Original Article

Public awareness and perception of clinical trials: Quantitative study in Pune

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Abstract

Context: Studies have reported that clinical research has experienced tremendous growth during past few decades with many multinational pharmaceutical companies recruiting millions of Indians in clinical trials (CTs). However, there is hardly any literature that talks about the participants, their knowledge, and awareness of CTs. It is important that the general public is aware about CTs so that they can take their own informed decision to participate in CTs. **Aim:** To assess public awareness, perceptions, and attitudes toward CTs and their views on various methods to create awareness about CTs. **Materials and Methods:** Cross sectional survey was conducted with 200 non trial participants (NTPs) and 40 trial participants (TPs). **Results:** TPs were significantly ($P < 0.0001$) older than NTPs. More than 80% of both TPs and NTPs mentioned participation in CT helps advance medical science and strongly felt that there is a need to create awareness about CTs. Nearly 70% of TPs could not remember the phase of the trial while 20% did not know which type of trial they had participated**.** The main reason for participation in the trial was physician's advice. About 80% of both TPs and NTPs felt that participation in CT will increase with free medications and advice from friends/relatives who had good experience with trial. **Conclusion:** Results of this pilot study revealed need to create CT awareness among the general public. However, considering ethno-cultural, regional, and literacy-level differences throughout the country, a nationwide study would be appropriate to provide reliable results about awareness of CTs among Indians.

Key words: Attitude, awareness, clinical trial, perceptions, public

INTRODUCTION

Clinical trials (CTs) have laid the foundation for impressive medical advances that have occurred in the past few decades. In spite of this, there are many diseases for which we still do not have treatments or only poor ones or with side effects and hence there is a need to improve these treatments. CTs are important because doctors and patients need evidence to know which treatments work best for particular type of patients. Without this evidence, there is a risk that people could be given treatments that have no advantage or might even be harmful.

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A lot has been said about CTs on various drugs, devices, treatments, surgical procedures, India's vast population with different types of diseases, multinational companies conducting trials in India,[1] and the revenue generated by pharmaceutical companies, but very few talk about the participants without whom CTs would not have been possible. By participating in CT, TPs assist researchers

understand the diseases, improve treatment therapies, asses safety of treatments and how well they work as well as study new ways to prevent, detect or treat the disease.

India's pharmaceutical industry, considered the world's third-largest by volume, is likely to lead the manufacturing sector.[2] Although the picture looks good for pharmaceutical industry, several news articles have emphasized on the unethical conduct of some CTs. Sree Sudha has reported in her article that cancer drug was tried on people without getting their consent and denying them the established treatment. The same author has given another example where the drug was tried on humans without conducting the toxicology study on animals.[3]

In this context, few researchers have tried to find out about the participants who volunteer for the research experiment, their knowledge, awareness, perception, and *attitude* toward participation in CTs. Few institutions formally teach what a CT is, and there are no significant efforts for public awareness through workshops, seminars, or mass media like programs on radio, TV, and write-ups in the print media. There is hardly any literature that talks about public awareness of CTs. Studies have been carried out in the West because patient recruitment is difficult particularly for cancer trials.[4,5] Meta analysis of qualitative studies revealed that advice from physician was one of the motivating factors for Indians to participate in the CT.[6] Participants also entered CTs for money and to get free treatment.[6,7] However, it has been observed that awareness about CTs as a treatment option is extremely low as seen in a study among cancer patients.[8] Several studies indicate that creating public awareness changes *attitudes* toward CTs, enrolment, and the benefits of participation.[9] Today, the world over, a need has been felt for transparency, accountability, and accessibility in CTs in order to re-established public trust in CTs.[10] Hence it would be highly beneficial to create awareness among the general public about CTs.

