

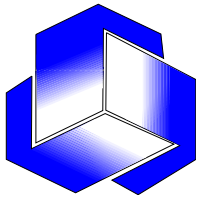
Development of an EORTC Fatigue Module

Phase III results

J. Weis

March 2009

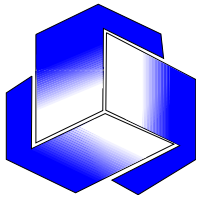
**Project funded by
EORTC QoL Deptm. Brussels and German Fatigue
Association, Cologne**



Phase III Collaborators

Study coordinator: J. Weis

- **Austria**
B. Holzner
- **France**
T. Conroy
- **Germany**
S. Singer, H. Flechtner, C. Fleissner
- **Italy**
F. Efficace
- **Sweden**
E. Hammerlid
- **Spain**
J.I. Arraras
- **UK**
A. Lanceley, T. Swift, L. Jones, A. Griffin,
C. Byrne
- **Data Centre**
A. Bottomley, Brussels
- **Translation Centre**
L. Dewolf, Brussels
- **IRT/DIF Analyses**
M. Wirtz, Freiburg Germany

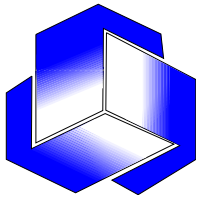


Cancer related fatigue (CRF)

Definition

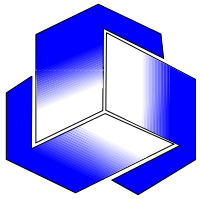
Cancer related fatigue is a distressing persistent subjective sense of physical, emotional and cognitive tiredness or exhaustion related to cancer or cancer treatment that is not proportional to recent activity and interferes with usual functioning

(NCCN Guidelines 2009)



