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ORIGINAL ARTICLE

Quality of life diagnosis and therapy as complex intervention for improvement of health in breast cancer patients: delineating the conceptual, methodological, and logistic requirements (modeling)

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Abstract

Background and aims A system for quality of life (QoL) diagnosis and therapy in breast cancer patients was developed according to the Medical Research Council (MRC) framework of complex interventions. Along MRC's five phases in the continuum of evidence, the present paper deals with phase I: modeling (i.e., delineating the conceptual, methodological, and logistic requirements).

Basic elements Theoretical background is a new conceptualization of QoL that provides a rational basis to diagnose "diseased" QoL. A care pathway as the central part of modeling is composed of the following interrelated structural elements: patients (n=170), clinicians (n=10), experts in a quality of life unit (n=5), coordinating practitioners (n=38), local opinion leaders (n=12), and professional therapists for QoL enhancing therapies (n=75). Networking of these structural elements was achieved by clinical algorithm. In the clinical center, the patient and doctor delivered a questionnaire (EORTC) and health status report. The QoL unit transformed it into a profile and experts' report. The coordinating practitioner transformed the latter into a decision on QoL therapy and the care pathway ended with the professional therapists. Implementation of this system used a multifaceted strategy including educational outreach visits, local opinion leaders, and quality circles.

Conclusion The suffering cancer patient is the main focus of this QoL diagnosis and therapy system. It will have to pass the rigorous test of a definitive randomized trial.

Keywords Complex intervention · Modeling · Quality of life · Breast cancer · Implementation

Introduction

MRC framework for complex interventions and its use in the quality of life area

In medical care, more and more complex situations arise [1, 2], in which the effectiveness of drugs, instruments, or measures can not be sufficiently evaluated by using the four classic phases laid down by the institutional bodies for drug development. Examples include the "magic bullets" for sepsis treatment [3], evaluation of ICU and stroke units,

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and treatment regimens in oncology involving predictive pathology [4].

The UK Medical Research Council (MRC) has developed a conceptual and methodological framework for evaluating interventions that address such complex situations [2]. The continuum of increasing evidence consists of five consecutive phases:

- Theory: in this first step, the theoretical basis is laid down suggesting that a specific intervention will have the expected effect (preclinical phase).
- Modeling: in this step, all the components of the interventions are described and their interrelations and expected outcomes are specified (phase 1).
- Exploratory trial: preliminary evidence is obtained that this treatment has the intended effect. This phase helps to fine-tune the final study design, intervention and control groups, as well as assessment strategies (phase 2).
- Definitive randomized controlled clinical trial (RCT): this crucial phase is designed to answer the question whether the complex intervention really works. This phase adheres to all rigorous standards that are characteristic for RCTs and allows the detection of a cause–effect relationship (phase 3).
- Long-term implementation: this final step includes a subsequent study that evaluates the validity of the complex intervention under real-life circumstances (phase 4).

A potential field for applying this MRC research framework is the use of information on quality of life (QoL) in the clinical context. Much of the work done so far has focused on the development of computer support systems for QoL assessment [5]. It has little been recognized, however, that the clinical application of QoL constitutes a "complex intervention" which consists of numerous diagnostic, therapeutic, and logistic elements.

A particularly important element is the distinction between good ("healthy") vs critically low ("diseased") QoL. The main criterion used to differentiate these conditions is "iatrotropy" [6]: patients seek medical advice because some aspect of their QoL has deteriorated to a degree that is no longer tolerable. In this study, the complex intervention includes a full range of medical, psychosocial, and complementary treatments that are embedded in management tools such as practice guidelines, care pathways, or questionnaires.

At the Tumor Center Regensburg, the development, implementation, and evaluation of a QoL diagnosis and therapy system (QoL system) has reached a mature stage with respect to the MRC phases of increasing evidence. Theory as the preclinical phase was published fully in two papers [7, 8]. The results of modeling and exploratory trials as phase I and II were presented as abstracts [9–11]. The study protocol of the definitive phase III RCT was published [12] and patient recruitment of the $n=200$ patients is completed.

The present report focuses on modeling phase I and provides a thorough description of all elements of the complex intervention and the QoL system. The theoretical foundations (described in detail in [6, 7], and [17]) are summarized at the beginning.

Theoretical foundations of the QoL system

Quality of life (QoL) as a matter of personal experience, common thought, and systematic analysis [13] has become a new paradigm in medicine and particularly in oncology. QoL vigorously challenges the reductionist biomedical concept of disease and illness in the Western world [14, 15]. However, the development of the QoL concept was neither systematically based on empirical evidence [7, 15] nor has the QoL concept been transformed into a practical tool for diagnosing and treating individual patients—a necessity for any good testable theory [8, 16]. Therefore, an empirically based conceptualization of QoL has been proposed [7, 8] in the preclinical phase of this project (and its practical operationalization is the focus of the present paper):

- QoL, when assessed in the clinical context, relates to disease, not to health [6, 14, 15],
- QoL is self-perception and self-report in three dimensions: somatic, psychological, and social,
- QoL includes expectations regarding therapeutic effects and future health as well as patients' capacity to cope with the situation,
- QoL is influenced by basic psychosocial variables such as negative affect and social stigma,
- QoL is part of a three-component outcome (TCO) model that includes objective and experiential endpoints and a qualitative analysis of clinical relevance; its application to breast cancer is shown in Fig. 1 [17].

The objective and experiential components of the TCO model may be easily understood, although not always accepted [18, 19]. However, clinical relevance as the third component may cause more problems. This dilemma was extensively discussed in the literature [8], and the true-endpoint concept of Troidl, Wechsler, and McKneally was accepted as solution: "the final test of relevance of an endpoint is its relationship to the well-being of the individual patient. In choosing endpoints, the doctors should envision themselves as advocates for the patients. The closer the chosen endpoint comes to answering the basic medical question 'How are you?' the more appropriate and relevant it will be" [20].

