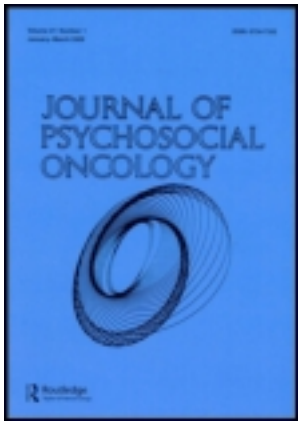

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Routine Monitoring of Quality of Life for Patients with Breast Cancer: An Acceptability and Field Test

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Routine Monitoring of Quality of Life for Patients with Breast Cancer: An Acceptability and Field Test

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As part of the development of a quality of life monitor for women with breast cancer, a qualitative acceptability test was conducted among 10 patients, to assess their suggestions for improvement. Next, a field test was conducted among 50 women with breast cancer receiving radiotherapy, chemotherapy, or both treatments to examine the use of the monitor in daily practice and to assess physicians' and patients' experiences with the monitor. Although patients in general held a positive attitude toward the monitor and compliance was high, patients regularly were unsure about how the quality of life information was used by physicians.

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KEYWORDS breast cancer, communication, distress, quality of life, screening

INTRODUCTION

It is well-known that the diagnosis and treatment of breast cancer have a severe impact on patients' quality of life (QoL). Depending on treatment type, potential physical symptoms include arm morbidity and lymph edema, skin irritations, pain, fatigue, nausea, hair loss, infertility, and menopausal symptoms (Montazeri, 2008; Rietman et al., 2006). Additionally, patients frequently suffer from a wide range of psychosocial consequences such as depression, fear of recurrence, sleeping problems, altered body image, problems with sexuality and difficulties in social interactions, some of which may persist long after completion of treatment (Amir & Ramati, 2002; Lethborg, Kissane, Burns, & Snyder, 2000; Longman, Braden, & Mishel, 1999; Reich, Lesur, & Perdrizet-Chevallier, 2008; Schnipper, 2001). Although it is widely acknowledged that these areas of QoL are frequently affected by disease and treatment, the individual patient's needs for care cannot be adequately addressed unless these problems are recognized by their health care providers (HCPs). Unfortunately, research had demonstrated that problems and needs of patients with cancer are often not adequately identified (Aranda et al., 2005; Farrell, Heaven, Beaver, & Maguire, 2005; Söllner et al., 2001).

Research has shown that most cancer patients wish to discuss psychological and social problems during the consultation, but 25% to 35% would like to discuss these issues only if their physician initiates this discussion (Detmar, Aaronson, Wever, Muller, & Schornagel, 2000; Taylor et al., 2011). As HCPs vary in the degree to which they feel it is their responsibility to initiate discussions about psychosocial matters with their patients, there is a high risk that psychosocial topics remain unaddressed, because both parties are hesitant to raise such issues without a clear signal from the other that this is appropriate or desired (Detmar et al., 2000). This is confirmed by observations of the communication between breast cancer patients and their HCPs showing that the exchange of biomedical information tends to dominate the interaction at the expense of the discussion of psychosocial issues (Hack et al., 2009). This concurs with the finding that a substantial proportion of patients with breast cancer indicate to experience problems in expressing feelings to their HCPs (Lerman et al., 1993).

One possible solution that may help the communication between patient and healthcare provider is the use of QoL assessments in daily practice. Recognizing the potential value of patient reported outcomes (PROs) for detection of otherwise unidentified problems, facilitating communication, monitoring changes in patients' well-being, and evaluating the results of treatment, a wide array of initiatives have been launched to incorporate PROs into daily practice (Gilbody, House, & Sheldon, 2002; Greenhalgh,

2009; Greenhalgh, Long, & Flynn, 2005; Marshall, Haywood, & Fitzpatrick, 2006; Valderas et al., 2008). Several reviews have concluded that the use of PROs in clinical practice is usually welcomed by patients and practitioners, appears to affect patient—provider communication, and improves detection of health related QoL problems (Gilbody et al., 2002; Greenhalgh, 2009; Marshall et al., 2006). Evidence for the effect on more distal outcomes such as patient satisfaction and health outcomes is less evident.

In oncology settings, several initiatives have been employed to integrate regular assessment of QoL and patient concerns into clinical practice. Detmar, Muller, Schornagel, Wever, and Aaronson (2002) provided oncologists with a graphic summary of patients' QoL, assessed with the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30 (EORTC QLQ-C30) during three consecutive consultations. This study showed that QoL issues were discussed more in the intervention group than in the control group, without lengthening the duration of the consultation. At the end of the study period patients in the intervention group were more satisfied with the emotional support received from their physician than patients in the control group. In another study, patients receiving chemotherapy were asked to complete the EORTC QLQ-C30 questionnaire and the Hospital Anxiety and Depression Scale (HADS) on a touch screen computer before every consultation, for approximately 6 months (Velikova et al., 2004). Compared with the control group, in the intervention arm a more frequent discussion of QoL topics addressed in the questionnaire (sleeping problems, lack of appetite, and fatigue) was observed, without prolonging the encounters. Furthermore, results showed that a larger proportion of patients in the intervention group showed clinically meaningful improvement in QoL over time than patients in the control group. In a secondary analysis, the research group discovered that patients who had completed the QoL monitor were more satisfied with the communication with their physicians (building rapport and improving interpersonal relation) (Velikova et al., 2010). Boyes, Newell, Girgis, McElduff, and Sanson-Fisher (2006) asked patients to complete a touch screen computer survey immediately before seeing their oncologist at three consecutive encounters or until the end of their course of treatment. The assessment included a list of physical symptoms, the HADS, and a list of supportive care needs. In the intervention arm a graphic summary of patients' answers was available to the oncologists, whereas in the control arm the oncologists did not receive feedback on patients' QoL. Although patients in the intervention group showed a sharper decrease in physical symptoms from the second to the third visit, both groups demonstrated a similar decrease in anxiety, depression, and supportive care needs. This lack of effect might be explained by the fact that patients in the intervention and control group had filled out the same questionnaire, and all patients were instructed to discuss their complaints with their physician. Furthermore, it was noticed that only three patients in the intervention group reported that their

oncologist discussed the feedback report with them. A study by De Bree, Verdonck-de Leeuw, Keizer, Houffelaar, and Leemans (2008) among patients with head and neck cancer investigated the acceptability of a repeated computerized QoL assessment, which included the EORTC QLQ C30, together with the 35-item Head and Neck cancer module (EORTC H&N35) and the HADS. Completing the questionnaire was considered as meaningful by 75% of the patients. However, 81% of the patients thought one or more important questions had not been addressed in the questionnaire. Furthermore, data showed that compliance rates dropped from 100% at the first visit to 67% during the follow-up visits.

