

# Willingness to participate in a study and the factors that influence the decision in a south Indian population

Rekha Raghavan, Vina Vaswani

**Abstract**— What is the understanding of a participant when he enrolls for a trial? What are the factors that influence or deter the decision to enroll in a trial? Very few studies have looked into the Indian participant's perspective and requirements when he/she decides to enroll in a trial. The aim of the study was to identify some of the factors that influence this decision. After IEC approval was obtained the participants were divided into 4 groups based on their socioeconomic status and education levels and provided with a questionnaire containing closed end questions. The answers data was tabulated and compared. Analysis of data suggests that the factors influencing people varied according to their level of education, income and their expectations from the trial. People belonging to the low socioeconomic groups were more likely to trust their doctor and were more influenced by the offers of incentives. They were mostly unaware of the controlled trial scenario and were not much aware of any risk in trials initially. Hence we suggest that the informed consent should be strictly adhered to, which may control exploitation of people in the low socioeconomic strata and low education.

**Index Terms** — Population, Questionnaire, Trial.

## 1 INTRODUCTION

For advancement of scientific knowledge research is unavoidable and many times, it involves trials on human subjects. It has been reported by Singh & Singh (2007) that whenever there is a conflict between patient vulnerability and mechanisms to ensure the protection of subjects in human research have been suggested, including the presence of witness during the informed consent process[1]. This may end up as a meaningless ritual or sometimes serve to coerce or intimidate the participant as suggested by Angeles-Lleranas and co-workers (2009) [2]. The decision to join the study or not is supposed to be voluntary, but many factors may influence the subject's decision. Béréterbide reported that in developing countries, participation in a clinical trial may provide the participant access to medical care and that this alone may serve as an influencing factor for participation [3]. Ethical complexities such as participant's diminished autonomy, coercion or monetary inducement, language difficulties, illiteracy or lack of true understanding of the entire study, cultural barriers due to social diversities were reported to exist as reported by Mystakidou et al (2009) [4]. India's prominence as a suitable location for health research has emerged partly because of its potential for enrolling patients in clinical trials. India has one of the largest enrollment rates in the world but, only some studies have been directed at the Indian population's view regarding the studies or the factors that influence their decision. The socio-cultural milieu in India is hugely diversified and there is a definite financial disparity among different sectors. The decision to enroll or not may be influenced by different factors in different groups. This study tries to identify the factors that influence the subject's decision to enroll in a study.

profit motives, the companies involved in the research often tilt towards the latter [1]. Various international guidelines and national regulations make the informed consent of the subject mandatory, in all research involving human subjects. Various

## 2 AIM AND OBJECTIVES

The aim of this study is to identify what are the factors that might influence a person's decision to join a study.

## 3 METHOD

IEC approval was obtained after submission of protocol and the questionnaire was validated by three experts. The study was conducted among the staff, students and the patients visiting an academic institution in Kerala. The subjects were divided into four groups based on their income and educational status.

**Group I:** 25 from medical and dental doctors earning in range of INR 10000 to 50000 per month

**Group II:** 25 undergraduate dental students with a monthly income (allowance) of Rs. 2500 per month

**Group III:** 25 medical and dental assistants earning Rs. 2500 to 6000 per month

**Group IV:** 25 from the public with an average monthly income in the range of Rs. 600 - 2000

Informed consent was obtained from the participants. The questionnaire was provided in the vernacular language for those subjects who were not English speaking. The questionnaire was self administered. The data was collected and compared.

