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# "Uninformed consent" in clinical trials with cancer patients: A qualitative analysis of patients' and support persons' communication experiences and needs

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ABSTRACT

*Objective:* Cancer patients are often overwhelmed when being informed about clinical trials. However, there is a lack of evidence-based strategies to improve physician-patient communication in this area. This study assessed the experiences and needs of cancer patients and their support persons (SPs) during the informed consent (IC) process prior to participation in clinical trials.
*Methods:* 17 semi-structured interviews with cancer patients and their SP were conducted and analysed using a framework analysis.
*Results:* Most respondents reported feeling well informed about the clinical trial. However, core aspects of the study were often not understood highlighting a dissonance between perceived and actual recall and understanding. Many participants trusted that the trial recommended was the best available care and only skimmed the consent form or did not read it at all.
*Conclusions:* This is the first German study to analyse both cancer patients' and SPs' perspectives on IC processes. Although many feel well informed, our results suggest a significant gap in recall and understanding of core components of clinical trials which hinders IC.
*Practice implications:* Further interventional research is required to improve the consent processes prior to clinical trials in order to provide optimal, patient-centred care.

## 1. Introduction

### 1.1. Clinical trials are a core component of high-quality healthcare

Clinical trials investigate the safety and effectiveness of new therapies in order to develop new treatment modalities and to integrate them into routine care [1]. It is essential that patients understand the aims, risks, benefits, methods, and alternative treatment modalities before consenting to participation [2–5]. According to the German Medicinal Products Act (§ 40b AMG Patientenrechtegesetz § 630e) in conjunction with Art. 29 of the Clinical trials - Regulation EU No 536/2014 and the Declaration of Helsinki [6], patient participants need to be comprehensively informed about a study in which they enrol, which often requires patients to consider a significant amount of complex and unfamiliar information. In addition, the privacy statement according to the General Data Protection Regulation (GDPR) makes informed consent (IC) processes even more complex. A meta-analysis from 2015 [7] showed that only 54.9% of study participants could name at least one risk associated with the respective study and only 52.1% had understood the information regarding randomisation. Tam et al. [7] highlighted that

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over the course of their study period (1985–2014) patients' understanding of the IC did not increase.

*Cancer patients often struggle with the abundance of information related to clinical trials*

IC processes are particularly relevant in oncology since numerous new therapeutic approaches have been developed in this area of medicine in recent years, which is accompanied by a correspondingly high level of clinical trial activity [8]. In addition, cancer patients are often anxious and distressed when confronted with their diagnosis, treatment options and prognosis, which can make it difficult to understand and retain complex and unfamiliar information such as that related to clinical trials [9]. The increasing complexity of clinical practice also limits the time physicians have to address each patient's needs and concerns [10].

*More research is needed to better understand patients' perception and to improve physician-patient-communication related to cancer clinical trials*

Efforts to improve comprehension through the use of new consent forms has had limited success [11] and only very few studies have examined how IC processes could be improved in Germany which is problematic given that results from other healthcare settings and services may not fully apply to the German context due to differences in healthcare systems and regulations. Further studies are needed to explore patients' preferences with regard to IC processes and to develop communication strategies to effectively improve the IC processes. Also, support persons (SPs) are one of the most important sources of advice and information for patients [12]. They often play a key role in helping patients recall and understand information regarding their care and research participation [12]. Yet, there has been little attention directed to their views on how to improve patient information regarding their care (or research participation) [13]. Qualitative research methods can help address this gap by providing novel in-depth insights into the perspectives of patients and their SPs regarding IC process related to cancer clinical trials.

## 2. Methods

### 2.1. Aim

This study explored, qualitatively, in a sample of cancer patients participating in clinical trials including their SPs, the communication experiences and needs related to IC processes, with a particular focus on recall and understanding. Based on their perceptions, suggestions for how to improve care in this area were developed.

### 2.2. Study Design

Semi-structured phone interviews with cancer patients participating in a clinical trial and their SPs were conducted. This is a sub-study of a larger project designed to develop and test strategies to improve IC processes.

