Original Article

A survey of knowledge and variables influencing perceptions about clinical research: A cross-sectional study from Mumbai

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Abstract

Purpose: Clinical research in India has been besieged by controversies. While studies have addressed other stakeholders, few have addressed the patient. The present study was conducted to assess the extent of awareness and understanding about the nature and conduct of CR among people of Mumbai.

Methods: Institutional Ethics Committee approval was taken (EC/OA-12/15) and written informed consent was obtained. Adults who were residents of Mumbai were enrolled. A prevalidated and published 48-item questionnaire based on six themes, namely awareness and participation, voluntariness and autonomy, compensation, confidentiality, safety, and involvement in CR were administered. Perception based on themes and association of variables such as age, gender, socioeconomic class, and education on this perception was assessed. Descriptive statistics along with Chi-square test/Chi-square test for trend and crude odds ratio (cOR) were assessed.

Results: Of the 453 participants approached, 400 (age 32 [18–96]) consented. Only 210/400 (52.5%) were aware of CR and 194/400 (48.5%) said they needed permission for participation. Only 226/400 (56.5%) were aware of their rights and 111/400 (27.75%) felt that clinical trial participants received compensation. The socioeconomic class influenced awareness of CR ($P < 0.00001$; $r^2 = 0.495$) as did the age ($P < 0.0001$; $r^2 = 0.82$). Men were less likely to need permission to participate relative to women (cOR [95% confidence interval (CI)] 2.47 [1.6, 3.6] [$P < 0.00001$]). Those who had heard of CR were twice more willing to participate (cOR [95% CI] 1.72 (1.2, 2.6); $P = 0.008$).

Conclusions: There is a greater need to improve awareness, especially about safety, compensation, and confidentiality in CR.

Keywords: Clinical research, compensation, confidentiality, patient safety, public awareness

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INTRODUCTION

India has emerged as one of the key destinations for the conduct of clinical research (CR) over the last decade.[1] A slew of regulatory changes was introduced in the country in recent times to foster growth of CR and

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protect patient rights. These include, among others, the mandatory registration of ethics committees, specification of conditions required for the conduct of clinical trials, and defining the quantum of compensation for trial-related injuries.[2]

Studies which assessed public awareness and attitude toward CR in India found that people lack adequate understanding about compensation for adverse outcomes and safety of the participants enrolled in trials.[3-6] Similarly, a meta-analysis of seven studies including three from India found that an overwhelming 64% denied participation in research owing to reasons such as mistrust of the trial organization, concerns about safety and efficacy, and breach of confidentiality.[7] Studies have shown that creating awareness, changes the attitude toward clinical trials, enrolment, and the benefits of participation.[8] Furthermore, a well-informed public is always in a better position to safeguard their rights.

Understanding the existing perceptions and knowledge about CR among people is crucial for designing better awareness programs. Mumbai, a cosmopolitan city in India, is home to people from diverse cultural backgrounds, ethnicities, and religions. In addition, a large number of clinical trial sites are located in Mumbai.[9] Despite this, there is no data on the public attitudes and perceptions toward research in Mumbai.

The present study was conducted with the primary objective of evaluating public knowledge and perceptions about CR in the city. A secondary objective was to study the association of variables such as age, gender, and socioeconomic class with these perceptions.

METHODS

Ethics

The Institutional Ethics Committee of Seth GS Medical College and KEM Hospital approved this study and written informed consent was obtained from the participants. The Trial was registered in the Clinical Trial Registry of India (CTRI/2017/07/009066).

Study design

This was a cross-sectional study.

Study site and duration

The study was conducted in Mumbai between June 2015 and October 2016.

Study instrument

A 48-item prevalidated and published questionnaire developed by Tal Burt *et al*.,[5] was used after obtaining permission from the author. The questionnaire was translated into two regional languages, namely Marathi and Hindi by a study team member and the translation authentication was performed by the respective subject experts. Reliability assessment was done for the translated version prior to administration.

Sample size and sampling

The sample size of 400 participants for the study was calculated using Yamane equation.[10] The study team members screened the potential participants from across the 24 administrative wards of Mumbai by visiting public places and residential areas in each ward. Those above 18 years of age and who provided written, informed consent and confirmed their willingness to answer the study questionnaire were eligible and enrolled in the study.

