Patient experiences of randomised placebo-controlled trial participation during end-of-life palliative cancer care

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ABSTRACT

Background Performing clinical trials in palliative cancer care is known to be challenging.

Objective This study aimed to explore how patients with advanced cancer experienced their participation in a randomised, placebo-controlled trial while receiving palliative cancer care at end of life.

Method A descriptive design with a qualitative approach was used. 14 patients who had participated in the ‘Palliative-D’ study were interviewed. Data were analysed using content analysis.

Results Three categories were identified: understanding the study design, willingness to participate and collaboration with the research team alongside standard care. Being randomised, with the risk of receiving placebo, was perceived as non-problematic since it was understood as being important for the quality of the research. Patients showed a willingness to participate for the sake of others and also for their own sake, hoping for a cure or at least to live as long as possible. Patients felt proud of being useful and contributing to research. Consent to participate was made autonomously without discussing with others. Patients considered the study design uncomplicated and well-integrated into the standard care.

Conclusion Study participation in a randomised, placebo-controlled trial can be a positive and meaningful experience for patients despite advanced cancer in end of life. Participation may support patients' autonomy and give hope, and therefore, might have a positive effect on quality of life. A carefully planned and simple study design, well integrated into standard care, can facilitate the feasibility of clinical studies in specialised palliative home care.

WHAT IS ALREADY KNOWN

⇒ Performing clinical trials in palliative care is known to be challenging.

WHAT ARE THE NEW FINDINGS

⇒ Patients felt proud of being useful and contributing to research.
⇒ The use of placebo was experienced as non-problematic
⇒ Participation in clinical trials can support patients’ autonomy
⇒ A simple study design facilitates feasibility of clinical studies in palliative care.

WHAT IS THEIR SIGNIFICANCE

⇒ Participation in a clinical trial in palliative care can be experienced as positive and meaningful.

INTRODUCTION

Conducting randomised controlled trials (RCTs) in specialised palliative care can be challenging from several perspectives, including gatekeeping, high drop-out rates, logistical challenges, ethical issues and the risk of impairing the quality of life of patients with a short life expectancy.1–3 A recent study addressed the difficulties of recruiting patients with palliative care needs to placebo-controlled trials; of 1097 patients admitted to specialised palliative care, only 157 were included in the per protocol analysis.4 Furthermore, pooled data in a systematic meta-analysis of barriers to clinical cancer trials established that only 8% of eligible patients were enrolled in trials. However, trials were also only available for one in four patients with cancer, highlighting the need for adjustment of organisational structures to promote clinical research.3 In comparison, a systematic meta-analysis from the USA showed that when being
presented with the opportunity to participate in a trial, 55% of patients with cancer consented; patients’ motives for participation in trials need, therefore, to be explored. In addition, study outcomes should be carefully selected since patients in the palliative care setting often have an increased symptom burden and deteriorate as their disease progresses. Consequently, the study design needs to be tailored to make it feasible and as easy as possible for patients to participate.

There is currently a lack of RCTs including patients with advanced cancer, especially those in the late palliative phase. Consequently, the evidence base for treatments offered to these patients is often weak. This is in contrast to oncological treatments given earlier in the disease trajectory where guidelines and recommendations are based on solid evidence from well-conducted RCTs. The lack of RCTs in palliative care is highlighted in a recent study showing that less than 5% of all published studies in palliative care performed in Australia during 2000–2018 were RCTs.

Between 2017 and 2020, we conducted the ‘Palliative-D’ study. This was a double-blind, placebo-controlled randomised trial on the effects of vitamin D supplementation. To the best of our knowledge, no such study had previously been conducted in specialised palliative home care in Sweden. All the participants suffered from advanced cancer and had an assessed remaining survival time for more than 3 months at time for inclusion.

Patients’ perspectives might contribute to future study development and design. Thus, this study aimed to explore how patients with advanced cancer experienced their participation in an RCT, while receiving specialised palliative home care.

