Patient involvement in breast cancer clinical trials: What do patients and professionals want?

Under embargo
Chapter 7 – Patient involvement in breast cancer clinical trials: What do patients and professionals want?

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Abstract

This research aims at gaining insight in possibilities for patient involvement in breast cancer clinical trials (CTs) from the perspectives of patients and health care professionals in order to improve the quality of CTs. A qualitative study in the Netherlands was conducted in which patients and health care professionals were involved in different ways. The approach comprised four phases: (1) exploration, (2) consultation of 28 patients and 18 professionals, (3) advisory by a patient advisory board and (4) a actor dialogue. Three possible forms for patient involvement were formulated: (1) an advisory committee of patients, (2) patient research partners in CT teams, and (3) patient representatives for individual and specific tasks. Involved patients could perform tasks in different stages of a CT, e.g. think about, reflect on research design, improve patient informed consent forms, write and reflect on feedback of findings. By identifying a more integrated and sustainable form of patient involvement in CTs, it is hoped that patient involvement contributes to improvements in trial design and conduct, and thereby lead to better and new treatments. The added value of the layered approach was that the different forms of involvement complemented each other and provided different opportunities for patients and professionals to be involved.

Submitted as:

7.1 Introduction

Over the past years, the number of initiatives for patient involvement in health research has grown substantially (Boote et al. 2002; McCormick et al. 2004; Caron-Flinterman et al. 2005). Several levels of involvement can be distinguished, namely providing information to researchers about their disease and experiences (consultation); an equal discussion partner (collaboration) or even being in control (Oliver 2008; Faulkner 2010; Barber et al. 2011). A higher level of patient involvement does not necessarily lead to more impact. Instead, appropriate ways for patients to be involved depends on the objectives of involvement (Tritter and McCallum 2006; Tritter 2009). However, there is little systematic documentation of which form of involvement fits what situation, and which form of involvement leads to optimal use of patient experiential knowledge and input (Caron-Flinterman 2005). At the same time, several scholars argue that patient involvement should be flexible and a suitable and effective way of involvement needs to be developed (Tritter 2009). Furthermore, patients are hardly involved in the question how they would like to shape patient involvement.
In clinical research, there is also increasing attention for involving patients in the design and execution of clinical trials (CTs). Currently, CTs face low inclusion rates and are not always considered patient friendly (regarding logistics, communication, burden of treatment) (Hill et al. 1994; Ellis and Butow 1998; Ellis et al. 2001; Wright et al. 2002; Marsden et al. 2004; Dellson et al. 2010; Brintnall-Karavelas et al. 2011). This is worrying because randomized-controlled CTs are considered to be the most reliable basis (‘golden standard’) for developing new treatments (Baum and Houghton 1999; Dellson et al. 2010). Various scholars argue that patient involvement in CTs is likely to be beneficial (Goodare and Lockwood 1999; Langston et al. 2005) because it might contribute to higher patient recruitment levels, improve the quality and effectiveness of CTs and reduce patients’ reservations about participating in CTs (Thornton 2008; Smit 2009; Boote et al. 2010). These improvements could result in ‘earlier results and quicker application [of new treatments] in clinical practice’, beneficial for patients and society (O’Connell and Mosconi 2006). Although several initiatives have actively involved patients in design and execution of CTs (Bradburn et al. 1995; Hanley et al. 2001; Lemer 2003; Marsden et al. 2004; O’Connell and Mosconi 2006; Terry et al. 2007; PatientPartner 2011; PatientPartner 2011), more needs to be known about how to involve patients effectively in CTs and what patients themselves would like.

The article considers possibilities for patient involvement in breast cancer CTs from the perspectives of patients and health care professionals, aiming to improve the quality, patient inclusion rates and patient-friendliness of CTs. To this end, a qualitative study involving patients and health care professionals was undertaken in the Netherlands.

### 7.2 Methodology

The research project comprised four phases: (1) exploration, (2) consultation, (3) advisory and (4) actor dialogue. The approach was based on the Dialogue Model which provides tools for consultation of and dialogue between actors (Broerse et al. 2009; Abma and Broerse 2010) and the FIRST-model (Hewlett et al. 2006; de Wit et al. 2013) which provides guidelines for patient involvement in a research project over a longer period of time. Research activities took place between February 2011 and June 2012.