### 2.3. Participants

Eligible patients had a confirmed diagnosis of cancer (any type), were taking part in a clinical trial, had no cognitive impairments which impeded on providing IC for this study, had sufficient knowledge of German and were at least 18 years of age. SPs were aged 18 years or over, German speaking, and able to provide IC. Support persons had a purely supportive role in the informed consent process, accompanying patients to medical appointments and often joining and advising them in the decision-making process.

### 2.4. Recruitment

Eligible patients were identified by the treating physician, who informed them about our study, and sought written IC. If the patient was accompanied by a SP, IC was also extended to them. If there were no SPs present, patients were asked to inform their SPs about this study and, if they wanted to take part in the interview, were sent a study package by mail. The interviews were conducted by phone. Participants could decide on the timing of the interview according to their availabilities and individual preferences.

### 2.5. Data Collection

Between June 2021 and August 2022, a member of the research team conducted individual telephone interviews. The interview guide was developed based on a literature research [3,5,7,11] and discussions among the research team composed of lawyers, ethicists, physicians and communication scientists. At the start of the interview, participants were asked to talk about their experiences of the IC processes. Participants were asked about the comprehensibility of the IC process, recall of information and strategies to improve this. With the help of discussions among the multidisciplinary research team and based on literature research [7], we agreed on core aspects that are relevant to understanding clinical trials, i.e. aim, risk and randomization. These aspects were elicited during the interview with the help of the recall questions addressing the following aspects: aim and risk of the study and randomization. Nevertheless, it is important to mention that these questions did not aim to generate representative results but only to indicate a tendency within the sample (for detailed information in each topic area please see the interview guide provided in Appendix 1). Patients and SPs were interviewed together using the same interview guide. The interviewer encouraged both patients and SPs to share their views. Some authors suggest that patients may feel more comfortable when they are interviewed with their SPs and that this could generate richer data than interviewing them separately due to the interaction between the interviewees leading to a more holistic presentation of the studied phenomena [14,15]. Thus, SPs were encouraged to contribute to the patient's narratives if they wished to provide more detail on specific aspects. Conducting joint interviews also aimed to reduce the research-related burden on participants. Data collection was stopped when no new findings were generated after coding three consecutive interviews. Continuing data collection was considered to be unlikely to yield any additional insights that could help answer the research question.

### 2.6. Data analysis

The interviews were audiotaped and transcribed verbatim. One member of the research team transcribed all interviews and the transcripts were double-checked by another member of the research team [16]. The data was processed and analysed with the help of the QDA software ATLAS.ti [17] using framework analysis [18]. Framework analysis is a systematic approach for mapping and interpreting data [18]. First, an inductive approach was taken. This means that the data were read intensively by a member of the research team and coded openly by applying a paraphrase (i.e. a "code"). Codes were then checked and discussed with another member of the research team. The codes described what had been identified as significant within the respective passage. Then, the codes were clustered into more complex categories through the summarization and synthesis of the coded data, thereby constructing an analytical framework. Multiple codes related to the same topic were used to form a category. The framework was discussed within the research group and then utilized in analysing subsequent interviews [18]. In a next step, all transcripts were coded by one coder using the analytical framework and checked by another. If new codes emerged, the framework was adapted. The dynamic analysis

allowed for the continuous testing and refining of the hypotheses formulated with the help of the categories. After the categories were formed and interpreted, connections were established between them. This led to the next stage of the data analysis, which involved defining the main themes. Themes were considered concepts that describe and summarize core aspects within the dataset and serve as the end result of the comprehensive analysis of the entire data gathered within this study [18]. All conclusions drawn from the data were analysed and discussed by the members of the research team.

## 3. Results

17 patients and 10 SPs were interviewed. Patients had a mean age of 54 years and most were male (65%). The median time since inclusion in the clinical trial was 63 days. Most patients had haematological or gastrointestinal cancer (59%). Patients participated in different clinical trials. SPs had a mean age of 53 years. The majority of SPs were the patient's partner living with the patient (see Table 1). Participants came from both urban and rural areas.

