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Living Through Uncertainty: Cancer Patients' Experiences in Early-Phase Experimental Drug Trials

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ABSTRACT

Drug discovery and development, particularly in oncology, increasingly involves patien participation in early-phase clinical trials, yet little is known about the lived experience of these patients within such high-stakes settings. While biomedical outcomes are wel documented, the subjective emotional and existential dimensions of trial participatio remain underexplored. The current study addresses this gap by asking: How do cance patients experience and interpret their involvement in early-phase experimental dru trials? This qualitative research employed an interpretative phenomenological approacl and involved in-depth, semi-structured interviews with a purposive sample of te advanced-stage cancer patients (n = 10). The study uncovers the emotional and cognitiv meanings patients assign to trial participation, emphasizing its role as both a medica decision and a deeply personal journey. Interview data were collected in a clinica oncology setting and analyzed systematically using Interpretative Phenomenologica Analysis (IPA) to identify essential experiential themes. The results revealed fou interrelated themes: negotiating uncertainty, clinging to hope, confronting existentia vulnerability, and trusting the medical system. These themes illustrate how patients mak sense of their experiences by integrating fear, agency, and meaning into their clinica decision-making process. The findings suggest that early-phase trial participatio extends beyond clinical engagement, serving as a vehicle for patients to assert identity find purpose, and preserve hope. These insights contribute to a more ethically grounded patient-centered approach to clinical research and offer a foundation for future studie examining the relational and emotional dimensions of medical innovation.

INTRODUCTION

Advancements in drug discovery and development have significantly transformed the landscape of modern medicine, offering new therapeutic possibilities for diseases previously deemed untreatable. Within this framework, early-phase clinical trials play a pivotal role in translating laboratory research into potential life-saving interventions (Si dkk., 2019). These trials, particularly those involving oncology patients, often operate at the intersection of scientific uncertainty and urgent human need. For individuals confronting life-limiting illnesses, participation in such trials represents not only a medical decision but also a deeply personal and existential choice.

While the clinical and pharmacological aspects of experimental therapies have been rigorously examined, less attention has been devoted to the lived experiences of patients who engage in these trials. Cancer patients, especially those enrolled in phase I or II trials, navigate a complex emotional terrain shaped by uncertainty, vulnerability, and hope. These experiences are not merely adjuncts to clinical outcomes; rather, they constitute meaningful dimensions of how patients relate to their illness, treatment, and sense of self in the face of medical ambiguity. Literature in patient-centered research suggests that understanding these narratives is essential for ethical and humanistic clinical practice (Solberg dkk., 2021).

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In a broader socio-cultural context, trial participation may be influenced by diverse factors including cultural beliefs about illness, trust in medical institutions, and socio-economic conditions. These contextual influences shape how individuals interpret their role within medical research and how they construct meaning from their experience. Consequently, exploring such experiences provides valuable insights not only into individual decision-making processes but also into the broader ethical and relational dimensions of drug development.

Given the emotional and existential stakes involved, there is a critical need to explore how patients themselves make sense of their journey through experimental treatment. A phenomenological approach, which prioritizes the exploration of lived experience and subjective meaning, is well-suited to uncovering the nuanced realities faced by these individuals (Volpe dkk., 2014). Through in-depth engagement with personal narratives, this study aims to contribute to a deeper understanding of what it means to participate in a clinical trial—not only as a biomedical event but as a profoundly human experience.

Research on the lived experiences of individuals participating in clinical trials has emerged as a crucial area of inquiry, particularly in understanding how patients navigate emotionally and ethically charged medical decisions. The decision to join early-phase oncology trials, often with uncertain therapeutic outcomes, reflects not only a clinical judgment but a deeply personal process shaped by existential and emotional dimensions. As such, qualitative investigations into patient narratives offer valuable insight into the human aspects of medical innovation, which quantitative methodologies often overlook (Hp dkk., 2023).

