Psychometric validation of the European Organization for Research and Treatment of Cancer – Quality of Life Questionnaire Sexual Health (EORTC QLQ-SH22)

E. Greimel[a], E. Nagele[a], A. Lanceley[b], A. Oberguggenberger[c], A. Nordin[d], K. Kuljanic[e], J. I. Arraras[f], C. W. Chie[g], P. T. Jensen[h], K. A. Tomaszewski[i], C. L. Creutzberg[j], R. Galalae[k], H. Toelen[l], K. Zimmermann[m], V. Bjelic-Radisic[n], A. Costantini[o], T. Almont[p], S. Serpentini[q], L. Paskeviciute Frøding[r], I. Vistad[s], C. Schmalz[t] on behalf of the EORTC Quality of Life Group

[a]Medical University of Graz, Graz Austria
[b]University College London, London, United Kingdom
[c]Medical University of Innsbruck, Austria
[d]East Kent Hospitals University Foundation NHS Trust, Kent, United Kingdom
[e]Clinical Unversity Hospital Centre Rijeka, Croatia
[f]Complejo Hospitalario de Navarra, Pamplona, Spain
[g]Institute of Epidemiology and Preventive Medicine, National Taiwan University, Taiwan
[h]Department of Gynecology, Aarhus University Hospital, Denmark
[l]Faculty of Medicine and Health Sciences, Andrzej Frycz Modrzewski Kraków University, Kraków, and Scanmed St. Raphael Hospital, Kraków, Poland
[j]Leiden University Medical Center, Leiden, Department of Radiation Oncology, Netherlands
[k]Evangelische Kliniken Gelsenkirchen GmbH, Gelsenkirchen, Germany
[l]University Hospitals Leuven, UZ Campus Gasthuisberg, Belgium
[m]Bundeswehrzentralkrankenhaus Koblenz, Klinik für Urologie, Koblenz
[n]Helios University Clinic, University Witten/Herdecke, Wuppertal, Germany
[o]Psychoncology Unit, Sant'Andrea Universitary Hospital, Rome, Italy
[p]Institut Universitaire du Cancer, Toulouse, France
[q]Unit of Psycho-oncology/Breast Unit, Veneto Institute of Oncology IOV-IRCCS Comprehensive Cancer Centre, Padova, Italy
[r]Department of Gynecology, Copenhagen University Hospital, Denmark
[s]Sørlandet Hospital, Kristiansand, Norway
[t]Department for Radiation Oncology, University Clinic Schleswig-Holstein, Kiel, Germany

Corresponding author: Prof. Elfriede Greimel, Department of Gynecology, Medical University Graz, Auenbruggerplatz 14, 8036 Graz, Austria. (E-mail: elfriede.greimel@medunigraz.at)

Disclosure: The authors have declared no conflicts of interest.

Abstract

Background: The European Organization for Research and Treatment of Cancer (EORTC) Quality of Life Group developed a questionnaire to assess sexual health in cancer patients and cancer survivors. This study evaluates the psychometric properties of the questionnaire.

Methods: The 22-item EORTC sexual health questionnaire (EORTC QLQ-SH22) was administered with the EORTC QLQ-C30 to 444 cancer patients. The hypothesized scale structure, reliability, and validity were evaluated through standardized psychometric procedures.

Results*:* The cross-cultural field study showed, that the majority of patients (94.7%) were able to complete the QLQ-SH22 in less than 20 minutes, 89% of the study participants did not need any help to fill in the questionnaire. Multi-item multi-trait scaling analysis confirmed the hypothesized scale structure with two multi-item scales (sexual satisfaction, sexual pain) and 11 single items (including five conditional items and four gender-specific items). The internal consistency yielded acceptable Cronbach's alpha coefficients (0.90 for the sexual satisfaction scale, 0.80 for the sexual pain scale). The test-retest correlations (Pearson's r) ranged from 0.70 to 0.93 except for the scale communication with professionals (0.67) and male body image (0.69). The QLQ-SH22 discriminates well between subgroups of patients differing in terms of their performance and treatment status.

Conclusion: The study supports the reliability, the content, and construct validity of the QLQ-SH22. The newly developed questionnaire is clinically applicable to assess sexual health of cancer patients at different treatment stages and during survivorship for clinical trials and for clinical practice.

Keywords: Sexual health, quality of life, cancer, questionnaire development, EORTC, cross-cultural validation, psychometric properties

Funding

This study was supported by the European Organization for Research and Treatment of Cancer - QLG (Grant number: 001-2016). Anne Lanceley was supported by the National Institute for Health Research (NIHR) UCLH/UCL Biomedical Research Centre which is funded by the Department of Health. Juan Ignacio Arraras received funding from "la Caixa" Foundation (ID 1000010434), Caja Navarra Foundation and UNED Pamplona, under agreement LCF/PR/PR15/51100007.

Introduction

Cancer and related treatments can impair sexual function and body image (1). Sexual problems such as sexual unattractiveness, alterations to the patient´s sexual self-conception, or reproductive concerns can develop across the entire disease and treatment trajectory and persist in the survivorship period (2,3). Common sexual problems are a lack of sexual desire, problems achieving an erection in men (4), and painful intercourse in women (5). More than 50% of patients with pelvic related cancers (2,6–9) and 25-30% with other cancer sites report sexual problems following cancer treatment (10–12). Despite the prevalence of up to 85%, sexual problems are often not identified during routine clinic appointments (13). The ASCO Clinical Practice and Adaptation of the Cancer Care Ontario Guideline, suggested to address and manage sexual problems in cancer patients during and after treatment (14). At the first Survivorship Summit, the European Organization for Research and Treatment of Cancer (EORTC) recommended to develop an instrument for assessing sexual health (SH) specific to cancer patients and cancer survivors (10).

The EORTC Quality of Life Group (QLG) followed this recommendation and developed a multifaceted SH measure. There are numerous tools for assessing sexual functioning but well-validated measures are lacking (15). Most questionnaires have limited multicultural applicability and were initially developed as screening and outcome measures limited to sexual functioning (16–18). However, SH is a much broader concept comprising a psychosexual and socio-behavioral component (19). This view corresponds to the World Health Organization (WHO) definition of SH as a state of physical, emotional, mental, and social well-being related to sexuality (20,21). Based on this broad definition the EORTC QLG developed a multidimensional questionnaire suitable for all cancer sites. The objective of this study was to evaluate the psychometric properties of the EORTC Quality of Life Questionnaire – Sexual Health (QLQ-SH22).

Methods

This study was conducted according to the EORTC QLG guidelines for developing questionnaires including a four-phase methodology (22). This process include: the generation of issues related to the specific population (phase 1); the transformation of issues into a provisional questionnaire (phase 2); pretesting the preliminary questionnaire for relevance and acceptability (phase 3). Phases 1-3 have been published elsewhere (23). In phase 4, the hypothesized scale structure was tested in an international validation study.