**METHOD**

**Design**
This study used a descriptive design with a qualitative approach.

**Study context**
Participating patients in this study were enrolled in one of three specialised palliative home care services in the Stockholm Region. These services provided 24-hour-a-day care from a multiprofessional home care team including physicians, nurses, nurse assistants, occupational therapist, physiotherapists and social workers. The patients were diagnosed with advanced cancer and were receiving specialised palliative care. This study is based on a previous large randomised, placebo-controlled study, the ‘Palliative-D’ study. Three of the authors of this study, CK, MH-F and LB-B, were part of the study team of the Palliative-D study.

The Palliative-D study
The ‘Palliative-D’ study was conducted between 2017 and 2020 and the objectives were to test if correction of vitamin D deficiency could decrease pain, improve fatigue, increase quality of life and decrease infection burden. To be included, patients should have advanced cancer, vitamin D deficiency, understand Swedish and have a life expectancy of at least 3 months. The participants were randomised to take a placebo or vitamin D for 12 weeks. Outcomes were measured at baseline and at 4, 8 and 12 weeks using blood samples and self-assessment tools. Out of a total of 530 screened patients, 244 were randomised to the intervention and 150 patients completed the trial. The major reason for drop-out was death due to cancer. In the recruitment process for the ‘Palliative-D’ study, all patients received study information orally via a telephone call from one of the members of the research team. Patients were explicitly asked if they wanted written information to be sent to their home to allow time for further reflection. The information was repeated at the screening visit for patients who consented to participate. Visits for data collection were planned in line with regular visits from the home care team to minimise the burden on the patient. The visits were performed by the home care teams, when possible, otherwise by the research team, of which three members worked in one of the three services. As a courtesy, all participants were offered vitamin D (Detremin) supplements immediately after their participation rather than after the unblinding of the randomisation process at end of the trial in June 2020. Patients who were still alive when the assigned interventions were disclosed received information regarding whether they had been randomised to receive the placebo or vitamin D.

**Procedure and participants**
Patients who had completed the 12-week intervention in the ‘Palliative-D’ study (n=150) constituted the recruitment base for this study. At screening, 40 patients were still alive; however, 15 were considered too ill to participate by the home care team. The remaining 25 patients were telephoned by the research team and given oral information about the study. Those who were interested received written study information by mail to their home to allow time for further consideration. A total of 15 patients accepted participation by returning a signed informed consent form by mail. One patient withdrew consent before the interview due to rapid deterioration. Ultimately, 14 patients, 7 men and 7 women, were included in this study. Their mean age was 68 years and half were married. They were all diagnosed with advanced cancer (gastrointestinal, prostate, pancreatic, ovarian or breast cancer). 12 patients had received palliative chemotherapy and 2 had received hormonal treatments. At the time of reporting the findings, two patients were still alive.

**Data collection**
Data were collected through semistructured interviews. An interview guide was used with open-ended
questions formulated in collaboration by the researchers (online supplemental material 1). The interview guide addressed three areas: (1) expectations, (2) experiences during the conduction of an RCT and (3) collaboration between patient, healthcare and research team. Prior to the study start, two pilot interviews were conducted with two researchers outside of the research group to assess face validity; data from these interviews were not included in the analysis. Due to the COVID-19 pandemic, interviews were performed by phone or via a digital platform. In an attempt to establish trust and respect between the patient and the researcher, patients were asked to choose the type of media and the time for the interview. All 14 patients preferred to be interviewed by phone. To protect the patients’ integrity, the researcher strove to create a safe atmosphere by balancing questions regarding patients’ experience and attitudes with more intrusive questions. Patients could choose not to respond to probing questions such as ‘can you elaborate?’ or ‘how did this make you feel?’. All interviews were recorded and ranged in length from 35 to 120 min.