With regard to the care of patients with breast cancer, Hilarius, Kloeg, Gundy, and Aaronson (2008) showed that repeated assessment of cancer generic (EORTC QLQ-C30) and condition specific (EORTC BR23 breast cancer module) questionnaires together with a graphical summary of patients' QoL available to the healthcare providers resulted in a more frequent discussion of QoL-related issues such as sleeping problems, diarrhea and constipation, sexuality, arm and breast symptoms, and body image. Eighty-nine percent of the patients believed that the QoL summary improved their HCP's awareness of their symptoms and concerns and should be used as a standard element of care for patients with breast cancer.

Based on these promising results a study was initiated at the Clinical Oncology Department of Leiden University Medical Center (LUMC) to incorporate repeated QoL assessment into the routine care for patients with breast cancer. It was considered essential for successful implementation to investigate and optimize the acceptability to patients of such regular QoL assessment. By collecting their opinions and suggestions during interviews, the aim of this pilot study was to involve patients in the development process of the QoL monitor and to examine the acceptability of such a monitor to patients. A second aim of this study was to conduct a field test to investigate the use of the monitor and to assess patients' and physicians experiences with the monitor.

METHOD

Instrument Development

In the development process of the monitor criteria outlined by Greenhalgh et al. (2005) and Pigott, Pollard, Thomson, and Aranda (2009) were followed (Greenhalgh et al., 2005; Pigott et al., 2009). First, the instrument needed to be "patient centered," consisting of validated QoL questionnaires that had been developed in collaboration with patients. The instrument should capture not only cancer generic problems but also site-specific complaints (Velikova et al., 2008). Furthermore, the monitor should cover physical, emotional, social, and functional domains. Finally, the instrument should allow patients to report additional relevant complaints or care needs that had not been addressed in the previous questions (Snyder, Jensen, Courtin,

Wu, & Website for Outpatient QOL Assessment Research Network, 2009; Velikova et al., 2008).

Second, the instrument should allow practitioners to monitor changes in QoL during active treatment and follow-up. It was deemed important to include a baseline assessment before the start of treatment and to continue monitoring QoL until after the end of treatment. As the instrument was aimed to facilitate patient–provider communication, QoL assessments would be synchronized with patients' regular hospital visits.

Third, the tool must be user friendly. Patients should experience little difficulty in completing the questionnaire. Additionally, time investment for patients should be minimal. With these criteria in mind a questionnaire was developed containing the following components (in this order):

1. The Distress Thermometer (DT; Roth et al., 1998). This single-item thermometer is used to assess the global level of patient distress (0–10 scale). A recent validation study of the DT in a Dutch sample of cancer patients showed that a score of 5 or higher may be regarded as a sign for elevated distress (Tuinman, Gazendam-Donofrio, & Hoekstra-Weebers, 2008).
2. The EORTC BR-23 breast cancer questionnaire (Sprangers et al., 1996). This questionnaire is widely used to assess breast cancer–related problems. It covers physical and psychosocial domains.
3. The Care Notebook (CNB; Kobayashi et al., 2005), a 24-item cancer-generic instrument that was specifically designed and validated for frequent assessment of patients' QoL in daily practice. The questionnaire contains items about physical complaints, emotional status, daily functioning, social functioning, and subjective QoL. Questions are answered on a 0 to 10 scale.
4. One free text dialog box (Jones et al., 2002; Wells, Falk, & Dieppe, 2004), inviting patient to list concerns, complaints or questions they would like to discuss during the next visit.
5. One question assessing supportive care needs. Patients could indicate (tick box) whether they would like to discuss specific complaints or their condition in general with persons other than their physician (e.g., fellow patients, physiotherapist, psychologist).

The National Comprehensive Cancer Network (NCCN; 2011) recommends combining the Distress Thermometer with a Problem List, when screening for distress. Our decision to combine the DT with two QoL questionnaires instead of the Problem List originated from the wish to monitor changes in intensity of the symptoms over time, which is not possible with the Problem List, as it uses a dichotomous (yes/no) answering format.

As the LUMC was in the middle of a transition phase during which paper medical files were replaced by electronic medical files, it was decided to develop an online version of the QoL monitor. Through the web portal,