Patient eligibility criteria were histological confirmed diagnoses of cancer, any tumor site and stage during and after treatment, no cognitive impairment, and 18 years of age or above. Study participants were recruited from 18 collaborating institutions in 13 countries across Europe and Taiwan. Eligible patients were invited to participate in accordance with the ethical and governance requirements of each center. The Ethical Committee of the Medical University of Graz, Austria was responsible for the Principle Investigator's application and approved the study protocol according to the national requirements. Written informed consent was requested in all countries. The study sample included a consecutive series of cancer patients and survivors allocated into four groups. The study design is shown in table 1.

Table 1

Data of all patients (Groups A-D) were used to evaluate the scale structure, internal consistency, convergent and discriminant validity. For clinical validity Groups A, B, and C were compared. Test-retest analyses were performed in a subsample of patients (Group D). Patients in Groups A, B, and D had two assessment points whereas patients in Group C had only one assessment. The EORTC QLQ-C30 and the QLQ-SH22 were administered during an inpatient stay or during a follow-up visit. Patient demographic and clinical data were recorded using standardized case report forms. A debriefing form surveyed the time to complete the QLQ-SH22, the need for help completing the questionnaire and whether the items were difficult to understand, confusing or upsetting. Reasons for non-completion were noted on a missing questionnaire form.

Measurements

The EORTC QLQ-C30 (version 3.0) consists of five functional scales (physical, role, emotional, social, and cognitive functioning), three symptom scales (fatigue, nausea/vomiting and pain), an overall QoL scale and six single items (25). All items are scored on a four-point Likert scale from 1 to 4 (not at all, a little, quite a bit and very much) except for the overall health and QoL scales that are rated on the seven-point scale. Higher QLQ-C30 scores on the functioning scale and the global QoL scale indicated better functioning or better QoL, whereas higher scores in the symptom scales represent a higher level of symptoms. The scores of QLQ-C30 were linearly transformed to a 0-100 scale according to the scoring manual of the EORTC QLG (27). The QLQ-SH22 incorporates two multi-item scales assessing sexual satisfaction and sexual pain and 11 single items including five partner-related items, and four gender-specific items. The scoring for the QLQ-SH22 is identical to the QLQ-C30. The QLQ-SH22 was translated into 10 languages (Chinese Mandarin, Croatian, Danish, Dutch, French, German, Italian, Norwegian, Polish, and Spanish) following the EORTC translation guidelines (24).

Statistical analysis

Multi-item multi-trait analysis was performed to evaluate the scale structure, internal consistency, and convergent and discriminant validity. Confirmatory factor analysis was used to test the hypothesized scale structure. Principal factors and oblique promax rotation were used to explore the factor structure of the QLQ-SH22. According to Tabachnik and Fidell (26) at least 10-15 subjects per item are required. All analyses were performed using SPSS. The reliability of the multi-item questionnaire scales was assessed by Cronbach´s alpha coefficient. Internal consistency estimates of a magnitude of ≥ 0.70 were considered acceptable (28). The test-retest reliability of scales and single item measures were assessed in a subgroup of patients with no change in health status. Convergent and discriminant validity were examined by Pearson´s product moment correlations between the QLQ-C30 and the QLQ-SH22 scales. It was expected that those scales that are conceptually related correlate substantially with one another (≥ 0.40). Conversely, those scales with less conceptual overlap are expected to exhibit lower correlations (< 0.40) (29). Clinical validity was assessed using the method of known-group comparison exploring the extent to which the questionnaire scores are able to discriminate between subgroups of patients (29). Differences in the QLQ-SH22 scales by patient group, state of disease, ECOG performance status, treatment intention, comorbidity, age, and sex were analyzed by means of the Kruskal-Wallis test with post hoc comparisons. A power calculation (0.5 standard deviations, power 90%, and p-value 5%) indicated that a sample size of 400 patients allowed multivariate analysis techniques in order to generate stable reliability and validity estimates.

Results

Sample

A total of 444 patients with various cancer sites were enrolled. The socio-demographic data are shown in Table 2. The sample included slightly more females (57%) than males (43%). The age ranged from 20 to 91 years. The majority of the participants had a sexual partner (84%) and lived with a partner or family (72%). Cultural regions were well balanced. Table 2 shows the clinical characteristics of the study sample including all major tumor sites. The majority of patients (76.9%) were treated with curative intention, 23.1% received palliative treatment. Almost half of the patients were newly diagnosed, 37% had NED and 16% had a recurrence. Less than half (43.8%) suffered from various comorbidities.

Tables 2 and 3

The completion rate was 84.2%. Reasons for missing data were administrative failure (N=37), patient refused (N=7), patient felt too ill (N=3), HCP felt the patient was too ill (N=1), unknown (N=22). Reasons

for missing data because of sexual inactivity were explored separately. At the first assessment, one third did not complete the questionnaire because they were not sexually active. The main reasons were no partner at present (N=34); too tired (N=24); not interested in sex (N=39); partner not interested in sex (N=8); physical impairments (N=23); partner has a physical problem (N=4). Fifty-two patients in Group A (88%) and 84 patients in Group B (66%) provided a second assessment; 110 patients in Group D (72%) were included for the test-retest analysis. Three patients could not be assigned to a group due to missing information and were excluded. The majority of patients (94.7%) were able to complete the QLQ-SH22 in less than 20 minutes. Forty-seven patients (11%) needed assistance reading the items and 23 patients (5.4%) found some items too personal and intimate. The majority (89%) of the study participants did not need any help to compete the questionnaire.

Scale structure

The analyses confirmed the hypothesized scale with two multi-item scales and 11 single items (Table 4). The internal consistency yielded satisfactory Cronbach's coefficient alpha values of .90 for the sexual satisfaction scale and 0.80 for the sexual pain scale. There were no scaling errors in the multi-item multi-trait analysis. Floor and ceiling effects were detected on all scales: ceiling effects ranged from 1% to 28%, floor effects ranged from 6% to 50% except for the item ´worry about incontinence´ (68%) and ´communication with HCP´ (75%). The retest correlations (Pearson's r) ranged from 0.70 to 0.93 except for the scale communication with professionals (0.67) and male body image (0.69). The confirmatory factor analysis revealed an acceptable fit with 95% confidence level ranging from .95 to 98 and standardized root mean square residual (SRMR)=.07. The 95% confidence level ranged from .06 to .09. All factor loadings were statistically significant at the 5% level (Table 5).

Tables 4 and 5

Most scales of the QLQ-SH22 were weakly correlated with the QLQ-C30 scales ($r < 0.40$) (Table 6). The correlations between the QLQ-C30 functioning scales and the QLQ-SH22 fatigue scale were higher (physical functioning and fatigue $r = -0.43$; role functioning and fatigue $r = -0.45$; social functioning and fatigue $r = -0.45$; global health status and fatigue $r = -0.49$). The highest correlation was found between the QLQ-C30 fatigue scale and the QLQ-SH22 fatigue scale ($r = 0.54$).