In view of this, a study was planned with the objective of reporting public awareness about, perception of, and *attitudes* toward participation in CTs. The results of this study would help in planning target-specific education programs for the general public about CTs. India being a multicultural country; this study has to be carried out at national level. Increase in awareness about CTs would certainly be beneficial to the public as they will be able to make their own decision about participation rather than depending on others. Moreover, they can get free treatment especially when there is no treatment available and they will be able to protect themselves from any unethical conduct by trial conductors. From the investigators' point of view, they will benefit by getting the right kind of patients and volunteers for the right trials. Additionally participants' compliance with trial procedure will increase and the results would improve.

MATERIALS AND METHODS

Cross sectional survey was conducted with Non Trial Participant (NTP) and Trial Participant (TP) after getting approval from Institutional Ethics Committee of Deenanath Mangeshkar Hospital and Research Centre (DMHRC).

NTPs and TPs were recruited by contacting friends and relatives of patients who were seeking treatment at outpatient clinics at a tertiary hospital in Erandawane, Pune. The recruitment criterion for NTPs was age above 21 years, they themselves and their friends or relatives have never participated in a CT, and they are willing to participate in this study. Few TPs were recruited by contacting doctors and showing them the survey questionnaire. The recruitment criteria for TPs was age above 21 years, he/she is/was a TP and was willing to participate in this study.

To recruit NTPs, we used stratified sampling based on socioeconomic status (SES) of participants for each of eight SES categories (Table is shown in Appendix A). Recruitment of TPs was totally dependent on the availability and willingness to participate in the study.

Questionnaire was designed based on the themes derived from Focus group discussions,[11] which were conducted during November–December 2011. Additional questions related to participants' experience with the trial were included in the questionnaire that was used for TPs.

The questionnaires included questions about CT awareness and perceptions of CT in addition to demographic information. TPs were asked the phase and type of trial they had participated and the same questions on perceptions of CT were asked to NTPs. Twenty-seven questions were asked to assess participants (both NTP and TP) perceptions toward CT. Answers for these questions were scored using five point Likert scale: Strongly agree (score of 1) to strongly disagree (score of 5). The total 27 questions were divided into nine categories. The weighted average was found for these nine categories.

- Freedom and respect for participant's decision: four questions (4Q)

Reasons for participation or no participation:

- Treatment benefits (2Q),
- Society benefits (3Q),
- Benefit for science (2Q)
- Institutional/doctor's benefit (1Q),
- Life risks (3Q)
- Trust (4Q),

About CT awareness
- CT awareness (4Q), and
- How to create CT awareness (4Q)

Index score was found for the 9 categories of 27 questions on perceptions. Index score was out of 5. Two research coordinators were trained to conduct the survey. Higher SES was defined as education at college level and above. Data was entered in Excel. Analysis was carried out using SPSS-20. Statistical tests used were *t* test, chi square test, and analysis of variance (ANOVA).

RESULTS

Non trial participants

CT awareness

Total 235 people were contacted. 200 out of 235 (85%) people agreed to participate in the study and completed the questionnaire. Analysis was based on responses from these 200 participants.

Average age of NTPs was 39 ± 14 years. 64% of the participants were below 40 years of age. 48% were men [Table 1]. Sample was stratified according to eight categories of SES, each group of SES had equal number of participants (12.25%).

When asked "Are you aware of CTs?" 25% of the respondents claimed that they were aware of CTs. These respondents got the information about CT from multiple sources such as looking at advertisements of medicines on TV (35%), discussions with relatives/friends (39%), from internet (35%), reading about CT course in news papers (65%) and from doctors (43%).

Out of these 25% respondents who claimed that they were aware of CT,
20% did not know that CTs are conducted on animals
16% did not know that CTs are conducted on humans
6% did not know that CTs are conducted for the development of new drugs and
18% thought that CTs are conducted only on terminally ill patients.

