



Patient Experiences in Regenerative Therapy Clinical Trials: Insights on Effectiveness and Challenges

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ABSTRACT

The rapid advancement of digital technologies in healthcare has led to an increased reliance on digital media for medical communication. However, little is known about how healthcare practitioners and patients use and understand these technologies, especially within the context of doctor-patient interactions. This study aims to address this gap by exploring the subjective experiences of both medical practitioners and patients using digital platforms for healthcare communication. Using a phenomenological approach, we examine how these technologies are adopted and integrated into healthcare practices, focusing on the lived experiences of users. Data was collected through in-depth interviews with healthcare practitioners and patients, which were analyzed thematically to uncover key themes regarding their experiences, challenges, and perceptions. The findings suggest that while digital media can enhance communication, significant barriers such as technological literacy and trust issues remain. These results provide a deeper understanding of the nuances of digital media adoption in healthcare settings and offer important implications for improving patient-practitioner digital interactions in the future.



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INTRODUCTION

Regenerative medicine, a field focused on repairing or replacing damaged tissues and organs, has rapidly advanced over the past few decades, offering new hope for patients suffering from degenerative diseases (Allen dkk., 2023). At the core of this innovation are therapies such as stem cell treatment, gene therapy, and tissue engineering, which aim to restore function to damaged cells or tissues. These therapies have shown promising results in clinical trials, particularly for conditions such as osteoarthritis, neurological disorders, and heart disease (Alzahrani dkk., 2021). Despite their potential, the adoption of regenerative medicine faces significant challenges, including the uncertainty of long-term outcomes, risk of side effects, and limited patient understanding of the underlying technologies.

A key aspect of understanding the impact of these therapies lies in exploring the lived experiences of patients who have undergone these treatments (Belluomini dkk., 2022). While clinical trials provide critical data on the efficacy and safety of regenerative therapies, they often overlook the subjective experiences of the participants. Patients' perceptions, emotional responses, and the social contexts within which they navigate these treatments are crucial to fully understanding the potential of regenerative medicine. Previous research has focused primarily on clinical outcomes, often repeating discussions on effectiveness and technical challenges, leaving gaps in understanding patients' personal experiences (Buja dkk., 2023). While randomized controlled trials (RCTs) and quantitative surveys offer valuable insights into efficacy, they do not capture the nuanced, subjective experiences that shape a patient's perception of treatment. Previous research on regenerative medicine has primarily

focused on the biological and technical aspects of these therapies, with less attention given to the personal, emotional, and social dimensions of treatment (Buja dkk., 2023). Approaches such as randomized controlled trials (RCTs) and quantitative surveys have been instrumental in assessing the effectiveness of these therapies from a clinical perspective. However, these methods do not capture the nuanced, subjective experiences that can shape a patient's overall perception of treatment. Phenomenology, with its emphasis on understanding individuals' lived experiences and the meanings they attach to those experiences, offers a valuable approach for gaining deeper insights into how patients perceive and react to regenerative therapies.

This study aims to address this gap by focusing on the experiential realities of patients undergoing regenerative therapy (Desmoulin-Canselier, 2019). By adopting a phenomenological approach, the research seeks to explore the meanings patients attach to their participation in clinical trials, shedding light on the personal and emotional aspects that influence their views on therapy effectiveness, risk, and overall treatment experience.

Research into the lived experiences of individuals undergoing regenerative therapies has emerged as a critical area of investigation, particularly as these treatments continue to gain clinical and public attention (Edelstein dkk., 2015). Unlike traditional treatments, regenerative therapies such as stem cell and gene therapy are often experimental and carry a high degree of uncertainty, making it essential to understand how patients perceive their experiences. While clinical trials focus on efficacy and safety, they often fail to capture the subjective realities of participants, including emotional responses, social factors, and personal meanings attached to the treatment. As a result, there has been an increasing recognition of the importance of phenomenological research, which can uncover these hidden dimensions of patient experience.

However, the exploration of deep, personal experiences presents significant methodological challenges. Traditional quantitative methods, such as surveys or randomized controlled trials, are unable to capture the richness of individual narratives or the complex emotional and psychological factors that influence treatment outcomes (Forman dkk., 2018). These approaches often reduce the patient experience to measurable data points, neglecting the nuances of personal perception, emotional resilience, and social context. In contrast, phenomenological methods offer the potential to explore the lived experience in its entirety, but they too face challenges, particularly in accessing and interpreting the intimate details of a patient's journey. The reliance on qualitative data, often derived from interviews or personal reflections, can make it difficult to draw generalized conclusions or validate findings across larger populations.

