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Research article

A Questionnaire based Survey on Awareness of Clinical Trials among General Population.

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ABSTRACT

The aim of the questionnaire based survey was to find the extend of awareness of clinical trials among general population among the different category of people in Chennai. The project was carried out among the general population living in and around Chennai. While recruiting the subjects care was taken to include different strata of the society and the informed consent was obtained from each subject before starting the study The participants was provided with the "Evaluation tool to assess the perception of clinical trials among general population".

KEY WORDS: Clinical trial, History of clinical research.

INTRODUCTION

Clinical trial is a research work conducted in human subjects intended to study the safety, efficacy and pharmacokinetic parameter of a new investigational product, procedure or a device.

History of clinical research

The fundamental tools of modern medicine are research and the clinical trials in fact, the clinical trial has contributed to nearly all the life saving medicines available today The evolution of clinical research dates back to 3000 years. The ancient Egyptians (1500BC) regularly documented their prescriptions. It wasn't until 600 BC in the Book of Daniel the Bible describes what might be the first comparative trial. Daniel tested two diets to see which was healthier, a vegetarian diet or a diet rich with meats and wine. After a 10-day test, the vegetarian diet was judged most healthy. The first modern clinical trial was conducted in 1946. British epidemiologist, Sir Austin Bradford Hill put patients into experimental and control groups at random. This eliminated any bias that only the test medicine would account for differences seen in the health of the two groups. With the establishment of guidelines for ethical clinical trial conduct and regulations for drug development, more than 1019 novel drug therapies have been approved by the Food and Drug Administration – that's virtually all the medicines used today [1].

Phases of clinical trials

Phase I

Phase I trials are the first stage of testing in human subjects. Normally a small (20-50) group of healthy volunteers will be selected. This phase includes trials designed to assess the safety, tolerability, pharmacokinetics, and pharmacodynamics of the investigational agent.

Phase II

The initial safety of the study drug has been confirmed in phase I trials. The primary objective of phase II trials is to explore therapeutic efficacy in patients. Phase II trials are performed on larger

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groups (20-300) and trials are usually randomized and controlled to evaluate the efficacy of the drug and its safety for a particular therapeutic indication.

Phase III

Phase III studies are randomized controlled multicenter trials on large patient groups (300-3000). Primary objective of this study is to confirm therapeutic benefit. Phase III trials assess the effectiveness of the drug and are compared with current 'gold standard' treatment. Because of their size and comparatively long duration phase III trials are expensive, time consuming and difficult trials to design and conduct the trial. Certain phase III trials will continue while the regulatory submission is pending this will allows the patients to receive possibly lifesaving drugs until the drug can be obtained in the market. Other reasons for performing trials at this stage are to obtain additional safety data or to support marketing claims for the drug.

Phase IV

Phase IV trials are also known as Post marketing surveillance trial. Phase IV trials involve the safety surveillance and ongoing technical support of drug after it receives the approval for marketing. This studies include additional drug-drug interaction, dose-response or safety studies and studies designed to support use under the approved indication. The safety surveillance is designed to detect any rare or long term adverse effects over a much larger population and longer time period than was possible during the phase I – III clinical trials [2,3].

Development of Clinical Trials

The first clinical trial of a novel therapy was conducted unintentionally by the Renaissance surgeon Ambroise Pare in 1537. He used a concoction of turpentine, rose oil and egg yolk to prevent the infection of battlefield wounds, noting that the new treatment was much more effective that the traditional formula. James Lind documented the fact that citrus fruits in the diet could prevent scurvy. From 1800 onwards, clinical trials began to proliferate and more attention was paid to study design. Placebos were first used in 1863, and the idea of randomization was introduced in 1923. The first trial using properly randomized treatment and control groups was carried out in 1948 by the Medical Research Council, and involved the use of streptomycin to treat pulmonary tuberculosis [4].

Global Scenario in Clinical Research

Clinical trials market now witness a paradigm shift. A Naïve heterogeneous patient population in the developing nations is opening up new avenues for the clinical trials market. Developing countries also offer faster go to market which is triggering major pharmaceutical companies to direct their investment in these regions. Apart from this, stringent regulations and tight R&D budgets in the Pharma-Biotech industry are also forcing companies to move to east. This scenario has further boosted the alliances between the Pharma-Biotech companies and the clinical research organizations, with the latter accounting for major chunk of the trials conducted [5]. Over the years the cost of inventing new drugs (NCEs) or biological is increasing due to global inflation and this is increased from $ 802 million in 2003 to $ ~1.2 billion in 2010. Due to this high cost incurred the companies around the world are focusing more on development of existing drugs with new dosage forms [6].

