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Patient participation in multidisciplinary tumour conferences in breast cancer care (PINTU): a mixed-methods study protocol

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ABSTRACT

Introduction A central instrument of multidisciplinary care is the multidisciplinary tumour conference (MTC). In MTCs, diagnosis and treatment of cancer patients are discussed, and therapy recommendations are worked out. As we found previously, patients participate in MTCs in some breast cancer centres in the state of North Rhine-Westphalia, Germany. However, studies on risks and benefits of patient participation have not provided substantiated findings. Therefore, the study’s objective is to analyse differences between MTCs with and without patient participation.

Methods and analysis This is an exploratory mixed-methods study. MTCs in six breast and gynaecological cancer centres in North Rhine-Westphalia, Germany, are examined. MTCs will be conducted with and without patient participation. First, interviews with providers concentrating on the feasibility of patient participation and quality of decision-making will be carried out, transcribed and analysed by means of content analysis. Second, videotaped or audiotaped participatory observations in MTCs will be executed. Video data or transcribed audio data from video and audio recordings will be coded using the established “Observational Assessment Rating Scale” for MTCs and analysed by comparing centres with and without patient participation. Third, all patients will fill out a questionnaire before and after MTC, including questions on psychosocial situation, decision-making and expectations before and experiences after MTC. The questionnaire data will be analysed by means of descriptive and multivariate statistics and pre-post-differences within and between groups.

Ethics and dissemination Consultation and a positive vote from the ethics committee of the Medical Faculty of the University of Cologne have been obtained. For all collected data, relevant data protection regulations will be adhered to. All personal identifiers from patients and providers will be pseudonymised, except video recordings. Dissemination strategies include a discussion with patients and providers in workshops about topics such as feasibility, risks and benefits of patient participation in MTCs.

Trial registration number DRKS00012552.

INTRODUCTION

Many developments in oncological healthcare have taken place over recent years: among them multidisciplinary care and patient-centred care. In oncology, multidisciplinary care is implemented in the form of multidisciplinary tumour conferences (MTCs) as a central instrument of treatment decision-making.1 MTCs are defined as regular meetings of a multidisciplinary team in which the diagnosis and treatment of cancer patients are discussed. In Germany, MTCs are widely established and are required by accreditation programmes for cancer centres.2,3 Usually, patients do not participate in MTCs.

The international research on MTCs without patient participation reveals that treatment decisions are often made without considering patient information and preferences.4–7 Therapy recommendations in MTCs are in fact often developed solely on the basis of clinical information. However, the need for further discussions and conversations with the patients and their relatives is one of the most common reasons for postponing decisions in the MTC.8,9 Patient preferences are not considered comprehensively in MTCs although in

| Strengths and limitations of this study |
|----------------------------------------|
| One of the first studies on patient participation in multidisciplinary tumour conferences (MTCs). |
| Mixed-methods study triangulating qualitative interviews of healthcare providers (eg, organisational aspects of MTCs), qualitative observations of MTCs (eg, decision-making) and a quantitative survey of patients with and without patient participation (eg, individual psychosocial situation, needs and experiences). |
| Observational design with potential methodological problems like Hawthorne effect and observer-expectancy bias. |
| Future research on this topic would benefit from interviews with patients and a survey with providers as well as an interventional study design. |
| Limited number of breast and gynaecological cancer centres and surveyed patients, but detailed analyses. |
many MTCs, patients are supposedly represented by nurses or by the patients’ most frequently attending doctor. Furthermore, studies prove that MTC recommendations which consider patient information and preferences (health condition, comorbidity) are more likely to be implemented, as they are clinically more appropriate and accepted by the patients. In addition, for decision-making processes in different oncological contexts, observations in a large German university hospital demonstrate that patient preferences might be better included in decision-making if patients are present during the process of developing recommendations.

But so far, very few studies on patient participation in MTCs exist, not least because it is seldom practised in healthcare. Until now, only a few publications have explored the attitudes of patients and other MTC participants with regard to patient participation. As potential benefits for patients, a better understanding of diagnosis and treatment, stronger involvement in decision-making, patient empowerment and better treatment adherence and confidence have been named. But authors also point out risks, such as uncertainty, excessive burden and anxiety. Among the benefits from the providers’ point of view (eg, physicians, psycho-oncologists, nurses), the support in recommendation development and better patient-physician communication have been mentioned. The possible disadvantages or challenges discussed are the longer duration of MTCs, the need to adjust to lay language and the discussion being restrained in the presence of patients. However, these assumptions have not been proven in rigorous observational studies.