Table 6

Clinical validity

The uni- and multivariate analyses showed that sexual activity was significantly more important for newly diagnosed patients (mean 57.80; SD 32.22) and for survivors with no evidence of disease (mean 45.53; SD 32.84) than for patients with recurrence or disease progression (mean 36.36; SD 30.32, *P*<.001). Sexual activity was less important for patients with comorbidities (mean 43.46; SD 32.99) compared to patients without comorbid diseases (mean 54.33; SD 32.81, *P*<.001). Sexual activity was significantly more important for patients aged 36-50 years (mean 57.80; SD 29.80) compared to patients aged 66 years or older (mean 42.18; SD 31.22, *P*=.022). Male patients within the age range 36 to 50 years were more confident with respect to their erection than those aged 66 years or higher (mean 77.78; SD 30.56 vs 36.67; SD 35.63, *P*<.001). Concerning gender differences, we found that females reported significantly more severe sexual pain than men did (mean 22.45; SD 27.96 vs mean 9.24; SD 15.68, *P*<.001). Furthermore, an active sex life was rated as less important by female patients compared to male patients (mean 44.44; SD 33.38 vs mean 56.48; SD 31.73, *P*<.001). Patients who underwent curative treatment intention had significantly higher sexual satisfaction scores (mean 47.37; SD 26.25) and higher scores on the sexual activity scale (mean 52.53; SD 32.81) compared to patients with palliative treatment intention (mean 37.04; SD 26.47 and mean 38.83; SD 31.32, respectively *P*<.001). Curatively treated patients had significantly lower fatigue scores and their treatment effects were less severe compared to patients undergoing palliative care (mean fatigue 35.34; SD 35.34 vs mean 51.81; SD 37.27; mean treatment effect 38.47; SD 39.28 vs mean 60.54; SD 39.87 *P*<.001). Patients with lower ECOG performance status had significantly higher fatigue scores (mean 63.44; SD 37.86 vs 37.33; SD 35.47, *P*<.001) and their treatment effects were less severe compared to patients with a higher ECOG performance status (mean 76.19; SD 39.25 vs 41.17; SD 39.50, *P*<.001). The libido was also significantly higher in patients with a higher ECOG performance status (mean 71.30; SD 34.87) compared to patients with lower ECOG performance status (mean 52.51; SD 35.96, *P*=.003) (table 7-12).

Tables 7 and 12

Discussion

This study evaluated the psychometric properties of the QLQ-SH22 in a cross-cultural sample of cancer patients and cancer survivors. The questionnaire includes a sexual satisfaction scale and a sexual pain scale with acceptable internal consistency (Cronbach's alpha > 0.80). The hypothesized scale structure with two multi-item scales and 11 single items was confirmed. Five partner-related items are

conditional dependent upon the presence of a partner: three are included in the sexual satisfaction scale, one in the sexual pain scale and one is a single item scale. We explored the item ("Have you been sexually active") and found that this can be used as a screening item. It has a good factor loading and it fits very well in the sexual satisfaction scale. The item informs us if patients have a sex life that may vary throughout the course of disease/treatment. Newly diagnosed patients under treatment may not be as sexual active as patients during follow-up. They may return to a more active sex life after completion of treatment or in the survivorship phase.

The QLQ-SH22 discriminates well between subgroups of patients differing in terms of their performance and treatment status. The results of the known-group comparisons confirmed differences in the expected direction e.g. sexual activity was less important for patients with comorbid diseases, recurrence or disease progression and more important for younger patients. Instruments that are sensitive to change are useful for recording adverse effects of cancer and the consequences treatment that patients experience (30). The QLQ-SH22 was developed as a stand-alone measure and the domains are distinct from those assessed by the QLQ-C30. Only the fatigue scales correlated > 0.40 with most functioning scales. All other scales were weakly correlated.

One strength of this study was that we paid specific attention to missing data due to sexual inactivity. About one third of the participants were sexually inactive. In other validation studies of site specific EORTC modules the percentage of patients who had not been sexually active was higher (31,32). This can be explained by the fact that women with gynecologic malignancies may have more severe treatment effects in the pelvic region (2,33,34). In order to avoid scoring inconsistencies or lower scoring validity we excluded patients who did not have a sexual partner or were not sexually active. From a psychometric perspective it is important that any scale score of zero to an item explicitly relates to the content assessed by that specific item (35).

Another strength of the QLQ-SH22 is the cross-cultural and cross-lingual applicability and validity of the questionnaire. We succeeded to involve a balanced distribution of countries throughout the entire development process. In the initial development phases information was gained from in depth-interviews to construct a culturally sensitive measurement, and to shape the scope of the QLQ-SH22 (36). This methodological approach fulfills an important criterion of questionnaire development(37).

Some limitations of the validation study need to be addressed. The sample includes only five percent of participants under the age of 35 years. Although cancer is predominant in older age groups, sexual health is an important issue in younger patients. Therefore, the validity of the QLG-SH22 should be further validated in a selected sample of younger adults. Another limitation is that patients with breast

and gynecologic cancer were overrepresented whereas prostate cancer patients were not sufficiently presented in this study. However, almost half of the participants had a cancer diagnosis related to the pelvic region. Almost half of the study participants were male patients indicating a well-balanced sample. The validity of the QLQ SH-22 should further be tested in patients who may have been underrepresented in this study. Nevertheless, this study showed that the QLQ-SH22 has good psychometric properties and is clinically applicable to assess SH of cancer patients at different treatment stages as well as in the survivorship phase. The tool can be implemented in clinical practice as well as in survivorship research as sexual impairments often persist into survivorship (38).

Conclusion

The QLQ-SH22 meets the methodological quality criteria and psychometric properties according to the Consensus based Standards for Selection of health Measurement (COSIM) (39). The newly developed EORTC QLQ-SH22 is available for use and can be obtained via the EORTC Quality of Life Department www.eortc.org.

Acknowledgement

We would like to thank all the patients who kindly participated in this study, and all collaborators who participated in phase 1-3: Brigitte Bliem (Medical University of Graz, Department of Obstetrics and Gynecology); Sara Dehandschutter (University Hospitals Leuven, Campus Gasthuisberg, Leuven); Dimitrios Kardamakis, Maria Pittaka (School of Health Sciences, University of Patras Medical School, Patras); Remi Nout (Department of Clinical Oncology, Leiden University Medical Center, Leiden); Elisabeth Inwald (University Medical Center, Department of Gynecology and Obstetrics, Regensburg); Zoe Winters and Maryam Afzal, (School of Clinical Sciences, University of Bristol, Southmead Hospital, Bristol); Madeleine King (Psycho-oncology Co-operative Research Group, The University of Sydney); Francesco Di Fabio (Colorectal Surgery, University Hospital Southampton, United Kingdom); Brenda den Oudsten (Tilburg University, Medical Psychology, Tilburg The Netherlands); Astrid Liavaag (Department of Gynecology and Obstetrics, Sørlandets Sykehus, Arendal, Norway); Ann Charlotte Waldenström (University Hospital Göteborg, Sweden); Linda Tunkara (East Kent Hospital, Kent, United Kingdom); Eric Huyghe (Institut Universitaire du Cancer, CHU de Toulouse, Département d'Urologie, Toulouse, France). Special thank to Fedor Daghofer for the statistical support.

