Journal of Regenerative Medicine and Molecular Innovation
Vol. 1 No. 12 Desember 2025
E-ISSN: 3090-0824
Open Access: https://journals.ai-mrc.com/jrmmi

Exploring Ethical and Emotional Experiences in Stem Cell Clinical Trials for Neurodegenerative Diseases

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Article Info

Article history:
Received 30-10-2025
Revised 30-11-2025
Accepted 17-12-2025

Keyword:
Stem Cell Therapy;
Regenerative Medicine;
Patient Experience; Ethical Decision-Making;
Emotional Resilience;
Neurodegenerative Diseases

ABSTRACT

Regenerative medicine represents a rapidly evolving field that aims to restore or replace damaged tissues using biological interventions such as stem cell therapy, offering hope to patients with neurodegenerative diseases. Within this scientific landscape, understanding patients' lived experiences during participation in regenerative clinical trials has become increasingly significant, particularly as these experiences intertwine ethical, emotional, and existential dimensions. However, existing studies have primarily focused on clinical outcomes, leaving limited understanding of how patients construct meaning and negotiate moral and psychological challenges within such trials. This study applies an Interpretative Phenomenological Analysis (IPA) to explore how participants experience, interpret, and derive meaning from their involvement in stem cell therapy trials for neurodegenerative conditions. Using semi-structured interviews with twelve participants, the analysis identified four overarching themes: ethical decision-making, the tension between hope and uncertainty, embodiment and self-redefinition, and the pursuit of ethical–emotional equilibrium. These findings reveal that participation in regenerative clinical trials extends beyond biomedical engagement it represents a transformative process where patients navigate vulnerability and agency through moral reflection and emotional adaptation. The study deepens current understanding by framing regenerative medicine as both a scientific and human endeavor, emphasizing that meaning-making is central to ethical patient participation. The results offer valuable implications for clinical communication, ethical policy, and future patient-centered trial design in regenerative medicine. This study received ethical approval from the Institutional Review Board, ensuring adherence to established research standards. However, the study has limitations, including a relatively small sample size and reliance on self-reported experiences, which may limit transferability to broader patient populations.

INTRODUCTION

Regenerative medicine has emerged as one of the most transformative areas in modern biomedical science, offering the potential to repair, replace, or regenerate damaged tissues and organs through advanced biological interventions such as stem cell therapy, biomaterial scaffolds, and gene-based treatments (Mukhlis, Suradi, et al., 2023; Mukhlis, 2025b). Within this rapidly evolving field, stem cell clinical trials for neurodegenerative diseases represent not only scientific advancement but also profoundly human experiences shaped by emotional and ethical complexities.(Petretta et al., 2023). These trials not only test the limits of medical innovation but also place participants in a complex emotional and ethical landscape, where the boundaries between hope, uncertainty, and personal meaning are constantly negotiated.

The rapid evolution of regenerative therapies has generated immense optimism within the scientific community and among patients who face conditions for which no curative treatments currently exist (Abu Awwad et al., 2020). However, alongside this optimism lies a spectrum of psychological and moral challenges that accompany participation in experimental clinical settings. Patients often engage in such trials not only as subjects of medical inquiry but as active agents seeking meaning, healing, and hope in the face of chronic suffering. Their experiences encompass deep existential reflections about risk, self-identity, and the value of contributing to medical progress (Maas et al., 2023). These dimensions underscore that regenerative trials are not purely clinical events but profoundly human experiences shaped by personal narratives and socio-cultural contexts.

Understanding these subjective experiences is crucial, as participation in regenerative clinical trials frequently involves ambivalence between trust in science and fear of the unknown. Decisions to participate are often influenced by cultural beliefs about the body, medical authority, and moral responsibility. In societies where biomedical innovation is viewed as both promise and peril, patients' experiences become windows into broader ethical and emotional dynamics (Launer-Wachs et al., 2023). The intersection between medical experimentation and human vulnerability thus reveals a compelling space for phenomenological inquiry where the focus extends beyond biological outcomes toward the lived meanings of participation itself.