**Phase 1: Exploration**

The project team consisted of three researchers of the Athena Institute (VU University Amsterdam, CACMP, JEE, JEWB), the study manager of the Dutch Breast Cancer Trialists Group (Borstkanker Onderzoeksgroep, BOOG), a policymaker and a patient representative of the Breast Cancer Patient Organization (Borstkanker Vereniging Nederland, BVN), and a policymaker of the Dutch Cancer Society (KWF Kankerbestrijding). The researchers were responsible for execution of the research and facilitation of the process. The project team was responsible for steering the process, setting the focus, and reflecting on and discussing the findings. Furthermore, they identified ways of recruiting participants and shared preliminary findings with actors. The patient representative was responsible for providing patient perspective. It was collectively decided to structure the findings in the four steps of a CT: (1) design of the CT, (2) recruitment and information supply, (3) treatment, and (4) feedback and reporting.
To gain insights into the experiences of breast cancer patients as input to subsequent phases and to gain more insight in which social conditions are relevant on how the project would become more inclusive and participatory, three semi-structured interviews were held with patients. They were recruited via BVN.

Phase 2: Consultation

The consultation phase aimed to better understand patient experiences with CTs and to explore options for patient involvement. Semi-structured interviews and focus group discussions with patients and health care professionals working on breast cancer CTs (researchers/clinicians and research nurses) were undertaken.

For the consultation of patients, one focus group with eight patients who had taken part in a CT in the last four years was organized. In addition, 20 semi-structured interviews were held with fourteen primary diagnosed female patients who participated in a CT and had no metastases, three patients who had decided not to participate in a CT, and three male patients. Patients were recruited via BVN, KWF, internet fora and several hospitals. The focus group lasted two hours and comprised four elements: (1) introduction of the project and general stories about living with breast cancer, (2) experiences of participating in a CT, (3) positive elements and points for improvement, and (4) possibilities for patient involvement in CTs. The interviews had an average duration of 90 minutes and discussed the same topics as the focus group. For patients who had decided not to participate in a CT, additional attention was paid to reasons for this decision. Since there are no CTs in the Netherlands in which male patients are able to participate, attention was paid towards their opinion on CTs for male breast cancer patients. Originally, four focus group discussions with patients were planned. During recruitment it became apparent that only a small number of patients participated in a clinical trial in the last four years, so the target group was very small, which made recruitment difficult. This was enforced by compassionate and protective health professionals who careful in approaching patients for focus group discussions. Interviews were considered less burdensome by the professionals. Most patient who were willing to participate preferred an interview. Therefore, it was decided to perform additional interviews until saturation of data was achieved.

For the consultation of professionals, two focus group discussions (respectively four clinicians and nine research nurses) were organized. Five additional semi-structured interviews were held with clinicians (four) and a research nurse to reach saturation of data. The professionals were recruited by BOOG. The focus group discussions lasted two hours and the interviews approximately 75 minutes. During the focus group discussions and the interviews, options for patient involvement in CTs were discussed.

Phase 3: Advisory

The outcomes of the consultation phase were used to develop advice on how CTs could be optimized and how patient involvement could be realized. The advice was developed by an advisory board of seven women who have had breast cancer. Recruitment took place via BVN. The members of the advisory board were selected based on group criteria: at least four should have higher education and five should have participated in a CT. Personal competences were also taken into account: being constructive and critical, being open to new ideas, having an interest in CTs, being able to think beyond their own experiences, and strong communication skills. Based on interviews, seven of the eleven candidates were selected. They have had breast cancer in different phases in their life (e.g. women with young children, single women, retired women), and were able to use their personal experiences to represent a bigger patient group.
Three work sessions were organized. In Box 7.1 the designs of the sessions are described.

**Box 7.1. Design of the three work sessions of the advisory board**

Before every work session, a time schedule was set and topics were selected for discussion (design) which could be amended when regarded necessary by the advisory board. Below, the design is described per work session. During every session, the advisory board reflected on content provided by the researchers related to the topics to discuss, provided complementary information, and made aspects more concrete. To support the advisory board in its task, the researchers processed the input into a (preliminary) advisory report after every meeting which formed the input for the next session. After the third session, the advisory report was finalized and, after extensive feedback from the advisory board, agreed upon by all members.

To work together fruitfully over a period of time, much attention was paid to creating good social conditions within the advisory board. The facilitators allocated considerable time for personal stories and experiences, and gave members opportunities to provide input and to react to each other.