Indian Scenario in Clinical Research

Till 1990, India was not the preferred destination for major global pharmaceutical companies, even though some of them were conducting clinical trials here. In the last 10 years however, there has been a steep rise in the global demand for world class clinical trial management capacity and productivity. The international biopharmaceutical sector now finds India's pool of highly skilled doctors, trained medical personnel, investigators, and the support research infrastructure to be highly attractive and as a result, large numbers of international companies are now viewing India as a potential center of knowledge, skills and resources, and are hoping to derive expertise-based synergies from Indian partners [7].India presently occupies only a small quiche of the global market. The total numbers of clinical trials conducted in India were 221 in 2007 and had increased to just over 700 trials in 2008. Although there was an increase of 65%, it associates to only single digit percentage of the global clinical trial market. The country is projected to conduct nearly 5% of the global clinical trials by 2012. However, to achieve its goal of becoming a global center of clinical trials, the country has to overcome few challenges [8].

Challanges in Clinical Research

Information flowing from the clinical research enterprise directly influences over the cost, quality, and efficiency of our health care system. The pressure for our clinical research enterprise to produce high quality information and to speed the translation of advances from basic science to clinical care, and then to better health, will continue to grow [9]. Even more serious is the lack of confidentiality. Unlike China, India does not yet grant protection for data gleaned from clinical trials, which makes it easy for generic drug makers to copy the drug under trial. Under India's existing laws, only those drugs that have already passed Phase 1 safety trials in the country of their origin can be tested on Indians. In India, opportunities will become limited unless there is a very strong patent law and mechanism to enforce it. Drafting patent laws with the help of industry experts and its implementation is highly essential [10].

METHODOLOGY

A preliminary version of the questionnaire was assembled using information from the literature. It was then reviewed by experts not directly involved in the study design, tested in a small independent sample of health consumers, then administered twice to a small group of students. Debriefing interviews to test face validity and formally evaluate reliability showed which were the most valid and reliable questions. The final version was regarding awareness and opinions about general issues pertaining to clinical research and regarding the attitude towards participation in clinical trials.

Briefly, the questions were about the awareness of clinical trials

Perception of clinical trials

	Yes / No
1. Have you heard "clinical trial"?	
2. Do you know what clinical trial is?	
3. Do you know why Clinical trials are conducted?	
4. Is a clinical trial, an experiment in humans?	
5. Do u think will the clinical trials benefit the society?	
6. Are clinical trials unethical?	
7. Is there risk involved in participating in a clinical trial?	
8. Is it necessary for a company to get approval from the government for conducting a clinical trial?	
9. Will the participant be paid money to participate in a clinical trial?	
10. Should India allow pharmaceutical companies to conduct clinical trials in India?	

Describe clinical trial in your own words.

RESULTS & DISCUSSION

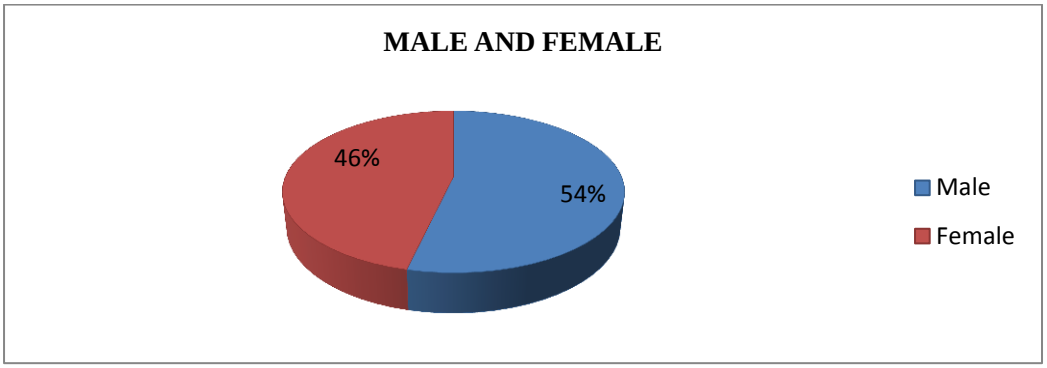
A total group of 505 participants were participated in this survey. Among them 272 were males and the remaining 233 were females. Their age, educational qualification, annual income are provided in Tables 1.2, 1.3 & 1.4 and also in Figures 1.2, 1.3 & 1.4. The mean age, annual income, education qualification was 33.22, 157582.18 and 63.12.

