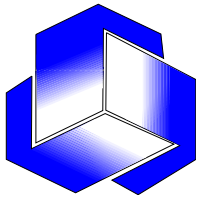


Development of EORTC Fatigue Module Phase III

Final results

March 2008

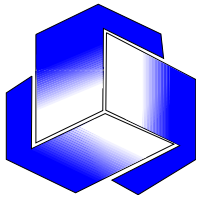
J. Weis, A. Görög



Current Phase III Collaborators

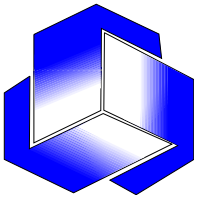
Study coordinator: J. Weis

- **Austria**
B. Holzner
- **France**
T. Conroy
- **Germany**
C. Fleissner, S. Singer, H. Flechtner
- **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



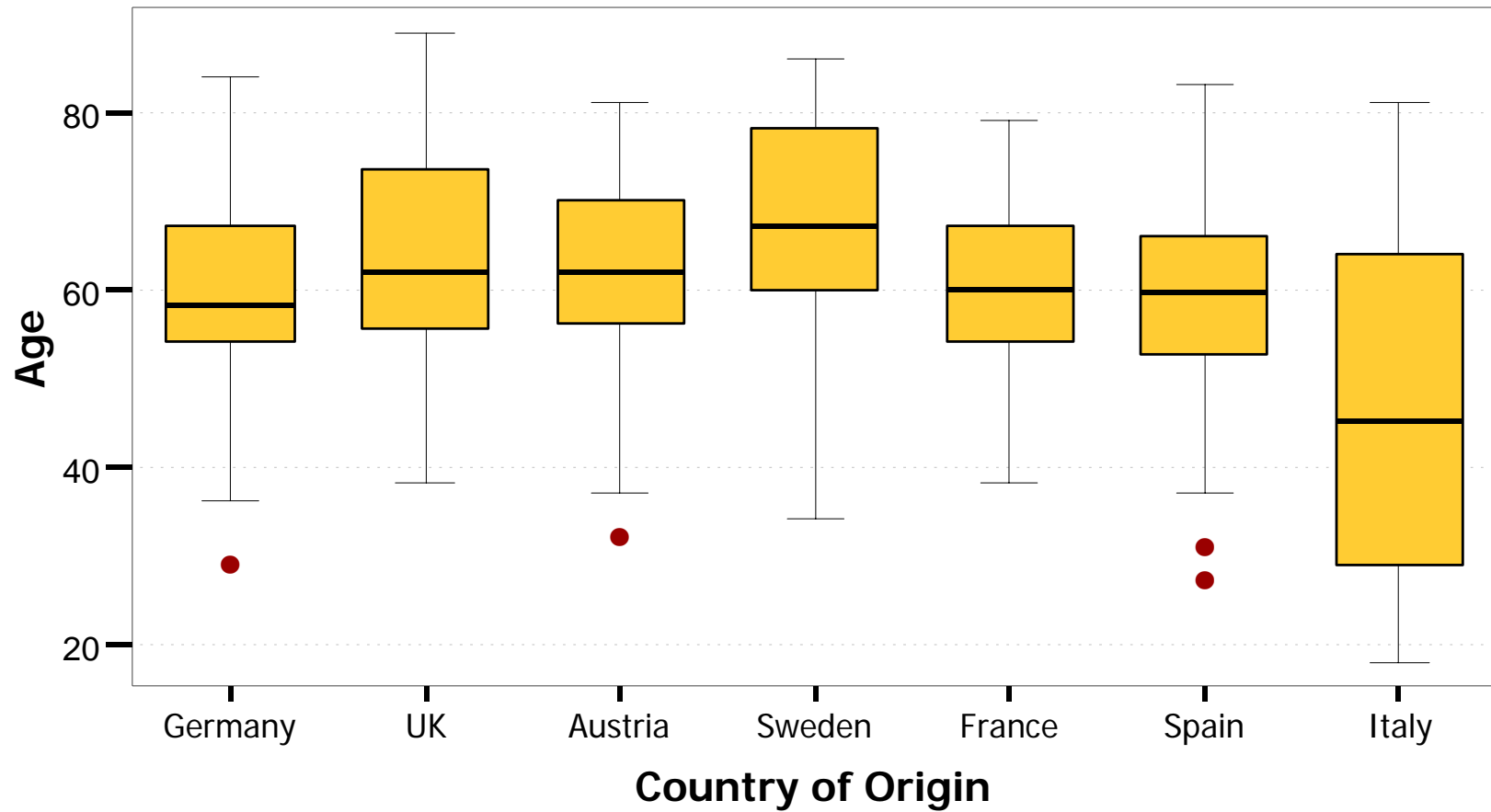
Current State

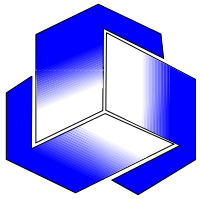
- N=318 completed questionnaires (Dec 2007)
- 1/3 of all quantitative data entered twice – Error Rate ~ 0.8 ‰ (Dec 2007)
- Descriptive analyses (Jan 2008)
- IRT/DIF Analyses (March 2008)



