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*Research Article*

# A Study on Understanding the Opinion of Parents of India Towards Recruiting their Children in Clinical Trials: A Historic Comparative Study, Difference in A Decade

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## *Abstract*

*The face of clinical research changes rapidly and new ethical dilemmas will arise continually to challenge all clinical research professionals and regulatory agencies this would also change the perception of individuals. Patient's perspectives in clinical research have become increasingly interesting and important. Much effort has recently been made to understand, evaluate and promote the patient's active roles in and unique views on their involvement in clinical research, and how these may help resolve old and new problems/ issues in research planning, conduct, and implementation of a successful trial. This study provides a clear picture of the awareness in the Indian population and their knowledge and perception of clinical research. The responses from participants indirectly provide a few suggestions where we can improve our standard, and can minimize ethical challenges. Findings from the study can help to improve enrollment in pediatric clinical trials.*


***Keywords:*** *Parent's perspective, pediatric trials, historic comparison, recruitment.*

## Introduction

Research and subsequent clinical trials involving human subjects have often been controversial and have been long associated with a not-so-glorious legacy. The term 'human experimentation' still brings back the ghastly impression of the infamous experiments conducted on war prisoners during the Second World War**[**1**]**. The present-day concepts of research with human subjects is guided by three influential documents, conceived in the aftermath of the episodes of research misdemeanor, such as the example mentioned in the beginning. The Nuremberg Code**[**1**]** is a legal and ethical code promulgated by the U.S. judges at the trial of the Nazi doctors at Nuremberg after the Second World War. Widely considered as the most authoritative legal reference on the subject of human experimentation, the code is based on universal principles of natural law and human rights, and it establishes the basic principle that the participation in research requires the free, informed consent of the participating subject.

The Declaration of Helsinki[2] is one of the most widely known and influential guideline in medical research worldwide. It is an official policy of the World Medical Association (WMA), which was adopted for the first time in 1964 and has since undergone a number of revisions. The Declaration can be viewed as an expression of the WMA's determination in harmonizing the need to generate sound medical knowledge along with the need to protect the health and interests of research participants. Finally, the Belmont Report[3] is a short document on moral principles that was published in 1978 by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, in the aftermath of scandals of research misconduct that were uncovered in the 1970s. The Belmont Report is especially known for establishing a framework of basic moral principles, which include respect for persons, beneficence, and justice; factors that should guide the conduct of research. Apart from these international guidelines, each country has prepared its own sets of guiding principles, which are often based on ideals and objectives established in the above-mentioned documents. The focus of these legislations has been to standardize and oversee the ethical implementation of clinical trials involving human beings.

All research in children requires the consent or more accurately, assent of the child. However, there are several questions surrounding such assent. At the most basic level it can be agreed upon that, assent is an affirmative agreement by the child to participate in research. However, in many cases a proxy obtains the consent from the child's parents or guardians. This often puts them in an uncomfortable situation as they are often concerned about unknown or unexpected future side effects and the possibility that the treatment their child receives might later be discovered to be ineffective or even harmful4. Some parents acknowledge being more reluctant to consent for their children's participation in trials than if they were being asked to consent for their own participation. Many guidelines stipulate that the child's assent should also be sought if they are old enough to comprehend the relevant issues.

Apart from the assent from the participating child, another important factor in pediatric clinical trials is the consent of the parent. The balance of perceived benefits and potential barriers or risks of participation, and the importance of the study plays a major role in influencing the parents' willingness to participate [4,5,6].

Potential benefits in the eyes of the parents often include the opportunity to access new treatments, better care being given to their child and gaining greater access to health-care professionals. It also gives them new health information through meeting others in similar circumstances, gaining hope when no other effective treatments are available, and the satisfaction of knowing they are helping other children in the future. Potential barriers to parental consent often include protective parental instincts which often center

around the fear of their child being treated as a "Guinea pig" along with anxiety about the unknown factors inherent in research, and concern that researchers' priorities might not be in the child's best interest. Parents often consider the risks involved in such clinical studies which include known and unknown side effects, the chance that their child might be randomized to an ineffective treatment, and the inconvenience associated with participation. Such inconvenience often involves extra blood tests and time demands encompassing additional clinic visits **[**7,8,9**]**.