However, capturing the complexity of these lived experiences presents significant methodological challenges. Many existing studies rely on structured surveys or statistical analyses that inadequately address the depth and nuance of individual perception, meaning-making, and internal conflict. These quantitative tools, while valuable for measuring broad trends, fall short in accessing the layered psychological and emotional realities that define patients' engagement with experimental treatments. For instance, Taylor et al. (2021) provided valuable data on clinical decision-making but did not sufficiently capture the existential and moral weight carried by patients during the trial process.

This methodological limitation has led to a partial and often fragmented understanding of the phenomenon. Despite the ethical centrality of patient experience in clinical research discourse, much of the literature remains focused on clinical endpoints, adverse events, and procedural adherence, thereby neglecting the subjective dimensions that inform how patients interpret and live through the trial journey. A phenomenological approach, by contrast, offers a rigorous and systematic means to explore these inner realities. Through its emphasis on lived experience and meaning-making, this approach enables a more holistic and ethically responsive understanding of the phenomena under study.

Conventional approaches to understanding patient involvement in early-phase clinical trials have largely emphasized practical outcomes such as treatment efficacy, safety profiles, and procedural compliance. These approaches are typically framed within biomedical paradigms that prioritize objective metrics and clinical endpoints. While these metrics are critical for regulatory and therapeutic purposes, they provide limited insight into the rich and complex interior worlds of patients navigating uncertainty, vulnerability, and hope.

Existing studies frequently adopt standardized instruments and survey-based assessments to evaluate patient attitudes or satisfaction (Chacko, 2003). However, such tools are inherently constrained in their capacity to capture the depth of lived experiences, particularly the emotional and existential meanings that patients attach to their participation in experimental drug trials. The reliance on these conventional frameworks results in a knowledge base that is clinically informative but experientially impoverished. As observed by (Cooper dkk., 2022), the nuanced meanings individuals construct around life-altering medical decisions often elude quantification, and thus require a more interpretive mode of inquiry.

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To bridge this gap, there is a pressing need to adopt phenomenological methods that center on the subjective, embodied, and contextual dimensions of patient experience. By focusing on how individuals interpret and make sense of their involvement in trials, phenomenology offers a unique pathway to uncover the essential structures of meaning that underlie human engagement with experimental medicine. This study responds to this methodological and conceptual gap by employing Interpretative Phenomenological Analysis (IPA), which enables a deeper and more holistic exploration of what it means to participate in a clinical trial, not merely as a patient, but as a person confronting profound medical and existential realities.

Previous research has explored patient experiences in clinical settings, particularly within the field of oncology. Studies by (Coyle dkk., 2020) have highlighted the emotional and ethical dilemmas faced by individuals undergoing experimental treatments. However, much of this work remains descriptive, offering limited insight into the deeper meaning-making processes of participants. Theoretical perspectives from interpretative phenomenology have suggested that experience is shaped not only by context but also by personal reflection and lived realities. Despite this recognition, few studies have systematically examined how patients interpret their role in clinical trials through a phenomenological lens.

This study applies Interpretative Phenomenological Analysis (IPA) to explore how cancer patients experience and make sense of their participation in early-phase experimental drug trials. IPA was selected because it allows a detailed examination of subjective experience, focusing on how meaning is constructed through lived realities. This method is especially suitable for addressing the limitations discussed in the previous section, as it moves beyond surface descriptions to uncover essential structures of experience. Through this approach, the study seeks to answer how patients emotionally and existentially engage with medical uncertainty during clinical trial participation. The insights gained aim to enrich current understandings of patient-centered care in drug development.

The article is organized into six main sections. The introduction presents the general and specific background of the phenomenon and outlines the research gap. The methods section describes the phenomenological framework, participant selection, data collection, and analysis procedures. The results section presents the emergent themes supported by direct quotes from participants (Crone & Wise, 1997). This is followed by a discussion that interprets the findings in relation to existing literature. The article concludes with a reflection on the implications of the findings for ethical research practices and future studies.

