FATIGUE OG LUNGEKREFT

Fatigue hjå pasientar med ikkje-småcella lungekreft fem månader etter lungekirurgi.

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MASTEROPPGÅVE

DEL 1 ARTIKKEL

Predictors and correlations of fatigue in non-small cell lung cancer surgery patients at five-month follow-up.

DEL 2 REFLEKSJONSOPPGÅVE

Evaluering av psykometriske eigenskapar til The Brief Fatigue Inventory og EORTC QLQ – fatigue subscale.

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Navn:	**Dato:**
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Tittel og undertittel: Fatigue og lungekreft, Fatigue hjå pasientar med ikkje små-cella lungekreft fem månader etter lungekirurgi, prediktorar og samanhengar. Evaluering av psykometriske eigenskapar av The Brief Fatigue Inventory og EORTC QLQ-fatigue subscale.

Sammendrag:
Formål: Formålet med denne studien har vore å undersøke prediktorar og samanhengar mellom fatigue og ikkje små-cella lungekreft fem månader etter operasjonen.
I refleksjonsoppgåva skal eg vurdere dei psykometriske eigenskapane til to instrument som måler fatigue, The Brief Fatigue Inventory (BFI) og European Organization for Research and Treatment of Cancer Quality of Life Core Questionnaire-fatigue subscale (FA).
Teoretisk forankring: Lungekreft er ein av dei vanlegaste formene for kreft på verdsbasis i dag og fatigue er eit svært vanleg symptom hjå kreftpasientar. For å utøve god sjukepleie til kreftpasientar trengst det meir kunnskap om fatigue.
Det finst mange ulike skjema for å måle fatigue. Å vurdere dei psykometriske eigenskapane til instrument er ein metode for å vurdere om instrumentet er eigna til bruk på ulike pasientgrupper
Metode: Sosiodemografiske-, kliniske- og symptomdata blei samla inn med spørjeskjema. Medisinske data blei henta frå pasientjournalar. Variablar med signifikant bivariat korrelasjon med fatigue blei inkludert i ein hierarkisk lineær regression.
Som rammeverk til gjennomgangen valgte eg å bruke ei sjekkliste med desse hovedkriteria: konseptuell modell, innhaldsvaliditet, reliability, konstruksjonsvaliditet, skåring og tolking av resultat og respondent belastning og presentasjon.
Resultater: 196 pasientar blei inkludert i studien. Det var bivariate samanhengar mellom fatigue og kliniske variablar som komorbiditet og spirometriprøver og symptom (tungpust, hoste, depresjon, angst og søvnforstyrrelsar og smerter). I den hierarkiske lineære regressionen var det berre hoste som hadde signifikant innverknad på fatigue preoperativt. Tungpust var den einaste variabelen som predikerte nivå av fatigue etter fem månader. Sjekklista har eit pasientsentrert fokus som instrumenta ikkje oppfyller, men begge instrumenta skårar adekvat på tradisjonelle parameter for reliabilitet og validitet. FA har ein tak/golv effekt som kan redusere presisjonen til å måle fatigue hjå lungekreftkirurgipasientar.
Konklusjon: Fatigue ved fem månaders kan predikerast av tungpust. Desse pasientane bør få oppfølging og behandling for tungpust som i nokon grad kan behandlast. BFI og FA er reliable og valide i henhold til tradisjonelle parameter for testing av psykometriske eigenskapar.

Nøkkelord:
Fatigue, lungekreft, kirurgi, psykometri,

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Title and subtitle: Fatigue and Lung Cancer, Predictors and correlations of fatigue in non-small cell lung cancer patients at five-month follow-up. Evaluation of the psychometric properties of The Brief Fatigue Inventory and the EORCT QLQ- fatigue subscale.

Abstract:

Purpose: The purpose of this study was to examine whether specific patient, disease, and symptom characteristics correlated or predicted the levels of fatigue in lung cancer surgery patients before surgery and at five-month follow-up. The purpose of the second task is to evaluate the psychometric properties of The Brief Fatigue Inventory and European Organization for Research and Treatment of Cancer Quality of Life Core Questionnaire-fatigue subscale.
Literature review: Fatigue is associated with cancer and its treatment but there is a paucity in the knowledge about fatigue in lung cancer surgery patients. There are many instruments measuring fatigue, evaluating the psychometric properties is helpful in validating the use in a spescific patient cohort.
Method: 196 patients were included in this study. Sociodemographic, clinical and symptom data were collected with questionnaires. Treatment variables were collected thru patient records. A hierarchical linear regression with fatigue as dependent variable were conducted at baseline and five-month follow-up. To guide the psychometric evaluation of the chosen instruments a checklist was chosen according to the criteria of a patient centered approach.
Results: In the bivariate analyses fatigue was correlated to comorbidity, and symptom variables (shortness of breath, coughing, depression, anxiety, sleep disturbances, and pain). At five-month follow-up shortness of breath was the only predictor of fatigue. The BFI is valid according to traditional standards of psychometric criteria. The FA has a roof/floor effect that might have an impact on measuring fatigue in lung cancer surgery patients.
Conclusion: Shortness of breath was the only predictor of fatigue at five-month follow-up. Interventions and treatment should particularly focus on shortness of breath as this is partly a modifiable symptom. The Brief Fatigue Inventory and European Organization for Research and Treatment of cancer Quality of Life Core Questionnaire-fatigue subscale have valid psychometric properties according to traditional measurement theory.

Key words:

Fatigue, lung cancer, surgery, psychometric,

Forord

Det er rart og godt å bli ferdig med ei masteroppgåve. Det har vore ein lærerik prosess og eit privilegium å få bruke tida si til å studere. Det er mange som skal ha takk for hjelpa.

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Predictors and correlations of fatigue in non-small-cell lung cancer surgery patients at five-month follow-up.

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Abstract:

Objectives: Fatigue has a negative impact on quality of life in non-small-cell lung cancer surgery patients, but there is a paucity in the knowledge about lung cancer surgery patients and fatigue. We wanted to examine whether specific patient, disease, and symptom characteristics predict the levels of fatigue.

Materials and methods: We included 196 patients in this study and collected sociodemographic, clinical and symptom data with questionnaires. Treatment variables were collected from patients` medical records. Fatigue was measured with the Lee Fatigue Scale. Data were collected prior to surgery and at five-month follow-up. A hierarchical linear regression with fatigue as dependent variable were conducted at baseline and five-month follow-up.

Results: In the bivariate analyses fatigue was correlated to comorbidity, and symptom variables (shortness of breath, coughing, depression, anxiety, sleep disturbances, and pain). In the final model age and sex was not related to fatigue at baseline, nor the clinical variables. Coughing was related to fatigue after controlling for clinical variables and the other symptoms. At five-month follow-up shortness of breath was the only predictor of fatigue after controlling for age and sex, clinical variables, symptom variables and fatigue at baseline. We did not find any correlations between fatigue and treatment variables.

Conclusion: Patients should be screened for symptoms and comorbidities before surgery and routines for follow-up should be established. Interventions and treatment should particularly focus on shortness of breath as this is partly a modifiable symptom and predictor of fatigue in lung cancer surgery patients.

Innholdsfortegnelse

DEL 2 REFLEKSJONSOPPGÅVE

OVERSIKT OVER TABELLAR

OVERSIKT OVER VEDLEGG/ APPENDIX

1 Introduction

Lung cancer (LC) is one of the most common malignancies in the world today. It is estimated that 20 % of cancer-related deaths are caused by lung cancer[1].
Five-year survival in LC generally is 19,2% in women and 13,2% in men in Norway in 2014[1]. In surgery patients' five-years survival is 50%-70%, depending on the stage of tumor at time of surgery. Only 20% of the patients diagnosed with non-small-cell lung cancer (NSCLC) meet the criteria for surgery because of the late stage of NSCLC at diagnosis. For these patients surgery may be curative. For the other 80% of NSCLC patients and for those with small-cell lung cancer it is mostly life-prolonging treatment available[2].

1.1 Fatigue

Cancer-related fatigue is a sense of tiredness related to cancer or its treatment that interferes with usual functioning[3]. Fatigue has been described as a complex multidimensional symptom. It can be defined as a sense of exhaustion, lack of energy, or tiredness distinct from sleepiness, sadness or weakness[4]. However, clinically significant fatigue is unrelieved by a night of good quality sleep[4]. Because we don't know the etiology of fatigue we don't know if there is a difference between cancer-related fatigue and fatigue accompanying other illnesses. Understanding fatigue and how to manage it is a challenge for researchers and clinicians because fatigue is a multidimensional and multifactorial symptom that is difficult to define or measure in a standardized manner.

1.2 Prevalence of fatigue

Fatigue is a common symptom among cancer patients and is an expected part of the deconditioning that occurs after surgery. Studies have estimated that 75%- 90% of lung cancer patients are affected by fatigue after cancer treatment[5, 6]. In one study about symptom severity after thoracotomy fatigue was reported as the most common severe symptom at all time points [7].

1.3 Fatigue severity

Fatigue has a negative impact on patients' health-related quality of life (HRQOL)[8], their ability to receive treatment and their long-term prospects. It reduces physical, psychological, and social functioning and results in significant distress for patients and their caregivers[6]. There is limited data on lung cancer and fatigue in surgery patients. Yet we know that fatigue has a negative impact on the QOL of LC survivors[9] and in one study fatigue was a significant predictor of survival at all time points[10]. One study found that HRQOL returned to preoperative value by 6 months[11]. The information available about fatigue is mostly due to research in HRQOL.

1.4 Fatigue and other symptoms

Data on fatigue is also derived from literature concerning symptoms. Fatigue accompanies symptoms of a respiratory nature like dyspnea and cough[2, 10]. In one study[2] they found that dyspnea and fatigue were strongly associated with poor clinical outcomes in LC survivors. Several studies have found a close interrelationship between fatigue, cough and dyspnea [3, 10, 12, 13]. Fatigue is also strongly related to mood symptoms like depression and anxiety[7, 14]. Sarna[7] found a close relationship between pain, fatigue, and dyspnea.

Hoffman et al[15] found relationships of fatigue, pain, insomnia and gender in a general LC population. Studies about fatigue in populations with mixed cancer groups also have found strong correlations between fatigue and sleep disturbances[8, 16-18].

1.5 Fatigue and comorbidity

Sarna [7] studied symptom severity in surgical patients and found that the severity of symptoms was related to the extent of comorbid condition. Other studies concerning LC patients also have found correlations between fatigue and comorbidity[8] and others have found a strong correlation between fatigue and pulmonary diseases like COPD and asthma[5, 19].

1.6 Fatigue in lung cancer surgery patients

We know that fatigue has a negative impact on LC patients in general and in LC survivors[20], but we have not found any studies investigating fatigue in LC surgery patients. We know from research in symptoms and HRQOL that fatigue is a prevalent symptom. The presence of comorbid conditions like COPD and asthma, symptoms like dyspnea, cough, pain, sleep disturbance, depression and anxiety, receipt of more extensive surgery, and adjuvant therapy are associated with poorer post-operative HRQOL and fatigue[14]. We want to know the impact of these variables on fatigue.

Thus, the aim of this study is to examine the relationships between levels of fatigue and patients' disease-, symptoms- and treatment. We hypothesized to predict the levels of fatigue at five-month follow-up by; 1) clinical variables (comorbidity, preoperative FEV1 and FVC), 2) preoperative symptoms (shortness of breath, coughing, depression, anxiety, and sleep disturbances) and 3) treatment and medical variables (type of surgery, stage of cancer, adjuvant therapy, physiotherapy, rehabilitation). Controlling for age and sex and fatigue at baseline.

2 Design and methods

This sub-study is part of a longitudinal study of symptoms in lung cancer patients whom were eligible for surgery[21-23]. We collected data prior to surgery and prospectively four times after surgery. Only data from prior to surgery, and at five-month follow-up in addition to treatment variables, is used in this study.

2.1 Patients and settings

Patients were included if they were 18 years or older, were scheduled for primary lung cancer surgery, and could understand, read and write Norwegian. The patients with a benign or metastatic disease, or had their surgery canceled, or had cognitive impairment were excluded. We recruited patients from three university hospitals in Norway (i.e., Oslo University Hospital, St. Olav University Hospital and Haukeland University Hospital).

2.2 Study procedures

Research staff at the hospitals approached the patients and explained the purpose of the study. 91% of the patients were recruited in the hospital one to three days before surgery. The rest of the sample was recruited in outpatient clinic prior to surgery. The patients completed several self-report questionnaires that provided information on demographic and clinical

characteristics and symptoms prior to surgery and at five-month follow-up. Data on type of tumor, stage of cancer, surgery type and lung function was collected from the patients' medical records. Forced expiratory volume in one second (FEV1) and forced vital capacity (FVC) were measured pre-operatively using a spirometer. Five months after the surgery, patients received questionnaires on paper by regular mail, along with a postage-paid return envelope for returning filled-out questionnaires.

2.3 Instruments and assessment

2.3.1 Comorbidity

Comorbidity was measured using a self-administered comorbidity questionnaire-19 (SCQ-19)[24]. The patients were asked to choose from three alternatives concerning 16 common comorbidities; if they had the condition, if they got treatment for it and if it limited their activities. The score can range from 0-57. A higher score indicates a more severe comorbidity profile. Comorbidity was measured as a mean of the total score of the questionnaire. The SCQ-19 has well-established validity and reliability and was used to assess comorbidity in Norwegian oncology patients[24].

2.3.2 Lung capacity

Patient lung capacity was assessed by spirometry tests. Forced expiratory volume in one second (FEV1) (i.e. the amount of air that can be forcibly exhaled from the lungs in the first second of a forced exhalation) and forced vital capacity (FVC) (i.e. the amount of air that can be exhaled from the lungs in one exhalation) were measured pre-operatively using a spirometer. Assessment of pulmonary function allowed us a more objective measure of health status.

2.3.3 Fatigue

The Lee Fatigue Scale (LFS)[4] was used to measure fatigue at baseline and five-month follow-up. The LFS consists of 18 items designed to assess fatigue (13 items) and energy (5 items). We used only the 13 fatigue items in this study. Patients were asked to rate each item on a 0 to 10 scale, with higher score indicating greater fatigue severity. A fatigue score for each patient was calculated by using the mean score of the 13 items for each time of measurement. Patients with more than 20% missing LFS items were excluded in this study. LFS has well established validity and reliability[25].

2.3.4 Shortness of breath and cough

The European Organization for Research and Treatment of Cancer Quality-of-Life Questionnaire –Lung Cancer Module (EORTC QLQ-LC13)[26] was used for measuring shortness of breath (SOB) and cough. SOB was measured by completing the three items scale (i.e. SOB at rest, SOB walking, SOB climbing stairs). Cough was measured by asking the patients if they did cough. The severity of each item (SOB and cough) was rated using a four-point Likert-scale (i.e. 1=not at all, 2=a little, 3=quite a bit, 4=very much). A total score is calculated as a mean of the items. The EORTC QLQ-LC13 was validated in Norwegian lung cancer patients[27, 28].