Study procedure

The questionnaire was self-administered, and each participant was given adequate time to answer. Demographic details for the language, monthly income, gender, education, occupation, and age were collected for each participant. Socioeconomic class of the study participants was assessed using the modified Kuppuswamy scale 2015.[10]

Outcome measures

Responses given to the six themes and expressed in proportions and association of that response with variables such as age, gender, socioeconomic class (with education being part of socioeconomic class).

Statistical analysis

Data were analyzed using both descriptive and inferential statistics. The age was expressed as median [range] and gender, language, socioeconomic class, and education were expressed as proportions. The association between the response to the main question (in all six themes) with age, gender, and socioeconomic class was analyzed using the Chi-square for trend, and the strength of this association was expressed as crude odds ratio along with 95% confidence intervals (CIs). All analyses were performed at 5% significance using GraphPad Software version 5.0 manufactured by Graphpad Software Inc. 2365, Northside Dr.Suite 560 San Diego, CA 92108, USA.

RESULTS

A total of 453 participants were screened and counseled out of which 400 participants agreed to participate. A total of 53 participants declined to participate.

Age: Only 353/400 (88.25%) participants had mentioned their age and majority (168/353, 47.59%) were between

the age group of 18–30 years. Gender: More than 50% of the participants were male. Socioeconomic class as per the Kuppuswamy scale: Three hundred and eighty-three out of four hundred (95.75%) participants had mentioned information pertaining to their socioeconomic class and more than >60% belonged to the upper-middle class. Language: More than 50% were Marathi speakers. Education as per Kuppuswamy scale: Three hundred and ninety-seven out of 400 (99.25%) had mentioned their education and 191/400 (48.1%) were either graduates, postgraduates or had a professional degree [Table 1].

Table 1: Demographics of the study participants as per socioeconomic class, education, and language

Variables	*n* (%)
Age (*n*=353)	
18-30	168 (47.59)
31-50	147 (41.64)
Above 50	38 (10.76)
Gender (*n*=400)	
Males	233 (58.25)
Females	167 (41.75)
Socioeconomic class (*n*=383)	
Upper middle class	262 (68.40)
Upper class	47 (13.31)
Upper lower class	56 (15.86)
Lower middle class	15 (4.2)
Lower class	3 (0.84)
Language (*n*=398)	
Marathi	225 (56.53)
Hindi	101 (25.37)
Gujarati	28 (7.03)
Sindhi	10 (2.51)
English	6 (1.5)
Other	28 (7.14)
Education (*n*=397)	
Professional	28 (41.05)
Graduate or postgraduate	163 (7.05)
Intermediate	73 (18.38)
High school certificate	76 (19.14)
Middle school certificate	38 (9.57)
Primary school education	19 (4.7)

Overall response with respect to the six themes [Table 2]

A little over half (210/400, 52.5%) had heard about research and were willing to participate (238/400, 59.5%). An overwhelming (359/400, 89.8%) felt that participation in clinical trials is voluntary, yet (196/400, 48.5%) said they would need permission from a family member or their family physician to participate in research. Majority (342/400, over 80%) had a positive perception about research; however, awareness about compensation for adverse outcomes during study conduct was low (45% – not aware) [Table 2].

Associations within the themes

A few associations were found 1) Awareness with willingness - those who were aware of CR were approximately twice more willing to participate relative to those who were not aware of CR [cOR(95% C.I 2); 1.725(1.15-2.57)] 2) Autonomy and willingness - Those who had autonomy were twice as likely to participate relative to those who did not [cOR(95% C.I); 2.372(1.58-3.57)] 3) Gender and autonomy- Women were twice more likely to need permission to participate relative to men [cOR(95% C.I); 2.5 (1.61-3.64)] [Table 3].

Association of variables on the six themes

Socioeconomic class

The socioeconomic class was associated with awareness (lower awareness in [lower socioeconomic classes relative to other classes ($P < 0.00001$)], willingness to participate [decrease in willingness to participate among lower class; $P = 0.012$], voluntariness [A large number required permission to participate in lower classes; $P = 0.041$], and understanding of confidentiality [higher in upper classes) among the study participants ($P < 0.05$)] [Figure 1].

Age

The age was seen to be associated with awareness [reduced awareness with increasing age; $P = 0.00006$], willingness [reluctance to participate with rising age; $P = 0.0004$] and confidentiality (older individuals less concerned about confidentiality, $P = 0.009$).