Data analysis
Data were analysed using content analysis according to Granheim and Lundman. All interviews were performed and transcribed by the first author. In this study, whole interviews were considered units of analysis. Interviews were read repeatedly while listening to the recordings to gain a sense of the content. The first step in the analysis involved the abstraction of meaning units from the transcripts by retrieving whole sentences directly from the text dealing with aspects of the content. In a second step, the meaning units were condensed into shorter text units while preserving the core meaning of the content. Finally, these condensed units were further shortened and labelled with codes describing the content. The last author analysed three transcripts independently and this analysis was later compared with that performed by the first author for credibility reasons. A total of 1054 codes were abstracted in the analysis. The deconstruction of data into codes allowed for the next step in the analysis which comprised reconstruction and organisation of codes into clusters of codes according to similarities and differences. Clusters of similar content were then grouped into categories. Six categories were initially formulated regarding content area. After discussion, triangulation of the data, and further analysis by all five authors, the data were organised into five categories. After an additional peer-review process performed by all authors, the data collapsed into three categories. Each category is labelled with a description of the content area. Quotes are used throughout the presentation of the findings to further demonstrate the origin of the analysis for each category.

RESULTS
The analysis led to three categories: understanding the study design, willingness to participate in research and collaboration with the research team alongside standard care.

Understanding the study design
Patients reported that the oral study information they had received by telephone had been important, clarifying and helpful. They said that receiving the oral information prior to the written information had facilitated the process of understanding the study design. Patients considered it important that they were given the opportunity to decline the written study information and participation. Receiving information as early as the first telephone call about the possibility to withdraw from participation at any time was seen as helpful.

Patients’ understanding of the use of a placebo and the randomisation process as a part of the study design revealed mainly positive perspectives. The anticipated effect of the study drug was not regarded as ‘a magic bullet to cure cancer or to suddenly help them become fit and healthy’. Patients stated that even if they were randomised to the placebo group, they had made an important contribution to research; randomisation was, therefore, considered non-problematic. Patients believed that the placebo was harmless since they were already very ill and diagnosed with non-curable cancer. Since the study drug did not aim to treat cancer, they did not consider the use of the placebo, or the study itself, to be ethically challenging. They explained that they were aware of the placebo effect and described being well informed about the placebo, the study design with an untreated control group and the randomisation process.

It was more of a practical point of view; it’s how trials are planned, not much to be concerned about. I’m well aware of the placebo effect, but from that point of view, I bought it in full. It must be randomized.

During the ‘Palliative-D’ study, patients were curious about whether they had been randomised to vitamin D or to the placebo and had reflected on the expected effects. However, they knew that it would take a long time before any study results were obtained and that they were at risk of dying before learning whether they had received the placebo or vitamin D. They also talked about what the negative consequences would be for the study if they died soon. Even though patients showed an understanding and acceptance of the randomised controlled design, they still expressed hope that they were randomised to the intervention group.

I took a chance, I don’t really care that much. I took that risk. But then, you hoped you were receiving vitamin D. On the other hand, I would get it afterwards, just like everybody else.
Patients reflected on the possibility of a protective effect of vitamin D regarding their cancer and based on that, they also expressed a willingness to wait for vitamin D supplementation until the end of the trial.

Volunteers are necessary for this, even if you get the placebo. But yes, it is definitely worth waiting 12 weeks for vitamin D.

When asked if the name ‘Palliative-D’ had influenced their expectations and understanding of the study, the patients gave various responses. If they had not previously reflected on the term ‘palliative’ it had no impact on their understanding of the study and their participation. They did not relate their own disease stage to the term ‘palliative’.

No, I didn’t think about it then, I didn’t think that my disease was untreatable then. I thought instead about obtaining more knowledge about the disease, for the future... for sick people. I didn’t think about the name.

Others reflected on the term ‘palliative’ in relation to an acceptance of being severely ill with a non-curable disease. Patients described the term as their reality since a deterioration of their illness was expected. In contrast, new thoughts about their impending death were also expressed.

I reacted to the term palliative care, because then, you are almost on the verge of moving to the next dimension. But palliative care is not that you are going to die within the next six months.

Uncertainty regarding estimated survival time in relation to the term was also reported. Being confronted with the term ‘palliative’ was expressed by a patient as:

Being told, you have cancer, and it is palliative. When you google palliative, it says non-curable disease at the end of life. What is the end of life, one day or ten years? It’s detrimental for people in general, it triggers phantom thoughts.