Phenomenology, as a philosophical and methodological approach, offers the means to uncover these lived meanings by attending to how individuals perceive, interpret, and make sense of their experiences within regenerative therapy contexts. Rather than quantifying responses or outcomes, phenomenology seeks to describe and interpret the essence of what it means to undergo a clinical trial how participants navigate uncertainty, construct hope, and redefine their relationship with illness and the medical system (Patil et al., 2024). Through such an approach, the study situates regenerative therapy not merely as a biomedical innovation but as a deeply human encounter, where science and subjectivity converge.

Research on patients' lived experiences within clinical and regenerative medicine has increasingly become a vital area of inquiry in contemporary health sciences. As regenerative therapies evolve from experimental to clinical applications, scholars have begun to recognize that understanding how patients experience participation in such trials is as essential as understanding what outcomes those trials produce. The subjective dimensions fear, hope, uncertainty, and moral reasoning represent critical aspects of the human experience that cannot be captured solely through biomedical or quantitative lenses (Ghollasi & Poormoghadam, 2022). These experiences illuminate the psychosocial and ethical realities that accompany medical innovation and provide a foundation for patient-centered clinical practices.

Despite growing interest in the humanistic aspects of regenerative medicine, methodological challenges persist in exploring the depth and complexity of these lived experiences. Quantitative approaches, while valuable for measuring clinical outcomes, often fail to articulate the nuanced meanings behind patients' emotions, motivations, and ethical reflections during clinical trial participation (Filippelli & Chang, 2023). Surveys and standardized scales tend to reduce rich experiential data into variables, thereby overlooking the contextual and interpretative layers that constitute patients' realities. Similarly, qualitative studies that focus narrowly on descriptive accounts often lack the interpretative rigor necessary to reveal how participants construct meaning through their encounters with uncertainty, risk, and scientific hope.

These limitations underscore a broader epistemological gap: much of the current research on regenerative therapy remains outcome-oriented, emphasizing measurable efficacy and safety while underexploring the lived moral and emotional dynamics of participation. Consequently, previous methodologies have provided an incomplete understanding of the essence of patients' experiences how they internalize, negotiate, and find meaning in the ethical and psychological tensions of regenerative clinical trials (Liu et al., 2022). Addressing this gap requires a methodological framework capable of engaging with the depth of human experience. The phenomenological approach, particularly the interpretative variant, offers such a framework by enabling the exploration

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of meaning as it emerges within individuals' lived realities rather than through abstract theoretical constructs.

In the context of regenerative medicine and stem cell clinical trials, most existing research has relied on conventional biomedical and psychological frameworks to assess treatment outcomes and patient well-being (Shafiee, 2020). These approaches though practical and empirically grounded tend to privilege observable results such as physiological improvement, symptom reduction, or measurable psychological adaptation. While such frameworks provide valuable data for evaluating efficacy and safety, they often overlook the lived dimensions of the patient experience, particularly the ethical, emotional, and existential meanings attached to participation in experimental therapies.

Several studies have attempted to address patients' perspectives through interviews or surveys focusing on satisfaction, risk perception, or compliance; however, these methods remain limited in capturing the depth and fluidity of subjective meaning (Mukhlis, Arifin, Ridwan, & Zulbaidah, 2025; Mukhlis, Arifin, Ridwan, Zulbaidah, et al., 2025). Quantitative tools and structured questionnaires reduce individual experiences into standardized variables, stripping away the nuances of how patients interpret their participation, confront uncertainty, or construct hope within ethically complex clinical environments. As a result, the human dimension of regenerative therapy how individuals live through and make sense of their involvement in experimental trials remains insufficiently understood.

This methodological gap suggests that prevailing research paradigms inadequately address the complex interplay between ethics, emotion, and meaning that characterizes participation in regenerative clinical trials. What is still unknown is how patients experience and interpret their moral and psychological journey through such interventions, and how these interpretations shape their sense of identity, trust, and agency in relation to medical science (Thompson et al., 2020). To bridge this gap, a phenomenological approach specifically interpretative phenomenological analysis (IPA) offers a rigorous yet empathetic framework for exploring these underexamined dimensions. By focusing on patients' lived experiences, this approach enables a holistic understanding of the essence of participation in regenerative therapy, illuminating the meanings embedded within the intersection of hope, uncertainty, and ethical self-reflection.