Age

F = 11.3
p = .000

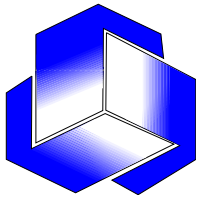




Type of Care

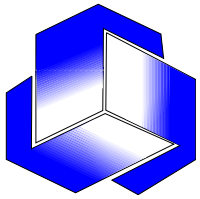
Country of Origin	Acute care (in-, outpatient)	Rehabilitation	Palliative care / Hospice	None	Total
Germany	17	15	12	1*	45
UK	27	0	4	16	47
Austria	15	15	15	0	45
Sweden	15	13	14	3	45
France	16	15	15	0	46
Spain	15	14	16	0	45
Italy	22	15	8	0	45
Total	127	87	84	20	318

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



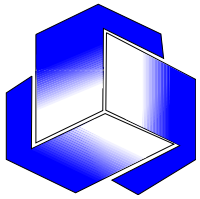
Location of Tumor (n=318)

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

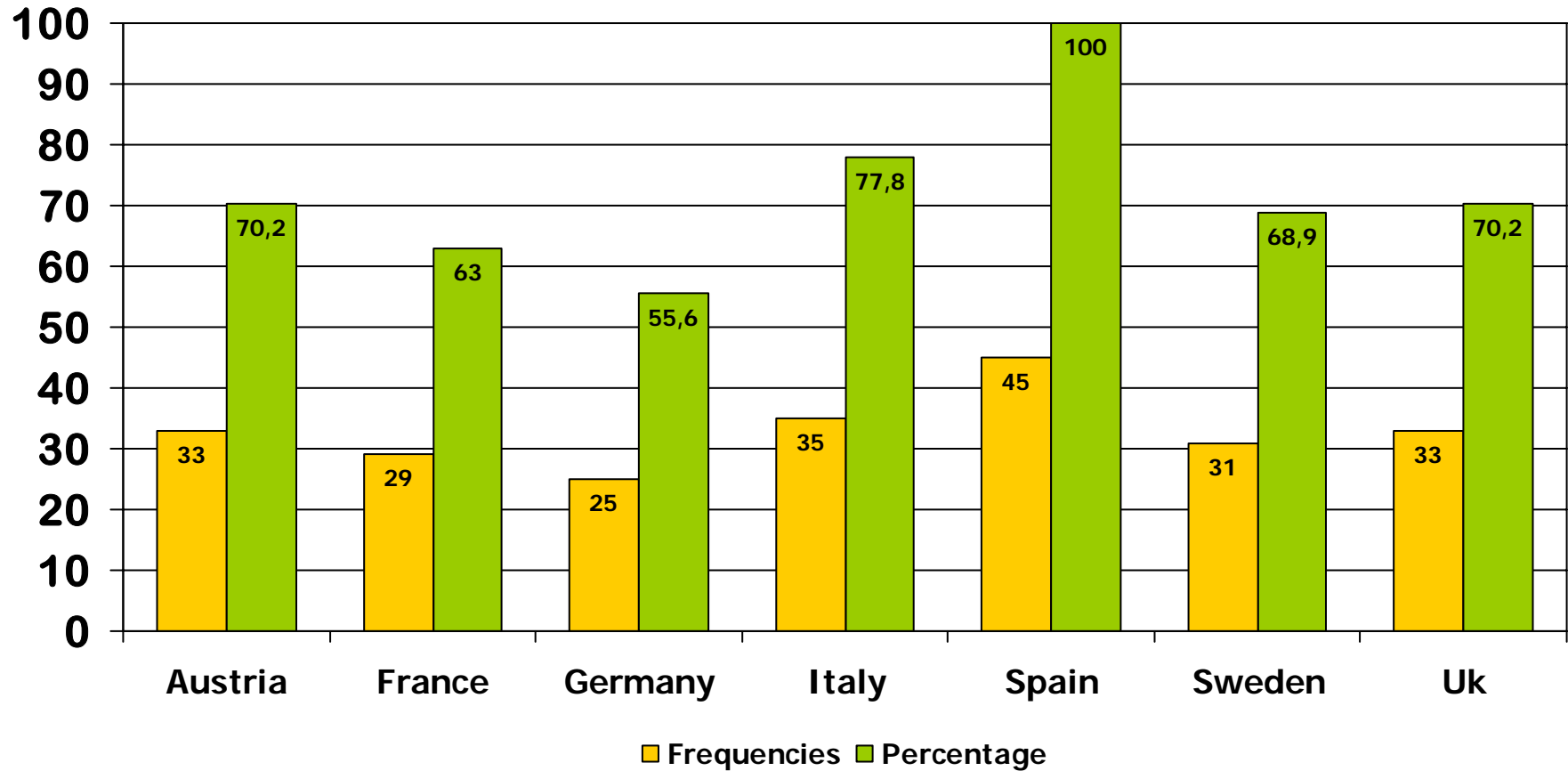


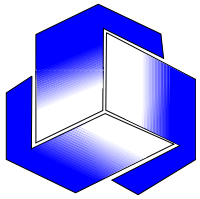
ECOG Score

ECOG Score	Frequency	Percentage
0 Fully active	80	25.2
1 Restricted	108	34.0
2 Selfcare	84	26.4
3 Limited selfcare	38	11.9
4 Completely disabled	7	2.2
Missing	1	.3