## Methodology

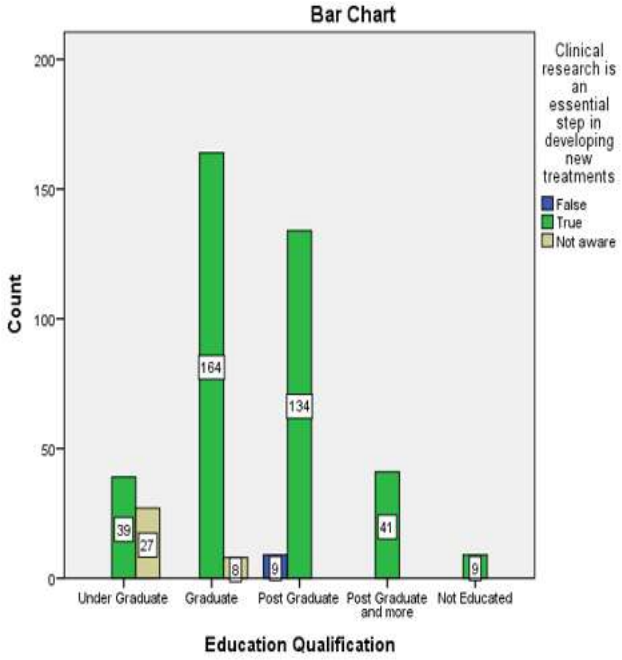
The primary objective of this research was to understand the opinion of parents in India regarding recruiting their children in clinical trials. This was achieved by asking the parents or guardians to complete the survey that will provide an overview of their take on clinical trials and the ease of allowing their child to participate in these trials. The target population would be chosen from geographical locations across India to get a vast pool of information that may enable in improvising enrollment rates in pediatric clinical trials. The results obtained from this survey were compared with another survey that was taken in 2016 which was to understand the perspective of the general population in India regarding clinical research.

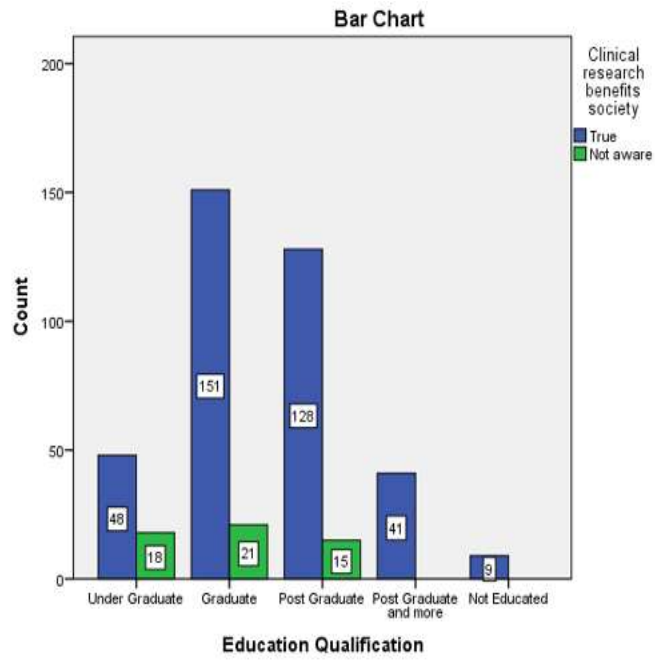
## Results

The total number of participants in the survey was 431, of which 122 (28.3%) were males and 309 (71.7%) were females. Based on age, 49.4% of participants were aged between 35 to 45 years, and 41.5% were between the ages of 25 to 35 years. Most of the participants were found to be either graduates (39.9%) or post-graduates (33.2%), with respect to their educational qualifications. 95.1% of the participants were from urban regions. 33.4% of them had an annual income between INR 2,00,000 to 6,00,000, while 26.9% earned more than 6,00,000 and 21.1% earned more than INR 15,00,000 per annum. The majority of these participants (57.3%) were employed in the private sector.

