***Short communication***

**Clinical Trials in Physiotherapy in India: Current Barriers and Strategic Pathways Forward**

**Abstract**

Clinical trials are regarded as the gold standard evidence for establishing the effectiveness and efficacy of different therapeutic strategies. Clinicians are advised to base their treatment decisions on clinical trials that have good research validity. Patients, physicians, and policymakers rely heavily on the knowledge gained from high-quality clinical trials to make appropriate evidence-based healthcare decisions. Consequently, it is imperative to have well-designed methodological studies as the foundation for making sound clinical decisions. Physiotherapy, as a discipline within healthcare, encompasses a broad spectrum of sophisticated interventions, including therapeutic exercises, manual manipulations, electrotherapeutic modalities, and biophysical agents. These therapeutic strategies are meticulously designed to alleviate nociceptive symptoms, facilitate the restoration and augmentation of motor function, enhance cardiopulmonary efficiency, mitigate the progression of physical impairments, and foster autonomous functional capacity. India has the potential to assert itself as a prominent global participant in physiotherapy research, thereby catalyzing the enhancement of patient care through interventions validated by rigorous scientific inquiry.

Keywords: Clinical trials, Physiotherapy, therapeutic interventions, chronic pathologies

**Introduction**

Physiotherapy has evolved significantly over the past few decades, transitioning from a support service in clinical settings to a crucial discipline in rehabilitative and preventive healthcare. At the heart of this transformation lies the integration of **evidence-based practice (EBP)**, which seeks to align clinical decision-making with the best available scientific evidence, practitioner expertise, and patient preferences1. One of the most effective ways to generate high-quality, reliable evidence in physiotherapy is through **clinical trials**—structured research studies designed to assess therapeutic interventions' safety, efficacy, and effectiveness. Clinical trials in physiotherapy (CTPs) serve as a fundamental pillar of evidence-based practice (EBP), playing a crucial role in optimizing functional recovery and elevating the overall quality of life for patients2

Physiotherapy, as a discipline within healthcare, encompasses a broad spectrum of sophisticated interventions, including therapeutic exercises, manual manipulations, electrotherapeutic modalities, and biophysical agents. These therapeutic strategies are meticulously designed to alleviate nociceptive symptoms, facilitate the restoration and augmentation of motor function, enhance cardiopulmonary efficiency, mitigate the progression of physical impairments, and foster autonomous functional capacity. Amidst the global paradigm shift toward non-pharmacological, individualized healthcare delivery, physiotherapy has emerged as an indispensable component in the management of both acute and chronic pathologies. Nevertheless, the widespread integration of these interventions into conventional medical frameworks necessitates their empirical substantiation through methodologically rigorous clinical trials and scientific inquiry.3,4

Within the Indian healthcare milieu, physiotherapy has experienced a pronounced escalation in prominence and clinical utilization across a wide array of medical specializations, including but not limited to orthopedics, neurology, cardiopulmonary rehabilitation, geriatrics, pediatrics, and sports medicine.5 This progressive expansion has been paralleled by an intensifying academic and professional impetus to embed clinical trials within routine physiotherapeutic praxis. Academic institutions, governing regulatory bodies, and the broader scholarly community are increasingly recognizing the critical necessity of conducting methodologically rigorous and scientifically validated clinical research. Such endeavors are pivotal in formulating evidence-based therapeutic frameworks, informing and shaping national healthcare policy directives, and restructuring educational curricula to meet the evolving demands and complexities of modern clinical practices.6,7

In recent years, there has been a discernible proliferation in both the volume and heterogeneity of physiotherapy-centric clinical trials undertaken within the Indian subcontinent. These investigative endeavors encompass a broad spectrum of rehabilitative domains, including but not limited to musculoskeletal restoration—addressing conditions such as chronic lumbar pain, osteoarthritic degeneration, and rotator cuff pathologies; neurological rehabilitation—targeting post-cerebrovascular accident recovery and the clinical management of neurodegenerative disorders like Parkinson’s disease; as well as cardiopulmonary rehabilitation—focusing on chronic obstructive pulmonary disease and postoperative convalescence following cardiac surgical interventions. Moreover, this empirical expansion extends into niche specializations such as women’s health physiotherapy and pediatric rehabilitation. The augmentation of this indigenous research corpus is indispensable for the contextualization and nuanced adaptation of globally endorsed therapeutic paradigms, particularly in light of India's profound cultural heterogeneity, linguistic multiplicity, and socioeconomic stratification6,7.

