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Patient Participation in Multidisciplinary Tumor 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 so-called multidisciplinary tumor conference (MTC). In MTC, diagnosis and treatment of cancer patients are discussed and therapy recommendations are worked out. As we found in previous studies, patients participate in MTC in some breast centres in the state of North Rhine-Westphalia, Germany. However, studies on risks and benefits of patient participation have not yet provided substantiated findings.

Methods and analysis

In an explorative study, MTCs in six breast and gynaecological centres in North Rhine-Westphalia, Germany, with and without patient participation, are examined triangulating different methods. Firstly, interviews with providers concentrating on the feasibility of patient participation and the quality of decision-making. The transcribed interviews will be analysed by means of content analysis. Secondly, video- or audiotaped participatory observations in MTC are executed. Video- and transcribed audio data will be coded using an established rating scale and analysed compared between centres with and without patient participation. Thirdly, patients participating and not participating in the MTC fill out a questionnaire before and after the MTC including questions on therapy confidence, health literacy, need for information, decision-making as well as expectations before and experiences after the MTC in the case of participation. The questionnaire data will be analysed by means of descriptive and multivariate statistics (regression models) and pre–post-differences in 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, the relevant data protection regulations will be adhered to. All personal identifiers from patients and health professionals will be pseudonymized, except video recordings. Dissemination strategies contain a discussion with patients and providers in workshops about e.g. feasibility, risks and benefits of patient participation in MTC for patients and providers.

Registration Details

The study is registered in the German Clinical Trials Register (DRKS00012552).

ARTICLE SUMMARY

Strengths and limitations of this study

Strengths

- One of the very few first studies on patient participation in MTC.
- Mixed methods study triangulating qualitative interviews of health-care professionals, qualitative observations of MTC and a quantitative survey of patients with and without patient participation.
- Patient perspective (individual psychosocial situation, needs and experiences) and health-care provider perspective (organizational aspects) on relevant health-care processes and outcomes (e.g. decision-making).

Limitations

- This study follows an observational design as a first step to analyse existing care; in the future, research on this topic would benefit from interventional study designs.
- The number of breast and gynaecological centres and surveyed patients is limited, but analyses are detailed.

INTRODUCTION

Many developments in oncological health care can be observed to have taken place over recent years: among them multidisciplinary care and patient centred care. In oncology, multidisciplinary care is realized in multidisciplinary tumor conferences (MTCs) as a central instrument of treatment decision decision-making.[1] MTCs are defined as regular meetings of a multidisciplinary treatment team in which the diagnosis and treatment of cancer patients are discussed. In Germany, MTCs are widely established and are required in accreditation programmes for cancer centres.[5, 6] Usually, patients do not participate in MTCs.

The international research on MTCs without patient participation reveals that treatment decision-making often lacks the involvement of patient information and preferences.[7–10] 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 the decision in the MTC.[11, 12] Although in many MTCs the patients are supposedly represented by nurses or by the patients' most frequently attending doctor, a comprehensive lack of consideration of patient preferences was found.[12, 13] Furthermore, studies prove that MTC recommendations, which consider patient preferences, their health condition and comorbidity, are more likely to be implemented, as they are clinically more appropriate for and also acceptable to the patients.[14] In addition, observations in a large German university hospital show – with regard to decision-making processes in different oncological contexts – that patient preferences might be more included in decision-making if patients are present during the process of developing recommendations.[15]

But so far, very few studies on patient participation in MTCs exist, not least because they are seldom practised in health care. Until now, only a few works have explored the attitudes of patients and other conference participants with regard to patient participation.[3, 4, 16] While a better understanding of diagnosis and treatment, a stronger involvement in decisions, empowerment of the patients and a better treatment adherence and confidence have been named as potential benefits for patients, the authors also point out the risks, such as uncertainty, excessive demand and anxiety. Among the benefits from the point of view of the providers (e.g. physicians, psycho-oncologists, nurses), the support in developing recommendations, a greater attention and a better patient-physician communication have been mentioned. The possible disadvantages or challenges discussed are the longer duration of MTCs, the need to adjust to the layman's 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 unanswered how patient participation changes the arrangement and interaction in the MTC, whether patient participation is feasible and which benefits and risks the patients and providers can expect. This information is highly relevant for health-care practice in oncology, since MTCs are the central decision-making tool in oncology. In our study 'Patient Participation in Multidisciplinary Tumor Conferences in Breast Cancer Care' (PINTU), for the first time information about the arrangement of and interaction in MTC with and without patient participation will be generated and the perspective and experiences of participating patients and providers with regard to patient participation will be revealed.