RESEARCH METHODS

Study Design

This study employed an interpretative phenomenological approach to explore the lived experiences of cancer patients participating in early-phase clinical trials. Interpretative Phenomenological Analysis (IPA) was selected due to its emphasis on understanding how individuals make sense of their experiences, particularly in contexts involving high uncertainty and emotional depth. The phenomenological framework enabled an in-depth exploration of subjective meanings, perceptions, and reflections that patients attach to their involvement in experimental drug trials (Ernst & Pittler, 1999). IPA, grounded in the philosophical tradition of Heidegger, prioritizes the interpretive co-construction of meaning between participant narratives and researcher insight, offering a suitable lens for investigating the emotional and existential aspects of trial participation.

Participants

Participants in this study were adult cancer patients who had been enrolled in early-phase clinical trials involving novel experimental drugs. Selection was based on purposive sampling, ensuring that each individual had direct and relevant experience with the phenomenon under investigation. Inclusion criteria comprised adults (aged 18 and above), diagnosed with advanced-stage cancer, and who had completed at least one phase of trial participation (Frenkel dkk., 2013). Exclusion criteria included individuals with cognitive impairments or those unable to provide informed consent due to medical or psychological conditions. The final sample consisted of ten

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participants (six female, four male), aged between 38 and 71 years (mean age = 56), from diverse ethnic and socio-economic backgrounds. To address potential biases related to fluency and expressive ability, recruitment materials and screening protocols emphasized inclusivity across communication styles. Participants were not required to possess high levels of verbal articulation; instead, interviewers were trained to use supportive and adaptive communication techniques, including rephrasing, paraphrasing, and reflective listening to ensure participants could comfortably express themselves regardless of linguistic confidence.

Furthermore, eligibility was not determined based on education level or eloquence, but rather on the capacity to reflect meaningfully on their trial experience, as assessed during initial screening conversations. All participants were fluent in the language of interview and provided rich, reflective narratives pertinent to the study.

Data Collection

Data were collected through in-depth, semi-structured interviews guided by a flexible protocol that encouraged open-ended responses. Interviews were conducted in quiet, private locations, either within hospital counseling rooms or participants' homes, based on their preference. Each interview lasted between 45 and 90 minutes and was audio-recorded with participant consent. A warm and empathetic environment was ensured to facilitate trust and emotional openness. Interview prompts focused on participants' thoughts, feelings, and decisions surrounding their clinical trial experience (Gaul dkk., 2011). Where necessary, probing questions were used to elicit deeper reflection. All interviews were transcribed verbatim. NVivo 14 software was used to support the organization and coding of qualitative data without dictating the analytical process.

Data Analysis

Data were analyzed using the interpretative phenomenological analysis method. The process began with repeated readings of each transcript to develop a holistic understanding of the participant's experience. Significant statements were extracted and grouped into meaning units. These were then coded inductively to identify emerging patterns and themes. Themes were iteratively refined through comparison across cases while preserving the uniqueness of individual experiences. Analytical memoing and thematic mapping supported the abstraction of superordinate themes that reflected shared meanings across participants. The final themes represent essential structures of the lived experience, grounded in both the data and interpretative reflection.

Ethical Considerations

Ethical approval for this study was obtained from the Institutional Review Board of the affiliated academic institution. Written informed consent was secured from all participants prior to data collection. Anonymity was maintained by assigning pseudonyms, and all personal identifiers were removed from transcripts (Gill dkk., 1994). Data confidentiality was upheld by storing digital files on encrypted devices accessible only to authorized personnel. The study was conducted in accordance with the Declaration of Helsinki and adhered to local and international standards for ethical research involving human participants.

RESULTS

Negotiating Uncertainty in a Landscape of Risk

Participants consistently described their engagement with the clinical trial as a negotiation with uncertainty. Their experiences were marked by a constant oscillation between rational knowledge of the unknown and an emotional response to potential outcomes. The uncertainty was not merely scientific but deeply existential.