References:

1. Incrocci L, Jensen PT. Pelvic Radiotherapy and Sexual Function in Men and Women. J Sex Med [Internet]. 2013;10(SUPPL.):53–64. Available from: http://dx.doi.org/10.1111/jsm.12010
2. Froeding LP, Ottosen C, Rung-Hansen H, Svane D, Mosgaard BJ, Jensen PT. Sexual functioning and vaginal changes after radical vaginal trachelectomy in early stage cervical cancer patients: A longitudinal study. J Sex Med. 2014;
3. Whicker M, Black J, Altwerger G, Menderes G, Feinberg J, Ratner E. Management of sexuality, intimacy, and menopause symptoms in patients with ovarian cancer. Am J Obstet Gynecol [Internet]. 2017;217(4):395–403. Available from: http://dx.doi.org/10.1016/j.ajog.2017.04.012
4. Schover LR, Fouladi RT, Warneke CL, Neese L, Klein EA, Zippe C, et al. Defining sexual outcomes after treatment for localized prostate carcinoma. Cancer. 2002;95(8):1773–85.
5. Huffman LB, Hartenbach EM, Carter J, Rash JK, Kushner DM. Maintaining sexual health throughout gynecologic cancer survivorship: A comprehensive review and clinical guide. Gynecol Oncol [Internet]. 2016;140(2):359–68. Available from: http://dx.doi.org/10.1016/j.ygyno.2015.11.010
6. Abbott-Anderson K, Kwekkeboom KL. A systematic review of sexual concerns reported by gynecological cancer survivors. Gynecologic Oncology. 2012.
7. Potosky AL, Davis WW, Hoffman RM, Stanford JL, Stephenson RA, Penson DF, et al. Five-year outcomes after prostatectomy or radiotherapy for prostate cancer: The prostate cancer outcomes study. J Natl Cancer Inst. 2004;96(18):1358–67.
8. Krychman ML, Pereira L, Carter J, Amsterdam A. Sexual oncology: Sexual health issues in women with cancer. Oncology. 2007;71(1–2):18–25.
9. Perz J, Ussher JM, Gilbert E. Feeling well and talking about sex: psycho-social predictors of sexual functioning after cancer. BMC Cancer. 2014;14(1).
10. Schover LR, van der Kaaij M, van Dorst E, Creutzberg C, Huyghe E, Kiserud CE. Sexual dysfunction and infertility as late effects of cancer treatment. Eur J Cancer, Suppl [Internet]. 2014;12(1):41–53. Available from: http://dx.doi.org/10.1016/j.ejcsup.2014.03.004
11. Hendren SK, O 'connor BI, Liu M, Asano T, Cohen Z, Swallow CJ, et al. Prevalence of Male and Female Sexual Dysfunction Is High Following Surgery for Rectal Cancer. Ann Surg. 2005;242:212–23.
12. Almont T, Bouhnik AD, Ben Charif A, Bendiane MK, Couteau C, Manceau C, et al. Sexual Health Problems and Discussion in Colorectal Cancer Patients Two Years After Diagnosis: A National Cross-Sectional Study. J Sex Med [Internet]. 2019;16(1):96–110. Available from: https://doi.org/10.1016/j.jsxm.2018.11.008
13. Haboubi NHJLN. Views of health professionals on discussing sexual issues with patients. Disabil Rehabil. 2003;25(6):291–6.
14. Carter J, Lacchetti C, Andersen BL, Barton DL, Bolte S, Damast S, et al. Interventions to address sexual problems in people with cancer: American society of clinical oncology clinical practice guideline adaptation of cancer care Ontario guideline. J Clin Oncol. 2018;36(5):492–511.
15. DeRogatis LR. Assessment of sexual function/dysfunction via patient reported outcomes. Int J Impot Res. 2008;20(1):35–44.
16. Hoole J, Kanatas A, Calvert A, Rogers SN, Smith AB, Mitchell DA. Validated questionnaires on intimacy in patients who have had cancer. Br J Oral Maxillofac Surg [Internet]. 2015;53(7):584–93. Available from: http://dx.doi.org/10.1016/j.bjoms.2015.05.003
17. White ID, Sangha A, Lucas G, Wiseman T. Assessment of sexual difficulties associated with multi-modal treatment for cervical or endometrial cancer: A systematic review of measurement instruments. Gynecol Oncol [Internet]. 2016;143(3):664–73. Available from: http://dx.doi.org/10.1016/j.ygyno.2016.08.332
18. Bartula I, Sherman KA. Screening for sexual dysfunction in women diagnosed with breast cancer: Systematic review and recommendations. Breast Cancer Res Treat. 2013;141(2):173–85.
19. Cleary, Hegarty. Sexuality in Irish Women With Gynaecological Cancer. Eur J Oncol Nurs [Internet]. 2011;3(2):87. Available from: https://www.ncbi.nlm.nih.gov/pubmed/21356646
20. World Health Organization. Defining Sexual Health: Report of technical consultation on sexual health 28-31 January 2002, Geneva. Sex Heal Doc Ser [Internet]. 2006;(January):0–30. Available from: http://www.who.int/reproductivehealth/publications/sexual_health/defining_sexual_health.pdf?ua=1
21. Edwards WM, Coleman E. Defining sexual health: A descriptive overview. Vol. 33, Archives of Sexual Behavior. 2004. p. 189–95.
22. Johnson C, Aaronson N, Blazeby JM, Bottomley A, Fayers P, Koller M, et al. EORTC QUALITY OF LIFE

GROUP Guidelines for Developing Questionnaire Modules Quality of Life Group. 2011;(April).
23. Oberguggenberger AS, Nagele E, Inwald EC, Tomaszewski K, Lanceley A, Nordin A, et al. Phase 1-3 of the cross-cultural development of an EORTC questionnaire for the assessment of sexual health in cancer patients: The EORTC SHQ-22. Cancer Med. 2018;
24. Kuliś D, Bottomley A, Velikova G, Greimel E, Koller M on behalf of the EQ of LG. EORTC Quality of Life Group Translation Procedure. In: 4th ed Brussels. 2016.
25. Aaronson NK, Ahmedzai S, Bergman B, Bullinger M, Cull A, Duez NJ, et al. The European organization for research and treatment of cancer QLQ-C30: A quality-of-life instrument for use in international clinical trials in oncology. Vol. 85, Journal of the National Cancer Institute. 1993. p. 365–76.
26. Tabachnik BJ FL. Using multivariate statistics. 4th edition. 2001. Boston.
27. Fayers P, Aaronson N MK. EORTC QLQ-C30 scoring manual. Brussels. EORTC Publicatons; 2001.
28. Nunnally, J.C. and Bernstein IR (1994). Psychometric Theory. 1994.
29. Fayers PM, Langston AL, Robertson C. Implicit self-comparisons against others could bias quality of life assessments. J Clin Epidemiol. 2007;60(10):1034–9.
30. Dische S, Saunders MI. Complexity and simplicity in the measurement and recording of the adverse effects of cancer treatment. Radiother Oncol. 2003;66(3):249–51.
31. Greimel ER, Vlasic KK, Waldenstrom A-C, Duric VM, Jensen PT, Singer S, et al. The European Organization for Research and Treatment of Cancer (EORTC) Quality-of-Life questionnaire cervical cancer module: EORTC QLQ-CX24. Cancer. 2006;107(8).
32. Greimel E, Nordin A, Lanceley A, Creutzberg CL, Van De Poll-Franse LV, Radisic VB, et al. Psychometric validation of the European organisation for research and treatment of cancer quality of life questionnaire-endometrial cancer module (EORTC QLQ-EN24). Eur J Cancer. 2011;47(2).
33. Froeding LP, Greimel E, Lanceley A, Oberguggenberger A, Schmalz C, Radisic VB, et al. Assessing Patient-reported Quality of Life Outcomes in Vulva Cancer Patients: A Systematic Literature Review. Vol. 28, International Journal of Gynecological Cancer. 2018. p. 808–17.
34. Jensen PT, Groenvold M, Klee MC, Thranov I, Petersen MA, Machin D. Longitudinal study of sexual function and vaginal changes after radiotherapy for cervical cancer. Int J Radiat Oncol Biol Phys. 2003;56(4):937–49.
35. Baser RE, Li Y, Carter J. Psychometric validation of the female sexual function index (FSFI) in cancer survivors. Cancer. 2012;118(18):4606–18.
36. Oberguggenberger A, Hubalek M, Sztankay M, Meraner V, Beer B, Oberacher H, et al. Is the toxicity of adjuvant aromatase inhibitor therapy underestimated? Complementary information from patient-reported outcomes (PROs). Breast Cancer Res Treat. 2011;
37. Kluetz PG, Chingos DT, Basch EM, Mitchell SA. Patient-Reported Outcomes in Cancer Clinical Trials : Cancer Institute ' s Patient-Reported Outcomes Version of. 2016;
38. Dizon DS, Suzin D, McIlvenna S. Sexual health as a survivorship issue for female cancer survivors. Oncologist [Internet]. 2014;19(2):202–10. Available from: http://www.ncbi.nlm.nih.gov/pubmed/24396051
39. Mokkink LB, Terwee CB, Knol DL, Stratford PW, Alonso J, Patrick DL, et al. The COSMIN checklist for evaluating the methodological quality of studies on measurement properties: A clarification of its content. BMC Med Res Methodol. 2010;10(June 2016).