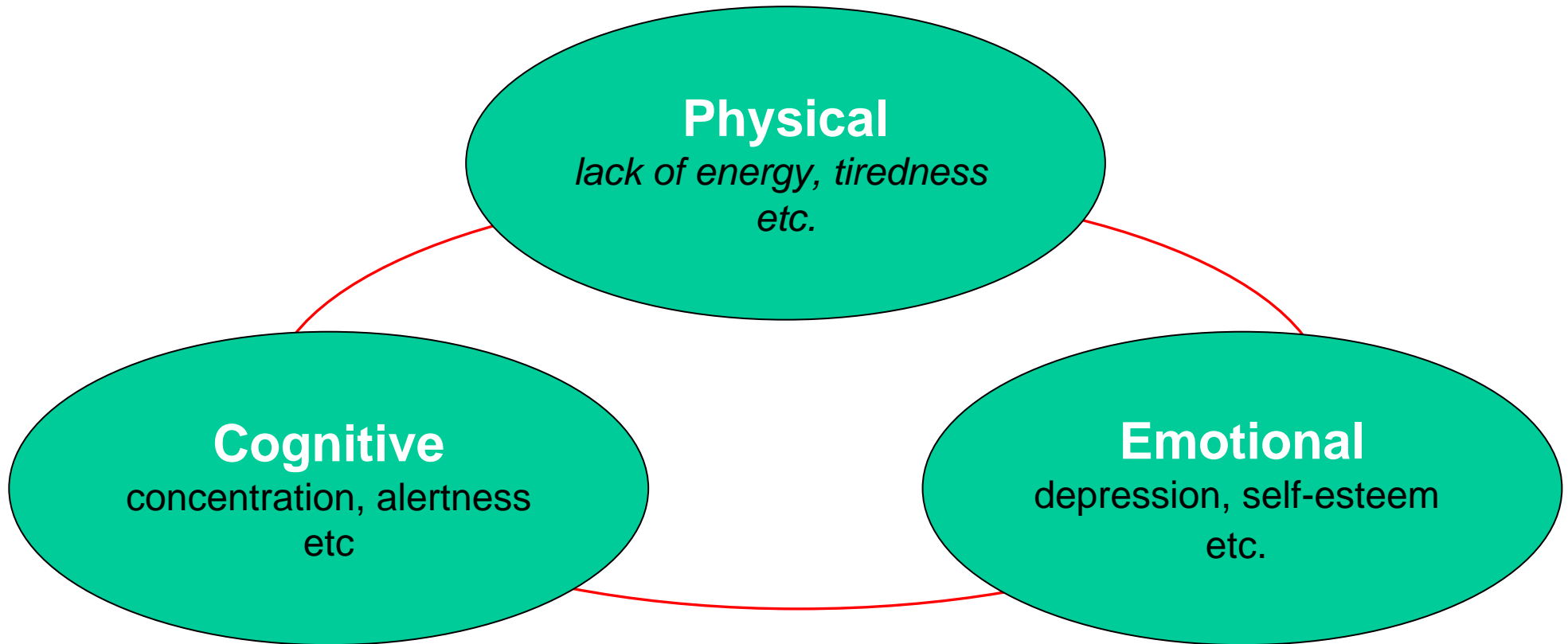
Scientific background

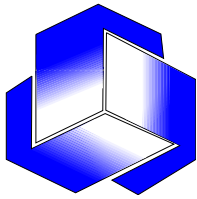
- Increasing rates of publications within the last two decades
- Cancer related fatigue is one of the most common side effects of cancer treatment. Prevalence rates: 59%-96%
- Approximately 70-80% of cancer patients receiving radiation therapy or chemotherapy
- Acute and chronic fatigue
- Fatigue is associated with depression: fatigue = major symptom of depression (psychiatric comorbidity), fatigue may cause reactive depression



Cancer related Fatigue (CRF)

Multidimensional Approach

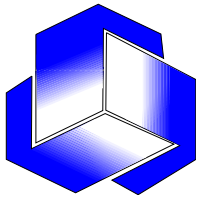




Assessment of CRF

existing measurement tools 1

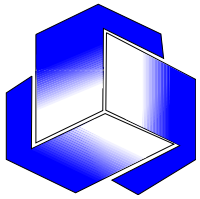
- *Piper Fatigue Scale (PFS)* (Piper et al. 1989; 1999): intensity, interference with activities of daily living. Multidimensional (time, sensoric, affective) , 44 items (revised form 20 items)
- *Multidimensional Fatigue Inventory (MFI)* (Smets et al. 1995): intensity. Multidimensional approach: general fatigue, physical, mental, reduced activity, reduced motivation, 20 items.
- *Functional assessment of cancer therapy fatigue scale /anemia scale (FACT-F/An)* (Cella 1997): Intensity, unidimensional: physical, FACT-F: 13 items, FACT-An: 7 items
- *Fatigue symptom inventory (FSI)* (Hann et al 1998) intensity, duration and interference with ADL, Multidimensional structure



Assessment of CRF

existing measurement tools 2

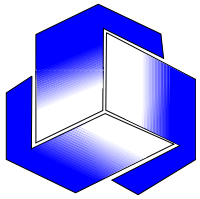
- *Brief Fatigue Inventory (BFI)* (Mendoza et al. 1999): intensity, interference with activities of daily living. Single dimension, 9 items
- *Schwartz Cancer Fatigue Scale (SCFS)* (Schwartz et al. 1999): intensity. Multidimensional: physical, emotional, cognitive, temporal 28 items (short form 6 items).
- *Fatigue Assessment Questionnaire (FAQ)* (Glaus 1998): Intensity, multidimensional: physical, affective, cognitive, 20 items
- *Cancer Fatigue Scale (CFS)* (Okuyama et al. 2000): intensity, multidimensional: physical, affective, cognitive, 15 items.



EORTC Fatigue Module

characteristics

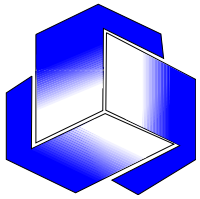
- all treatment areas (chemotherapy, radiatio, surgery, curative vs. palliative care)
- generic (all cancer diagnoses)
- all phases and stages of cancer and its treatment settings (acute, rehab, aftercare, hospice)
- Self-Rating questionnaire
- Multidimensional approach: physical, emotional, cognitive
- Types of scaling (Intensity according to EORTC QLQ C30; interference with ADL)



