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Computerized assessment of quality of life in daily oncological practice

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Evaluation Software Development

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Overview

1. Introduction
2. Development of the PC-software “Computer based Health Evaluation System” (CHES) – Update
3. Implementation in various clinical Settings
4. Some practical experiences
5. Development of a flag system for identification of patients with “conspicious QoL graphs“

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Background

Computerized assessment of PROs (QOL) in clinical practice provides a useful tool for clinical decision making:

⇨Physician receives information on patient‘s QOL in a standardized way at each patient visit

⇨Allows „online monitoring“ of the course of QOL and patient reported symptoms and hence facilitates individualized treatment

An adequate, flexible and well-designed software is required for this purpose

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Software Development: Computer-based Health Evaluation System – CHES

PC-software for the assessment, calculation and presentation of psychosocial and medical data

- ⇨ JAVA Software, client – server solution (database e.g. MySQL, SQL, oracle), data security
- ⇨ Software adapted to the requirements of the user (e.g. assessment instruments, graphical presentation, print for medical records...)
- ⇨ Data entry by the patients themselves via a tablet-PC
- ⇨ Presentation of results as eye-catching graphs in real time
- ⇨ „Flag system“ for detecting and marking patients with clinically relevant problems
- ⇨ Linking of course of disease and treatment with Qol data, presentation in the graphical output
- ⇨ data export and import interface (CIS-HL7, SPSS)
- ⇨ Specific med. interventions can also be easily incoporated in the graphical output
- ⇨ print module, statistic module

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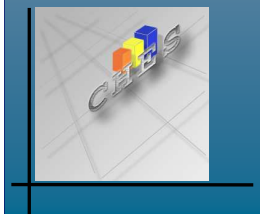

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New CHES-Features 1

⇨ Upgrading of the „Flag“ system: various Sets of Reference values can be defined

⇨ Study monitoring module:

-) For each study the required sociodemographic, clinical and questionnaire data can be definded for the various assessment time-points

-) Outstanding data is marked in the entry mask

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New CHES-Features 2

In final testing

- ⇨ English version (in the process of installation the languages either german or english can be chosen)
- ⇨ User management
  - various access authorisations can be defined
  - access protocol is written automatically
- ⇨ Back-up system

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Ongoing CHES - Projects

- ⇨ QoL-assessment of oncological outpatients
  Department of Internal Medicine, County Hospital Kufstein, Austria
  (for 2 years patients were used for an evaluation study)
- ⇨ Comprehensive QoL-assessment of patients with colorectal cancer in the palliative setting
  Department of Internal Medicine, Wels Hospital, Austria
- ⇨ Comprehensive Geriatric Assessment of oncological patients (age>65a)
  Department of Internal Medicine, Hospital Merciful Brethren, Vienna, Austria
- ⇨ Routinely QoL Assessment of patients during Radiotherapy
  Department of Radiotherapy, Medical University of Innsbruck, Austria
- ⇨ QoL-assessment of patients with brain tumor and their relatives
  Department of Neurology, Medical University of Innsbruck, Austria

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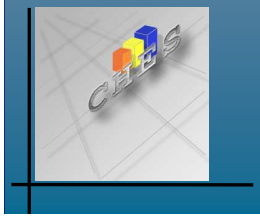

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CHES – Projects in implementation

- Comprehensive QoL-assessment of QoL of patients with testicular cancer (from diagnosis to long-term follow up)
  Department of Urology, Medical University of Innsbruck, Austria
- QoL-assessment and psychooncological indication in oncological outpatients
  Department of Oncology, Medical University of Graz, Austria
- Multicenter study: Prospective single arm phase II clinical trial in pat. with recurrent or progressive malignant glioma, Sunitinib (Sutent)
  Department of Neurology, Medical University of Innsbruck, Austria

CHES – Projects in planning

- QoL-assessment of outpatients with multiple myeloma
  Medical Clinic - Hematology and Oncology, Charité Berlin, Germany
- QoL-assessment and psychooncological indication in oncological outpatients
  Department of Psychosocial Medicine, University Leipzig, Germany

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Study: Computerized assessment of QOL in patients with brain tumors

Procedure

- ⇨ outpatients suffering from brain tumors
- ⇨ at each visit: computerized assessment of QOL (EORTC QLQ-C30 / +BN20) judged by
  - – the patient himself (self – assessment)
  - – a relative (proxy - assessment)
- ⇨ QOL-profile is automatically generated (CHES)
- ⇨ QOL-Profile is used in the physician-patient contact