These challenges highlight the limitations of previous research methods in fully capturing the essence of the patient experience (Greppi dkk., 2019). While clinical trials and quantitative studies are invaluable for determining the clinical effectiveness of regenerative therapies, they cannot provide the depth of understanding necessary to appreciate the emotional, psychological, and social dimensions of patient experiences. Consequently, there is a need for studies that integrate both the clinical and subjective aspects of regenerative therapy, allowing for a more holistic understanding of its impact on patients' lives.

Although practical approaches such as clinical trials and quantitative surveys have been widely used to assess the effectiveness of regenerative therapies, these methods have limitations in capturing the subjective experiences and deep meanings experienced by patients. Previous research has tended to focus on objective outcomes, such as physical changes or measured clinical parameters, while neglecting the emotional, psychological, and social dimensions of the patient's journey. Therefore, while data collected through quantitative methods provide insights into the success of therapies in terms of efficacy, they often fail to offer a comprehensive picture of how these therapies are perceived and accepted by individuals within the context of their everyday lives.

It is important to note that while clinical trials and surveys provide valuable information about short- and long-term outcomes, they often fail to capture the complexity of the personal meanings experienced by patients, such as fear, hope, or emotional struggles faced during or after therapy. In other words, the existing methods cannot fully represent the essence of these phenomena. This creates

a need for a more holistic approach that can explore subjective experiences more deeply and comprehensively.

As an alternative solution, the phenomenological approach offers a more suitable framework for exploring the meanings and subjective experiences of patients in depth. By focusing on the perceptions and experiences of individuals, phenomenology allows researchers to explore how patients understand and interpret their experiences with regenerative therapy. This method provides space for a richer understanding of the essence of the phenomenon under study, encompassing not only clinical outcomes but also the emotional and social dimensions that shape how patients perceive and manage therapy. Therefore, phenomenology provides a stronger foundation for understanding the experiences of patients involved in clinical trials of regenerative therapies and offers new insights that may have been overlooked in quantitative-based research.

Several studies have explored the experiences of patients undergoing innovative treatments like regenerative therapies. However, most of these studies have relied on quantitative methods, focusing on objective outcomes such as symptom improvement or clinical measures. These studies, while valuable for understanding therapeutic efficacy, often overlook the rich, subjective experiences of patients. Recent research emphasizes the importance of capturing these personal experiences to develop a fuller understanding of how patients perceive and navigate experimental treatments. Theoretical frameworks such as phenomenology, which centers on lived experience and meaning-making, offer a compelling approach to understanding the deeper dimensions of patient experiences with regenerative therapy.

To address this gap, the current study adopts a phenomenological approach, specifically to uncover and interpret the lived experiences of patients participating in clinical trials for regenerative therapy. Phenomenology allows for an in-depth exploration of the personal and emotional dimensions that quantitative methods cannot capture. By focusing on the meaning patients attribute to their treatment experiences, this approach seeks to provide a more holistic understanding of regenerative therapy, addressing the limitations of previous research that only measured physical outcomes. This study uses semi-structured interviews to gather rich, qualitative data and applies thematic analysis to identify core themes within the patient narratives, providing insights into their perceptions, challenges, and hopes throughout the treatment process.

This article is structured as follows: First, the introduction provides a background on regenerative therapy and the importance of understanding patient experiences. Next, the methodological approach is outlined, detailing the phenomenological framework used to explore the subjective experiences of patients. The article then describes the data collection process, followed by an explanation of the analysis technique. The results section presents key findings based on the participants' stories, followed by a discussion of the implications for clinical practice and future research. Finally, the conclusion summarizes the study's contributions to the understanding of patient experiences with innovative therapies.

RESEARCH METHODS

Research Design

This study employed a phenomenological approach to explore the lived experiences of patients participating in clinical trials of regenerative therapies (Keesom dkk., 2024). Phenomenology is particularly suited for investigating the subjective experiences and meanings that individuals attach to their involvement in innovative medical treatments, making it an ideal method for addressing the research questions related to the perception of effectiveness, risks, and challenges of regenerative therapy. The focus of this approach is on understanding how patients experience and interpret their treatment journeys, offering insights into the deeper, often unspoken aspects of their experiences. Specifically, the study applied descriptive phenomenology, which aims to uncover the essence of participants' experiences without preconceptions, providing a rich and detailed account of the phenomenon under study.