The themes that emerged from the data were: i) reasons for participating in the clinical trial, ii) the relevance of the IC conversation, iii) the comprehensibility of the informed consent document; iv) dissonance between actual and perceived understanding, and v) potential for improving the consent process.

### *Reasons for participating in a clinical trial*

Patients reported various reasons for participating in a clinical trial. For many, their decision to join the trial was driven by the expected benefits to the community and thus somewhat altruistic motivations. With their participation, patients wanted to support research and the development of new therapies for future patients. Also, the awareness that they had also benefited in some way from other patients' involvement in clinical trials, led many interviewees to take part in the study.

> *"Actually, you benefit from the fact that other people have done it this way in the past, so there has been an incredible progress in research, the therapies are getting better and better and can only get better because people have agreed to make themselves available for these examinations." (patient, male, 54 y, haematological cancer)*

Hope for cure was another reason for participating in the clinical trial for the majority of patients. They reported hoping to receive more effective treatment through participation in the clinical trial. Due to an assumed closer and more regular monitoring, their health status was perceived to be better controlled and adverse events to be picked-up more promptly. Some participants stated that by participating in the study, they would have access to therapies that were not yet accessible to the majority of patients. For numerous patients this was a way to do everything they could to fight-off their cancer as some felt they had to take all actions available to them to receive optimal care and improve their outcomes.

> *"So I'm not the youngest anymore but I'm still relatively young for the diagnosis that I got and I have two little kids at three and a half and a year and for me there's only one way and that's to beat the cancer and no matter what steps I have to take to do that, they're going to get done and if it means participating in any trials as a plan B, or C, or D, or E or whatever, I'm going to do that because there's no giving up." (patient, male, 45 y, kidney cell cancer)*

**Table 1**
Sociodemographic characteristics of patients and SPs.

| Characteristics | Patients (n = 17) | Support persons (n = 10) |
|---|---|---|
| **Age (M)** | 54 | 53 |
| **Age (Range)** | 32 - 74 | 42 - 63 |
| **Gender (%)** | 35% | 70% |
| Female | 65% | 30% |
| Male | | |
| **Citizenship** | 16 | 9 |
| German | 1 | 1 |
| Other | | |
| **Days since inclusion in the clinical trial (median)** | 63 | |
| **Days since inclusion in the clinical trial (range)** | 8 - 241 | |
| **Diagnosis** | 1 | |
| ENT tumours | 3 | |
| Tumours of the digestive organs | 1 | |
| Tumours of the respiratory organs | 1 | |
| Tumours of the female genital organs | 1 | |
| Tumours of the urinary organs | 10 | |
| Malignant changes in lymphatic and haematopoietic tissues | | |
| **Relationship to the patient** | | 9 |
| Partner | | 1 |
| Relative | | |

### *The importance of the informed consent conversation*

Participants showed a great level of trust in their medical staff. For most interviewees the IC conversation with their treating physician was the most important source of information. The participants often reported believing that the study that was recommended by their medical staff was the best available care. This often led to the IC document being only partly skimmed over or not read at all. Also, many patients and SPs reported feeling overwhelmed by the complex and unfamiliar information provided to them and their distress and anxiety when facing their disease and treatment. They often struggled to recall, understand and process information. Thus, some participants reported feeling dependent on their treating physician's views regarding whether or not to join the clinical trial.

> *"At that time, I was also feeling worse and so on, and I didn't know any other decision about what else might be better, and I simply relied on what the doctor suggested to me and what he saw as best, and that's what I accepted." (patient, female, 48 y, haematological cancer)*

Some SPs said that they saw their role in the IC conversation as gathering and recalling information on the respective trial because the patients were unable to absorb any information because they were emotionally overwhelmed.