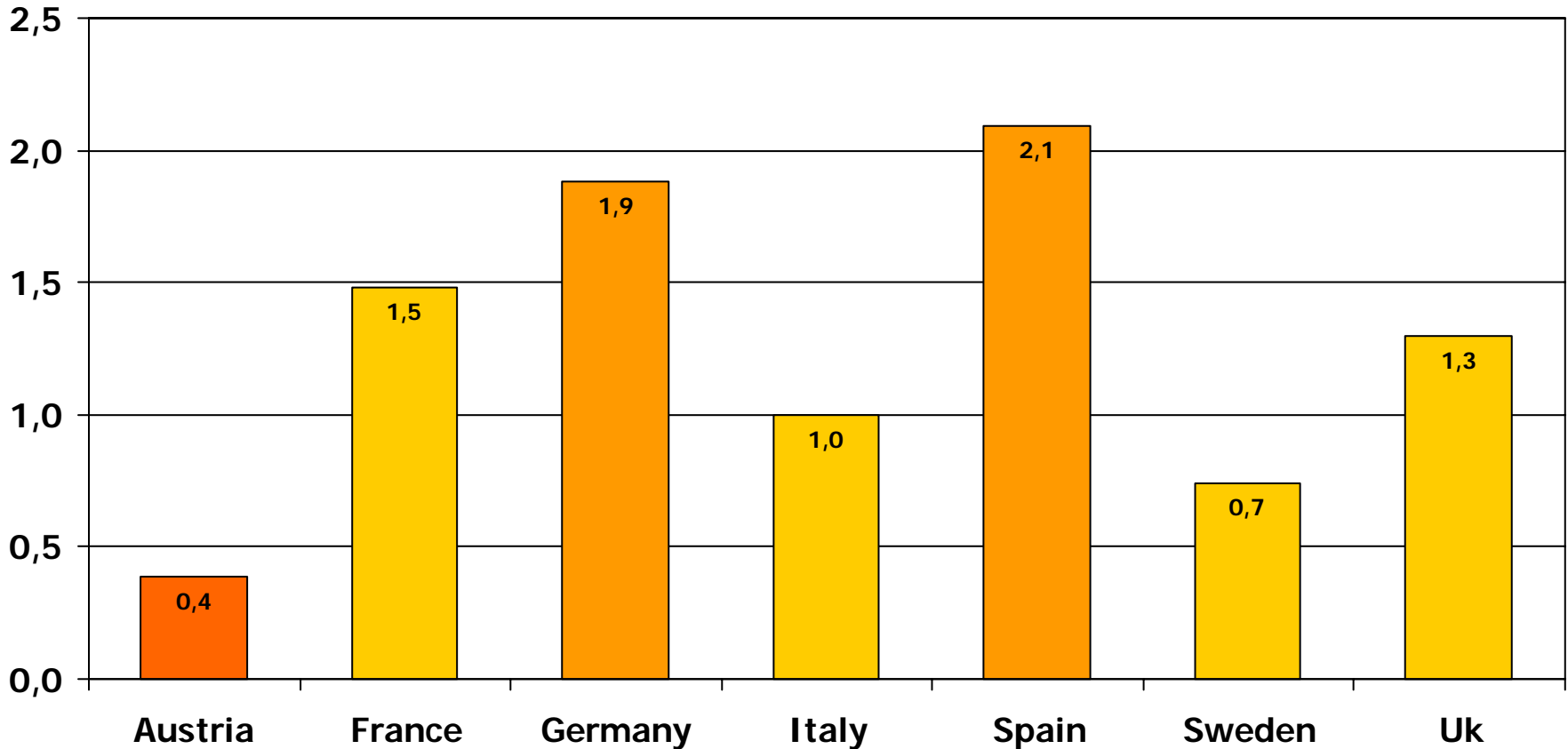


Comments per country

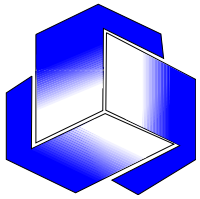




