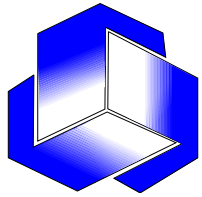


Development of the Fatigue Module (EORTC FA25; FAR15)

**Weis, J. (D) Flechtner, H. (D), Bottomley, A. (B),
Brédart, A.(F), Singer, S. (D), Holzner, B.(A), Larsson, G.
(S), Jones L. (UK), Gledhill, J. (UK)**

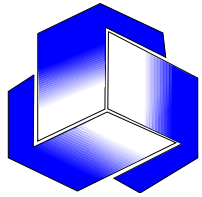
EORTC Quality of Life Group Meeting

November 2005



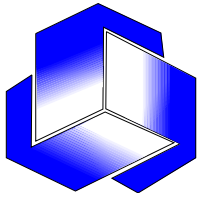
Update I November 2005

- development of the module has passed phase I/II based on n=36 expert interviews (physicians, nurses, psychologists) from 8 different European countries.
- The phase II fatigue module is now available in two versions:
 - FA-R15 (reduced version with 15 items) to be used in combination with EORTC QLQ;
 - FA25 (with 25 items) to be used without EORTC QLQ C30. FA25 includes items of the EORTC QLQ C30.



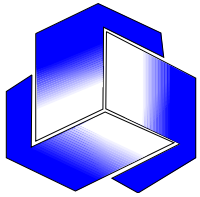
Update II November 2005

- A grant application has been submitted to start phase III of module development with the testing of FA–R15 (January 2005).
- A part of the total funds has been approved by German Fatigue Society
- **ISOQOL 2005 poster:** Weis, J., Flechtner, H., Bottomley, A., Brédart, A., Singer, S., Holzner, B., Larsson, G., Jones L, Gledhill, J. (2005) Development of an EORTC module for the assessment of cancer related fatigue (EORTC FA25; FAR15). *Quality of Life Research*, 14, P34, 2035.
- Collaboration with Center of Methodology in Social Sciences Department Rehabilitation Psychology University Freiburg (IRT analyses) (M. Wirtz PhD)



Phase III Module development

- **Pretesting of the provisional module (FA-R15)**
- **Patients will be interviewed: relevance and adequacy of coverage of the items:**
 - 1) to identify and solve potential problems in its administration (e.g. phrasing of items, sequence of questions);**
 - 2) to determine the need for additional questions;**
 - 3) to shorten the module as well as avoiding overlapping**
 - 4) to ask for patients priority rating**



Collaborators (Phase III)

- Andrew Bottomley Brussels, Belgium
- Anne Brédart Paris, France
- Thierry Conroy Nancy, France
- Henning Flechtner Cologne, Germany
- Claudia Fleissner Berlin, Germany
- Susanne Singer Leipzig, Germany
- Eva Hammerlid Goteburg, Sweden
- Bernhard Holzner, M. Kopp Innsbruck, Austria
- Kroll Gisela Aachen, Germany
- Louise Jones Jane Gledhill Andrea Griffin Clare Byrne Liverpool, UK
- Minna-Liisa LuomaHelsinki, Finland
- Gunnel Larsson Uppsala, Sweden

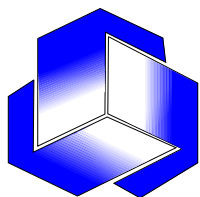
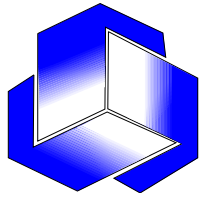


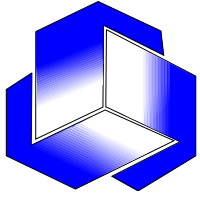
Table 1 Samples Phase III: patient interviews

Country	Acute treatment	Rehabilita- tion /Recovery	Hospice/palli ative care
Germany	15	15	15
UK	15	15	15
France	15	15	15
Italy	15	15	15
Netherlands	15	15	15
Spain	15	15	15
Total	90	90	90 Σ 270



Phase III Patients interviews

- EORTC QLQ Module development guidelines:
 - patients complete the core questionnaire and the provisional module (FA-R15)
 - structured interview asking for any questions that were difficult, upsetting etc., irrelevant items, important items which are not included
 - patients will be asked to select 10-15 items from the fatigue modules that they think should definitely be included in the final version.
 - medical and sociodemographic data



Informed consent and ethical issues

- The QL protocol must be approved by local ethical committees according to the national requirements. Each patient's informed consent must be obtained prior to administration of the provisional module and interviews. The interviewer may take notes during the interview, but the discussion will not be tape-recorded. All patient data will be kept anonymous using only study number or initials.