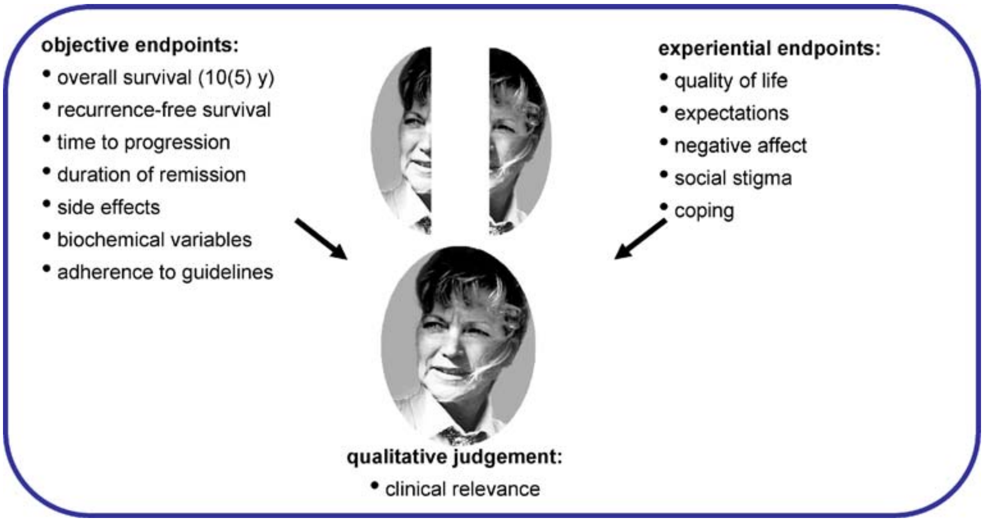


Fig. 1 Three-component outcome model including disease-related quality of life. From Lorenz and Koller [17]. In the original version objective endpoints were named mechanical or clinical while experiential endpoints were named hermeneutic. Hermeneuo in ancient Greek philosophy means: I describe, explain, exchange my complaints, views, judgments

To find out what is best for the patient, the modeling process includes a QoL unit, experts' reports, and coordinating practitioners (CPs). The empirically based definition of QoL and the TCO concept constituted the first two key elements of the theory for QoL diagnosis and therapy. The third one included the clinical decision [4, 21, 22], at which level of QoL action should be taken to change "diseased" QoL into "healthy" QoL:

- QoL is assessed using the EORTC QLQ-C30 plus BR23. Patients' responses to the questionnaire are transformed into a QoL profile with nine dimensions and a further dimension for global QoL. All items are scaled from 0 (very bad) to 100 (very good). In each scale, 50 score points were taken as the cutoff point between "diseased" and "healthy". The reason for this is straightforward: Patients position themselves into the lower half of the spectrum, thus indicating that they suffer in the very domain ("quite a bit" or "very much" of a given symptom). Consequently, it can be inferred that patients do not consider their QoL as tolerable and are ready to seek and accept professional medical help. More arguments in favor of the 50 score point criterion can be found in [7, 23].
- Patients' judgments were critically evaluated by five experts representing different disciplines: a gynecologist, a general practitioner, decision analyst in surgery [24], social psychologist, and psycho-oncologist. In addition to the patient-based QoL profile, information on comorbidity, cofatality, medical treatment, and objective health status were available for each patient for analysis (see the section below describing the QoL unit). The consideration of this whole body of information, the input of all five experts, and their agreement was necessary to classify the measured QoL as "diseased". "Diseased" QoL required at least one value below 50 points, while, in theory, all 10 dimensions could be below 50 in an individual patient.
- Therapy was recommended by the experts' group for one dimension, for a second one in an additive manner or for a combination with a preference for a sequence of actions that depended on the analysis of the experts group and/or the doctor caring for the patient.

Modeling complex intervention: the central role of the care pathway

In accordance with the MRC framework [2], the components of the intervention were first identified followed by the development of the operational system for QoL diagnosis and therapy. Implementation started immediately thereafter using the infrastructure of the Tumor Center. The structural elements of the QoL system were completed stepwise and networked in the care pathway. The first patient entered the care pathway in December 2002. A total of $n=170$ patients were recruited in the implementation study. Recruitment ended in June 2004 and 6 months follow-up was completed in December 2004.

Structural elements of the care pathway

The structural elements of the QoL system comprised the service area of the Tumor Center Regensburg [25] according to the concept "small area analysis" [26] (Fig. 2). The following individuals were selected to cooperate and form a network along the care pathway (Fig. 3): 170 patients with primary breast cancer, two clinicians from each of the five hospitals in the area, the QoL unit with five experts (among them two study coordinators) plus two data managers, 38 coordinating practitioners (CPs), 12 opinion leaders, and 75 professional therapists providing QoL therapeutic options.

The patients considered for participation in the modeling project were recruited by the clinicians in the participating