Aims of the study

We aim to answer the following 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 the decision-making?; (2) how do MTCs with and without patient participation differ with regard to the organization, interaction and patient orientation? (3) and lastly, 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. Recently, the combination of qualitative and quantitative research methods can also be observed in health services research.[17–20] As a mixed methods study approach combines elements of quantitative and qualitative scientific theory and methodology, new opportunities arise to use and combine sources of data leading to new findings in social sciences, and therefore also in health services research.[21] Next to theoretical benefits of combining methods,[22] relevant practical implications can also be mentioned concerning this study: information from quantitative data might not be identified in qualitative data and vice versa; non-sampling errors might be reduced because of providing data from different sources (e.g. interview and observation); common method bias (e.g. only using self-reported items in questionnaires) might be reduced. As combining both approaches is the key factor of mixed methods studies, but their execution and reporting is not finally clarified,[23, 24] we will use the well-described triangulation technique from O'Cathain et al.[25]

The mixed methods design in our study (see Figure 1) includes in the qualitative part of the study a) providers participating in MTCs being invited to interviews, and b) participatory observations in MTCs with and without patient participation, which are video- or audiotaped. In the quantitative part of the study c) all patients – participating in the MTC or not – are asked to answer a standardized questionnaire shortly before and after the MTC.

Figure 1 to be inserted here.

Sample

The study takes place in breast and gynaecological centres in North Rhine-Westphalia, Germany, the most populous German state. Study hospitals were selected following purposeful sampling criteria,[26] 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 organization of the MTC, because in larger breast and gynaecological centres more cases are discussed in the MTC, and/or these cases are discussed more often, and in teaching hospitals more employees, especially assistant doctors, participate in the MTC.[27]

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

Inclusion criteria for participating patients are: a minimum age of 18 years; at least one breast or gynaecological diagnosis (C50.xx - C58.xx, D05.xx - D07.xx); sufficient German language skills to understand the survey questions; and the physical, psychological and cognitive ability to participate. An average of ten discussed patients (a total of n=180 patients) can be expected per conference.[15] Three conferences take place in each of the three breast and gynaecological centres that do not invite any patients to the MTC, and three in each of the three breast and gynaecological centres where patients are generally invited to the MTC (that means up to 90 patients participating in MTCs). If less than 90 patients participate in the MTC, more observations are executed.

Recruitment

The recruitment of the breast and gynaecological centres starts with the help of the search engine Oncomap. From our former studies we were able to identify suitable breast and gynaecological centres where some patients participate in MTCs.[2, 28] Next, the managers of the centres (usually chief physician) are contacted and the research team personally introduces the study at the centres. Staff council in the centres are being informed about the research project. All participating providers in the MTC and all participating and non-participating patients are informed in written and oral form about the purpose, the conduct, and data protection aspects of the study.

Interviews

All providers participating in MTCs in the breast and gynaecological centres, are being invited as study participants. The interviews with providers take place a few weeks before the participatory observation and video analyses of the MTC. To capture the perspective of the providers, approximately five interviews are conducted in each of the six breast and gynaecological centres (n=30) until we reach data saturation.

Participatory observation and video- or audiography

Experiences from other studies, in which the group interaction in institutions was recorded on video or audio have shown that it is important to build up trust in the research team. Observations in the MTC without data collection will help to get used to the organizational processes in the breast and gynaecological centres and to build up trust in the participants.

Patient survey

Participating and non-participating patients are screened by hospital staff for inclusion criteria. If patients meet the inclusion criteria they are informed in written and oral form about the study. Those patients who give their written consent are included in the study. The CONSORT flow chart (see Figure 2) shows the project process.