2.3.5 Depression

The Center for Epidemiologic Studies –Depression Scale (CES-D)[29] was used measuring depression. The scale has 20 items related to depression and the patients were asked to report how they felt the past week. Each item was rated on a four point Likert-scale (possible score

0-60). A total depression score was calculated as mean of the total score. Acceptable reliability and validity have been reported[30].

2.3.6 Anxiety

The State-Trait Anxiety Inventory-Y-2 (STAI)[31] was used to measure anxiety. The STAI includes 20 items related to anxiety and the patients were asked to fill in a four point Likert scale. The score can range from 20-80. A higher score indicates a higher level of anxiety. Anxiety was measured as a mean of the total score.

2.3.7 Sleep disturbances

The General Sleep Disturbance Scale (GSDS)[32]was used to measure sleep disturbances. The GSDS consists of 21 items related to sleep disturbance. Each item is rated on a numeric rating scale (NRS) that ranges from 0(never) to 7 (every day). A sleep disturbance score was calculated as a mean of the items of the scale.

2.3.8 Pain

The Brief-Pain Inventory (BPI)[33] was used measuring pain. The BPI is a multidimensional questionnaire including 21 items, 11 of which are grouped into two scales; pain intensity and pain impact. The measurement scale ranges from 0-10. A pain score is calculated as the mean of the pain items. The BPI has been validated in Norwegian cancer patients[34].

2.4 Ethics

The Regional Ethics Committee for South-East 2010/1508, and the Institutional Review Boards (Personvernombudet) at the hospitals involved approved the study. All the patients received written information about the study and signed a consent form.

2.5 Statistical analyses

Descriptive statistics were used to describe the demographic, clinical and medical characteristics of the patient sample. Differences between genders were analyzed using chi-square for categorical variables and independent students't-test for the continuous variables. One-way ANOVA was used to explore differences within groups on levels of fatigue. The bivariate relations to fatigue prior to surgery and at five-month follow-up with other variables was initially assessed by linear regression. Examination of residual plots and collinearity reports indicated that statistical assumptions of normality, homoscedasticity, and collinearity were within suggested limits for each analysis. Variables with significant correlations in the bivariate analyses were included in the hierarchical linear analyses.

Age and gender were entered in step one. Clinical variables like comorbidity, FEV1, FVC was entered in in step two. Finally, symptom variables; shortness of breath, cough, depression, anxiety, sleep disturbance and pain were entered. At five-month follow-up the model also included a step with fatigue at baseline. The entry of all the variables into different steps in the model were done according to theoretical and logical considerations. For all analyses, $p<0.05$ was considered statistically significant. Post-hoc statistical power calculation for hierarchical multiple regression: With an effect size (f^2) for set B (five-month follow-up) at 0.15 (medium)[35] and 11 predictors in set A and 12 in set B and a probability level of 0.05 and a sample size of 196 the observed power for the addition of set B is 0.95[36].

Data were analyzed using SPSS (IBM corporation, Armonk, NY, USA) version 24.0.

3 Results

3.1 Sample characteristics

264 patients consented to participate in the study. Among these, 196 patients had valid scores on fatigue and were included in the study. Characteristics of the sample are shown in Table 1. More men than women participated and the men were in average 2.6 years older than women. Most of the sample had adenocarcinoma stage 1A or 1B, received no preoperative treatment and had a lobectomy. 84% (n=89) of the men and 69% (n=58, P=0.015) of the women were living with someone. Only a small group had more than 12 years of education.

There were significant differences between men and women regarding age and cohabitation, men were older and more men than women were living with someone. Men also had significant lower FVC than women and they reported higher scores for shortness of breath (SOB) than women in the sample. Otherwise the analyses did not reveal significant gender differences for the study variables. The mean fatigue score at baseline were for men 2.49 (SD=2.02) and 2.47 for women(SD=1.96). At five-months follow-up the fatigue scores were 3.0 (SD=2.1) for men and 2.9 (SD= 2.1) for women. There were no differences in levels of fatigue at baseline in those who completed the fatigue scale at five months and the ones that did not.

3.2 Bivariate analyses

The bivariate analyses between the symptom variables are shown in Table 2. Medical and treatment characteristics like stage of cancer, tumor type, type of surgery and post-operative treatment like radiation therapy, chemotherapy, physiotherapy and rehabilitation did not have significant bivariate correlation and were not included in the final model. Sociodemographic variables like work, education and cohabitation were excluded before the final analyses for the same reason.

3.3 Multivariate analyses

Hierarchical multiple regression was used to assess the impact of the chosen variables on the levels of fatigue at baseline and five-month follow-up. The results are shown in Table 3. Age and sex was not related to fatigue at baseline, nor the clinical variables. Among the symptoms only coughing was related to fatigue at baseline after controlling for age and sex, clinical variables and the other symptoms. The total model explained 47.0% of the variance while 30.9% was explained by the other symptoms. At five-month follow-up the only variable who predicts fatigue after controlling for age and sex, clinical variables, fatigue at baseline, and symptoms was SOB. The total model explained 54.6% of the variance while 23.4 was explained by the other symptoms.

4 Discussion

To our knowledge this is the first study to examine fatigue in lung cancer surgery patients with pre-surgical data and data from five-month follow-up. Fatigue at baseline and at five-month follow-up was related to comorbidity and a number of symptoms in the bivariate analyses. However, shortness of breath was the baseline variable which predicted fatigue at five-month follow-up when controlling for age and sex, clinical variables, and other symptoms at baseline including fatigue.

4.1 Clinical variables

In our study comorbidity did not predict fatigue, but showed a bivariate relationship with fatigue both at baseline and at five-month follow-up. Other studies have also found correlations between comorbidity and fatigue[7, 8]. Especially respiratory comorbidities and cardiac disease are related to fatigue in lung cancer patients[5, 37]. There is also a correlation between fatigue and spirometry results in our data. Lover FEV1 and FVC was related to higher levels of fatigue at both measurement times. These variables are related to comorbidity and is an important factor in identifying and screening for patients at risk for developing fatigue. Lower levels of respiratory tests could indicate SOB or respiratory comorbidities and lead to distress and exhaustion and contribute to fatigue in these patients.

4.2 Symptoms

The symptoms included in this study; SOB, coughing, depression, anxiety, sleep disturbance and pain is correlated with levels of fatigue before surgery and at five-month follow-up. Before surgery cough had a significant contribution, but at five-month follow-up SOB was the only predictive symptom found in our study. SOB is a prevalent and disturbing symptom in these patients which is naturally based on the localization of the disease and the potential damage caused by lung tumors, the history of smoking. SOB requires intensive effort for the patients to breath, thus making them get tired. The constant use of rib and respiratory muscles caused by SOB can exacerbate fatigue[38]. Consistent with previous research we found that fatigue in lung cancer surgery patients is correlated with other symptoms and might cluster with other symptoms[2, 39]. Cheville and Novotny[2] found a cluster of fatigue, cough and dyspnea in lung cancer survivors which lasted thru 8 years but in a later study, they found that the cluster did not predict outcomes in patients but fatigue and dyspnea, alone and together, were sufficient to determine important outcomes[10].

4.3 Fatigue and treatment variables

Surgery type has been a predictor of fatigue in lung cancer survivors [20] and surgery have been associated with a greater symptom burden generally[20]. In our study treatment and pathological variables did not show any correlation with fatigue at five-month follow-up. These findings is not consistent with other studies who have found correlations between fatigue and chemotherapy[12] and radiotherapy[13]. But our findings are consistent with findings in a cluster analyses in a general cancer population on the symptom cluster of pain, fatigue, sleep disturbances, and depression. They found that symptom experiences were independent of demographic, disease, or treatment effects and suggested that different

subgroups of patients may harbor different determinants (e.g. genetic) for experiencing symptoms and suggested etiology that are independent of demographic, disease or treatment characteristics[40].

4.4 Limitations and conclusions

Several limitations need to be acknowledged. Detailed information on symptom management interventions is not available and we don't know much about follow-up regime between the two measurement points. The variables physiotherapy and rehabilitation was included in the study although they are not detailed in type and length.

Findings from this study suggests that patients should be screened before surgery and treated for their symptoms. Special attention should be given to treatment of patients SOB since this is a modifiable predictor with treatments available. Further research needs to pay attention to the pair of symptoms that SOB and fatigue is and to the effects of fatigue and QOL when treated for SOB.

Acknowledgements

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Tabell 1Demographic, Clinical and Treatment Characteristics of the Patients (N=196)

	Total	Men	Women	Statistics	p-value
Socio-demographics					
Age in years (mean, sd)	196	66.7 (8.23)	64.1 (7.91)	t 2.28 (194)	**0.024**
		% (n)	% (n)	χ (df)	
Cohabitation (Living with someone)	147	84.0 (89)	(69.0) 58	5.95 (1)	**0.015**
Work status					
Full or part time	58	27.6 (29)	34.9 (29)	.80 (2)	0.25
Sick leave or disability	47	22.9 (24)	27.7 (23)		
Retired	83	49.5 (52)	37.3 (31)		
Education					
12 years and lower	158	81.1(86)	86.7 (72)	1.07 (1)	0.30
13 years and higher	31	18.9 (20)	13.3 (11)		
Clinical variables		Mean (sd)	Mean (sd)	t (df)	
Comorbidities (SCQ)	193	3.72 (3.35)	4.66 (3.97)	-1.74 (161.4)	0.08
FEV1 (Percent expected)	190	76.7 (19.2)	80.4 (22.81)	-1.20 (188)	0.23
FVC (Percent expected)	183	91.2 (15.00)	102.4 (19.4)	t -4.30(149.8)	**<. 001**
Symptoms					
Fatigue (LFS) baseline	196	2.49 (2.02)	2.47 (1.96)	t-0.07 (194)	0.94
Fatigue (LFS) five-month follow-up	196	3.0 (2.16)	2.9 (2.10)	t 0.32 (194)	0.75
Shortness of breath (EORTC)	194	2.24 (0.78)	2.00 (0.74)	t-2.28 (192)	**0.023**
Cough (EORTC)	193	1.96 (0.74)	1.98 (0.84)	t -0.11 (191)	0.92
Depression (CES-D)	190	10.49 (8.82)	12.92 (8.82)	t-1.89 (188)	0.06
Anxiety (STAI)	192	51.22 (3.11)	50.79 (2.95)	t 0.96 (190)	0.34
Sleep disturbance (GSDS)	191	2.26 (1.05)	2.32 (1.00)	t -0.36 (189)	0.72
Pain (BPI)	88	2.69 (2.12)	2.61 (1.97)	t -0.16 (86)	0.87
Pathology and treatment		% (n)	% (n)	χ (df)	p-value
Tumor type					
Adenocarcinoma	106	45 (50)	65.9 (56)	24 (4)	**<.001**
Squamous cell	66	45 (50)	12.9 (11)		
Small cell	5	1.8 (2)	3.5 (3)		
Carcinoid	6	1.8 (2)	4.7 (4)		
Other	18	6.3 (7)	12.9 (11)		
Stage of cancer disease					
IA	58	25.2 (27)	41.3 (31)	9.12 (4)	0.06
IB	59	35.5 (38)	28 (21)		
II	35	24.3 (26)	12 (9)		
IIIA	31	14 (15)	18.7 (14)		
IIIB-IV	1	0.9 (1)	-		
Preoperative treatment					
None	192	97.3 (108)	98.8 (84)	1.58 (3)	0.66
Radiation	1	0.9 (1)	-		
Chemotherapy	1	0.9 (1)	-		
Combination	2	0.9 (1)	1.2 (1)		
Type of surgery					
Lobectomy	133	67.6 (75)	68.2 (58)	1.26 (4)	0.87
Bilobectomy	15	6.3 (7)	9.4 (8)		
Pneumonectomy	18	9 (10)	9.4 (8)		
Wedge resection	18	9.9 (11)	8.2 (7)		
Thoracoscopic	12	7.2 (8)	4.7 (4)		
Postoperative complications					
Reoperation	9	3.6 (4)	5.9 (5)	0.57 (1)	0.45
Pneumonia	50	27 (30)	23.8 (20)	0.26 (1)	0.61
Post treatment					
Radiation therapy	16	9.9 (11)	5.9 (5)	1.04 (1)	0.31
Chemotherapy	57	30.6 (34)	27.1 (23)	0.30 (1)	0.56
Physiotherapy	58	24.3 (26)	38.1 (32)	4.24 (1)	**0.04**
Rehabilitation	24	7.5 (8)	19.3 (16)	5.90 (1)	**0.015**

Abbreviations: SCQ, Self-administered comorbidity questionnaire; FEV1, forced expiratory volume in one second; FVC, Forced vital Capacity; EORTC, European Organization for Research and Treatment of Cancer; CES-D, Center for Epidemiologic Studies- Depression Scale; STAI, State-Triat Anxiety Inventory; GSDS, The General Sleep Disturbance Scale; BPI, The Brief Pain Inventory; LFS, Lee Fatigue Inventory. Notes: Fatigue, range 0-10, higher score indicating grater fatigue severity; shortness of breath and cough range 1-4, higher score indicating more shortness of breath and cough; depression, range 0-60, higher score indicating more depression; pain, range 0-10, higher score indicating more pain; comorbidity, range 0-57, higher score indicating more comorbidity; anxiety, range 20-80, higher score indicating more anxiety; sleep disturbances, range 0-7, higher score indicating more severe sleep disturbances.

Tabell 2 Correlation Matrix for Symptoms at baseline, and fatigue baseline and five-month follow-up (N=196)

	1	2	3	4	5	6	7	8	9
1 Fatigue (LFS) Baseline	1								
2 Fatigue (LFS) five-month follow-up	.52*	1							
3 Comorbidities (SCQ)	.29*	.30*	1						
4 Shortness of breath (EORTC)	.35*	.62*	.31*	1					
5 Cough (EORTC)	.33*	.33*	-.04	.17*	1				
6 Depression (CES-D)	.47*	.31*	.17*	.17*	.12	1			
7 Anxiety (STAI)	-.24*	-.12	-.08	-.00	-.1	-.28*	1		
8 Sleep disturbance (GSDS)	.50*	.41*	.18*	.26*	.14	.57*	-.22*	1	
9 Pain (BPI)	.43*	.18	.25*	.07	.10	.41*	-.24*	.56*	1

*. Correlation is significant at the 0.05 level (2-tailed).

Abbreviations: SCQ, Self-administered comorbidity questionnaire; FEV1, forced expiratory volume in one second; FVC, Forced vital Capacity; EORTC, European Organization for Research and Treatment of Cancer; CES-D, Center for Epidemiologic Studies- Depression Scale; STAI, State-Triat Anxiety Inventory; GSDS, The General Sleep Disturbance Scale; BPI, The Brief Pain Inventory; LFS, Lee Fatigue Inventory.