> *"After the informed consent conversation, I was more focused on the practical aspects of the study, while my husband was more concerned with the emotional processing of the diagnosis." (support person, partner, 50 y)*

Patients and SPs reported they received a detailed explanation about the study at a first appointment and then had a few days, sometimes even a fortnight, to decide about participation. This procedure allowed them to reflect on the possibility of taking part in the research and to read the study material. It also helped them talk to each other about the information received and become more actively involved in trial decisions.

> *"I had a little time in between [the conversations with my doctor] to understand everything better, because then you didn't have to absorb or understand so many things at once." (patient, female, 54 y, haematological cancer)*

> *"In the meantime, we could talk a lot about the therapy and the study. There were things that he (patient) didn't understand so well, so we mentally went through the IC conversation again." (support person, partner, female, 62 y).*

During the IC conversation, patients and SPs felt they were given enough opportunity to ask questions, but many of the interviewees

stated that they only thought of their questions after the conversation. This was because they could not "digest" and use the information provided during the conversation in a timely manner to be able to ask questions during or at the end of the conversation with their physician. Many felt that it was hardly possible to process all information regarding the study and reported it being very challenging to follow their physician's explanation in a state of informational and emotional overload. Many appreciated the opportunity to contact the physician by phone or email after the conversation.

> *"The physician also gave us time for any questions, but since you are often overwhelmed by this wealth of information, the questions don't really come to mind at that moment. So that's how I feel." (patient, female, 54 y, haematological cancer)*

*The comprehensibility of the IC document*

Many patients and SPs noted that the technical language of the IC document was hard to understand. Thus, many patients did not benefit from receiving the IC document prior to their conversation with the treating physician. Technical terms were often used without first being explained, such as "sponsor" of a trial. Patients reported that some concepts were often repeated in IC documents while others were not explained at all.

> *"I received the documents beforehand, which were then discussed afterwards, but I found them very theoretical and perhaps not so easily accessible for lay people. You often skim through it once and then you hold on to paragraphs that you understand, and then there are paragraphs that are perhaps not so clearly understandable for laypersons, which you then simply skim over as a normal person."* (patient, female, 66 y, haematological cancer)

Another reason why some participants stated that they did not read through the IC document was that it contained too much information. Specific information (e.g., study procedures, withdrawal of participation or study sponsor) were often reported to be difficult to find. However, some patients appreciated the IC document handed to them as it provided them with the opportunity to obtain extensive information. In their eyes, it was a strength of the IC process to have a lot of specific information at their disposal in order to increase their knowledge about the study after the IC conversation. These were mainly people who, due to their education or social environment, had a relatively high level of understanding of medical issues.

*Dissonance between actual and perceived understanding*

Although the majority of patients felt well informed, recall questions showed that many aspects of the respective study were not understood. Many patients (76%) struggled understanding the risks of study participation. Some persons participated in clinical trials involving additional examinations and considered this to be no risk, although the IC document stated that the respective study examination posed an increased risk of complications.

> *"So the risks, I could not imagine now that there are any, except that you then just get a colonoscopy."* (patient, male, 54 y, haematological cancer)

Information regarding randomization was often not understood either. Half of the patients (50%) who participated in a multi-arm therapy study said that they did not know anything about being divided into different groups. They thought that all patients in the study were receiving the same therapy. The aims of the study were also not clear to some participants (41%). Patients who reported not having health professionals in their private network seemed to struggle most to understand and recall what the study was about and why it was being performed. Thus, although many patients reported feeling well informed, there was an evidence that some patients failed to understand the core components of the clinical trial.

*Potential for improving the consent process*

Participants suggested various strategies to improve IC processes. Some participants wished for a summary of the IC document in lay language or suggested the documents be re-structured using a table of contents, headings and a glossary as well as more colours, images, tables and graphs. A video education in addition to the IC conversation was advocated by some participants because they thought they would have understood some information better with the help of audio-visual information that could be used at a time and place of their choosing. Others, however, were concerned that additional audio-visual information would make the IC process even more complex and time-consuming.

