	262	0.86	[0.82–0.89]
Partner relation stronger	1	202	0.68	[0.60–0.75]
Positive health behaviour change	2	262	0.70	[0.63–0.76]
Positive impact on behaviour towards others	2	261	0.67	[0.60–0.74]
Positive life outlook	4	262	0.77	[0.71–0.81]
Positive social functioning	2	262	0.67	[0.60–0.73]
Problems insurances loans mortgages	1	62	0.92	[0.87–0.95]
Sexual functioning	2	246	0.76	[0.70–0.81]
Sexual pleasure	1	106	0.53	[0.38–0.66]
Sexual problems	2	237	0.77	[0.71–0.81]
Sexual problems female	1	65	0.71	[0.57–0.82]
Sexual problems male	1	86	0.77	[0.67–0.84]
Sexual problems when sexually active	2	106	0.70	[0.59–0.79]
Social isolation	2	262	0.76	[0.71–0.81]
Symptom awareness	2	262	0.73	[0.66–0.78]
Symptom checklist	17	256	0.86	[0.83–0.89]
Treated differently	1	262	0.66	[0.59–0.73]
Work	4	107	0.85	[0.79–0.90]
Worry cancer risk family	1	262	0.65	[0.57–0.71]
Worry impact of cancer on children	1	182	0.63	[0.53–0.71]

Note. ICC = intraclass correlation coefficient; CI = confidence interval.

six of these were related to social relationships – e.g., "*Have you worried about the impact of your cancer on your children?*". Across the eight scales with ICCs < 0.7, changes of more than one point on the response scale were uncommon (~10% of respondents in the most extreme cases).

3.3. Known-groups validity

As hypothesised, the QLQ-SURV100 was sensitive to clinical differences (Table 6 and Table 7). Survivors treated with combined radiotherapy and chemotherapy reported statistically significant and clinically meaningful differences on almost all hypothesised scales as compared to those who had received radiotherapy only, or chemotherapy only. The only exceptions were the three scales on sexual functioning. As hypothesised, the combined modality treatment group had poorer scores on *cognitive functioning*, *fatigue*, *financial difficulties*, *pain*, *social interference*, *body image*, *negative health outlook*, *social isolation* and the symptom checklist. Conversely, the combined treatment group had higher (i.e., better) scores on the three scales related to positive change – *positive health behaviour change*, *positive impact on behaviour towards others*, and *positive social functioning* (Table 6).

As expected, survivors with multiple comorbidities reported lower HRQoL on most hypothesised scales, to a clinically meaningful extent (i.e. $d \geq 0.2$); although we observed no significant differences in *cognitive functioning*, *work*, *positive impact on behaviour toward others*, and *positive*

Table 6
Results of known-groups analysis (i.e. construct validity) of QLQ-SURV100 scales at baseline for different treatment groups.