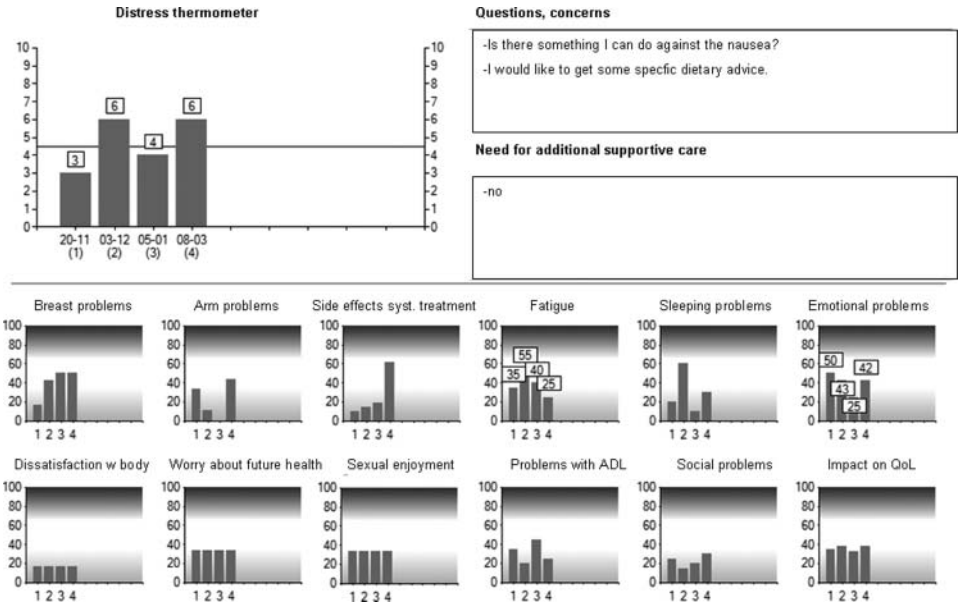

FIGURE 1 Graphic summary of patients' distress, QoL, questions and care needs.

patients' answers would be stored in patients' digital file, increasing accessibility of the data. The system was designed to calculate subscales for QoL domains automatically from the answers in the database. Together with clinicians a format for presentation of the QoL information was developed (see Figure 1). This graphic summary contains the DT, patients' information and care needs, six domains from the EORTC BR23 (arm problems, breast symptoms, effects of systemic treatment, future perspective, sexual enjoyment, body image), and six domains from the CNB (trouble sleeping, fatigue, mental well-being, activities of daily living, social functioning, subjective QoL). To facilitate interpretation of the QoL summary, some subscales were reverse-scored so that higher score in all domains represent more symptoms or worse functioning.

Patient Recruitment

Approval for this study was obtained from the LUMC ethics committee. For the qualitative acceptability study 10 consecutive patients were invited to participate by the nurse practitioners (EKW, GR) during regular follow-up visits. Patients were eligible if they had completed treatment, or currently received only long-term hormone therapy (See also Table 1). No other inclusion criteria (e.g., specific computer skills or sociodemographic background) were used. Consenting patients were contacted by the researcher (MJF) to make an appointment for the interview.

For the field test patients were recruited by the researcher after patients had discussed their treatment plan for adjuvant treatment. Patients scheduled

TABLE 1 Patient Characteristics (Acceptability Test)

Patient no.	Age	Partner	TNM stage	Surgery	Adjuvant Treatment
1	55	No	T2N1M1	Mastectomy	RT+CT+HT
2	48	Yes	T2N1Mx	Mastectomy	RT+CT
3	55	Yes	T1N1Mx	Lumpectomy	RT+CT+HT
4	51	Yes	TisNxMx	Lumpectomy	RT
5	56	Yes	TisNxMx	Lumpectomy	RT
6	62	No	TisNxMx	Mastectomy	RT
7	37	Yes	TisNxMx	Mastectomy	RT
8	39	Yes	T2N0Mx	Mastectomy	RT+CT
9	40	Yes	T2N1Mx	Mastectomy	CT+HT
10	67	No	TisNxMx	Mastectomy	RT

RT = radiotherapy; CT = chemotherapy; HT = hormone therapy.

to receive radiotherapy, adjuvant chemotherapy, or both treatments were eligible to participate in this field test.

Interview Procedure

During the interview patients were shown a concept version of the questionnaire on a computer and discussed their opinions with the interviewer. Participants were instructed to give their most critical opinions to reduce chances of social desirable answers. It was explained that the monitor was designed to systematically assess patients' symptoms, well-being, and care needs several times (prior to the start of adjuvant treatment, halfway through treatment, at the end of treatment, and two times during posttreatment follow-up) with the aim of facilitating the discussion of these topics.

A semi-structured interview protocol was used for this study (see Appendix). For Questions 1 through 6, patients were asked to rate different aspects of the questionnaire on a 5-point scale ranging from *not at all* to *very much* and were invited to comment on their answers. Questions 7 through 11 pertain to patient preferences regarding the QoL assessment. Patients' statements were written down. Basic thematic analysis was used for the qualitative data. Patients' statements were read and summarized. Meaningful units were extracted from patients' comments. A matrix was created containing the respondents' condensed statements for each interview topic. This matrix allows for comparing statements between patients and relating the findings to patients' medical and sociodemographic status.

RESULTS

Acceptability Test

Eleven women with breast cancer were invited to participate in the acceptability test. One patient declined as she did not have a computer. All but two

interviews were conducted in the participants' homes. One patient preferred to answer the questions by e-mail. One other patient was interviewed in the researcher's office. Mean age of the respondents was 51 years ($SD = 10$) (see also Table 1). Most patients were cohabitating and had paid employment.

Interview Themes

Understandability of questions. All patients thought the questions were easy to understand (Table 2). In specific comments however, three patients expressed their concerns about the DT. They indicated it was difficult to give one single score for global distress:

> What if my daily functioning was alright, my physical functioning was poor and my social functioning was fine. How would that generate one mean score? (Patient 3)

Other comments pertained to the CNB items "quality of life" (for two patients this was an unfamiliar expression) and "Satisfaction with life" (one patient indicated this to be a relevant but difficult question). A minority ($n = 3$) of the patients indicated that an 11-point answering scale for the CNB might be too detailed for them.

Applicability of items. Most patients considered the items to be applicable to their situation (Table 2). Logically, questions about the side effects of systemic treatment (BR23) were considered not applicable by those patients who had not received chemotherapy or hormone therapy.

Two patients suggested that the questionnaire should be tailored to the situation of the individual patient. More specifically, one patient suggested using different questionnaires for each type of treatment. One other patient suggested creating three questionnaires for each phase of treatment (before, during, and after). Another suggestion was to add the answer category "Not applicable."