## 4 LITERATURE REVIEW

Shah et al conducted a study on the Indian population regarding the factors influencing the willingness to participate in a

- Rekha Raghavan Is Reader At Dept. Of Periodontics, Educare Institute Of Dental Sciences, Malappuram, Kerala India. PH-+919349118552. E-mail: rekha.raghavan.dr@gmail.com
- Vina Vaswani Is Director Of Centre For Ethics Professor & Head Of Forensic Medicine & Toxicology At Yenepoya University, Manglore, India.

trial in 2010[5]. They concluded that the factors like education, age, means of communication, altruism and personal health benefits affected the decision in a positive manner where as mistrust of the organization conducting the study, concern regarding the safety of the trial, dependency issues and financial and trial burden acted as barriers. They also reported that the spheres of consent mattered in case of Indian women. The Indian women often do not have the freedom to express their consent, and often require the assent of their spouse, or other senior family members to participate in trials. Joshi & Kulkarni (2012) in a study conducted in Pune, India reported that 80% of the participants were not willing to participate in drug trials [6]. Hussain-Gambles et al (2004) conducted a study on South Asian population and concluded that the motivation to participate in a trial was to help the society, to improve one's own health, out of obligations and to improve the scientific knowledge [7]. The barriers as noted by them included fear of side effects, busy lifestyles, language, previous bad experiences and mistrust regarding conduct of the trial.

Trauth and coworkers in a study conducted in 2000 on willingness of respondents to participate in medical research found that 46% were willing if the disease under study was of importance to them. They also reported that people whose friend or close relatives were affected by the disease were more likely to enroll in trials concerning the disease. They also concluded that the people who had a college degree were relatively undecided when compared to people who had not got college education [8]. Ohmann & Deimling reported that people were willing to participate in a trial if they considered trials to be important, had general knowledge about clinical trials and had previous trial participation[9].

The term conditional altruism was described by McCann, Campbell & Entwistle (2010). They said that people may be willing to help others and enroll in a trial, but unlikely to continue to participate in practice unless they feel that they will benefit from it personally [10]. Zammar et al(2010) in their study among Brazilians reported the main motivating factor to enroll to be altruism and the major barrier was the fear of side effect. In the same study they also reported that when comparing the Brazilian attitude and Indian attitude, the Indians showed poor willingness to participate in studies [11]. Bartholow et al (1997) reported that the willingness to participate was more in people with low education and high risk behavior among HIV positive subjects [12]. Hall and co-workers (2010) found that the physicians had low willingness to participate in cancer prevention trials [13]. O'Connelet al (2002) have reported in their study among HIV positive individuals that the willingness to participate increased among the disadvantaged [14].

It was reported by Agoritsas Deom & Perneger (2010) reported that participants were more willing to enroll if they were sure that the new drug had no side effects and no additional visits were required. Random allocation into study groups and placebo controls lowered the willingness to participate [15]. Ravikoff, Cole & Korzenik (2012) in their study conducted among bowel disease patients reported that random allocation and invasive procedures decreased the willingness to enroll in a study [16]. The fear of random allocation and side effects were also quoted as barriers in the studies conducted by Mer-

opol et al (2007), Hussain-Gambles et al (2004), and Mills et al (2006) [7],[17],[18]. Symonds and colleagues (2012) reported that the willingness to participate were more if subjects were approached by a senior doctor [19]. Volkmann, Claiborne & Currier (2009) in a study conducted among HIV positive subjects reported that the trust in the provider increases willingness to participate in a trial [20].

Dhalla et al in 2012 reported the willingness to participate in a trial to be directly related to their self efficacy levels [21]. In a study conducted among cancer patients Virani S. and colleagues (2011) stated that the respondents were more willing to participate in prevention or screening trials compared to therapeutic trials. They also reported that the decision to participate or not was influenced by monetary concerns, the oncologist's opinion, difficulty to commute and lack of information[22]. Similarly Wong cited in 2011 that payment for research participation unjustly influenced patients especially the financially needy in case of potentially harmful studies [23].

Geller et al(2003) found that parents were more willing to let their children enroll in trials if the child was older and if the research was less risky [24]. Most of the parents wanted the final decision to be theirs. Buscariollo et al (2012) in a study conducted on parental willingness to enroll the children for Type I diabetes trials reported that willingness was more if the child was diabetic than if the child was healthy [25]. Factors predicting willingness to enroll children with diabetes included healthcare provider trust, comfort with consent by proxy, low fear of child being a "guinea pig," and comfort with placebo.