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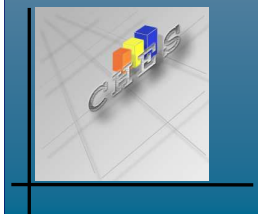
Patients and Methods

- ⇨ Start of the project: July 2005
- ⇨ Inclusion criteria: outpatients with primary brain tumor, age 18-80 y., German speaking, expected survival time of at least 6 months and informed consent
- ⇨ 85 Patients: 42 female (49.4%), mean age 47.6+/-14.1 (range 23-80) 357 assessments in total (26.7% proxy ratings, 4.2 assessments per patient)
- ⇨ Diagnoses: Astrocytoma (38.8%), Oligodendroglioma (21.2%), Glioblastoma (15.3%), Meningeoma (8.2%), others (16.5%)
- ⇨ Exclusion criteria: cognitive impairment and poor general condition (8/13 patients with Glioblastoma)
- ⇨ Course of treatment: chemotherapy, aftercare



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Example: male, 30 years; diagnose: Oligodendroglioma

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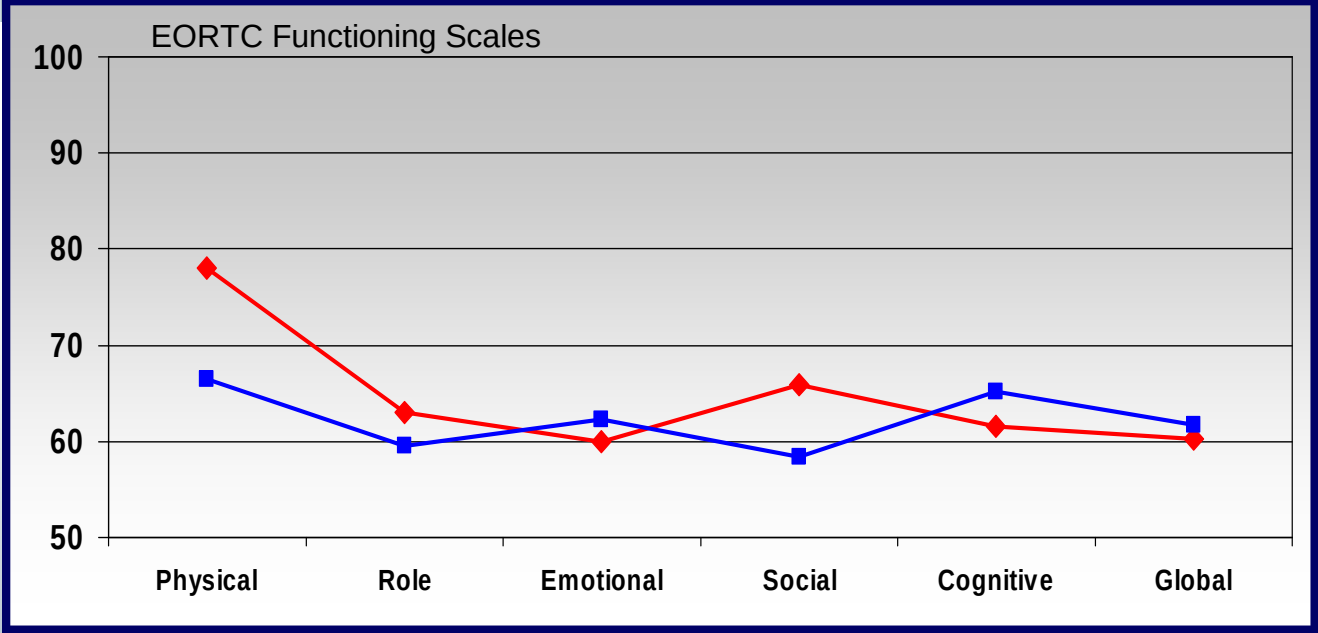
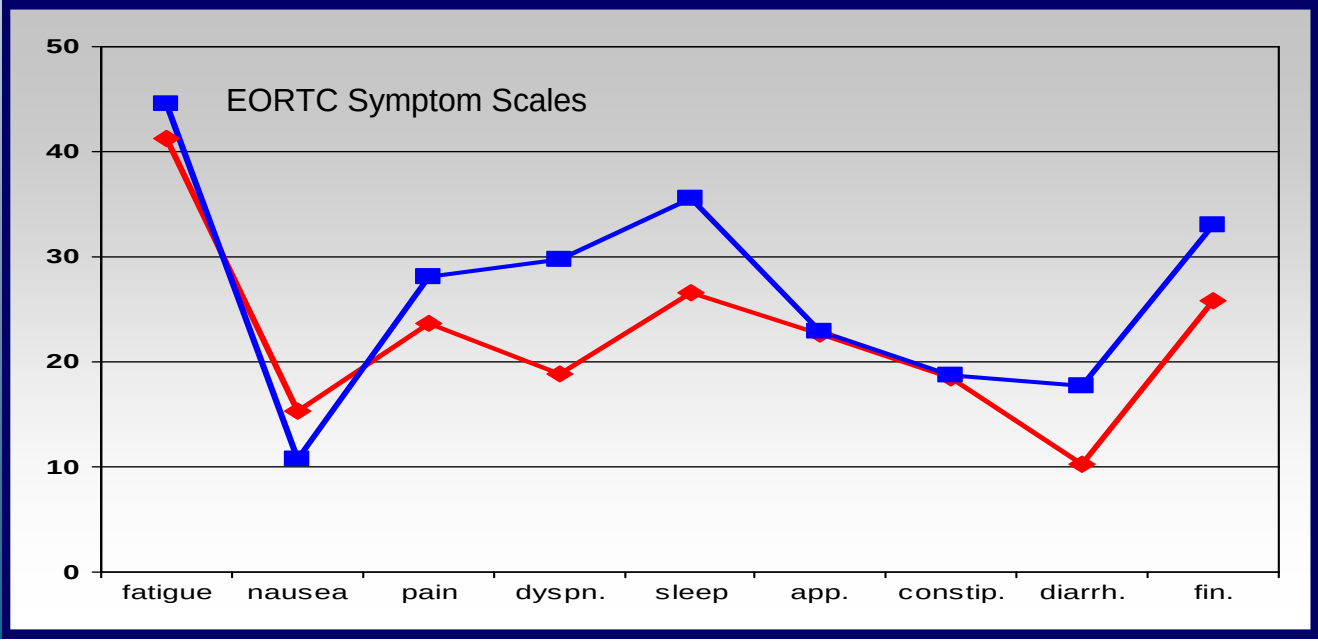
Results