Three patients had no partner and considered the questions about sexuality not applicable. The other patients considered sexuality as a relevant but sensitive topic. Five respondents indicated that asking about sexuality

TABLE 2 Patients' Rating of the Questionnaire

	Not at all %	Hardly %	Somewhat %	Quite %	Very much %
Easy to understand	0	0	0	20	80
Applicable	0	10	20	20	50
Comprehensive	0	0	0	40	60
Useful for communication	10	10	0	40	40
Unpleasant/burdensome to complete	60	20	10	0	10
Disturbing/confronting questions (N = 9)	33	44	11	0	11

was good because it was evident that most patients are likely to experience difficulties with regard to sexuality after treatment for breast cancer. Three respondents suggested that answering these questions should be optional.

Comprehensiveness of the questionnaire. All patients considered the questionnaire to be comprehensive (Table 2). Also, all patients agreed there were no redundant questions. Nevertheless, according to the respondents some questions might be added to the questionnaire, such as joint stiffness during chemotherapy ($n = 2$), changes in partners' behavior and the intimate relationship ($n = 2$), memory and concentration ($n = 1$), restless legs ($n = 1$), and additional effects of hormone therapy (heart problems and reduced physical condition) ($n = 1$).

Usefulness for communication. Most patients expected the monitor to be useful for the patient–provider interaction. Respondents indicated that visiting the hospital was a stressful event. Often they felt they did not have the presence of mind to ask all they wanted to know. Therefore, it was considered helpful to review their complaints, needs, and questions at a convenient time before the consultation. Additionally, patients expected the information could serve as a checklist for physicians, reducing chances of missing important information.

Patients expected that the monitor could facilitate the discussion of personal or intimate topics. Three patients indicated that they were sometimes hesitant to express their worries or discuss sensitive matters with their physician. These patients felt that answering personal questions on a questionnaire would be easier than answering the same direct questions from a HCP.

> For those patients who find it difficult to discuss personal matters, it [filling out a questionnaire] might be easier because nobody is sitting directly in front of you. This feels less confronting. It can be difficult to take that first step. Once they have answered those questions on a computer, they will feel more confident to discuss them in person with their physician. (Patient 6)

However, although all patients were of the opinion that it was important for HCPs to be attentive to nonphysical issues, three patients explicitly stated they would prefer to discuss emotional or intimate matters with their female nurse practitioner rather than with their doctor, as they felt the relationship with their physician did not allow for discussion of these topics.

> Whether one discloses about psychological issues or not depends on what the professional can do with the information. Of course they are not trained to handle these matters. How one experiences the illness and treatment is very important, but this can result in a very uncomfortable conversation. I'd rather not discuss these matters if my physician could not deal with them. (Patient 8)

Another perceived benefit was the wide range of questions about their well-being. Three women expected that the answers on the questionnaire would provide a good starting point for further exploration of their complaints and needs. They commented that their physician's question: "How are you doing?" was often replied by the answer: "Very good," which was considered uninformative. Respondents expected that the specific questions would lead to a more efficient conversation.

Some women considered it useful to be able to compare present and past answers. Two patients indicated that during treatment they had been living day by day. They found it difficult to remember how their symptoms had changed over time. Repeated administration of the questionnaires would make it possible to identify whether symptoms had improved or worsened. Finally, one patient expected that the routine assessment would lead to greater chances for patients to determine the agenda of the consultation as the questionnaire has the option for patients to formulate their questions and concerns in the free text space.

Respondents also expressed several concerns regarding the QoL monitor. First, two patients were concerned that given the existing time pressure, the introduction of the monitor would lead to an information overload for physicians. They expected that the information provided by patients might not be used, which would make completing the questionnaires pointless.

Second, two patients expected that providing information about QoL to physicians would not improve the already high quality of care. One patient said all relevant topics had been addressed during her treatment. The other respondent indicated that, for her, introducing the questionnaire would not have an added value as she was already used to making a list of questions in preparation for consultation and did not experience any trouble in expressing her concerns.

Finally, one patient feared that physicians might not be the right HCPs to share information with on emotional and social functioning. According to this patient information about these topics might better be fed back to the nurse practitioners.

Costs of filling out the questionnaire. Most patients regarded the routine assessment as a minor time investment, as long as they were convinced about the benefits (Table 2). There was no indication that the participants experienced questionnaire fatigue from the number of questions asked:

> No trouble at all because you can express your concerns. And then the doctor knows what's going on in your mind. (Patient 4)

Only one respondent perceived the questionnaire as disturbing (Table 2). This pertained to questions about body image and sexuality. Two patients commented that before starting treatment one might wish not to be confronted with questions about symptoms possibly experienced in the near

future. At the same time, they expected that patients normally would receive written or oral information about the possible side effects of treatment and therefore were confronted with these topics anyway.

Patients differed with regard to how they would experience the confrontation with their previous answers. This appeared to depend on how the disease or symptoms would develop.

> It is nice to realize when certain symptoms have disappeared. (Patient 9)

> Later on, you want to leave it behind you and say: 'that's all in the past.' As if it's not there. You must have a good reason to continue filling out these forms. (Patient 3)

> I would not show graphs including past assessments to patients. That can be very confronting. (Patient 7)

Patient preferences. Most patients ($n = 8$) indicated they would like to be able to print their answers after completing the questionnaire to be able to compare present with previous answers, to check whether all questions have been answered, or to take it with them to hospital as a reminder of their questions for their doctor.

Although all interviewed patients had a computer with Internet access, patients differed in their preference for an online versus paper-and-pencil questionnaire assessment. Five patients preferred to do this online. Perceived benefits of this method were the immediate and cost-free information exchange, and not having to go to the post box for each questionnaire. Three patients preferred the paper-and pencil method of completing the questionnaire, and two patients were indifferent.

All patients preferred to complete the questionnaire at home as opposed to filling out the questionnaire in the hospital waiting room because of the limited time and privacy in the waiting room, and the emotional tension patients experienced just before the consultation interfering with their symptom perception and reducing the ability to quietly think of questions they would like to ask.