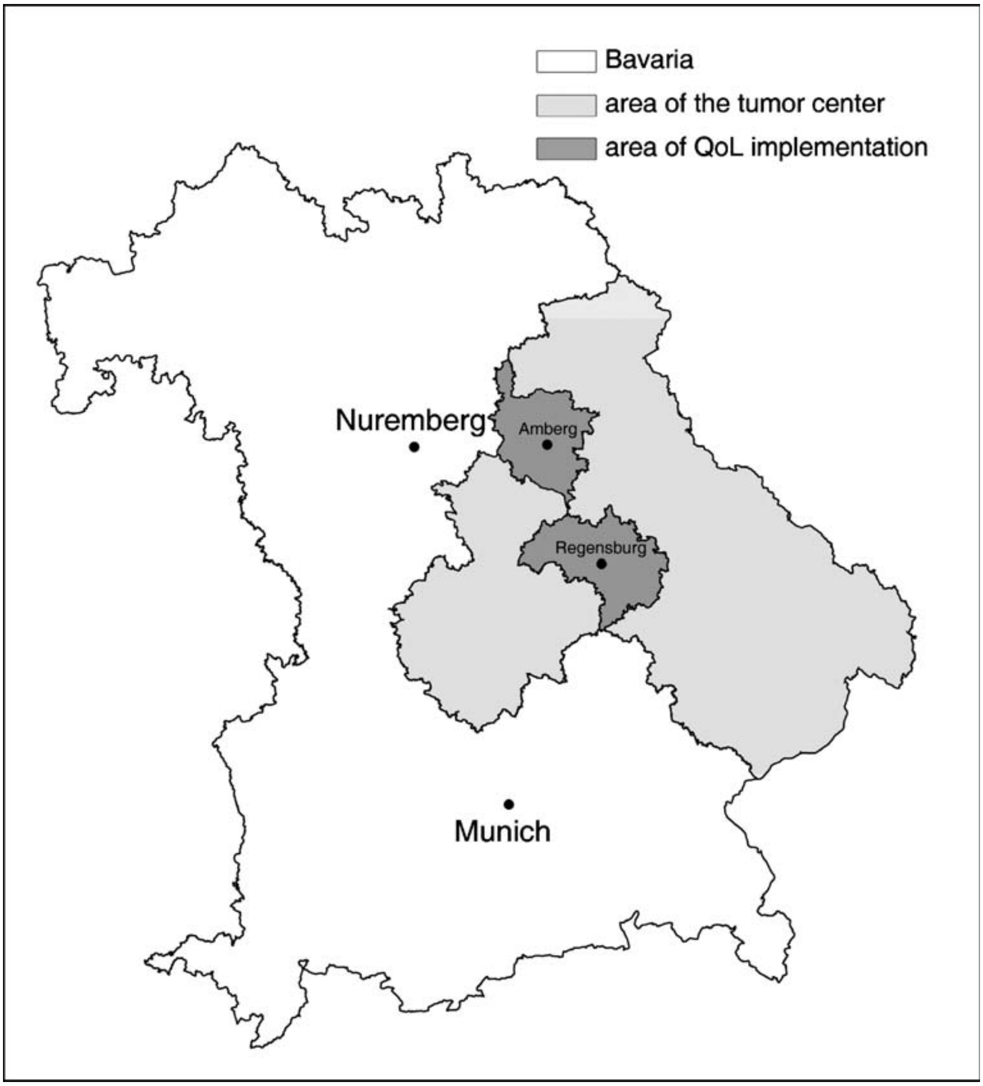


Fig. 2 Small area in Bavaria selected for modeling the QoL system

five hospitals or by the CPs. It was planned that each study site should enter two to six patients. Criteria for patient selection were women with pathologically confirmed breast cancer including carcinoma in situ. Criteria for exclusion were refusal by the patient, mental incapability to fill out questionnaires, poor command of the German language, residence outside the area (Fig. 2), pregnancy or age <18 years. There was no upper age limit.

The two clinicians in each of the five hospitals were at least proficient on the Dreyfus scale of clinical expertise [27] and were chosen by the chairs of the gynecology departments.

The five experts from the QoL unit covered several professions complementary to each other such as a gynecologist, general practitioner, decision analyst in surgery [24], social psychologist, and psycho-oncologist. They prepared the experts' reports in consensus with at least four experts present at each case.

The CPs were also defined and selected using a systematic approach. In general, CPs were doctors who, besides traditional follow-up, diagnosed and treated patients with breast cancer for clinically relevant deficits in quality of life. They were responsible for patient follow-up after surgery and acted – according to the care pathway (Fig. 3) – either by themselves or, most frequently, in combination with one or several other professional therapists. They were informed about the comprehensive documentation from the Tumor Center by scanned discharge letters from the hospital clinicians. Furthermore, CPs had to have managed at least three patients with breast cancer between 1999 and 2001. Finally, they had to agree to inclusion and had to have completely participated in the systematic implementation procedure described below. In total, 67 physicians (mostly gynecologists and general practitioners in the German Health System) were identified in the area, 39 fulfilled the criteria and only one refused to participate. Hence, 38 CPs cared for 170 patients (median=3) in the context of the QoL system.

The local opinion leaders were also selected systematically. After outreach visit by members of the QoL unit (see