Scale	F statistic	RT + CT[a]		RT			S		
		n	M (SD)	n	M (SD)	d	n	M (SD)	d
Scales adapted from the EORTC QLQ-C30									
Physical functioning[b]	7.35**	195	69.61 (28.53)	123	70.37 (26.46)	NS	299	77.74** (22.74)	0.32
Role functioning[b]	11.37**	195	74.44 (27.65)	122	79.33 (24.76)	NS	298	84.92** (20.99)	0.44
Emotional functioning[c]	5.05*	195	75.84 (23.30)	123	79.91 (19.33)	NS	299	81.87** (19.28)	0.29
Cognitive functioning	5.41*	195	78.19 (23.77)	123	84.15** (17.48)	0.3	299	83.74** (18.06)	0.28
Social interference	9.14**	195	26.07 (29.65)	123	18.02** (22.74)	0.32	299	16.39** (22.70)	0.39
Fatigue[b]	8.66**	194	30.31 (25.25)	123	26.94 (22.96)	NS	299	21.95** (19.54)	0.38
Pain	8.35**	195	24.62 (28.68)	123	17.75* (24.40)	0.27	299	15.27** (22.58)	0.37
Sleep problems[c]	5.32*	195	32.45 (24.89)	123	34.28 (25.92)	NS	299	27.09 * (21.65)	0.23
Financial difficulties	11.13**	195	17.44 (29.37)	123	8.13** (20.17)	0.41	298	8.17** (18.26)	0.41
New survivorship scales									
Body image	10.28**	195	73.16 (28.53)	123	80.22* (25.19)	0.28	299	83.67** (22.80)	0.42
Symptom awareness[b]	3.70*	195	53.76 (28.87)	123	48.37 (28.42)	NS	298	46.64* (28.69)	0.25
Work[b]	4.56*	97	76.52 (30.11)	47	84.28 (24.39)	NS	126	86.71** (21.29)	0.4
Health distress	9.24**	195	41.20 (29.03)	123	34.42* (26.67)	0.25	299	30.62** (25.19)	0.4
Negative health outlook	10.46**	195	29.30 (23.35)	123	23.58* (19.72)	0.28	299	20.72** (18.60)	0.42
Social isolation	9.35**	195	31.88 (33.96)	123	20.05** (28.31)	0.39	297	20.88** (27.98)	0.37
Symptom checklist	11.22**	192	22.82 (18.43)	120	18.25* (14.08)	0.29	289	15.94** (14.14)	0.44
Positive health behaviour change[d]	6.44**	195	52.48 (27.04)	123	48.24 (26.98)	NS	298	43.74** (26.16)	0.33
Positive impact on behaviour towards others[d]	6.49**	194	58.59 (29.20)	123	52.30 (31.75)	NS	299	48.94** (27.81)	0.33
Positive social functioning[d]	5.98**	195	51.03 (31.42)	123	44.31 (29.63)	NS	298	41.61** (28.57)	0.32
Sexual functioning[c]	0.56	187	29.68 (27.87)	117	32.76 (25.52)	NS	288	31.77 (26.66)	NS
Sexual problems[c]	1.94	184	36.23 (37.22)	113	30.24 (35.53)	NS	286	30.01 (33.42)	NS
Sexual problems when sexually active[c]	0.32	88	29.73 (31.71)	55	25.76 (28.29)	NS	139	28.78 (28.36)	NS

Note. d = Cohen's d (pairwise comparisons); n = number of complete observations; M = mean; SD = standard deviation; NS = non-significant pairwise comparison; RT = radiotherapy only (surgery possible); RT + CT = radiotherapy and chemotherapy (surgery possible); S = surgery only; [a]reference group; [b]significant differences were hypothesised between RT + CT and both RT and S groups, but found only between RT + CT and S groups; [c]significant difference was not hypothesised; [d]differences were hypothesised in the opposite direction; * $p < 0.05$; ** $p < 0.01$. Multiple comparisons correction was performed using the Benjamini-Hochberg procedure.

social functioning (Table 7).

The QLQ-SURV100 was also sensitive to demographic differences, namely age (Supplementary Table S4), sex (Supplementary Table S5), and educational status (Supplementary Table S6).

3.4. Measurement invariance

We examined measurement invariance (whether items perform similarly across geographic regions and sexes) using differential item functioning (DIF) analysis. Of the 100 items, 71 could be tested as these items comprised multi-item scales and hence the necessary statistical adjustments for overall scale score (i.e., a 'matching criterion') could be implemented. Most items showed no significant bias, but some items did demonstrate DIF in certain languages, when compared with English (Table 8). Specifically, the Turkish and Semitic linguistic groups showed uniform DIF in nine and 12 items respectively. We also observed uniform DIF in a small number of items within the Romance (four items), Japanese/Korean (five items), and Scandinavian (six items) groups. The West-Germanic translations showed DIF in one item (item 50: *"Have you been limited in doing physically demanding recreational activities (e.g., swimming or cycling)?"*). One item showed DIF by sex (item 92: "*Have you been interested in sex?*"). We did not observe non-uniform DIF in any items, in either of the analyses.

3.5. Time since treatment completion

After adjusting for multiple comparisons, only the *negative health outlook* scale significantly differed between the dichotomised groups; all other scales showed no significant differences (see Table 9). When divided into three groups, ANOVA showed no significant group differences on any scale (results not shown). When time since treatment was analysed as a continuous variable (in days), statistically significant, but very weak, inverse associations were observed with *negative health outlook* ($r = -0.08$, $p < 0.01$); and *positive social functioning* ($r = -0.08$, $p < 0.01$). No other scales were significantly correlated with time since treatment.