Table 1: Study design

	Patients and Treatment	**First Assessment**	**Second Assessment**
Group A N=59	Newly diagnosed patients with surgery without any adjuvant treatment (curative intention)	Before surgery (time window 1 week)	8-12 weeks after surgery
Group B N=128	Newly diagnosed patients with surgery plus adjuvant first line treatment (curative intention)	Before start of treatment (time window 1 week)	3-6 months after start of treatment
Group C N=101	Patients with recurrence receiving second or third line treatment with or without surgery (palliative intention)	Within 3 months after start of treatment	No assessment
Group D N=153	Cancer survivors after first line therapy with or without surgery and no evidence of disease (NED)	6 months – 5 years after treatment	7 days after 1st assessment

Table 2: Patient characteristics (N=444)

Variable	*N* (%)
Gender	
Female	253 (57%)
Male	191 (43%)
Age groups	
20-35 years	23 (5%)
36-50 years	99 (22%)
51-65 years	215 (49%)
66-91 years	106 (24%)
Missing	1
Living situation	
Living with partner/family	309 (72%)
Living alone	62 (14%)
Living with others	61 (14%)
Missing	12
Sexual partner	
Yes	361 (84%)
No	69 (16%)
Missing	14
Education	
Compulsory school or less	156 (36%)
Post compulsory school education	154 (36%)
University level	124 (29%)
Missing	10
Country	
Austria	55 (12.4%)
Belgium	43 (9.7%)
Croatia	21 (4.7%)
Denmark	7 (1.6%)
France	9 (2.0%)
Germany	66 (14.9%)
Italy	33 (7.4%)
Norway	2 (0.5%)
The Netherlands	43(9.7%)
Poland	61(13.7%)
Spain	23 (5.2%)
Taiwan	60(13.5%)
United Kingdom	21 (4.7%)

Missings are absolute numbers

Table 3: Clinical characteristics (N=444)

Variable	N (%)
Tumor site	
Breast	115 (26.5%)
Gyneacologic	87 (20.0%)
Prostate	61 (14.1%)
Other Genito-urinary	18 (4.1%)
Head and Neck	45 (10.4%)
Colorectal	29 (6.7%)
Lung	38 (8.8%)
Brain	2 (0.5%)
Others (liver, lung, thyroid, gall bladder)	13 (3.0%)
Missing	12
ECOG performance status	
Fully active	245 (57.8%)
Restricted	141 (33.3%)
Self-care possible	30 (7.1%)
Limited self-care	8 (1.9%)
Missing	20
Treatment	
Curative	332 (76.9%)
Palliative	100 (23.1%)
Missing	12
Status of disease	
No evidence of disease (NED)	161 (37%)
Newly diagnosed	200 (46%)
Recurrence/ Progression	71 (16%)
Missing	12
Comorbidity	
No	243 (56.3%)
Yes	189 (43.7%)
Missing	12

Missings are absolute numbers

Table 4: Results of multi-item multi-trait analysis of the EORTC QLQ SH-22

Scale	Items	Mean	SD	% Ceiling	% Floor	Scaling Error	Cronbach's Alpha	Test-retest Pearson's r	Valid N
Multi-Item scales									
Sexual satisfaction	8	2.35	0.80	1%	6%	0 (0.0%)	0.90	.88	403
Sexual pain	3	1.50	0.73	2%	53%	0 (0.0%)	0.80	.93	392
Single Item scales									
Importance of sexual activity	1	2.49	1.00	17%	20%	n.a.	n.a.	.84	417
Decreased libido	1	2.63	1.09	28%	19%	n.a.	n.a.	.70	412
Worry incontinence	1	1.55	0.93	7%	68%	n.a.	n.a.	.76	408
Fatigue	1	2.18	1.09	16%	36%	n.a.	n.a.	.80	391
Treatment effect on sexual activity	1	2.32	1.22	26%	38%	n.a.	n.a.	.78	389
Communication with professionals	1	1.39	0.76	4%	75%	n.a.	n.a.	.67	405
Insecurity with partner	1	1.87	1.04	11%	50%	n.a.	n.a.	.83	379
Confidence erection	1	2.40	1.15	23%	30%	n.a.	n.a.	.83	171
Body image (male)	1	2.03	1.13	16%	47%	n.a.	n.a.	.69	172
Vaginal dryness	1	2.08	1.10	16%	40%	n.a.	n.a.	.84	205
Body image (female)	1	1.91	1.06	12%	50%	n.a.	n.a.	.74	224

SD standard deviation. n.a. not available

All correlations are statistically significant at the 1% level.