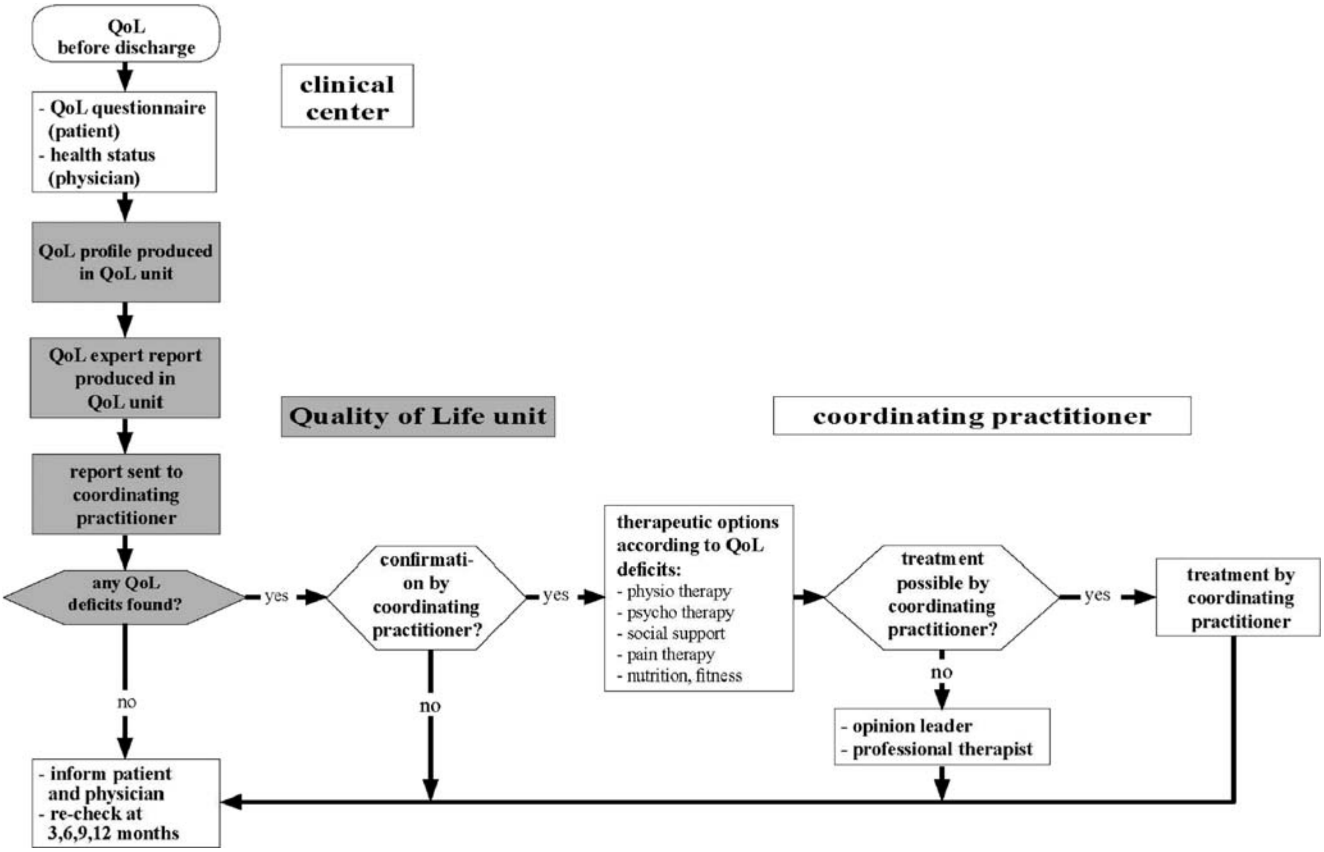


Fig. 3 Care pathway for QoL diagnostics and therapy in breast cancer patients

below), the CPs completed a questionnaire about items of the care pathway: This included explicitly that CPs had to nominate local colleagues as influential opinion leaders [28, 29]. These should be peers who provided knowledge, supported problem solving, and helped decision making in individual cases. At the outreach visit, the CPs were asked by the QoL unit coordinators whether they had nominated an opinion leader. In total, 12 colleagues were selected (with a maximum of 18, minimum of two votes); four general practitioners and eight hospital clinicians (gynecologists, radiologists, hemato-oncologists) were involved. Their skills covered all somatic aspects of the disease (Fig. 1), but none particularly covered the QoL aspects. Hence, it was also necessary for opinion leaders to undergo the implementation procedure within the QoL system that included an outreach visit, a quality circle, and interactive learning in the tumor board and the project groups of the Tumor Center.

Finally, the professional therapists, i.e., the crucial agents to provide the QoL-enhancing therapy options, were selected systematically. First of all, the therapeutic options themselves had to be identified conceptually and thereafter empirically. This was achieved by creating a quality circle that consisted of all participants in the QoL system including patients. Using the method of barrier analysis, 18 specific therapies were proposed initially and later grouped into five therapeutic options: psychotherapy, pain therapy, social support, physiotherapy, and lymph drainage, as well as fitness (nutrition, sports) [30]. For each of these, professional therapists with reasonable experience had to be located in both areas of implementation (Fig. 2). This was carried out as follows. First, CPs were asked to provide addresses of professional therapists for each therapy option. Then these names were collected by the QoL unit, completed, and checked for plausibility. The lists were improved by a quality circle using PDCA (plan, do, check, act) methodology [31] and finally returned to the CPs, clinicians, and opinion leaders to help them locate their professional therapists in case they were needed for treating patients according to the experts' report from the QoL unit (Fig. 3). In total, 11 colleagues (mainly anesthetists) were listed for pain therapy, 25 colleagues (mainly physiotherapists in private practices or in clinical centers) for lymph drainage, 10 for psychotherapy (mainly clinical psychologists, some psychiatrists), 16 for nutrition, and six for sports (specialized fitness centers) and ambulant rehabilitation. Finally, seven social workers were registered to deal with social problems such as insurance and pension matters or debts.

Networking the structural elements in the care pathway

In the phase I modeling process, the various interrelated components of patient care had to be systematically combined to relate to and interact with each other in a rational way [2]. This was done by means of a clinical algorithm (Fig. 3) [32].

Patients should enter the system in the hospital, and readmission was scheduled at 3, 6, 9, and 12 months. This ideal situation was designed for and put into practice in the RCT (phase III of the MRC framework). In the modeling phase, all 170 patients started with the first action box (QoL questionnaire and health status) and finished with a modified last action box (informing the patient and physician). Sequentially, the care pathway involved the clinical center, QoL unit, CP, and professional therapists (Fig. 3).

In the clinical center – or in case of readmission in the office of the CP – the patient filled out QoL questionnaires (EORTC QLQ-C30, version 2 and breast cancer module QLQ-BR 23). Each patient performed this task independently and without assistance to avoid response bias (e.g., social stigma [33]). To satisfy the objective part of the outcome model (Fig. 1), the physician in the clinical center filled out a comprehensive health status questionnaire that collected diagnostic, therapeutic, and social data [12]: (1) patient age, profession, family status, and children; (2) tumor classification (TNM, grading) and hormone receptor status; (3) time relationship between QoL measurement and adjuvant therapy shown in Fig. 4, classified as "completed, ongoing, or planned"; (4) current serious events not related to the tumor (so-called cofatalities, e.g., social problems, death of a family member, or debts); (5) comorbidities including fixed-format yes/no answers for cardiovascular, lung, urogenital, metabolic, blood, or CNS illness. These questions were taken from and defined by the ASA classification of preoperative status [12]; (6) global health status and QoL using the seven-step Likert scales of the EORTC questionnaire (questions number 29 and 30). These physician-based reports were of crucial importance for the experts in the QoL unit for the interpretation of the patient's