Tabell 3 Results from the hierarchical linear regression (N=196)

	Fatigue at baseline			Fatigue at five-month follow-up		
		Multivariate analyses			Multivariate analyses	
	Beta	β	p	Beta	β	p
Socio-demographics						
Age	-0.04	-0.14	0.13	0.02	-0.07	0.43
Gender	-0.26	-0.06	0.53	0.03	0.007	0.94
Explained variance (R^2)		5.5%	0.12		2.9%	0.33
Clinical variables						
FEV1	-0.01	-0.05	0.69	-0.001	-0.01	0.91
FVC	-0.00	0.03	0.80	0.003	0.02	0.85
Comorbidity	0.09	0.16	0.13	0.06	0.11	0.27
R^2 change		**10.6%**	**0.035**		**12.1%**	**0.022**
Explained variance		16.1			15.0	
Fatigue at baseline						
Fatigue				0.21	0.2	0.09
R^2 change					**16.2%**	**<0.001**
Explained variance					31.2%	
Other symptoms at baseline						
Shortness of breath	0.41	0.16	0.13	**1.24**	**0.45**	**<0.001**
Cough	**0.61**	**0.24**	**0.013**	0.48	0.18	0.06
Depression	0.05	0.20	0.08	0.01	0.03	0.79
Anxiety	-0.05	-0.07	0.47	-0.01	-0.02	0.87
Sleep disturbance	0.01	0.15	0.24	0.02	0.17	0.16
Pain	0.15	0.15	0.19	-0.11	-0.10	0.36
R^2 change		**30.9%**	**<0.001**		**23.4%**	**<0.001**
Explained variance		47.0%			54.6%	

Abbreviations: FEV1, forced expiratory volume in one second; FVC, Forced vital capacity.

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Innholdsfortegnelse

VEDLEGG

Vedlegg 4 Manual for utfylling av Sjekklista

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Vedlegg 6 Sjekkliste med resultat frå gjennomgangen av BFI

Vedlegg 7 Tabell over reliabilitet og konstruksjonsvaliditet av BFI

1 Innleiing

I arbeidet med denne oppgåva, frå prosjektskissa, arbeidet med artikkelen og førebuing til dette refleksjonsnotatet, har eg reflektert over måling av *fatigue* hjå lungekreftkirurgipasientar. Fatigue blir definert som ein form for utmatting, manglande energi eller trøyttheit som skil seg frå søvnigheit, tristheit eller svakheit (Krupp, Alvarez, LaRocca, & Scheinberg, 1988; Lee, Lentz, Taylor, Mitchell, & Woods, 1994; Lerdal, 1998). Noko av det som eg har merka meg er at tala på kor mange som er ramma av fatigue spriker, og at instrumenta er så ulike både i lengde og i val av kva for dimensjonar av fatigue dei måler . I denne oppgåva vil to ulike instrument som har til hensikt å måle fatigue bli vurdert.

1.1 Problemstilling

Problemstillinga i denne refleksjonsoppgåva er å (1) vurdere dei psykometriske eigenskapane til *The Brief Fatigue Inventory(BFI)* og *The European Organization for Research and Treatment of Cancer Quality of Life Core Questionnaire -fatigue subscale* (FA) ved hjelp av *Checklist to operationalize measurement characteristics of patient-reported outcome measures* (Francis, McPeeters, Noud, Penson, & Feuer, 2016). Deretter å (2) diskutere kva resultata betyr for måling av fatigue hjå lungekreftkirurgipasientar.

1.2 Val av instrument

Ein gjennomgang av artiklane som er brukt i dette arbeidet, som omhandla fatigue hos lungekreftoperasjonspasientar og lungekreftoverlevarar, synte at mange ulike instrument har blitt brukt; BFI (Hung et al., 2011), Lung Cancer Symptom Scale (Cheville et al., 2011a, 2011b), FA (Win et al., 2004), M.D. Anderson Symptom Inventory (Lin, Chen, Yang, & Zhou, 2013), Quality of life instruments for cancer patients-lung cancer (Lin et al., 2013), The Schwartz Cancer fatigue scale (Sarna et al., 2008) og SF-36v2(Ostroff et al., 2011) er nokre av dei. Bakgrunnen for å velje BFI og FA var at i studien der FA var brukt til å måle fatigue (Win et al., 2004), hadde ikkje pasientane lenger fatigue tre månader etter operasjonen. Medan i studiane der BFI var brukt for å måle fatigue hjå overlevande etter lungekreft hadde høvesvis 57% (Hung et al., 2011) og 59,8% (Huang, Zhou, & Zang, 2015) fatigue 1-6 år etter lungekirurgi. Denne skilnaden i nivå av fatigue er interessant. Kan det ha noko med korleis instrumenta er bygde opp på? Og kan ein gjennomgang av psykometriske

eigenskapar forklare noko av skilnaden i nivå av fatigue? Begge skjemaene er dessutan mykje brukt for å måle fatigue hjå kreftpasientar.

1.2.1 EORTC-fatigue skala

The European Organization for Research and Treatment of Cancer Quality of Life Core Questionnaire (EORTC) er eit instrument som er utvikla for å måle helserelatert livskvalitet hjå kreftpasientar (Aaronson et al., 1993). Skjemaet er validert for lungekreftpasientar i ulike fasar av sjukdommen i Europa, Nord-Amerika, Australia og Japan (Bergman, Aaronson, Ahmedzai, Kaasa, & Sullivan, 1994). Det blei også utvikla eit tilleggsskjema som måler fatigue, FA, som eg skal vurdere. FA inneheld tre spørsmål: *Did you need to rest?, Have you felt weak? og Were you tired?*. Tidsintervallen pasientane vert bedne om å svare ut i frå er den siste veka, og spørsmåla blir kryssa av på ein fire-punkts Likert skala. I litteratursøk, samt ved å sjekke litteraturhenvisningar, har eg funne ein artikkel som vurderer dei psykometriske eigenskapane til FA. Det er ein norsk studie frå 2003 (Knobel et al., 2003) som validerer skjemaet på pasientar som får palliativ behandling og kreftoverlevarar med fleire ulike typar kreft. Eg kjem også til å bruke den originale valideringsartikkelen (Aaronson et al., 1993), som validerer heile EORTC livskvalitetsskjemaet inkludert FA.

1.2.2 The Brief Fatigue Inventory

BFI blei utvikla for å få eit enklare skjema til å måle fatigue (Mendoza et al., 1998). Instrument er mykje brukt for å måle fatigue i ulike populasjonar. I valideringsartikkelen gjer Mendoza et al (1998) greie for korleis mange av instrumenta som fantest var lange og kompliserte å fullføre, særleg for alvorleg sjuke pasientar i ein klinisk setting. Dei ønskte difor å utvikle eit kortare skjema. Eit viktig poeng under utviklinga av BFI var at språket skulle vere enkelt og forståeleg for pasientar, slik at ein enkelt kunne omsette det til andre språk. BFI består av 9 element som ein svarar på via ein numerisk rangeringsskala frå null til ti. Dei tre første spørsmåla spør om gradering av fatigue no (*now*), vanlegvis (*usual*) og verst (*worst*) innanfor siste 24 timar. Deretter kjem fire spørsmål om korleis fatigue har hatt innverknad på generell aktivitet, humør, evne til å gå, normalt arbeid, relasjonar til andre menneskjer og livsglede. Det blei utvikla eit forslag til kvar ein skal setje *cut off* mellom mild, moderat og alvorleg fatigue. Ein til fire blir karakterisert som mild fatigue, mens fire til seks vert klassifisert som moderat fatigue. Frå sju til ti karakteriserast det som alvorleg fatigue (Mendoza et al., 1998). Tilfanget av valideringsartiklar er større når det gjeld BFI som

er validert på blanda kreftpopulasjon i USA (Mendoza et al., 1998), samt på friske heimebuande eldre >65 (Shuman-Paretsky, Belser-Ehrlich, & Holtzer, 2014). I tillegg er valideringsstudiane som er gjort på tysk (Radbruch et al., 2003), gresk (Mystakidou et al., 2008) og italiensk (Catania et al., 2013) inkludert. Dei italienske og greske studiane er gjennomførte på blanda kreftpopulasjon, medan den tyske er gjennomført på smertepasientar, der somme har kreft og andre ikkje. For å avgrense oppgåva har eg valt å ikkje inkludere studiane frå Kina, Taiwan og Korea. Sosiale, økonomiske, politiske og kulturelle faktorar påverkar denne typen målingar (*Handbook of Psychiatric Measures*, 2008) og eg vurdert at det er meir relevant og overførbart å samanlikne norske forhold med Europa og Nord-Amerika, enn Asia.

1.3 Bakgrunn

1.3.1 Fatigue

Fatigue er eit subjektivt symptom som rammar ulike dimensjonar av mennesket og for pasientar som opplever fatigue vil det verke inn på kva dei maktar å gjere fysisk, psykisk, sosialt og kognitivt (Lai, Crane, & Cella, 2006). Fatigue er svært vanleg hjå kreftpasientar, då av og til referert til som kreftrelatert fatigue. Pasientar med kroniske sjukdommar som til dømes HIV/AIDS (Lerdal, Gay, Aouserat, Portillo, & Lee, 2011), multippel sklerose (Krupp et al., 1988) og slag (Lerdal et al., 2009) har også fatigue i ulik grad. Fatigue kan hos nokre vere ein biverknad til ulike typar medisinsk behandling som strålebehandling (Ozturk, Sarihan, Ercan, & Karadag, 2009), cytostatika (Kober et al., 2016; Long, Thanasilp, & Thato, 2015), biologisk behandling (Portenoy & Itri, 1999) og kirurgi (Sarna et al., 2008). Etiologien er ukjend, noko som er ein stor del av kompleksiteten ved fatigue. Fleire studiar har funne at fatigue om morgonen og om kvelden kan ha ulike prediktorar, og difor kanskje og ulik etiologi (Wright et al., 2015a, 2015b). Ein annan retning innanfor forskinga på fatigue dreier seg om symptomcluster, sidan fatigue er eit symptom som ofte kjem saman med andre symptom i ulike konstellasjonar (Cheville et al., 2011a, 2011b). Det finst ikkje noko tilbod om behandling for fatigue utover gode råd om korleis ein kan leve med vanskane, og oppmoding om moderate mengder fysisk aktivitet (Carino, Di Stefano, & Novello, 2016). Spørsmåla kring etiologien er dei same både for fatigue og kreftrelatert fatigue.

På norsk brukar enkelte ordet trøttheit eller utmatting om fatigue. Nokre meiner også at trøttheit bør erstatte fatigue i norsk samanheng, fordi ordet fatigue er eit framandord som

bidreg til mystifisering av fenomenet (Loge, 2014). Eg er usikker på om det gir eit presist nok bilete. I denne oppgåva vel eg difor å bruke ordet fatigue, då begrepet er innarbeida og brukt innanfor forskinga på dette feltet.

1.3.2 Å måle fatigue

Å måle fatigue er ei utfordring fordi ein manglar ein felles definisjon på omgrepet, og derfor gjerne vektlegg ulike eigenskapar og dimensjonar ved fenomenet(Minton & Stone, 2008). Sidan fatigue er eit subjektivt fenomen er det viktig å ha reliable og valide instrument for å måle fatigue (Lerdal & Kottorp, 2011a). Det er semje om at det er behov for meir kunnskap om fatigue, kvifor pasientar får fatigue og kva som kan gjerast for å behandle fatigue. Dei ulike instrumenta som måler fatigue varierer mykje i kor mange element dei inneheld, kva for dimensjonar av fatigue dei ønsker å måle og psykometriske eigenskapar (Minton & Stone, 2008).

1.3.3 Lungekreft

I 2015 fekk 3035 personar lungekreft i Noreg. Av desse var 1471 kvinner (Kreftregisteret, 2017). Dette er det høgaste talet Kreftregisteret nokon gong har registrert. Dei siste åra har særleg andelen kvinner som får lungekreft auka. Åtte av ti tilfelle skyldast røyking (Kreftregisteret, 2017). Lungekreft er den kreftforma som tek flest liv, og i 2015 stod lungekreft for om lag 20% av dødsfalla av kreft i Noreg. Prognosane er generelt dårlege for dei som får diagnosen, men dersom ein får diagnosen tidleg i sjukdomsforløpet er utsiktene betre. For dei få, omlag 20%, som tilfredsstiller kriteria for kirurgisk behandling er overlevinga betydeleg betre, men vi treng meir kunnskap om korleis lungekrftkirurgipasientane har det etter operasjonen.

2 TEORI

2.1 Validering av instrument

Å evaluere reliabiliteten og validiteten til eit instrument er nøkkelen til å vurdere om instrumentet passar i ein bestemt samanheng (*Handbook of Psychiatric Measures*, 2008). Eg skal sjå på dei psykometriske eigenskapane til to instrument, som båe er brukt for å måle fatigue hjå lungekreftpasientar. *Å teste instrument som måler fatigue i ulike pasientpopulasjonar er ønskeleg og vil kunne avdekke generiske karakteristika av fatigue på kryss av ulike diagnostiske grupper så vel som meir sjukdomsspesifikk informasjon om fatigue* (Lerdal & Kottorp, 2011b, s 1259). Det vil vere ulike omsyn å ta når ein skal bruke eit instrument, som til dømes tilgjengelegheit og pasientbelastning. *Classical measurement theory* har vore den førande teorien innanfor måling av affektive konstruksjonar, men *Item Respons Theory* (IRT) har vorte gradvis meir populært (Polite & Beck, 2012s 328). Dette er ein meir sofistikert framgangsmåte for å måle styrker og svakheiter ved individuelle element i eit skjema, og ein brukar då ofte ein Rasch model (Polite & Beck, 2012, s 353).

2.1.1 Reliabilitet

Reliabilitet er eit uttrykk for stabilitet og konsistens i resultata av ein test. Reliabilitet blir målt i indre konsistens, og seier noko om i kva grad dei ulike testledda samvarierer med kvarandre (*Handbook of Psychiatric Measures*, 2008). Saman skal dei ulike delane gi eit individuelt mål på variasjonen til eit gitt fenomen. Indre konsistens blir oftast oppgitt i Cronbach's alfa. *Item total correlation* måler også reliabilitet, og gir eit mål på korrelasjonen mellom kvart enkelt element/spørsmål og den totale summen. Test-retest reliabilitet måler om resultata er samstemte når ein test vert gjennomført på ulike tidspunkt. Denne målinga er særleg nyttig i samband med sjølvrapporteringsskjema, og blir vanlegvis uttrykt ved korrelasjon mellom målingane(*Handbook of Psychiatric Measures*, 2008). Dette omtalast som stabilitetskoeffisienten. Ein annan vanleg måling på reliabilitet er interrater reliabilitet. Dette er ei måling som seier noko om kor samstemt ulike fagfolk er når dei skal observere det same og konkludere utifrå til dømes diagnosekriterier (*Handbook of Psychiatric Measures*, 2008).