Participants

The participants were selected through purposive sampling, focusing on individuals who had participated in clinical trials of regenerative therapies for degenerative diseases such as osteoarthritis and neurological disorders. Inclusion criteria required participants to have undergone regenerative therapy (e.g., stem cell therapy, gene therapy) for a minimum of six months, as this period allowed for adequate reflection on the treatment's effects. Participants were also required to be able to communicate their experiences through in-depth interviews. Exclusion criteria involved patients with a history of severe allergic reactions to the therapy materials or psychological conditions that could impair their ability to provide reliable feedback. The sample size of 15 participants was determined based on the principle of data saturation, a common criterion in qualitative research. Data saturation occurs when additional interviews no longer yield new themes or insights, ensuring that the collected data sufficiently captures the depth and variability of experiences relevant to the study objectives. While this sample size provides rich, detailed data appropriate for a phenomenological study, it may limit the generalizability of the findings to broader populations. This limitation is acknowledged, and the study's primary aim is to provide in-depth insights rather than statistically generalizable results.

A total of 15 patients participated in the study, with a balanced representation of genders and varying ages, ranging from 40 to 70 years. The demographic diversity of the participants was deemed important for capturing a broad spectrum of experiences related to regenerative therapy. The majority of participants were diagnosed with osteoarthritis or nerve degeneration, while a few were receiving treatment for other degenerative conditions.

Data Collection

Data were collected through in-depth, semi-structured interviews conducted with each participant. The interviews aimed to capture the participants' personal experiences, perceptions of therapy effectiveness, and reflections on any challenges faced during the clinical trial process (Mahner dkk., 2014). Each interview lasted approximately 60 to 90 minutes and was conducted in a private, comfortable setting to ensure confidentiality and encourage open dialogue.

A semi-structured interview guide was used, focusing on key areas such as the perceived impact of the therapy, experiences with side effects, and emotional reactions to the treatment process. The guide allowed for flexibility in exploring topics that emerged during the conversation, ensuring that the participants' voices and experiences were fully represented. Prior to the interviews, participants were informed of the study's purpose and provided with informed consent, ensuring they understood their rights to privacy and voluntary participation.

Data Analysis

Data were analyzed using thematic analysis, a common technique in phenomenological research that involves identifying and interpreting key themes within the qualitative data. The analysis was conducted in a systematic manner, beginning with the transcription of interviews and followed by an initial reading to gain an understanding of the data. Relevant codes were generated from the transcriptions, focusing on recurrent patterns in participants' descriptions of their experiences. These codes were then grouped into broader themes that captured the essence of the patients' perceptions and experiences.

Thematic analysis allowed for an in-depth exploration of the central issues surrounding patients' experiences with regenerative therapy, such as the emotional impact of treatment, the perceived efficacy, and the challenges faced during the trial. NVivo software was used to assist with organizing the data, but the focus remained on the interpretive process of identifying themes that were directly grounded in the participants' narratives.

Ethics

Ethical approval for the study was obtained from the relevant research ethics committee. All participants provided written informed consent before taking part in the study, ensuring that they were fully aware of the research objectives, potential risks, and their rights to confidentiality and voluntary participation. The study adhered to international ethical standards for research involving human

participants, including principles of respect for persons, beneficence, and justice. Data were kept confidential, and any identifying information was removed to maintain participant anonymity. The findings were reported in aggregate, with no individual identifiable information included in the results.

RESULTS

Perception of Effectiveness and Treatment Outcomes

The experiences shared by patients regarding the effectiveness of regenerative therapies revealed a range of subjective perceptions. The majority of participants expressed an overall sense of improvement in their health conditions, particularly those undergoing stem cell therapy for degenerative diseases like osteoarthritis and neurological disorders. Many participants noted improvements in mobility and a reduction in pain, which were central to their positive evaluations. As one participant mentioned:

"After the treatment, I can move more freely and the pain that used to bother me constantly has become more manageable. It feels like I'm getting a second chance." (P5)

Despite these positive changes, some patients still reported uncertainty about the long-term effectiveness of the treatment. A common theme that emerged was a feeling of hope tempered by concerns about the durability of the results. One patient reflected:

"I'm happy with the improvement, but I wonder if it will last. Will I have to undergo more treatments in the future? I just don't know." (P12)

These mixed responses suggest that while patients acknowledge immediate improvements, their confidence in the lasting impact of regenerative therapies remains uncertain, highlighting the need for further clarity and communication from healthcare providers regarding the long-term benefits.