3.6. Item redundancy using item response theory

Examination of IRT plots (category characteristic curves and item information functions) and residual correlation matrices confirmed that all items analysed were informative and contributed meaningfully to their scales (see Supplementary Tables S7–S26 and Supplementary Figures S1–S30) with one exception, namely the relationship between item 70 (*'Do you work fewer hours than you would like?'*) and item 71 (*'Do you perform your work less well?*) on the *work* scale, which produced a moderately strong residual correlation coefficient of 0.58. Despite this, we decided to retain both items 70 and 71 because their content is qualitatively distinct. Thus all items were retained.

4. Discussion

We have demonstrated that the EORTC QLQ-SURV100, as of 2026 available in 21 languages (http://qol.eortc.org/questionnaires/), has strong psychometric properties across a large and heterogenous international sample of cancer survivors, supporting its potential for broad application in clinical survivorship research and care.

Our results from analysis of the multi-item scales (comprised of 69 of the 100 items) confirmed the hypothesised scale structure of 21 latent factors, constructed from previous work involving 492 cancer survivors [21]. Due to sample size limitations, our analysis evaluated the scale-level structure only and should not be interpreted as confirmation of a three-domain higher-order model; rather, the physical, mental, and social domains served as the conceptual framework for questionnaire development and content organisation. Standardised factor loadings were consistently strong and model fit indices were acceptable. Our findings provide robust evidence of the structural validity of the questionnaire across different cancer types, and clinical and geographical settings. Responses to the questionnaire items were well distributed and showed good variability. We did not reassess content validity in the

Table 7
Results of known-groups analysis (i.e. construct validity) of QLQ-SURV100 scales at baseline for different comorbidity groups.

Scale	F statistic	No comorbid conditions[a]		One comorbid condition			Two comorbid conditions			Three or more comorbid conditions		
		n	M (SD)	n	M (SD)	d	n	M (SD)	d	n	M (SD)	d
Scales adapted from the EORTC QLQ-C30												
Physical functioning	45.11**	517	78.80 (23.68)	329	74.52* (24.47)	0.17[d]	199	67.55** (26.34)	0.45	224	56.43** (27.15)	0.90
Role functioning	24.67**	516	84.32 (21.67)	328	80.74* (24.56)	0.14[d]	199	79.06* (23.26)	0.22	223	67.89** (28.47)	0.69
Emotional functioning	5.09**	517	77.65 (21.20)	329	78.12 (22.34)	NS	199	76.57 (22.38)	NS	224	71.41** (22.58)	0.28
Cognitive functioning[c]	2.61	517	80.51 (21.10)	329	81.21 (21.84)	NS	199	79.65 (20.42)	NS	224	76.34 (22.35)	NS
Social interference	12.83**	517	16.54 (23.16)	329	19.96 (26.06)	NS	199	21.19* (24.71)	0.18[d]	224	29.09** (29.62)	0.49
Fatigue	24.13**	516	23.68 (21.52)	329	27.68* (24.20)	0.17[d]	199	30.82** (22.51)	0.31	224	39.12** (25.32)	0.67
Pain	27.07**	517	15.99 (21.29)	329	19.81* (25.48)	0.15[d]	199	23.37** (25.01)	0.30	224	33.71** (31.27)	0.71
Sleep problems	14.59**	517	29.35 (22.89)	329	31.97 (23.75)	NS	199	32.15 (24.18)	NS	224	42.00** (27.06)	0.53
Financial difficulties	7.27**	516	13.37 (25.27)	329	11.55 (24.31)	NS	199	14.24 (26.02)	NS	224	21.73** (31.79)	0.32
New survivorship scales												
Body image[d]	6.40**	517	77.92 (26.20)	329	77.10 (27.32)	NS	199	75.54 (27.61)	NS	223	68.61** (29.87)	0.34
Symptom awareness[d]	0.71	516	52.55 (28.32)	329	51.93 (29.30)	NS	198	50.42 (30.25)	NS	223	54.41 (27.57)	NS
Work[c]	2.08	285	81.22 (26.72)	156	78.61 (25.23)	NS	78	78.81 (23.78)	NS	73	72.68 (29.77)	NS
Health distress[d]	2.55	517	37.55 (28.08)	329	37.71 (27.92)	NS	199	41.46 (30.37)	NS	224	42.96 (30.08)	NS
Negative health outlook[d]	6.83**	516	26.87 (23.17)	329	25.61 (20.92)	NS	198	27.14 (22.00)	NS	223	34.01** (25.43)	0.31
Social isolation[d]	2.6	516	28.75 (31.11)	328	25.86 (30.42)	NS	198	23.15 (28.82)	NS	222	30.41 (31.23)	NS
Symptom checklist	31.07**	513	17.61 (15.02)	322	20.25* (16.98)	0.19[d]	196	21.91** (16.52)	0.26	213	30.59** (19.64)	0.78
Positive health behaviour change[d]	1.81	517	50.77 (27.68)	328	47.10 (27.73)	NS	198	50.08 (25.88)	NS	222	46.85 (27.28)	NS
Positive impact on behaviour towards others[c]	1.75	517	55.09 (29.53)	329	55.98 (29.01)	NS	198	60.44 (27.60)	NS	223	55.16 (29.67)	NS
Positive social functioning[c]	1.96	516	48.26 (30.69)	329	50.00 (29.82)	NS	198	49.41 (30.10)	NS	223	43.95 (29.96)	NS
Sexual functioning	4.10*	503	31.88 (28.01)	316	31.54 (27.54)	NS	191	26.53* (27.52)	0.19[d]	206	25.24* (27.39)	0.24
Sexual problems	7.88**	504	30.36 (33.45)	312	30.88 (36.03)	NS	184	27.45 (33.15)	NS	202	42.82** (39.47)	0.35
Sexual problems when sexually active	5.13**	243	26.82 (27.60)	154	25.43 (28.15)	NS	86	29.46 (30.96)	NS	77	40.26** (31.80)	0.47

