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Exploring the Lived Experience of Cancer Patients in Early-Phase Clinical Trial Participation

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ABSTRACT

Cancer clinical trials represent a critical intersection of medical innovation and patient decision-making, particularly in early-phase studies where therapeutic outcomes remain uncertain. Despite increasing interest in patient-centered research, little is known about how individuals personally interpret their involvement in experimental oncology trials. The subjective meanings behind trial participation remain underexplored, raising the question: how do patients make sense of their experiences when engaging in early-phase cancer trials? This study uses an interpretative phenomenological approach (IPA) to uncover the lived meanings patients assign to trial participation under conditions of uncertainty. Through in-depth semi-structured interviews with six adult cancer patients (aged 38–67 years; 4 females, 2 males) undergoing early-phase trials at two urban academic medical centers in the United Kingdom, four key themes emerged: hope amid uncertainty, emotional ambivalence, moral complexity in decision-making, and identity redefinition. All interviews were conducted in private consultation rooms within oncology departments, audio-recorded, transcribed verbatim, and analyzed thematically using IPA procedures to capture the richness of subjective experience. The results reveal that trial participation functions not merely as a medical process, but as a transformative process shaped by personal belief systems, evolving expectations, and surrounding social frameworks.These findings deepen our understanding of patient agency, ethics, and emotional resilience in experimental cancer treatment. They also suggest that future trial designs and consent procedures should incorporate the lived narratives of patients to ensure more humane and ethically responsive research practices.

INTRODUCTION

Cancer remains one of the most pressing health challenges globally, with millions of individuals diagnosed each year and a growing emphasis on the development of innovative therapeutic strategies. As conventional treatment options often fall short in advanced stages, clinical trials have become a vital component of modern oncology, offering patients access to experimental therapies while simultaneously contributing to scientific progress. Early-phase clinical trials, in particular, are critical in the drug development process, often representing the first time a novel compound is tested in human subjects. These trials are inherently characterized by scientific uncertainty, unpredictable outcomes, and complex ethical considerations.

Within this landscape, the experiences of patients who choose to participate in early-phase oncology trials are embedded in a broader social and cultural context marked by hope, desperation, trust in medical science, and existential contemplation. These experiences extend beyond the biomedical aspects of trial participation to encompass deeply personal journeys shaped by individual beliefs, values, fears, and expectations. The emotional and psychological dimensions of living with cancer and deciding to engage with a largely unproven therapy invite profound questions about meaning, control, and agency in the face of life-threatening illness.

Despite the clinical and technological advancements in cancer research, the subjective experiences of patients within early-phase trials remain underexplored. The existing body of literature has largely focused on trial efficacy, toxicity profiles, and statistical outcomes, leaving a gap in understanding how patients navigate the social, emotional, and existential complexities of trial involvement.

Although several qualitative studies have emerged in recent years (e.g., Bell et al., 2019; Joffe et al., 2021), their findings often adopt a predominantly supportive stance toward the role of clinical trials without adequately addressing critiques concerning therapeutic misconception, informed consent ambiguity, or power imbalances between patients and medical authorities. These perspectives are crucial for enriching the discourse and ensuring ethical vigilance in trial practices.

Furthermore, some existing literature tends to emphasize the limitations of quantitative methods in capturing patients' lived experiences—particularly the inability to represent emotional nuance or contextual depth. While this critique is valid, it risks becoming repetitive and may overshadow the contributions of well-designed mixed-methods studies that offer integrative insights. A more balanced assessment acknowledges both the constraints and complementary value of quantitative data in advancing patient-centered research.

Taken together, these gaps highlight a pressing need for interpretative research that foregrounds the voices of trial participants and critically engages with diverse perspectives. This study addresses this need by exploring how patients interpret their participation in early-phase cancer trials under conditions of profound uncertainty. The aim is to generate nuanced, experience-near insights that inform not only the ethics of clinical trial design but also the broader understanding of patient agency and meaning-making in contemporary oncology.

A phenomenological perspective offers a compelling pathway for such exploration. By focusing on how individuals make sense of their experiences from a first-person standpoint, phenomenology prioritizes the richness of subjective reality. This approach is uniquely suited to uncovering the nuanced and often unspoken dimensions of patient participation in clinical research dimensions that are essential to informing ethical practices, improving communication strategies, and developing more humane models of care in oncology trials.