The participants were first asked whether they had heard about clinical trials. To this 317 (73.5%) responded in the affirmative compared to the 57.63% in the previous survey. The participants were then asked if they believed that clinical research benefitted the society. To this majority of the participants (89.8%) stated that the statement was true. This awareness was present irrespective of their educational qualification. In the historical comparison, 50.85% of the participants believe it to be beneficial to the society.

The participants were then asked if they felt that clinical research is an essential step in developing new treatments. Which was estimated to be true by most participants (89.8%) and 44.70% of the participants in the previous survey agreed to the above statement. The participants were then asked if they felt that advancement of science is reason behind the development of new drugs. Which was estimated to be true by most participants (379 of 431) in the current survey and 47.46% of the participants in the historical comparison agreed to the above statement.



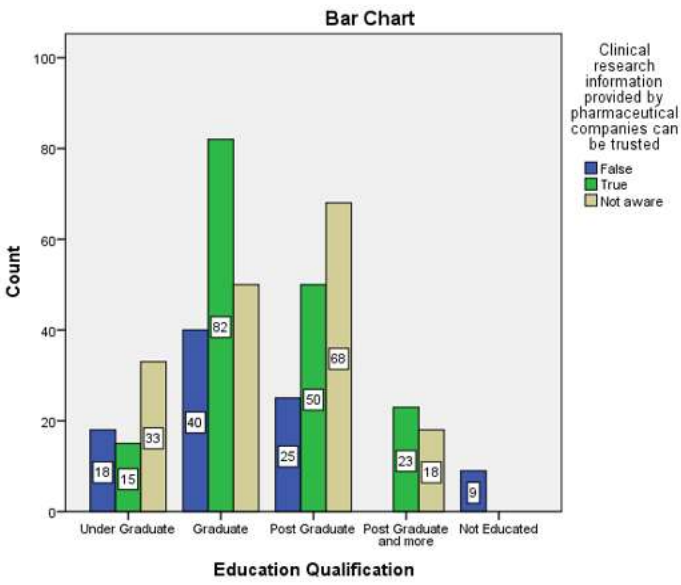



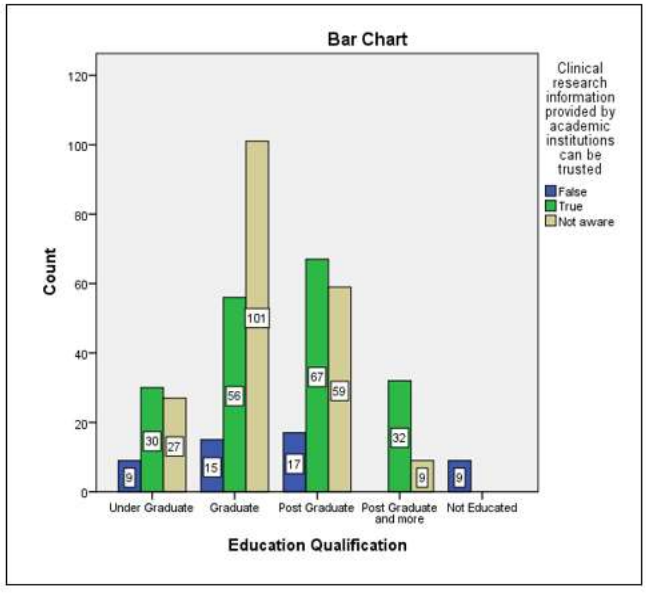

The participants were next asked if they thought hospitals participating in clinical trials provided better healthcare. To which, the participants in the current study were almost equally divided between 'True' (48.3%) and 'Not aware' (43.4%). In the previous study, 31.37% of the participants found the above statement to be true and 41.50% believe that there is no difference between the services provided by the hospitals who participate in clinical trials and the ones which do not.