2.1.2 Validitet

Validitet er eit kriterium på om instrumentet vi brukar faktisk måler det vi ønsker å måle og om det reflekterer kjerna i fenomenet vi undersøker. Det finst mange ulike omgrep for å skildre dei ulike aspekta av validitet. Dei ulike aspekta har ulike grenser og terminologien for å beskrive er ikkje alltid konsistent (*Handbook of Psychiatric Measures*, 2008). Handbook of Psychiatric Measures (2008) har delt validitet inn i desse kategoriane: 1) I kva grad emna måler det som det blir stilt spørsmål ved (av og til kalla *face validity*). 2) Dekker omgrepa vi brukar det relevante fenomenet/domenet (av og til kalla *content validity*). 3) Samsvarer resultatet av målinga med ein gullstandard eller med kriterier for nøyaktigheit (av og til kalla *criterion-*, *predictive-*, or *concurrent validity*). 4) Og i kva grad målinga korrelerer som forventa med eksterne validatorar/instrument (av og til kalla *construct validity* som kan inkludere *convergent-*, *divergent-*, og *diskriminant validity*).

2.1.3 Sensitivitet

Det er diskusjonar om i kva grad sensitivitet (*responsiveness*) er ein eigen kategori på linje med reliabilitet og validitet eller om omgrepet høyrer til under dei nemnde kategoriane. Sensitivitet handlar om i kva grad eit instrument er i stand til å måle endringar. Sensitivitet er særleg viktig i longitudinelle studiar der ein er interessert i å måle endringar i eit fenomen på ulike tidspunkt.

3 METODE

3.1 Val av metode

Som eit hjelpemiddel for å systematisere gjennomgangen av instrumenta og psykometriske eigenskapar, har eg velt å bruke ei sjekkliste som blir presentert i denne artikkelen: *Checklist to operationalize measurement characteristics of patient-reported outcome measures* (Francis et al., 2016). Heretter referert til som sjekklista.

Bakgrunnen for å utarbeide denne sjekklista var å utvikle eit hjelpemiddel som kunne guide både erfarne og uerfarne forskarar og klinikarar, med varierande ekspertise, i å evaluere styrker og svakheiter ved instrument som er meint til å måle *patient-reported outcome* (PRO) (Francis et al., 2016). Ein definerer det som: *any report on the status of a patient´s health condition that comes directly from the patient, without interpretation of the patient`s response by a clinician or anyone else* (Lasch et al., 2010, s 1087).
For å samle informasjon og faglege anbefalingar har dei gjennomført ein litteraturgjennomgang, sett på ulike kjelder for å sjå kva som er konsensus, samt kva andre meiner er naudsynt å evaluere når ein vurderer eit instrument. Ei viktig kjelde var *the COnsensus-based Standards for the Selection of health Measurement INstruments* (COSMIN), som er ein anerkjent standard i evaluering av PRO- målingar (Mokkink et al., 2010). Francis et al (2016) meiner likevel at COSMIN checklist blir for omfattande og komplisert å bruke for dei som ikkje har ekspertise i *measurement theory*. Dei har tatt utgangspunkt i dette arbeidet samt andre teoriar på området for å identifisere anbefalingar for evaluering av instrument. Deretter har dei analysert og kome fram til ei forenkla sjekkliste. Hovudkriteria for å evaluere eit instrument var (1) konseptuell modell, (2) innhaldsvaliditet, (3) reliabilitet, (4) konstruksjonsvaliditet, (5) skåring og tolking av resultat og (6) respondent belastning og presentasjon.

Kriterie 1, 2, 5 og 6 er svara på ut i frå den originale valideringsartikkelen som er skrive. I gjennomgangen av kriteriene 3 og 4 som omhandlar reliabilitet og validitet, som er tradisjonelle kategoriar for psykometriske eigenskapar, har eg inkludert vurderingar av psykometriske eigenskapar frå andre valideringsartiklar.

4 GJENNOMGANG, RESULTAT OG DELANALYSE

Vedlegg 5 Sjekklista med resultata frå gjennomgangen av FA.
Vedlegg 6 Sjekklista med resultata frå gjennomgangen av BFI.

4.1 Konseptuell modell

Ein konseptuell modell skal grunngje og skildre konseptet som ein har som intensjon å måle, samt den populasjonen som skal målast (Francis et al., 2016). I følgje Francis (2016) er det naudsynt å gå attende til den originale valideringsartikkelen for å kartlegge korleis det er tenkt konseptuelt.

EORTC blei utvikla for å måle helserelatert livskvalitet, og i den originale artikkelen som blei skriven i forbindelse med utviklinga av den første utgåva av skjemaet, er fatigue eit av tre symtomskjema som kjem i tillegg (Aaronson et al., 1993). Dei andre tilleggsskjemaene måler smerter og kvalme/oppkast. Slik eg kan sjå det, er det gjort grundig greie for livskvalitet og behovet for å måle det. Når det gjeld fatigue blir det sett på som eit så viktig symptom i samband med livskvalitet, at ein ønsker å gjere greie for det spesifikt. Utover det blir det ikkje gjort greie for til dømes dimensjonar av fatigue som ein ønsker å måle. EORTC er retta mot kreftpasientar, både palliative, under aktiv behandling og overlevande. Skjemaet er meint til bruk i internasjonale kliniske studiar. Dei har ikkje definert fatigue.

BFI blei laga for å ha eit kort og lett forståeleg instrument til å måle fatigue hos kreftpasientar. Mendoza et al (1998) meinte at mange av dei instrumenta som eksisterte for måling av fatigue var for lange og kompliserte for alvorleg sjuke pasientar. I utviklinga av instrumentet blei fatigue samanlikna med smerte, og målinga av fatigue var basert på konseptet om fatigue som ei subjektiv erfaring; det er det personen som erfarar det seier det er. Dei brukte The Brief-Pain Inventory som mal i utviklinga av BFI. Dei ønsker å måle kor alvorlig fatigue var. Eg meiner det kan stillast spørsmål til det å samanlikne fatigue med smerter. Bortsett frå denne subjektive kjennsgjerninga at både smerter og fatigue er det den enkelte seier at det er, vil det være mange ulikheiter ved fatigue og smerter. Smerter er veldefinert fenomen, det finst mange typar behandling for smerter, og ofte er etiologien kjend. Eit anna viktig moment er at personar som har smerter veit at det er det smerter det dreier seg om. Slik er det ikkje alltid med fatigue, som manglar ein felles definisjon, der det

ikkje finnest nokon effektiv behandling og det gjerne er ukjend etiologi. Ved å samanlikne desse to fenomena meiner eg at ein på mange måtar overser kompleksiteten i fatigue. Dette treng sjølvsagt ikkje ha innverknad på korleis BFI måler fatigue.

4.2 Innhaldsvaliditet

Validitet som psykometrisk eigenskap er eit uttrykk for kor godt eit mål reflekterer fenomenet som er meint å måle. Sjekklista etterspør i denne kategorien om pasientgruppa som skal målast har hatt innverknad i utviklingsprosessen for å optimalisere relevans og klarheit i spørsmål som blir velde til instrumentet. Dette meiner dei kan gjerast ved intervju, individuelle eller fokusgruppe. Deretter etterspør dei om fagpersonar med kompetanse innanfor fagfeltet har medverka. Det skal også gjerast greie for metodologien i utvikling av element og spørsmål (Francis et al., 2016).

Når det gjeld EORTC gjer dei greie for ein lang prosess med ulike spørjeskjema for å kartlegge livskvalitet, men dei gjer ikkje greie for fatigue spesifikt. Pasientar har blitt inkludert ved bruk av spørjeskjema. Dei har i heile prosessen hatt fagpersonale med, og instrumentet er utvikla i samarbeid med ei ekspertgruppe sjølv om dei ikkje spesifiserer kva dei er ekspertar i. Sjølv om EORTC har vore gjennom ein grundig utviklingsprosess, er det meir uklart korleis ein har kome fram til og utvikla delen om fatigue.

BFI er utvikla ved hjelp av eit større spørjeskjema basert på data om fatigue. Slik det er framstilt i hovudartikkelen er det ekspertar på smerter og kreft som har utvikla instrumentet (Mendoza et al., 1998). Dei gjer greie for ein prosess i fire delar, der dei først samla data ved hjelp av eit spørjeskjema om fatigue. Del to i prosessen var å utvikle spørsmål/element på bakgrunn av spørjeskjemaet, for deretter å validere skjemaet som presentert i artikkelen. Til slutt har dei utvikla ein mal for kategorisering av alvorlegheitsgrad av fatigue, basert på kor stor innverknad fatigue hadde på funksjon. Pasientar er inkludert ved å svare på spørjeskjema, men ikkje ved bruk av intervju.

Sjekklista er moderne, med eit meir pasientsentrert fokus, der dei held fram kvalitative tilnærmingsmetodar som intervju, individuelle og fokusgruppeintervju, som idealet i utviklinga av eit konsept for å få med pasienten sine innspel og synspunkt. Ein slik standard i utviklinga av instrumentet vektlegg behovet for å inkludere kvalitative metodar i utviklinga, for å forsikre seg om at instrumenta inkluderer synspunkt frå den pasientgruppa som er målgruppa. Dette vil bidra til eit meir naturleg språk som pasientar vil forstå og lettare kunne

svare på. Det vil også bidra til å identifisere kva som er viktig i samanhengen for pasientane (Burbridge et al., 2013). Sjølv om både FA og BFI er utvikla på bakgrunn av lengre prosessar, kjem dei til kort i høve til det pasientsentrerte fokus som sjekklista representerer. Dette treng ikkje å bety at dei måler fatigue dårlegare av den grunn.

4.3 Reliabilitet

Sjekklista viser til innarbeidde konvensjonar og oppgjev tradisjonelle grenser for realiabilitets koeffisient på 0,70 for samanlikningar på gruppenivå, og 0,90-0,95 for individuelle samanlikningar. Dei opnar også for at lågare verdiar kan aksepterast dersom det er gode argument for det (Francis et al., 2016).

I originalstudien blir det oppgitt at FA korrelerte mellom 0,53 til 0,63 med fysisk funksjon og rollefunksjon. Mellom fatigue og emosjonell- og sosial funksjon var korrelasjonskoeffisienten 0,41. Knobel et al (2003) testa korrelasjonen mellom FA og Fatigue Questionnaire (FQ). FQ er delt inn i ein del for fysisk fatigue og ein for mental fatigue. FA korrelerte mellom 0,67-0,75 med fysisk fatigue og mellom 0,49 og 0,61 med mental fatigue.

I originalstudien til BFI var indre konsistent koeffisient 0,96. Shuman-Paretsky et al (2014) testa dei psykometriske eigenskapane til BFI på friske heimebuande eldre, og oppgav Cronbach's alfa mellom 0,58 og 0,79. Studiane frå Hellas, Tyskland og Italia fekk det dei sjølv kalla akseptable verdiar for indre konsistens og konkluderte med at BFI var reliabelt i henhold til deira analysar og populasjon. Sjølv om både FA og BFI hadde akseptable verdiar i henhold til klassisk testteori og akseptable verdiar av Cronbach`s alfa meiner enkelte at *Item respons Theory* og bruk av Rash analyse gir eit meir nøyaktig svar på reliabilitet. I validering av *Fatigue Severity Scale*, ved bruk av Rasch analyse, avdekka ein inkonsistens i elementa (*items*) der tidlegare valideringsstudier hadde rapportert akseptable verdiar på indre konsistens (Johansson, Kottorp, Lee, Gay, & Lerdal, 2014; Lerdal, Johansson, Kottorp, & von Koch, 2010; Lerdal & Kottorp, 2011a) Underteikna kan ikkje sjå at det er gjennomført Rash analyser på verken FA eller BFI.

Vedlegg 7 Inneheld detaljerte resultat frå realiabilitet og konstruksjonsvaliditet for BFI. (Det er ikkje laga nokon tabell for FA då det ikkje er så mange resultat å presentere).

4.4 Konstruksjonsvaliditet

Sjekklista ber her om å gjere empirisk greie for dimensjonalitet. Dei etterspør faktoranalyse, prinsipal komponentanalyse eller tilsvarande, sensitivitet for endring, konvergent validitet, divergent validitet eller prediktiv validitet/ kriterierelatert validitet (Francis et al., 2016).

Knobel et al (1998) gjennomførte ein faktoranalyse på FA for å finne ut om instrumentet kunne seiast å dekke fleire enn ein dimensjon. Faktoranalysen bekrefta at FA hadde ein dimensjon, fysisk fatigue. Dei gjennomførte ein valideringsstudie på pasientar med langtkomen lungekreft og lungekreftoverlevarar. Når det gjaldt å måle skilnad i fatigue mellom pasientgrupper, såg det ut til at FA skilde dårleg mellom dei ulike gruppene i denne studien. Studien gjennomførte ei samanlikning mellom FA og FQ og synte at FA korrelerte med fysisk fatigue delen av FQ. Både faktoranalysen og samanlikning mellom FQ og FA, synte at FA var eindimensjonalt og målte fysisk fatigue. Vidare fann dei ut at FA ikkje var sensitivt nok til å måle endringar hjå pasientar med alvorleg langtkomen kreft eller kreft overlevarar i andre enden av skalaen. Målinga synte eit tak/golv problem. For alvorleg sjuke og palliative pasientar fann dei ein tak effekt der dei fleste skåra høgt og målinga blei for unyansert. Den motsette effekten fann dei hjå kreftoverlevarar der dei fleste skåra lågt på skalaen. Variansen blei for unyansert i begge endar av skalaen (Knobel et al., 2003). Det blei ikkje gjennomført test-retest i nokon av studiane.

Faktoranalyse av BFI synleggjorde ein dimensjon som dei kalla *severity of fatigue* (Mendoza et al., 1998). Når det gjaldt *concurrent validity* sjekka dei om BFI korrelerte med eksisterande og validerte instrument for måling av fatigue. BFI korrelerte både med POMS-fatigue (Pearsons R=0,84) og FACT subskala for fatigue (Pearsons R=-0,88). Både den greske og den tyske studien synte test-retest korrelasjon på Pearsons R over 0,90. Når det gjaldt ulike dimensjonar i BFI var alle studiar einige om at den var eindimensjonal bortsett frå Shuman-Paretsky et al (2014) som argumenterte for at den hadde to dimensjonar, *severity* og *interference.* Elles brukte dei ulike studiene ulike metodar for å teste validiteten i instrumentet. Dei fann ut at BFI skilde mellom ulike grupper pasientar (divergent validitet) (Shuman-Paretsky et al., 2014), hadde convergent validitet (Mystakidou et al., 2008). For å måle diskriminant validitet hadde dei samanlikna graden av fatigue hos pasientar med meir alvorleg sjukdom, og fann ut at dei har meir fatigue enn pasientar med mindre grad av alvorleg sjukdom (Gianluca et al., 2012).