> The waiting room is no 'safe' environment. It is far too busy. There is little privacy and everybody would be looking over your shoulder on the PC screen. (Patient 8)

> There is no time to do this in the hospital. Besides, you are too nervous. (Patient 1)

All patients expected to have been able to complete the questionnaire alone ($n = 8$), or with help from a partner or relative. Finally, the proposed

frequency of administration was considered appropriate by all patients. Extending the assessment beyond the phase of intensive treatment was regarded as essential.

> At every visit would be fine. Some symptoms only appear after a while. At first, your main concern is to survive. You are focused on physical aspects. Later, the emotions arise. (Patient 3)

Modification of the Monitor Design

Based the respondents' comments and suggestions, several changes were made to the questionnaire. First of all, the order of the questions was changed. As in other studies (Dabrowski et al., 2007; Morita et al., 2008) the DT was placed after the QoL questionnaires, because patients considered it easier to summarize their global level of distress after reflecting on the specific domains of QoL. Second, the original plan to include mandatory fields in the online assessment was abandoned. Instead, in the information leaflet patients were informed that they were allowed to skip questions they considered too personal or irrelevant. Additionally, after the last question patients were requested to check whether they had answered all questions they wanted to answer. Third, the option was built in to print the answers after completing the online questionnaire. Finally, as patients differed in their preferences, it was decided to offer patients the choice between completing the online questionnaire or a paper-and-pencil version.

We did not add questions to the questionnaire, as had been suggested by a minority of the patients because these suggestions were quite heterogeneous and patients commented that adding their additional complaints or topics in the free text space would be an acceptable alternative. We also decided not to follow the suggestion to create separate questionnaires for each stage of the disease. This was done because the aim was to allow clinicians to compare patients' symptoms and complaints longitudinally, which requires the use of identical questionnaires for each assessment.

Field Test

After the monitor had been adapted a field test was undertaken. In plenary sessions physicians received instructions about the aim, logistics, and technical aspects of the project, were informed about the domains of QoL within the monitor using hypothetical data, and were shown the results of the acceptability test. Physicians also were contacted individually when they were about to see their first patient who participated in this project. This was done to check whether the project and process was understood by the

TABLE 3 Patients' Characteristics (Field Test) $N = 50$

	M	(*SD*)	*n*	%
Age	58.6	(10.9)		
Surgery				
Mastectomy			4	8
Breast conserving			45	90
Axillary lymph node dissection			1	2
Adjuvant treatment				
RT			29	58
CT			2	4
RT + CT			7	14
RT + HT			8	16
RT + CT + HT			2	4
RT + IT			1	2
CT + HT + IT			1	2

RT = radiotherapy; CT = chemotherapy; HT = hormone therapy; IT = immunotherapy.

physicians and to discuss possible questions. No specific guidelines were provided on how the monitor should be used during the consultation

Fifty-eight women with breast cancer were invited to participate in the field test, to which 51 (88%) agreed (see Table 3 for patient characteristics). One woman was excluded as her actual treatment did not meet the inclusion criteria. Depending on personal preference, patients received either a paper questionnaire at their home address or an e-mail directing them to the hospital portal to complete the assessment a few days before their next regular hospital visit. New data were stored and presented graphically in patients' electronic medical files (see Figure 1). One day before the patients' visit the treating physicians received an e-mail to alert them that new QoL information had been added to the patient's medical file. In addition, on the overview page of the patients' medical file statement was placed indicating that the patient participated in this study. After the visit physicians were asked to complete a short evaluation form. Patients were asked to complete an evaluation form after receiving three QoL questionnaires.

Patients' compliance in filling out the questionnaires was high. In total 134 (92%) questionnaires were returned out of the 146 (T1–T3) QoL questionnaires that were sent out. In addition, 41 patients completed the evaluation form. On average patients needed 10 minutes to complete the questionnaires ($SD = 6.2$). Confirming our qualitative data, the majority of the patients (64%) thought the questionnaire was "quite" or "very much" suited as a tool to communicate symptoms, questions and care needs, whereas only 10% considered it "not at all" or "hardly" suitable for this purpose (1–5 scale). Most patients (81%) confirmed our earlier finding that filling out the questionnaires had "not at all" or "hardly" been burdensome (1–5 scale). Completing the questionnaires was also considered "not at all" or "hardly" difficult by 81% of the patients (1–5 scale). According to the patients the results from the

questionnaires had been discussed explicitly at all three hospital visits (15%), during two visits (15%), during one visit (33%), or never (37%). According to patients, the discussion of patients' questionnaire results was typically initiated by the physician (89%). The perceived frequency at which patients felt the results of the monitor were discussed greatly affected the perceived usefulness (1–5 scale) of the monitor for the communication with their HCP, with more frequent discussion of the results being associated with higher perceived usefulness ($r = .59$, $p < 0.001$). In qualitative comments patients identified three major benefits of the questionnaire: it was considered useful for informing physicians about patients' current and previous well-being and concerns (six patients), it increases patients' own awareness of their symptoms, feelings and needs (four patients), and it was found to be beneficial for the interaction with the HCP (e.g., prevents questions being forgotten, broadens the agenda of the consultation) (seven patients).

> A very good initiative. You won't forget a single thing. If you say that everything is fine, the doctor will check the questionnaire and asks additional questions. I mean, you are different when you are in the doctor's office. The things you forget will be addressed by the doctor.

Patients who thought the monitor had not been useful mainly commented that they felt their results had not been discussed (eight patients) or indicated they did not experience serious symptoms or side effects to necessitate monitoring (seven patients). Nevertheless, 80% of all patients thought that the QoL monitor should be integrated as a standard element of care for all patients with breast cancer, whereas another 5% of the patients thought it might be useful to include the monitor for a specific subgroup of patients.

When patients had sent in a new questionnaire prior to their consultation, physicians ($N = 25$) were asked to complete an online evaluation form after the visit. Seventy-one forms have thus far been returned. The physicians considered the addition of the QoL information "very" or "quite" useful (1–5 scale) for the communication with their patients in 39% of the cases and "moderately" useful in 44%. Seventeen percent thought the information was "not at all" or "hardly" useful. Physicians thought that the addition of the QoL monitor had not influenced the duration of the consultation in 75% of the cases, whereas in 25% they perceived it to have increased the length of the visit.