Note. d = Cohen's d (pairwise comparisons); n = number of complete observations; M = mean; SD = standard deviation; NS = non-significant pairwise comparison; [a]reference group; [b]Cohen d< 0.2, indicating a non-relevant difference; [c]significant difference was hypothesised, but not observed; [d]significant difference was not hypothesised; * $p < 0.05$; ** $p < 0.01$. Multiple comparisons correction was performed using the Benjamini-Hochberg procedure.

Table 8
Results of differential item functioning (DIF) analysis using ordinal logistic regression models, for both linguistic groupings and sex.

Language grouping[a]	Number of items demonstrating apparent DIF	Items demonstrating apparent DIF
West Germanic	1	50
Scandinavian	6	8, 23, 24, 49, 50, 63
Semitic	9	15, 46, 47, 58, 59, 63, 78, 81, 82
Romance	4	6, 47, 49, 58
Japanese/ Korean	5	2, 4, 9, 14, 64
Turkish	12	5, 6, 14, 15, 46, 49, 53, 60, 63, 77, 78, 81
Sex[b]	**Number of items demonstrating apparent DIF**	**Items demonstrating apparent DIF**
Sex: females	1	92

Note. [a] Reference category: English; [b] Reference category: males.

present study. However, during the earlier development phases, literature review, international survivor and healthcare-professional interviews, and cognitive testing were used to evaluate and refine the relevance, comprehensiveness and comprehensibility of the questionnaire content [20,21]. These earlier findings provide supporting evidence for the content validity of the QLQ-SURV100.

The questionnaire was able to discriminate clearly between subgroups of survivors based on treatment received, comorbidity, age and sex. IRT models indicated that no items, with the exception of items 70 and 71, were psychometrically redundant or non-fitting. We decided to retain items 70 and 71 because of their qualitatively distinct content. Thus all items of the questionnaire were retained.

Test-retest reliability was generally acceptable, although weaker correlations were observed for some scales relating to social relationships. This may be indicative of weaker reliability of the scale items over time; or may reflect 'true' instability of the social constructs being assessed due to the influence of external events [36].

There were no substantial differences in item interpretation between males and females (apart from one item concerning participants' interest in sex). Cross-cultural equivalence was also broadly supported, although some potential issues were noted in Turkish, Hebrew, and Arabic translations, where some items may have been interpreted differently than in the English version. It is notable that the groups showing the greatest extent of DIF (Semitic respondents; Turkish respondents) were also the smallest in size of all the linguistic groups analysed. These findings indicate a need for further, targeted linguistic validation studies, with larger group sample sizes, to ensure cultural appropriateness and conceptual equivalence in all language versions.

Known-groups validity analysis showed that the QLQ-SURV100 can discriminate between patient groups that are circumstantially different. However, not all our pre-specified hypotheses were supported, which suggests the need for further exploration of variables and moderators that may impact the HRQoL of cancer survivors (it should be noted that, while some differences were statistically non-significant, there were numerical trends in the expected directions in all cases). Notably, more intensive treatment was associated with more positive scores on the scales related to post-traumatic growth, an observation consistent with prior literature [37].