Perceived Risks and Side Effects

Patients also shared a variety of concerns related to the risks and side effects of regenerative therapies. Several participants reported mild to moderate side effects, such as discomfort at the injection site, fatigue, and temporary increases in pain, which were common in the initial stages of the treatment. These side effects were often seen as a necessary part of the healing process, though they created a sense of anxiety among some patients. One participant expressed:

"The first few days after the treatment were really tough. I felt more pain than usual, and it made me worry that the treatment wasn't going to work." (P8)

However, it was important to note that while side effects were acknowledged, they were generally not viewed as a deterrent to continuing the treatment. In fact, many patients accepted them as an inevitable aspect of cutting-edge therapy. A recurring sentiment expressed by participants was the understanding that innovation often comes with risks. As P14 shared:

"I know it's experimental, so I'm prepared for a few setbacks along the way. But I trust the doctors and am willing to go through it to see if it really works." (P14)

Emotional and Psychological Impact

In addition to physical effects, patients also highlighted the emotional and psychological challenges they encountered during the course of their participation in clinical trials. Many patients expressed feelings of uncertainty and fear, especially at the beginning of the therapy, as they navigated the unknowns of the treatment process. This anxiety was compounded by the lack of guarantees regarding treatment outcomes. One participant noted:

"It's emotionally draining, not knowing if it's going to work. You're constantly on edge, wondering if you're just wasting time or if you're going to feel better. It's tough on your mind." (P6)

Furthermore, several patients described how the treatment process affected their relationships with their families and healthcare providers. While some patients felt supported by their families, others experienced difficulty discussing their concerns about the treatment, as they didn't want to worry their loved ones. One participant explained:

"I talk to my spouse a lot about the process, but sometimes I don't want to burden them with my worries. It's a lot to handle on your own." (P2)

This emotional toll reflects the need for more psychological support and guidance throughout the treatment journey, particularly for those who may struggle with uncertainty and fear of treatment failure.

Social Support and Community Involvement

Throughout the interviews, it became evident that social support played a critical role in the patients' experiences of regenerative therapy. Many patients reported that their families and healthcare teams were vital sources of emotional and logistical support during the clinical trial process. A number of patients expressed the importance of open communication with their doctors, with some highlighting how crucial it was to feel informed and heard. One patient shared:

"My doctor always took the time to explain everything to me, and that made a huge difference. I felt more confident when I knew what to expect." (P11)

On the other hand, some participants noted that their social circles, including extended family and friends, were less understanding of the nature of experimental treatments, leading to feelings of isolation. As P7 stated:

"I've had people question my decision to try this therapy, and it's made me feel a bit alienated. Not everyone gets it." (P7)

Nevertheless, the overall sentiment across interviews suggested that those who had strong support networks were more likely to have a positive outlook on the treatment, despite the challenges they faced.

The experiences of patients undergoing clinical trials for regenerative therapies reveal a complex interplay of optimism and uncertainty. While most patients reported physical improvements and positive treatment outcomes, concerns about the long-term efficacy of the therapies and the presence of side effects remained significant. Emotional challenges, particularly anxiety about treatment failure and the psychological toll of an uncertain recovery, were pervasive throughout the treatment process. Furthermore, social and familial support emerged as crucial in shaping the patients' overall experience, underscoring the importance of comprehensive care that extends beyond the clinical aspect of therapy.

DISCUSSION

The findings of this study reveal key insights into the lived experiences of patients undergoing regenerative therapy, particularly in the context of clinical trials (Meuth dkk., 2018). The core themes that emerged highlight the patients' complex emotions, challenges, and perceptions of the effectiveness and risks of regenerative treatments (Nguyen dkk., 2023). These experiences underscore the multifaceted nature of patient involvement in experimental therapies and provide a deep understanding of how individuals make sense of these innovative treatments. This aligns with the overarching research question concerning the subjective impact of regenerative therapy on patients' lives and perceptions.

In response to the primary research question, the findings of this study demonstrate that while patients acknowledge potential benefits, their experiences are shaped by significant uncertainty and emotional complexity. The sense of hope for recovery was often accompanied by anxiety about the long-term effects, and many patients expressed a desire for greater reassurance from healthcare providers. Notably, the emotional and psychological aspects of undergoing regenerative therapy—ranging from optimism to fear—emerged as critical elements in the overall experience of treatment

(Razlog dkk., 2023). This study contributes to a more nuanced understanding of patient experiences, moving beyond clinical efficacy to explore the internal, lived realities of those undergoing experimental treatments. By focusing on the personal meaning attached to regenerative therapies, the research provides valuable insights into the patient's journey, emphasizing the importance of considering these dimensions in clinical settings and therapeutic innovations.

