

## STRENGTHENING CLINICAL TRIALS: SOLUTIONS FOR RECRUITMENT CHALLENGES IN PAKISTAN

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Medical research advances healthcare by generating knowledge that enhances patient care and strengthens systems worldwide. Scholarly communication, especially in medicine, is crucial for improving health outcomes. Randomized controlled trials (RCTs) are considered the "gold standard" in establishing causal relationships between interventions and outcomes, minimizing bias through the comparison of control and intervention groups. However, bridging the gap between research findings and real-world clinical applications necessitates collaboration among basic and clinical researchers and healthcare providers, fostering a multidisciplinary approach to healthcare innovation.<sup>1</sup>

Despite the well-documented value of research evidence in healthcare decision-making, its integration remains inconsistent due to gaps in funding, limited training for healthcare professionals, and inadequate infrastructure to support research implementation. Limited resources and inadequate investment in healthcare have contributed to a substantial treatment-naïve population, compounded by a high burden of communicable and non-communicable diseases, minimal health coverage, and restricted access to care. As a lower-middle-income country, Pakistan faces significant gaps in scientific and technological advancements, which hinder research output and result in minimal representation in international research repositories.<sup>2</sup> Clinical trials play a crucial role in advancing medical care by evaluating the efficacy, safety, and potential side effects of new therapeutic interventions before widespread adoption. Given the high disease burden and resource constraints in developing countries, clinical research in these settings must prioritize cost-effective and innovative treatment strategies.<sup>3</sup> The landscape of clinical research in developing nations is continuously evolving, with international collaborations playing a critical role in enhancing research output in LMICs. Key factors driving the relocation of clinical trials to LMICs include lower operational costs, faster participant recruitment, and more streamlined regulatory approval processes.<sup>4</sup> The earliest documented clinical trials in Pakistan, available on PubMed, date back to the field trials of the cholera vaccine conducted in East Pakistan in 1963-1964.<sup>5,6</sup>

Recruitment challenges are among the most significant obstacles in both published and unpublished RCTs. Researchers often overestimate recruitment feasibility, assuming a higher willingness to participate and underestimating logistical challenges, which leads to diminished enthusiasm as challenges become evident.<sup>7</sup> Key barriers include participant reluctance, logistical constraints, and ineffective engagement strategies. Common concerns, such as mistrust of the research process, fear of adverse effects, and difficulties in identifying willing and eligible participants, further hinder recruitment efforts.<sup>8</sup> In mental health RCTs, additional complexities arise due to stigma, fluctuating mental states, and difficulties in obtaining informed consent, particularly during crisis situations, which can compromise recruitment rates and the validity of studies.<sup>9</sup> Furthermore, participants often experience physical and emotional distress due to their condition, and time constraints imposed by the urgency of clinical interventions add another layer of difficulty.<sup>10</sup>

Despite substantial public funding allocated to healthcare research and RCTs, failure to meet recruitment targets results in significant financial waste. Recruitment and retention have been identified as critical challenges in the successful conduct of RCTs by both trialists and funding bodies. For instance, in England, the National Institute for Health Research (NIHR) allocated over £250 million to 310 research projects in 2019–2020, with a significant portion dedicated to RCTs.<sup>11</sup> Recruitment challenges in LMICs stem from underfunded healthcare systems and a shortage of skilled researchers, resulting in inefficient resource use. Barriers such as patient burden, conflicts with standard care, and uncertainty regarding trial protocols often deter healthcare professionals from participating in recruitment efforts.<sup>10</sup> In Pakistan, these challenges are further compounded by a critical shortage of qualified research assistants and skilled personnel. Participant recruitment remains a significant hurdle in the execution of RCTs across diverse healthcare settings, from high-income countries to resource-limited LMICs in Africa and Asia.<sup>12</sup>

According to the WHO, Pakistan employs 5,185 full-time equivalent health researchers, representing only 7% of the regional total. The country's clinical research landscape is further constrained by inadequate funding, limiting the scope, quality, and impact of health research initiatives.<sup>4</sup> In LMICs such as Pakistan, recruitment bias poses a significant challenge by potentially selecting participants who do not accurately represent the general population. This limitation undermines the generalizability of RCT findings and may result in ineffective policy and public health interventions. Furthermore, participant attrition in longitudinal studies and RCTs presents serious methodological concerns that can compromise study outcomes. Addressing recruitment challenges in Pakistani RCTs is critical to improving the validity and applicability of research findings. Effective recruitment strategies ensure diverse and representative samples, enabling the development of interventions tailored to the unique demographic and healthcare needs of Pakistan.<sup>12,13</sup>

Effective recruitment of participants is essential for the successful conduct of RCTs.<sup>12</sup> Addressing local challenges through collaboration with community leaders and culturally appropriate communication has proven beneficial.<sup>11</sup> Logistical barriers to recruitment can be mitigated by offering flexible scheduling, transportation assistance, and establishing study sites closer to participants, which have been shown to improve recruitment rates.<sup>11,12</sup> Providing health benefits, aftercare, and small incentives has also been effective in overcoming participant reluctance in Pakistan. For example, a study conducted in Karachi found that offering transportation assistance and follow-up care increased recruitment rates by 25%.

Enhancing recruiter training in cultural sensitivity and streamlining trial regulations can further facilitate recruitment efforts. Simplifying ethics review and approval processes can accelerate trial initiation with minimal delays.<sup>14</sup> Additionally, integrating telehealth solutions for enrollment and remote follow-ups can enhance accessibility and convenience, reducing travel-related challenges for participants.<sup>10</sup>

In conclusion, clinical trials in Pakistan face significant recruitment challenges, including obtaining informed consent, participant eligibility, and logistical issues due to geographic dispersion and limited resources. Strategies such as community engagement, digital reminders, incentives, and cultural sensitivity training are essential to overcoming these barriers, improving participant recruitment, retention, and compliance. These approaches emphasize the need for tailored interventions to strengthen clinical trials in low-resource settings and to ensure that clinical research in Pakistan provides relevant, actionable insights for improving healthcare outcomes.

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