Others referred to ‘palliative’ as a term used in healthcare to explain a chronic condition regardless of estimated survival time. Overall, patients pointed to the importance of palliative care research as it could help with the alleviation of symptoms in the future and improve the quality of the life that remained.

Willingness to participate in research

Patients described an overall willingness to participate in research. A large variety of reasons were given for having accepted participation in the study, including the wish to contribute to research for the sake of others and for their own sake.

Despite having a severe illness, patients considered it important to contribute to research and improvements in care for those who might need it in the future. They talked about the value of being part of a process providing future evidence that might have an impact on the risk of dying in pain. They also reflected on a future development in alleviating fatigue and other distressing symptoms, thereby improving the quality of life of future patients. In addition, patients addressed the need for new drugs to alleviate the side effects of cancer treatments. Patients hoped that research in the future could eliminate cancer diseases in general, something that also influenced their willingness to participate. They wanted to help others without being sure of the benefits for themselves, stating participation as their duty. Consenting to participation was also considered a way to pay back for having received treatment and care. Patients reflected on playing their part regardless of the outcome of the study. In addition, they also regretted turning down previous study requests.

After being diagnosed, I cursed myself for having previously declined to participate in a study. Imagine having discovered it earlier. Now it’s good to take the bull by the horns and try to be of help, for others and for myself.

Patients expressed that their priority was to live as long as possible. They said that being diagnosed with cancer had evoked immediate thoughts of death. Initially, they had searched for second opinions or alternative care. They described how their disease had now progressed/ was beyond these alternatives. However, participation in the ‘Palliative-D’ study brought their attention and thoughts back to these opportunities.

Several times I’ve thought I’m done. I’ve been thinking about my disease and how I can put an end to the cancer.

Reflecting on reasons for study participation also raised existential feelings ranging from a fatalistic perspective to approaching changes as and when they appear. Patients reflected on knowing what to expect in relation to living with advanced cancer, as well as on not thinking about their disease when feeling well.

I know what I’ve got, but when I feel well it doesn’t feel like I have cancer and ‘I sometimes reflect upon how much time I have left. It just flutters through my mind.

Study participation was also associated with hope. Patients expressed hopes for a cure, increased well-being and decreased pain and tiredness. This meant they were willing to try everything that was available.

There’s always a wish in my situation. You are grasping for every straw.

They explained that they had nothing to lose, and even if they were aware of having non-curable cancer, hope still remained for a sudden recovery or the discovery of a new treatment.

I’m taking new treatments at my own risk, all the way to the end. I am not giving up. I feel ok and I’m still alive. I have nothing to lose.
The chance to increase vitamin D levels was also a reason to participate in the study. This was a particular motivator for patients who had avoided sun exposure to limit side effects from oncological treatment. Patients also expressed the hope that the correction of vitamin D deficiency could have positive effects on the cancer disease.

Patients described how they had made their decision to participate in the study independently without discussing it with others.

I'm really determined when it concerns my life. Nobody can make me do anything I don't want to do.

They reported not feeling the need to talk about it and had, therefore, consented to participate without discussing the potential benefits or disadvantages with anyone. However, patients stated that they might have engaged in conversations with others if a revolutionary effect was expected as a result of the study.

No, I can't really say that I have…because I do know. Me and my friends and those closest to me already know where this will lead, I will not survive this.

Patients had received positive responses when telling the family about the study. They had then discussed, for example, the use of a placebo, the effect of vitamin D and the importance of completing the trial. Patients also reported not feeling the need to discuss their study participation with any healthcare professionals before signing the informed consent form.

Collaboration with the research team alongside standard care

The patients talked about the study as being uncomplicated since all study procedures took place in their own home. Through the safe collaboration between the research team and the home care team they felt that the study was largely integrated into their everyday standard care.

I perceived blood samples and assessments as being part of the home care service, I never experienced it as a part of the study.