4.5 Skåring og tolking av resultat

Korleis ein skal tolke resultatet (*interpretability*), handlar om i kva grad skåring av instrumentet er lett å forstå. Dette fordrar ifølgje sjekklista at det blir tydeleg beskrive korleis ein skal handtere skåring av instrumentet, og at ein gjer greie for kva dei ulike skåringane betyr i klinisk samanheng. Vidare spør dei om det er gjort greie for kva som er *minimally important differences* for å kunne ha moglegheit til å differensiere mellom ulik grad av endring i eit instrument, og kva tid skilnaden er klinisk relevant. Heilt til sist spør dei om det er gjort greie for korleis ein skal handtere manglande svar (Francis et al., 2016).

EORTC skriv at dei i valideringsartikkelen har gjort alle skalaer om til ein 0-100 skala for å forenkle analysen. BFI har ein mal for skåring av skjemaet og eit forslag til kategorisering av svara i mild, moderat og alvorleg grad. Dei tek atterhald om at dette må utforskast vidare. Dei har også eit forslag til korleis ein skal handtere manglande svar.

4.6 Respondent belastning og presentasjon

Respondent belastning betyr kor mykje tid og energi som må brukast av dei som svarar på og administrerer skjemaet. For pasientar med fatigue kan dette være svært viktig fordi dei orkar ofte lite. Kva som er akseptabelt å bruke av tid og energi på eit skjema er gjerne ei subjektiv oppleving, men som ein hovedregel er det større aksept for lange skjema innan forsking, enn i ein travel klinisk kvardag (Francis et al., 2016). Om språket er enkelt å forstå skal også vurderast i denne kategorien.

EORTC oppgir at det tek omlag 12 min (SD=7,5 minutt) å fylle ut heile livskvalitetskjemaet inkludert FA. Når det gjeld spåket oppgir dei at 10% av pasientane oppgjev at eit eller fleire av spørsmåla var forvirrande eller vanskelege å svare på.

For BFI var intensjonen å lage eit kort skjema til bruk i klinikken. Dei har også gjort greie for at dei ønska eit enkelt språk som alle kunne forstå og som skulle vere enkelt å omsetje til andre språk. BFI er tilgjengelege for innsyn. Begrepet fatigue er komplisert å omsetje til andre språk og både den greske og tyske valideringsartikkelen skriv om utfordringar i å omsetje omgrepet på ein adekvat måte, der dei har erstatta fatigue med fleire ord for å på ein god måte få fram tydinga (Gianluca et al., 2012; Radbruch et al., 2003).

5 DISKUSJON

Frances et al (2016) presiserer at ein ikkje skal rekne ut ein sumskåre på sjekklista fordi ein vil måtte vektlegge ulike kategoriar for ulike formål. Både FA og BFI oppfyller tradisjonelle krav til reliabilitet og validitet sjølv om FA har litt svakare verdiar. Dei oppfyller ikkje alle krav i forhold til konseptuell modell og pasientmedverknad, men er klare på at det er kreftpasientar som er målgruppa.

Generelt oppfyller BFI fleire krav enn FA, som er ein liten del av eit større skjema der validerinsstudien fokuserar på livskvalitet og heilheita. Det går kanskje på bekostning av detaljar rundt eit tilleggsskjema som FA. FA har vist redusert sensitivitet i å registrere endringar hjå pasientar og eit tak/golv problem avdekka ein svakheit i å måle fatigue både hos palliative pasientar i øvre del av skalaen med mykje fatigue og overlevarar i nedre del av skalaen (Knobel et al., 2003). Dette kan ha innverknad på korleis FA måler fatigue hjå lungekreftkirurgipasientar og kan kanskje ha vore ein medverkande årsak til at studien til Win et al (2004) fann at kirurgipasientane ikkje lenger hadde fatigue fire månader etter operasjonen.

Korkje FA eller BFI er validerte på lungekreftkirurgipasientar aleine, men på populasjonar med ulike typar kreft og stadier. Lungekreftoperasjonspasientar lever med mange symptom etter operasjonen, i ei ny norsk studie opplever over 80% av pasientane både tungpust, mangel på energi, smerter og døsigheit ein månad etter operasjonen (Oksholm et al., 2015). Ei studie har funne at lungekreftoverlevarar ikkje har same livskvalitet som alderssamanliknande overlevarar av andre typar kreft (Yang et al., 2012). Dei har lavast skåre på livskvalitet blant overlevarar av alle krefttypar, og ein av fire lungekreftoverlevarar er fysisk redusert eller lider av depresjon (Yang et al., 2012). Medan ei studie fann at kvinnelege lungekreftkirurgipasientar i hovudsak hadde like god livskvalitet som friske på same alder (Sarna et al., 2010). Ein kvalitativ tilnærming for å kartlegge korleis pasientar som har gjennomgått lungekirurgi opplever å leve med fatigue vil vere verdifullt. Det ville gitt nyttig kunnskap om både dimensjonar og innverknad av fatigue. Dersom ein tek utgangspunkt i dei instrumenta som alt finnast kunne Rasch analyse med utgangspunkt i BFI og lungkreftkirurgipasientar også avdekka nyttig informasjon om måling av fatigue og korleis BFI måler fatigue hos desse pasientane.

BFI har i ei av studiene (Shuman-Paretsky et al., 2014) ein bidimensjonalitet der ein snakkar om *severity* og *interference*, men i dei andre studiene syner faktoranalyser at både

FA og BFI er unidimensjonale. Unidimensjonale instrument er enkle å bruke i mange samanhengar, men vil kanskje berre fange opp dersom fysisk fatigue er tilstade eller ikkje (Han, Heitkemper, & Jarrett, 2016). Enkelte har meint at det har avgrensa klinisk verdi å måle fleire dimensjonar av fatigue hos kreftpasientar og at det derfor er unødvendig med multidimensjonale skjema (Lai et al., 2006). Burbridge et al (2013) argumenterer for at dei ulike dimensjonane av fatigue korrelerer så høgt at ein ikkje mistar viktig informasjon ved å måle ein dimensjon. Dei meiner at dette best kan gjerast ved å spørje om symptomet fatigue og ikkje *severity* og *impact* som mange gjer (Burbridge et al., 2013). Eit av argumenta for unidimensjonale skjema er at for mange pasientar er den totale symptombelastninga så høg at dei ikkje ville kunne skilje kva som er fatigue frå alle dei andre symptoma (Burbridge et al., 2013). Eg meiner at dette argumentet ikkje automatisk kan overførast til kirurgipasientar, då mange av dei vil kunne skille fysisk, kognitiv og emosjonell fatigue frå kvarandre. Kanskje er det den emosjonelle og kognitive dimensjonen som er verst for enkelte av desse pasientane ?

Ei utfordring for forskarar er å forsikre seg om at sjukepleiarar og andre som jobbar pasientnært skal kunne tolke og bruke resultata i ein studie og kunne ha klinisk nytte av dei (Guyatt & Schunemann, 2007). Utan informasjon om skåring og korleis resultata skal tolkast kan det vere vanskeleg å konseptualisere og forstå korleis dei skal overførast til klinisk realitet. For pasientane handlar det om resultata blir tilgjengelege for å forbetre praksis og kjem pasientane til gode på den måten. BFI sin inndeling i mild. Moderat og alvorlef fatigue er lett forståeleg for ein klinikar.

5.1 Konklusjon

Både FA og BFI er utvikla under andre konvensjonar enn dei som Frances et al (2016) har utvikla sjekklista på bakgrunn så sjølv om det ikkje er gjort greie for alle kategoriar kan det vere at dei oppfyller kriteriene.

BFI har gode psykometriske eigenskapar i henhold til tradisjonell testteori som gjer det godt eigna til å måle fatigue. FA har har litt svakare verdiar og ein tak/golv problematikk som kan verke inn på måling av fatigue hjå lungekreftkirurgipasientar og er kanskje derfor ikkje like godt eigna til å måle fatigue hjå desse pasientane.

6 AVSLUTNING

6.1 Kritikk av metodeval og val av instrument

Psykometriske eigenskapar er svært avhengige av design og metodeval i valideringsstudien. Derfor blir validering av eit instrument også ei form for validering av designet på valideringsstudien, og ikkje berre den reelle validiteten. Fråvære av bevis for psykometriske eigenskapar, enten det kjem av at dataene ikkje er rapportert, at metodevalet var dårleg eller ikkje forstått, må ikkje forvekslast med bevis for at dei ikkje er tilstade.

Ein av svakheitene i denne oppgåva er at enkelte tilfelle kan det nok stillast spørsmål om eit valideringskriterie var utydeleg framstilt, eller om underteikna ikkje forstod det som stod i den enkelte artikkelen. Bruk av ulike omgrep er forvirrande og komplisert for ein nybegynnar. Det som innimellom også har vore vanskeleg, og der eg har vore usikker på eigne vurderingar, er i skildringa av framgangsmåten for ein test. Er det utydeleg framstilt kva som skal testast eller er det berre vanskeleg å forstå? Det er også vanskeleg å tyde enkelte testsvar, er dette verkeleg bra eller er det noko som ikkje blir sagt her?
Eg kunne nok ha brukt litt meir tid når eg valde kva for instrument eg ønskte å vurdere. Det hadde kanskje blitt meir interessant å også valgt eit multidimensjonalt skjema, i staden for to unidimensjonale skjema.

6.2 Perspektiv

Det har vore lærerikt å setje seg inn i validering av instrument og psykometriske eigenskapar. Det ligg mange val og beslutningar bak utviklinga av eit instrument. Det presiserar og understrekar at statistikk og kvantitative data også kan tolkast på ulike måtar og at dei ikkje er så objektive som ein kanskje trur. Derfor er dette viktig kunnskap for ein sjukepleiar som ønsker å påverke praksis og utgjere ein skilnad for pasientane og deira meistring av kvardagen.

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VEDLEGG/ APPENDIX

Vedlegg 1

LUNG CANCER

An International Journal for Lung Cancer and other Thoracic Malignancies

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PREPARATION
Use of word processing software
It is important that the file be saved in the native format of the word processor used. The text should be in single-column format. Keep the layout of the text as simple as possible. Most formatting codes will be removed and replaced on processing the article. In particular, do not use the word processor's options to justify text or to hyphenate words. However, do use bold face, italics, subscripts, superscripts etc. When preparing tables, if you are using a table grid, use only one grid for each individual table and not a grid for each row. If no grid is used, use tabs, not spaces, to align columns. The electronic text should be prepared in a way very similar to that of conventional manuscripts (see

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To avoid unnecessary errors you are strongly advised to use the 'spell-check' and 'grammar-check' functions of your word processor.

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Please note that it is expected that the word count of original research articles will be no more than 3500 words (excluding Abstract, Tables, Figures and References). Papers which are longer than 3500 words will be returned to the Author. Short communications will have a word count of 1500 and a limit of 2 figures.

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Divide your article into clearly defined and numbered sections. Subsections should be numbered 1.1 (then 1.1.1, 1.1.2, ...), 1.2, etc. (the abstract is not included in section numbering). Use this numbering also for internal cross-referencing: do not just refer to 'the text'. Any subsection may be given a brief heading. Each heading should appear on its own separate line.

Introduction
State the objectives of the work and provide an adequate background, avoiding a detailed literature survey or a summary of the results.

Material and methods
Provide sufficient detail to allow the work to be reproduced. Methods already published should be indicated by a reference: only relevant modifications should be described.

Results
Results should be clear and concise.

Discussion
This should explore the significance of the results of the work, not repeat them. A combined Results and Discussion section is often appropriate. Avoid extensive citations and discussion of published literature.

Conclusions
The main conclusions of the study may be presented in a short Conclusions section, which may stand alone or form a subsection of a Discussion or Results and Discussion section.

Appendices
If there is more than one appendix, they should be identified as A, B, etc. Formulae and equations in appendices should be given separate numbering: Eq. (A.1), Eq. (A.2), etc.; in a subsequent appendix, Eq. (B.1) and so on. Similarly for tables and figures: Table A.1; Fig. A.1, etc.

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• ***Title.*** Concise and informative. Titles are often used in information-retrieval systems. Avoid abbreviations and formulae where possible.
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Abstract

A concise and factual abstract of no more than 300 words is required. The abstract must be structured for original research articles and should be divided by subheadings as follows: Objectives, Materials and Methods, Results and Conclusion. An abstract is often presented separately from the article, so it must be able to stand alone. The abstract should not be structured for review articles. For this

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Immediately after the abstract, provide a maximum of 6 keywords, using American spelling and avoiding general and plural terms and multiple concepts (avoid, for example, 'and', 'of'). Be sparing with abbreviations: only abbreviations firmly established in the field may be eligible. These keywords will be used for indexing purposes.

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List funding sources in this standard way to facilitate compliance to funder's requirements:

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Text: Indicate references by number(s) in square brackets in line with the text. The actual authors can be referred to, but the reference number(s) must always be given.
Example: '..... as demonstrated [3,6]. Barnaby and Jones [8] obtained a different result ....'
List: Number the references (numbers in square brackets) in the list in the order in which they appear in the text.
Examples:
Reference to a journal publication:

[1] J. van der Geer, J.A.J. Hanraads, R.A. Lupton, The art of writing a scientific article, J. Sci. Commun. 163 (2010) 51–59.
Reference to a book:
[2] W. Strunk Jr., E.B. White, The Elements of Style, fourth ed., Longman, New York, 2000.
Reference to a chapter in an edited book:
[3] G.R. Mettam, L.B. Adams, How to prepare an electronic version of your article, in: B.S. Jones, R.Z. Smith (Eds.), Introduction to the Electronic Age, E-Publishing Inc., New York, 2009, pp. 281–304.
Reference to a website:
[4] Cancer Research UK, Cancer statistics reports for the UK. http://www.cancerresearchuk.org/aboutcancer/statistics/cancerstatsreport/, 2003 (accessed 13.03.03).
Reference to a dataset:
[dataset] [5] M. Oguro, S. Imahiro, S. Saito, T. Nakashizuka, Mortality data for Japanese oak wilt disease and surrounding forest compositions, Mendeley Data, v1, 2015. https://doi.org/10.17632/xwj98nb39r.1.

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Vedlegg 2

REK
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Region:	Saksbehandler:	Telefon:	Vår dato:	Vår referanse:
REK sør-øst	Mariann Glenna Davidsen	22845526	08.03.2017	2010/1508/REK sør-øst B
			Deres dato:	**Deres referanse:**
			01.03.2017	

Vår referanse må oppgis ved alle henvendelser

Tone Rustøen
Ullevål sykehus

2010/1508 Rehabilitering etter lungekreftoperasjon

Forskningsansvarlig: Oslo Universitetssykehus
Prosjektleder: Tone Rustøen

Vi viser til søknad om prosjektendring datert 01.03.2017 for ovennevnte forskningsprosjekt. Søknaden er behandlet av leder for REK sør-øst på fullmakt, med hjemmel i helseforskningsloven § 11.