The QLQ-SURV100 addresses relevant survivorship issues, in particular social determinants of health, employment, evaluation and management of symptoms and late effects, and psychosocial care [3]. The QLQ-SURV100 may also be well-suited for evaluating the HRQoL impact of enhanced models of care for cancer survivors that have recently been proposed [4], such as nurse-led survivorship care, integrated primary-secondary care, supported self-management, and long-term follow-up clinics. Moreover, it could be integrated into survivorship care models as a tool to identify what patients find challenging and to guide personalised care [38], as has already been done in one late effects clinic in Denmark, with encouraging early results regarding its applicability in this context [39].

Although a 100-item questionnaire may appear burdensome, the QLQ-SURV100 was completed in eight minutes on average and has been

Table 9
Results of between-group comparisons based on time since completion of primary treatment, using independent *t*-tests.

Scale	< 5 post-treatment		> = 5 years post-treatment			
	n	M (SD)	n	M (SD)	t statistic	d
Scales adapted from the EORTC QLQ-C30						
Physical functioning	908	72.28 (26.38)	572	72.29 (25.37)	−0.01	NS
Role functioning	905	78.93 (25.18)	571	81.38 (23.30)	−1.9	NS
Emotional functioning	908	76.33 (21.96)	572	78.00 (21.93)	−1.42	NS
Cognitive functioning	908	79.37 (21.74)	571	80.97 (20.72)	−1.42	NS
Social interference	908	21.05 (26.12)	572	18.09 (24.15)	2.22	NS
Fatigue	907	28.62 (24.26)	572	27.47 (22.45)	0.93	NS
Pain	908	21.22 (26.05)	527	20.80 (25.35)	0.3	NS
Sleep problems	908	32.44 (24.33)	572	33.20 (25.09)	−0.58	NS
Financial difficulties	908	13.44 (26.06)	571	13.89 (25.62)	−0.33	NS
New survivorship scales						
Body image	908	75.29 (27.96)	571	77.93 (25.85)	−1.85	NS
Symptom awareness	907	53.29 (28.72)	570	50.29 (29.08)	1.94	NS
Work	436	78.02 (26.61)	254	81.76 (24.83)	−1.86	NS
Health distress	908	39.26 (28.96)	572	37.98 (28.20)	1.43	NS
Negative health outlook	906	29.11 (23.58)	571	25.08 (21.90)	3.34*	0.18
Social isolation	904	27.56 (31.04)	570	25.20 (30.07)	1.45	NS
Symptom checklist	890	20.91 (17.36)	557	20.65 (16.85)	0.28	NS
Positive health behaviour change	906	49.91 (27.74)	570	46.81 (27.03)	2.12	NS
Positive impact on behaviour towards others	908	54.88 (29.14)	569	57.29 (29.19)	−1.55	NS
Positive social functioning	907	49.12 (30.14)	570	45.94 (30.77)	1.95	NS
Sexual functioning	870	30.59 (27.80)	552	29.95 (27.23)	0.43	NS
Sexual problems	856	32.32 (34.94)	545	32.35 (35.87)	−0.02	NS
Sexual problems when sexually active	400	27.83 (28.59)	279	30.41 (30.13)	−1.12	NS

Note. d = Cohen's d (pairwise comparisons); n = number of complete observations; M = mean; SD = standard deviation; NS = non-significant comparison; * $p < 0.05$. Multiple comparisons correction was performed using the Benjamini-Hochberg procedure.

Table 10
Frequency counts of responses to questions on the debriefing questionnaire.