## 5 RESULTS

On analysis of the collected data we found that all participants unanimously agreed that studies were required in the field of medical science.

### 5.1 Willingness to participate in a research study:

All subjects in Group I were willing to participate in the study. The willingness was found to decrease in group IV where only 72% of the subjects agreed to enroll in a study. In Groups III and IV 96% of subjects were willing to participate in studies. Only Group I had prior exposure to research studies and only 4% in this group had participated in research studies earlier.

### 5.2 Preference for the type of the study:

Willing if the study comprised of only questionnaire:  
24% of the participants of Group I preferred studies which required only answering of questionnaires; in Groups II and III 4% of subjects preferred this type of studies and 8% of subjects from group IV preferred questionnaire based studies.

### 5.3 Willing if the study comprised of questionnaires and external examination:

56% of the Group I subjects and 40% of Group II subjects preferred this type of studies. In Group III 28% and in Group IV 36% of subjects showed preference for this model of studies.

### 5.4 Willingness for invasive examination:

The preference for studies where invasive examination was needed was highest in Group II where 40% of subjects responded positively. The preference rate in the other groups was in the range of 4-20%.

Figure 1: Preference for the types of research studies

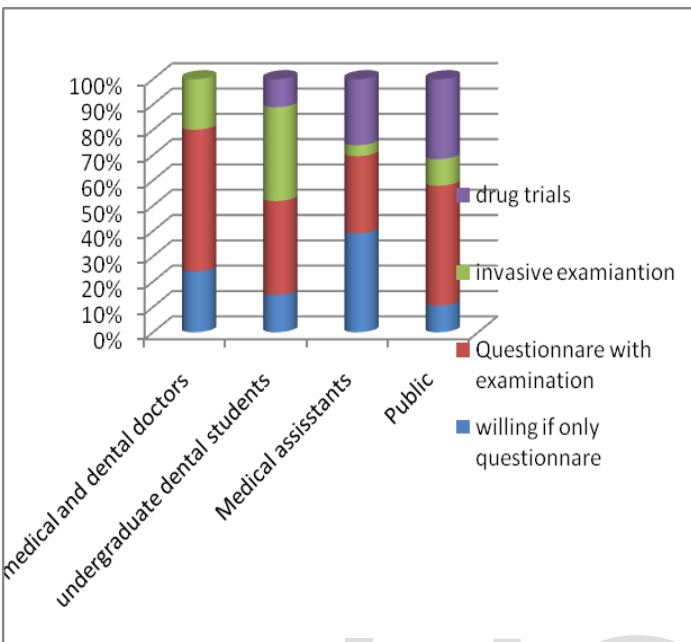
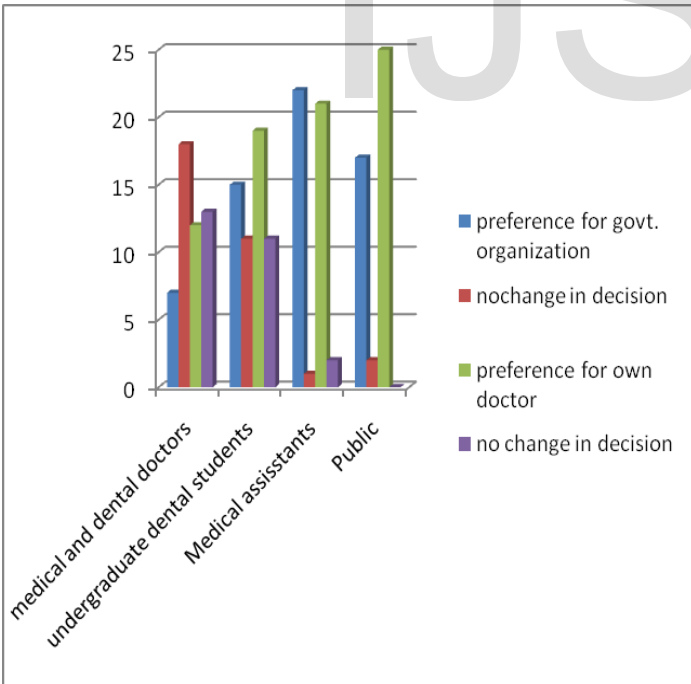


Figure 2: Effect of the study being conducted by government organization or by personal doctor.