De omsøkte endringene er beskrevet i skjema for prosjektendringer og gjengis her:

Nye prosjektmedarbeidere, som skal bruke data tilhørende studien til å skrive blant annet masteroppgaver:

Torhild Skarsvaag, Masterstudent, NTNU
Therese Hugøy, masterstudent, UIO
Kristin Kyte, Høgskolelektor, VID vitenskapelige høgskole

1. Torhild Skarsvaag er masterstudent ved NTNU. Problemstilling er: "How is HRQoL affected by preoperative and perioperative predictors 1 year after surgery for lung cancer?"
2. Therese Hugøy masterstuden ved sykepleievitenskal ved UIO. Problemstilling: "Fatigue hjå pasientar med ikkje-småcella lungekreft som har gjennomgått kirurgi. Frekvens, alvorlegheitsgrad og samanhengar fem månader etter operasjonen."
3. Høskolelektor Kristin Kyte ved VID Bergen. Problemstilling: Hvordan opplever pasienten det er å komme hjem etter lungekreftoperasjon.

<u>Gi en begrunnet avveining av fordelene og ulempene ved prosjektendringene.</u>
Det er ønskelig å anvende så mange data som mulig fra studien som skissert i tidligere REK søknad. Alle de tre nevnte vil analysere data i tett samarbeid med Trine Oksholm og undertegnede. Det er fordel at master studenter skriver sin oppgave på allerede innsamlede data. Det vil lette det for pasientene. Det er også veldig tidsbesprende for master studenter

Komiteens vurdering
Komiteen har ingen innvendinger til de omsøkte endringene

Vedtak
Komiteen har vurdert endringsmeldingen og godkjenner prosjektet slik det nå foreligger med hjemmel i helseforskningsloven § 11.

Godkjenningen er gitt under forutsetning av at prosjektet gjennomføres slik det er beskrevet i endringsmeldingen.

Komiteens vedtak kan påklages til Den nasjonale forskningsetiske komité for medisin og helsefag, jf. Forvaltningslovens § 28 flg. Eventuell klage sendes til REK Sør-øst. Klagefristen er tre uker fra mottak av dette brevet.

Vi ber om at alle henvendelser sendes inn via vår saksportal: http://helseforskning.etikkom.no eller på e-post til post@helseforskning.etikkom.no.

Vennligst oppgi vårt referansenummer i korrespondansen.

Med vennlig hilsen

Grete Dyb
professor, dr. med.
leder REK sør-øst B

Mariann Glenna Davidsen
rådgiver

Kopi til:
- Avdelingssjef Geir Godstad, Oslo Universitetssykehus HF
-Oslo Universitetssykehus HF ved øverste adminstrative ledelse

Vedlegg 3

Lungeopererte

”Vi vil vite hvordan du har det”

Spørreskjema til deltagere i studien

Dette er første spørreskjema til deg som har samtykket i å delta studien i studien. Du kan oppleve at noen av spørsmålene overlapper hverandre. Grunnen til dette er at vi bruker standardiserte skjemaer som gjør det mulig å sammenligne resultatene fra denne studien med andre studier. Vi ber deg svare på alle spørsmålene selv om du synes noen av dem ikke passer helt til deg.

Mange takk

Baseline

Registreringsnummer ☐☐☐

Dato for utfylling: ☐☐ ☐☐ ☐☐☐☐

dag måned år

BAKGRUNNSOPPLYSNINGER:

Vennligst sett kryss eller fyll inn det som mangler

1. Kjønn ☐ Mann ☐ Kvinne

2. Når er du født?

☐☐ ☐☐ ☐☐☐☐

dag måned år

3. Sivilstatus

☐ Gift/samboer

☐ Skilt/separert

☐ Ugift

☐ Enke/enkemann

4. Hvordan bor du?

☐ Bor alene

☐ Bor sammen med noen

5. Hvor mange barn har du?

☐☐

6. Hvor mange barn har du daglig omsorg for?

☐☐

7. Hvilken utdanning er den høyeste du har fullført (sett kun ett kryss)

☐ Grunnskole 7-10 (framhaldsskole)

☐ Ett- eller toårig videregående skole, yrkesskole, real- eller middelskole

☐ Artium, økonomisk gymnas, 3 år videregående skole

☐ Universitet og/eller høgskole opptil 4 år

☐ Universitet og/eller høgskole over 4 år

☐ Hvis annet, spesifiser, inkl. antall år

8. Arbeid/studier per dag (sett gjerne flere kryss)

☐ Ja, heltidsarbeid

☐ Ja, deltidsarbeid

☐ Sykemeldt

☐ Helt ☐ Delvis

☐ Uføretrygdet

☐ Alderspensjonert

☐ Arbeidsledig

☐ Annet

SYMPTOMLISTE (MSAS)

Veiledning: Vi har listet opp 32 symptomer nedenfor. Les hvert av dem nøye. Hvis du har hatt symptomet i løpet av siste uken, la oss få vite hvor ofte du hadde det, hvor kraftig det var det meste av tiden, og hvor mye det plaget eller bekymret deg, ved å sette ett kryss i den ruten du synes passer best. Hvis du IKKE HAR HATT symptomet, sett ett kryss i den ruten merket HAR IKKE HATT symptomet.

I løpet av den siste uken: **Har du hatt noen av de følgende symptomene?**	**Har ikke hatt symptomet**	**Hvis JA: Hvor ofte hadde du symptomet?**				**Hvis JA: Hvor kraftig var symptomet, det meste av tiden?**				**Hvis JA: Hvor mye plaget eller bekymret symptomet deg?**				
		Sjelden	Av og til	Ofte	Nesten hele tiden	Svakt	Moderat	Kraftig	Svært kraftig	Ikke i det hele tatt	Litt	En del	Ganske mye	Svært mye
Vanskelig å konsentrere seg	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Smerter	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Har lite energi	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Hoste	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Føler meg nervøs	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Tørr i munnen	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Kvalme	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Søvnig, mye trøtt	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Nummen / prikker i hender / føtter	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Søvnvansker	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Luft i magen / oppblåst	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Problemer med vannlating	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Kaster opp	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Kortpustet	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Diaré	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Føler meg trist	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Svette	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Bekymrer meg	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Problemer med seksuallyst / aktivitet	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

SYMPTOMLISTE (MSAS) - del 2

I løpet av den siste uken: **Har du hatt noen av de følgende symptomene?**	**Har ikke hatt symptomet**	**Hvis JA: Hvor ofte hadde du symptomet?**				**Hvis JA: Hvor kraftig var symptomet, det meste av tiden?**				**Hvis JA: Hvor mye plaget eller bekymret symptomet deg?**				
		Sjelden	Av og til	Ofte	Nesten hele tiden	Svakt	Moderat	Kraftig	Svært kraftig	Ikke i det hele tatt	Litt	En del	Ganske mye	Svært mye
Kløe	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Manglende matlyst	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Svimmel / ør	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Vanskelig å svelge	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Føler meg irritabel	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Sår i munnen	☐					☐	☐	☐	☐	☐	☐	☐	☐	☐
Maten smaker annerledes	☐					☐	☐	☐	☐	☐	☐	☐	☐	☐
Vekttap	☐					☐	☐	☐	☐	☐	☐	☐	☐	☐
Mistet håret	☐					☐	☐	☐	☐	☐	☐	☐	☐	☐
Treg mage / forstoppelse	☐					☐	☐	☐	☐	☐	☐	☐	☐	☐
Hoven i armer og ben	☐					☐	☐	☐	☐	☐	☐	☐	☐	☐
"Jeg ser ikke ut som meg selv lengre"	☐					☐	☐	☐	☐	☐	☐	☐	☐	☐
Forandringer i huden	☐					☐	☐	☐	☐	☐	☐	☐	☐	☐

Hvis du har hatt noen andre symptomer i løpet av den siste uken, vennligst skriv de opp nedenfor, og angi hvor mye det plaget eller bekymret deg.		Ikke i det hele tatt	Litt	En del	Ganske mye	Svært mye
Annet:		☐	☐	☐	☐	☐
Annet:		☐	☐	☐	☐	☐
Annet:		☐	☐	☐	☐	☐

Livskvalitetsskjema (EORTC)

Vi er interessert i forhold vedrørende deg og din helse. Vær vennlig å besvare hvert spørsmål ved å sette et kryss x i den boksen som best beskriver din tilstand. Det er ingen "riktige" eller "gale" svar.

	Ikke i det hele tatt	Litt	En del	Svært mye
1. Har du vanskeligheter med å utføre anstrengende aktiviteter, slik som å bære en tung handlekurv eller en koffert?	☐	☐	☐	☐
2. Har du vanskeligheter med å gå en lang tur?	☐	☐	☐	☐
3. Har du vanskeligheter med å gå en kort tur utendørs?	☐	☐	☐	☐
4. Er du nødt til å ligge til sengs eller sitte i en stol i løpet av dagen?	☐	☐	☐	☐
5. Trenger du hjelp til å spise, kle på deg, vaske deg eller gå på toalettet?	☐	☐	☐	☐

I løpet av den siste uka:	Ikke i det hele tatt	Litt	En del	Svært mye
6. Har du hatt redusert evne til å arbeide eller utføre andre daglige aktiviteter?	☐	☐	☐	☐
7. Har du hatt redusert evne til å utføre dine hobbyer eller andre fritidsaktiviteter?	☐	☐	☐	☐
8. Har du vært tung i pusten?	☐	☐	☐	☐
9. Har du hatt smerter?	☐	☐	☐	☐
10. Har du hatt behov for å hvile?	☐	☐	☐	☐
11. Har du hatt søvnproblemer?	☐	☐	☐	☐
12. Har du følt deg slapp?	☐	☐	☐	☐
13. Har du hatt dårlig matlyst?	☐	☐	☐	☐
14. Har du vært kvalm?	☐	☐	☐	☐

I løpet av den siste uka:	**Ikke i det hele tatt**	**Litt**	**En del**	**Svært mye**
15. Har du kastet opp?	☐	☐	☐	☐
16. Har du hatt treg mage?	☐	☐	☐	☐
17. Har du hatt løs mage?	☐	☐	☐	☐
18. Har du følt deg trett?	☐	☐	☐	☐
19. Har smerter påvirket dine daglige aktiviteter?	☐	☐	☐	☐
20. Har du hatt problemer med å konsentrere deg, f.eks. med å lese en avis eller se på TV?	☐	☐	☐	☐
21. Har du følt deg anspent?	☐	☐	☐	☐
22. Har du vært engstelig?	☐	☐	☐	☐
23. Har du følt deg irritabel?	☐	☐	☐	☐
24. Har du følt deg deprimert?	☐	☐	☐	☐
25. Har du hatt problemer med å huske ting?	☐	☐	☐	☐
26. Har din fysiske tilstand eller medisinske behandling påvirket ditt familieliv?	☐	☐	☐	☐
27. Har din fysiske tilstand eller medisinske behandling påvirket dine sosiale aktiviteter?	☐	☐	☐	☐
28. Har din fysiske tilstand eller medisinske behandling gitt deg økonomiske problemer?	☐	☐	☐	☐

Som svar på de neste spørsmålene, sett et kryss i den ruten som best beskriver din tilstand.

29. Hvordan har din helse vært i løpet av den siste uka?

☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7

Svært dårlig **Helt utmerket**

30. Hvordan har livskvaliteten din vært i løpet av den siste uka?

☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7

Svært dårlig **Helt utmerket**

EORTC QLQ - LC13

Endel pasienter opplever av og til at har noen av følgende symptomer eller problemer. Vær vennlig å angi i hvilken grad du har hatt disse symptomene eller problemene i løpet av den siste uka.

I løpet av den siste uka:	**Ikke I det hele tatt**	**Litt**	**Endel**	**Svært mye**
31. Hvor mye har du hostet ?	☐	☐	☐	☐
32. Har du hostet blod ?	☐	☐	☐	☐
33. Har du vært tungpustet i hvile ?	☐	☐	☐	☐
34. Har du vært tungpustet når du har gått ?	☐	☐	☐	☐
35. Har du vært tungpustet når du har gått i trapper ?	☐	☐	☐	☐
36. Har du vært sår i munnen eller på tungen ?	☐	☐	☐	☐
37. Har du hatt svelgproblemer ?	☐	☐	☐	☐
38. Har du hatt prikkinget (stikninger) i hendene eller i bena ?	☐	☐	☐	☐
39. Har du hatt håravfall ?	☐	☐	☐	☐
40. Har du hatt smerter i brystet ?	☐	☐	☐	☐
41. Har du hatt smerter i arm eller skulder ?	☐	☐	☐	☐
42. Har du hatt smerter i andre deler av kroppen ?	☐	☐	☐	☐

Hvis ja, hvor har du hatt vondt ? _____

43. Har du brukt smertestillende medisiner ?

1. Nei ☐ **2. Ja** ☐

Hvis Ja, hvor mye har det hjulpet ?	☐	☐	☐	☐

TRETTHET (LFS)

Vi ønsker å vite mer om energinivået ditt. Nedenfor er det 18 utsagn vi ber deg svare på.

INSTRUKSJONER: For hvert utsagn nedenfor - Sett ett kryss i den ruten som best indikerer hvordan du føler deg akkurat nå.

1.												
Ikke sliten i det hele tatt	**0** ☐	**1** ☐	**2** ☐	**3** ☐	**4** ☐	**5** ☐	**6** ☐	**7** ☐	**8** ☐	**9** ☐	**10** ☐	**Svært sliten**
2.												
Ikke trøtt i det hele tatt	**0** ☐	**1** ☐	**2** ☐	**3** ☐	**4** ☐	**5** ☐	**6** ☐	**7** ☐	**8** ☐	**9** ☐	**10** ☐	**Svært trøtt**
3.												
Ikke døsig i det hele tatt	**0** ☐	**1** ☐	**2** ☐	**3** ☐	**4** ☐	**5** ☐	**6** ☐	**7** ☐	**8** ☐	**9** ☐	**10** ☐	**Svært døsig**
4.												
Ikke utmattet i det hele tatt	**0** ☐	**1** ☐	**2** ☐	**3** ☐	**4** ☐	**5** ☐	**6** ☐	**7** ☐	**8** ☐	**9** ☐	**10** ☐	**Svært utmattet**
5.												
Ikke utslitt i det hele tatt	**0** ☐	**1** ☐	**2** ☐	**3** ☐	**4** ☐	**5** ☐	**6** ☐	**7** ☐	**8** ☐	**9** ☐	**10** ☐	**Svært utslitt**
6.												
Ikke energisk i det hele tatt	**0** ☐	**1** ☐	**2** ☐	**3** ☐	**4** ☐	**5** ☐	**6** ☐	**7** ☐	**8** ☐	**9** ☐	**10** ☐	**Svært energisk**
7.												
Ikke aktiv i det hele tatt	**0** ☐	**1** ☐	**2** ☐	**3** ☐	**4** ☐	**5** ☐	**6** ☐	**7** ☐	**8** ☐	**9** ☐	**10** ☐	**Svært aktiv**
8.												
Ikke sprek i det hele tatt	**0** ☐	**1** ☐	**2** ☐	**3** ☐	**4** ☐	**5** ☐	**6** ☐	**7** ☐	**8** ☐	**9** ☐	**10** ☐	**Svært sprek**
9.												
Ikke effektiv i det hele tatt	**0** ☐	**1** ☐	**2** ☐	**3** ☐	**4** ☐	**5** ☐	**6** ☐	**7** ☐	**8** ☐	**9** ☐	**10** ☐	**Svært effektiv**

10

	0	1	2	3	4	5	6	7	8	9	10	
Ikke livlig i det hele tatt	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	**Svært livlig**

11.