Comparing these findings with existing literature, our results resonate with previous research highlighting the significance of patient perceptions in medical treatments (Légaré et al., 2010; Paterson & Zderad, 1976). For example, studies on experimental cancer treatments and gene therapies have similarly found that while patients often view the treatments as promising, their experiences are colored by emotional challenges such as uncertainty and fear (Choudhury et al., 2019). However, this study extends the conversation by emphasizing how these emotional dimensions are not merely side effects of treatment but central to how patients interpret the meaning of the therapy (Scholes & Martin, 2010). The findings also echo Rogers' theory of diffusion of innovation (Rogers, 2003), which suggests that adoption of new technologies is influenced not only by perceived benefits but by emotional and social factors. Thus, this research supports the view that understanding the psychosocial dynamics of patient experiences is essential for improving patient-provider communication and the development of supportive care models in the context of innovative treatments.

Implications of Findings

The findings of this study have significant implications both in medical practice and in the development of policies related to innovative therapies, such as regenerative therapy (Taïb dkk., 2023). From a clinical perspective, a deeper understanding of patients' experiences can enhance communication approaches between healthcare practitioners and patients. Increased awareness of the uncertainty and anxiety experienced by patients during therapy may encourage the development of better emotional support during the treatment process (Van Loo dkk., 2024). Socially and culturally, the findings highlight how patients interpret new medical technologies within their cultural context and their expectations for healing. This underscores the importance of providing tailored, empathetic communication that acknowledges these diverse interpretations and experiences.

Study Limitations

This study has several limitations that should be noted. First, the limitations in sample size and the demographic diversity of participants may restrict the ability to generalize these findings to a broader population. While these findings provide in-depth insights into patients' experiences in the context of regenerative therapy, the limited sample may not fully represent the entire spectrum of patient experiences, particularly those from different socio-economic backgrounds. Second, while the phenomenological approach provides depth in understanding subjective experiences, it does not fully reveal broader contexts, such as health policies or access to medical technology. Therefore, further research is needed to expand this understanding, both by using a more diverse sample and by exploring the influence of external factors on patients' experiences.

Prospective Statement for Future Research

The findings of this study open numerous opportunities for future research, particularly in exploring how external factors, such as access to medical care and family support, influence patients' experiences with regenerative therapies (Vieta dkk., 2004). Further studies could investigate differences in the experiences of patients with full access to medical technologies and those hindered by socio-economic factors or health policies. Additionally, integrating the perspectives of healthcare professionals in this phenomenological research would provide a more holistic view of the dynamics between patients and healthcare providers in the context of innovative therapies. As a next step, research could expand its scope to include other emerging medical therapies, in order to compare how patients face various types of therapeutic innovations and how they interpret these experiences.

CONCLUSION

This study examined the subjective experiences of patients undergoing regenerative therapy, with the aim of understanding the meanings and impacts they perceive throughout the treatment process. The key findings of this research reveal that patients often face anxiety, uncertainty, and highly personal expectations about the outcomes of therapy, aspects that have not been extensively explored in previous studies. By employing a phenomenological approach, this research successfully investigated deep experiences that are often overlooked in quantitative or clinical studies, offering new insights into the importance of communication and emotional support within the context of innovative medical therapies.

This study makes several specific contributions to the field of regenerative therapy. First, it highlights the critical role of addressing emotional and psychological dimensions in patient care, which are often neglected in traditional clinical studies. Second, it underscores the need for enhanced communication strategies that are empathetic and tailored to individual patient experiences. These contributions provide a framework for integrating psychosocial support into clinical practices, ensuring a more patient-centered approach to regenerative therapy.

Furthermore, by focusing on the lived experiences of patients, this study advances our understanding of how patients perceive and navigate the uncertainties associated with experimental treatments. The findings emphasize that patient experiences are not merely adjuncts to clinical outcomes but are central to the overall success and acceptance of innovative therapies. This perspective shifts the focus from purely technical outcomes to a more comprehensive view of therapeutic effectiveness, integrating both clinical and experiential dimensions.

These contributions are directly grounded in the results and discussion sections, reinforcing the study's relevance to both research and clinical practice in regenerative therapy. By enriching our understanding of patients' experiences, this research provides a foundation for the development of more sensitive and holistic approaches in medical practice.

CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

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