When the participants were asked if they thought that, the most important reason for developing new treatments is financial gains, 57.1% of the participants in the current study stated that they believed this notion to be false. This sentiment was expressed by all participants across all educational qualifications. 40.68% of participants in the previous study believed the statement to be false and 52.54% were not aware. Next the participants were asked, if the government always adequately protects the public against unethical clinical research.

The responses were equally divided, with most stating that they believed it to be true (37.8%) or were unaware (37.6%) of it. In the previous survey the response to the same question was false by 6.78% of the participants and similarly vote for true is equivalently high (44.07%).

The next question posed to the participants was that, whether they felt that clinical research information provided by pharmaceutical companies can be trusted. The response was once again divisive, as 39.4% felt the statement to be true while, 39.2% stated that they were unaware of it. This was reflected across the different educational backgrounds. When the participants were asked, whether clinical research information provided by academic institutions can be trusted, the divisive response was again observed, with 42.9% stating it was true, and 45.5% stating they were unaware. This was reflected across the different educational backgrounds.




It was observed in the previous study that the participants believe on information provided by pharmaceutical companies as well as the academic institutions as the data obtained showed that it had maximum votes for true against false. 38.98% (460 out of 1180) true against 11.86% (140 out of 1180) false in case of information provided by pharmaceutical companies and 37.29% (440 out of 1180) true against 10.17% (120 out of 1180) false in case of information provided by academic institutions.

The participants were next asked, whether they thought doctors force their patients to participate in research. 68.4% of the participants stated that they believed the statement to be false. Similarly, in the previous study it was observed that, only 4.30% believed it to be true, 72.69% confirmed it to be false and 23% mentioned that they were not aware of the scenario. Next, the participants were asked if they believed, human

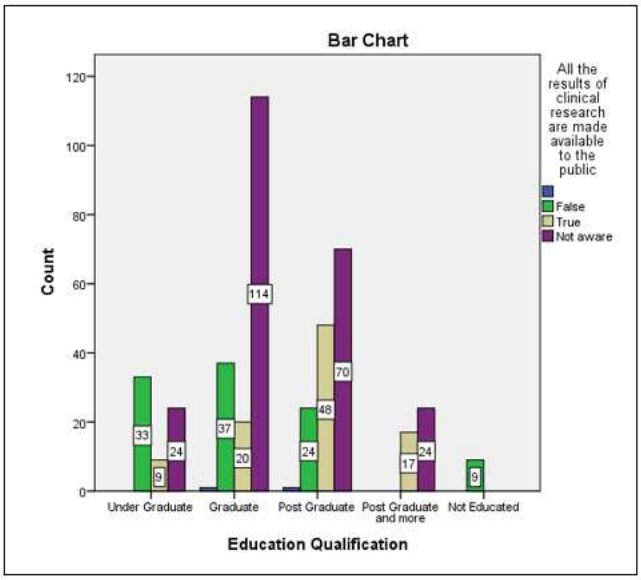
participants in clinical research are treated like experimental animals. Majority of the participants (47.6%) stated that they were not aware of such statement. In the previous study, majority of participants (49.15%) were not aware of the scenario and 16.95% of the participants believed it to be true.

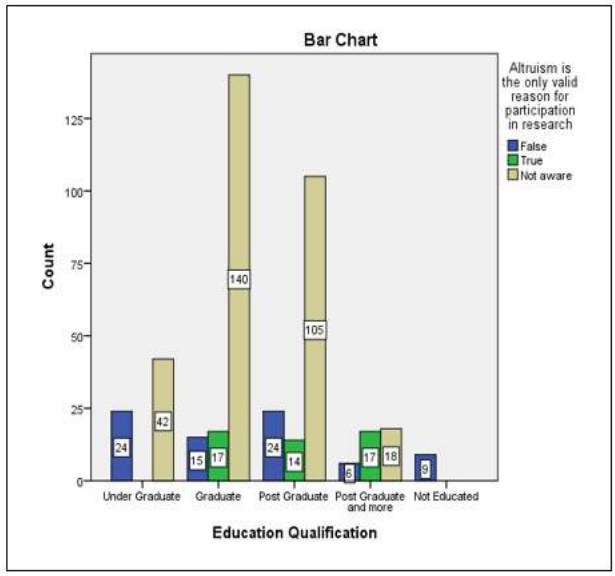
Next the participants, were asked if they thought confidentiality is a matter of importance to research participants. To which, overwhelming majority of participants (88.4%) found the statement to be true. 1.69% of the participants in the previous study think that confidentiality is not a matter of importance.