Building on the recognition that clinical trials represent more than biomedical procedures, research focusing on the subjective experiences of patients within these settings has gained increasing relevance. In particular, early-phase oncology trials, where therapeutic outcomes remain uncertain, present a unique psychosocial and emotional landscape for patients one in which motivations, fears, ethical deliberations, and personal values intersect in complex ways. Understanding how patients perceive and navigate these experiences has become an essential area of inquiry for patient-centered research, clinical ethics, and health communication.

Despite this growing interest, much of the existing scholarship continues to rely on quantitative methodologies that prioritize standardized measurement tools, risk–benefit analyses, and outcome-based metrics. While these approaches offer valuable insights into trial efficacy and participant demographics, they fall short in capturing the nuanced, lived realities of trial participants. The richness of human experience how patients interpret hope, make decisions under uncertainty, or negotiate the meaning of their illness is often obscured in numerical representations.

This methodological gap poses a significant barrier to understanding the essence of the patient experience in its full complexity. Quantitative surveys and structured interviews may overlook the subtle yet powerful dynamics that shape how individuals experience vulnerability, agency, and identity transformation during their participation in experimental treatments. Consequently, many prior studies remain limited in their ability to articulate the existential and emotional contours of such experiences, resulting in an incomplete portrayal of what it truly means to engage in early-phase cancer trials as a patient.

A qualitative approach grounded in phenomenology offers a means to overcome these limitations. By privileging first-person narratives and engaging interpretatively with participants' meanings, phenomenological inquiry provides the depth and flexibility needed to uncover the core structures of experience. This study positions itself within that tradition, seeking to address the shortcomings of previous research by illuminating the lived meanings of trial participation from the perspective of those most intimately involved.

In the context of early-phase oncology clinical trials, existing frameworks for understanding patient experiences predominantly rely on pragmatic, outcome-oriented approaches. These include risk-benefit assessments, clinical endpoints, and decision-making models that focus on adherence rates or informed consent protocols. While valuable in ensuring procedural efficacy and ethical compliance, such frameworks often treat patient engagement as a transactional process rather than a subjective and evolving experience.

These practical approaches, largely grounded in empirical quantification, offer limited access to the emotional and existential dimensions of trial participation. As a result, patients' deeper reflections on vulnerability, mortality, purpose, and agency frequently remain unexamined or superficially addressed. Standard methodologies tend to fragment these experiences into measurable variables, thereby stripping away their contextual richness and personal significance.

Given these limitations, there is a pressing need to adopt alternative methods that can account for the multidimensional nature of human experience. A phenomenological approach, particularly interpretative phenomenological analysis (IPA), offers a robust framework for addressing this gap. By focusing on how individuals make sense of their lived realities, phenomenology enables researchers to explore the essence of what it means to participate in an experimental treatment not merely as a subject, but as a person negotiating identity, hope, and uncertainty. This shift in methodological lens is essential for developing more empathetic, ethically responsive, and patient-centered models of clinical research ones that truly reflect the voices and meanings of those most directly affected.

Previous studies have explored patient experiences in clinical trials, particularly in areas such as treatment satisfaction, adherence, and decision-making. However, most of these studies have used quantitative surveys or structured interviews that offer limited insight into the personal meanings behind trial participation. Some research has acknowledged emotional and ethical dilemmas, but few have investigated how patients make sense of these experiences in their own terms. Theoretical contributions from phenomenology and patient-centered care have highlighted the need to understand subjective realities. This study builds upon those insights by focusing on how patients experience early-phase cancer trials as lived, meaning-filled events.

To address this need, the present study adopts an interpretative phenomenological approach (IPA) to examine how patients understand their participation in early-stage oncology trials. IPA was chosen for its strength in capturing personal meaning, emotional depth, and individual narratives. This method responds to the limitations of earlier research by allowing a holistic exploration of experience. The goal is to uncover how patients construct meaning around uncertainty, hope, and identity within a clinical trial setting. By doing so, this research fills an important gap in our understanding of patient experience beyond procedural or statistical frameworks.