Fatigue Module Group

Phase I/II 2001-2004

- MEDLINE search from 1994-2000 (key words: cancer related fatigue, assessment)
- 8 fatigue questionnaires (cancer specific) have been identified
- The questionnaires have been reviewed according to criteria (e.g. structure, psychometric characteristics, development, answer format)
- preliminary item list divided in three subdimensions (physical, emotional, cognitive)
- Expert interviews (31 specialists from eight countries)

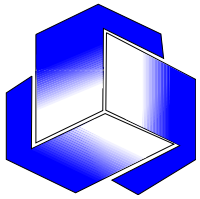


Phase II Results

The preliminary fatigue module phase II (2004) available in two versions:

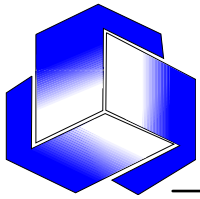
- a version with 15 items (**FA-R15**) to be used in combination with EORTC QLQ C30
- a version with 25 items (**FA25**) to be used without EORTC QLQ C30

The items in both versions are scaled as Likert scales asking for intensity (from 1 = not at all to 4 = very much) according to the QLQ C30. The interference of fatigue with the activities of daily living is measured by one global item at the end of the questionnaire. The FA25 includes 10 QLQ C30 items covering the emotional, physical and cognitive domain of fatigue.



Phase III (2006-2008)

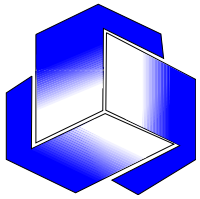
- Focus on **FA-R15** (15 items) to be used in combination with EORTC QLQ C30
- pre-testing of the preliminary module with respect to understanding, comprehensiveness and applicability (EORTC Module Development Guidelines)
- Collaboration with seven European Countries
- Aims:
 - ◆ to identify and solve potential problems in its administration (e.g. phrasing of items, sequence of questions);
 - ◆ to determine the need for additional questions;
 - ◆ to shorten the module as well as avoiding overlapping
 - ◆ to ask for patients priority rating



Phase III Sample characteristics

N=318

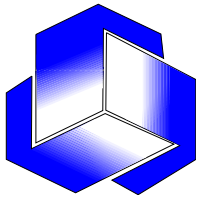
Age		
Mean (SD)	59.6	14.2
Range	18	89
Sex		
	N	%
Female	180	56.6
Male	138	43.3
ECOG Score		
	N	%
0 Fully active	80	25.2
I Restricted	108	34.0
II Self care	84	26.4
III Limited self care	38	11.9
IV Completely disabled	7	2.2
Metastases (only solid tumors)		
	N	%
No	162	50.9
Yes	146	45.9



Type of Care

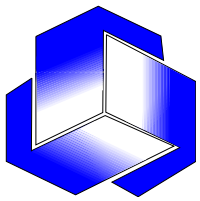
Country of Origin	Acute care (in-, outpatient)	Rehabilitation	Palliative care / Hospice	None	Total
Germany	17	15	12	1*	45
UK	27	0	4	16	47
Austria	15	15	15	0	45
Sweden	15	13	14	3	45
France	16	15	15	0	46
Spain	15	14	16	0	45
Italy	22	15	8	0	45
Total	127	87	84	20	318