Education

Education was also associated with a participant's willingness to participate (willingness being higher with greater education $P < 0.0001$), need for permission (less educated needed permission; $P = 0.001$), belief about confidentiality (more highly educated felt that confidentiality is important; $P < 0.0001$), belief about safety (individuals with higher education had better perception about safety; $P = 0.006$) [Figure 2].

DISCUSSION

We conducted a cross-sectional study among lay people in various administrative wards of the city of Mumbai and found that a majority (>50%) individuals were aware of CR and as many as 60% were willing to participate in the research. The extent of awareness seen by us (52%) was much higher than in the study by Burt *et al*. in Delhi and Joshi *et al*. in Pune where awareness was only 26% and 25%, respectively, among the population sampled[4,5] This variation was seen despite the fact that all three surveys were done in urban cities of India with similar literacy levels and a large number of young people (mean age [±standard deviation]: 32 [±12] in our study vs. 39.6 [±16.6] in Burt *et al*. vs. 39 [±14] in Joshi *et al*.). The extent of awareness reported in the studies conducted in Delhi and Pune as well as our study in Mumbai are expressed in proportions without CIs, and the true difference, therefore, cannot be assessed.

Table 2: Response based on themes

Themes and related questions	Response	Percentage
Awareness and participation		
Have you heard about clinical research?	210/400	52.5
From whom did you hear about clinical research?	Doctor - 46/210	21.9
	Media - 37/210	17.6
	Internet - 17/210	8.09
	Relatives - 18/210	8.5
	Friends - 17/210	8.09
	Colleagues - 10/210	4.76
	Other sources like company training, school, etc., - 24/210	11.42
	Multiple sources - 41/210	52
Are you willing to participate in clinical trials?	Yes - 238/400 (59.5%)	59.5
If yes, what type of study would you like to participate?	Noninterventional - 101/238	42.43
	Low-risk observational studies like single blood draw - 28/238	11.76
	Multiple visit interventional study - 30/238	12.60
	Multiple types of studies - 75/238	31.51
If No, can you state a reason	Concern about safety - 57/157	36.30
	Lack of time - 30/157	19.10
	Lack of trust - 13/157	8.29
Voluntariness and autonomy		
Participation in research is entirely voluntary	True - 359/400	89.8
Would you have to take permission from someone else to participate in research?	Yes - 196/400	49
If yes who would it be?	Family members - 139/196	70.91
Confidentiality		
Confidentiality is a matter of importance to research participants	Yes - 324/400	81
Compensation		
Participants in clinical research get adequate compensation for any adverse outcomes	Not aware - 180/400	45
	No - 103/400	25.75
	Yes - 112/400	28
	Not answered - 05/400	1.25
Safety		
Human participants in clinical research are treated like experimental animals (“human Guinea Pigs”)	64/400	16
Researchers make sure research is safe for participants.	223/400	55.8
Importance of clinical research		
Clinical research benefits society	342/400	85.5

Table 3: Associations within the themes

Associations	Awareness	Number of participants		cOR (95% CI)
		Willing	Not willing	
Awareness with willingness to participate	Yes	138	72	1.725 (1.15-2.57)
	No	100	90	
Associations	**Autonomy**	**Willing**	**Not willing**	**cOR (95% CI)**
Autonomy to participate with willingness to participate	No	142	63	2.372 (1.58-3.57)
	Yes	95	100	
Associations	**Participants**	**No autonomy to participate**	**Autonomy to participate**	**cOR (95% CI)**
Gender and autonomy to participate	Women (*n*=167)	103	64	2.5 (1.61-3.64)
	Men (*n*=233)	92	141	

cOR: Crude odds ratio, CI: Confidence interval

Physicians were stated as being the main source of knowledge about CR by most participants (21.9%) in our study. In the Pune study, similarly, 72% of participants knew about CR through physicians.[4] The greater willingness to participate in research among our participants was associated with low risk and noninterventional studies. This was similar to a study by Decosta *et al*.[11] conducted in rural North India, which found that participants preferred CR involving interview-based and low-risk studies that had a single blood sample collection.[12] Another study by Thaker *et al*. which assessed the reasons for consent refusal in CR had identified “*concerns about the risk*” as one among the several factors influencing the decision to participate.[13]

Individuals who were aware of CR were more willing to participate in CR as per our study. This finding was