### 5.5 Willingness for drug trials:

Generally the willingness to participate in a drug trial was low in all groups, but it was nil in Group I. The willingness in other groups were in the range of 4-24%.

### 5.6 Influence of study being conducted by government

### organization:

Groups II, III and IV preferred the study to be conducted by government organizations (60 -88%). 72% of the Group I subjects felt that this factor did not affect their decision to enroll in a study.

Influence of study being conducted by their personal doctor:

84 - 100% from Groups II, III, and IV reported that they would be more comfortable if the study was conducted by their personal doctor. In group I, 48% preferred their personal doctor to conduct the study, but 52% of the subjects from this group reported that this factor would not influence their decision to enroll in a study.

Figure 3: Compliance to repeated visits

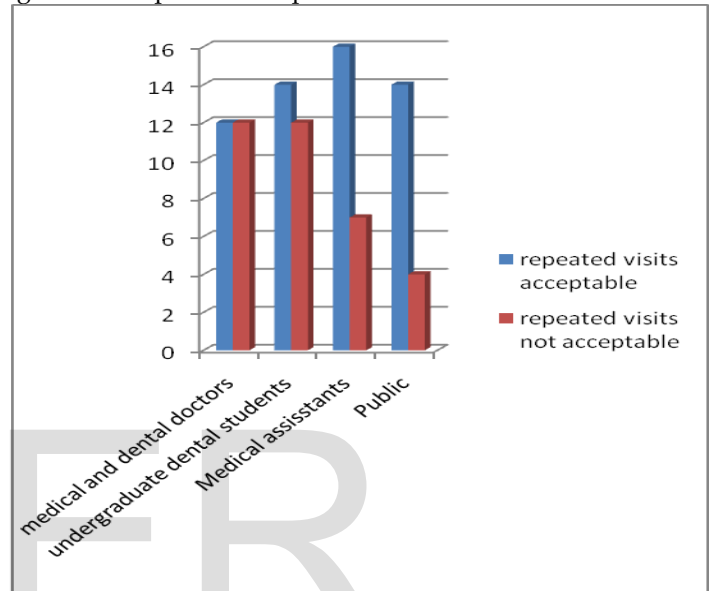
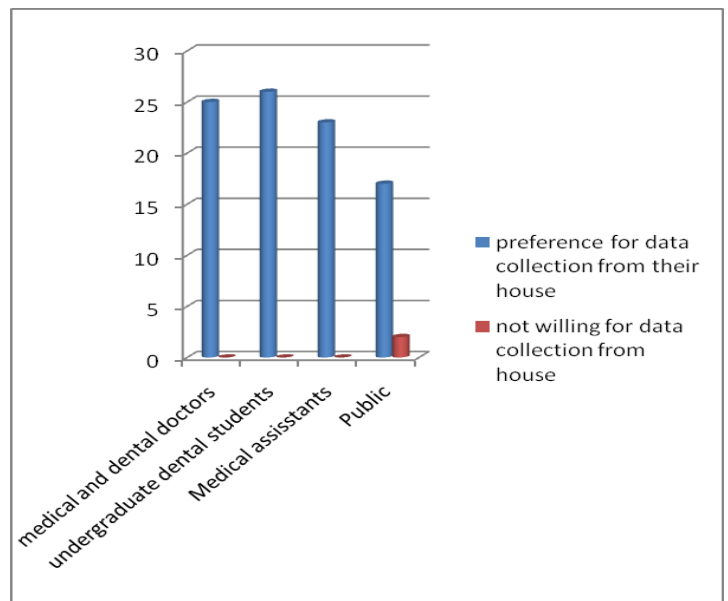