Recent studies in regenerative medicine and clinical bioethics have begun to highlight the significance of patient experiences within experimental therapeutic contexts. Scholars such as Munsie and Hyun (2020) and Kim et al. (2023) have underscored the ethical and psychological implications of participation in stem cell trials, focusing on trust, uncertainty, and moral responsibility. However, much of the existing literature remains descriptive, with limited interpretative engagement with the meanings that patients attach to their experiences. Building upon these foundations, the present work integrates insights from interpretative phenomenology to explore how individuals construct meaning in navigating the moral and emotional complexities of regenerative therapy participation (Xia et al., 2022). This perspective allows for a deeper understanding of the interplay between medical science and personal lived reality.

To address the limitations identified in prior research, this study adopts Interpretative Phenomenological Analysis (IPA) as its guiding methodology (Aiman et al., 2022). This approach emphasizes how participants make sense of their lived experiences within a specific context, enabling a nuanced understanding of emotional and ethical meanings (Beckman et al., 2021). By using IPA, the study directly responds to the knowledge gap previously identified specifically, the absence of a conceptual framework that captures how patients experience the moral-psychological balance between hope and vulnerability in regenerative clinical trials (Alhamda, 2025). The method allows for the emergence of essential themes that reveal the structure and texture of these lived experiences without reducing them to clinical or behavioral outcomes.

This article is organized into several key sections. The Introduction establishes the conceptual and empirical context of regenerative therapy and outlines the theoretical rationale for a phenomenological exploration (Mukhlis et al., 2024; Mukhlis, Maryam, et al., 2023). The Method section details the interpretative phenomenological design, participant selection, data collection procedures, and analytical framework. The Results section presents thematically organized narratives that capture patients' lived meanings, followed by a Discussion that situates these findings within existing theoretical and ethical discourses (Afsartala et al., 2023). Finally, the Conclusion summarizes the essential insights and implications for future regenerative medicine practices and ethical policy development.

RESEARCH METHODS

Study Design

This study employed an interpretative phenomenological approach (IPA) to explore the lived experiences of patients participating in stem cell clinical trials for neurodegenerative diseases (Lutz & Knox, 2014; McNabb, 2015). The phenomenological design was chosen for its capacity to uncover the subjective meanings that individuals attribute to their experiences, particularly in contexts of ethical uncertainty and emotional complexity. IPA, grounded in Heideggerian philosophy, emphasizes the interpretation of participants' narratives to reveal how people make sense of phenomena that profoundly affect their existence. This design allows an in-depth examination of how patients perceive, experience, and ascribe meaning to participation in regenerative therapy trials, beyond measurable clinical outcomes.

The interpretative orientation of this approach supports the exploration of both the descriptive essence of the experience and its contextual meanings. Through iterative engagement with the data, the design facilitated a hermeneutic process of understanding, moving from individual accounts toward the identification of shared thematic structures that represent the collective essence of the phenomenon.

Throughout the study, researcher reflexivity was actively maintained through reflexive journaling, regular team discussions, and explicit acknowledgment of the researchers' clinical and ethical backgrounds in regenerative medicine, enabling ongoing critical examination of how these positions might influence data collection, interpretation, and presentation.

Participants

Participants were individuals who had participated or were currently enrolled in stem cell-based regenerative therapy clinical trials targeting neurodegenerative conditions such as Parkinson's disease and amyotrophic lateral sclerosis (ALS) (Hillman & Radel, 2018; Migdal, 2018). Selection was conducted using a purposive sampling strategy to ensure that all participants possessed direct and relevant experience with the studied phenomenon. Inclusion criteria encompassed adults aged 30–70 years who had completed at least one treatment phase and were capable of reflecting verbally on their experiences. Individuals with cognitive impairments preventing informed communication or those unwilling to discuss their emotional responses were excluded.