Figure 2 (CONSORT Flow Chart) to be inserted here.

Measures

Interviews

Semi-structured interviews will be conducted to capture the experiences, opinions and concerns of the providers participating in the MTC, with regard to the feasibility of patient participation and the quality of decision-making in the MTC. The interview guideline will contain the following questions:

- organization before, during and after the MTC
- interaction before, during and after the MTC
- decision-making before, during and after the MTC
- differences between MTCs held with and without patient participation
- differences in patient participation (dis-)advantages regarding organization, patient–provider communication and decision-making are taken into account.

Participatory observation and video- or audiography

Observations by means of video- or audiography are planned in at least 18 MTC conferences in six breast and gynaecological centres in order to exploratively capture the interaction in and the organization of the tumor conferences both with and without patient participation. In contrast to audio recordings, videography provides the opportunity to observe all interaction modalities, i.e. verbal communication, gestures and facial expressions, as well as other relevant aspects, such as the arrangement of the persons in the room, the utilization of technology and the physical environment. In reference to a study on MTC by Taylor et al.[9] in which they developed the ‘Observation Assessment Rating Scale for multidisciplinary tumor conferences (MDT-OARS)’, our observation categories are the following:

- interaction between team members (e.g. hierarchy)
- interaction between the team and the patients
- organization and infrastructure for the MTC
- patient orientation and the decision-making process during the MTC. For the comparison of the patient orientation in MTCs with and without patient participation, the observation criteria for the category patient orientation will be differentiated more strongly for the research project.

Patient survey

In order to explore the compatibility, risks and benefits as well as the differences between patients participating and not participating in MTCs, all patients fill out standardized survey questions directly before (T0, all patients), directly after (T1, MTC participating patients) and four weeks after (T2, all patients) the MTC. With very few expectations validated scales are used as survey questions and authors agreement was obtained. Standards of survey development[29, 30] will be followed concerning self-developed scales. Because of the exploratory design, a differentiation between primary and secondary outcomes is not made. Outcomes, moderators / baseline characteristics and process measures in T0, T1 and T2 are shown in Table 1.

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

T0	T1	T2
Baseline characteristics / Moderators		**Moderators**
Sociodemographic characteristics[31]		Support from family[31]
(Health literacy)[32]		(Health literacy)
Need for participation[33]		Empathy[34]
Need for informational education[33]		Need for informational education[31]
Preference for paternalism[33]		
Preference for self-help[33]		
Information need before MTC		
	Process measures	**Process measures**
	Shared decision making[35]	Shared decision making
	Experience during MTC[3]	Decision regret scale[36]
	Interruptions during MTC	Health literacy communication[37]
Outcomes	**Outcomes**	**Outcomes**
Health related quality of life (EORTC)		Health related quality of life (EORTC)
Therapy confidence[31]	Therapy confidence	Therapy confidence
Trust in providers[33]	Trust in providers	Trust in providers
Need for psychological support[31]	Need for psychological support	Need for psychological support
Health literacy		Health literacy
Fear of cancer progression[31]	Fear of cancer progression	Fear of cancer progression

Data collection

Interviews

Each interview can take up to 1 hour and is pretested with providers for sense of duration and meaning of questions. The interviews take place at the breast and gynaecological centres. All interviews are recorded by means of an audio device for future transcription and analyses, according to established standards[38] and memory protocols will be used. The interview guideline can be adjusted after each interview if relevant new aspects were mentioned.

