The impact of lockdown on healthy volunteers' participation in early phase trials

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ABSTRACT

Introduction: The coronavirus disease 2019 (COVID-19) pandemic and subsequent lockdowns have globally impacted clinical trial conduct, but their local implications remain poorly understood. This study aims to assess the characteristics of healthy volunteers recruited and dropped out from early-phase clinical trials and the impact of the COVID-19 lockdowns. **Methods:** Data were collected from two studies conducted during the lockdown period (September to December 2021) and two studies conducted after the lockdown (August 2022 to January 2023). Sociodemographic characteristics, screening outcomes, and trial completion rates were analyzed to understand volunteer participation patterns. **Results:** There were 66 and 91 volunteers screened during and after lockdown periods respectively. The majority of volunteers had tertiary education (80.3%), were single (71%), employed (81%), and had prior trial experience (61%). Volunteers who participated after the lockdown were slightly older than those during the lockdown (mean age: 29.9 vs. 27.1 years, p=0.006). A higher percentage of volunteers passed the screening during the lockdown compared to those screened after the lockdown (86.4% versus 70.3%, p=0.018). Family emergencies (12.1%) were the primary reason for dropout during the lockdown, while adverse events were prominent post-lockdown (7.7%, p=0.004). **Conclusion:** The study revealed that volunteers with higher education levels and prior trial experience were more likely to participate in clinical trials during and after the COVID-19 lockdown periods. Although there were differences in age distribution and reasons for dropout between the two periods, trial completion rates remained similar, suggesting effective management of trial logistics and participant engagement during challenging circumstances.