Clinical trials in physiotherapy typically employ **rigorous scientific methodologies** to evaluate the effectiveness and safety of interventions8. Common research designs include **randomized controlled trials (RCTs)**, which are considered the gold standard in clinical research. These trials involve the random allocation of participants into experimental and control groups, allowing researchers to isolate the effects of the intervention from other confounding variables. Other critical features of well-designed trials include **blinding** (to minimize bias), use of **control groups** (to provide a comparison benchmark), and **predefined outcome measures** (to ensure consistent and objective assessment). Together, these elements enhance the **internal and external validity** of study findings and contribute to the development of reproducible, generalizable clinical evidence.8

Despite the promising trajectory, the implementation of physiotherapy-related clinical trials in India is fraught with several challenges. These include issues of **limited awareness among professionals and students**, **inadequate funding**, **complex regulatory requirements**, **fragmented research networks**, and **participant recruitment barriers**.6,7 These challenges can undermine the quality, scope, and impact of clinical trials, thus limiting their ability to shape practice standards and improve patient care on a national scale.

A major obstacle to the widespread adoption of clinical trials in Indian physiotherapy is the **lack of awareness and research literacy** among both students and practicing professionals. Many physiotherapists have limited exposure to research methodology and ethical practices, often due to insufficient emphasis on research training in undergraduate and postgraduate curricula. This gap not only hampers their ability to conduct trials but also restricts critical appraisal skills, thereby affecting their capacity to engage with or apply evidence in daily practice.

Another critical issue is the **scarcity and inconsistency of research funding**. Unlike pharmacological or surgical trials, physiotherapy interventions are often considered lower priority by funding agencies, including government bodies and private enterprises. This financial neglect results in small-scale studies with limited sample sizes, restricted geographic scope, and suboptimal statistical power. Without adequate funding, it becomes difficult to implement the infrastructure and manpower needed to conduct scientifically rigorous and ethically compliant research.

Moreover, **regulatory hurdles** add another layer of complexity. Clinical trials in India are governed by a regulatory framework primarily designed for drug and device research. Although physiotherapy trials are non-pharmacological, they must still navigate approval processes dictated by the **Drugs Controller General of India (DCGI)**, **Indian Council of Medical Research (ICMR)**, and **Institutional Ethics Committees (IECs)**. 8 These processes, while necessary for ethical oversight, are often time-consuming and bureaucratic, particularly for smaller institutions lacking administrative support. This can result in delays, increased costs, and even abandonment of planned research.

Adding to this, the **lack of collaborative research networks** stifles innovation and scalability. Many institutions conduct trials in isolation, without access to shared data, collaborative expertise, or multicentric research opportunities. This siloed approach limits the generalizability of findings and restricts the scope for interdisciplinary and trans-regional studies.9

Finally, **participant recruitment and retention** remain problematic, particularly in a country as demographically diverse as India. Variations in health literacy, language barriers, socioeconomic constraints, and cultural attitudes towards clinical research all influence a patient’s willingness and ability to participate in trials. Even after enrollment, logistical issues such as transportation, time commitment, and financial burdens can lead to high dropout rates and data attrition, thereby reducing the reliability and applicability of trial outcomes.8,9

Yet, amidst these challenges, there are encouraging signs of progress. Academic institutions are gradually incorporating research modules into physiotherapy curricula, while some government bodies have begun exploring specialized funding schemes for allied health research. Collaborative platforms and conferences are fostering professional dialogue, and international partnerships are offering Indian researchers opportunities to align with global best practices. The increasing publication of Indian clinical trials in indexed journals further reflects growing research capacity and recognition.