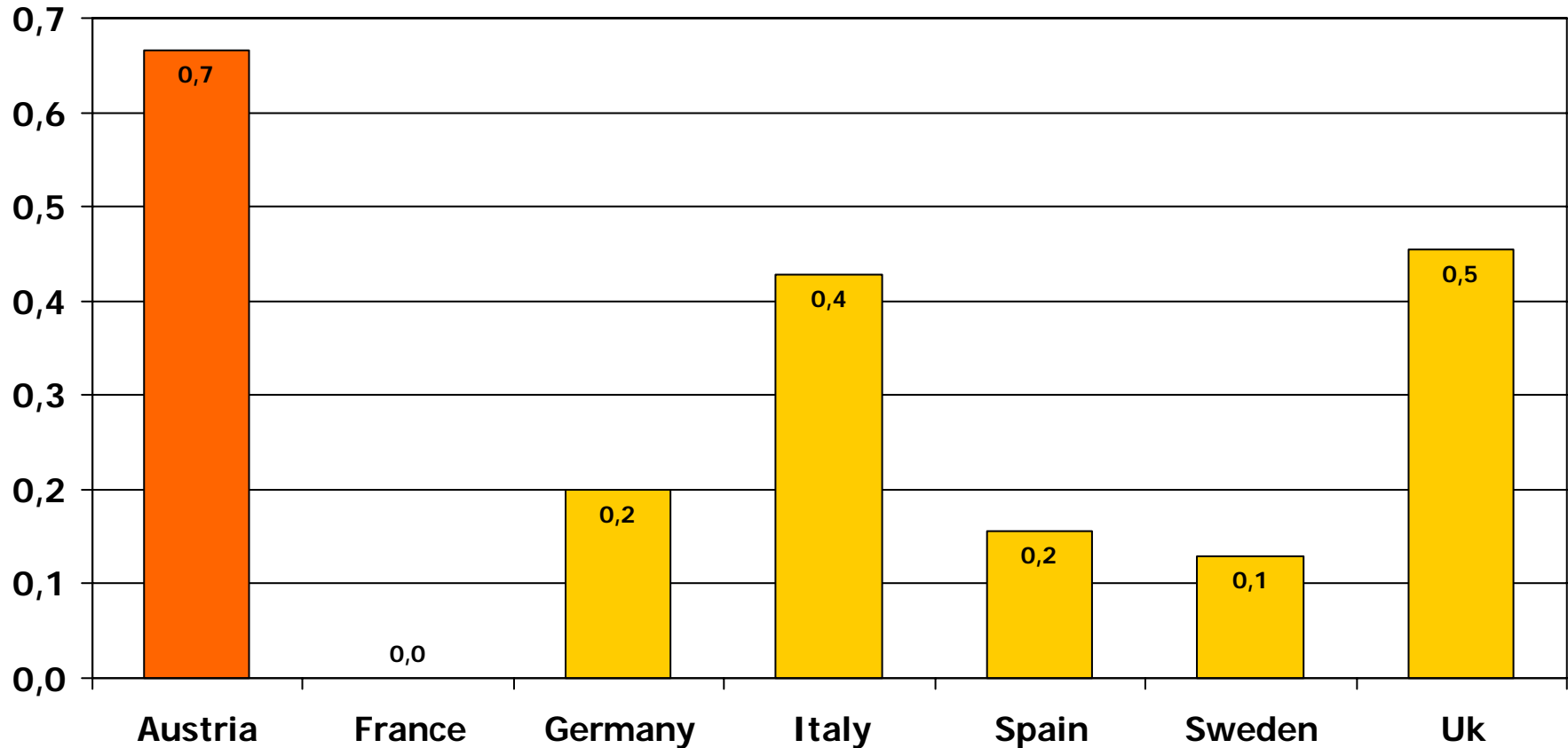
Number of questions found difficult/confusing per country in average