DISCUSSION

This article describes the results from an acceptability and field test regarding the implementation of a QoL monitor for women with breast cancer. Results showed that, in general, patients held a positive attitude toward the QoL

monitor. The instrument proved easy to understand and was considered as a comprehensive checklist for patients and physicians, possibly broadening the agenda of the conversation. For most patients the anticipated benefits of the assessment outweighed the burden of completing the questionnaires, resulting in high participation rates and good compliance in filling out the questionnaires.

Confirming previous investigation of the EORTC BR23 questionnaire in a Dutch sample, this study showed that questions were well accepted and understood by patients (Sprangers et al., 1996). The DT and CNB questions in general also proved easy to understand, although for some patients judging their global QoL and distress was a request that was considered relevant and easy to understand but difficult to answer. This may be explained by the fact that reviewing one's QoL is a more complex cognitive task than answering questions about the occurrence of a single symptom (Barofsky, 2003; Bloem et al., 2008). In addition, research has shown that for a minority of patients it is difficult to quantify their distress on a numerical scale ranging from 0 to 10 (Hughes, Sargeant, & Hawkes, 2011).

The perceived relevance of the questions in the CNB and EORTC BR23 in general was good but appeared to depend on patients' treatment and relational status. For some patients these inapplicable questions lead to their suggestion that several questionnaires should be developed for each stage of the disease or for each treatment type. However, for other patients seeing that several symptoms did not apply (any more) can be beneficial for their morale.

Most patients thought the routine assessment of QoL would be useful for the communication between patient and HCP. Patients often regard the question "How are you?" as a social greeting instead of a clinical assessment (Rogers & Todd, 2000). By contrast, asking specific questions about QoL was expected to lead to more informative answers, providing clinicians with systematic overview of patients' well-being and care needs. It was also thought that asking a wide variety of questions could broaden the agenda of the consultation, facilitating the discussion of concerns relevant to the individual patient (Shields et al., 2010). However, in the field test patients often thought the QoL information they had provided was not discussed, reducing the perceived usefulness of the monitor. Unfortunately, we do not have objective data about the actual use of the monitor. One obvious reason for not discussing the information is that on some occasions patients' questionnaires were received only after patients had visited their doctor. This delay further supports the important benefit of online information exchange. Alternatively, it is very possible that physicians reviewed the QoL information a day before the patients' visit, when they received the e-mail alert. Concluding that there were no important changes in patients' QoL or specific care needs, physicians may have used the information more implicitly rather than explicitly during the consultation. Clearly, more research is needed to

investigate objectively to what degree QoL information is discussed during the consultation.

Patients generally thought that filling out the questionnaire would not be emotionally disturbing. However, as in other studies, (Snyder et al., 2009; Velikova, Brown, Smith, & Selby, 2002; Velikova et al., 2008) patients differed in their wish to have a printed copy of the questionnaire, or would like to review scores from prior assessments. Comparison of present with past functioning is likely to boost patients' morale if they see that their symptoms have decreased and their well-being has improved. Alternatively, the questionnaires draw attention to their illness and associated symptoms, which patients might wish to ignore (Mills, Murray, Johnston, & Donnelly, 2008), especially when the condition deteriorates.

Several limitations to this study must be acknowledged. First, the number of patients in the acceptability study was small, limiting the generalizability of the results. Fortunately, the field test to a large extent confirmed the qualitative results. However, the potential benefits that are recognized by patients will need to be optimized in practice. A second limitation is that respondents were relatively young. In the qualitative and quantitative tests the mean age was younger than age 60 years. There was however a large range in patients' age (33–75), and no association was found between participants' age and responses on the evaluation form.

Notwithstanding these sample limitations, the advantage was that participants in this study had received a wide variety of treatment types for breast cancer. In this regard, it is encouraging that this heterogeneous sample considered the questionnaires in the monitor to be comprehensive and applicable.

IMPLICATIONS FOR PRACTICE

In sum, these two pilot studies support previous studies (Allenby, Matthews, Beresford, & McLachlan, 2002; Boyes et al., 2006; Detmar et al., 2002; Velikova et al., 2002; Velikova et al., 2004) showing that monitoring of QoL is generally acceptable to patients. The main differences of this system compared with most previous initiatives involving repeated QoL assessment in oncology (Boyes et al., 2006; Detmar et al., 2002; Velikova et al., 2004) are the inclusion of a site-specific questionnaire (EORTC BR23), the possibility for patients of completing the questionnaires at home and the automatic integration of QoL information into patients' electronic medical records, which is likely to increase user friendliness, specificity of information, and accessibility of the QoL data.

The next phase in this study will be to conduct a randomized controlled study to investigate the effects of including a regular assessment of QoL and care needs in daily practice. For this study it is necessary to further improve

logistic aspects of data exchange and to optimize the use of the monitor. For instance, providing patients with a copy of the graphical summary of their QoL data, and asking them to bring it along on their next visit might increase the explicit discussion of the results. Encouraging physicians to make reference to patients' questionnaire during the consultation (regardless of the intensity of symptoms or care needs), is likely to increase the perceived usefulness of the monitor for patients. Finally, practical instructions as to how information about QoL and distress can be used by HCPs in oncology have been included in a recently issued Dutch national guideline (Vereniging Intergale Kankercentra, 2010). Incorporating this guideline into the next phase of our project can improve the use and perceived usability of the monitor.

REFERENCES

Allenby, A., Matthews, J., Beresford, J., & McLachlan, S. A. (2002). The application of computer touch-screen technology in screening for psychosocial distress in an ambulatory oncology setting. *European Journal of Cancer Care (Engl)*, *11*, 245–253.

Amir, M., & Ramati, A. (2002). Post-traumatic symptoms, emotional distress and quality of life in long-term survivors of breast cancer: A preliminary research. *Journal of Anxiety Disorders*, *16*, 191–206.