It still remains unclear how patient participation changes the organisation, interaction and decision-making in MTCs. Especially the question whether patient participation is feasible and which benefits and risks the patients and providers can expect seems to be relevant.

Aims of the study
In our study ‘Patient Participation in Multidisciplinary Tumour Conferences in Breast Cancer Care’ (PINTU), information about the organisation of and interaction in MTCs with and without patient participation will be generated and the perspectives and experiences of participating patients and providers will be revealed. We aim to answer the following research questions: (1) How do the providers participating in MTCs perceive the participation of patients in the MTC with regard to the feasibility of participation and the quality of decision-making? (2) How do MTCs with and without patient participation differ with regard to organisation, interaction and patient orientation? (3) How do patients experience the participation and what direct cognitive and emotional effects does the participation have on the patients?

Methods and analysis
Study design
PINTU is a multicentre non-interventional study using a mixed-methods approach. The combination of qualitative and quantitative research methods and the use of mixed-methods study designs can frequently be observed in health services research. Since a mixed-methods study approach combines elements of quantitative and qualitative scientific theory and methodology, new opportunities arise for using and combining sources of data, leading to new findings in social sciences and therefore also in health services research. In addition to the theoretical benefits of combining methods, there are relevant practical implications for this study:

- Information from quantitative data might not be identified in qualitative data and vice versa.
- Non-sampling errors might be reduced since data from different sources are used (eg, interview and observation).
- Common method bias (eg, resulting from only using self-reported items in questionnaires) might be reduced.

As combining both approaches is the key element of mixed-methods studies, but their execution and reporting has not been finally clarified, we will use the well-described triangulation technique from O’Cathain et al.

The mixed-methods design of our study (see figure 1) includes, in the qualitative part, (a) an interview invitation to providers participating in MTCs and (b) participatory observations in MTCs with and without patient participation, which are videotaped or audiotaped. In the quantitative part of the study, (c) a standardised questionnaire will be given to all patients—MTC participants and non-participants alike—before and after the MTC.

Sample
The study is conducted in breast and gynaecological cancer centres in North Rhine-Westphalia, Germany, the most populous German state. Study hospitals were selected following purposeful sampling criteria, varying the size of the centre (case volume) and the teaching status (teaching hospital vs non-teaching hospital). These centre structures can have an impact on the organisation of MTCs because in larger breast and gynaecological cancer centres, more cases are discussed, and in teaching hospitals, more employees, especially assistant doctors, participate in MTCs.

Inclusion criteria for providers is frequent participation in MTCs. With regard to the above-mentioned purposeful sampling, participants shall represent a large variety of disciplines (medical, nursing, psychological) involved in the MTCs.

The inclusion criteria for participating patients are a minimum age of 18 years, at least one breast or gynaecological cancer diagnosis (C50.xx - C58.xx, D05.xx - D07.xx), sufficient German language skills to understand the written informed consent and the survey questions and the physical, psychological and cognitive ability to
participate. An average of 10 discussed patients per MTC meeting can be expected (n=180 patients in total). Three MTC meetings will be studied in each of the three breast and gynaecological cancer centres that do not invite any patients to MTCs (n=90 non-participating patients). Three MTCs will be analysed in each of the three breast and gynaecological cancer centres where patients are invited to the MTCs (n=90 participating patients). If less than 90 patients participate in the MTCs, more observations will be conducted.

Recruitment
The recruitment of the breast and gynaecological cancer centres was started with the aid of the search engine Oncomap. From our former studies, we were able to identify suitable breast and gynaecological cancer centres where some patients participate in MTCs. Next, the managers of the centres (usually chief physicians) will be contacted, and the research team will personally introduce the study at the centres. The staff council in the centres will be informed about the research project. All participating providers in the MTCs and all participating and non-participating patients will be informed in written and oral form about the purpose, conduct and data protection aspects of the study.