	0	1	2	3	4	5	6	7	8	9	10	
Ikke utkjørt i det hele tatt	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	**Svært utkjørt**

12.

	0	1	2	3	4	5	6	7	8	9	10	
Ikke utslått i det hele tatt	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	**Svært utslått**

13.

	0	1	2	3	4	5	6	7	8	9	10	
Å holde øynene åpne er ikke anstrengende i det hele tatt	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	**Å holde øynene åpne er veldig anstrengende**

14.

	0	1	2	3	4	5	6	7	8	9	10	
Å bevege kroppen er ikke anstrengende i det hele tatt	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	**Å bevege kroppen er veldig anstrengende**

15.

	0	1	2	3	4	5	6	7	8	9	10	
Å konsentrere seg er ikke anstrengende i det hele tatt	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	**Å konsentrere seg er veldig anstrengende**

16.

	0	1	2	3	4	5	6	7	8	9	10	
Å holde i gang en samtale er ikke anstrengende i det hele tatt	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	**Å holde i gang en samtale er veldig anstrengende**

17.

	0	1	2	3	4	5	6	7	8	9	10	
Jeg har absolutt ikke noe behov for å lukke øynene	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	**Jeg har et veldig sterkt behov for å lukke øynene**

18.

	0	1	2	3	4	5	6	7	8	9	10	
Jeg har absolutt ikke noe behov for å legge meg nedpå	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	**Jeg har et veldig sterkt behov for å legge meg nedpå**

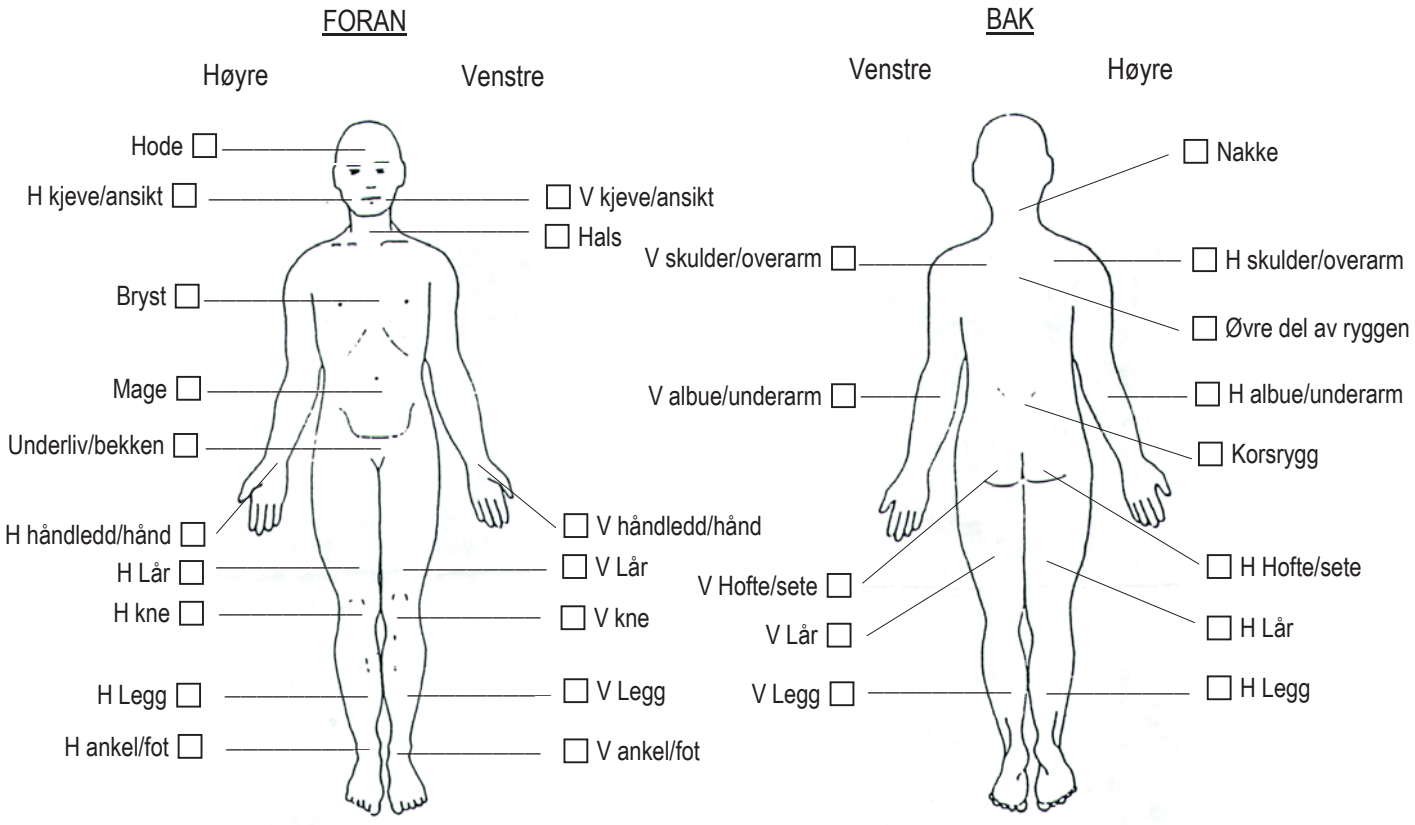
SMERTER (BPI)

1. Gjennom livet har de fleste av oss hatt smerter (som lett hodepine, forstuelser eller tannpine).

Har du i dag smerter av et annet slag enn slike dagligdagse smerter?

☐ Ja ☐ Nei **Hvis NEI, gå til side 14**

2. Dersom du har hatt smerter den siste uken, hvor har du hatt disse plagene?
Vennligst sett et eller flere kryss.



3. Vennligst sett ett kryss i den ruten som best beskriver de sterkeste smertene du har hatt i løpet av de siste 24 timer.

Ingen smerter	0	1	2	3	4	5	6	7	8	9	10	Verst tenkelige smerter
	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	

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4. Vennligst sett ett kryss i den ruten som best beskriver de svakeste smertene du har hatt i løpet av de siste 24 timer.

Ingen smerter	0	1	2	3	4	5	6	7	8	9	10	Verst tenkelige smerter
	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	

---

5. Vennligst sett ett kryss i den ruten som best angir hvor sterke smerter du har i gjennomsnitt.

Ingen smerter	0	1	2	3	4	5	6	7	8	9	10	Verst tenkelige smerter
	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	

---

6. Vennligst sett ett kryss i den ruten som best angir hvor sterke smerter du har akkurat nå.

Ingen smerter	0	1	2	3	4	5	6	7	8	9	10	Verst tenkelige smerter
	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	

---

7. Hvilken behandling eller medisiner får du for å lindre smertene dine?

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8. I hvor stor grad har behandling eller medisiner lindret smertene dine de siste 24 timene? Vennligst sett ett kryss i den ruten med prosenttallet som viser hvor stor smertelindring du har fått.

Ingen lindring	0%	10%	20%	30%	40%	50%	60%	70%	80%	90%	100%	Fullstendig lindring
	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	

Sett ett kryss i den ruten som for de siste 24 timene best beskriver hvor mye smertene har virket inn på:

9. Daglig aktivitet

Ikke påvirket	0	1	2	3	4	5	6	7	8	9	10	Fullstendig påvirket
	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	

10. Humør

Ikke påvirket	0	1	2	3	4	5	6	7	8	9	10	Fullstendig påvirket
	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	

11. Evne til å gå

Ikke påvirket	0	1	2	3	4	5	6	7	8	9	10	Fullstendig påvirket
	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	

12. Vanlig arbeid (gjelder både arbeid utenfor hjemmet og husarbeid)

Ikke påvirket	0	1	2	3	4	5	6	7	8	9	10	Fullstendig påvirket
	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	

13. Forhold til andre mennesker

Ikke påvirket	0	1	2	3	4	5	6	7	8	9	10	Fullstendig påvirket
	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	

14. Søvn

Ikke påvirket	0	1	2	3	4	5	6	7	8	9	10	Fullstendig påvirket
	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	

15. Livsglede

Ikke påvirket	0	1	2	3	4	5	6	7	8	9	10	Fullstendig påvirket
	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	

SØVNPROBLEMER (GSDS)

Tenk tilbake på den siste uken. Hvor mange dager har du: *(sett ett kryss i den aktuelle ruten)*

	Aldri						Hver dag
1. Hatt problemer med å sovne	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐	6 ☐	7 ☐
2. Våknet i løpet av søvnperioden	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐	6 ☐	7 ☐
3. Våknet for tidlig og fikk ikke til å sovne igjen	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐	6 ☐	7 ☐
4. Følt deg uthvilt når du våkner på slutten av en søvnperiode	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐	6 ☐	7 ☐
5. Sovet dårlig	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐	6 ☐	7 ☐
6. Følt deg søvnig i løpet av dagen	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐	6 ☐	7 ☐
7. Kjempet for å holde deg våken gjennom dagen	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐	6 ☐	7 ☐
8. Følt deg irritabel i løpet av dagen	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐	6 ☐	7 ☐
9. Følt deg trøtt eller utmattet i løpet av dagen	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐	6 ☐	7 ☐
10. Følt deg tilfreds med søvnkvaliteten	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐	6 ☐	7 ☐
11. Følt deg våken og energisk gjennom dagen	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐	6 ☐	7 ☐
12. Fått for mye søvn	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐	6 ☐	7 ☐
13. Fått for lite søvn	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐	6 ☐	7 ☐
14. Tatt en blund til planlagt tid	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐	6 ☐	7 ☐
15. Sovnet uten at det var planlagt	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐	6 ☐	7 ☐
16. Drukket alkohol for å få til å sovne	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐	6 ☐	7 ☐
17. Brukt tobakk for å få til å sovne	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐	6 ☐	7 ☐
18. Brukt andre stimuli for å sovne (f.eks: avslapping, musikk, lesing)	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐	6 ☐	7 ☐
19. Brukt naturmedisinske midler for å sovne	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐	6 ☐	7 ☐
20. Brukt reseptbelagt sovemedisin for å få til å sovne	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐	6 ☐	7 ☐
21. Brukt Paracet eller annet smertestillende for å sove	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐	6 ☐	7 ☐

ANGST (STAI Y-2)

Nedenfor finner du en rekke setninger som ofte brukes for å beskrive hvordan en føler seg i alminnelighet. Les hver setning og sett ett kryss i den ruten som passer best med hvordan du vanligvis har det. Det finnes ikke riktige eller gale svar. Ikke tenk for lenge på hver setning, men svar umiddelbart slik som du synes passer best med hvordan du har det til vanlig.

		Nesten aldri	Noen ganger	Ofte	Nesten alltid
1.	Jeg føler meg vel	1 ☐	2 ☐	3 ☐	4 ☐
2.	Jeg føler med nervøs og rastløs	1 ☐	2 ☐	3 ☐	4 ☐
3.	Jeg er tilfreds med meg selv	1 ☐	2 ☐	3 ☐	4 ☐
4.	Jeg skulle ønske jeg var like lykkelig som andre synes å være	1 ☐	2 ☐	3 ☐	4 ☐
5.	Jeg føler meg mislykket	1 ☐	2 ☐	3 ☐	4 ☐
6.	Jeg føler meg uthvilt	1 ☐	2 ☐	3 ☐	4 ☐
7.	Jeg er rolig og avbalansert	1 ☐	2 ☐	3 ☐	4 ☐
8.	Jeg føler at vanskelighetene hoper seg opp, slik at jeg ikke kan løse dem	1 ☐	2 ☐	3 ☐	4 ☐
9.	Jeg engster meg for mye over småting	1 ☐	2 ☐	3 ☐	4 ☐
10.	Jeg er lykkelig	1 ☐	2 ☐	3 ☐	4 ☐
11.	Jeg har urovekkende tanker	1 ☐	2 ☐	3 ☐	4 ☐
12.	Jeg mangler selvtillit	1 ☐	2 ☐	3 ☐	4 ☐
13.	Jeg føler meg trygg	1 ☐	2 ☐	3 ☐	4 ☐
14.	Jeg tar avgjørelser lett	1 ☐	2 ☐	3 ☐	4 ☐
15.	Jeg føler meg utilstrekkelig	1 ☐	2 ☐	3 ☐	4 ☐
16.	Jeg er fornøyd og tilfreds	1 ☐	2 ☐	3 ☐	4 ☐
17.	Jeg er plaget av uviktige tanker	1 ☐	2 ☐	3 ☐	4 ☐
18.	Jeg tar skuffelser så hardt at jeg ikke kan kvitte meg med dem	1 ☐	2 ☐	3 ☐	4 ☐
19.	Jeg er en stø og stabil person	1 ☐	2 ☐	3 ☐	4 ☐
20.	Jeg blir nervøs og ute av meg når jeg tenker på mine aktuelle problemer	1 ☐	2 ☐	3 ☐	4 ☐

DEPRESJON (CES-D)

Vennligst sett ett kryss i den ruten som markerer hvor ofte du har følt det slik i løpet av den siste uken.

	Aldri eller nesten aldri (Mindre enn 1 dag i uken)	**Litt av tiden** (1-2 dager i uken)	**En del av tiden** (3-4 dager i uken)	**Hele eller nesten hele tiden** (5-7 dager i uken)
1. Jeg var plaget av ting som vanligvis ikke plager meg	☐	☐	☐	☐
2. Jeg hadde dårlig appetitt	☐	☐	☐	☐
3. Jeg var nedstemt og kunne ikke riste det av meg, til tross for støtte fra familie og venner	☐	☐	☐	☐
4. Jeg følte meg like mye verdt som andre	☐	☐	☐	☐
5. Jeg hadde problemer med å konsentrere meg om det jeg holdt på med	☐	☐	☐	☐
6. Jeg følte meg deprimert	☐	☐	☐	☐
7. Jeg følte at alt var et ork	☐	☐	☐	☐
8. Jeg så lyst på framtiden	☐	☐	☐	☐
9. Jeg tenkte at livet mitt hadde vært mislykket	☐	☐	☐	☐
10. Jeg følte meg engstelig	☐	☐	☐	☐
11. Jeg sov urolig	☐	☐	☐	☐
12. Jeg følte meg lykkelig	☐	☐	☐	☐
13. Jeg var mer taus enn vanlig	☐	☐	☐	☐
14. Jeg følte meg ensom	☐	☐	☐	☐
15. Folk var uvennlige	☐	☐	☐	☐
16. Jeg satte pris på livet	☐	☐	☐	☐
17. Jeg gråt	☐	☐	☐	☐
18. Jeg følte meg trist	☐	☐	☐	☐
19. Jeg følte at folk mislikte meg	☐	☐	☐	☐
20. Jeg var initiativløs	☐	☐	☐	☐

TILLEGGSSYKDOMMER (SCQ-18)

Det følgende er en liste over vanlige medisinske problemer. Sett ett kryss for hvert problem om hvorvidt du har problemet nå (ja eller nei).
Hvis du HAR problemet, så svar på spørsmålene om behandling og aktiviteter til høyre.
Hvis du IKKE HAR problemet, gå videre til neste problem.