Figure 4: Preference for data collection from houses

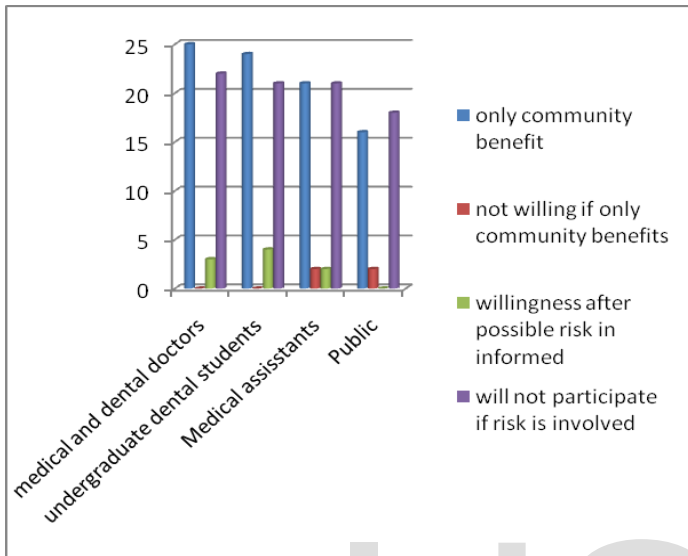


### 5.7 Influence of repeated visits:

An average of 50% from all groups did not object to repeated visits for the purpose of data collection. 4% of Group I subjects were willing if the number of visits were limited. Still, 98% of

subjects agreed that collection of data from their houses would make the study more acceptable. 8% of subjects from Group IV objected to collection of data from their houses and reported that they would not enroll if the data was to be collected from their houses.

Figure 5: Willingness after information regarding study is detailed.



**5.8 Benefit risk effects:**

100% of subjects from Group I and II were willing to participate even when they were informed that the study was solely for community benefit. 8% of subjects from Group II and IV declined to join a study which was conducted purely for community benefit.

96% of Group I subjects were willing to participate in a study which would not provide them with any direct benefits at present. The willingness in other groups were less ranging from 72% in Group II to 83% in Group IV

When informed that the study may actually pose some risk and may create health problems none of the Group IV subjects were willing to participate, but 8 -16% from the other Groups were willing to participate even when informed of such a risk.

**5.9 Influence of incentives:**

44% of Group III subjects said that they would be influenced to change their decision positively if incentives were promised; 24% of Group IV subjects also said that they would be influenced similarly, but only 8 - 16% of subjects in Group I and II reported that they would change their decision if incentives were promised.

**5.10 Influence of promise of free treatment for relatives:**

It was found that the willingness to participate from the Group III and IV increased by 92% and 70% respectively if free treatment was to be provided for their relatives. This factor was found to influence only 36% of subjects from Group I and Group II.

**5.11 Willingness to give parental consent:**

Willingness to give parental consent was low in the groups I and II - 28% and 40% respectively and it was relatively high in groups III (64%) and Group IV (70%).

Table 1.