The knowledge of clinical trial was assessed through the evaluation tool given in annexure 1

TABLE 1: Gender distribution

GENDER DISTRIBUTION	NO	%
MALE	271	53.66
FEMALE	234	46.34
TOTAL	505	100.00

FIGURE 1. Male and Female

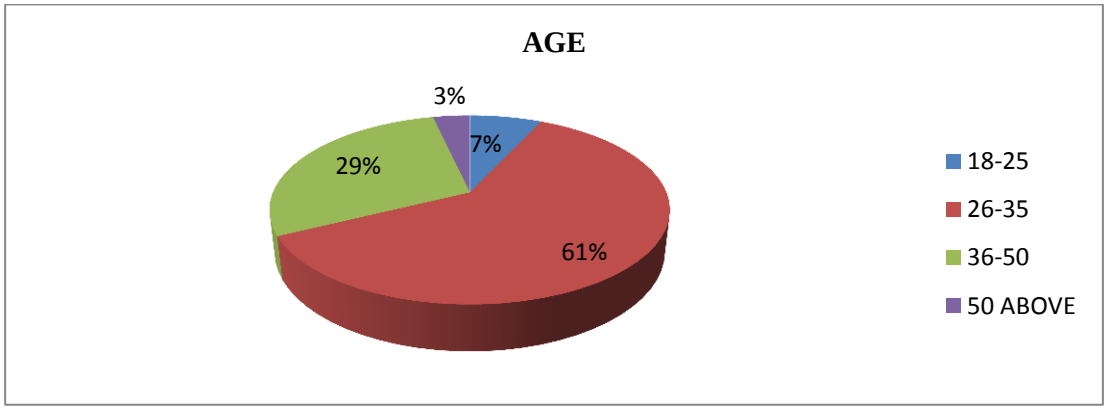


Among the participants 61% were in the age group of 26-35 and 29% in 36-50, 7% in 18-25 and the remaining 4% were 50 years and above.

TABLE 2 Age distribution

AGE	NO	%
18-25	35	6.93
26-35	307	60.79
36-50	145	28.71
50 ABOVE	18	3.56
TOTAL	505	100

FIGURE: .2 Age distribution

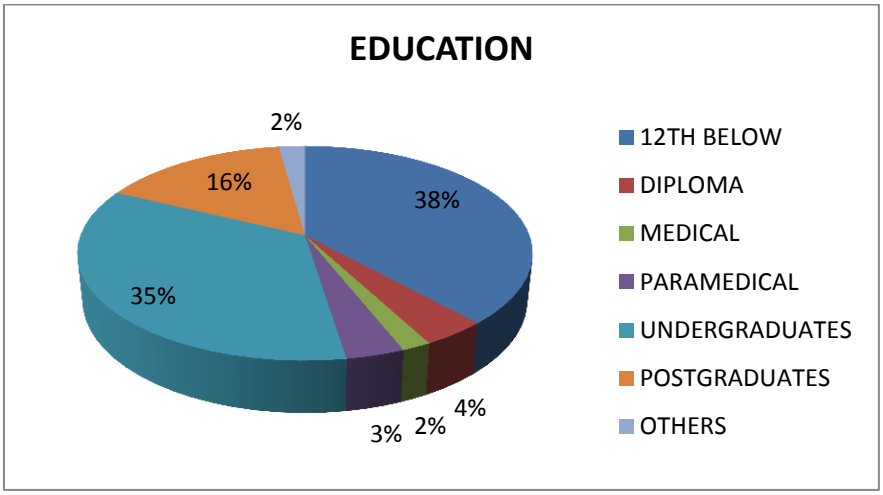


Among the participants 23% of participants were 12th standard and below, 35% of them were undergraduates, 16% were postgraduates, 4% of participants were diploma holders, 4% were paramedical workers and the remaining 1% was from medical personnel.