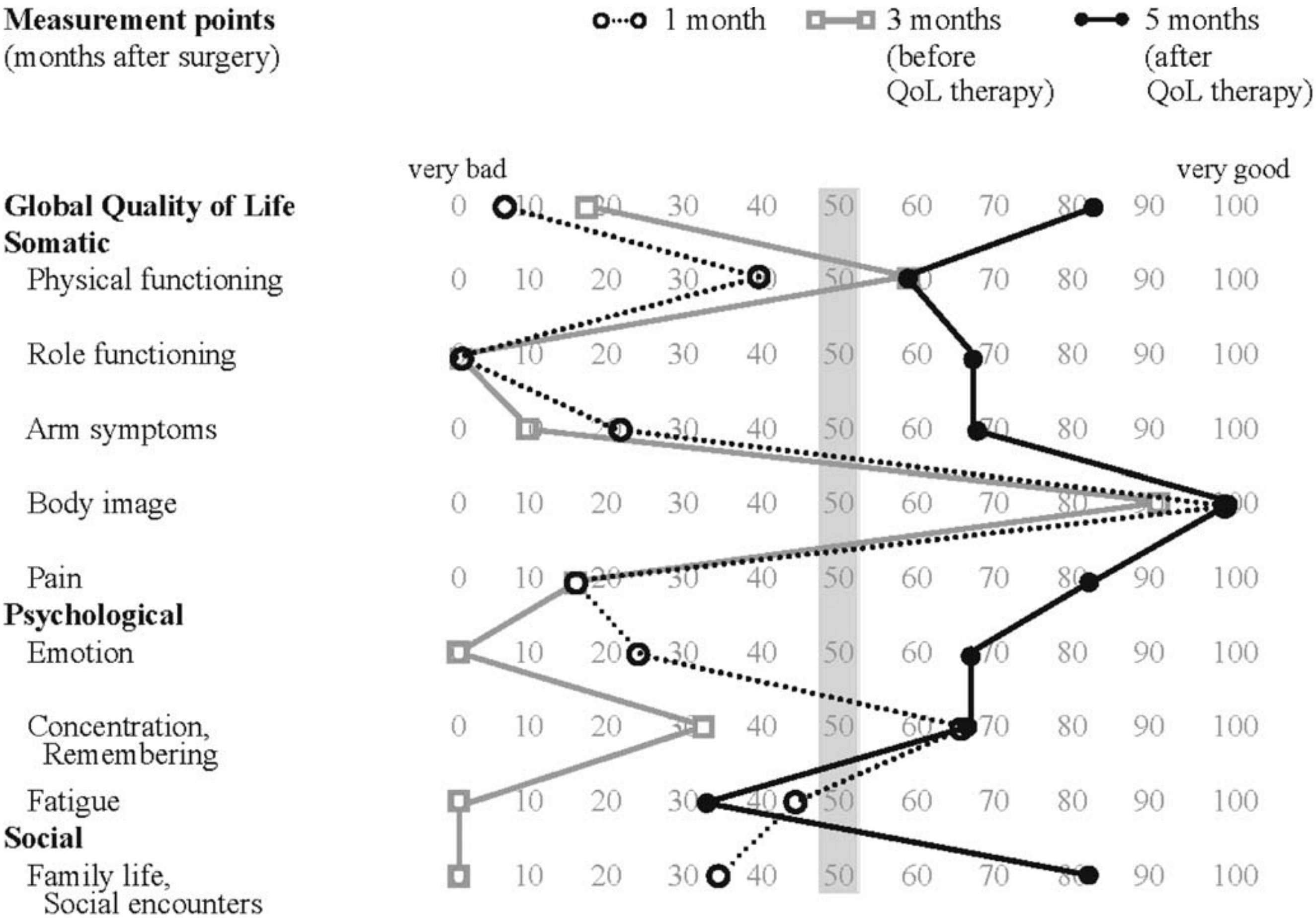


Fig. 4 QoL profile of a patient with breast cancer a few months after breast conserving surgery, before and after QoL therapy recommended in the experts' report. Data from the health status questionnaire show a patient 78 years old, married with two adult children. Prognostic classification of pT2, N0, M0, G3, hormone receptors ER^+, PR^+, $HER2neu^+$. *Solid line* At 5 months after surgery endocrine therapy, physiotherapy and lymph drainage are ongoing. *Shaded portion* Cut-off point between "healthy" and "diseased" QoL

QoL profile and for the recommendation of clinically relevant and reasonable therapies.

In the QoL unit the answers to the EORTC questionnaires were transformed into individual QoL profiles (Fig. 4) by a computerized QoL-Profiler visualization program [34]. A package containing a patient's current profile, past profiles, and health status reports by the CP was handed to each of the five experts in the QoL unit. The experts first wrote their diagnosis and treatment recommendations independently, then discussed them in a weekly consensus meeting to arrive at a group decision. This group consensus decision was formulated as an experts' report (Fig. 5) and sent to the CP chosen by the patient.

In contrast to other computerized programs for visualization of individual QoL data [5, 35], the QoL profile in this implementation study showed some specific characteristics directed to the clinician (Fig. 4): (1) All EORTC-QLQ-C30 scores were uniformly transformed on a scale ranging from 0 = very bad to 100 = very good. This is how clinicians usually read clinical findings at a glance at the bedside or in the ICU. The cumbersome distinction between functioning and symptom scores (for which the scoring is in the opposite direction: 0 = no symptoms, 100 = highest symptom burden) was avoided. (2) The aspect ratio of the graph was changed from a shallower axis for the score to a steeper one to elicit more urgency to provide help and to facilitate quicker decision making. This type of presentation was intensively studied and recommended by Cartmill and Thornton [36] and Wright et al. [37]. (3) Any previous QoL results are presented together with the most recent assessment, to ensure that all information and comparisons are available in a single profile. (4) The grey column at 50 points illustrates the cut-off point between "healthy" and "diseased" QoL. Scores less than 50 points in any