Clinical trials in physiotherapy represent a fundamental mechanism for advancing scientific knowledge, refining clinical interventions, and ultimately enhancing patient care. In the Indian context, where the demand for rehabilitative services is rising in parallel with the burden of chronic and lifestyle-related diseases, the importance of robust clinical research cannot be overstated. By identifying and addressing the current challenges and leveraging emerging opportunities, India can play a pivotal role in shaping the global future of physiotherapy through well-conducted, impactful clinical trials.10

**Current Trends and Challenges**

Clinical trials in physiotherapy (CTPs) are indispensable for advancing evidence-based practices, but their successful execution in India is hindered by several key challenges. Despite the growing importance of CTPs in improving patient outcomes and treatment efficacy, various barriers continue to impede their effectiveness. These challenges range from limited awareness and funding to regulatory complexities and issues surrounding patient recruitment. Each of these barriers affects the quality, generalizability, and validity of physiotherapy clinical research in India, thereby limiting its potential impact on both clinical practices and policy development.

1. Limited Awareness and Knowledge

A foundational barrier to the successful implementation of CTPs in India is the widespread lack of awareness among physiotherapy professionals and students regarding the critical role of clinical trials in evidence-based practice (EBP). While clinical trials are a gold standard in assessing the efficacy of medical interventions, physiotherapists in India often have limited knowledge about the methodologies, benefits, and potential outcomes of such research. This lack of awareness is particularly evident in educational institutions, where the focus tends to be on clinical skills rather than research-based evidence.

Misconceptions about the purpose, process, and ethical considerations of clinical trials contribute to the reluctance of many professionals to engage in or support such studies. Many physiotherapists are unfamiliar with the steps involved in conducting trials, such as randomization, blinding, and the importance of control groups. This knowledge gap often translates into poor patient recruitment, as practitioners may fail to recognize the value of clinical trials in validating new treatments. As a result, there is often limited stakeholder engagement in research initiatives, which undermines the reliability and generalizability of the trial findings

Educating physiotherapy professionals, including students, on the importance and methodology of clinical trials is therefore essential. This could be achieved through curriculum integration, professional development programs, and increasing exposure to research through collaborations with medical schools and research institutions.9

2. Inadequate and Irregular Funding

Another significant challenge facing CTPs in India is the issue of inadequate and irregular funding. Unlike pharmaceutical and medical device research, physiotherapy research often does not attract substantial funding from government agencies, private sector entities, or pharmaceutical companies. This lack of financial support is a critical roadblock for conducting high-quality clinical trials, as it directly affects the availability of resources, the scale of the study, and the quality of data analysis.

In many cases, physiotherapy trials are conducted with limited resources, resulting in small sample sizes that compromise the power and reliability of the study. Small sample sizes reduce the ability to detect statistically significant results and hinder the generalizability of the findings. Furthermore, the absence of adequate funding often leads to delays in data collection, inadequate follow-up, and the inability to conduct comprehensive data analysis, all of which undermine the rigor of the research. A study by Patel and Verma (2017) on research funding in India highlighted how the funding disparity between drug trials and non-pharmacological research contributes to the stagnation of physiotherapy research 10

To overcome this, there is a pressing need for increased investment from both the public and private sectors. Government agencies and philanthropic organizations could collaborate to establish dedicated funding programs for physiotherapy research. Additionally, partnerships with pharmaceutical and medical device companies could help open new channels for financial support.

3. Regulatory Complexity

India’s regulatory environment for clinical trials presents another considerable challenge for physiotherapy research. Although physiotherapy trials are non-pharmacological in nature, they must adhere to the regulatory standards established for drug and device research. The regulatory framework governing clinical trials in India is primarily designed for pharmaceutical and medical device research, which poses difficulties when it comes to conducting trials for therapeutic interventions such as exercise programs or manual therapy techniques.