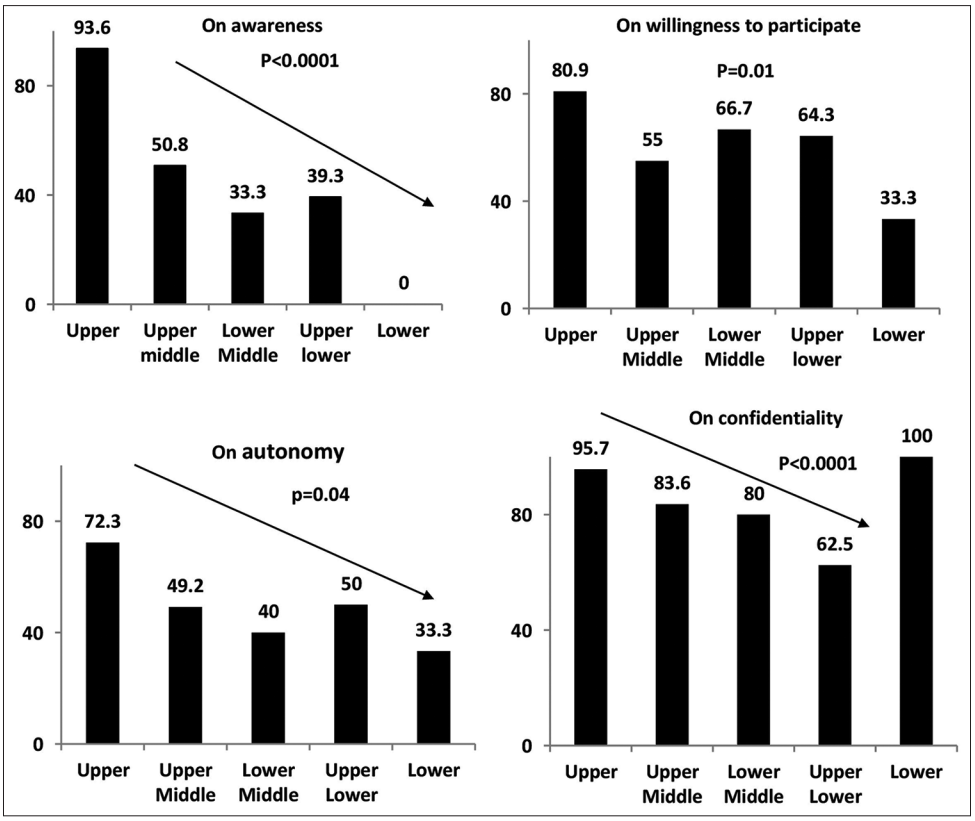

Figure 1: Association of socioeconomic class with the themes

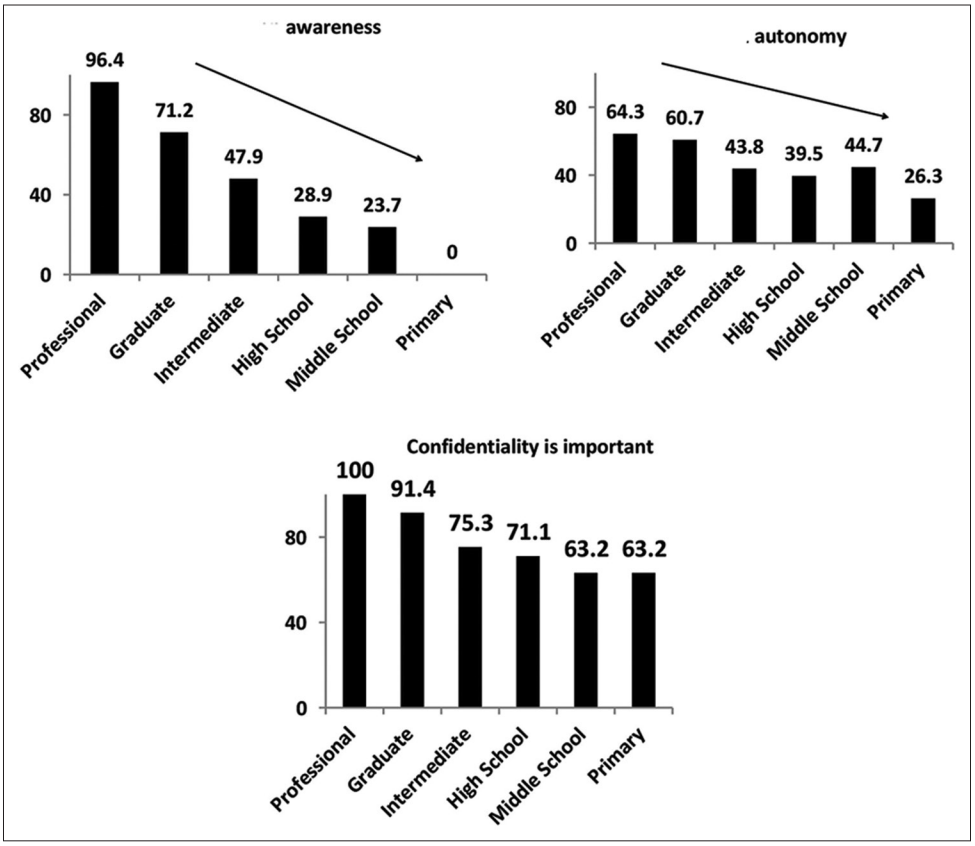

Figure 2: Association of education on the themes related to clinical research

corroborated by the findings from the "Haris interactive" survey conducted in a high-income country[14] in 2001 where it was seen that the majority (75%) of interviewed participants would have enrolled in a trial had they been made aware of it.[8]

An overwhelming number (89.8%) of individuals believed that participation in CR is voluntary yet; very few had the freedom to participate without consulting a family member or a physician. The "*need to seek permission"* before participating in a clinical trial reflects the social fabric of the country where decision-making process of an individual is invariably a "joint" decision of the individual with his/her family or even community.[15] Studies from various developing settings indicate that the decision of the females to participate in CR was especially guided by their spouse or a family member.[16] The low recruitment of women in CR with a high dropout is a reflection of this limited autonomy in women.[17]

The willingness to participate was better among individuals from upper socioeconomic class, as well as younger and individuals with a higher education. One of the reasons suggested by Unger *et al*., for less willingness among lower-income groups is the concern about excess expenditure which might be incurred during participation.[18] Our observation, however, differs from a study conducted by Chu *et al*., in the urban and rural areas of South Korea who found no correlation between age, gender, socioeconomic class, and education on the willingness to participate.[19] Social systems have the ability to impact an individual's attitude, knowledge, and decision-making regarding participating in CR;[20] and therefore, the setting in which CR is conducted may influence perceptions.

We found that many of the participants (68%) believed that the confidentiality of research participants is adequately protected by researchers. The belief in physicians (as researchers) among Indian patients is further corroborated by a study conducted by Doshi *et al*. in India that assessed the reasons that motivate participants to consent for nontherapeutic trials and found that 88% considered participation mainly on the physician's request.[21]