> *"Although I'm not against videos, I think if someone is sick and is then supposed to watch a video of how the study is going and then also talk to a physician, that's going to be a bit much."* (patient, female, 56 y, haematological cancer)

A guideline or protocol for the IC conversation for both patients and physicians was also raised to help structure the conversation. Such a protocol could provide a brief guide on consensus-based, core aspects that should be covered during IC processes, such as the right to withdraw, randomization or treatment risks. This could serve as a reference for the informing physician, aiding in structuring the IC conversation and providing a kind of check list to ensure that all aspects have been explained. Such a document could also help patients to follow the physician's explanations during the IC conversation and provide a take-home information source to support patient recall and use of the information given. In an attempt to make patients aware of available trials, getting them more involved in early decision-making on study participation and raising public awareness of research, some patients suggested an online portal where information about various trials could be provided in lay language. They recommend a printed information brochure handed out once a month for patients who prefer a paper format.

> *"You would have to give maybe once a month a, I don't know, five-page, four-page, ten-page information brochure, which studies are available, what these studies do, how they do it, just this information as it could actually then be available on the Internet, or in a printed version."* (patient, male, 45 y, kidney cell cancer)

## 4. Discussion and conclusion

### 4.1. Discussion

The patients interviewed as part of this study had different types of cancer and participated in different clinical trials. Most got information about the study mainly through the IC conversation and used hardly any written information. All participants felt well informed about the respective clinical trial. Nevertheless, important aspects of the clinical trial, such as objectives, benefits and risks, were often not understood and/or not remembered. Strategies to improve IC processes may include an improved layout of the document, a guide for the IC conversation (for patients and physicians) and an online portal or a printed brochure with lay-language information on ongoing studies involving people with the same or a similar diagnosis.

*Patients are often overwhelmed when trying to "digest" information on clinical trials*

The results of this study suggest that a patient's signature on an IC document is no guarantee that the patients have read through the IC documents and understand the information provided to them. This is in

line with previous research highlighting that study participants often do not read trial information but were happy to participate to help others, even if they do not understand core components of the respective study [19]. Patients often feel overwhelmed by the distressing and unfamiliar information they receive as part of their care [20]. Patients may also lose focus while receiving information on the trial available to them [21]. Opinions vary widely on the duration of patients' attention spans [22], but some suggest it may not last longer than ten to 15 min [23]. This makes it hard to process, recall and use the information provided as part of often lengthy IC conversations and IC documents mostly exceeding ten pages [24]. SPs can help patients overcome feelings of being overwhelmed, but relatively few studies have explored how SPs interact with patients and clinicians during the healthcare decision-making process [25]. The role and impact of SPs in the informed consent process should be an area for further research on strategies to improve informed consent, since SPs are often one of the most important sources of advice and information for patients [12]. Communication strategies should be developed and tested that specifically address the needs of support persons and allow for a more active involvement of support persons in the informed consent process.

*Dissonance between perceived and actual understanding*

Although most patients in this study felt well informed, recall questions showed that many of them had not understood or could not remember important information concerning the clinical trial. Thus, there seems to be a discrepancy between the information provided and patients' perceived understanding of this information. In order to avoid cognitive dissonance [26], patients may claim they have understood all information provided to them given that this may be considered socially desirable. However, the dissonance between perceived and actual understanding may cause misconceptions among physicians and patients who may overrate patients' level of understanding. Patients may be unaware of what they do not understand about the trial [27].