* at the moment only diagnostic procedures, palliative radiotherapy 3 weeks ago

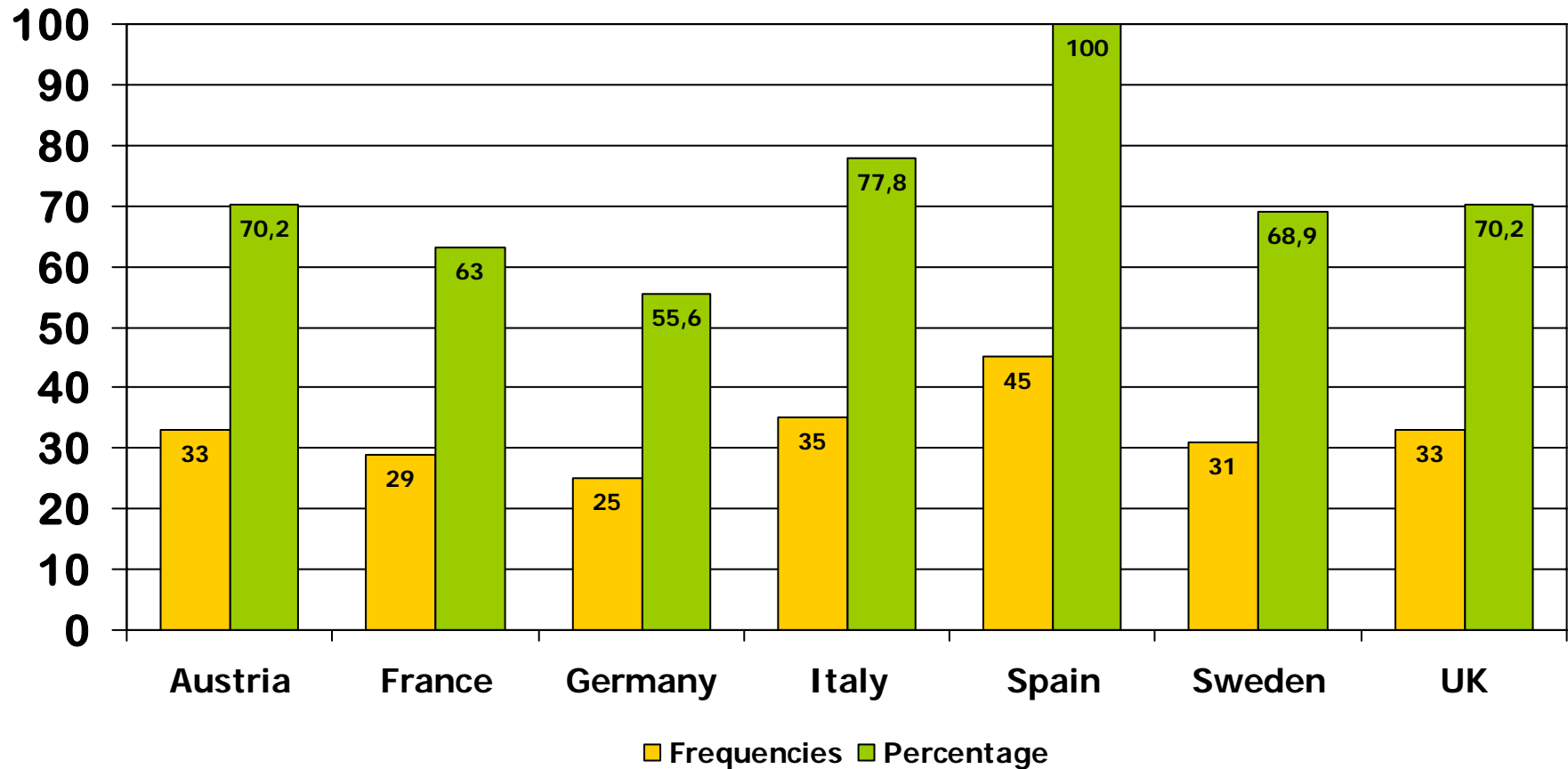


Location of Tumor (n=318)

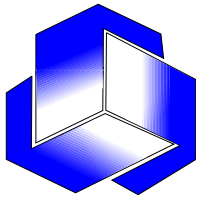
Location of Tumour	Frequency	Percentage
Haematological	73	23.0
Breast	54	17.0
Gynaecological	50	15.7
Head/Neck	29	9.1
Colorectal	27	8.5
Prostate	20	6.3
Lung	18	5.7
Testicular	5	1.6
Pancreatic	5	1.6
Others	30	9.4
Multiple Tumor Locations	7	2.2