Interviews
To capture the perspective of different providers, approximately five interviews will be conducted in each of the six breast and gynaecological cancer centres (n=30). Therefore, different providers (eg, oncology, gynaecology/senology, radiotherapy, psycho-oncology and nursing) will be selected to gain a comprehensive perspective on MTCs in each centre. The purposeful sampling strategy aims at including all professional groups and different hierarchical levels involved in MTCs in breast and gynaecological cancer centres. The interviews with providers will take place a few weeks before the participatory observation of the MTCs.

Participatory observation and video or audio recordings
Experience from other studies, in which the group interaction in institutions was recorded on video or audio, has shown that it is important to build trust in the research team. Two observations in MTCs without data collection will help to get used to the organisational processes in the breast and gynaecological cancer centres and to build the participants’ trust in order to agree to and become accustomed to the video or audio recordings.

Patient survey
Participating and non-participating patients will be screened by hospital staff for inclusion criteria. If patients meet the inclusion criteria, they will be informed by hospital staff verbally and with written material provided by the research team. Patients who give their informed written consent will be included in the study.

Measures
Interviews
Semistructured interviews will be conducted to capture the experiences, opinions and concerns of the providers participating in MTCs. The interview guideline will include the following topics:
- Organisation before, during and after the MTC (eg, setting the agenda, documentation of decisions, technical aids, invitation of providers and patients, seating arrangement).
- Interaction before, during and after the MTC (eg, interaction between providers and between providers and patients).
- Decision-making before, during and after the MTC.
- Perceived or expected differences between MTCs held with and without patient participation.
Perceived or expected differences in patient participation (dis-)advantages regarding organisation, patient-provider communication and decision-making.

Participatory observation and video or audio recordings
The database will consist of video or audio (transcribed) recordings, observation protocols and clinical protocols of the MTCs. Observations by means of video or audio recordings are planned in at least 18 MTC meetings in six breast and gynaecological cancer centres within a given time period of approximately 12 weeks. If the respective MTC team agrees to video recordings, video recording can take place after patients give their informed written consent. If the team does not agree to video recordings, audio recordings will take place after patients give their informed written consent. In contrast to audio recordings, videography provides the opportunity to observe all interaction modalities, ie, nonverbal communication, gestures and facial expressions, as well as other relevant aspects, such as the locations of the persons in the room, the use of technology and the physical environment. The use of observation protocols will also provide information about the mentioned aspects, especially if MTCs are audio recorded. Clinical protocols contain clinical information on grading, comorbidities, metastasis and type of surgery. In reference to a study on MTCs by Taylor et al in which they developed the ‘Observational Assessment Rating Scale for multidisciplinary tumour conferences (MDT-OARS)’, our observation categories are the following:

- Organisation and infrastructure of the MTC.
- Interaction between team members (eg, hierarchy).
- Interaction between the team and the patients.
- Patient orientation and the decision-making process during the MTC.

For the comparison of patient orientation in MTCs with and without patient participation, the observation criteria for the category ‘patient orientation’ will be differentiated more strongly. As the MDT-OARS was developed only in MTCs without patient participation, this differentiation is necessary for an adequate measurement of MTCs with patient participation in the research project.

Patient survey
In order to explore the feasibility, risks and benefits as well as the differences between patients participating and not participating in MTCs, all patients will fill out standardised survey questions directly before the MTC (T0, all patients), directly after the MTC (T1, MTC participating patients) and 4 weeks after the MTC (T2, all patients). Not all scales will be used in all three points of measurement. The main reason for the differences between time points is the scales’ sensitivity to change. Psychological scales might be affected more strongly during MTC and/or treatment than more stable moderators like health literacy. Thus, some scales which we believe to change through the MTC patient participation will have to be asked repeatedly, while other stable concepts and characteristics only need to be asked at baseline. Thereby, we also tried to reduce the survey length. With very few exceptions, validated scales are used as survey questions, and author agreement was obtained. Standards of survey development will be followed concerning self-developed scales (information need before MTC, interruptions during MTC). Because of the exploratory design, primary and secondary outcomes are not differentiated. Outcomes, moderators/baseline characteristics and process measures in T0, T1 and T2 are shown in table 1.

Data collection

Interviews
Each interview can take up to 1 hour and will be pretested with providers concerning the duration and comprehension of questions. The interviews will take place at the breast and gynaecological cancer centres. All interviews will be recorded by means of an audio device for future transcription and analyses, according to established standards. Additionally, field notes will be used. The interview guideline can be adjusted after each interview if relevant new aspects are mentioned.