Aranda, S., Schofield, P., Weih, L., Yates, P., Milne, D., & Faulkner, R. (2005). Mapping the quality of life and unmet needs of urban women with metastatic breast cancer. *European Journal of Cancer Care*, *14*, 211–222.

Barofsky, I. (2003). Cognitive approaches to summary measurement: Its application to the measurement of diversity in health-related quality of life assessments. *Quality of Life Research*, *12*, 251–260.

Bloem, E. F., van Zuuren, F. J., Koeneman, M. A., Rapkin, B. D., Visser, M. R. M., Koning, C. C. E., & Sprangers, M. A. G. (2008). Clarifying quality of life assessment: Do theoretical models capture the underlying cognitive processes? *Quality of Life Research*, *17*, 1093–1102.

Boyes, A., Newell, S., Girgis, A., McElduff, P., & Sanson-Fisher, R. (2006). Does routine assessment and real-time feedback improve cancer patients' psychosocial well-being? *European Journal of Cancer Care*, *15*, 163–171.

Dabrowski, M., Boucher, K., Ward, J. H., Lovell, M. M., Sandre, A., Bloch, J., … Buys, S. (2007). Clinical experience with the NCCN Distress Thermometer in breast cancer patients. *Journal of the National Comprehensive Cancer Network*, *5*, 104–111.

De Bree, R., Verdonck-de Leeuw, I. M., Keizer, A. L., Houffelaar, A., & Leemans, C. R. (2008). Touch screen computer-assisted health-related quality of life and distress data collection in head and neck cancer patients. *Clinical Otolaryngology*, *33*, 138–142.

Detmar, S. B., Aaronson, N. K., Wever, L. D. V., Muller, M., & Schornagel, J. H. (2000). How are you feeling? Who wants to know? Patients' and oncologists' preferences for discussing health-related quality-of-life issues. *Journal of Clinical Oncology*, *18*, 3295–3301.

Detmar, S. B., Muller, M. J., Schornagel, J. H., Wever, L. D. V., & Aaronson, N. K. (2002). Health-related quality-of-life assessments and patient-physician communication: A randomized controlled trial. *Journal of the American Medical Association*, *288*, 3027–3034.

Farrell, C., Heaven, C., Beaver, K., & Maguire, P. (2005). Identifying the concerns of women undergoing chemotherapy. *Patient Education and Counseling*, *56*, 72–77.

Gilbody, S. M., House, A. O., & Sheldon, T. (2002). Routine administration of health related quality of life (HRQoL) and needs assessment instruments to improve psychological outcome-a systematic review. *Psychological Medicine*, *32*, 1345–1356.

Greenhalgh, J. (2009). The applications of PROs in clinical practice: What are they, do they work, and why? *Quality of Life Research*, *18*, 115–123.

Greenhalgh, J., Long, A. F., & Flynn, R. (2005). The use of patient reported outcome measures in routine clinical practice: Lack of impact or lack of theory? *Social Science & Medicine*, *60*, 833–843.

Hack, T. F., Pickles, T., Ruether, J. D., Weir, L., Bultz, B. D., & Degner, L. F. (2009). Behind closed doors: Systematic analysis of breast cancer consultation communication and predictors of satisfaction with communication. *Psycho-Oncology*, *19*, 626–636.

Hilarius, D. L., Kloeg, P. H., Gundy, C. M., & Aaronson, N. K. (2008). Use of health-related quality-of-Life assessments in daily clinical oncology nursing practice: A community hospital-based intervention study. *Cancer*, *113*, 628–637.

Hughes, K., Sargeant, H., & Hawkes, A. (2011). Acceptability of the Distress Thermometer and Problem List to community-based telephone cancer helpline operators, and to cancer patients and carers. *BMC Cancer*, *11*, 46. Retrieved from www.biomedcentral.com/1471-2407/11/46.

Jones, R., Pearson, J., McGregor, S., Barrett, A., Harper Gilmour, W., Atkinson, J. M., … McEwen, J. (2002). Does writing a list help cancer patients ask relevant questions? *Patient Education and Counseling*, *47*, 369–371.

Kobayashi, K., Green, J., Shimonagayoshi, M., Kanemoto, N., Kasai, R., Itoh, Y., … Kudoh, S. (2005). Validation of the care notebook for measuring physical, mental and life well-being of patients with cancer. *Quality of Life Research*, *14*, 1035–1043.

Lerman, C., Daly, M., Walsh, W. P., Resch, N., Seay, J., Barsevick, A., … Martin, G. (1993). Communication between patients with breast cancer and health care providers: Determinants and implications. *Cancer*, *72*, 2612–2620.

Lethborg, C. E., Kissane, D., Burns, W. I., & Snyder, R. (2000). "Cast adrift" - The experience of completing treatment among women with early stage breast cancer. *Journal of Psychosocial Oncology*, *18*, 73–90.

Longman, A. J., Braden, C. J., & Mishel, M. H. (1999). Side-effects burden, psychological adjustment, and life quality in women with breast cancer: Pattern of association over time. *Oncology Nursing Forum*, *26*, 909–915.

Marshall, S., Haywood, K., & Fitzpatrick, R. (2006). Impact of patient-reported outcome measures on routine practice: A structured review. *Journal of Evaluation in Clinical Practice*, *12*, 559–568.

Mills, M. E., Murray, L. J., Johnston, B. T., & Donnelly, M. (2008). Feasibility of a standardised quality of life questionnaire in a weekly diary format for inoperable lung cancer patients. *European Journal of Oncology Nursing*, *12*, 457–463.

Montazeri, A. (2008). Health-related quality of life in breast cancer patients: a bibliographic review of the literature from 1974 to 2007. *Journal of Experimental & Clinical Cancer Research*, *27*, 32. Retrieved from http://www.jeccr.com/content/27/1/32

Morita, T., Fujimoto, K., Namba, M., Sasaki, N., Ito, T., Yamada, C., ... Noda, T. (2008). Palliative care needs of cancer outpatients receiving chemotherapy: An audit of a clinical screening project. *Supportive Care in Cancer*, *16*, 101–107.