Comparison of QOL (EORTC QLQ-C30): brain tumor patients, relatives





brain tumor

relatives

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Conclusions („preliminary“)

⇨ QOL of the neurooncological patients was significantly reduced compared to an age- and sex- matched group of healthy controls.

⇨ Relatives evaluate the QOL of the patients partly worse than the patients themselves (some patients with large discrepancies)

⇨ With the help of the computerized Qol charts problems with bladder control, appetite loss and taste problems, were recognized as clinically relevant

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Summary of practical experiences of the use of CHES in the oncological practice 1

- ⇨ Computerized data collection (with CHES) is well accepted by the patients and physicians
- ⇨ Computerized data collection has to be supervised
- ⇨ Use of the software and the profiles by the physicians depends on
  -) their attitude towards such QoL projects
  -) their „computer friendliness“
  -) the user-friendliness and the attractiveness of the tool (software)

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Summary of practical experiences of the use of CHES in the oncological practice 2

⇨ Physicians tend to overlook the individual EORTC Functioning scales and concentrate on the Global QoL subscale

⇨ Interpretation of functioning scales and its clinical meaning has to be learned
How can various symptoms and functioning scales and its impact on each other be interpreted? (e.g. fatigue, physical and emotional functioning...)
- regular training sessions with patient data

⇨ Physicians can be guided by an „intelligent“ software tool – e.g. by a flag system for monitoring QoL courses

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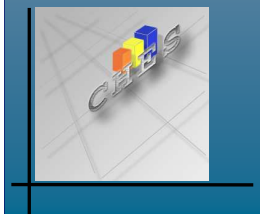
Development of a flag system for identification of patients with “conspicious QoL graphs“

(Georg Kemmler, Bernhard Holzner)

- Physicians need guidance for interpreting QOL scores concerning:

-) size of QOL scores ⇒ cut-off values
-) size of changes of QOL scores



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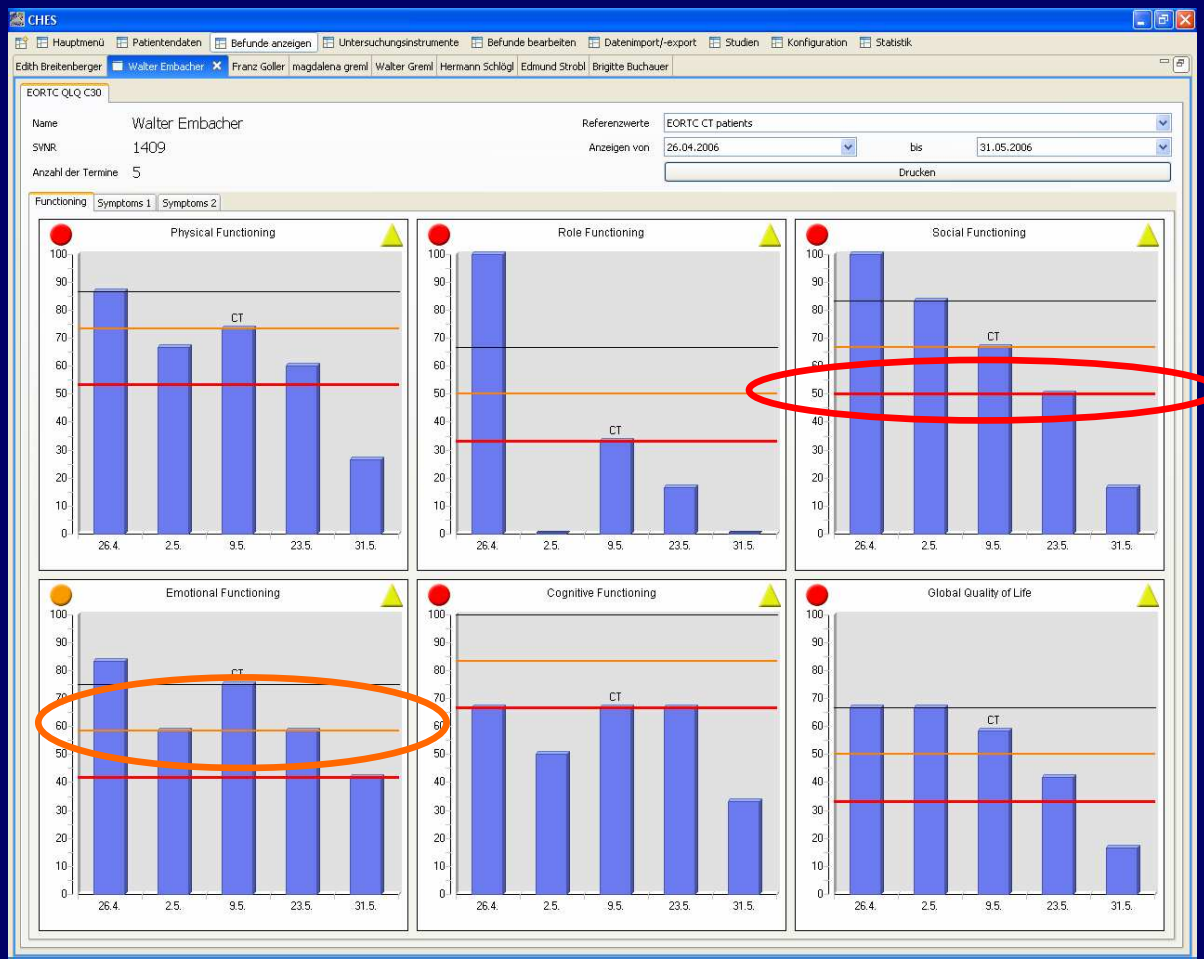
Cut-off values for marking patients with individual QoL deficits?