Table 1: Demographic characteristic of non trial participants and trial participants

Variables	Non trial (%)	Trial (%)	*P* value
Age (years)			
<40	10 (25)	129 (64.5)	<0.0001
40-50	6 (15)	28 (14)	
>50	24 (60)	43 (22)	
Average age (years)	38.87±14	50.98±14	
Gender			
Male	97 (48)	24 (60)	0.184
Female	103 (52)	16 (40)	
SES: Socio economic status			
Higher (college and above)	129 (65)	24 (60)	0.589
Lower (below college)	71 (36)	16 (40)	

Perception of CT

27 questions were asked about perceptions and these can be grouped into 9 categories.

The highest ranking given by the participants was for respecting participant's decision to participate (4.38). The second highest ranking given by the respondents was for the need to create awareness (4.36).

Significantly (P =0.035) more participants perceived participation in CT for advancement of medical science and for benefit of society rather than for their monetary benefit.

89% NTPs showed full trust with the doctor by saying that participation in a CT would be safe when advised by the doctor.

Most of the NTPs (88%) strongly agreed that signing consent for participant should be a must. If participant is a child, consent from the parent should be taken (88%).

Respondents believed that participation in a CT would increase if there is no other medicine for the particular disease (65%), if the drug is useful to improve their health (88%), if it is given free of cost (73%), if someone had a good experience with the drug (84%) and if doctors share the trial results with the public (80%).

For participation risk, equal number of respondents (46% each) had agreed and disagreed. 8% remained neutral.

Need to create CT awareness

Almost all the participants strongly agreed that CT awareness should be created among the general public (97%). CT awareness can be created by conducting seminars, putting trial-related posters in hospitals, clinics, conducting seminars, workshops and talks. Print media is also a best way in addition to radio and TV.

TP

As shown in Table 1, average age of TPs was 51 ± 15 years. 60% were men and more TPs were in lower SES as compared to higher SES. Participants in lower SES were older (53 years vs 40 years) as compared to participants in higher SES (P = 0.036)

Most of the TPs (72%) came to know about the CTs from their doctors. The remaining 28% got the information from clinic and their family members. Of these 72%, most (88%) got the CT information from doctors other than family doctors.

Most of the TPs (93%) had mentioned that the CTs were conducted at private hospitals while 7% of TPs had participated in a trial at clinics. 28/40 (74%) of the respondents participated in the trial because their doctor advised them and out of these 74%, for 71% (20/28) participants, this was their voluntary decision. 11% of the TPs thought the study to be promising. Almost all participants' family members were agreeable (98%) for their participation in the CTs. TPs participated in drug trials (65%), surgical intervention (7.5%), behavior trials (5%), device trial (2.5%) and 20% did not know which type of trial they had participated. Four, one and two TPs participated in phase one, two and three trials respectively. However, 70% of the TPs did not know the phase of the trial they participated and 13% could not remember.

Signing informed consent form (ICF)

36 (92.5%) TPs remembered that they had signed ICF before participating in the CTs, 2.5% had signed whatever their family member had asked them to sign and 5% (two participants) of older TPs (age above 60 years from lower SES) did not remember if they had signed any document.

TPs remembered that they were told; whom to contact for any reasons/queries (88%), benefits (75%) and risks (60%) of the clinical trial and they were assured that the results of trial will be informed to all participants (63%).

None of the TPs had withdrawn from the CTs.

TPs perceptions

TPs perceived that participation in CTs should be voluntary (97%), CT would advance medical science (87%) and would help society (86%). It seemed that risk from the trial was not a major issue for 56% of the participants. 69% of TPs thought that TPs are used for experimental purpose and according to 59% TPs there is a possibility of getting side effects of the drug. TPs agreed that people do not want to take part in CT because they do not trust Pharmaceutical companies. Also about half of the TPs felt that by taking part in a trial, they are helping doctors or hospitals.

Significantly more participants from higher SES (college and above) as compared with lower socio economic status believed that signing informed consent form is a must before participating in a trial ($P = 0.037$) and clinical trial will advance medical science ($P = 0.036$).

Significantly ($P = 0.014$) more men than women believed that people do not want to participate in a trial because they do not trust Pharma companies.

Age wise no difference was observed in term of perception.