Participatory observation and video or audio recordings
For the video or audio recording, one or more cameras or audio recorders will be set up in the MTC room, depending on the room and the seating arrangement. They will be positioned to ensure that they can preferably capture the entire room and all interactions between the participants. The camera set-up and angle and the recording quality of image and audio will be tested in advance. In order to ensure the quality of the recordings and to enable the participants to become accustomed to the cameras and recordings, we will pretest the organisation in all breast and gynaecological cancer centres. Additional observation protocols will serve as an instrument through which peculiarities and important background information can be documented directly.

Patient survey
The practicability of the surveys and the potential burden on patients will be pilot-tested prior to the study using cognitive pretest interviews following established methods, especially using the ‘think aloud’ method. Pretest participants will be recruited with the help of a cancer information centre and self-help groups (eg, breast cancer self-help group), which are cooperation partners in this study. Pretested patients will be inpatients or recently discharged from hospital. After patients have signed the written informed consent, T0 surveys can be filled out during hospitalisation and sent back to the research team. T1 will be filled out by participating patients after MTC and sent back to the research team. Two personalised reminders will be provided according to Dillman’s Total Design Method. T2 is a postal survey conducted 4 weeks after the MTC using the method.
mentioned above. Moreover, several strategies which increase response rates will be applied.34

**Triangulation**

The different data sources will be matched during data collection in the form of a mixed-methods matrix,23 24 to obtain comprehensive information with the help of quantitative and qualitative data. Because of pseudonymisation, we will be able to match data, for instance, from provider interviews conducted in one centre with observations in the MTCs of the same centre and survey data of patients treated in this centre. From a methodological perspective, this might also reduce common limitations like ‘Hawthorne effect’ (participants act differently because of the observation), ‘observer-expectancy bias’ (observer reactivity causing problems with internal validity) and ‘common method bias’ (potential systematic error in the variance of a variable owing to the use of only one measurement method). However, it should be noted that interviews will be held exclusively with providers and surveys conducted exclusively with patients. No patient interviews will be conducted as the questionnaire bases on qualitative data analysis of patients’ experiences during MTCs. As participating and non-participating patients will fill out the questionnaire we will be able to explore differences in the consideration of patient preferences. No provider questionnaire will be conducted as the number of cases per breast or gynaecological cancer centre would be low (five per centre).

**Data analysis**

**Interviews**

The audiotaped interviews will be transcribed verbatim and analysed by at least two independent researchers from different disciplines in accordance with the well-established methods of content analysis.35 36 Subsequently the analysis will be interpreted by a group of researchers. In this process, inductively identified categories can complement and modify the deductively derived categories from previous international research.6 10 37 38 The results will be used to inform patient survey development in this study. This might include questions regarding the positive and negative effects of patient participation in MTCs and to further explore how patient preferences are considered in decision-making in MTCs from the patients’ perspective.

**Participatory observation and video or audio recordings**

Audio data will be transcribed and analysed. Video recordings will be analysed directly, and their audio track will be transcribed and analysed. In the first instance, quantitative descriptive structural parameters can be gathered from the recorded observation and video data, on which basis descriptive comparisons between the MTCs with and without patients can already be made. Here, the key variables are the qualification and number of participants, duration of the MTCs, seating arrangements, length of conversations for each participant and technical support. The processes taking place in the

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**Table 1** Survey instruments used in T0, T1 and T2