TABLE: 3 Educational qualifications

Categories	NO	%
12TH BELOW	193	38.22
DIPLOMA	20	3.96
MEDICAL	9	1.78
PARAMEDICAL	18	3.56
UNDERGRADUATES	175	34.65
POSTGRADUATES	79	15.64
OTHERS	11	2.18

FIGURE: .3



All the 505 participants responded to all the questions and response rate was 100%. Maximum number of correct answers was obtained for the questions 6 and 10 and both the questions were related to general information regarding clinical trials. 79% of participants reported that clinical trials are ethical and 59% stated that regulatory authorities should allow pharmaceutical companies to conduct clinical trials in India.

58% of participants responded correctly to the question on the necessity to get government approval to conduct clinical trials. More than 50% of participants were reported that the clinical trials benefit the society and there is no risk in participating in trials. 46% of participants quoted that clinical trial is an experiment conducted in human. 44% of them reported that they will get compensation for the participation in clinical trials. Around 60% of participants reported that they don't know what clinical trial is and why it is conducted. 64% of people are not aware of the term clinical trial.

TABLE: 4 Response from participants

	CORRECT	**INCORRECT**
QUESTION	%	%
Q1	35.84	64.16
Q2	40.2	59.8
Q3	42.97	57.03
Q4	45.54	54.46
Q5	54.46	45.54
Q6	79.01	20.99
Q7	48.71	51.29
Q8	58.22	41.78
Q9	43.76	56.24
Q10	59.21	40.79