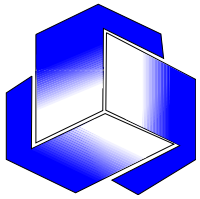
F=5.5, p=.000



Number of questions found Upsetting/annoying/intrusive per country

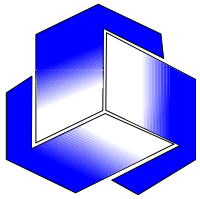


F=4.7, p=.000

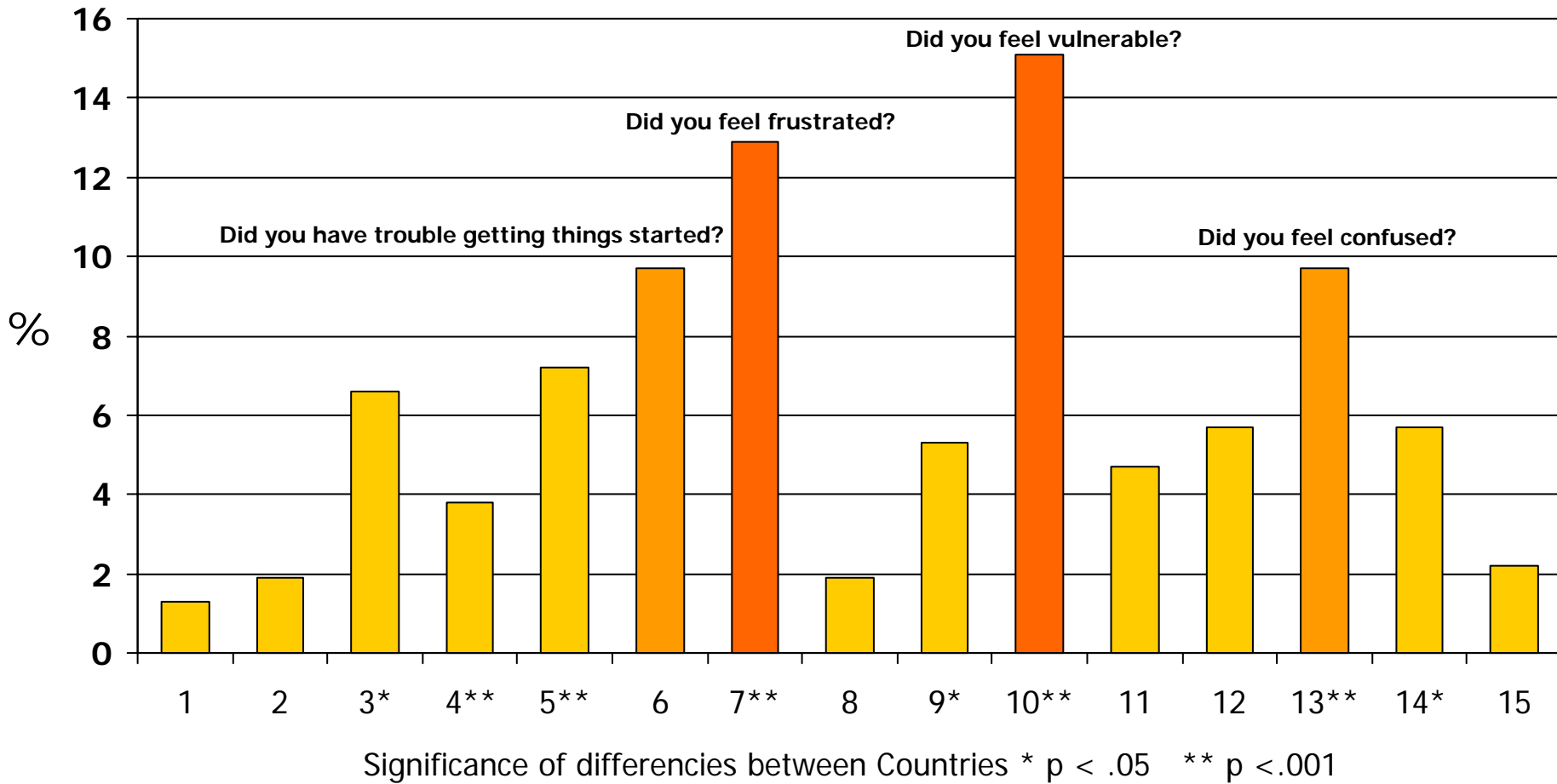


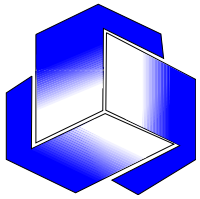
**231 Patients gave at least one comment (87 Patients have not commented at all)
(percentage rates referring to n= 318)**