| T0 | T1 | T2 |
|----|----|----|
| **Baseline characteristics/Moderators** | **Baseline characteristics/Moderators** | **Baseline characteristics/Moderators** |
| Sociodemographic characteristics40 | Support from family40 | Health literacy41 |
| Health literacy41 | Need for participation42 | Health literacy41 |
| Need for informational education42 | Need for informational education42 | Need for informational education42 |
| Preference for paternalism42 | Preference for self-help42 |
| Information need before MTC (self-developed) | **Process measures** | **Process measures** |
| | Shared decision-making43 | Shared decision-making43 |
| | Experience during MTC15 | Decision regret scale44 |
| | Interruptions during MTC (self-developed) | Health literacy communication45 |
| **Process measures** | **Process measures** | **Outcomes** |
| Shared decision-making43 | Shared decision-making43 | **Outcomes** |
| Experience during MTC15 | Decision regret scale44 | **Outcomes** |
| Interruptions during MTC (self-developed) | Health literacy communication45 | **Outcomes** |
| **Outcomes** | **Outcomes** | **Outcomes** |
| Health related quality of life46 | Health related quality of life46 | **Outcomes** |
| Therapy confidence40 | Therapy confidence40 | **Outcomes** |
| Trust in providers42 | Trust in providers42 | **Outcomes** |
| Need for psychological support46 | Need for psychological support46 | **Outcomes** |
| Fear of cancer progression40 | Fear of cancer progression40 | **Outcomes** |
| Therapy confidence40 | Therapy confidence40 | **Outcomes** |
| Trust in providers42 | Trust in providers42 | **Outcomes** |
| Need for psychological support46 | Need for psychological support46 | **Outcomes** |
| Fear of cancer progression40 | Fear of cancer progression40 | **Outcomes** |
MTCs will furthermore be analysed with the aid of the videos, transcripts and observation protocols. In addition, the above-mentioned MDT-OARS by Taylor et al. will be used for quantitative evaluation of the video-based or audio-based observations. The tool was used by them to capture the quality of the MTCs in observations. The tool, including the criterion ‘patient orientation’, will be differentiated more strongly in the research project for the comparison of patient orientation in MTCs with and without patient participation. To increase inter-rater reliability, the material will be coded by two researchers independently from one another, and the preliminary results will be discussed in the work group consisting of patient representatives, clinicians as well as social scientists who were not directly involved in the data collection. Data from clinical protocols will be analysed descriptively, comparing participating and non-participating patients, and as independent variables and covariables in regression models.

**Patient survey**

Data will be electronically recorded and processed with the Teleform data capturing software. Afterwards, plausibility tests will be run. Data from validated scales in the survey will be constructed according to the coding manuals after demonstrating the psychometric properties. Data from self-developed instruments on measured constructs will be psychometrically analysed. The survey data will be analysed by means of the statistics programme IBM SPSS V.25. Open-ended questions will be evaluated content-analytically. The next step is to conduct multivariate analyses (regression models) for differences between the patients with versus patients without MTC participation, between time points and between patient subgroups.

**Triangulation**

In addition to the above description of triangulation, the qualitative results will be used for explaining the quantitative results by applying the triangulation method. Consequently, it will be possible to match, for example, the providers’ perspective on shared decision-making with observations in MTCs and patients’ assessments of shared decision-making in the survey.

**Patient and public involvement**

Healthcare providers, patients and self-help groups are involved in the planning of the study design, recruitment and instrument development. Data and results will be discussed in yearly workshops. PINTU explicitly involves researchers, providers and patients in a community-based participatory research design.

**ETHICS AND DISSEMINATION**

**Ethical considerations**

For all collected data, the relevant data protection regulations will be adhered to. Video recordings are an especially sensitive field. In order to adequately consider ethical and data protection aspects, consultation and a positive vote has been obtained from the ethics committee of the Medical Faculty of the University of Cologne. The British General Medical Council created ethical and data protection guidelines for audio and video recordings of patients, which underlie the research project. All participants in this study will receive written information about the aims and procedures of the study. Furthermore, all patients and providers will be asked for informed written consent to collect their data in interviews (providers), MTCs (patients and providers) and surveys (patients) as well as to analyse and save their data. All personal identifiers will be pseudonymised. By request, all personal data can be deleted immediately without stating reasons.

**Dissemination plan**

The results can provide guidance on the feasibility, risks and benefits of the participation of patients in MTCs. Patients will be invited to a workshop in order to discuss the study results (eg, on the Patients Day of the German Cancer Congress). In a transfer workshop, the results will be discussed with the providers in the breast and gynaecological cancer centres to plan and arrange subsequent intervention studies. On the one hand, the workshops will supply providers with feedback regarding the research results, and on the other hand, they will serve as a platform for the exchange between providers for mutual organisational learning. With the publication of the results in national and international scientific journals and at conferences, the applicants additionally expect a nationwide and international impetus for the patient-oriented treatment of cancer patients.

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**Contributors**

All authors designed the study. CH drafted and revised all sections of the paper and is guarantor. AD, LA and NE revised the paper. CH, AD, LA and NE designed data collection tools.

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**Competing interests**

None declared.

**Patient consent for publication**

Obtained.

**Ethics approval**

Ethics Committee of the Medical Faculty of the University of Cologne, Germany.

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