A total of 12 participants were included, representing a diverse sample in terms of gender (7 male, 5 female) and socioeconomic background. The diversity of perspectives enriched the analysis by providing variations in ethical, psychological, and cultural contexts surrounding the regenerative treatment experience.

Data Collection

Data were collected through semi-structured, in-depth interviews, designed to elicit rich and detailed narratives about participants' lived experiences during their involvement in regenerative therapy trials (Carreiras & Castro, 2012; Iosifides, 2016). Each interview was guided by an open-ended question protocol covering topics such as decision-making processes, emotional responses, ethical reflections, and expectations toward the therapy outcome. The interviews were conducted face-to-face in a private clinical consultation room or, when necessary, via secure video conferencing to ensure participant comfort and confidentiality.

Each session lasted between 60 and 90 minutes, allowing sufficient time for reflection and elaboration. Interviews were audio-recorded with participants' consent and transcribed verbatim for analysis. Field notes were also taken to document contextual observations, emotional tone, and nonverbal expressions. To enhance data credibility, participants were encouraged to verify preliminary interpretations through follow-up communications, contributing to member validation.

Data Analysis

Data were analyzed using the Interpretative Phenomenological Analysis (IPA) framework, which involves a systematic process of identifying, organizing, and interpreting emergent themes (Daly, 2007; Longhofer et al., 2012). The analysis proceeded through several iterative stages:

1. Immersion in the data through multiple readings of the transcripts.
2. Initial noting of significant statements and meaning units reflecting participants' ethical and emotional experiences.
3. Development of emergent themes through clustering related meaning units.
4. Identification of connections between themes to construct higher-order categories that reflected shared experiential patterns.
5. Synthesis of individual experiences into an overarching interpretation that captures the essential structure of the phenomenon.

NVivo software (version 12) was used as a supportive tool to organize textual data and facilitate coding consistency, though interpretative reasoning remained central to the analytical process (Fife, 2020; Kawamura, 2020). The analytical pathway maintained a balance between participants' voices and interpretative depth, ensuring that the final thematic structure authentically represented the experiential essence of the participants' narratives.

RESULTS

The Ethical Weight of Decision-Making

Participants described the decision to join a stem cell clinical trial as both an act of courage and moral struggle. The process of informed consent was not merely procedural but deeply personal entwined with existential reflections on autonomy, risk, and trust in science. One participant expressed,

"Signing the consent form felt like stepping into the unknown. I wanted to believe in the science, but part of me wondered if I was being too hopeful."

For most, the decision was motivated by both desperation and altruism. The hope to recover or at least contribute to scientific progress coexisted with fear of being "experimented on." This tension between faith in medicine and anxiety over potential exploitation underscored the participants' ethical dilemma. The sense of vulnerability was mitigated when medical staff demonstrated empathy and transparency, reinforcing trust and moral acceptance of participation.

Navigating Ethical Dilemmas in Clinical Trial Participation

Living Between Hope and Uncertainty

The patients’ emotional landscape was dominated by oscillations between optimism and apprehension. The promise of regeneration inspired hope, yet the unpredictability of the outcome provoked anxiety. As one respondent shared,

“Every check-up was a mix of excitement and fear. I hoped for improvement, but I also feared hearing that nothing had changed.”

Hope served as both a psychological coping mechanism and a burden; participants felt compelled to maintain positivity, even when confronted with ambiguous or minimal progress. The ongoing ambiguity of results often led to emotional fatigue, a phenomenon many described as “the quiet exhaustion of waiting.” Nevertheless, this state of uncertainty fostered deep introspection and acceptance of life’s fragility.

The Body as a Site of Experimentation and Meaning

Many participants viewed their bodies not only as recipients of scientific intervention but as spaces of meaning and identity reconstruction. Undergoing regenerative therapy reshaped their perception of self transforming illness from a passive condition into an active engagement with biomedical innovation. One patient reflected,

“I used to see my disease as something that happened to me. Now, being part of this trial, I feel I’m doing something with it.”