% of the 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

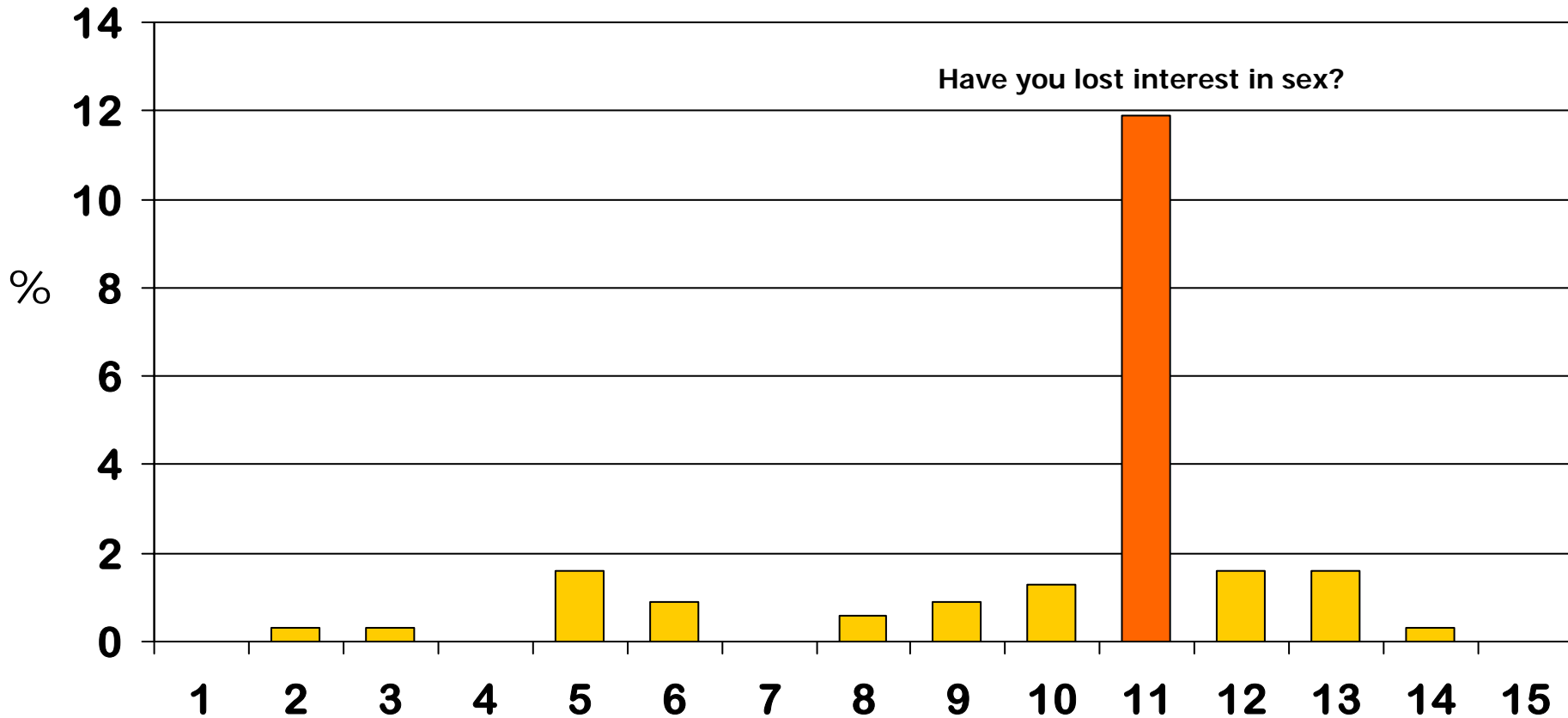


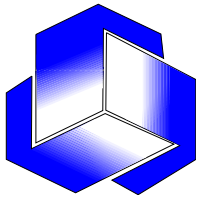
Questions found difficult or confusing



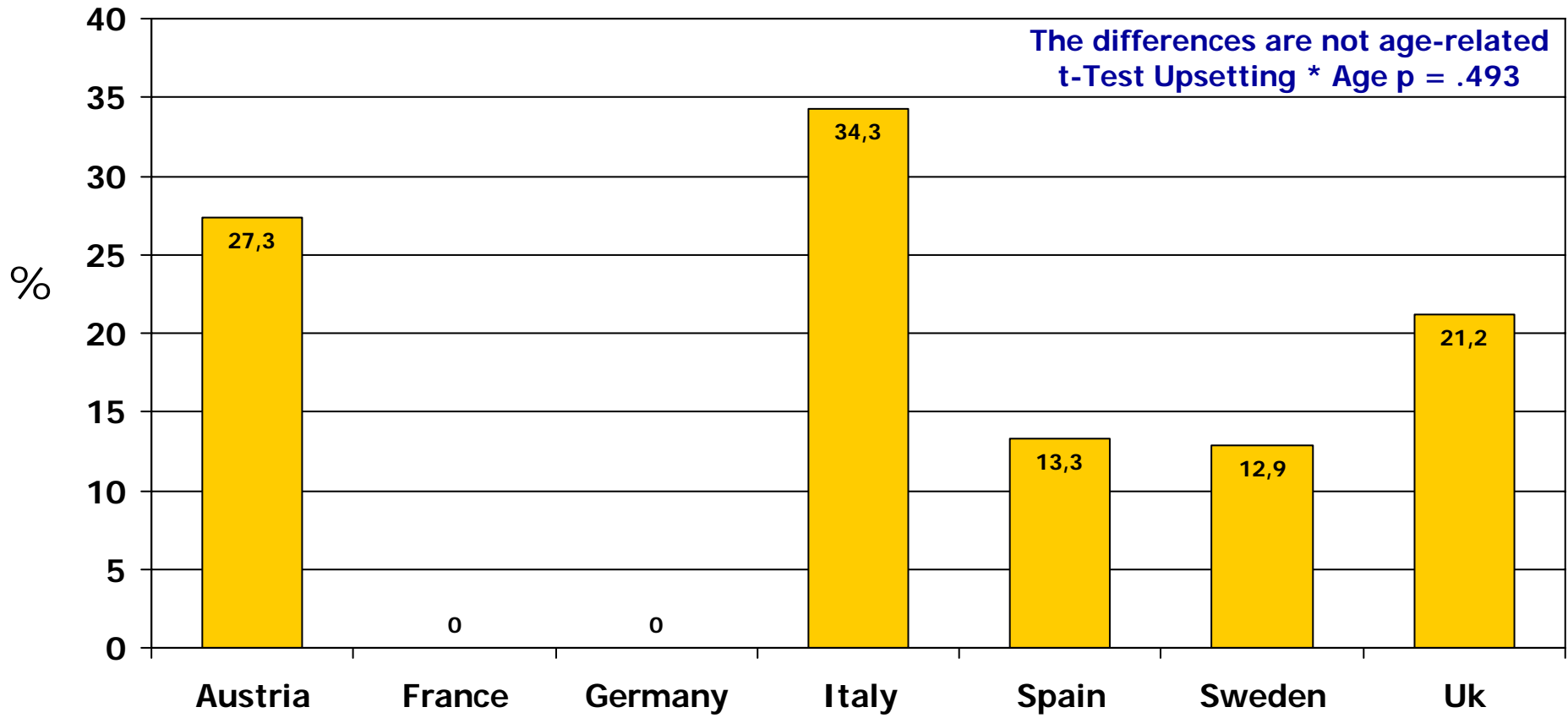


Upsetting/annoying/intrusive



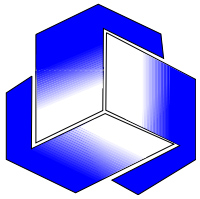