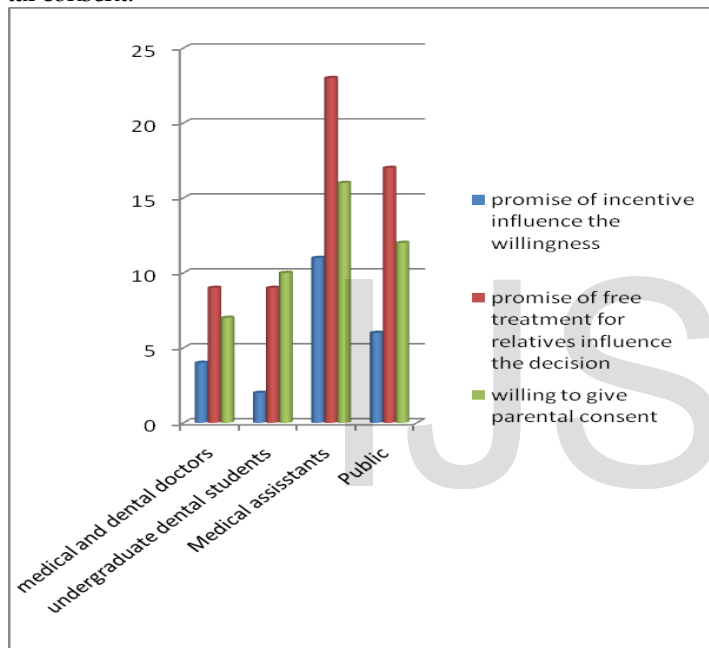
	Medical and Dental doctors	Undergraduate dental students	Medical assistants	Public
Number of subjects	25	27	24	25
Avg. monthly income	10000 - 50000	2500	3000 - 5000	600 - 2000
No. of subjects who feel study is needed	25	27	24	25
Willing to enroll	25	26	23	18
Not willing to enroll	0	1	1	7
Earlier participation in studies	1	0	0	0
Willing if only questionnaire	6	4	9	2
Willingness for invasive examination	5	10	1	2
Willingness for drug trials	0	3	6	6
Study by Govt. organization will improve compliance	7	15	22	16
Compliance improves if study is done by personal doctor	12	19	21	25
Repeated visits acceptable	12	14	16	14
Repeated visits not acceptable	12	12	7	4
Limited no. of visits acceptable	1	0	0	0
Preference for data collection from their house	25	25	23	16
Not willing for data collection from house	0	0	0	2
Willing to participate even if only community benefits	25	24	21	16
Not willing if only community benefits	0	0	2	2
Willingness when informed of the possible risks	3	4	2	0
Promise of incentive will influence positively	4	2	11	6
Free treatment for relatives will influence positively	9	9	23	17
Willing to give parental consent	7	10	16	12

**6 DISCUSSION**

This study reflects 4 segments of the society with different income levels and different levels of education. We found that the understanding regarding the necessity of research studies was high in all the segments regardless of their income and their educational status. The willingness to participate showed a decrease with the decrease in income. This points to the fact that the lower socioeconomic group might not be having confidence to participate in the study or might be feeling that they will be exploited in some manner. Shah et al (2010) had similarly reported that mistrust of the organization conducting the study, concern regarding the safety of the trial, dependency issues and financial and trial burden acted as barriers in enrollment in a research study [5]. The

higher willingness in the educated groups would suggest an altruistic model or a socially acceptable answer. Bartholow et al (1997) had reported that low education increased the willingness to participate in a trial [12]. Similar findings were reported by Trauth et al (2000) [8]. Mc Cann, Campbell & Entwistle (2010) had reported a situation called conditional altruism where subjects would enroll in a trial for community benefit but later drop out if they did not have any personal benefits [10]. As this study was based on a hypothetical situation we cannot rule out the possibility of such a factor affecting the answers given. It was reported by Hussain-Gambles and coworkers that the social class rather than the educational status affected the decision to enroll in trials. It was found that subjects belonging to the lower socioeconomic class were more distrustful of the trial arena [7].

Figure 6: Influence of incentives and willingness to give parental consent.



The preference for various models of studies suggests that with higher education people are aware of the trial arena and hence are suspicious to join a drug trial. This is further strengthened by the fact that the willingness for drug trial was seen to be more in the group IV comprising of subjects with low income and education. In our study we found that only 18% of the total subjects were willing for studies which required invasive examinations. Ravikoff, Cole & Korzenik (2012) in his study in inflammatory bowel disease patients reported that invasive procedures decreased the willingness to participate in a study [16]. As invasive procedures are uncomfortable if not painful and are reported to make a person feel vulnerable it is expected to reduce the compliance of the subject. Judge et al (2013) in their study among melanoma patients reported that the requirement of an invasive procedure like skin biopsy decreased the willingness to participate and that it was not correlated to the size of the scar [26].