**First work session**
The first session comprised two parts. First, the focus was on getting to know each other, understanding the process, and agreeing on how to work as a board. Second, the outcomes of the consultation phase were extensively discussed and complemented. The board members had previously received a report of the findings of the consultation phase and these findings were also presented during this session.

**Second work session**
The members of the board reflected in plenary on the draft advisory report (in which the input of last session was integrated) considering how to involve patients and possible roles of patients during a CT. Patient involvement in practice was also considered. A short Dutch overview of possibilities for patient involvement in CTs known from literature was provided.

**Third work session**
In this final session, the advisory report was finalized. Improvements and options for patient involvement were discussed including patient informed consent forms (PIFs), questionnaires and outcome measures of CTs. In preparation, members had previously received three PIFs, two questionnaires and examples of standard outcome measures for CTs. Potential follow-up steps in terms of responsibility and financing were proposed.

**Feedback**
After the last session, the researchers finalized the advisory report. This was send around to the advisory board who provided text amendments and comments. All members also wrote a brief expose about themselves and how they experienced the advisory board. After approval of all members, the advice was finalized and sent to the project team.

**Phase 4: Dialogue**

The dialogue phase discussed the final advisory report with different actors and they identified opportunities for implementation. In total 17 people attended the dialogue meeting; four members of the advisory board, a policymaker from the Dutch Federation of Cancer Patient Organizations (Nederlandse Federatie voor
kankerpatientenorganisaties, NFK) a policymaker from BVN, the director and a study manager of BOOG, two professors involved in breast cancer CTs, who are highly respected in the field and have experience with patient involvement in CTs, and three representatives of KWF (head of the research department, a research coordinator and a policymaker).

The dialogue lasted three hours, and was facilitated by a professor with assistance from the two researchers. In preparation, the participants had previously received the advisory report, a brief overview of the literature and summaries of the consultation phase. The dialogue comprised: (1) a review of the process and findings of the project, (2) a reflection by each actor group about their experiences with the project, and (3) a dialogue on implementation of the advisory report with attention for feasibility, budget, collaborations between actors, responsibility and follow-up activities.

Analysis

The interviews, focus group discussions, advisory board meetings and the dialogue were all audio-taped after approval of the participants and verbatim transcribed. A summary was sent to participants for member checks. The participatory process and the outcomes were analyzed following three guiding questions:

1. How do patients experience participating in a CT?
2. What options for patient involvement in breast cancer CTs did patients and professionals articulate?
3. What did the forms of involvement in the different phases of the project contributed to the final product?

Two researchers coded the transcripts separately, and discussed the findings. A coding structure was developed to analyze the data that reflected the topics relevant for answering the study questions. The project team reflected on and discussed the coding, and agreed upon the findings.

7.3 Results

Phase 2: Consultation

Experiences with participation in a CT

Participation in a CT was overall positively experienced by most consulted patients. Often this was related to good support during the treatment giving by a care provider (often a research nurse) who took time to listen, to provide information and to answer questions. The nature of the condition was thought to play a role in this positive experience: breast cancer is experienced as a severe condition, with an emotional and hectic treatment period for many patients. Many patients focused on the outcome of the treatment (being cured) and the experiences with the CT were secondary. Interestingly, most patients did not make a distinction between participation in a CT and medical treatment possibly because:

‘I think that you [as a patient] have something else on your mind’.

Patients assigned to the control group did not feel that they were part of the CT because they received standard treatment. As a result, patient experiences were mostly related to recruitment and information supply.

During recruitment and information supply, the research nurse had a central role. Most patients were asked to participate in the CT by the research nurse. She verbally explained the CT in a way which was generally thought to be understandable. Almost all patients stated that the written information, the patient informed consent forms
(PIFs), was too complicated and scientific to understand properly but this was not always considered problematic because it was secondary to the verbal explanation. Most patients were asked to participate immediately after being diagnosed, and they had, on average, a week to decide. Some patients criticized the timing since it was an emotional period and they were not able to make a considered decision. Some patients were advised to discuss their decision with a third party, such as their general practitioner or family members. Most of them followed this advice and considered it useful.

Various factors played a role in the decision to participate. Extra travel time, a higher burden of treatment (e.g. extra or more invasive treatment) and more clinical visits were important reasons to drawback. The type of CT also played a role. A few patients were very insecure about whether they made the right decision. Random assignment also caused uncertainty. Some patients had a preference for a certain treatment, and only wanted to participate in a CT if they were assigned to this group. Given that patients could stop their participation in the CT whenever they wished, they awaited the results of the random assignment before deciding whether to continue.