Participatory observation and video- or audiography

For the video or audio recording, one or more cameras or audio recordings are set up in the conference room, depending on the room and the seating arrangement, in a way in which they can preferably capture the entire room and the interactions between the participants. Set-up and angle of the camera(s) and the recording quality of image and audio are tested in advance of the MTC of each of the participating breast and gynaecological centres in an organization pretest to ensure the quality of the recordings and to enable the participants to become accustomed to the cameras and recordings. Additional observation protocols 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 the patients is piloted prior to the study in cognitive pretest interviews following established methods, especially using the 'think aloud' method.[39] Pretest participants are recruited e.g. with the help of self-help groups. After patients have agreed to the written informed consent form, T0 surveys can be filled out during hospitalization and sent back to the research team. T1 is filled out by participating patients after MTC and sent back to the research team. Two personalized reminders[40] will be conducted according to Dillman's Total Design Method. T2 is a postal survey 4 weeks after the MTC and is also conducted according to the just mentioned method. Moreover, several strategies shown to increase response rates will also be applied.[41]

Data analysis

Interviews

The audiotaped interviews are being transcribed verbatim and analysed by at least two independent researchers from different disciplines in accordance with the well-established methods of content analysis.[42, 43] Subsequently the analysis will be interpreted by a group of researchers. Here, inductively identified categories can complement and modify the deductively derived categories from former international research.[9, 13, 44, 45] The results will be used to inform survey development as well as to generate hypotheses regarding the positive and negative effects of patient participation in the MTC and to further explore how patient preferences are considered in decision-making in MTCs.

Participatory observation and video- or audiography

The database is formed by video and audio (transcribed) recordings, observation protocols and clinical protocols of the MTC. 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 MTC with and without patients can already be made. Here, the key variables are: qualification and number of participants; duration of the MTC; seating arrangements; length of conversations for each participant and technical support. The analysis of the processes taking place in the MTC is furthermore performed through the use of the videos, transcripts and observation protocols. In addition, the above-mentioned MDT-OARS by Taylor et al.[8, 9] will be used for quantitative evaluation of the video- or audio-based observations. The tool was used by the authors to capture the quality of the MTCs in observations. The tool including the criterion 'patient orientation' will be differentiated more strongly for the research project for the comparison of patient orientation in MTCs with and without patient participation. To increase the intersubjective reliability, the material is coded by two researchers, independently from one another, and the preliminary results are being discussed in the work group consisting of patient representatives, clinicians, as well as social scientists, who were not directly involved in the data collection.

Patient survey

Data will be electronically recorded and processed with the Teleform® software, which is a software for data capturing. 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 is analysed by means of the statistics program IBM SPSS version 25. Open-ended questions data are evaluated content-analytically. The next step is to execute multivariate analyses (regression models) for differences between the patients with vs. patients without MTC participation, between time points and between patient subgroups.

Triangulation

Finally, the different data sources are matched as a mixed methods matrix[24, 25] and consequently the qualitative results are used for the explanation of the quantitative results applying the triangulation method.

Patient and public involvement

Health-care 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 have 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 underline the research project.[46] All participants in this study will receive written information about the aims and procedures of the study and will be asked for written consent to collect, analyse, and save their data. All personal identifiers will be pseudonymized.

Dissemination plan

The results can give guidance on the feasibility, risks and benefits of the participation of patients in MTCs. Patients are invited to a workshop in order to discuss the study results (e.g. on the patient's day of the German Cancer Congress). In a transfer workshop the results are going to be discussed with the providers in the breast and gynaecological centres to plan and arrange subsequent intervention studies. On the one hand, the workshops serve as a feedback of the results from research to providers, and on the other hand as a platform for the exchange of providers for mutual organizational 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 a patient-oriented treatment of cancer patients.

AUTHOR CONTRIBUTIONS

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.

FUNDING STATEMENT

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COMPETING INTEREST STATEMENT

The authors declare no conflicts of interest.

DATA STATEMENT

Data cannot be accessed in a repository yet. Data and all other materials for this study are kept at the Centre for Health Communication and Health Services Research, University Hospital Bonn, Germany. The data sets generated and analysed during the current study are not publicly available due to the terms of written informed consent to which the participants agreed.