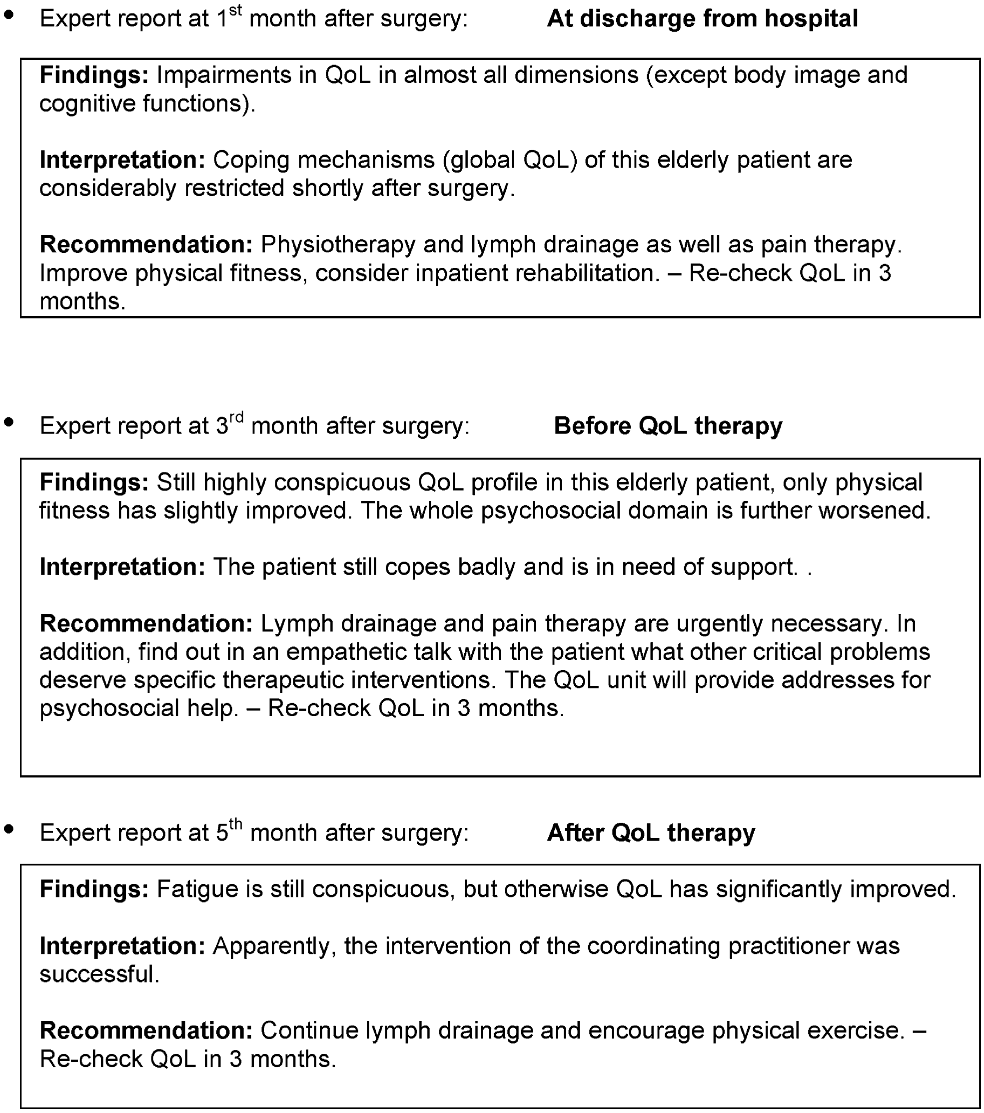


Fig. 5 Expert reports to a coordinating practitioner about the QoL of the patient illustrated in Figure 5: after surgery and before and after QoL therapy

- Expert report at 1st month after surgery: **At discharge from hospital**

Findings: Impairments in QoL in almost all dimensions (except body image and cognitive functions).

Interpretation: Coping mechanisms (global QoL) of this elderly patient are considerably restricted shortly after surgery.

Recommendation: Physiotherapy and lymph drainage as well as pain therapy. Improve physical fitness, consider inpatient rehabilitation. – Re-check QoL in 3 months.

- Expert report at 3rd month after surgery: **Before QoL therapy**

Findings: Still highly conspicuous QoL profile in this elderly patient, only physical fitness has slightly improved. The whole psychosocial domain is further worsened.

Interpretation: The patient still copes badly and is in need of support. .

Recommendation: Lymph drainage and pain therapy are urgently necessary. In addition, find out in an empathetic talk with the patient what other critical problems deserve specific therapeutic interventions. The QoL unit will provide addresses for psychosocial help. – Re-check QoL in 3 months.

- Expert report at 5th month after surgery: **After QoL therapy**

Findings: Fatigue is still conspicuous, but otherwise QoL has significantly improved.

Interpretation: Apparently, the intervention of the coordinating practitioner was successful.

Recommendation: Continue lymph drainage and encourage physical exercise. – Re-check QoL in 3 months.

dimension are judged as pathological and classified in the experts' report as "worthy of comment" or "a low level which needs attention" (Fig. 5).

The experts' report, which has no predecessors in the literature, also showed some special features. (1) It was organized like a pathology report including sections on findings, interpretation, and therapeutic recommendations (Fig. 5), which was consistent with the outcome model (Fig. 1). (2) Recommendations were given for any of the low levels individually, and findings were combined by experts' consensus (Fig. 5) that considered the QoL profile, the health status data, and expert knowledge about the side effects of adjuvant treatment. (3) The experts also added the addresses of professional therapists if necessary. (4) Evidence-based decision making [38] was promoted by identifying knowledge from breast cancer [39] and psycho-oncology [40] guidelines as well as recommendations for treatment given by Continuous Medical Education (CME) within the quality circle (see below). (5) These features demonstrate that the experts' report was intended not only to change communication between patient and doctor [5, 35] but also to improve treatment given by CP and professional therapists.