The patients were used to being attentive to their own body and its functioning, and to changes in well-being because they were severely ill. However, they said that they had paid extra attention to this during the study period. When changes were absent, they thought that they probably had been randomised to the placebo. It was, however, difficult to know what to expect and what to compare with. They also reflected on it being difficult to differentiate between effects potentially caused by the study drug and effects caused by the oncological treatments they received. Patients being treated with chemotherapy said that they were mainly occupied with those related to the cancer treatment so the effects of the study drug became secondary. They explained how the chemotherapy had a clear, perceptible effect on their well-being, whereas the study drug did not.

When explicit changes were experienced, patients felt both uncertain and curious about whether these were caused by the study drug, other treatments or the disease. They relied on blood samples to receive additional information concerning their improvement. They found it helpful that the study team monitored biomarkers since they sometimes perceived symptom assessment as difficult. Patients also said that they expected a natural deterioration in biomarkers and symptoms over time due to disease progression.

My cancer is insidious and deceptive, that's why I didn’t discover it. By participating in the study I have received interesting information about my blood tests, to help me monitor the disease.

The patients perceived the extra blood samples and self-assessments of symptoms as being well integrated into the weekly routines of the home care team. They reflected on the interaction between the home care team and the research team, and how information was shared. They perceived the home care team to be the performers of study-related tasks delivered through short visits. Patients also reported a lack of continuity in the visits by the home care team, which made receiving feedback about study-related questions difficult. However, they were aware that the focus of the home care team differed from that of the research team. Although their experience of the home care team performing study-related tasks was good, they realised that complicated studies would be less suitable to perform in the home care setting.

Patients described good collaboration with the research team and that participation had made them feel special, valuable and cared for.

In this study, it felt as someone cared about me. Yes, I mean, someone cared about improving my situation in addition to my standard care.

Patients described taking part in the study as a positive and fun experience. They talked about feelings of happiness, excitement, being specially chosen and feeling proud of themselves for still being of use in this important matter. Patients experienced their participation as enjoyable, interesting and having an important responsibility to contribute. They perceived the study as taking place in the background where the intake of the study drug was incorporated into their ordinary routines. Remembering to take the study drug was said to be their only obligation.

I feel good about myself. It feels as I have taken part in something important.

Patients appreciated the collaboration with the research team. They experienced the study as being easy to participate in, well planned and straightforward. Participation did not put any strain or burden
on their time or daily life, did not include any surprises and had not intruded on their personal integrity. Everything that was needed for each visit had been delivered to them by the home care nurses. Patients especially appreciated having a contact person in the research team to call if any unforeseen event or symptom appeared. However, they said that, due to careful and good initial planning, no additional contact was needed.

Patients gave some suggestions for improving the study. They commented on the difficulty in opening the bottles of the study drug and measuring eight drops, and that an easier method would be to use tablets instead. They would also have appreciated the possibility to fill in symptom assessments with an engaged healthcare provider to obtain a greater understanding of the context.

If you don’t get an explanation of the question, you’re not sure that you get it right, that’s important.

Patients also suggested that an oral explanation of their symptoms could have enhanced and affected their answers and would not have been more time consuming. After the end of the trial, they said they would have liked earlier feedback regarding the unblinding of the study drug and the results of the study but had accepted that no information could be given. They also spoke of the lack of a treatment plan after finishing the vitamin D treatment they were offered after the end of the trial. In general, patients reported being positive to participation in future trials. However, the study aim and estimated survival time in relation to the burden of the study were described as important factors affecting their willingness to participate.

DISCUSSION

In this study, we aimed to explore how patients with advanced cancer experience participation in an RCT. The analysis showed that the participating patients accepted the randomisation and the risk of receiving a placebo since they understood that it was important for the quality of the research. They were willing to participate for the sake of others as well as for their own sake, hoping for a cure or to live as long as possible despite being aware of the non-curable stage of their disease. Patients felt proud of being of use in this important matter and being offered the opportunity to contribute to research. Consent to participate was made autonomously without any discussion with others. The study design was experienced as uncomplicated and well-integrated into the standard care.