None of the consulted patients received information about the end-results of the CT despite the fact that many patients were curious about whether their participation contributed to better treatment for cancer. They also considered that feedback would have represented a token of appreciation, given that participation in the CT represented an extra investment during their treatment.

Possibilities for patient involvement

Most patients and professionals reacted positively to the idea of patient involvement in CTs. Most patients indicated that patient involvement in CTs is desirable since their experiences can complement the scientific knowledge of clinicians. However, many patients had difficulties with giving concrete examples of how this might work. For professionals, patient involvement was also desirable since they hoped it would result in higher inclusion rates. However, some professionals also indicated that they are concerned that patient involvement might involve an extra time investment from them. Most patients and professionals considered that patient involvement should become an integral part of CTs, and patients should be involved in all stages of a CT, in particular in design and recruitment and information supply. For design, patients could provide suggestions for outcome measurements (particularly concerning quality of life), research questions and trial logistics (like combining standard medical visits with trial visits). Patients could also assist in improving PIFs. Tasks specifically mentioned by patients concerned assisting in recruitment, assisting in writing feedback about end results for patients, and the availability of a patient representative to answer patients’ questions based on actual experience of participating in CTs. As a patient stated:

‘A patient representative [to answer questions of patients] could also tell you about, yes, feelings you have, emotions you have, fears...’

Additionally, some professionals pointed out that patients could provide useful input regarding the balance between the potential benefits and burden of CT participation. Establishing an advisory committee of patients reflecting on all stages of CTs was proposed by most patients and professionals. Their advice should contain directions and suggestions for project teams of CTs. A few professionals emphasized that it is important to clearly define roles, tasks and expectations. Other professionals suggested appointing patient research partners as members of the CT project team so that they can be actively involved during the entire process. As a result, a patient research partner would be able to identify quickly where patients’ input could be of additional value.
Phase 3: Advisory

Context
In the first session, the women were somewhat reserved towards each other and unsure about their role and tasks in the advisory board. There was a considerable change in attitude between the first session, and the second and third sessions. The atmosphere became more open and pleasant, the women greeted each other and the facilitators with enthusiasm, they asked each other about their personal situation and they made jokes. They showed less hesitation in providing inputs, became more critical of the inputs provided and paid more attention to details. After the third work sessions, all seven women reflected positively on their participation in the advisory board:

‘It is special and valuable to work in a constructive way with your own experiences with breast cancer.’

‘I have considered it a privilege to be a member of the advisory board. To actively contribute to the improvement of care for breast cancer patients has meant a lot to me.’

Optimizing CTs
The output from phase 2 was complemented by the advisory board and reformulated as points to improve CTs. Regarding the design, the advisory board considered the commonly used outcome measures as relevant and important. However, they indicated that outcome measures related to quality of life and tolerance of treatment should receive more attention. The importance of these outcome measures is dependent on the stage of disease: survival and cure should have more priority in curative care, whilst quality of life is more important in palliative care. Also, aspects like age, cultural background and comorbidity are important in determining outcome measures. A younger women with small children in the advisory board indicated that a long survival time is very important for them while more older women (retired or with adult children) considered that quality of life is more important.

Regarding recruitment and information supply, the advisory board considered that attention should be paid to managing the expectations of patients. First, the advisory board indicated that clinicians should explain more about the physical impact and expected outcomes of participation in the CT (short versus long term side-effects, and comorbidity). Patients often have difficulties in weighing between the long term side-effects and the potential improvement of health because life-threatening effects of the disease are uppermost in their minds. In addition, patients are often unable to make a well-thought through decision regarding quality of life versus extension of life, particularly important for palliative care. Second, the advisory board felt that PIFs could be further optimized. Currently, they are considered too complicated and not sufficiently tailored to specific patient groups. PIFs should be written in such a way that patients understand the information and are aware of the relevance of their personal participation. A few members indicated that the information in PIFs should be more specific to a patient group or individual. Other members added that it is also important that the provided information is complete and detailed because this gives patients more confidence in the science behind the CT. Furthermore, it was pointed out that the compulsory section about insurance leads to uncertainty and supposes there are major risks associated with participation. The advisory boards considered it important to clarify that the insurance section in PIFs is a legal obligation, and does not necessarily indicate a great risk. Third, the advisory board indicated that patients with metastases often think that life extension concerns several months to years, while often the expected extension is a few months at most. This should be well communicated. Fourth, recruitment should become much more tailor-made. For example, because of a patient’s personal situation (e.g. family situation, work, and mental condition)
participation in a CT could be too stressful. A clinician should therefore take a patient’s personal situation more into account when providing advice on CT participation. Clinicians should also consider which trial is most suitable for a patient and not just ask the patient because she meets certain criteria.