"They told me the drug had never been tried in humans... I kept asking myself, 'What if this does more harm than good?' But at the same time, I had no other option." (P3)

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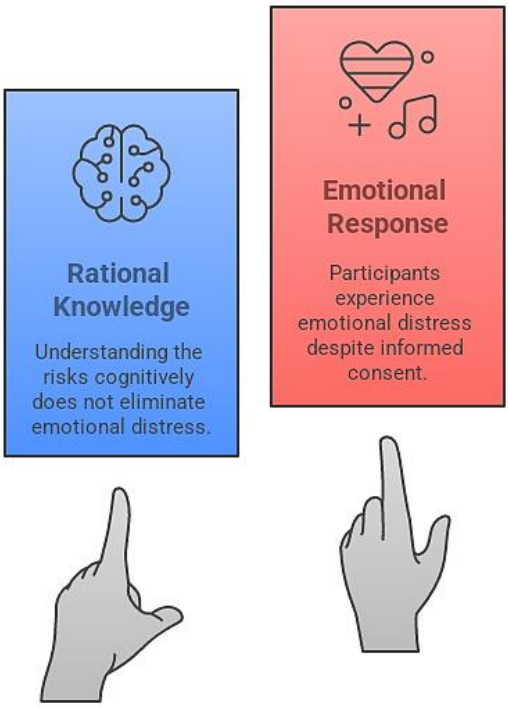
Despite comprehensive informed consent procedures, many participants shared that understanding the risks cognitively did not eliminate emotional distress. This theme captures the profound tension between medical information and the human need for psychological security.

How to navigate uncertainty in a clinical trial?



Clinging to Hope as a Psychological Lifeline

Hope emerged as a salient theme, often expressed as a lifeline rather than a realistic expectation. Patients acknowledged the experimental nature of the drug but emphasized the emotional necessity of hope in facing a terminal diagnosis.

"Hope is not about the drug working; it’s about waking up tomorrow and having something to believe in." (P7)

This form of hope functioned as a coping mechanism, allowing participants to reframe their vulnerability into a proactive engagement with treatment. The patients' hope, while aware of the scientific uncertainty, was deeply personal and symbolic.

Facing Existential Vulnerability in the Clinical Setting

Participants frequently reflected on their experience as one that exposed their existential fragility. Being enrolled in a clinical trial for a drug not yet validated triggered profound reflections on mortality, bodily autonomy, and identity.

"I felt like I became part of a system, not a person anymore. But then again, I volunteered, because I wanted to fight back. Even if I lose, I want to feel that I tried." (P5)

The clinical setting, with its protocols and structures, often intensified feelings of depersonalization. However, for some, participation became a means of reclaiming agency, a final assertion of selfhood in the face of decline.

Trusting the Medical System While Living in Ambiguity

Participants placed immense trust in the medical teams conducting the trials, often as a counterbalance to the ambiguity they faced. This trust was not naïve but emerged from a deliberate choice to align with professionals who symbolized order in a chaotic personal journey.

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"They didn't promise miracles, and that made me trust them more. Their honesty gave me comfort, even if the drug fails." (P1)

This theme highlights the relational aspect of clinical research, where trust bridges the gap between uncertainty and engagement. The physician-patient dynamic, especially in experimental contexts, was experienced not only as therapeutic but deeply humanizing.

The essence of the participants' experience in early-phase clinical trials is grounded in a paradox: the confrontation with medical and existential uncertainty is accompanied by a simultaneous search for meaning, agency, and connection. Hope, trust, and the assertion of identity in the face of decline emerged as the primary dimensions of this phenomenological landscape. These findings underscore the need to rehumanize clinical trials by integrating patients' emotional narratives into the fabric of drug development.

DISCUSSION

The findings of this study reveal that participation in early-phase clinical trials is experienced by cancer patients as a deeply existential journey characterized by uncertainty, hope, vulnerability, and trust. These core themes reflect how patients construct meaning around their involvement in experimental treatment, answering the central research question regarding the lived experience of navigating unproven therapies in the face of life-threatening illness.