Table 5: Results of the confirmatory factor analysis of the EORTC QLQ SH-22

Scale	Standardized factor loadings (95% CI*)
Sexual satisfaction	
Have you been satisfied with your level of sexual desire?	.65 (.57; .71)
Has sexual activity been enjoyable for you?	.83 (.79; .87)
Have you been satisfied with your ability to reach an orgasm?	.79 (.73; .85)
Have you been satisfied with the communication about sexual issues between yourself and your partner?	.48 (.38; .57)
Have you been satisfied with your level of intimacy?	.63 (.54; .71)
Have you been sexually active?	.75 (.70; .79)
To what extend did you feel sexual enjoyment?	.85 (.81; .88)
Have you been satisfied with your sex life?	.82 (.76; .86)
Sexual pain	
Have you felt pain during/after sexual activity?	.65 (.54; .77)
Have you been worried that sex would be painful?	.96 (.87; 1.00)
Have you been worried that your partner may cause you pain during sexual contact?	.69 (.58; .80)
Correlation between the scales	**Factor correlation (95% CI*)**
Sexual satisfaction with sexual pain	-.11 (-.22; -.01)
Goodness of fit statistics	**Value (95% CII*)**
Goodness of fit index	.98 (.97; .99)
Adjusted goodness of fit index	.97 (.95; .98)
Standardized root mean square residual	.07 (.06; .09)

* CI: Confidence levels are based on bootstrap-estimation with 1000 replications. Unweighted least squares was used as discrepancy function. Note: Single item scales were not used in the analysis.

Table 6: Correlations between the EORTC QLQ-SH22 and the EORTC QLQ-C30

	EORTC QLQ-SH22												
	SXSAT	**SXP**	**ISXA**	**DLI**	**WI**	**FA**	**TX**	**CHCP**	**ISP**	**CE**	**BIM**	**VD**	**BIF**
EORTC QLQ -C30													
Physical functioning	.26**	-.17**	.10*	-.26**	-.19**	-.43**	-.28**	-.01	-.03	.20*	-.29**	-.10	-.22**
Role functioning	.20**	-.12*	.02	-.31**	-.12*	-.45**	-.26**	.00	-.11*	.11	-.22**	.00	-.15*
Emotional functioning	.16**	-.27**	-.11*	-.36**	-.13*	-.34**	-.17**	-.08	-.21**	.02	-.31**	-.05	-.24**
Cognitive functioning	.19**	-.25**	.04	-.27**	-.07	-.33**	-.20**	.03	-.11*	.16*	-.28**	-.10	-.21**
Social functioning	.22**	-.29**	.03	-.34**	-.13**	-.45**	-.20**	-.03	-.18**	.03	-.30**	-.05	-.30**
Global health status	.27**	-.18**	.01	-.35**	-.21**	-.49**	-.21**	.04	-.13*	.08	-.29**	-.03	-.18**
Fatigue	-.23**	.14**	-.05	.29**	.19**	.54**	.32**	.00	.06	-.15*	.31**	.05	.25**
Nausea and vomiting	-.15**	.06	-.04	.15**	.05	.29**	.18**	-.04	.04	-.07	.31**	.02	.10
Pain	-.19**	.23**	-.02	.24**	.17**	.35**	.25**	-.01	.09	-.19*	.30**	.05	.21**
Dyspnoea	-.12*	.09	.04	.18**	.07	.32**	.13*	-.02	.06	-.03	.26**	-.04	.10
Insomnia	-.18**	.19**	.01	.26**	.11*	.31**	.18**	.08	.19**	-.10	.32**	.01	.25**
Appetite loss	-.24**	.10	-.09	.21**	.08	.30**	.07	.00	.19**	-.09	.31**	-.12	.21**
Constipation	-.12*	.06	-.09	.09	.03	.10*	.00	.06	.02	.01	.12	.02	.07
Diarrhoea	-.09	.13**	-.10*	.08	.20**	.16**	.18**	.03	.14**	-.05	.06	.04	.11
Financial difficulties	-.17**	.23**	-.06	.14**	.07	.25**	.21**	.03	.03	-.03	.12	-.06	.13

* $p < .05$, ** $p < .01$.
SXSA, Sexual satisfaction. SXP, Sexual pain. ISXA, Importance of sexual activity. DLI, Decreased libido. WI, Worry incontinence. FA, Fatigue. TX, Treatment effect on sexual activity. CHCP, Communication with professionals. ISP, Insecurity with partner. CE, Confidence erection. BIM, Body image (male). VD, Vaginal dryness. BIF, Body image (female).

Table 7: Differences in the SHQ22 scales by state of disease

	Newly diagnosed (Groups A,B)			No evidence of disease (Group D)			Recurrence/progression (Group C)			
	M ± SD	Median (interquartile range)	N	M ± SD	Median (interquartile range)	N	M ± SD	Median (interquartile range)	N	p
Sexual satisfaction	49.18 ± 26.07	50.00a (29.17; 70.83)	179	42.80 ± 26.39	41.67 (21.58; 62.50)	152	38.64 ± 25.70	35.42b (18.45; 54.17)	62	.008
Sexual pain	14.37 ± 21.72	0.00 (0.00; 22.22)	172	19.98 ± 27.50	11.11 (0.00; 33.33)	151	16.01 ± 22.34	0.00 (0.00; 33.33)	59	.258
Importance of sexual activity	57.80 ± 32.22	66.67a (33.33; 66.67)	188	45.53 ± 32.84	33.33b (33.33; 66.67)	153	36.36 ± 30.23	33.33b (0.00; 66.67)	66	<.001
Decreased libido	55.92 ± 35.12	66.67 (33.33; 100.00)	183	46.84 ± 36.56	33.33a (0.00; 66.67)	153	65.66 ± 34.08	66.67b (33.33; 100.00)	66	.001
Worry incontinence	17.59 ± 31.40	0.00 (0.00; 33.33)	180	17.97 ± 29.80	0.00 (0.00; 33.33)	154	21.88 ± 32.65	0.00 (0.00; 33.33)	64	.492
Fatigue	36.24 ± 35.29	33.33 (0.00; 66.67)	172	37.97 ± 35.70	33.33 (0.00; 66.67)	151	50.57 ± 38.10	66.67 (0.00; 100.00)	58	.037
Treatment effect on sexual activity	31.91 ± 39.83	0.00a (0.00; 66.67)	164	51.32 ± 39.47	66.67b (0.00; 100.00)	152	61.38 ± 36.52	66.67b (33.33; 100.00)	63	<.001
Communication with professionals	9.52 ± 22.32	0.00 (0.00; 0.00)	182	17.44 ± 29.02	0.00 (0.00; 33.33)	151	12.37 ± 24.32	0.00 (0.00; 8.33)	62	.011
Insecurity with partner	28.65 ± 34.93	0.00 (0.00; 66.67)	171	29.63 ± 35.06	16.67 (0.00; 66.67)	144	29.63 ± 33.44	33.33 (0.00; 66.67)	54	.927
Confidence erection	55.42 ± 36.91	66.67a (33.33; 100.00)	83	39.39 ± 37.46	33.33 (0.00; 66.67)	55	34.44 ± 38.64	33.33a (0.00; 66.67)	30	.009
Body image (male)	27.71 ± 37.47	0.00 (0.00; 66.67)	83	39.88 ± 35.63	33.33 (0.00; 66.67)	56	41.11 ± 39.81	33.33 (0.00; 66.67)	30	.051
Vaginal dryness	29.02 ± 31.62	33.33a (0.00; 50.00)	85	46.21 ± 39.93	33.33b (0.00; 100.00)	88	28.00 ± 31.45	33.33 (0.00; 33.33)	25	.010
Body image (female)	26.16 ± 33.64	0.00 (0.00; 50.00)	93	34.03 ± 37.14	33.33 (0.00; 66.67)	96	30.95 ± 36.21	16.67 (0.00; 66.67)	28	.326

Note: the p-value is based on the Kruskal-Wallis test.