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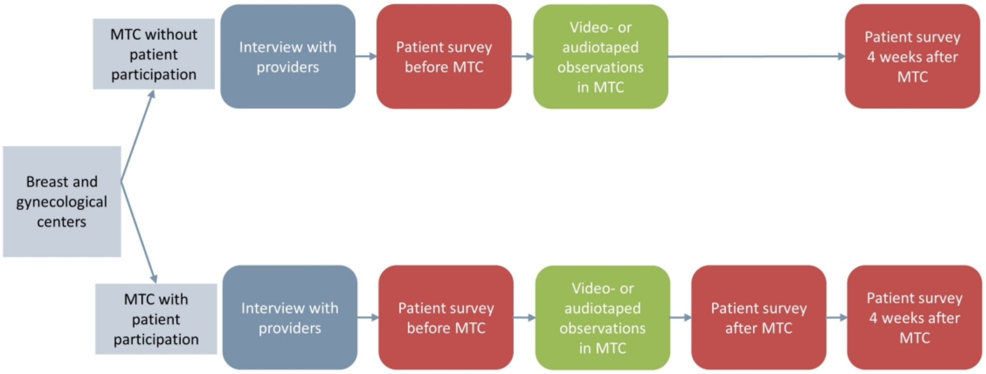

PINTU mixed-methods study design

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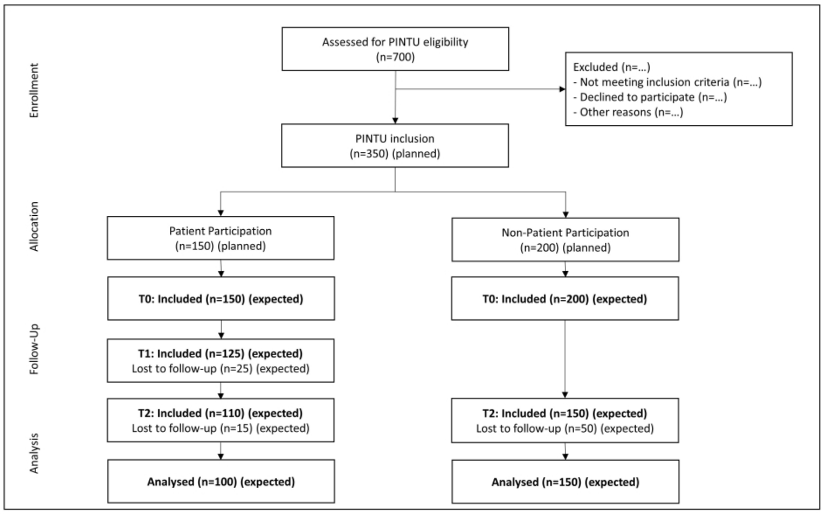

CONSORT flow chart for PINTU

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CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	p.1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	p.2
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	p.4
	2b	Specific objectives or hypotheses	p.4
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	p.5
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	p.5
Participants	4a	Eligibility criteria for participants	p.5
	4b	Settings and locations where the data were collected	p.5-6
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	p.5-6
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	p.6-7
	6b	Any changes to trial outcomes after the trial commenced, with reasons	p.6-7
Sample size	7a	How sample size was determined	p.8
	7b	When applicable, explanation of any interim analyses and stopping guidelines	-
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	purposeful sampling criteria, p.5
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	p.5
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	p.5
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to	p.5

		interventions	
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	p.5
	11b	If relevant, description of the similarity of interventions	-
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	p.6
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	p.6-7
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	Not mentioned because study has not been enrolled
	13b	For each group, losses and exclusions after randomisation, together with reasons	-
Recruitment	14a	Dates defining the periods of recruitment and follow-up	-
	14b	Why the trial ended or was stopped	-
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	-
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	-
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	-
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	-
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	-
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	-
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	Not mentioned because study has not been enrolled
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	-
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	-

Other information			
Registration	23	Registration number and name of trial registry	p.1
Protocol	24	Where the full trial protocol can be accessed, if available	In this study protocol
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	p.9

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

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Patient Participation in Multidisciplinary Tumour Conferences in Breast Cancer Care (PINTU): A Mixed-Methods Study Protocol

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Patient Participation in Multidisciplinary Tumour Conferences in Breast Cancer Care (PINTU): A Mixed-Methods Study Protocol

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Multidisciplinary Tumour Conferences, Tumour Boards, Mixed-Methods, Patient Participation, Health Services Research

Word Count

3,370

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. Firstly, 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. Secondly, 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 MDT-OARS rating scale and analysed by comparing centres with and without patient participation. Thirdly, 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 pseudonymized, 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.