National Comprehensive Cancer Network. (2011). *NCCN Clinical Practice Guidelines in Oncology Distress Management V.1.2010*. Retrieved from http://www.nccn.org/professionals/physician_gls/f_guidelines.asp

Pigott, C., Pollard, A., Thomson, K., & Aranda, S. (2009). Unmet needs in cancer patients: Development of a supportive needs screening tool (SNST). *Supportive Care in Cancer*, *17*, 33–45.

Reich, M., Lesur, A., & Perdrizet-Chevallier, C. (2008). Depression, quality of life and breast cancer: A review of the literature. *Breast Cancer Research and Treatment*, *110*, 9–17.

Rietman, J. S., Geertzen, J. H. B., Hoekstra, H. J., Baas, P., Dolsma, W. V., de Vries, J., ... Dijkstra, P. U. (2006). Long term treatment related upper limb morbidity and quality of life after sentinel lymph node biopsy for stage I or II breast cancer. *European Journal of Surgical Oncology*, *32*, 148–152.

Rogers, M. S. & Todd, C. J. (2000). The 'right kind' of pain: Talking about symptoms in outpatient oncology consultations. *Palliative Medicine*, *14*, 299–307.

Roth, A. J., Kornblith, A. B., Batel-Copel, L., Peabody, E., Scher, H. I., & Holland, J. C. (1998). Rapid screening for psychologic distress in men with prostate carcinoma: A pilot study. *Cancer*, *82*, 1904–1908.

Schnipper, H. H. (2001). Life after breast cancer. *Journal of Clinical Oncology*, *19*, 3581–3584.

Shields, C. G., Ziner, K. W., Bourff, S. A., Schilling, K., Zhao, Q., Monahan, P., ... Champion, V. (2010). An intervention to improve communication between breast cancer survivors and their physicians. *Journal of Psychosocial Oncology*, *28*, 610–629.

Snyder, C., Jensen, R., Courtin, S., Wu, A., & Website for Outpatient QOL Assessment Research Network (2009). PatientViewpoint: A website for patient-reported outcomes assessment. *Quality of Life Research*, *18*, 793–800.

Söllner, W., DeVries, A., Steixner, E., Lukas, P., Sprinzl, G., Rumpold, G., & Maislinger, S. (2001). How successful are oncologists in identifying patient distress, perceived social support, and need for psychosocial counselling? *British Journal of Cancer*, *84*, 179–185.

Sprangers, M. A., Groenvold, M., Arraras, J. I., Franklin, J., te Velde, A., Muller, M., ... Aaronson, N. K. (1996). The European Organization for Research and Treatment of Cancer breast cancer-specific quality-of-life questionnaire module: First results from a three-country field study. *Journal of Clinical Oncology*, *14*, 2756–2768.

Taylor, S., Harley, C., Campbell, L. J., Bingham, L., Podmore, E. J., Newsham, A. C., … Velikova, G. (2011). Discussion of emotional and social impact of cancer during outpatient oncology consultations. *Psycho-Oncology*, *20*, 242–251

Tuinman, M. A., Gazendam-Donofrio, S. M., & Hoekstra-Weebers, J. E. (2008). Screening and referral for psychosocial distress in oncologic practice: use of the Distress Thermometer. *Cancer*, *113*, 870–878.

Valderas, J. M., Kotzeva, A., Espallargues, M., Guyatt, G., Ferrans, C. E., Halyard, M. Y., … Alonso, J. (2008). The impact of measuring patient-reported outcomes in clinical practice: A systematic review of the literature. *Quality of Life Research*, *17*, 179–193.

Velikova, G., Awad, N., Coles-Gale, R., Wright, E. P., Brown, J. M., & Selby, P. J. (2008). The clinical value of quality of life assessment in oncology practice: A qualitative study of patient and physician views. *Psycho-Oncology*, *17*, 690–698.

Velikova, G., Booth, L., Smith, A. B., Brown, P. M., Lynch, P., Brown, J. M., & Selby, P. J. (2004). Measuring quality of life in routine oncology practice improves communication and patient well-being: A randomized controlled trial. *Journal of Clinical Oncology*, *22*, 714–724.

Velikova, G., Brown, J. M., Smith, A. B., & Selby, P. J. (2002). Computer-based quality of life questionnaires may contribute to doctor-patient interactions in oncology. *British Journal of Cancer*, *86*, 50–59.

Velikova, G., Keding, A., Harley, C., Cocks, K., Booth, L., Smith, A. B., … Brown, J. M. (2010). Patients report improvements in continuity of care when quality of life assessments are used routinely in oncology practice: Secondary outcomes of a randomised controlled trial. *European Journal of Cancer*, *46*, 2381–2388.

Vereniging Intergale Kankercentra. (2010). *Richtlijn detecteren behoefte psychosociale zorg [Guideline detection of need for psychosocial care]*. Retrieved from http://oncoline.nl/detecteren-behoefte-psychosociale-zorg

Wells, T., Falk, S., & Dieppe, P. (2004). The patients' written word: A simple communication aid. *Patient Education and Counseling*, *54*, 197–200.

APPENDIX

Interview protocol

1. To what degree did you find the questions easy to understand?
2. Did you think the questions applied to your situation?
3. Do you think that filling out this questionnaire before the hospital appointment is useful for the interaction between patient and practitioner?
4. Did you think the questionnaire was comprehensive?
5. Would you consider filling out this questionnaire regularly as burdensome or unpleasant?
6. To what degree did you find the questions disturbing or confronting?
7. Would you like to be able to print out your answers after completing the questionnaire?
8. Would you prefer a computerized version of this questionnaire or would you prefer a paper and pencil method?

9. Would you prefer filling out this questionnaire at home or in the hospital waiting room?
10. Do you think you would have been able to fill out this questionnaire alone?
11. What is your opinion on the proposed frequency of administration?
12. Do you have any comments or suggestions that could help us improve the questionnaire?