As mentioned before, most patients are not fully aware of their participation in a CT. The advisory board emphasized that, as a consequence, insights in certain outcome measures and unexpected side-effects cannot be monitored optimally because participants do not mention them. Clinicians and research nurses should therefore pay more attention to the CT when talking to patients, for example by highlighting that a questionnaire is used for the trial. The advisory board also considered that CTs could be improved if more was known about satisfaction of patients participating in a CT. An overview of patient satisfaction could, for instance, be acquired through evaluative questionnaires or focus group discussions. Finally, the quality of life questionnaires, currently in use by CTs, could be improved. These questionnaires have little to no options for individual narratives and they do not take the context into account. The advisory board also indicated that these questionnaires currently do not have an introduction in which the purpose of the questionnaire is explained.

Regarding feedback and reporting, they emphasized that a token of appreciation is indeed desirable, and they suggested this could be in the form of a ‘thank-you letter’, a simple gesture highly valued by patients.

The advisory board considered it very important to raise awareness of CTs. In general, the Dutch public has little knowledge about the existence and relevance of CTs and CTs are even related to the somewhat negative image of pharmaceutical companies. It is expected that more patients would consent to participation, or would even actively look for suitable CTs, when they have more knowledge about the relevance of CTs beforehand. To raise awareness about CTs, one member stated:

‘Just by popularizing CTs, by portraying a patient for example. That could be broadcasted on tv, for five minutes.’

Options for patient involvement
Based on the outcomes of the consultation phase, the advisory board made a distinction between forms (the role of a patient) of patient involvement and specific tasks (an activity undertaken by a patient) that could be performed by patients, as presented in Figure 7.1.
Forms of patient involvement
- Advisory committee of patients
- Patient research partners in CT teams
- Patient representatives for single tasks

Tasks for patient representatives per stage of a clinical trial

<table>
<thead>
<tr>
<th>Design</th>
<th>Recruitment and information supply</th>
<th>Treatment</th>
<th>Feedback and reporting</th>
</tr>
</thead>
<tbody>
<tr>
<td>Think about, reflection Research design (e.g., research questions, outcome measures, trial logistics, feasibility)</td>
<td>Recruitment</td>
<td>Exchange of experiences Evaluation of patient satisfaction</td>
<td>Write and/or reflect on report of findings</td>
</tr>
<tr>
<td>Questionnaires (quality of life)</td>
<td>Exchange of experiences</td>
<td></td>
<td>Write and/or reflection Thank-you letter</td>
</tr>
</tbody>
</table>

Figure 7.1. Schematic overview of options for patient involvement in CTs.

Forms of patient involvement
The advisory board formulated three forms of patient involvement: (1) an advisory committee of patients, (2) patient research partners in CT teams, and (3) patient representatives for individual and specific tasks. An advisory committee provides predominantly advice to project teams, research partners are full members of a project team, and patient representatives have, in particular, an informative function. One form does not exclude the other and a combination of forms of patient involvement might be preferable since they could complement each other.

A patient advisory committee could monitor CTs from start to finish. The main task for the committee is to reflect regularly on documents or activities, and to give advice to the project team on how CTs could be improved from a patient perspective. To be successful, an ongoing dialogue between the advisory committee and the researchers of the CT should be started, and clear agreements for collaboration should be made. Preferably, the advisory committee should be composed of about five patients to guarantee continuity. Members should be able to put their experiences in the perspective of the general patient population and should, preferably, have experience with representing patients. As a member described:

‘For me, someone is a patient representative, when that someone has experience with the topic and is able to transcend own experience.’

Advisory committee members should also have insights into opportunities for input from a patient perspective. The advisory board did not consider training necessary. The members of the committee should have general knowledge about CTs but do not need to be medical experts because their expertise is their experiential knowledge. For their contribution, the members should receive a small financial compensation. The establishment
of an advisory committee has most priority because of its practical applicability, the reactive nature of the patient involvement form and the feasibility within the current context of CTs for breast cancer.