We found that the lower income groups were more willing to participate if the study was conducted by government organizations or their personal doctor. The reason might be that these factors increase the trust of the subject and they feel that they will

not be exploited or misled in such a circumstance. Symonds et al (2012) in their study on recruiting ethnic minority in UK reported that mistrust of the organization was a major barrier for enrollment [19]. Volkman and colleagues (2009) reported that the trust in the care provider increased the willingness to participate in trials among HIV positive subjects [20]. Sherber NS et al in their study on the effect of personal physician as the investigator reported that the study being conducted by the personal physician or familiar doctor increased the willingness to participate in trials [27]. Symonds et al (2012) reported the willingness to participate to increase when subjects were approached by a senior doctor. Chu et al (2012) had reported findings contrary to this, where he found that many subjects who trusted their personal doctor for treatment felt that they might be persuaded by the doctor into participating in trials or they might be given a new drug during the course of the trial and hence preferred the studies where the doctor would have no role [28]. We found comparable findings in the higher income groups where the study being conducted by government organization or personal doctor did not have much influence on the participant's decision to enroll in the trial. They did not object to the trial being conducted by the personal doctor or government organization, yet reported that it would not affect their decision to enroll or not in the study.

Majority of the participants did not object to making repeated visits. This again might be construed as giving a socially right response. Only 1 participant specified that limited number of visit was preferred. This is in contrast to the study by Agoritsas et al (2011) who noted that willingness decreased with additional visits [15]. Bartholow et al (1997) in his study among HIV positive subjects reported that the willing to participate decreased when the study took extended time and required additional visits [12]. Once again the hypothetical nature of the study might have influenced the answer as the subjects were well aware that this particular study did not need any additional visits. Almost all subjects reported that the data collection from their houses would positively influence their decision to enroll in a study, but 8% of subjects from the low socioeconomic group actually objected to the data being collected from their houses. This might give an insight of the cultural pattern existing in at least some places where the spheres of consent may make it difficult for them to participate in trials in such eventualities, especially in case of Indian women as reported by Shah et al (2010) [5].

In the response of the participants regarding participation in trials for community benefit alone most of them exhibited altruistic tendency and were willing to participate, especially from the higher income group. Some of the participant from the lower income groups reported that they were not interested in participating in trials which were conducted solely for community benefits. Zammar et al (2010) had reported that among Brazilians the main motivating factor to enroll in a trial was altruism [11]. Hussain-Gambles et al (2004) in their study among South Asians in United Kingdom found that many were willing to participate to help the society, out of obligation to the physician and improve scientific knowledge [7]. Truong et al (2011) in the study in cancer patients reported that altruism was a major factor for participation in trials [20]. In this study we could not claim that it is the sole motivating factor, but it has to be agreed that altruistic tendencies exist. This exhibit of altruism again could be due to the tendency to give a socially accepted answer.

In response to the situation where placebo might be given and the subjects may not receive any benefit the willingness to participate decreased in the groups with low income. Mills et al (2006) also reported the presence of placebo or no treatment group was a major barrier for enrollment in trials [18]. Meropol et al (2007) also quoted this to be a major barrier in cancer trials [17]. Buscariollo and others (2012) in their study on parental attitudes described the fear of random allocation into the placebo group as a deterrent for enrollment [25]. In our study it did not seem to alter the willingness of the higher income and educational groups. This might be due to the fact that the subjects were aware that they would not be required to receive any drug.

When the information regarding possible risk was provided the willingness to participate decreased considerably and none from the lower income and literacy strata was willing to participate. This is similar to the finding in the study by Zammam et al (2010) where they reported that the fear of side effects was the main deterrent to participate in a study [11]. It was noted by Agoritsas et al (2011) also that the participants were more likely to enroll if they were sure that the new drug had no side effects [15]. Joshi and Kulkarni (2012) in their study from India reported that though most of the participants understood that the trials are a must for advancement of scientific research the willingness to enroll in trials were low due to the fear of side [6]. The fear of side effects and fear of being treated as a guinea pig was quoted by other investigators namely Meropol et al (2007) and Millset al (2006) [17], [18].