Use of percentiles:

-) e.g. 75th percentile (orange flag)

-) e.g. 90th percentile (red flag)



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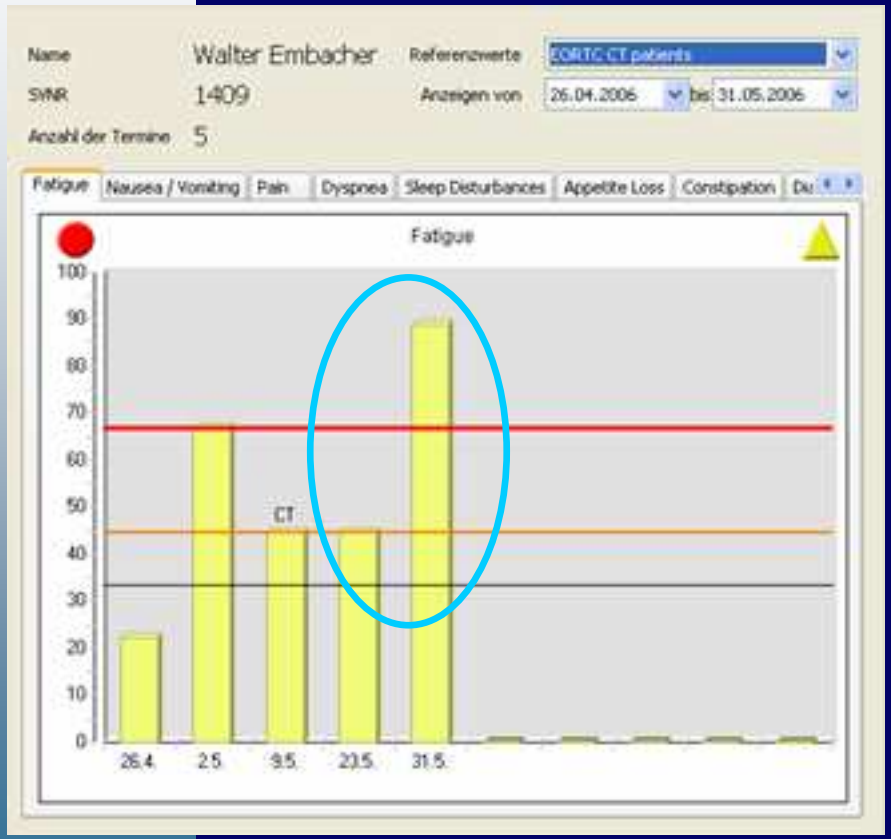
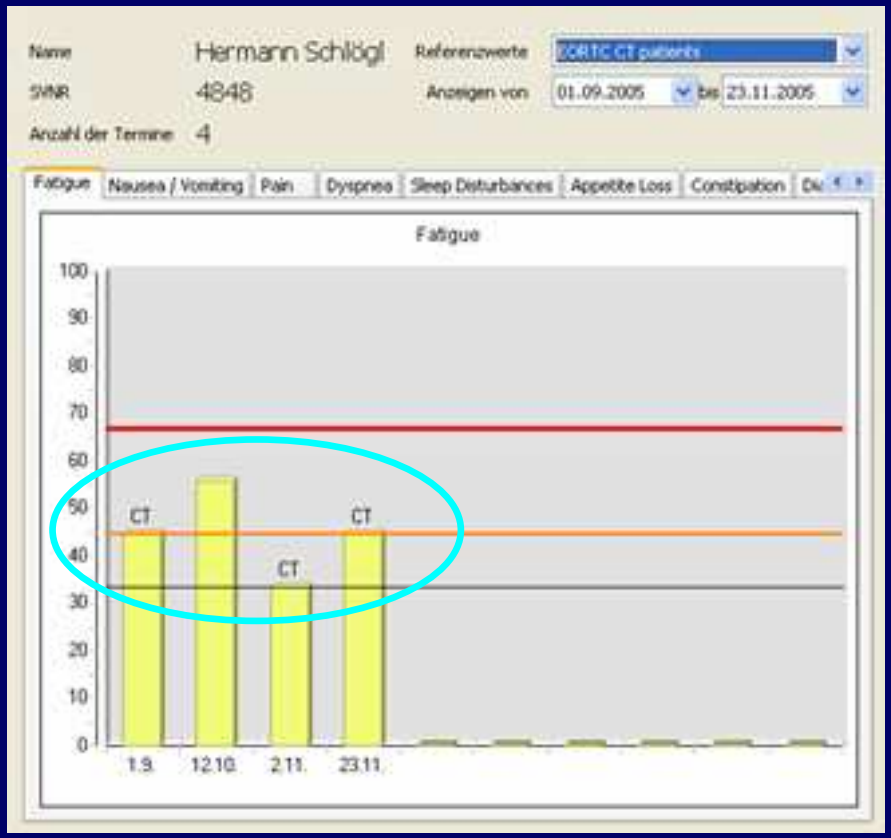
What criteria should we use for monitoring QoL changes?