Patient research partners participate in meetings of the project team and provide input from a patients’ perspective on different aspects in a CT. Since they are directly engaged in design and execution of a CT, they are able to identify where patients’ perspectives could be of additional value. As a member pointed out:

‘You experience everything from close-by, the development [of the CT], the conduct, what the conditions are and why things happen.’

Although the advisory board considered this form of patient involvement as very valuable, they do not believe it is feasible to appoint a research partner to every CT in the Netherlands. Moreover, it is not easy for patient research partners to become full member of a project team because many researchers are not familiar with the potential added value of this form of patient involvement. Also, CTs often take place over a long time period (with accrual time of 3 – 5 years and a follow-up period of 10 – 15 years) with relatively long periods in which there are few activities relevant for a patient research partner. The advisory board pointed out that, for this reason, it could be difficult for patient research partners to stay committed to the CT. Patient representatives are, unlike patient research partners, only involved for accomplishing a single task, such as improving PIFs. Advantages of this construction are the relatively low burden for patient representatives, a relatively short time frame in which tasks take place and the option to involve patient representatives with specific competences for the different tasks.

Specific tasks

In figure 1 several potential tasks for patients are described. These tasks are based on the earlier identified experiences and points for improving CTs. For most tasks, all three forms of patient involvement are suitable.

Phase 4: Dialogue

All participants indicated that they considered the advisory report very useful and concrete with feasible suggestions. There was consensus on the idea that patient involvement could contribute to improvement of CTs in order to have better and new treatments, to higher inclusion rates and to trials more suited to needs of patients. Participants had a shared vision of patient involvement which led to an open and constructive discussion in which different perspectives were shared and reflected upon.

Although different forms of involvement were suggested by the advisory board, most participants were in favor of an advisory committee. This form was considered most feasible because it is relatively easy to integrate within current procedures and structures, and because patients could provide advice in all stages of CTs.

It was stated by BOOG and the researchers that to raise support for implementation of patient involvement in CTs, it is of primary importance that the activities and tasks of a patient advisory committee fit into the complex process and timelines of CT designation, grant writing and execution of the CT. In order to fit in with existing structures, and relations with project teams of CTs, the participants considered BOOG most suitable for coordination of the advisory committee. Moreover, BOOG has already an infrastructure for advisory committees and they are well placed for convincing researchers to use patient input. Participants emphasized that BOOG should work in close collaboration with BVN, since they have the capacity and knowledge of representing patients.
The participants agreed that it is important to start with a pilot project so that the approach could develop over time and could be adjusted to findings and experiences. The pilot could further explore which tasks can be performed by an advisory committee. As a participant explained:

‘This is not a ‘take-big-steps project’. You need to take really small steps, for support. So in that sense, I think it is a very good idea to start with a pilot’

BOOG indicated that some tasks could be implemented at short notice, such as a thank-you letter after participation in a trial that describes preliminary results, and amendments to PIFs. Representatives of BOOG express the thought that tasks related to trial design would be limited for patients because of the complexity of the designs. However, members of the advisory board emphasized that it is a very important phase for patients’ input, despite the complexity. Next, the participants discussed the possible characteristics of the proposed committee. They indicated the committee should be composed of about ten people, who understand the English language, are able to tell their own story, but also represent a general patient group.

Commitment and continuation were also discussed. Structural finances are needed for a committee. Although the costs are not expected to be very high, members should be able to receive training, reimbursements or a fee. Most trials run for many years so that it is important that advisory committee members commit themselves for several years. However, given that the members of the committee are patients, there is a chance that they will not be able to attend meetings due to illness or treatment. In the future, ideally, there would be a mixture of experienced committee members and new members who can learn from the experienced ones.

The level of influence is discussed as well. The advisory committee should provide advice from a patient perspective. This advice should be taken seriously. When the advice is not taken up, this should be clearly explained to the committee. For example, certain regulations or scientific principles may preclude the trial from following the advisory committee’s advice.

The option of patient research partners was discussed. Some of the participants were skeptical about the feasibility. Patient research partners would have to comply with many requirements, some of which you cannot expect that from a patient. Also, there was some doubt if patient research partners could represent a general patient group. In addition, organizing this would be quite a challenge because many patients are needed since there are many trials, patients need to commit themselves for a long period of time (at least three years), and researchers and clinicians also need to adapt.