Physiotherapy trials must comply with the approval processes of the Drugs Controller General of India (DCGI), the Indian Council of Medical Research (ICMR), and Institutional Ethics Committees (IECs). These approval processes, although crucial for ensuring ethical oversight, are often time-consuming and bureaucratic. The process can be particularly burdensome for smaller institutions with limited administrative support, leading to delays in study initiation, higher costs, and sometimes the abandonment of trials altogether. Moreover, regulatory requirements, including documentation and reporting, often add significant administrative overhead, further complicating the trial process.11

Streamlining the regulatory framework to better accommodate non-pharmacological trials is essential. Creating guidelines specific to physiotherapy clinical trials could expedite approval processes and reduce administrative burdens. Additionally, training regulatory bodies and ethics committees in the unique aspects of physiotherapy research could help accelerate trial implementation.

4. Lack of Collaboration and Networking

The absence of collaborative research networks in India is a critical hindrance to the growth and scalability of physiotherapy clinical trials. Many research institutions, hospitals, and clinics conduct trials in isolation, without access to shared resources, interdisciplinary expertise, or multicentric research opportunities. This siloed approach limits the reach and generalizability of findings, as trials conducted at a single site may not accurately reflect the diversity of the broader population.12

Collaborative networks offer numerous benefits, including access to a larger participant pool, shared data, and the ability to conduct multicentric studies that can increase the robustness of findings. Furthermore, collaboration between institutions and research centers fosters the exchange of ideas, encourages innovation, and facilitates the development of best practices in research design and methodology. However, the lack of a collaborative ecosystem, combined with institutional competition and limited funding, prevents the formation of these essential research networks13

To overcome this, fostering partnerships between research institutions, universities, and clinical practices is crucial. National and regional conferences, joint funding initiatives, and online platforms for data sharing could help build a collaborative environment that facilitates high-quality, multicentric research.

5. Participant Recruitment and Retention

Participant recruitment and retention are perennial issues in clinical trials, and this is particularly true in a country like India, with its vast demographic diversity. Variations in health literacy, language barriers, socioeconomic conditions, and cultural attitudes towards clinical research all influence a patient’s willingness and ability to participate in trials. These factors can significantly reduce the pool of eligible participants, making it difficult to achieve the sample size needed for statistically reliable results. Furthermore, even after recruitment, logistical challenges such as transportation, time constraints, and financial burdens can lead to high dropout rates, further reducing the reliability of trial outcomes

Efforts to address these challenges should focus on improving patient engagement strategies, such as using community outreach programs, offering flexible trial schedules, and providing financial or transportation assistance. Additionally, it is essential to engage local communities in clinical research and educate them about the benefits and safety of participating in trials.

6. Relevance of Interventions

Finally, the relevance of the interventions tested in clinical trials remains a critical issue in India. Many trials continue to evaluate outdated or less effective physiotherapy interventions, which can skew the overall impact of physiotherapy practices. For example, the continued emphasis on posture correction for chronic low back pain (CLBP) in clinical trials persists, despite growing evidence supporting more effective interventions such as targeted exercise and cognitive-behavioral therapy. This gap often arises from the limited access to updated research literature and global trends in physiotherapy, particularly in resource-constrained settings.9

To enhance the relevance of interventions tested in trials, it is essential to keep abreast of global research trends and incorporate more evidence-based practices into clinical trial designs. Collaborations with international research bodies and the implementation of updated clinical guidelines could help bridge this gap.