Table 8. Differences in the SHQ22 scales by comorbidity (Groups A-D)

	Comorbidity			No comorbidity			
	M ± SD	Median (interquartile range)	N	M ± SD	Median (interquartile range)	N	p
Sexual satisfaction	42.54 ± 25.80	41.67 (24.40; 62.50)	173	46.21 ± 27.08	45.83 (25.00; 68.75)	221	.212
Sexual pain	16.34 ± 22.61	0.00 (0.00; 33.33)	169	17.47 ± 26.00	0.00 (0.00; 33.33)	214	.787
Importance of sexual activity	43.46 ± 32.99	33.33 (0.00; 66.67)	181	54.33 ± 32.81	66.67 (33.33; 66.67)	227	.001
Decreased libido	57.12 ± 36.69	66.67 (33.33; 100.00)	178	52.44 ± 35.71	66.67 (33.33; 100.00)	225	.181
Worry incontinence	20.67 ± 31.42	0.00 (0.00; 33.33)	179	16.67 ± 30.47	0.00 (0.00; 33.33)	220	.083
Fatigue	43.06 ± 37.26	33.33 (0.00; 66.67)	168	36.76 ± 35.36	33.33 (0.00; 66.67)	214	.108
Treatment effect on sexual activity	44.25 ± 41.20	33.33 (0.00; 100.00)	171	44.18 ± 40.69	33.33 (0.00; 100.00)	209	.977
Communication with professionals	9.52 ± 21.99	0.00 (0.00; 0.00)	175	15.54 ± 27.80	0.00 (0.00; 33.33)	221	.022
Insecurity with partner	30.83 ± 35.77	33.33 (0.00; 66.67)	160	27.78 ± 34.13	0.00 (0.00; 33.33)	210	.452
Confidence erection	41.30 ± 39.34	33.33 (0.00; 66.67)	92	53.15 ± 36.56	66.67 (33.33; 75.00)	74	.048
Body image (male)	39.30 ± 38.59	33.33 (0.00; 66.67)	95	29.17 ± 36.66	0.00 (0.00; 66.67)	72	.075
Vaginal dryness	35.78 ± 35.65	33.33 (0.00; 66.67)	68	35.84 ± 37.07	33.33 (0.00; 66.67)	133	.912
Body image (female)	31.58 ± 34.38	33.33 (0.00; 66.67)	76	29.40 ± 36.02	0.00 (0.00; 66.67)	144	.536

Note: the p-value is based on the Mann-Whitney U-test.

Table 9. Differences in the SHQ22 scales by age (Groups A-D)

	20 - 35 years			36 - 50 years			51 - 65 years			66 - 85 years			
	M ± SD	Median (interquartile range)	N	M ± SD	Median (interquartile range)	N	M ± SD	Median (interquartile range)	N	M ± SD	Median (interquartile range)	N	p
Sexual satisfaction	57.95 ± 28.74	64.29 (32.29; 84.38)	22	49.18 ± 25.06	50.00 (29.17; 70.83)	95	41.20 ± 26.23	41.67 (20.83; 62.20)	193	44.85 ± 27.03	40.83 (25.00; 70.83)	92	.011
Sexual pain	18.18 ± 23.64	5.56 (0.00; 36.11)	22	19.94 ± 26.76	0.00 (0.00; 33.33)	95	18.06 ± 25.59	5.56 (0.00; 33.33)	184	10.43 ± 17.66	0.00 (0.00; 13.89)	90	.095
Importance of sexual activity	63.64 ± 28.93	66.67 (58.33; 75.00)	22	57.80 ± 29.80	66.67a (33.33; 66.67)	94	48.02 ± 35.01	33.33 (33.33; 66.67)	202	42.18 ± 31.22	33.33b (0.00; 66.67)	98	.002
Decreased libido	39.39 ± 35.09	33.33 (0.00; 66.67)	22	55.20 ± 33.51	66.67 (33.33; 66.67)	93	56.17 ± 36.54	66.67 (33.33; 100.00)	200	52.78 ± 37.98	66.67 (33.33; 100.00)	96	.218
Worry incontinence	12.12 ± 21.93	0.00 (0.00; 33.33)	22	11.23 ± 23.12	0.00 (0.00; 0.00)	95	19.97 ± 33.95	0.00 (0.00; 33.33)	192	24.15 ± 32.03	0.00 (0.00; 33.33)	98	.014
Fatigue	30.30 ± 32.38	33.33 (0.00; 66.67)	22	40.78 ± 33.57	33.33 (0.00; 66.67)	94	43.60 ± 37.71	33.33 (0.00; 66.67)	185	31.84 ± 35.86	33.33 (0.00; 66.67)	89	.044
Treatment effect on sexual activity	28.57 ± 32.12	33.33 (0.00; 33.33)	21	47.87 ± 40.18	50.00 (0.00; 100.00)	94	46.41 ± 41.95	33.33 (0.00; 100.00)	181	39.49 ± 40.12	33.33 (0.00; 66.67)	92	.161
Communication with professionals	16.67 ± 26.73	0.00 (0.00; 33.33)	22	12.06 ± 25.33	0.00 (0.00; 0.00)	94	12.95 ± 26.34	0.00 (0.00; 0.00)	193	12.28 ± 23.85	0.00 (0.00; 33.33)	95	.687
Insecurity with partner	16.67 ± 27.57	0.00 (0.00; 33.33)	20	29.75 ± 34.21	33.33 (0.00; 66.67)	93	30.90 ± 33.99	33.33 (0.00; 66.67)	178	27.59 ± 38.11	0.00 (0.00; 66.67)	87	.214
Confidence erection	71.43 ± 40.50	100.00 (33.33; 100.00)	7	77.78 ± 30.56	100.00a (66.67; 100.00)	24	42.62 ± 36.96	33.33b (0.00; 66.67)	79	36.67 ± 35.63	33.33b (0.00; 66.67)	60	<.001
Body image (male)	42.86 ± 46.00	33.33 (0.00; 100.00)	7	33.33 ± 34.69	33.33 (0.00; 66.67)	25	38.10 ± 39.63	33.33 (0.00; 66.67)	77	29.57 ± 36.27	0.00 (0.00; 66.67)	62	.549
Vaginal dryness	43.59 ± 36.98	33.33 (16.67; 83.33)	13	33.33 ± 34.63	33.33 (0.00; 66.67)	64	36.63 ± 36.97	33.33 (0.00; 66.67)	101	37.04 ± 40.65	33.33 (0.00; 66.67)	27	.804
Body image (female)	35.90 ± 28.74	33.33 (0.00; 66.67)	13	37.81 ± 38.00	33.33 (0.00; 66.67)	67	28.57 ± 35.19	0.00 (0.00; 66.67)	112	17.71 ± 29.31	0.00 (0.00; 33.33)	32	.046

Note: the p-value is based on the Kruskal-Wallis test.