	Har du problemet?		**HVIS JA: Får du behandling for det?**		**HVIS JA: Begrenser det dine aktiviteter?**	
1. Hjertesykdom	☐ Ja	☐ Nei	☐ Ja	☐ Nei	☐ Ja	☐ Nei
2. Høyt blodtrykk	☐ Ja	☐ Nei	☐ Ja	☐ Nei	☐ Ja	☐ Nei
3. Andre lungesykd. (KOLS)	☐ Ja	☐ Nei	☐ Ja	☐ Nei	☐ Ja	☐ Nei
4. Diabetes	☐ Ja	☐ Nei	☐ Ja	☐ Nei	☐ Ja	☐ Nei
5. Magesår/magesykdom	☐ Ja	☐ Nei	☐ Ja	☐ Nei	☐ Ja	☐ Nei
6. Tarmsykdom	☐ Ja	☐ Nei	☐ Ja	☐ Nei	☐ Ja	☐ Nei
7. Nyresykdom	☐ Ja	☐ Nei	☐ Ja	☐ Nei	☐ Ja	☐ Nei
8. Leversykdom	☐ Ja	☐ Nei	☐ Ja	☐ Nei	☐ Ja	☐ Nei
9. Anemi eller annen blodsykdom	☐ Ja	☐ Nei	☐ Ja	☐ Nei	☐ Ja	☐ Nei
10. Hodepine	☐ Ja	☐ Nei	☐ Ja	☐ Nei	☐ Ja	☐ Nei
11. Depresjon	☐ Ja	☐ Nei	☐ Ja	☐ Nei	☐ Ja	☐ Nei
12. Slitasjegikt/artrose	☐ Ja	☐ Nei	☐ Ja	☐ Nei	☐ Ja	☐ Nei
13. Rygg/nakkesmerter	☐ Ja	☐ Nei	☐ Ja	☐ Nei	☐ Ja	☐ Nei
14. Leddgikt/revmatoid artritt	☐ Ja	☐ Nei	☐ Ja	☐ Nei	☐ Ja	☐ Nei
15. Sykdom i bindevev eller muskulatur	☐ Ja	☐ Nei	☐ Ja	☐ Nei	☐ Ja	☐ Nei
16. Hudlidelser	☐ Ja	☐ Nei	☐ Ja	☐ Nei	☐ Ja	☐ Nei
17. Andre medisinske problemer (angi)						
			☐ Ja	☐ Nei	☐ Ja	☐ Nei
			☐ Ja	☐ Nei	☐ Ja	☐ Nei
			☐ Ja	☐ Nei	☐ Ja	☐ Nei

Vedlegg 4

Figure 2. Written description of patient reported outcome measure concepts included in checklist

Conceptual Model

1. Has the PRO construct to be measured been specifically defined?
The goal of PRO measures is to measure a construct (i.e., concept). This must be defined clearly before developing the measure. Examples of constructs include intelligence, disability, and anxiety.

2. Has the intended respondent population been described?
The population that is targeted for measurement should be clearly described. An example is a PRO measure trying to evaluate disability in patients with depression.

3. Does the conceptual model address whether a single scale or multiple subscales are expected?
Some measures intend to measure a single concept (i.e., pain) whereas others intend to measure multiple concepts. For example, a PRO measure of intelligence may **expect** *a priori* to have separate subscales measuring 1) emotional, 2) mathematical, and 3) spatial intelligence.

Content Validity

4. Is there evidence that members of the respondent population were involved in the development of the PRO measure?
Participants targeted by the PRO instrument should be intimately involved in its developmental process. This should be explicitly stated in the manuscript. For example, patients with depression should be included and their perspectives incorporated when developing a PRO measure aiming to quantify depression.

5. Is there evidence that content experts were involved in development of the PRO measure?
Input from experts that care for or have specific expertise in the construct area should be included and their perspectives incorporated into the development of the patient reported outcome measure. An example would be psychiatrists who treat patients with depression being involved in the development of PRO measure of depression.

6. Is there a description of the methodology by which items/questions were derived?
It should be explicitly stated how the items or questions were derived. Specifically, this should address how the respondent population and content experts were accessed and ultimately how questions/items in the PRO measure were created from this process. Examples include focus groups and interviews of respondents or content experts.

Reliability

7. Is there evidence that the reliability of the PRO measure was tested (e.g., test-retest, internal consistency)?
It is important that there has been some mention that reliability was tested during the development process. Examples of reliability include test-retest and internal consistency reliability.

8. Are reported indices of reliability adequate (e.g., ideal: r>=0.80; adequate r>=0.70; or lower if justified)?
The authors should provide some quantification of degree of reliability and that documented should meet those thresholds listed or should be otherwise justified.

Construct Validity

9. Is there reported mathematical justification that a single scale or multiple subscales exist in the PRO measure (e.g., factor analysis, item response theory)?
It is important that if authors claim to have multiple subscales in the PRO measure that they empirically demonstrate their existence. For example, if a PRO measure says they have 3 subscales: 1) emotional, 2) physical, 3) functional; then some mathematical principle should be applied to show commonness of items within each subscale and difference from other subscales. Examples of approaches to test for unique scales include factor analysis and item response theory (IRT) techniques.

10. Is the PRO measure intended to measure change over time? If yes, is there evidence of both test-retest reliability and responsiveness to change? Otherwise, award 1 point if there is an explicit statement that PRO measure is NOT intended to measure change over time.

It is important that PRO measures whose goal is to measure change over time show evidence of stability of score when no change is expected. Instability of scores will make identifying "real" from random or "chance" differences difficult. This stability is assessed using test-retest reliability technique. Secondly, evidence is also needed that the PRO measure changed meaningfully in an expected direction after an intervention (responsiveness to change). This can be established using anchor- or distribution-based approaches.

11. Are there findings supporting expected correlations with existing PRO measures or other clinical data?
It is important that the PRO measure scores correlate in an expected way with either an existing PRO measure(s) or clinical data that quantify the same concept (e.g., convergent validity).

12. Are there findings supporting expected differences in scores between known groups?
The PRO measure scores should be able to differentiate respondents who are expected to differ. For example, a measure of depression should be able to identify those with depression compared to those that do not (controls).

Scoring & Interpretation

13. Is there documentation how to score the PRO measure?
There should be a clearly explained scoring approach or algorithm.

14. Has a plan for managing and/or interpreting missing responses been described?
The authors should explain a method to deal with PRO measures that are not fully completed.

15. Is there information provided on how to interpret the PRO measure scores?
It is important that information is available to interpret PRO measure scores. For example, are there thresholds or explanations for what would indicate a mild, moderate, severe degree of the construct being measured?

Respondent Burden & Presentation

16. Is time to complete reported and reasonable? If not, are number of questions appropriate for the intended application?
Authors should indicate and justify the time necessary to complete the PRO measure. Those that do not include this information put the onus on the reviewer to determine whether the burden of time needed to complete the PRO measure is appropriate considering its intended application. For example, those intended for use in a busy clinical setting may need to be shorter than those used purely for research purposes.

17. Is there a description of the literacy level of the PRO measure?
It is important that the PRO measure is written at a level that intended respondents can understand. This should, at a minimum, be described in the manuscript. Most believe that a 6^{th} grade reading level is appropriate, but different education-reading levels may be more appropriate.

18. Is the entire PRO measure available for public viewing?
It is important to be able to access the PRO measure items/questions in order to evaluate the appropriateness of the questions and to assess the applicability for a particular purpose.

Vedlegg 5

Tabell 1 Sjekkliste FA		
	Skåring	Notat
Konseptuell modell		
1. Has the PRO construct to be measured been specifically defined?	0	Ønsker å måle fatigue, men manglar definisjon og dimensjon
2. Has the intended respondent population been described?	1	Kreftpasientar
3. Does the conseptual model address whether a single scale or multiple subscales are expected?	0	
Innhaldsvaliditet		
4. Is there evidence that members of the respondentpopulation were involved in the developement of the PRO measure?	0	Berre via spørjeskjema
5. Is there evidence that content experts were involved in development of the PRO measure?	1	
6. Is there a description of the methodology by which items/questions were derived?	0	Prosessen beskriv livskvalitetskjemaet og presiserae ikkje fatigue
Reliability		
7. Is there evidence that the reliability of the PRO measure was tested(e.g. test-retest, internal concistency?	1	Indre konsistens 0,53-0,64, fysisk funksjon
8. Are reported indicies of reliability of the PRO measure adequate (e.g.: ideal r>=0.80; adequate r>=0.70; or lower if justified)?	1	Samanlikning FA og FQ, 0,67-0,75 fysisk fatigue, 0,49-0,61 mental fatigue
Konstruksjonsvaliditet		
9. Is there reported mathematical justification that a single scale or multiple subscales exists in the PRO measure (e.g., factor analyses, item response theory)?	1	Multitriat scaling analyses
10. Is the PRO measure intended to measure change over time? If yes, is there evidence of bouth test-retest reliability and responsiveness to change? Otherwise, award 1 point if there is an explicit statement that PRO measure is NOT intended to measure change over time.	0	Klarer ikkje å måle responsiveness, forklarar det med heterogen pasientgruppe Tak/golv problem (Knobel)
11. Are there findings supporting expected correlations with existing PRO measures or other clinical data?	1	Korrelerar med fysisk fatigue i FQ (Knobel)
12. Are there findings supporting expected differences in scores between knownn groups?	0	
Skåring & tolking av resultat		
13. Is there documentation how to score the PRO measure?	1	
14. Has a plan for managing and/or interpreting missing responses been described?	0	
15. Is there information provided on how to interpret the PRO measure scores?		
Respondentbyrde & Presentation		
16. Is time to complete reported and reasonable? If not, are numbers of questions appropriate for the intended application?	1	Gjennomsnittleg 12 min
17. Is there a description of the literacy level of the PRO measure?	0	Men oppgir at 10% av respondentane syntest enkelte spørsmål var vanskelege.

Merknad: Skåring 1=kriterie oppfylt, 0=kriterie ikkje oppfylt

Vedlegg 6

Tabell 2 Sjekkliste The Brief Fatigue Inventory		
	Skåring	Notat
Konseptuell modell		
1. Has the PRO construct to be measured been specifically defined?	0	Fatigue, men ikkje med definisjon og dimensjonar
2. Has the intended respondent population been described?	1	
3. Does the conseptual model address whether a single scale or multiple subscales are expected?	1	
Innhaldsvaliditet		
4. Is there evidence that members of the respondentpopulation were involved in the developement of the PRO measure?	0	Gjennom spørjeskjema ja,men ikkje etter dei kriteria sjekklista spør etter.
5. Is there evidence that content experts were involved in development of the PRO measure?	1	Under tvil, ekspertar på kreft og smerter, men ikkje fatigue
6. Is there a description of the methodology by which items/questions were derived?	1	Spørjeskjema for å kartlegge
Reliability		
7. Is there evidence that the reliability of the PRO measure was tested(e.g. test-retest, internal concistency?	1	
8. Are reported indicies of reliability of the PRO measure adequate (e.g.: ideal r>=0.80; adequate r>=0.70; or lower if justified)?	1	
Konstruksjonsvaliditet		
9. Is there reported mathematical justification that a single scale or multiple subscales exists in the PRO measure (e.g., factor analyses, item response theory)?	1	Faktor analyse og prinsipal komponent analyse
10. Is the PRO measure intended to measure change over time? If yes, is there evidence of bouth test-retest reliability and responsiveness to change? Otherwise, award 1 point if there is an explicit statement that PRO measure is NOT intended to measure change over time.	0	
11. Are there findings supporting expected correlations with existing PRO measures or other clinical data?	1	
12. Are there findings supporting expected differences in scores between knownn groups?	1	Pasientar med kreft og frisk kontrollgruppe
Skåring & tolking av resultat		
13. Is there documentation how to score the PRO measure?	1	NRS(numerisk rating skala 0-10) og cut points
14. Has a plan for managing and/or interpreting missing responses been described?	1	
15. Is there information provided on how to interpret the PRO measure scores?	1	Forslag til mild , moderat og alvorleg fatigue
Respondentbyrde & Presentasjon		
16. Is time to complete reported and reasonable? If not, are numbers of questions appropriate for the intended application?	1	
17. Is there a description of the literacy level of the PRO measure?	1	
18. Is the entire PRO measure available for public viewing?	1	

Merknad: Skåring 1=kriterie oppfylt, 0=kriterie ikkje oppfylt

Vedlegg 7

Tabell 3 Reliabilitet og konstruksjonsvaliditet av The Brief Fatigue Inventory			
	Vurdering		
BFI Italia (Gianluca et al., 2012)			
Reliabilitet	1	-Indre konsistens 0,94 -Item total correlasjon 0,66-0,83	
Konstruksjonsvaliditet	1	-Concurrent validitet, SF 36 vitality subscale -Discriminant validitet	
Populasjon		-Blanda kreftpopulasjon, mest hematologi	
BFI Germany(Radbruch et al., 2003)			
Reliabilitet	1	Indre konsistens 0,92	
Konstruksjonsvaliditet	1	-Faktoranalyse, ein dimensjon -Test-retest Pearsons R 0,93-0,75 -Korrelasjonskoefficient 0,611-0,888	
Populasjon		-Smertepasientar, både kreft og ikkje kreft	
BFI Greece(Mystakidou et al., 2008)			
Reliabilitet	1	-Indre konsistens 0,954	
Konstruksjonsvaliditet	1	-Faktor analyse, ein dimensjon -Test-retest, koefficient 0,90 -Korrelerar med EORTC-fatigue	
Populasjon		-Kreft, blanda, palliativ avdeling	
BFI (Shuman-Paretsky et al., 2014)			
Reliabilitet	1	-Indre konsistens, interference 0,87 og severity 0,82 -Item total correlation interference 0,62-0,75, severity 0,58-0,79	
Konstruksjonsvaliditet	1	-Prinsipal komponentanalyse -Faktoranalyse, 2 dimensjonar -Divergent validitet	
Populasjon		-Community-dwelling older adults, over 65	

Merknad: 1=kriterie oppfylt, 0=kriterie ikkje oppfylt, Sjekklista oppgir reliabiltets koefficient på minimum ≥0,70 som akseptable verdiar på gruppenivå og ≥0,90 til 0,95 for individuelle samanlikningar, men dersom det er argumentert godt for verdiar under dette kan det også vere berettiga.