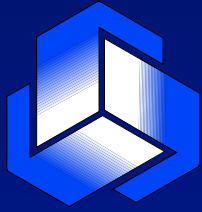


An International Field Study of the
EORTC QLQ-C30 and a Prostate
Cancer Module (QLQ-PR 25)

EORTC Quality of Life and
Genitourinary Cancer groups

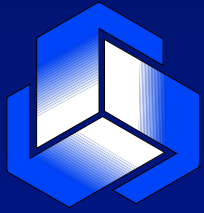
Study Coordinators: N. Aaronson and G. van
Andel



An International Field Study of the EORTC QLQ-C30 and a Prostate Cancer Module (QLQ-PR 25)

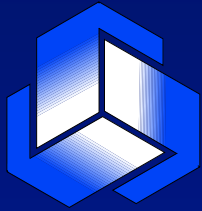
Quality of Life and Genitourinary Cancer Groups

Study Coordinators: N. Aaronson and G. van Andel



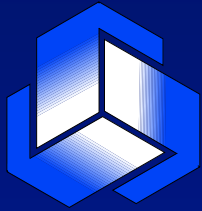
Study Endpoints - Psychometrics

- **Scaling properties**
- **Internal consistency reliability**
- **Clinical validity**
- **Responsiveness to change over time**



Eligibility Criteria

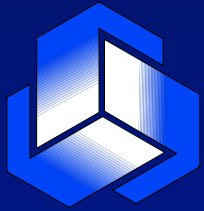
- **diagnosis of prostate cancer**
- **mentally fit to complete a questionnaire**
written informed consent before baseline assessment
- **no previous treatment (e.g. hormonal treatment) for prostate carcinoma before study entry, no cerebral metastases, no concurrent malignancies, no concurrent participation in other quality of life studies, no interstitial radiation therapy**
- **no age limit or minimum performance status**



Stratification by disease stage

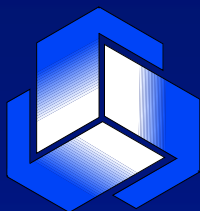
**Group 1: localized disease treated with radical
prostatectomy or local or locally advanced
disease treated with external radiation therapy**

**Group 2: metastatic disease treated by hormonal
treatment**



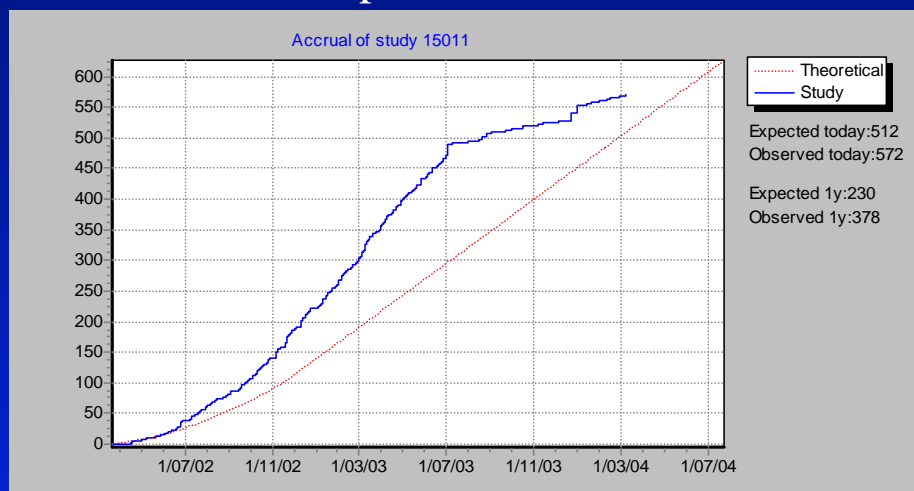
Data Collection Schedule

- Baseline: prior to the start of surgery or radiation therapy (group 1) or hormonal therapy (group 2)
- Second assessment: 3 months after start of treatment
- Third assessment: 6 months after start of hormonal therapy (only for group 2)



Accrual

Achieved versus planned accrual

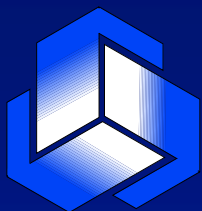


Accrual per EORTC group

EORTC group affiliation	Number of patients (%)
GUTCG	476 (83.2%)
QLG	70 (12.2%)
QLG+GUTCG	26 (4.6%)
Total	572

Geographical/linguistic categories in group 1

	surgery	sur+horm.	radiotherapy	radio+horm.	Total
Anglo-Saxon	29	0	17	19	65
Northern Europe	168	2	67	24	261
Southern Europe	104	2	41	26	173
Other	1	0	0	0	1
Total	302	4	125	69	500



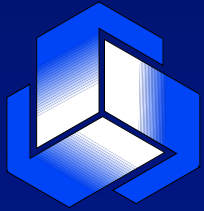
Special issues

- **Evaluation and eligibility**
- **Baseline characteristics**
- **Compliance (of 235 evaluated files)**

Eligible	Number of patients
yes	219
no	16
Total	235

	Group 1	Group 2
Group	500	72

	QL in accordance with the protocol	QL not in accordance with the protocol	Ineligible
Total	200 (85.1%)	19 (8.1%)	16 (6.8%)



An International Field Study of the EORTC QLQ-C30 and a Prostate Cancer Module (QLQ-PR 25)

- **Study Coordinators:** N. Aaronson (Amsterdam, The Netherlands), G. van Andel (Amsterdam, The Netherlands)
- **Cooperating Groups:** EORTC QLG, EORTC GU
- **This is a cross-cultural descriptive, correlational, pretest-posttest questionnaire validation study.**
- **Stratification for:** stage of disease
 - Group 1: localized prostate cancer treated with radical prostatectomy or local or locally advanced prostate cancer treated with external radiation therapy
 - Group 2: metastatic prostate cancer receiving hormonal treatment
- **Main endpoint:** To test the scale structure, psychometric validity and reliability of the QLQ-C30 and the prostate cancer-specific module (QLQ-PR25) among men with local, locally advanced or metastatic prostate cancer
- **Main eligibility criteria:** diagnosis of prostate cancer, no age limit or minimum performance status levels mentally fit to complete a questionnaire, absence of psychological, familial, sociological or geographical conditions potentially hampering compliance, written informed consent before baseline assessment, no previous treatment (e.g. hormonal treatment) for prostate carcinoma before study-entry, no cerebral metastases, no concurrent malignancies, no concurrent participation in other quality of life studies, no interstitial radiation therapy
- **Completion of the questionnaires:**
 - Baseline: prior to the start of surgery or radiation therapy (group 1) or hormonal therapy (group 2)
 - Second assessment: 3 months after start of treatment
 - Third assessment: 6 months after start of hormonal therapy (only for group 2)