Upsetting/annoying/intrusive – Differences between the countries for the question: “Have you lost interest in sex?”

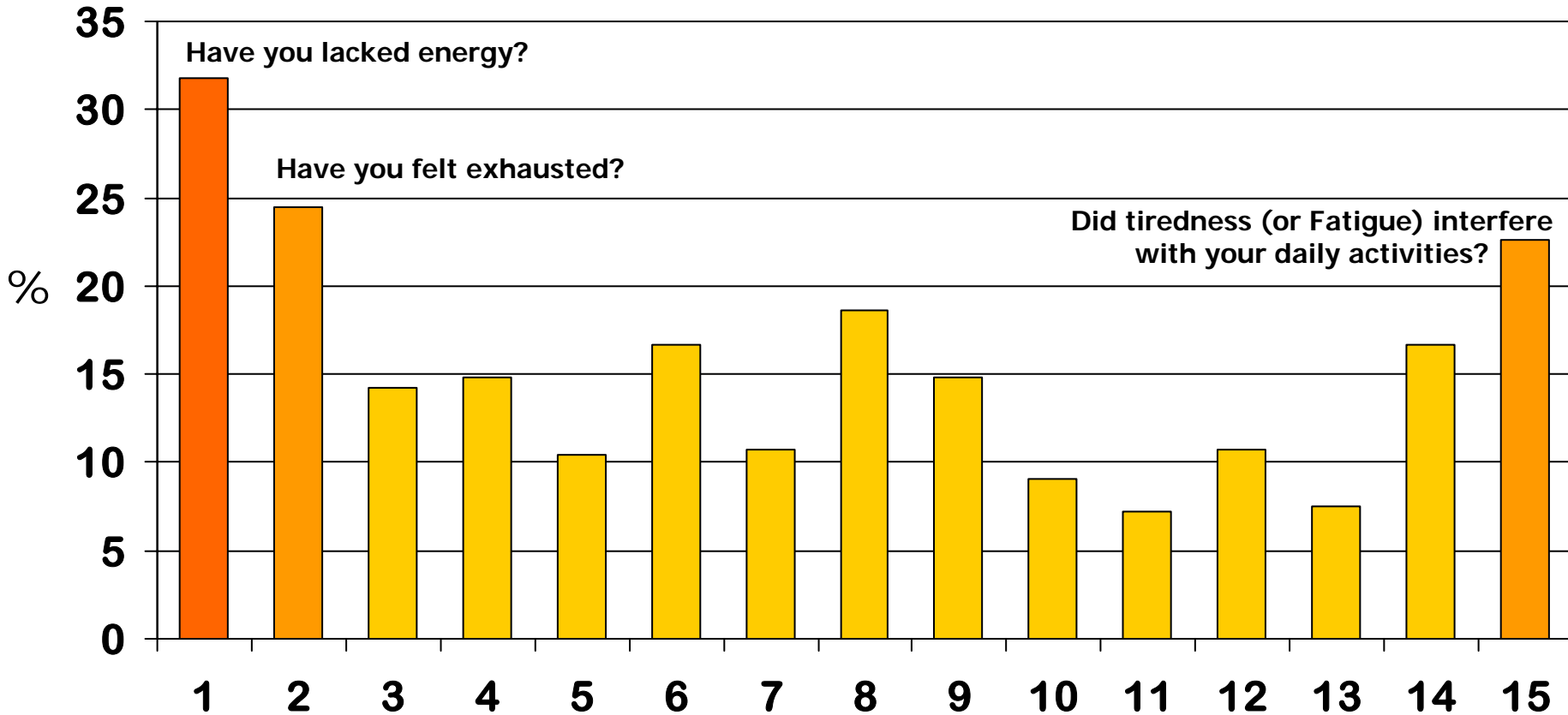


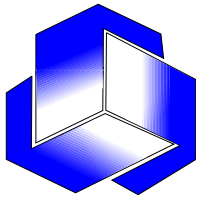
The differences are not age-related
t-Test Upsetting * Age p = .493