We wanted to assess the curiosity of the participants, that is, if the TPs clarified their droughts related to the trial before they actually sign the consent form. The results are shown in Figure 1. About half of the participants did not ask if the treatment had been tried out before, whether participant will be treated if any adverse events happen while they were on the trial, confidentiality of their information, purpose of the study, duration of the study, etc.

Men were more inquisitive as compared to women; significantly more men wanted to know what will happen if trial subject falls sick while on trial ($P = 0.01$), about travel allowance ($P = 0.01$) and if subject can withdraw from the CTs anytime ($P = 0.046$).

Age-wise, more younger TPs (<50 years of age) as compared with TPs aged above 50 years, asked the purpose of the study ($P = 0.003$, 81% vs 33%) and if the treatment had been tried before ($P = 0.054$, 50% vs 20%). SES wise no significant difference was observed.

Difference and similarities between TP and NTP

TPs were significantly ($P < 0.0001$) older than NTP. Gender and SES-wise no significant difference was observed between TP and NTP. Significantly more *TPs* knew about phases and different types of *CTs* as compared with NTP.

Perception wise, significant differences were observed between TP and NTP [Table 2]. Significantly ($P < 0.05$) more NTPs as compared with TPs felt that CT participation should be voluntary, participation in CT will increase if free medicines are given to TP, advice from friends/relatives who had good experience with the trial would increase participation in the clinical trial and TV serial on clinical study is the best way to create awareness about clinical trial. Significantly more TPs as compared with NTPs believed that people do not want to participate in a CT because they do not trust Pharma companies.

Both, NTPs and TPs have perceived CT similarly. Both thought that CTs are useful for society and advancement of medical science. Besides that no significant difference

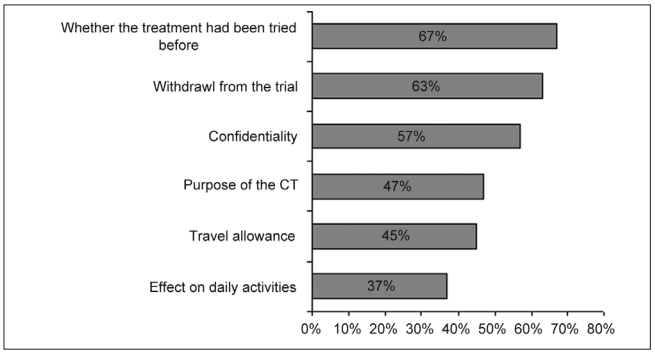

Figure 1: Participants did not ask following information before signing the consent

Table 2: Perceptions about CTs (Using 5 point Likert scale) (1=strongly agree and 5=strongly disagree) Numbers in bold indicate which group the difference is higher

Questions	Non trial participants (NTPs)		Trial participants (TPs)		*P* value
	Mean	Std. deviation	Mean	Std. deviation	
Participation in a clinical trial should be voluntarily	1.44	0.716	1.18	0.69	0.046
People do not want to participate in a clinical trial because they do not trust pharma companies	2.43	1.291	3.09	1.48	0.009
Advice from friends/relatives who had good experience with the trial would increase participation in the clinical trial	1.86	0.991	1.50	1.109	0.044
Participation in trial would give free medical care	2.01	1.166	1.59	1.18	0.045
TV serial on clinical study is the best way to create awareness about clinical trial	1.65	0.911	1.29	0.835	0.023

Table 3: Perception Index

Scale	Non trial participants (NTPs)	Trial participants (TPs)
Expectation of freedom/respect of participant's decision	4.38	4.65
Reasons for participation		
Treatment benefit	3.94	4.13
Advance medical science	4.06	4.40
Benefit for society	4.36	4.49
Institutional/doctor benefit	2.68	2.39
Life risk	3.54	3.5
Trust	4.03	3.96
Need to create awareness	4.35	4.70
How to create awareness	4.36	4.60

was found for perception index between TP and NTP [Table 3].