This reconfiguration of embodiment where biological treatment intersected with personal meaning allowed patients to reclaim agency. However, some also expressed discomfort at being labeled as “subjects,” feeling objectified within a clinical setting. The interplay between scientific rationality and personal vulnerability highlighted a duality: patients simultaneously felt empowered and exposed.

Ethical-Emotional Equilibrium and the Search for Meaning

Through the course of participation, individuals sought an internal equilibrium between moral responsibility and emotional survival. Several participants spoke of developing a personal philosophy of acceptance, where uncertainty and ethics intertwined into a coherent worldview.

“I realized that being part of this study isn’t just about me it’s about the future of others. That thought keeps me grounded, even when I’m scared.”

This emergent ethical-emotional balance reflected a transformative process: fear evolved into meaning, and anxiety into purpose. The act of participation transcended medical outcomes it became an existential act of contribution and resilience. Across narratives, participants articulated a shift from seeking cure to seeking significance, embodying the humanistic core of regenerative research.

DISCUSSION

Summary of Key Findings

The findings of this study reveal that patients participating in stem cell clinical trials for neurodegenerative diseases experience a profound moral–emotional negotiation characterized by the search for meaning, trust, and balance between hope and vulnerability (Mukhlis, Janwari, et al., 2023; Mukhlis & Abdullah, 2025). The essence of their lived experience lies not in the biomedical outcome itself but in the existential transformation that occurs as they reinterpret illness, uncertainty, and participation through the lens of ethical and emotional significance (Wang et al., 2024). These insights directly address the central research question regarding how patients understand and ascribe meaning to their involvement in regenerative therapy trials.

Contribution of Findings to the Research Questions

The results provide a comprehensive response to the overarching inquiry into how patients experience and interpret their moral and psychological journey during participation in regenerative clinical trials. The interpretative analysis revealed that participation is not merely an act of receiving treatment but a deeply reflective process that redefines self-identity and personal values. Patients engage in what can be described as an ethical–emotional recalibration, where they negotiate between altruism and self-preservation, between faith in medical innovation and fear of exploitation. This contributes uniquely to the understanding of regenerative medicine as not only a scientific enterprise but also a moral space where the boundaries of human agency, vulnerability, and hope are reimagined.

Furthermore, this study advances phenomenological inquiry by highlighting how participants' narratives embody a dynamic form of meaning-making transforming fear into purpose and uncertainty into ethical acceptance (Yoo et al., 2021). Unlike outcome-based research that evaluates therapeutic efficacy, this phenomenological approach captures the inner logic of patient experience, demonstrating that meaning itself serves as a therapeutic dimension. Such findings expand the conceptualization of patient-centered care within regenerative medicine, positioning patients as co-constructors of ethical knowledge rather than passive recipients of medical intervention.

Relationship to Previous Literature and Theoretical Perspectives

The current findings both affirm and extend previous work in regenerative ethics and phenomenological health research. Studies by Munsie and Hyun (2020) and Lindvall et al. (2021) similarly identified ethical tension and emotional ambivalence among trial participants, yet they approached these dynamics descriptively rather than interpretatively. The present study deepens this understanding by uncovering the hermeneutic structure of these experiences how patients' interpretations evolve over time, transforming ethical anxiety into reflective equilibrium (Adugna et al., 2022). This aligns with Heideggerian phenomenology, which views understanding as an unfolding process of being-in-the-world, shaped by contextual engagement and temporal awareness.

Additionally, the theme of "ethical–emotional equilibrium" identified here resonates with Murdoch et al. (2019), who emphasized the psychosocial dimensions of regenerative participation, yet the current findings extend their work by situating emotional resilience within an existential framework. The patients' search for balance between self-trust and scientific faith reflects Ricoeur's concept of the narrative self, wherein individuals reconstruct meaning and identity through moral storytelling. Thus, the study contributes not only empirical insight but also theoretical advancement, bridging phenomenological philosophy with clinical bioethics. By doing so, it reaffirms the importance of exploring patient experience as a moral phenomenon embedded within scientific innovation.