Decisions on QoL therapy were made in the office of the coordinating practitioner (Fig. 3). The CP received the QoL profile and experts' report, a list with the addresses of professional therapists, and a letter with several statements and recommendations:

(1) You are free in your decision to neglect or to accept any of the recommendations.
(2) If you accept, then decide whether you carry out the recommendations yourself,
(3) Ask one of the opinion leaders or send the patient to a professional therapist such as a psychotherapist or physiotherapist. Addresses are included.

One month later, the CP received a telephone reminder from the QoL unit, which was also used for evaluation of the QoL system and included six questions: "(1) Did you carry out any QoL therapy for this patient? (2) If yes, did you translate any recommendation from the QoL unit into action? (3) Did you do anything in addition which was not recommended? (4) Did you inquire an opinion leader? (5) In what kind of therapy and in which cycle was your patient (e.g., radiotherapy, chemotherapy)? (6) Did you see any influence of this therapy on the QoL of your patient? If yes, what kind of influence?"

The care pathway ended with the professional therapists who were directly approached by the CP but did not receive the experts' report of the QoL unit. Audit and feedback processes supervising the effectiveness of QoL therapy (e.g., pain therapy, physiotherapy) connected the QoL unit directly with the CP, who received the QoL profiles and experts' reports with notes of success or failure of the therapists 3 months after intervention. The QoL unit recommended only implemented professional therapists (those involved in quality circles).

Implementation of the complex intervention

To transform participants' classical biomedical concept of disease and outcome into the TCO model (Fig. 1) and to elicit changes in every day medical practice, more effort was needed than the simple presentation of academic material at scientific conferences or their dissemination in published form. In general, implementation strategies were required that derived from analyzing the positive and negative effects of clinical practice guidelines [29, 41, 42]. Hence, a multifaceted approach was chosen, which included those strategies for CME [29, 43] that have been shown to be effective: outreach visits to the work place of the CP and opinion leaders, involvement of opinion leaders in the process of change, and interactive learning in quality circles, especially for the professional therapists. Finally, following organizational theories of facilitating change [29, 41], the fourth strategy included adherence to the care pathway.

Educational outreach visits were conceptually and practically based on the insights derived from several systematic reviews [29, 41, 43–48]. Following the recommendation of O'Brien et al. [44], the outreach visits were performed by two trained individuals involved in the study. They met with the physicians (CPs, opinion leaders, and clinicians) in their own practice settings and presented information that should stimulate behavioral change (i.e., changing provider performance). The information given included feedback about their previous performance.

Conceptually, the outreach visit was standardized and included (1) so-called "priming", i.e., making doctors dissatisfied with some aspect of their own practice such as a sole focus on the biomedical treatment of cancer [45] and motivating doctors to use the new procedure [46], (2) "focusing" by helping participants to learn about alternative practices [45], and (3) "follow-up" by providing further information or advice regarding the intended change [45] in several steps including reminders and feedback. The presentation of the QoL system used standard academic detailing techniques [47] and worked against barriers previously identified such as shortage of time, poor experience using QoL assessment tools, and lack of insights into the practical consequences of measuring QoL [30, 48].

Practically, and guided by these principles, the care pathway and QoL system were implemented in the offices of 38 CPs residing in the defined geographical area (Fig. 2) within the time schedule of this study. (1) Two experts from the QoL unit, in each case one clinician and one psychologist (with knowledge in academically based detailing [53]), visited each CP in their office for 1 to 1.5 h at a time convenient to the particular CP. (2) The face-to-face presentation of the care pathway was standardized using a set of colored transparencies and comprehensively written information material. The latter consisted of articles written for patients about QoL in breast cancer [49], health care system policies concerning QoL [50], a short brochure about the Tumor Center Regensburg [51], and a half-page guide about how to measure QoL and how to handle the new QoL system. (3) The academic detailing aims were further strengthened by asking participants to handle a simulated case similar to the real process and setting. We especially emphasized the gain in time, because the QoL profile provided information on specific breakdowns in any QoL dimension (Fig. 4) at a glance, thus overcoming an important barrier [48]. (4) In addition, participants were primed for follow-up by requesting at least two cases from each participant documented using the EORTC questionnaire and the complete care pathway. (5) Finally, follow-up, reminder and audit, and feedback were implemented by using the five QoL therapy options. After the first outreach visit, the QoL unit waited 4 weeks for the CP to perform the two sample cases. Then either a telephone reminder followed or, if the diagnostic part of the cases was completed, a second outreach visit that included an interpretation of the profile and experts' report, a semi-structured interview asking whether the analysis was plausible and comprehensible, which recommendations the CP would translate into action, and what else he/she would do. After another 4 weeks, the CP was asked whether any therapy option had in fact been adopted. Finally, at the patient's next regular cancer follow-up 2 months later, the result of any intervention was reported to the CP using the next QoL profile and experts' report (Figs. 4 and 5).

The entire outreach visit procedure was not only designed to facilitate change but was also useful for evaluation and allowed a needs analysis [43] for the therapy options to be carried out.

The selection and function of local opinion leaders has already been described above. Their selection and briefing was implemented by the experts from the QoL unit in the same way as for the CPs. The opinion leaders exerted their influence less often than expected with individual CPs because they were rarely asked by CPs to give advice. In the quality circles, however, the opinion leaders were effective by professing their own change in attitudes and behavior concerning QoL and supporting the QoL system in group discussions.

Quality circles played a crucial role in fulfilling the following functions: (1) continuously improving the quality of QoL-specific therapy options, (2) presenting and discussing new evidence-based knowledge, and (3) bringing patients and providers together in a self-regulating health care system and the care providers into a cooperative group. Hence, according to Grol and Lawrence's methods [52], two types of quality circle (peer review groups) [53] were implemented as ongoing processes that involve the definition of criteria and the evaluation of performance and focus on continuous change.