Chi-square = 22.7, df = 6, p = .001

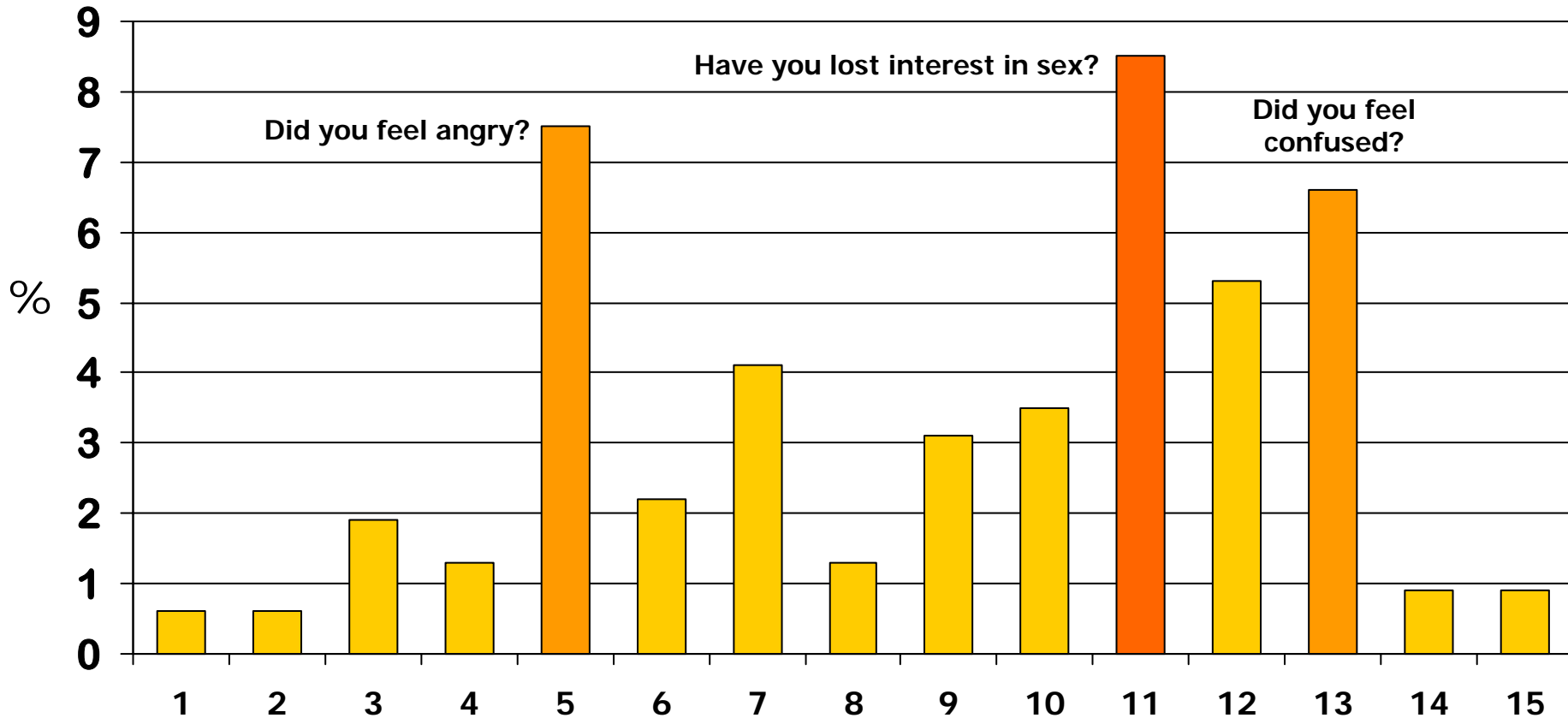


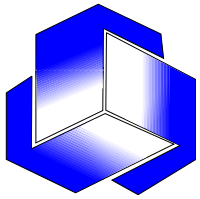
Important questions





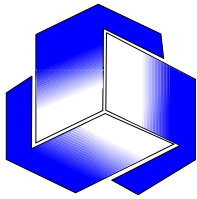
Irrelevant questions





IRT Analysis

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



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 (was) not understood by the people who are close to you ?	1	2	3	4