**Future Recommendations for Enhancing Physiotherapy Clinical Trials in India**

As the field of physiotherapy in India continues to grow and evolve, clinical trials play an increasingly pivotal role in shaping evidence-based practices. However, despite the ongoing advancements, various challenges continue to hinder the effectiveness and scope of clinical trials in the country. In light of these challenges, several strategic recommendations must be implemented to overcome barriers and enhance the future of physiotherapy research in India. These recommendations focus on raising awareness, improving funding mechanisms, streamlining regulatory frameworks, fostering collaborations, adapting recruitment strategies, encouraging international collaborations, and promoting long-term follow-up studies. By addressing these areas, India can elevate its clinical trial landscape, leading to improved patient outcomes and contributing to the global body of knowledge in physiotherapy.

1. Enhancing Awareness and Education

A significant challenge facing clinical trials in physiotherapy in India is the lack of awareness among both professionals and the general public about the importance and value of such research. Many physiotherapists, students, and even patients are unaware of how clinical trials contribute to evidence-based practice and the improvement of treatment protocols. This knowledge gap leads to limited participation in clinical trials and undermines the general acceptance of research as a crucial part of clinical practice. As such, it is essential to implement targeted educational campaigns aimed at raising awareness about the value of clinical trials.

These campaigns should include collaborations with patient advocacy groups, professional societies, and academic institutions to educate the public and physiotherapy professionals about the role of clinical trials in validating and improving treatment methodologies. Additionally, clinical trial literacy should be integrated into the physiotherapy curriculum across institutions, ensuring that future generations of physiotherapists are well-versed in research methodologies and their importance in improving patient outcomes. Such initiatives will help foster a culture of research within the profession and encourage more practitioners and students to engage in or support clinical trials 9

2. Strengthening Funding Mechanisms

The success of any clinical trial is heavily dependent on the availability of adequate funding. In India, one of the most pressing issues facing physiotherapy clinical trials is the irregular and insufficient funding from both public and private sectors. Research in physiotherapy often fails to attract the same level of financial support as pharmaceutical or medical device trials. This funding disparity restricts the resources available for research, limiting the scope of studies, the size of participant groups, and the ability to conduct comprehensive data analysis.

To address this issue, there is a critical need to strengthen funding mechanisms for physiotherapy trials. Government bodies, private enterprises, and philanthropic organizations must recognize the importance of funding physiotherapy research and allocate resources accordingly. This could include establishing dedicated grants for physiotherapy studies and facilitating partnerships with private organizations. Furthermore, collaborations with pharmaceutical and medical technology companies could open new avenues for financial support and create research opportunities in areas where physiotherapy interventions intersect with medical devices or drug treatments 10

Strategic funding would not only enhance the quality and scale of clinical trials but also promote innovation in physiotherapy treatments. Public-private partnerships could play a significant role in bridging the gap between funding availability and the research needs of the physiotherapy profession.

3. Streamlining Regulatory Frameworks

The regulatory environment for clinical trials in India presents a significant barrier to the effective implementation of physiotherapy research. Currently, clinical trials in India must navigate a complex regulatory framework designed primarily for pharmaceutical and medical device research. While these standards are essential for ensuring safety and ethical compliance, they can be overly burdensome for non-pharmacological trials, such as those in physiotherapy.

To improve the efficiency of clinical trials in physiotherapy, the regulatory framework must be simplified. Government agencies, including the Drugs Controller General of India (DCGI) and the Indian Council of Medical Research (ICMR), should consider developing dedicated guidelines tailored specifically to non-pharmacological research. These guidelines would help streamline the approval process, reduce administrative burdens, and facilitate the timely initiation of trials. Additionally, these regulatory bodies should collaborate with professional associations to ensure that their standards are aligned with the unique requirements of physiotherapy trials 11

Efforts should also be made to increase transparency in the approval process. Clear, accessible information on the steps required for approval, along with a more efficient, time-bound review system, will encourage more institutions to engage in clinical research. Regulatory bodies must work towards creating an environment that supports, rather than hinders, the progress of physiotherapy research.