When further inquired, if they thought confidentiality of research participants is adequately protected. The response was almost equally divisive between those who thought the statement was true (46.4%) and those who stated that they don't know (41.3%). 40.68% of the participants in the previous study believed that their confidentiality will be taken care of in an appropriate and ethical manner.

When asked, if they thought results of clinical research are made available to the public, most of the participants (53.8%) stated that they were unaware. This lack of awareness was higher among graduates. Similar lack of awareness (70.8%) was observed in response to the statement, altruism is the only valid reason for participation in research.

People participated in the previous survey are with the right perception "yes.... Results of clinical research are made available to public" 3.39% append to vote that it is not made available. Simultaneously a huge number of individuals are not aware (52.54%). The obtained data was almost equally distributed for true and false and maximum votes received were for not aware i.e. 64.41% (760 out of 1180), for the question "Altruism is the only valid reason for participation in research."



## Discussion

Public perception is a major factor in shaping policies and outlooks toward emerging fields and new developments. This factor becomes more important in the case of public health. When people's lives are at stake, public perception of the approach plays a pivotal role in determining the policies implemented on it. Government policies thus are often shaped by public perception. However, the nature of public perception is a complicated matter, as public perception can vary with time, region, societal understandings, cultures, and most of all, education. In the case of public health, public perception has a key role in one particular aspect. This role is so major that it can impact the public health domain and the medical sector for a long period of time. Instances, where public perception has shaped human lives, particularly in matters of public health, can be observed throughout human history.

All participants across the group were first evaluated regarding their awareness and depth of knowledge trials. 73.5% of the general population were aware of what is meant by clinical trials. The data revealed that there was not much disparity among the surveyed population with respect to their level of education. The rate of awareness seems to have improved in the present data, as compared to previous reports. In a similar survey conducted by Kapadia and Parmar, the rate of awareness was found to be lower at 57.63%10. This increase might be attributed to greater access to the internet and social media achieved during the last few years in India.

When the general population representing parents of children was asked if they would try to convince their children of joining such trials. This was somewhat contradictory to the previous report, where 74.58% of parents had stated that they are willing to respect their children's opinions regarding participation in clinical trials**[**10**]**. Several factors are known to influence how parents seek and process information about a clinical trial and whom they decide to involve. The process of informed consent is not just a linear chain of events between the investigators, parents, and child, but a very complex experience. Snethen et al. reported that there are three dimensions or factors of decision-making in the informed consent process**[**11**]**. The first dimension of the decision-making process reported was parental goals for decision-making. The second dimension was how much involvement the child would have in the decision-making about whether the child would participate in the clinical trial. The final dimension was the role a parent thought they would hold in decision making and the degree of input they decided they would have.

In low- and middle-income countries similar to India, poverty, fear of exploitation, and mistrust represent additional challenges[12]. However, clinical research involving children is essential for advancing child health[13]. Without sound drug studies in children, children may not benefit from and may even be harmed by drugs with an indication for use in adults[14].

## Conclusion

The present study was conducted through a questionnaire survey involving parents with a focus on issues persisting with recruitment and recruitment rate in pediatric clinical trials. Educational qualification was also not found to be a significant variable in the perspective of parents regarding enrolling their child in clinical trials. This meant that the variables behind their choices still remain undiscovered. This study also shows a difference in the responses of parents as compared to a survey taken previously. The study identified the key concerns that exists in the minds of parents while agreeing to volunteer their children for such trials.

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