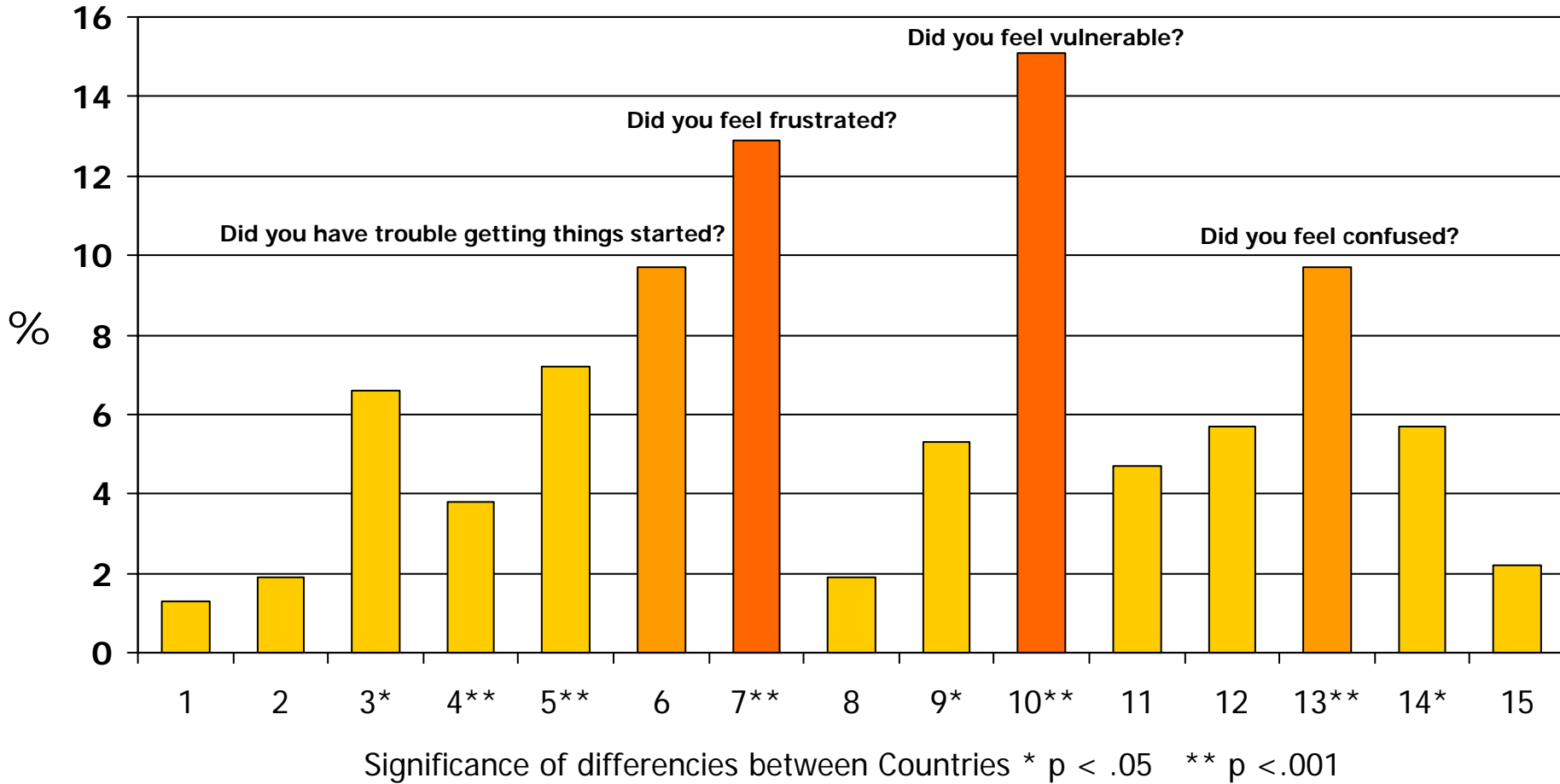
Comments per country

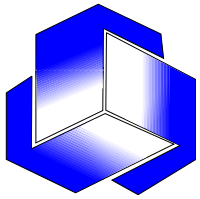


231 Patients gave at least one comment (87 Patients have not commented at all)

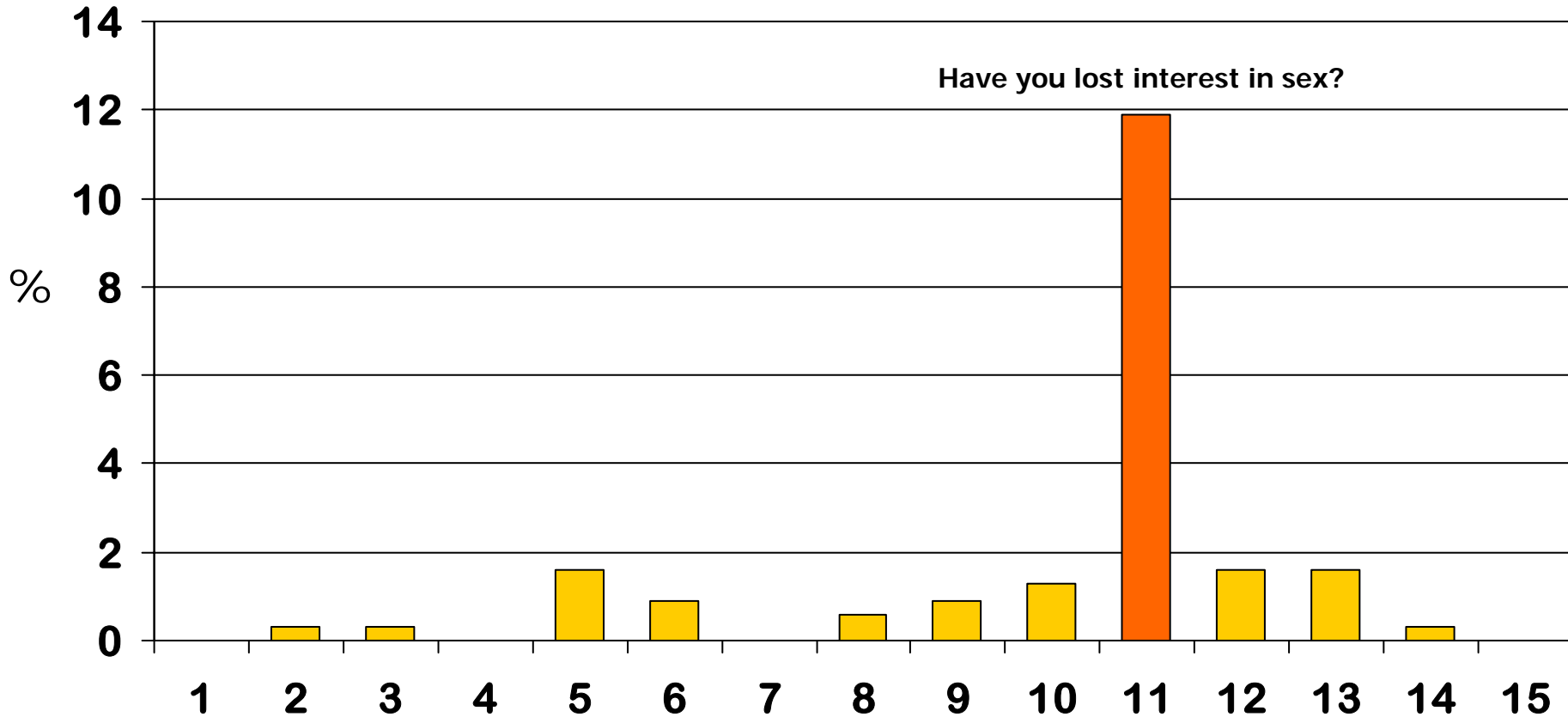


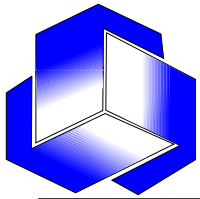
Questions found difficult or confusing





Upsetting/annoying/intrusive

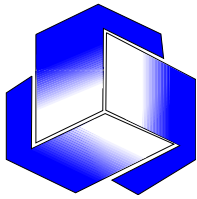




Summary: Interview results

231 Patients gave at least one comment (87 Patients have not commented at all)

% (of 318 Patients)	confusing/ difficult	upsetting/ annoying/ intrusive	both	important	irrelevant
Have you lacked energy?	1.3	-	-	31.8	.6
Have you felt exhausted?	1.9	.3	-	24.5	.6
Have you felt slowed down?	6.6	.3	-	14.2	1.9
Did you feel sleepy during the day?	3.8	-	-	14.8	1.3
Did you feel angry?	7.2	1.6	.6	10.4	7.5
Did you have trouble getting things started?	9.7	.9	.3	16.7	2.2
Did you feel frustrated?	12.9	-	-	10.7	4.1
Did you feel discouraged?	1.9	.6	-	18.6	1.3
Did you feel helpless?	5.3	.9	.3	14.8	3.1
Did you feel vulnerable?	15.1	1.3	.3	9.1	3.5
Have you lost interest in sex?	4.7	11.9	.3	7.2	8.5
Did you have trouble thinking clearly?	5.7	1.6	-	10.7	5.3
Did you feel confused?	9.7	1.6	-	7.5	6.6
Did you have trouble completing things?	5.7	.3	.3	16.7	.9
Did tiredness (or Fatigue) interfere with your daily activities?	2.2	-	-	22.6	.9