Figure 4.Response from participants

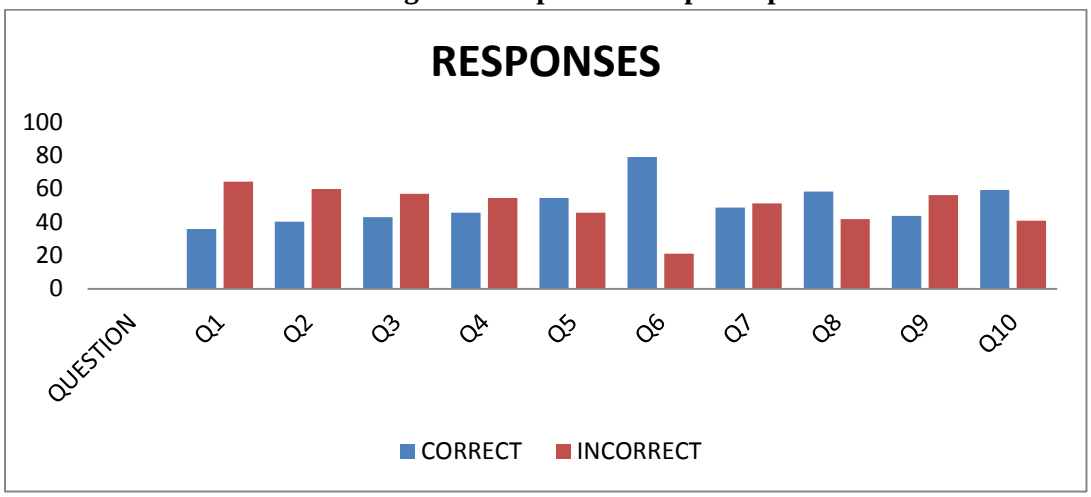


Table 5. Education

Education / Question	10th and 12th	Medical and Paramedical	Diploma & UG	Post Graduate	CHI-SQUARE(P-Value)
Q1					.001*
NO	159(77.9)	4(14.8)	115(59.3)	46(57.5)	
YES	45(22.1)	23(85.2)	79(40.7)	34(42.5)	
Q2					
NO	151(74.0)	4(14.8)	103(53.1)	43(53.8)	.001*
YES	53(26.0)	23(85.2)	91(46.9)	37(46.3)	
Q3					
NO	132(64.7)	7(25.9)	100(51.5)	48(60.0)	.001*
YES	72(35.3)	20(74.1)	94(48.5)	32(40.0)	
Q4					
NO	121(59.3)	5(18.5)	112(57.7)	36(45.0)	.001*
YES	83(40.7)	22(81.5)	82(42.3)	44(55.0)	
Q5					
NO	111(54.4)	7(25.9)	87(44.8)	25(31.3)	.001*
YES	93(45.6)	20(74.1)	107(55.2)	55(68.8)	
Q6					
NO	172(84.3)	23(85.2)	142(73.2)	61(76.3)	.040*
YES	32(15.7)	4(14.8)	52(26.8)	19(23.8)	
Q7					
NO	128(62.7)	8(29.6)	93(47.9)	29(36.3)	.001*
YES	76(37.3)	19(70.4)	101(52.1)	51(63.8)	
Q8					
NO	95(46.6)	4(14.8)	80(41.2)	31(38.8)	.016*
YES	109(53.4)	23(85.2)	114(58.8)	49(61.3)	
Q9					
NO	121(59.3)	6(22.2)	109(56.2)	48(60.0)	.003*
YES	83(40.7)	21(77.8)	85(43.8)	32(40.0)	
Q10					
NO	90(44.1)	8(29.6)	71(36.6)	37(46.3)	.193
YES	114(55.9)	19(70.4)	123(63.4)	43(53.8)	

The chi-square table for education when compared with questions reveals a significant difference when compared with education level. The major contributors to the significant chi square test are based on the percentages. It was identified that the cells "10^{th}&12^{th} "column and the "medical & paramedical" column show a significant difference with 55.8(77.9-22.7) for "10^{th}& 12^{th} " column and 70.4 difference for "medical & paramedical" column.

For Q2, Q3, Q4, Q5, Q6,Q7,Q8,Q9 the p –value is significant, hence education is a major contributor for perception of clinical trials. The probability of chi square test statistic is 4.76 with the p=0.193, greater than α level of significance of 0.05.

Table 6: Age

AGE / Question	18-25	26-35	36-45	ABOVE 46	P- Value
Q1					
NO	23(65.7)	189(61.6)	106(71.6)	6(40.0)	.040*
YES	12(34.3)	118(38.4)	42(28.4)	9(60.0)	
Q2					
NO	25(71.4)	173(56.4)	99(66.9)	4(26.7)	.004*
YES	10(28.6)	134(43.6)	49(33.1)	11(73.3)	
Q3					
NO	20(57.1)	160(52.1)	101(68.2)	6(40.0)	.006*
YES	15(42.9)	147(47.9)	47(31.8)	9(60.0)	
Q4					
NO	24(68.6)	153(49.8)	88(59.5)	9(60.0)	.068
YES	11(31.4)	154(50.2)	60(40.5)	6(40.0)	
Q5					
NO	18(51.4)	128(41.7)	78(52.7)	6(40.0)	.135
YES	17(48.6)	179(58.3)	70(47.3)	9(60.0)	
Q6					
NO	27(77.1)	240(78.2)	121(81.8)	10(66.7)	.527
YES	8(22.9)	67(21.8)	27(18.2)	5(33.3)	
Q7					
NO	23(65.7)	141(45.9)	88(59.5)	6(40.0)	.011*
YES	12(34.3)	166(54.1)	60(40.5)	9(60.0)	
Q8					
NO	14(40.0)	128(41.7)	63(42.6)	5(33.3)	.915
YES	21(60.0)	179(58.3)	85(57.4)	10(66.7)	
Q9					
NO	22(62.9)	162(52.8)	89(60.1)	11(73.3)	.186
YES	13(37.1)	145(47.2)	59(39.9)	4(26.7)	
Q10					
NO	13(37.1)	116(37.8)	69(46.6)	8(53.3)	.221
YES	22(62.9)	191(62.2)	79(53.4)	7(46.7)	