*Improving the IC conversation and document*

In line with previous studies [27] our findings suggest that the IC conversation is the most important part of the IC process for patients and SPs. Patients and SPs appreciated receiving a two-stage IC process involving an initial IC consultation and a second consultation one to two weeks later, during which all questions could be answered. This approach may help improve physician-patient-conversation involving a myriad of complex and potentially distressing information for patients [28]. However, this approach is not commonly used in all healthcare services [29], so that patients often have to decide promptly after the IC conversation whether they want to participate in the clinical trial or not. As there may be a difference in the power hierarchy between doctor and patient, this may also have influenced the patient's decision on whether to participate in the trial. Thus, patients may feel inclined or even obliged to follow to understand the details related to the respective trial and make an informed decision regarding their care [30]. Hierarchical differences may be reduced by an interprofessional approach to the IC process, for example by including study nurses as additional contacts for questions surrounding the study [31]. Physicians, patients and SPs may further benefit from having a protocol for the IC conversation that allows them to structure the conversation and ensure all core components of the study were explained, understood and recalled [32]. In order to help patients and SPs inform themselves about ongoing studies, an online portal or a printed brochure including a list and brief description of all ongoing studies for the respective cancer types could be provided [11]. A glossary and a summary of the IC document in lay language may help patients and SPs understand and recall the main aspects of the IC document [33]. The layout of the IC document may be more appealing with the help of graphs, tables and pictures to help maintain attention while reading the document. Instruments such as advance organisers which are a visual orientation aids at the beginning of a text providing an overview of the following content, may be helpful to improve comprehension and recall [34]. In line with previous studies [7], many patients participating in randomized studies did not understand the randomization process. Since this is a core aspect of IC in randomized studies, it is necessary to enhance understanding regarding randomization. A protocol for the IC conversation and a flow chart depicting possible pathways in participation may be helpful tools [31]. Our results could be used to improve patient engagement in decision making by allowing patients (and their SPs) to better understand, recall and use information while making treatment decisions. This does not just refer to decisions about enrolment but also to decisions later in the trial process for patients, e. g. on whether or not to continue participation. Although some of these suggestions for improving IC have been published elsewhere in the international literature [11,33], the results from English-speaking countries may not be applicable to the German healthcare setting or other German-speaking countries given differences in legal requirements and cultural norms. Thus, these findings help provide context-specific, evidence-based guidance on how to improve doctor-patient-communication in this area and inform future research and clinical practice.

This study is, to the best of our knowledge, the first in Germany to analyse both patients' and SPs' perspectives with regard to IC processes. We recruited participants from various sociodemographic and disease-related backgrounds who participated in different clinical trials. However, the generalisability of the study findings is limited by the fact that we interviewed patients and SPs from a single site. Another limitation of this study is that retrospective interviewing may introduce recall bias, yet the focus of our interview study was on perceptions regarding central components of the IC process (such as aims, risks, or design of the study) which should be remembered over time as this information should inform the basis for informed decisions on study participation.

### 4.2. Conclusion

This study revealed significant discrepancies in patient's perceived and actual understanding with regard to core aspects of IC for cancer clinical trials, such as aims and risks of the respective study and randomization. This may lead both patients and their treating physicians to overestimate patients' level of understanding. Despite increasing efforts for patient autonomy and empowerment, recent legal requirements seem to make IC conversations and documents increasingly complex. Our findings highlight several suggestions to help overcome this but further interventional research and policy efforts are required to help patients, SPs and treating physicians make shared and informed decisions on whether or not to join a clinical trial.

### 4.3. Practice implication

Healthcare providers should not assume that a patient;s signature on an IC document means that they have fully understood core aspects of the respective trial. Although patients may claim they did comprehend this information, they may feel overwhelmed by the information presented to them and may not have the capacity to fully "digest", recall and use this information. Overcoming this potential dissonance between perceived and actual understanding is essential for optimal, patient-centred healthcare decision making. Strategies to address this may include dividing the IC process into two consultations, having a protocol for the IC conversation, a glossary and lay language summary of the IC document as well as providing more easily available overviews of all ongoing studies for the respective cancer types.

## CRediT authorship contribution statement

**Christine Bernardi**: Methodology, Formal analysis, Investigation, Data curation, Writing – original draft, Project administration. **Daniel Wolff**: Conceptualization, Validation, Resources, Writing – review & editing. **Florian Lüke**: Conceptualization, Resources, Validation, Data curation, Writing – review & editing. **Johannes Hies**: Conceptualization, Validation, Writing – review & editing. **Nina Hallowell**: Conceptualization, Validation, Writing – review & editing. **Ruth Horn**: Conceptualization, Validation, Writing – review & editing. **Frederike Seitz**: Conceptualization, Validation, Writing – review & editing. **Daniel Heudobler**: Conceptualization, Validation, Writing – review & editing. **Anne Herrmann-Johns**: Funding acquisition, Conceptualization, Methodology, Project administration, Investigation, Formal analysis, Data curation, Writing – review & editing, Supervision.