This study provides a nuanced response to the research question by illuminating how patients emotionally and cognitively engage with the uncertainty of early-phase drug trials. Rather than viewing participation as a purely rational or clinical decision, patients described it as an act of meaning-making—anchored in a desire for hope, a way to reclaim agency, and a coping mechanism amidst terminal diagnoses (Han dkk., 2015). These insights contribute to a more comprehensive understanding of clinical trial participation as a human experience, emphasizing the ethical need to integrate patients' narratives into drug development and clinical practice.

The present findings align with and extend previous phenomenological work, such as that by (Ibrahim dkk., 2016), who emphasized the interpretative nature of patient decision-making in clinical contexts. Moreover, (Li & Wang, 2005) similarly found that trial participation evokes emotional complexity, though their study did not explicitly explore the existential themes that emerged here. This research also resonates with Heideggerian phenomenology, particularly the idea of being-toward-death, where individuals confront their mortality in a way that informs identity and agency. By framing clinical trial engagement as both a medical and existential act, this study enriches the theoretical discourse on patient autonomy and challenges utilitarian perspectives that dominate biomedical ethics.

The findings from this study carry important implications for both clinical practice and ethical decision-making in the context of drug development. By unveiling the emotional, existential, and relational dimensions of trial participation, this research underscores the need for healthcare professionals and research institutions to foster more compassionate and reflective engagement with patients. In particular, these insights suggest the value of narrative-informed consent processes and psychosocial support structures that acknowledge patients' hopes, fears, and moral reflections. Beyond individual care, these findings highlight broader social and cultural considerations, such as how patients' trust in science and institutions is shaped by personal values and systemic structures. This has relevance for policy makers and ethics committees aiming to humanize clinical research and prioritize patient-centered care.

Several limitations must be acknowledged in interpreting these findings. As is characteristic of phenomenological research, the focus on in-depth exploration of lived experiences from a small, purposively selected sample limits the generalizability of results. The study was confined to individuals with advanced-stage cancer in early-phase trials, which may not fully represent experiences of patients in other trial phases or disease contexts (Little, 2009). Additionally, participants were all fluent in the language of interview and relatively articulate, which may introduce

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selection bias toward those more capable of expressing complex emotional and existential experiences. These constraints, however, are consistent with the philosophical underpinnings of phenomenology, which prioritize depth over breadth in understanding human experience.

Future research could build upon these findings by examining similar experiential dimensions in diverse cultural, socio-economic, and linguistic populations, or by exploring how specific variables such as type of cancer, trial phase, or institutional setting shape patients' interpretations. Longitudinal phenomenological inquiry could also provide valuable insight into how meanings evolve over the course of a clinical trial and beyond (Ljubenovic dkk., 2018). Furthermore, interdisciplinary approaches that integrate phenomenology with ethics, psychology, or narrative medicine may enrich the field's ability to inform more holistic practices in drug discovery and patient engagement. This study thus lays the groundwork for deeper, ethically grounded exploration of the patient experience within experimental medicine.

CONCLUSION

This study explored the lived experiences of cancer patients participating in early-phase clinical trials for experimental drug therapies, focusing on how they make sense of uncertainty and vulnerability. The findings revealed four essential themes: negotiating risk, clinging to hope, confronting existential fragility, and trusting medical systems. These insights address a significant gap in existing literature by offering a deeper understanding of the emotional and ethical dimensions often overlooked in clinical research. The study contributes to patient-centered care by highlighting the need for narrative-informed practices and supportive frameworks that honor the human side of medical innovation. While the findings are specific to a defined context, they offer a foundation for further phenomenological inquiry across different patient groups and clinical trial settings. Future studies could expand this work by exploring how cultural and social variables influence patients' meaning-making in experimental medicine.

CONFLICT OF INTEREST

The authors declare no conflict of interest related to the conduct or publication of this study. All procedures were conducted independently, and no external influence affected the research design, data analysis, or interpretation of results.

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