Figure 5: Education

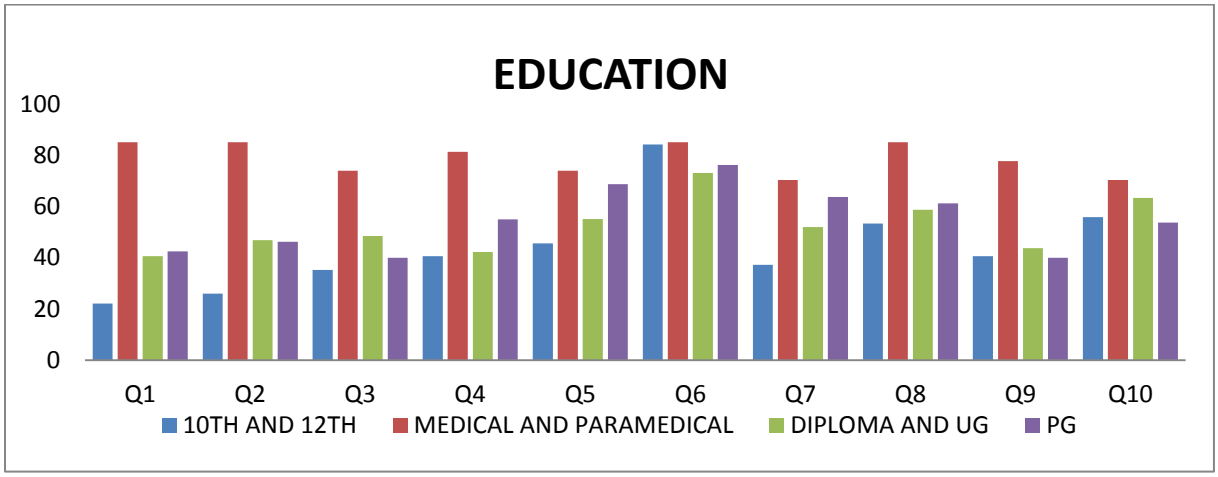


Figure 6: Age

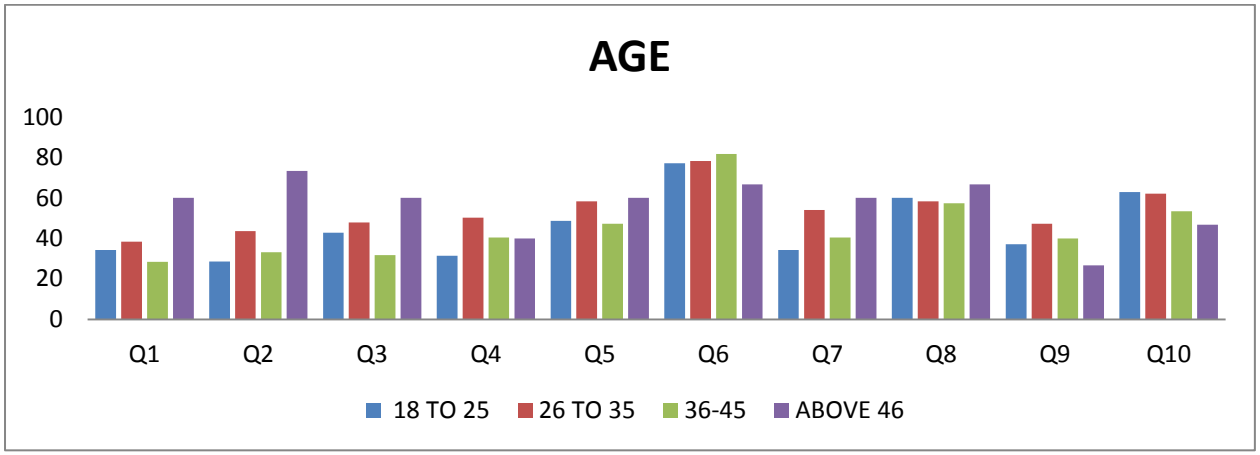
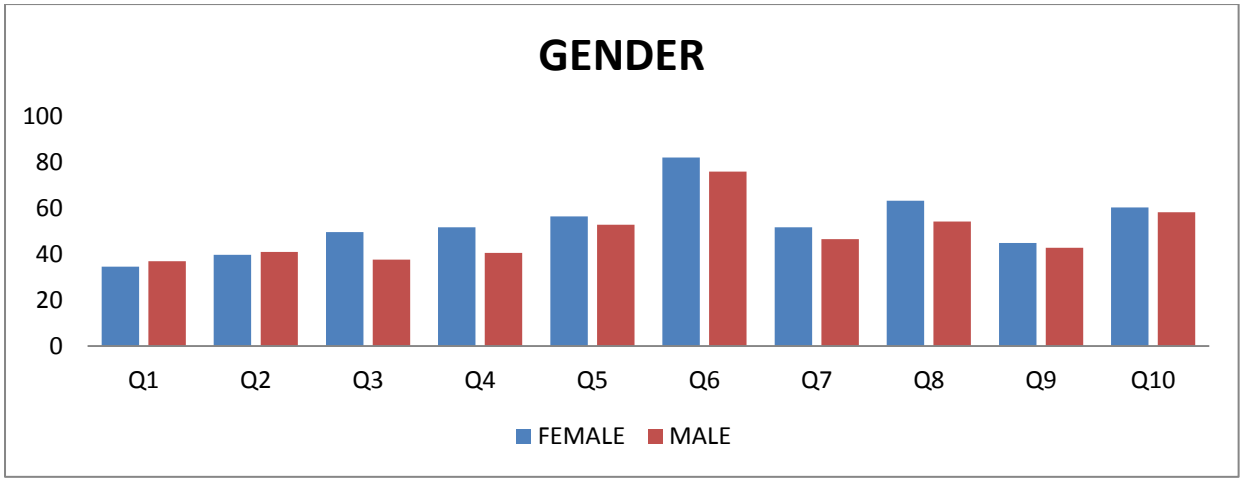