In this study, we found, interestingly, that the participating patients perceived being randomised to a placebo as important for research and therefore non-problematic. This finding supports the possibility that more placebo-controlled studies could be performed in patients receiving palliative care. However, at the same time, there is a risk that patients with a poor prognosis are willing to try everything available. Thus, it is of the utmost importance that patients are provided with sufficient information concerning the aim and the effect of the trial in order to support the patient’s ability to make informed decisions about participation.

Our findings showed that the decision to participate was made autonomously without discussing with others. This challenges the role of gatekeepers and is to some extent in contrast with previous studies in palliative care showing that both relatives and physicians often play a prominent influential role in the patient’s decision to participate in trials. The reasons given for participation in our study were feeling a duty to give back to society, to help future patients in need, that is, altruistic motives, but also hoping for personal benefit. They communicated realistic thoughts but still nourished the hope of a sudden cure and living as long as possible. Hope is known to be an important concept in palliative care. Earlier studies show that patients often keep hope as private wishes and thoughts, seldom explicitly communicating this to healthcare professionals. All kinds of medical treatment seem to contribute to hope and may awaken thoughts of the possibilities of a miracle cure. Previous studies on patients’ reasons for participating in clinical trials in palliative care have shown similar results, comprising hope for improvement or cure, the wish to obtain evidence for others and for their own benefit.

The patients reported that the study being largely integrated into their everyday standard care was an advantage. The study procedure did not affect their well-being and had not intruded on their personal integrity. This highlights how a carefully planned, simple study design can facilitate the feasibility of placebo-controlled studies in patients receiving special palliative home care. This is also strengthened by a previous report on trial design in palliative care which showed that a design that minimises the burden on participants and clinical staff is the most successful and that the study protocol being as close to clinical practice as possible is an advantage.

This first Swedish study investigating the experiences of participating in a placebo-controlled trial in a cohort of patients with advanced cancer admitted for specialised palliative home care contributes important novel knowledge. It would have been valuable to include all patients still alive. However, due to progressing illness, only 14 of 40 could participate in an interview. Still, the interviews performed provided rich data and a variation of experiences concerning participation in the study. Due to the COVID-19 pandemic, all interviews in this study were performed by phone even though face-to-face interviews are considered the gold standard since they allow for interaction and non-verbal cues. However, interviews conducted by phone might have enhanced patients’ feelings of being safe due to
the absence of influence from the researcher, allowing increased reflection before responding. The influence of the previous involvement of the three authors in the ‘Palliative-D’ study needs to be addressed for dependability and credibility reasons. The peer-review process conducted by the two additional authors during the analysis was therefore important. It should also be noted that the participants only constitute a small portion of the larger cohort that participated in the ‘Palliative-D study’. It is possible that more variation in experiences might have been found if more patients had been interviewed. However, even though the interviews were initiated as soon as possible, the majority of the patients who had participated in the ‘Palliative-D study’ had died. This highlights one of the major limitations of performing studies in a vulnerable population where time, logistics and methodology is of the essence in the attainment of high-quality research.

The participants in the Palliative-D study had a median survival time of 6.1 months from study inclusion, ranging from 1 week to several years.6 Thus, a large proportion of the participants were not in a late palliative stage of their disease. Therefore, the results from this study might not be applicable to patients in a very late palliative stage, close to death.

Another limitation that needs to be addressed is that the Palliative-D study might not be representative of all RCTs in palliative care. Vitamin D treatment is a non-harmful drug with negligible side effects. Thus, the participants in the study did not risk any bothersome effects. Moreover, the study design was uncomplicated and well integrated into standard care. The participants’ experiences might have been different if a more harmful treatment had been tested, or if the study design had been more demanding for the participants. However, when performing RCTs in palliative care, it is important that the potentially harmful effect of the treatment is minimised, and that the study should not impair the quality of life of the participants. In that respect, we consider Palliative-D to be a representative study.

CONCLUSION

Our findings indicate that participation in an RCT was experienced as important and meaningful for patients with advanced cancer enrolled in palliative care. Participation supported patients’ autonomy, gave them meaning in life and might therefore have had a positive effect on their quality of life. A simple study design, well integrated into the standard care, seems to facilitate the feasibility of clinical studies in specialised palliative home care in end-of-life patients.

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