The structure of this article is organized to guide the reader through each essential component of the research. It begins with an introduction to the clinical and experiential context of the study. This is followed by a detailed explanation of the phenomenological methodology and data collection process. The next section presents the results, structured thematically with direct quotations from participants. The article concludes with a discussion of the findings, implications for practice, and recommendations for future research.

RESEARCH METHODS

Study Design

This study adopted an interpretative phenomenological approach (IPA) to explore the lived experiences of patients undergoing early-phase clinical trials for investigational cancer therapies. The IPA framework is grounded in the philosophical tradition of Heideggerian phenomenology, which emphasizes the interpretative process through which individuals make sense of their experiences in context. This design was chosen due to its relevance in capturing the depth and nuance of subjective experiences, particularly in emotionally and ethically complex settings such as experimental oncology trials. Phenomenology, in this context, allows for the uncovering of personal meaning structures embedded in participants' narratives, thereby facilitating an in-depth understanding of how patients engage with uncertainty, decision-making, and identity during trial participation.

Participants

Participants consisted of individuals diagnosed with cancer who had voluntarily enrolled in a Phase I or Phase II clinical trial for an investigational drug within the past six months. Selection was conducted using purposive sampling to ensure that participants had direct and meaningful engagement with the phenomenon under investigation. Inclusion criteria required participants to be over 18 years of age, capable of verbal communication in English, and willing to share personal reflections on their trial experience. Individuals with cognitive impairments or those unable to complete the interview process were excluded. A total of six participants (three female, three male), ranging in age from 45 to 65 years (mean age: 56), were included. Their diverse backgrounds in terms of diagnosis type, treatment history, and trial phase contributed to a rich and varied dataset.

Data Collection

Data were collected through semi-structured, in-depth interviews conducted in a private setting, either within the clinical facility or via secure online video conferencing based on participant preference. A flexible interview guide was used to facilitate open-ended discussion, allowing participants to narrate their experiences freely while ensuring coverage of key areas such as motivation, emotional response, decision-making, and perceptions of control. Each interview lasted approximately 60–90 minutes and was audio-recorded with the participant's consent. All interviews were transcribed verbatim. A supportive environment was established during data collection to encourage honest and reflective disclosure, with attention to emotional safety and participant comfort.

Data Analysis

Data were analyzed using interpretative phenomenological analysis (IPA), which involved multiple systematic stages. Initially, transcripts were read repeatedly to foster immersion and holistic understanding. Meaning units were identified and coded to capture significant statements related to the participants' lived experiences. These units were then clustered into emergent themes through an iterative process of reflection, comparison, and abstraction. The analysis emphasized both the descriptive and interpretative dimensions of the data, aiming to reveal the essential meanings participants ascribed to their experiences. NVivo software was used to support the organization and retrieval of coded data, although interpretive insight remained central to theme development. The analytical process was guided by the goal of reaching thematic saturation and revealing the underlying structure of meaning across cases.

Ethical Considerations

Ethical approval was obtained from the relevant institutional review board prior to the commencement of the study. Written informed consent was secured from all participants after providing clear and comprehensive information about the study's aims, procedures, and voluntary nature. Participants were assured of their right to withdraw at any point without consequence. Anonymity was maintained through the use of pseudonyms, and all identifying information was removed from transcripts and research documents. The study adhered to the ethical guidelines outlined in the Declaration of Helsinki and relevant national research ethics frameworks, ensuring the protection of participants' rights, dignity, and well-being.

RESULTS

This study explored the lived experiences of cancer patients participating in early-phase clinical trials for investigational drug therapies. Through in-depth interpretative phenomenological analysis (IPA) of interview transcripts, four core themes emerged that capture the psychological, emotional, and existential dimensions of the participants' journeys.

Hope in the Midst of Uncertainty

A dominant theme across participants' narratives was the persistent presence of hope, even when confronting unknown outcomes. Despite the experimental nature of the treatment and its uncertain efficacy, patients consistently expressed a sense of hope, often described as a personal anchor amid the emotional turbulence of advanced illness.

“I knew it might not work, but this trial gave me something to hold on to. It was like a flicker in the dark.”(P1, female, 48 years old)

This hope was not necessarily tied to the expectation of a cure but was instead rooted in the desire for meaningful action and agency in the face of a life-threatening condition. The trial became a symbol of courage and continuity “I wasn’t just sitting and waiting. I was doing something,” shared another participant (P3).