Registration details

The study is registered in the German Clinical Trials Register (DRKS00012552).

ARTICLE SUMMARY

Strengths and limitations of this study

Strengths

- One of the very first studies on patient participation in MTCs
- Mixed-methods study triangulating qualitative interviews of healthcare providers, qualitative observations of MTCs and a quantitative survey of patients with and without patient participation
- Patient perspective (individual psychosocial situation, needs and experiences) and healthcare provider perspective (organizational aspects) on relevant healthcare processes and outcomes (e.g., decision-making)

Limitations

- Observational design as a first step to analyse existing care; future research on this topic would benefit from interventional study designs as well as interviews with patients and/or a survey with providers
- Limited number of breast and gynaecological cancer centres and surveyed patients, but detailed analyses

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] A comprehensive lack of consideration of patient preferences was found although in many MTCs, patients are supposedly represented by nurses or by the patients' most frequently attending doctor.[9, 10] 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 also accepted by the patients.[11] 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.[12]

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.[13–15] 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 (e.g., 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 organization, 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 organization 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 organization, 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 can also be observed in health services research.[16–

19] 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.[20] In addition to the theoretical benefits of combining methods,[21] there are also 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 (e.g., interview and observation).
- Common method bias (e.g., 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,[22, 23] we will use the well-described triangulation technique from O'Cathain et al.[24]

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 video- or audiotaped. In the quantitative part of the study, (c) a standardized questionnaire will be given to all patients – MTC participants and non-participants alike – before and after the MTC.

Figure 1 to be inserted here.

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,[25] 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 organization 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.[26]

Inclusion criterion 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 survey questions and the physical, psychological and cognitive ability to participate. An average of ten discussed patients per MTC meeting can be expected (n=180 patients in total).[12] 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.[27, 28] 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 (e.g., 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 organizational processes in the breast and gynaecological cancer centres and to build the participants' trust in order to persuade them to participate in the video or audio recording and in order to become accustomed to the 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

Semi-structured 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:

- Organization before, during and after the MTC
- Interaction before, during and after the MTC
- 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 organization, 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, i.e., verbal communication, gestures and facial expressions, as well as other relevant aspects, such as the locations of the persons in the room, the utilization 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.[6] in which they developed the 'Observation Assessment Rating Scale for multidisciplinary tumour conferences (MDT-OARS)', our observation categories are the following:

- Organization and infrastructure of the MTC
- Interaction between team members (e.g., 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 standardized survey questions directly before the MTC (T0, all patients), directly after the MTC (T1, MTC participating patients) and four 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[29, 30] 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.

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

T0	T1	T2
Baseline characteristics / Moderators		**Moderators**
Sociodemographic characteristics[31]		Support from family[31]
Health literacy[32]		Health literacy[32]
Need for participation[33]		
Need for informational education[33]		Need for informational education[33]
Preference for paternalism[33]		
Preference for self-help[33]		
Information need before MTC (self-developed)		
	Process measures	**Process measures**
	Shared decision-making[34]	Shared decision-making[34]
	Experience during MTC[15]	Decision regret scale[35]
	Interruptions during MTC (self-developed)	Health literacy communication[36]
Outcomes	**Outcomes**	**Outcomes**
Health related quality of life[37]		Health related quality of life[37]
Therapy confidence[31]	Therapy confidence[31]	Therapy confidence[31]
Trust in providers[33]	Trust in providers[33]	Trust in providers[33]
Need for psychological support[31]	Need for psychological support[31]	Need for psychological support[31]
Fear of cancer progression[31]	Fear of cancer progression[31]	Fear of cancer progression[31]

Data collection

Interviews

Each interview can take up to one 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[38]. 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 organization 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.[39] Pretest participants will be recruited with the help of a cancer information centre and self-help groups (e.g., breast cancer self-help group), which are also 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 hospitalization 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 personalized reminders[40] 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 also be applied.[41]

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 pseudonymization, 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 observer bias, Hawthorne effect and common method bias. However, it should be noted that interviews will be held exclusively with providers and surveys conducted exclusively with patients.