Were there any questions that you found confusing or difficult to understand?	**n**	**(%)**
No	1210	(81.8)
Yes	226	(15.3)
[No response]	*[44]*	*([3.0])*
Were there any questions that you regarded as too personal or disturbing?	**n**	**(%)**
No	1313	(88.7)
Yes	122	(8.2)
[No response]	*[45]*	*([3.0])*
Sometimes patients fill in a questionnaire entirely by themselves; sometimes they do so with the help of someone else. How did you fill in the questionnaires?	**n**	**(%)**
Entirely by myself	1227	(82.9)
With the help of someone else	206	(13.9)
[No response]	*[47]*	*([3.2])*
How were you assisted in completing the questionnaire?	**n**	**(%)**
The questions were read to me	144	(9.7)
The answers were selected for me	67	(4.5)
We discussed the meaning of one or more questions	82	(5.5)
We discussed the answers on one or more questions	44	(3.0)
Other	4	(0.3)
[No response]	*[1139]*	*([77.0])*
How often would you be willing to fill out this questionnaire?	**n**	**(%)**
Once a month	234	(15.8)
Once per half year	464	(31.4)
Once per year	390	(26.4)
Once per two years	58	(3.9)
One time only	248	(16.8)
[No response]	*[86]*	*([5.8])*
Were there any questions that you considered unnecessary?	**n**	**(%)**
No	1205	(81.4)
Yes	187	(12.6)
[No response]	*[88]*	*([5.9])*
Were any important topics missing in this questionnaire?	**n**	**(%)**
No	1179	(79.7)
Yes	215	(14.5)
[No response]	*[86]*	*([5.8])*
What topics were missing?		
[209 free-text comments were provided]		
Do you have any other comments on this questionnaire? If so, please write them below.		
[278 unique free-text comments were provided]		

shown in the Danish study by Tolstrup et al. to be broadly acceptable to patients in a real-world setting [39]. The questionnaire is multifaceted, covering a wide range of HRQoL domains that might otherwise require several separate PROMs. We would note that the QLQ-SURV100 can, if needed (particularly in clinical trials with multiple assessments), be reduced to a 75-item list of essential items; with the other 25 items remaining optional [21]. However, we would encourage the inclusion of all items and scales, as they provide optimal content validity. Importantly, the QLQ-SURV100 is structurally and conceptually aligned with the EORTC QLQ-C30 [16]. Hence it enables longitudinal studies to be conducted, in which patients who are on treatment (or up to 1 year post-treatment) can be assessed with the QLQ-C30 before transitioning to assessment with the QLQ-SURV100 one year after completion of treatment, while maintaining continuity and integrity of HRQoL measurement.

A limitation of the study was that we did not have a specific focus on adolescent and young adult cancer survivors, who represent a unique survivorship population with specific needs, including identity development, education and employment transitions and specific follow-up care [40]. Recognising these unique challenges, the EORTC QLG is currently developing a separate survivorship questionnaire specifically for AYA cancer survivors. Efforts are being made to align the conceptual framework and content of the AYA-specific tool with the QLQ-SURV100, to ensure consistency and potential comparability across age groups.

The QLQ-SURV100 can be considered valid as a cancer-generic, standalone questionnaire akin to the EORTC QLQ-C30. Ideally however, the QLQ-SURV100 would be combined with additional measures of diagnosis-specific survivorship issues, as is done with the EORTC QLQ-C30 questionnaire modules. Validation results of such modules in breast, colorectal, and prostate cancer survivors will be reported in subsequent publications, and this work will be further extended to encompass other cancer diagnoses. Other areas for future work include: 1) language-specific studies to further scrutinise the cross-cultural validity of the QLQ-SURV100 and potentially refinement of certain language translations, where necessary; 2) investigation of how HRQoL in the survivorship phase is differentially affected in differing disease and treatment contexts, and by interventions, using the QLQ-SURV100; and 3) further examination of how the QLQ-SURV100 can be used in clinical practice, and to guide interventions.

5. Conclusion

In conclusion, these findings support the structural validity, test-retest reliability and construct validity of the EORTC QLQ-SURV100, as well as the comparability of scores across the sex and language groups examined. Other measurement properties, including responsiveness and interpretability, require further evaluation. Developed through extensive international qualitative and psychometric work, the QLQ-SURV100 captures physical, mental and social aspects of cancer survivorship and provides a robust research tool. The questionnaire could potentially support clinical practice, by identifying areas where survivors experience challenges; this is an area that requires additional research efforts.

CRediT authorship contribution statement

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Declaration of Competing Interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: Louis Fox reports financial support was provided by European Organisation for Research and Treatment of Cancer. If there are other authors, they declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Appendix A. Supporting information

Supplementary data associated with this article can be found in the online version at doi:10.1016/j.ejca.2026.116959.

Data availability

Deidentified data used for this study can be made available for research and quality assurance purposes via a request to the EORTC Quality of Life Group, with approval of any such requests provided on a case-by-case basis and subject to relevant agreements governing the appropriate use of the data.

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