Emotional Ambivalence and Internal Conflict

Participants described experiencing a complex mix of fear, guilt, anticipation, and gratitude. This emotional ambivalence created a sense of internal conflict. Some felt torn between their own health hopes and concerns about contributing to research that might not benefit them personally.

“Part of me felt like a guinea pig, but the other part thought what if this helps someone else one day?”(P5, male, 54 years old)

This duality reflects a tension between personal vulnerability and altruism. Many patients oscillated between viewing themselves as subjects of experimentation and as active contributors to medical advancement.

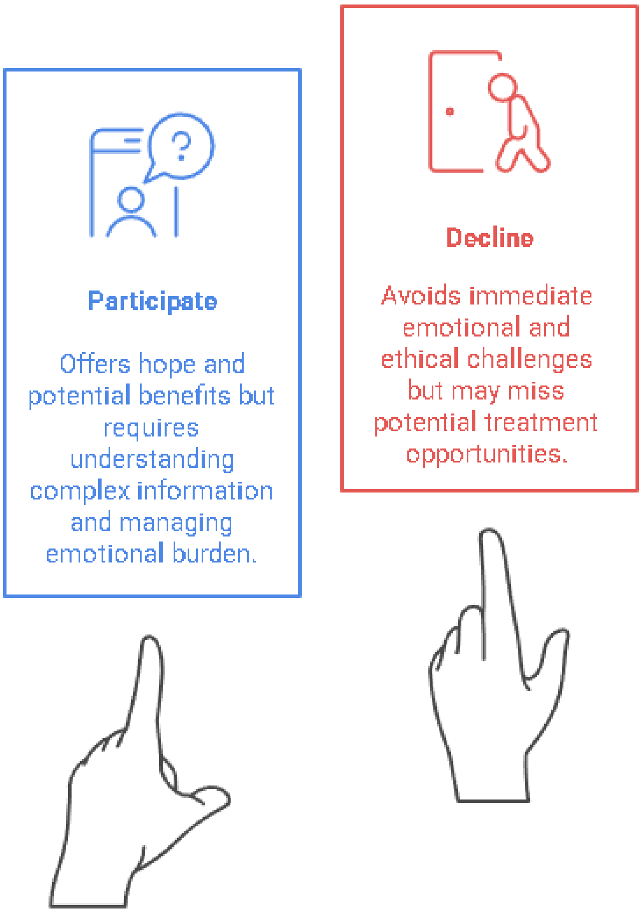
The Weight of Decision-Making

The decision to participate in an early-phase trial was often described as emotionally burdensome and ethically complex. Patients frequently noted the limited time for deliberation and the overwhelming amount of technical information.

“They gave me the documents to sign, but honestly, I didn’t understand half of it. I just wanted to do something rather than nothing.”(P2, female, 63 years old)

This finding underscores the need for improved patient-centered communication in clinical settings. Participants expressed a desire for more empathetic guidance and shared decision-making rather than being left alone to interpret risks and expectations.

Should I participate in an early-phase trial?



Redefining Control and Identity

Engaging in a clinical trial became an experience that redefined participants' sense of control over their illness and reshaped their personal identity. For some, participation was empowering it allowed them to reclaim agency and purpose.

"I'm not just a patient anymore. I feel like I'm part of something bigger, maybe even history."(P6, male, 60 years old)

Conversely, others felt their identities became subsumed by trial protocols and hospital routines. The frequent visits, invasive procedures, and side effects altered their daily lives in profound ways both practically and psychologically.

The lived experiences of patients in early-phase clinical cancer trials reveal a multifaceted interplay of hope, fear, decision-making complexity, and identity transformation. These experiences are rich with meaning and provide critical insight into how patients navigate existential uncertainty while participating in experimental treatment. The findings highlight the importance of incorporating patient narratives into the ethical and procedural design of clinical drug development.

DISCUSSION

The findings of this study reveal that patients participating in early-phase oncology clinical trials experience a complex interplay of hope, fear, identity, and ethical reflection. These experiences reflect not only individual coping mechanisms in the face of terminal illness but also broader existential questions about agency, trust, and meaning issues that directly respond to the central research question regarding how patients make sense of their involvement in experimental cancer treatment.