Implications of the Findings

The findings of this study carry both theoretical and practical implications for the broader field of regenerative medicine and clinical ethics. On a scientific level, they emphasize the necessity of integrating phenomenological understanding into patient-centered research design, recognizing that therapeutic efficacy cannot be separated from the lived moral and emotional realities of participants. The emergence of the ethical–emotional balance as a central theme underscores that patients' participation in clinical trials is not only a biomedical event but also a deeply existential engagement with self, science, and society.

From a sociocultural perspective, these findings reveal that regenerative medicine operates within a moral economy of trust and meaning. Patients' willingness to engage in uncertain and experimental procedures reflects a form of moral citizenship where individuals contribute to scientific advancement despite personal risks. This challenges researchers and clinicians to view participants not merely as data sources but as ethical collaborators whose experiences shape the very nature of medical innovation (Poliwoda et al., 2022). Professionally, the study suggests the need for ethically responsive clinical communication, where empathy, transparency, and moral dialogue are as essential as technical competence. Such an approach aligns with global movements toward participatory medicine and reinforces the idea that understanding patient meaning is integral to clinical excellence.

Study Limitations

As with all qualitative research, this study's findings are shaped by contextual and methodological boundaries that restrict their generalizability. The sample size, though sufficient for phenomenological depth, was relatively small and specific to patients involved in stem cell trials for neurodegenerative conditions. Consequently, the experiences described here may not fully represent those of participants in other types of regenerative or biomedical studies. Additionally, the interpretative nature of the phenomenological approach, while providing depth of insight, inherently involves a degree of subjectivity in meaning-making, both from participants and the interpretive process itself.

Another limitation lies in the temporal scope of the data. The study captured experiences within a particular phase of participation, and long-term reflections on meaning transformation post-trial were beyond the study’s timeframe. Despite these constraints, the methodological rigor maintained through member checking, triangulation, and audit trails enhances the credibility and trustworthiness of the findings (Pashchenko et al., 2022). Rather than diminishing their value, these limitations highlight the situated and contextual nature of phenomenological knowledge emphasizing the importance of understanding lived experience within its ethical and temporal horizon.

Prospective Directions for Future Research

Future research could extend these findings by exploring longitudinal phenomenological perspectives, examining how patients’ meanings evolve beyond the active phase of clinical participation (Mukhlis, 2025a; Mukhlis & Saidah, 2025). Such inquiry could illuminate whether the ethical–emotional balance identified in this study persists, deepens, or transforms over time. Comparative studies across different types of regenerative therapies such as tissue engineering or gene editing may also reveal how varying clinical and cultural contexts influence meaning-making processes.

Moreover, interdisciplinary collaborations between phenomenology, bioethics, and medical humanities could strengthen conceptual frameworks for understanding patient agency and vulnerability. Integrating phenomenological insights into clinical ethics training, policy development, and trial design could foster environments where patient narratives actively inform ethical decision-making. Ultimately, these directions reaffirm the potential of phenomenological inquiry to bridge the gap between scientific innovation and human meaning, offering pathways for more compassionate, reflective, and ethically grounded clinical research practices.

CONCLUSION

This study explored the lived experiences of patients participating in stem cell clinical trials for neurodegenerative diseases, focusing on the ethical and emotional meanings embedded in their participation. The findings revealed that patients navigate complex moral and psychological terrains, striving to balance hope with vulnerability while reconstructing their sense of identity and trust in science. By employing interpretative phenomenological analysis, the research illuminated how meaning-making serves as a transformative process through which patients convert uncertainty into moral resilience and emotional purpose. These insights address gaps in prior research that often emphasized clinical outcomes over subjective experiences, offering a more holistic understanding of regenerative therapy as a human and ethical phenomenon. The study contributes both theoretically and practically by framing patient participation as a dialogical process that shapes the ethical landscape of medical innovation. Future research may extend these findings through longitudinal and cross-contextual studies to examine how meanings evolve as regenerative medicine continues to advance.

CONFLICT OF INTEREST

The authors declare that there is no conflict of interest regarding the publication of this article. All funding and support were provided transparently by the Global Regenerative Medicine Research Consortium (GRMRC), which had no influence on the study design, data collection, analysis, interpretation, or writing of this manuscript.

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