We observed that a majority (55%) of the participants perceived that research was safe for participants, and this observation is similar to a study conducted in Mexico by González-Saldivar *et al*. in which they found 68.95% of the individuals who had not participated in trials felt "*protected in case of a serious adverse event related to the experimental drugs*."[22] In our study, we found that 45% of the participants were not very well aware of compensation for adverse research-related events, and 25.7% believed that compensation is not given in CR. Despite regulations for compensation in case of serious adverse events,[23-26] the lack of awareness remains a concern.

An overwhelming number of participants in our study emphasized the importance of CR with 93% stating that "*Clinical Research was important in the development of new treatment*." This observation is similar to the findings from a qualitative study conducted in Ghana, where participants believed that trial studies are needed to determine efficacy and to "*come out with new knowledge on whether the drugs were suitable for human beings to use*."[27]

Our study is limited by the fact that it is cross-sectional and therefore inferences about causality cannot be truly drawn. The distribution of the participants with respect to socioeconomic class may not represent the actual census data for the city of Mumbai as classification was based on the Kuppuswamy scale[12] and census data on socioeconomic class was unavailable at the time of conduct. There is selection bias in the study due to the operational challenges such as denial of permission by some residential societies, and thus, those who agreed when approached were ultimately enrolled. A pre-validated questionnaire was used, and only reliability analysis was done for the translated versions.

CONCLUSION

In summary, our study showed that potential participants in Mumbai were aware of CR and their rights as research participants. However, they were less aware of key aspect like compensation for trial-related injuries and safety of trial participants in CR. The study provides baseline awareness about CR in the city, and awareness programs about CR will help promote patient engagement in trials beyond mere participation.

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Conflicts of interest

Authors have no competing interest to state.

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