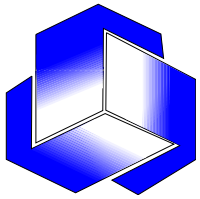


IRT Analysis

confirmatory approach

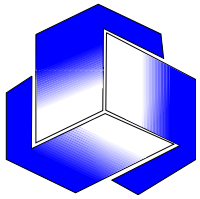
Domain	Item	Measure	Infit		Corr.
			MNSQ	ZSTD	
Physical Fatigue Person Reliability .79 Separation 1.94	4. Did you feel sleepy during the day?	.50	1.13	1.6	.83
	3. Have you felt slowed down?	.22	1.07	.9	.85
	2. Have you felt exhausted?	-.10	.87	-1.6	.89
	1. Have you lacked energy?	-.62	.89	-1.4	.87
Emotional Fatigue Person Reliability .71 Separation 1.55	7. Did you feel frustrated?	.17	.95	-.5	.80
	8. Did you feel discouraged?	.16	.72	-3.5	.82
	9. Did you feel helpless?	.15	.93	-.8	.81
	10. Did you feel vulnerable?	-.04	1.17	1.8	.75
Cognitive Fatigue Person Reliability .5 Separation .99	6. Did you have trouble getting things started?	-.43	1.22	2.4	.76
	13. Did you feel confused?	.85	.92	-.7	.80
	12. Did you have trouble thinking clearly?	-.11	.79	-2.3	.86
	14. Did you have trouble completing things?	-.75	1.28	2.7	.80

Items excluded: lost interest in sex; feeling angry



Revision of FA R15

- **Item 5:** (did you feel angry) deleted based on the results of IRT analyses and the patients comments (unclear meaning in the context of fatigue).
- **Item 8:** (did you feel discouraged) controversially discussed, due to IRT analyses and percentage rates of the patients responses we decided to keep this item.
- **Item 10** (did you feel vulnerable) was deleted due to patients comments and translation problems.
- **Item 11** (have you lost interest in sex) was deleted due to highest percentage of patients responses in both categories (difficulty and annoyance); IRT analyses show that this item does not correspond to the scales.
- **New items** (Item number referring to the new version FA R13).
Item 13: Did you feel that your tiredness is not understood by the people who are close to you ?

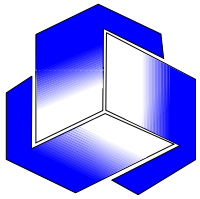


EORTC QLQ-FA-R13 (revised Version Phase III)

Patients sometimes report that they have the following symptoms or problems. Please indicate the extent to which you have experienced these symptoms or problems during the past week. Please answer by circling the number that best applies to you.

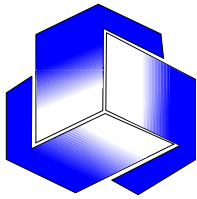
During the past week	Not at all	A little	Quite a bit	Very much
1. Have you lacked energy?	1	2	3	4
2. Have you felt exhausted?	1	2	3	4
3. Have you felt slowed down?	1	2	3	4
4. Did you feel sleepy during the day?	1	2	3	4
5. Did you have trouble getting things started?	1	2	3	4
6. Did you feel discouraged?	1	2	3	4
7. Did you feel helpless?	1	2	3	4
8. Did you feel frustrated	1	2	3	4
9. Did you have trouble thinking clearly?	1	2	3	4
10. Did you feel confused?	1	2	3	4
11. Did you have trouble completing things?	1	2	3	4
12. Did tiredness interfere with your daily activities	1	2	3	4
13. Did you feel that your tiredness is not understood by the people who are close to you ?	1	2	3	4

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References: Fatigue Measurement

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