DISCUSSION

The important finding of this study was the need felt by both TP and NTP to create CT awareness among the general public.

TPs and NTPs both felt that participation in a CT should be voluntary and agreed on usefulness of conducting CTs, importance of signing a consent form, facility for the participant to withdraw from the trial without giving any reason, and ways to improve CT participation.

NTPs seemed unaware about the management and conduct of CTs.

Results have shown altruistic attitude of TPs and NTPs toward participation in CTs, they would like to participate in the study for the improvement of the health of the society and for the benefit of medical science. This result is consistent with a study carried out on participants in the Women's Estrogen for Stroke Trial; women's reasons for participation in the trial were found to be of an altruistic nature.[12] Other reasons like monetary gain and getting free treatment were also important for participation in a CT. This result was consistent with the findings from meta analysis study by Shah.[6] From this pilot study it was noticed that, though, about 25% of the respondents had said that they were aware of CT, not all had clear knowledge of CT. It appeared that these 25% of the respondents perceived CT as some information related to medicine or a course in clinical research. It was also noted that even before participating in the trial, the TPs were not inquisitive or curious enough to know the details about the CT. This was probably because they were embarrassed because they were older and came from lower SES background.

In most of the countries, recruitment for CTs is not easy. In India, it was observed that participants participated without knowing many things about the trial and it was noticed that participants' participation was only based on trust in the physician. We found this result to be consistent with results from a meta analysis study that showed that a recommendation by their physician was the primary factor influencing patients' decision to enroll in a trial.[6] Participants from our study did not take any initiative to find out the details of the trial, for example, what is the objective of the study, if confidentiality of his records will be maintained, safety, and compensation, etc., It is important to bring about patient awareness so that voluntary, educated, and informed decision-making would be possible on the patients' part.

Studies have reported unethical conduct of trials.[3] Awareness will help the participant to decide about safety, duration, compensation, who should participate in the trial and participant's rights.

Results of this study helped us in understanding the lack of awareness about CT among the general public. This was only a pilot study. Small studies may produce less reliable results than the large ones. Hence a nationwide study is necessary to prove the reliable results of lack of CT awareness among Indians.

Appendix A: Socio-economic classification grid

Education/ occupation	Illiterate	School up to 4 years/illiterate but no formal schooling	School 5-9 years	SSC/ HSC	Some college but not graduate	Graduate/ post graduate general	Graduate/ post graduate professional
Unskilled workers	E2	E2	E1	D	D	D	D
Skilled workers	E2	E1	D	C	C	B2	B2
Petty traders	E2	D	D	C	C	B2	B2
Shop owners	D	D	C	B2	B1	A2	A2
Entrepreneurs employees none	D	C	B2	B1	A2	A2	A1
Entrepreneurs employees <10	C	B2	B2	B1	A2	A1	A1
Entrepreneurs employees >10	B1	B1	A2	A2	A1	A1	A1
Self-employed professionals	D	D	D	B2	B1	A2	A1
Clerical/salesmen	D	D	D	C	B2	B1	B1
Supervisory level	D	D	C	C	B2	B1	A2
Officer/executives:-junior	C	C	C	B2	B1	A2	A2
Officer/executives:-middle/senior	B1	B1	B1	B1	A2	A1	A1

LIMITATIONS

The study was conducted in a particular area of the city, which may have created sample bias. There is no standard validated questionnaire to assess the awareness and perceptions. Therefore the results of this study are based on our developed questionnaire. There is lack of literature on the same topic in India and even outside India and therefore it was not possible to compare results of our study in comparison with other populations.

CONCLUSION

There is an urgent need to increase public awareness and understanding of clinical research in India. Television, radio and newspaper advertising should explain the public the importance of CT, importance of informed consent document, understanding the pre requisites of conducting a trial and participants' rights. The media campaigns should include interviews of TPs and results of completed successful trials. Further efforts would be required on evaluation of this hard work of creating and spreading messages and campaigns.

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