Figure:7 Gender



	GENDER				
ANNUAL INCOME / **Question**	**BELOW 1,00,000**	**1,00,001-2,00,000**	**2,00,001-3,00,000**	**ABOVE 3,00,001**	**P- Value**
Q1					
NO	177(76.6)	106(54.1)	9(33.3)	32(62.7)	.000*
YES	54(23.4)	90(45.9)	18(66.7)	19(37.3)	
Q2					
NO	167(72.3)	101(51.5)	5(18.5)	28(54.9)	.000*
YES	64(27.7)	95(48.5)	22(81.5)	23(45.1)	
Q3					
NO	145(62.8)	104(53.1)	12(44.4)	26(51.0)	.077
YES	86(37.2)	92(46.9)	15(55.6)	25(49.0)	
Q4					
NO	139(60.2)	94(48.0)	13(48.1)	28(54.9)	.078
YES	92(39.8)	102(52.0)	14(51.9)	23(45.1)	
Q5					
NO	122(52.8)	77(39.3)	13(48.1)	18(35.3)	.017*
YES	109(47.2)	119(60.7)	14(51.9)	33(64.7)	
Q6					
NO	193(83.5)	146(74.5)	20(74.1)	39(76.5)	.120
YES	38(16.5)	50(25.5)	7(25.9)	12(23.5)	
Q7					
NO	143(61.9)	86(43.9)	7(25.9)	22(43.1)	.000*
YES	88(38.1)	110(56.1)	20(74.1)	29(56.9)	
Q8					
NO	102(44.2)	77(39.3)	6(22.2)	25(49.0)	.094
YES	129(55.8)	119(60.7)	21(77.8)	26(51.0)	
Q9					
NO	141(61.0)	100(51.0)	15(55.6)	28(54.9)	.224
YES	90(39.0)	96(49.0)	12(44.4)	23(45.1)	
Q10					
NO	98(42.4)	74(37.8)	11(40.7)	23(45.1)	.707
YES	133(57.6)	122(62.2)	16(59.3)	28(54.9)	

One of the important players of clinical trials is the volunteers. Volunteers, either patient or healthy, are recruited from the general population. Hence awareness of clinical trial among the public, especially its importance in new drug development would help them take part in clinical trials. But it is not known to what extent the public are aware of clinical trials. Hence this study was under taken to find out whether the public know about clinical trials. The evaluation tool used was a questionnaire containing questions regarding general knowledge about clinical trials. From the evaluation tool, it was observed that majority of the participants have not heard the term clinical trial. A few of them have heard the term but they do not know about the clinical trials. Many participants did not know why clinical trials are conducted and whether it is tested in humans or not. But majority of them had said that clinical trial is an ethical one and it benefits the society. Both the male and female participants have responded almost equally. But the level of education and the age of the participants have influenced the response. The medical and para medical graduates have responded better than the others. The older participants (above 50 years) and those between 26 to 35 have scored better than the rest of the participants.

CONCLUSION

The older participants would have had the chance to participate more than one trial and that would have improve their performance. It can be stated from the present study that specific knowledge pertaining to clinical trials among the general populations is inadequate hence conducting awareness program is essential in order to improve both the public participation and the current status of clinical trials in India. According to this expert group, the most important forms of scientific misconduct in clinical trials are selective reporting and the opportunistic use of the play of chance. Fraud and misconduct in clinical research can be overcome only by proper education to participant.

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