4. Promoting Collaborative Research Networks

Collaboration is a cornerstone of high-quality research, yet it remains one of the most underdeveloped aspects of clinical trials in physiotherapy in India. Many research institutions, universities, and clinical centers conduct trials in isolation, leading to fragmented research efforts and a lack of access to shared resources and interdisciplinary expertise. This siloed approach limits the ability to conduct multicentric trials, which are crucial for enhancing the generalizability and impact of research findings.

To address this issue, fostering intra- and inter-institutional collaborations should be a priority. Establishing national research networks that bring together academic institutions, clinical centers, and research organizations can facilitate the sharing of data, resources, and best practices. National conferences, joint research grants, and digital platforms for data sharing and discussion could help build a robust collaborative ecosystem.

By creating these research networks, physiotherapy clinical trials can benefit from a broader pool of expertise and resources, allowing for larger and more comprehensive studies. Moreover, collaboration between institutions can help build a culture of research, where innovation and knowledge-sharing become central to advancing the field.12

5. Developing Culturally Sensitive Recruitment Strategies

One of the persistent challenges in clinical trials in India is the difficulty in recruiting and retaining participants, particularly in a country as diverse as India. Variations in health literacy, socioeconomic status, language barriers, and cultural perceptions about clinical research all influence a patient’s willingness to participate. These challenges can significantly hinder the recruitment process and lead to high dropout rates, compromising the validity and reliability of the study outcomes.

To improve patient recruitment and retention, culturally sensitive strategies must be developed. These strategies could include localized community engagement initiatives that raise awareness about the benefits and safety of clinical trials, particularly in underserved areas. Additionally, patient education should be offered in vernacular languages to overcome language barriers and ensure better understanding. Other strategies, such as offering flexible trial schedules, providing transportation support, and addressing financial barriers, could make participation more accessible to a broader range of individuals.

Culturally appropriate recruitment strategies will help improve patient engagement and retention, leading to more robust and inclusive research studies that reflect the diverse patient population of India 13

6. Encouraging International Collaborations

While India has made significant strides in the field of physiotherapy research, there is much to be gained from global collaboration. International partnerships can bring diverse perspectives, advanced methodologies, and cross-cultural insights that can significantly enhance the quality of research. Collaborating with international research institutions can also provide access to global funding sources, advanced research infrastructure, and opportunities for sharing data and resources.

Establishing collaborations with global research networks can elevate the visibility of Indian physiotherapy research on the international stage. These partnerships would allow Indian researchers to co-develop trials, share best practices, and gain access to a wider pool of resources. Furthermore, international collaborations can foster a spirit of innovation and help Indian researchers stay updated with global trends in physiotherapy practice and clinical research 9

7. Conducting Long-Term Follow-Up Studies

Lastly, there is a growing need for longitudinal studies that assess the long-term impact of physiotherapy interventions. While many clinical trials focus on short-term outcomes, the sustainability and lasting effects of physiotherapy interventions are equally important. Long-term follow-up studies can help determine whether the benefits of physiotherapy treatments are maintained over time, providing valuable insights into the long-term efficacy of various interventions.

Conducting longitudinal studies would also contribute to the continuous improvement of physiotherapy practices by providing a more comprehensive understanding of the effectiveness of treatments in real-world settings. These studies could also guide clinical decision-making, ensuring that patients receive interventions that are not only effective in the short term but also beneficial throughout their recovery 12

**Conclusion**

Clinical trials in the realm of physiotherapy serve as a fundamental cornerstone for the establishment of evidence-based clinical decision-making. In India, while the discipline is progressively advancing, numerous structural, financial, and educational impediments persist, necessitating urgent attention. To optimize the ecosystem for clinical trials, it is imperative to augment funding mechanisms, streamline regulatory processes, foster strategic interdisciplinary collaborations, and implement recruitment strategies that are cognizant of cultural nuances. By overcoming these multifaceted challenges, India has the potential to assert itself as a prominent global participant in physiotherapy research, thereby catalyzing the enhancement of patient care through interventions validated by rigorous scientific inquiry.

**Conflict of Interest-** None

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