7.4 Discussion and conclusions

In this study, patients and health care professionals have been involved in developing ideas for improving CTs from a patients’ perspective, and options for active patient involvement.

The findings from this study regarding patient experiences with participation in CTs are also known from literature, for example motivational factors (Cox and McGarry 2003; Kemeny 2004; Cohen et al. 2007), randomization (Gross and Fogg 2003; Marsden et al. 2004; Avis et al. 2006), the complexity of PIFs (Ferguson 2002; Tosounidis and Kontakis 2008), and lack of receiving feedback (Madsen et al. 1999; Kerrison et al. 2008; Tosounidis and Kontakis 2008).
In the advisory board and during the dialogue meeting, tasks for patients in CTs were formulated. Similar examples are described in the scientific literature: collaboration in designing clinical trials (Marsden et al. 2004), assisting in recruitment (Hanley et al. 2001; Tomlin et al. 2012), or improving PIFs (Hanley et al. 2001; Dellson et al. 2010). However, patient involvement presented in the literature often consists of single initiatives and involvement is often limited to restricted parts of a CT (Hanley et al. 2001). The members of the advisory board and the participants of the dialogue meeting proposed a form of patient involvement which is more sustained during a CT and across CTs, and which could be used as a ‘template’ for patient involvement in clinical trials in general. The options reported in this paper include different forms of patient involvement – from consultation to collaboration – complementing each other, and with input on different stages of CTs and different levels of responsibility. By identifying a more integrated and sustainable form of patient involvement in CTs, it is hoped that patient involvement may contribute to improvements in trial design and conduct, and thereby better and newer treatments (Langston et al. 2005; PatientPartner 2011; PatientPartner 2011). Langston et al. (2005) reported that an integrated relationship between researchers of a CT and a patient organization (and their members) resulted in improvements of trial design and conduct, and higher inclusion rates (Langston et al. 2005). As Avins and colleagues (2007) describe, patient involvement in CTs could also contribute to more public awareness of CTs, greater support for participation and more funding for CTs (Avins and Goldberg 2007).

Among the different possible forms of patient involvement, an advisory committee of patients was considered most preferable. Patient panels in health research appear to be valuable forums for debate and advisory because of the reflective powers of their members who bring valuable experiential knowledge (Uhm et al. 2012). However, panels that only consist of patients are more distant from decision-making than panels with a mix of patients and researchers. Another aspect that should receive attention when implementing an advisory committee is that panels are only effective when there is attention for procedural and structural aspects, and the acknowledgement of emotional and interpersonal aspects of the members (Uhm et al. 2012).

Reflection on the approach

The added value of this phased approach is that the different forms of involvement complemented each other and provided different opportunities for patients and professionals to be involved. In the consultation phase, experiences and ideas of a broad group of patients and professionals were collected. Although convenience sampling was used, we aimed at maximum variation by involving patients with different types of breast cancer, partaking in different types of CTs, and treated in both academic and local hospitals. Moreover, interviews were planned until saturation of data was reached. As a result, the consultation provided a general overview, but lacked in-depth details. Patients considered patient involvement a difficult concept and they found it difficult to propose concrete tasks or forms of patient involvement. Professionals also indicated that patients should be involved although only some had current experience. The advisory board structured, deepened and made more concrete the general overview identified in the consultation phase. It converted the overview into tangible points for improvement, and structured the ideas for patient involvement into options by deepening and complementing the input from the consultation phase. It provided clear insights in how patients would like to become involved in clinical trials and what they consider suitable methods for involvement. During the dialogue meeting, different actors reflected on possibilities of implementation, covering different perspectives. Options were considered and explored, leading to suggestions that all actors could work with. The dialogue meeting resulted into a shared vision for patient involvement and agreements on how to proceed. During the dialogue, actors were willing to consider
patient involvement because it was considered a possible solution for experienced difficulties in their work/experiences related to CTs. In the advisory board and during the dialogue meeting, patients and health care professionals agreed that it is important to start with small things that can be easily changed at short notice and which are considered important by the actors (e.g. a thank-you letter, improvements of patient informed consent forms). A pilot study to gain experience with an advisory committee of patients was preferred. In conclusion, the phased approach appeared to be successful for patient involvement in an advisory process like this, since the different forms of involvement complemented each other and resulted in a focused and concrete advice. According to the involved actors, the aim of the project is well achieved. We expect that this approach is suitable in other advisory processes in which patients are challenged to formulate an advice on a new unfamiliar topic.