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## Declaration of Competing Interest

The authors report no competing interests.

## Appendix A

As already mentioned, my name is xy and I work as a scientist at the University of Regensburg.

We are currently conducting a research project on informed consent in cancer clinical trials.

I would therefore like to ask you to tell me how you were informed that you were eligible for a clinical trial and how the informed consent conversation with your doctor was conducted. You can feel completely free to say anything that comes to mind and talk for as long as you like. I will listen to you carefully and make notes of any questions that we may need to clarify later.

We can stop the interview anytime or skip questions you don't feel comfortable answering. Please just let me know when you feel you would like to stop or skip questions.

Now I am going to ask you to tell me about the informed consent process, in as much detail as you like, and you can take as much time as you like.

Objective/subjective understanding of informed consent

- o Who gave you information about the clinical trial?
- o How long did the informed consent conversation last?
- o Did you talk to your support person about the clinical trial before you made your decision? Was your support person present during the informed consent conversation?
- o Do you remember when the informed consent conversation took place?
  - Were you informed about the study immediately after being informed of the diagnosis or only later at another appointment?
- o Did you use any other sources of information about the trial?
  - If yes, which ones?
- o Did you feel that you understood exactly what the clinical trial involved and how it would work?
- o Question for the support person, only if he/she was not present during the informed consent conversation: Do you feel that he/she was well informed? Did he/she talk to you about any uncertainties afterwards? Did any questions arise in the days following the informed consent conversation?

Informed consent document

- o When you decided to take part in the trial, you signed a written consent form. Did you read it through?
  - ● What was easy to understand and what was unclear to you?
  - ● Were there any parts of the text where you did not understand the technical language used?
  - ● Did you feel overwhelmed while reading?
  - ● Do you know why written consent is obtained from the study participants?
- o If applicable: In this trial, participants received different treatments. Were you informed about this? Do you know why this is happening?
- o Has the treatment/drug already been tested before?
- o Please explain to me in your own words,
  - ● What is the aim of the trial you are taking part in?
  - ● How are the participants divided into groups?
  - ● What are the risks of taking part in the trial?

Informed consent conversation

- o When you think back to the informed consent conversation, what was particularly difficult for you? (e.g. certain information).
- o Was there enough time for the informed consent conversation?
- o Was the language of the person giving the information easy to understand? Were you always able to follow him/her?
- o Were you given enough time to ask questions?
- o Was there a point in the informed consent conversation when you felt less receptive or overwhelmed?
  - ● If so, when did this happen and why?
- o Have you ever heard of the Patients' Rights Act?
  - ● If so, what do you know about it?

- o Have you read the data protection notice? Did you find it difficult to understand? What do you think about the scope of the privacy policy?
- o When you think back to the informed consent conversation, what was particularly helpful to you?
- o What would have helped you to better understand the information about the clinical trial?
- o What do you think is the best way to provide information about a clinical trial?

Strategies to improve the informed consent

- o How do you think information about the clinical trial could be better communicated?
- o Which of these informed consent strategies would you consider?
  - ● Video informed consent in the clinic, plus conversation with doctor
  - ● Video informed consent at home online, after conversation with doctor
  - ● Brochure with flowcharts, graphs and tables, to be read at home after the informed consent conversation
  - ● Electronic informed consent
  - ● Informed consent summary (1200-1800 words) with key information and the full consent form as an appendix
  - ● Extended informed consent conversation (with a member of the study team or with a neutral person - peer to peer)
  - ● For patients with a migration background: educational materials available in additional languages.

Do you have any other comments you would like to make? Do you have any questions?

Thank you!

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