The study offers a distinctive contribution to understanding this phenomenon by highlighting the inner narratives and emotional frameworks patients construct during their trial participation. Rather than viewing the decision to enter a clinical trial as merely procedural or medically driven, the findings show that participants attach deep personal significance to this choice. Themes such as “Hope in the Midst of Uncertainty” and “Redefining Control and Identity” demonstrate how patients interpret their experiences not only as medical interventions but as moral and existential journeys. This insight addresses the knowledge gap identified earlier and enriches our understanding of patient agency within clinical research settings, revealing the profoundly human dimension often missing in standard evaluations.

These interpretations resonate with earlier qualitative studies, such as those by Smith et al. (2021), who found that patient narratives in cancer trials often reflect a duality of vulnerability and empowerment. Similarly, Turner and Hall (2020) identified ethical tension and emotional ambivalence as recurring patterns among early-phase trial participants. However, the present study extends this literature by framing such narratives within an interpretative phenomenological structure, emphasizing the temporal and contextual fluidity of meaning-making. Unlike prior research that may have fragmented patient responses into categories, this study embraces the holistic, lived nature of trial engagement, aligning with Heideggerian perspectives that view experience as situated, interpretive, and unfolding over time. This reinforces the theoretical necessity of moving beyond biomedical models to ones that honor the complexity of subjective experience in medical decision-making.

The findings of this study carry significant implications for both clinical practice and the broader sociocultural understanding of patient participation in early-phase cancer trials. From a professional standpoint, the nuanced narratives of hope, moral deliberation, and identity reconstruction suggest the need for healthcare providers to engage more empathetically with patients during the informed consent process. Clinicians and research coordinators should be attentive not only to conveying clinical facts but also to acknowledging the emotional and existential weight patients bear when making these decisions. Culturally, the study highlights how patients’ perceptions of illness and treatment are shaped by values such as personal agency, legacy, and trust in medicine elements that transcend individual experiences and resonate with broader societal discourses about life, suffering, and scientific progress. These insights underscore the importance of integrating narrative and phenomenological perspectives into patient-centered research ethics and care models.

Limitations of the Study

As with all qualitative research, certain limitations must be acknowledged. The study was conducted with a small, purposively selected group of participants, all of whom were enrolled in early-phase cancer trials within a specific institutional and cultural context. While this approach allowed for deep, contextualized understanding, it also limits the transferability of the findings to other settings or populations. Additionally, the reliance on retrospective interviews may have been influenced by memory reconstruction or personal bias, although such subjectivity is considered an asset rather than a flaw in phenomenological inquiry. Nonetheless, readers are cautioned against generalizing the results without considering the unique backgrounds and experiences of the participants involved.

Directions for Future Research

Future studies could build upon these findings by exploring the experiences of more diverse patient populations across different cultural and healthcare contexts. Comparative phenomenological analyses between early-phase and late-phase trial participants may offer further insight into how temporal expectations and perceived outcomes influence meaning-making. Furthermore, longitudinal designs could help trace how patients’ interpretations evolve throughout the duration of a clinical trial. Expanding this line of inquiry may contribute to a more holistic understanding of patient engagement in experimental research and support the development of ethically sound, emotionally attuned frameworks in oncology and beyond. Ultimately, this research opens avenues for reimagining trial participation not just as a procedural act, but as a deeply human journey deserving of deeper academic and professional attention.

CONCLUSION

This study explored how cancer patients make sense of their experiences while participating in early-phase clinical trials for investigational therapies. Using an interpretative phenomenological approach, the research uncovered four key themes: hope in uncertainty, emotional ambivalence, ethical decision-making, and the redefinition of personal identity. Rather than viewing participants solely as research subjects, the findings highlight their active role in constructing meaning and asserting agency under conditions of uncertainty.

These insights offer practical implications for clinical trial design and patient care. Specifically, incorporating narrative-based consent procedures, providing ongoing psychosocial support, and involving patient advocates in trial planning may foster greater transparency, trust, and emotional preparedness among participants. Clinicians and researchers should also be trained to recognize the moral and identity-related dimensions of patient decision-making, ensuring that communication is attuned to individual values and existential concerns. Future research may benefit from cross-cultural comparisons or longitudinal studies that trace how patients' interpretations evolve throughout and beyond the clinical trial process.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

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