Table 10. Differences in the SHQ22 scales by sex (Groups A-D)

	Females			Males			
	M ± SD	Median (interquartile range)	N	M ± SD	Median (interquartile range)	N	p
Sexual satisfaction	44.13 ± 25.93	41.67 (25.00; 62.50)	227	45.77 ± 27.34	45.83 (25.00; 70.83)	176	.669
Sexual pain	22.45 ± 27.96	11.11 (0.00; 33.33)	223	9.24 ± 15.68	0.00 (0.00; 11.11)	169	<.001
Importance of sexual activity	44.44 ± 33.38	33.33 (0.00; 66.67)	237	56.48 ± 31.73	66.67 (33.33; 66.67)	180	<.001
Decreased libido	54.45 ± 35.49	66.67 (33.33; 100.00)	232	54.07 ± 37.15	66.67 (33.33; 100.00)	180	.951
Worry incontinence	16.67 ± 28.85	0.00 (0.00; 33.33)	230	20.79 ± 33.41	0.00 (0.00; 33.33)	178	.331
Fatigue	40.21 ± 36.11	33.33 (0.00; 66.67)	223	38.29 ± 36.59	33.33 (0.00; 66.67)	168	.566
Treatment effect on sexual activity	44.70 ± 40.24	33.33 (0.00; 100.00)	217	43.41 ± 41.44	33.33 (0.00; 100.00)	172	.705
Communication with professionals	11.99 ± 24.69	0.00 (0.00; 0.00)	228	13.94 ± 26.48	0.00 (0.00; 33.33)	177	.517
Insecurity with partner	25.69 ± 33.60	0.00 (0.00; 33.33)	218	33.75 ± 35.74	33.33 (0.00; 66.67)	161	.020
Confidence erection	n.a.	n.a.	n.a.	46.59 ± 38.17	33.33 (0.00; 66.67)	171	n.a.
Body image (male)	n.a.	n.a.	n.a.	34.50 ± 37.79	33.33 (0.00; 66.67)	172	n.a.
Vaginal dryness	36.10 ± 36.57	33.33 (0.00; 66.67)	205	n.a.	n.a.	n.a.	n.a.
Body image (female)	30.21 ± 35.37	33.33 (0.00; 66.67)	224	n.a.	n.a.	n.a.	n.a.

n.a., not applicable.

Note: the p-value is based on the Mann-Whitney U-test.

Table 11: Differences in the SHQ22 scales by intention of treatment (Groups A-D)

	Curative			Palliative			
	M ± SD	Median (interquartile range)	N	M ± SD	Median (interquartile range)	N	p
Sexual satisfaction	47.37 ± 26.25	50.00 (29.17; 66.67)	306	37.04 ± 26.47	29.17 (19.05; 54.17)	87	.001
Sexual pain	17.06 ± 24.38	0.00 (0.00; 33.33)	300	14.66 ± 22.78	0.00 (0.00; 22.22)	83	.318
Importance of sexual activity	52.53 ± 32.81	66.67 (33.33; 66.67)	316	38.83 ± 31.92	33.33 (0.00; 66.67)	91	.001
Decreased libido	51.34 ± 36.18	66.67 (33.33; 66.67)	311	61.54 ± 35.11	66.67 (33.33; 100.00)	91	.018
Worry incontinence	17.91 ± 30.56	0.00 (0.00; 33.33)	309	19.63 ± 31.16	0.00 (0.00; 33.33)	90	.564
Fatigue	35.34 ± 35.34	33.33 (0.00; 66.67)	299	51.81 ± 37.27	66.67 (33.33; 100.00)	83	<.001
Treatment effect on sexual activity	38.47 ± 39.28	33.33 (0.00; 66.67)	292	60.54 ± 39.87	66.67 (33.33; 100.00)	87	<.001
Communication with professionals	14.27 ± 26.51	0.00 (0.00; 33.33)	306	8.24 ± 20.28	0.00 (0.00; 0.00)	89	.041
Insecurity with partner	28.64 ± 34.31	0.00 (0.00; 66.67)	291	27.85 ± 34.36	0.00 (0.00; 66.67)	79	.829
Confidence erection	51.24 ± 37.53	66.67 (33.33; 100.00)	121	35.51 ± 38.75	33.33 (0.00; 66.67)	46	.016
Body image (male)	30.30 ± 35.75	0.00 (0.00; 66.67)	121	46.10 ± 41.44	33.33 (0.00; 100.00)	47	.023
Vaginal dryness	38.29 ± 36.96	33.33 (0.00; 66.67)	168	26.26 ± 32.01	33.33 (0.00; 33.33)	33	.093
Body image (female)	30.19 ± 35.18	33.33 (0.00; 66.67)	180	28.95 ± 35.66	0.00 (0.00; 66.67)	38	.790

Note: the p-value is based on the Mann-Whitney U-test.

Table 12. Differences in the SHQ22 scales by ECOG performance status (Groups A-D)

	Higher performance			Lower performance			
	M ± SD	Median (interquartile range)	N	M ± SD	Median (interquartile range)	N	p
Sexual satisfaction	46.33 ± 26.77	45.83 (25.00; 66.67)	350	33.42 ± 22.67	25.00 (16.67; 53.33)	35	.005
Sexual pain	16.12 ± 23.50	0.00 (0.00; 33.33)	343	22.40 ± 28.27	11.11 (0.00; 44.44)	31	.274
Importance of sexual activity	49.95 ± 33.55	66.67 (33.33; 66.67)	363	50.00 ± 30.34	66.67 (33.33; 66.67)	36	.987
Decreased libido	52.51 ± 35.96	66.67 (33.33; 100.00)	358	71.30 ± 34.87	100.00 (33.33; 100.00)	36	.003
Worry incontinence	17.80 ± 30.11	0.00 (0.00; 33.33)	354	27.78 ± 36.95	0.00 (0.00; 66.67)	36	.120
Fatigue	37.33 ± 35.47	33.33 (0.00; 66.67)	342	63.44 ± 37.86	66.67 (33.33; 100.00)	31	<.001
Treatment effect on sexual activity	41.17 ± 39.50	33.33 (0.00; 66.67)	336	76.19 ± 39.25	100.00 (66.67; 100.00)	35	<.001
Communication with professionals	12.82 ± 25.39	0.00 (0.00; 0.00)	351	12.04 ± 22.75	0.00 (0.00; 25.00)	36	.998
Insecurity with partner	29.00 ± 34.59	33.33 (0.00; 66.67)	331	28.89 ± 34.72	16.67 (0.00; 66.67)	30	.998
Confidence erection	48.65 ± 37.77	33.33 (0.00; 66.67)	148	30.00 ± 38.84	0.00 (0.00; 66.67)	20	.036
Body image (male)	32.00 ± 36.82	33.33 (0.00; 66.67)	150	50.88 ± 43.56	33.33 (0.00; 100.00)	19	.055
Vaginal dryness	36.83 ± 36.94	33.33 (0.00; 66.67)	181	36.36 ± 40.70	33.33 (0.00; 66.67)	11	.904
Body image (female)	28.89 ± 35.22	0.00 (0.00; 66.67)	195	38.10 ± 31.64	33.33 (0.00; 66.67)	14	.201

Note: the p-value is based on the Mann-Whitney U-test.