Use of changes:

-) yellow flag (marked with a „delta“ or „triangle“)



potentially relevant change



relevant changes or just chance fluctuations?

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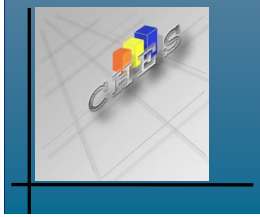
Study Aims

Compare several proposed criteria for „relevant change“(from literature) on the basis of empirical data (N = 109 oncological outpatients, 626 EORTC QLQ C30 assessments), regarding

- „Prevalence“ of changes in the study population
- Statistical significance of changes (on the individual-patient level)

Future aim: Selection of the most appropriate criterion/a



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Methods 1

Criteria for „clinically important“ change used

- Anchor based criteria: proposed for subscales of QLQ-C30 (Osoba et al., 1998)
  - small („MID“*): 5 - 10 points
  - moderate: 10 - 20 points
  - large: > 20 points, e.g. 30

- Distribution based criteria: multiples of the standard deviation (effect size)
  - 0.5 SD (proposed as „MID“ → Sloan et al., 2005)
  - 1.0 SD (large effect size)

* MID = minimal important difference

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Methods 2

Statistical significance of changes for N=1

prerequisites:

- SD of QOL measure in target population known
- reliability of QOL measure known (Cronbach's α)

$\Rightarrow$ Individual change in QOL measure is significant ($p \leq 0.05$), if it exceeds

$1.96 * (\sqrt{2}) * \sqrt{(1 - \alpha)} * SD$ (Reliable change index, RCI*)

* Jacobson & Truax, 1991
extended by Speer 1992, and others

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Results 1: Thresholds for significant changes (reliable change index, RCI*)

QLQ-C30 Subscale	Mean	SD	Reliability, α	Smallest sign. change (RCI)
Physical fct. (PF)	79.6	20.1	0.84	**22.4**
Role fct. (RF)	65.1	26.7	0.84	**29.5**
Emotional fct. (EF)	70.7	21.6	0.79	**27.2**
Social fct. (SF)	77.6	23.8	0.75	**33.0**
Cognitive fct. (CF)	87.1	19.8	0.68	**31.1**
Global QOL	60.6	21.2	0.93	**15.6**
Pain	23.0	26.8	0.82	**31.7**
Fatigue	37.6	23.6	0.85	**25.3**

$* \text{RCI} = 1.96 * (\sqrt{2}) * \sqrt{(1 - \alpha)} * \text{SD}$

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Results 2

How many of the „clinically relevant“ changes are statistically significant?

xx % = proportion of „clinically relevant“ changes according to the change criterion

xx % = proportion of „clinically relevant“ changes attaining statistical significance according to the „reliable change index“ criterion (RCI)

Subscale	Δ ≥ 10/ 0.5 SD „MID“		Δ ≥ 20/ 1 SD „Moderate“		Δ ≥ 30 „Large“	
Physical fct. (PF)	30.5%	**31%**	16.4%	**57%**	4.5%	
Role fct. (RF)	54.2%	**39%**	21.4%	**100%**	21.4%	
Emotional fct. (EF)	37.2%	**21%**	16.5%	**46%**	7.6%	
Social fct. (SF)	46.2%	**36%**	16.4%	**100%**	16.4%	**100%**
Cognitive fct. (CF)	38.6%	**31%**	11.7%	**100%**	11.7%	
Global QOL	48.9%	**100%**	21.9%	**100%**	15.1%	
Fatigue	60.9%	**21%**	28.9%	**45%**	13.0%	
Pain	47.4%	**47%**	22.2%	**100%**	22.2%	

„10 points change“ matches with „0.5 SD“, „20 points“ with „1 SD“
(same for all other functioning subscales and subscale pain)

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Conclusion

When monitoring QOL changes in the individual patient consider modification of criteria of „relevant“ change,

e.g.

a) 2 x usual „MID“ (1 SD instead of 0.5 SD, ...)

b) criterion a) plus statistical significance

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"Computer based Health Evaluation System" (CHES)

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