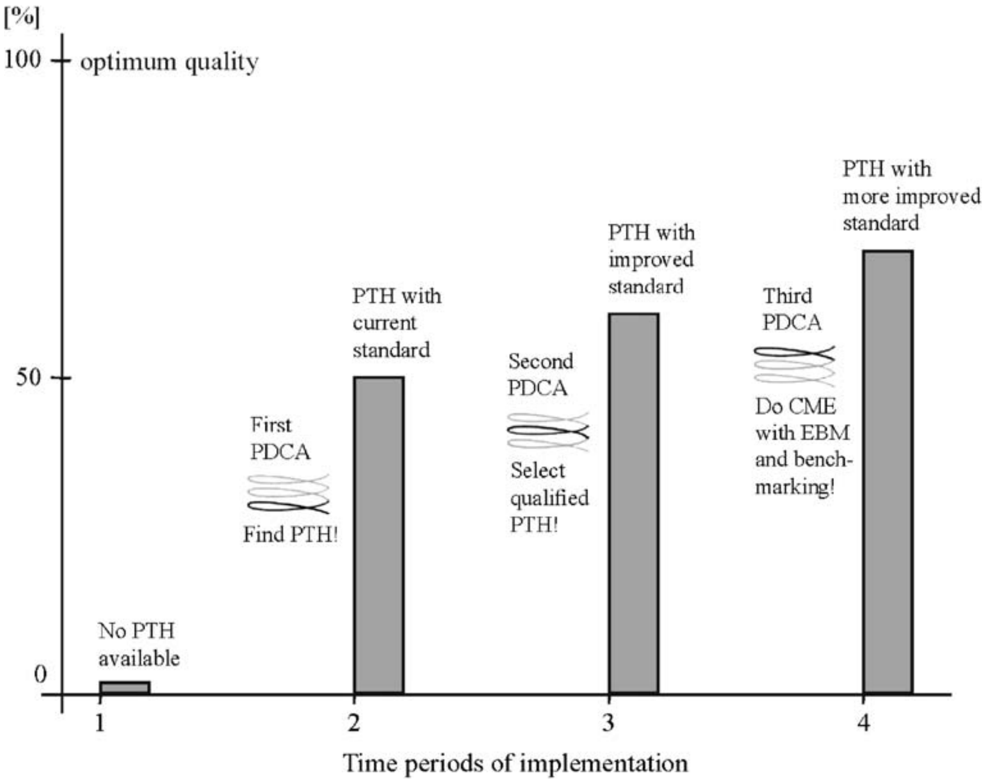
There were two types of quality circle: (1) A general group meeting of 41 members from all previously mentioned parties, who observed the progress of the overall QoL system, sought knowledge from external sources, and were consistently involved in solving problems, especially between the subgroups of the QoL system. For this task, we recruited a trained moderator, who was not biased for any subgroup [54]. (2) There were also five small interactive groups for each of the therapy options, which consisted of 5 to 10 specialists (peers) in physiotherapy, psychotherapy, etc. Their moderators were the best experts from the particular field but they were monitored for bias by the general group moderator. These five interactive groups provided consensus about processes, quality indicators, and evidence tables for each of the therapy options, but the final decision was made by the general quality circle. The general group met four times a year, the interactive groups about twice as often.

Quality improvement for each of the therapy options in the QoL system was designed and evaluated as a model that involved several PDCA cycles (Fig. 6). Each quality circle performed three cycles: (1) analysis of the need for each therapy option (Fig. 7) [43], (2) development of quality indicators for each therapy option, and (3) survey of the evidence using evidence tables for the highest level trials, e.g., RCTs. Recommendations were developed by consensus.

Conclusion

The present paper set forth the conceptual, methodological, and logistic background of a QoL system for the treatment of breast cancer patients. It thus dealt with the phase I modeling according to the MRC nomenclature for complex interventions. The description made clear how many individuals, institutions, decisions, and actions make up such a system. This complexity notwithstanding, the most important element in this system is the patient. Our basic goal is to identify and provide help for those patients who are suffering, who are ready to accept QoL enhancing therapeutic options and to design the care system in a way so that help can be provided by competent therapists in a timely manner. Therefore, the concept of "diseased" QoL and the clinical relevance criterion for identification of patients in need is of central importance for such a QoL system.

Fig. 6 Model for quality improvement of QoL-related therapy options in the QoL system for breast cancer over the course of 18 months. *PTH* Professional therapist, *PDCA* quality cycle with phases of plan, do, check, and act, *CME* continuous medical education



We are readily aware of the ongoing debate about meaningful interpretations of QoL scores using statistical [55], anchor-based [56], consensus conference approaches [57] and very thoughtful combinations [58, 59] of all these methods. Our concept based on a decision-making model is different from those approaches as it combines the psychometric aspects with the medical field. The individual patient and her personal needs rather than anonymous groups of patients become the focus of attention. Our question is not whether a change in QoL scores is of "minimal clinical importance", but whether the patient needs help, is ready to consult a doctor (iatrotropy) and whether she can receive therapeutic options that promise to improve her quality of life.

QoL diagnostics is important because doctors are poor judges of their patients' wellbeing and potentially QoL-enhancing therapies are often provided (or overlooked) without evidence or transparent decision rules. In the end, our system to diagnose and treat QoL deficits will have to pass the rigorous test of a randomized controlled clinical trial.

Fig. 7 Quality (PDCA) cycles for improvement of therapies directed against QoL deficits

PDCA cycle 1		**PDCA cycle 2**	
• Plan	Trace specialists in the region for 5 specific QoL therapies	• Plan	Select qualified specialists for 5 QoL therapies in the region
• Do	Make outreach visits to all 38 coordinating practitioners: Who is your specialist? Who is opinion leader?	• Do	Establish quality indicators for all 5 therapies
• Check	Analyse deficits	• Check	Analyse specialists found in the region
• Act	Develop registers of specialists for all coordinating practitioners	• Act	Invite external experts to evaluate indicators and use quality circles to evaluate specialists

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