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.[42, 43] 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, 44, 45] 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 also 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 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.[5, 6] will be used for quantitative evaluation of the video- 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 program IBM SPSS version 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 vs. 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, e.g., 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 have 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.[46] 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 pseudonymized. 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 (e.g., 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 organizational 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.

AUTHOR CONTRIBUTIONS

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.

FUNDING STATEMENT

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COMPETING INTEREST STATEMENT

The authors declare no conflicts of interest.

DATA STATEMENT

Data cannot be accessed in a repository yet. Data and all other materials for this study are kept at the Centre for Health Communication and Health Services Research, University Hospital Bonn, Germany. The data sets generated and analysed during the current study are not publicly available due to the terms of written informed consent to which the participants agreed.

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FIGURE LEGEND

Figure 1: PINTU mixed-methods study design

TABLE LEGEND

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

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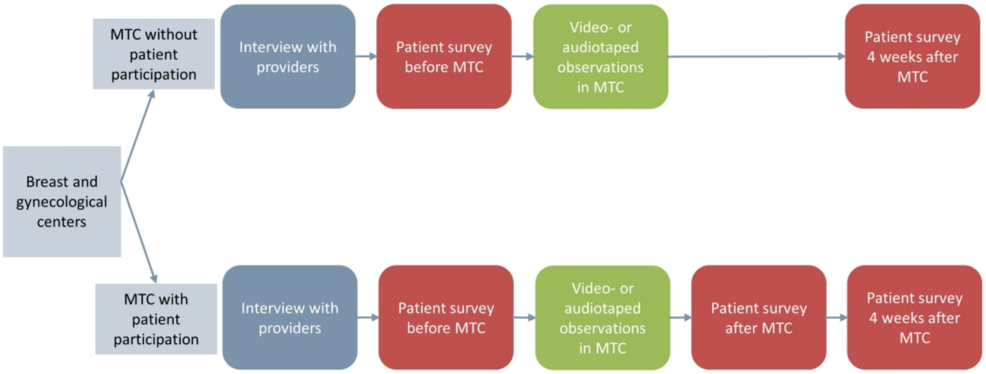

PINTU mixed-methods study design

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Patient Participation in Multidisciplinary Tumour Conferences in Breast Cancer Care (PINTU): A Mixed-Methods Study Protocol

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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. Firstly, 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. Secondly, 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 MDT-OARS rating scale and analysed by comparing centres with and without patient participation. Thirdly, 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 pseudonymized, 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.

Registration details

The study is registered in the German Clinical Trials Register (DRKS00012552).

ARTICLE SUMMARY

Strengths and limitations of this study

Strengths

- One of the first studies on patient participation in MTCs
- Mixed-methods study triangulating qualitative interviews of healthcare providers (e.g., organizational aspects of MTCs), qualitative observations of MTCs (e.g., decision-making) and a quantitative survey of patients with and without patient participation (e.g., individual psychosocial situation, needs and experiences)

Limitations

- 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

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 many MTCs, patients are supposedly represented by nurses or by the patients' most frequently attending doctor.[9, 10] 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.[11] 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.[12]

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.[13–15] 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 (e.g., 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 organization, 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 organization 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 organization, 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.[16–19] 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.[20] In addition to the theoretical benefits of combining methods,[21] 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 (e.g., interview and observation).
- Common method bias (e.g., 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,[22, 23] we will use the well-described triangulation technique from O'Cathain et al.[24]

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 video- or audiotaped. In the quantitative part of the study, (c) a standardized questionnaire will be given to all patients – MTC participants and non-participants alike – before and after the MTC.

Figure 1 to be inserted here.