In this study we found that the willingness to give parental consent was very low in the high income group and that it increased in the low income group. Buscariollo (2012) et al in their study on parental attitudes on participation in Type I diabetes trials reported that parents were more likely to give consent if the child was a diabetic rather than healthy [25]. Geller et al (2003) had reported that while enrolling minors for trials, the willingness was more if the child was older and that the parents would like the initial decision to be theirs. [24] On the contrary the children, though they valued parental input, wanted the final decision to be theirs. All of the parents and children were against coercing the children into nontherapeutic research. Hoberman et al (2013) found that higher socioeconomic status and having insurance cover decreased the willingness to give parental consent [30]. When considering the willingness for parental consent we have only a minority of subjects who responded positively from the higher socioeconomic group. The high degree of parental willingness among the other groups in our study could be related to the study settings which was familiar to them. It could also be that the treatment cited in the questionnaire would have unintentionally suggested dental treatments, which otherwise might be costly.

The incentives and promise of free treatment for relatives increased the interest to participate in the study for subjects from the lower socioeconomic groups when compared with the other groups who had higher income and literacy levels. Wong and Bernstein (2011) in their study had reported that payment for participation would unjustly influence the participants decision, especially in case of financially needy [23]. Catania et al (2008) in their study in breast and lung cancer patients reported that majority of subjects enrolled in the trial with the hope of receiving a new chance of cure [31]. Halpern et al (2004) in a study in hyper-tensive patients found that the payment positively influenced the

decision to participate among wealthy patients [32]. Cryder et al (2010) also reported that higher incentives increased the participation rates and that it also was associated with higher perceived risk [33]. Though compensation for the time and travel of a participant is acceptable, we also feel that high incentives should not be promised as a lure especially to subjects in the lower income strata. As the study was primarily conducted in a dental treatment facility, the free treatment must have unintentionally suggested availability of costly dental treatments to the subjects and hence this also can be considered as an unjust means of influence.

According to Shiv Raman Dugal, Chairman, BoD, Institute of Clinical Research, New Delhi, at least eighty Indian hospitals were engaged in conducting clinical trials in 2010 [34]. The figure was projected to go up to 14,000, which means involvement of 500,000 doctors, 700,000 beds, and 17,000 medical graduates in 160 medical colleges. If the results of our study and the above figures are compared we find that there is no positive correlation. This brings to fore front the legitimate doubt as to whether the informed consent procedure is being strictly adhered to, as from our study we have found that the compliance to participate decreases when the perceived risk is higher. If the data from this study is projected we would not expect such a huge population to enroll in studies were they informed of the proper procedure, the conduct expected of them and the risks they are exposed to including no expected effect as with placebo trials, minor side effects of the drug and chances of a more severe adverse reaction. So one could suspect that some of the information that ought to be rightfully made available to the participants must have been withheld to improve the participation rates. Naturally the question "how informed is an informed consent?" arises.

Our study is not representative of the whole India, as the cultural issues in different parts will be entirely different with India's diverse cultures. As we have considered only apparently healthy subjects, the results of this study might not be duplicated if conducted in a sample affected by some disease, which might increase their vulnerability especially in cases of terminal diseases. In such cases even the higher income group subjects might be expected to enroll in trials if it would give them free treatment or new treatments as Trauth and coworkers (2000) and Catania et al (2008) reported [8], [31].

## 7 CONCLUSION

With an exponentially growing clinical trial market, India promises to be a global laboratory. In such a scenario increased awareness of the common public only will prevent their exploitation either by means of concealing the risks or by promising financial or other incentives. Along with the education of the public in the domain of scientific research participation, the medical society should rise to the occasion by meeting the ethical demands of their profession. The informed consent process should be strictly adhered to in order to avoid covert exploitation of the participants. The government also should devise policies and implement them to protect the citizens from undue exploitation. In the present scenario just one of the above might not suffice to overcome the problems related to research studies in India. Hence proper patient education, strict adherence to ethical conduct of research along with

laws with a proper administrative and monitory mechanism to ensure its working is necessary to conduct research studies.

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