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,[25] 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 organization 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.[26]

Inclusion criterion 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 survey questions and the physical, psychological and cognitive ability to participate. An average of ten discussed patients per MTC meeting can be expected (n=180 patients in total).[12] 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.[27, 28] 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 (e.g., 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 organizational 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
Semi-structured 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:

- Organization before, during and after the MTC (e.g., setting the agenda, documentation of decisions, technical aids, invitation of providers and patients, seating arrangement)
- Interaction before, during and after the MTC (e.g., 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 organization, 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, i.e., verbal communication, gestures and facial expressions, as well as other relevant aspects, such as the locations of the persons in the room, the utilization 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.[6] in which they developed the 'Observation Assessment Rating Scale for multidisciplinary tumour conferences (MDT-OARS)', our observation categories are the following:

- Organization and infrastructure of the MTC
- Interaction between team members (e.g., 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 standardized survey questions directly before the MTC (T0, all patients), directly after the MTC (T1, MTC participating patients) and four 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[29, 30] 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.

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

T0	T1	T2
Baseline characteristics / Moderators		**Moderators**
Sociodemographic characteristics[31]		Support from family[31]
Health literacy[32]		Health literacy[32]
Need for participation[33]		
Need for informational education[33]		Need for informational education[33]
Preference for paternalism[33]		
Preference for self-help[33]		
Information need before MTC (self-developed)		
	Process measures	**Process measures**
	Shared decision-making[34]	Shared decision-making[34]
	Experience during MTC[15]	Decision regret scale[35]
	Interruptions during MTC (self-developed)	Health literacy communication[36]
Outcomes	**Outcomes**	**Outcomes**
Health related quality of life[37]		Health related quality of life[37]
Therapy confidence[31]	Therapy confidence[31]	Therapy confidence[31]
Trust in providers[33]	Trust in providers[33]	Trust in providers[33]
Need for psychological support[31]	Need for psychological support[31]	Need for psychological support[31]
Fear of cancer progression[31]	Fear of cancer progression[31]	Fear of cancer progression[31]

Data collection

Interviews

Each interview can take up to one 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[38]. 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 organization 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.[39] Pretest participants will be recruited with the help of a cancer information centre and self-help groups (e.g., 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 hospitalization 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 personalized reminders[40] 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.[41]

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 pseudonymization, 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 (5 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.[42, 43] 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, 44, 45] 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 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.[5, 6] will be used for quantitative evaluation of the video- 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 program IBM SPSS version 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 vs. 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, e.g., 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 have 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.[46] 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 pseudonymized. 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 (e.g., 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 organizational 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.

AUTHOR CONTRIBUTIONS

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 INTEREST STATEMENT

The authors declare no conflicts of interest.

DATA STATEMENT

Data cannot be accessed in a repository yet. Data and all other materials for this study are kept at the Centre for Health Communication and Health Services Research, University Hospital Bonn, Germany. The data sets generated and analysed during the current study are not publicly available due to the terms of written informed consent to which the participants agreed.

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FIGURE LEGEND

Figure 1: PINTU mixed-methods study design

TABLE LEGEND

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

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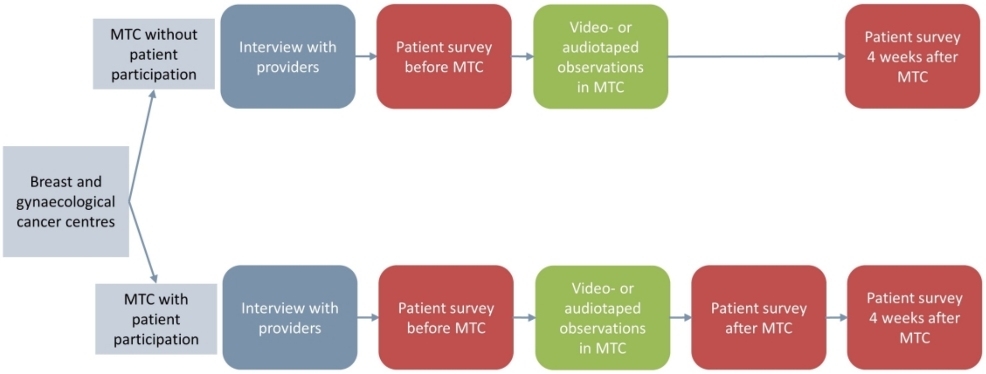

PINTU mixed-methods study design

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