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Research Article

INFORMAL DIALOGUE WITH PROSPECTIVE VOLUNTEERS: A TOOL TO IMPROVE SUBJECT RECRUITMENT IN CLINICAL TRIALS

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ABSTRACT

Objective: To find out the impact of informal dialogue on the subjects' willingness to participate in clinical trials.

Methodology: The awareness, previous participation and willingness to participate in clinical trials were recorded randomly from the patients' relatives who attended Chettinad hospital & Research institute. The participants who responded negatively were selected with their consent and given a leaflet containing information about clinical trials. Sufficient time was given for them to read the leaflet and clarify doubts. Their willingness to participate in clinical trial was recorded. The subjects who were not willing to participate were individually met and explained about the clinical trials outside the official environment. Willingness to participate in clinical trials was recorded again and the difference between before and after personal interaction was statistically analyzed.

Results: 200 subjects (99-males, 101-females) participated in this study. Before informal dialogue, 188 subjects (94%) were unwilling to participate and 12 (6%) expressed their willingness. After personal dialogue 137 (68.5%) were ready to participate and 63 (31.5%) were still unwilling to participate. The data was analyzed using Fisher's exact test which showed that informal dialogue significantly improved the willingness to participate in clinical trials.

Conclusion: Informal dialogue outside the formal official environment has positively influenced the decision to take part in clinical trials.

Keywords: Clinical trials, Willingness, Informal dialogue, subjects

INTRODUCTION

The current challenges for the ethical conduct of clinical trials include successful patient recruitment, obtaining informed consent from the trial participants, safety of the trial medication and adequacy of compensation. Among these, subject recruitment plays a key role in clinical trials and providing necessary information to the volunteers is vital in subject recruitment. Most of the time, consent is taken in an official set up in a CRO or an academic institution which can affect the decision making. If consent is taken informally through a friendly chat it might influence the decision making.

Hence the current study is undertaken to find out the role of informal dialogue in taking a decision to participate in clinical trial by the volunteers.

Informed consent

Informed consent is an official acceptance given by the participant to take part in clinical trials after fully understanding the details of the trial, including the benefits and risks of participation which will be explained by the investigator verbally as well as through a written document (1). A copy of the consent document is reviewed by the IRB before it is presented to the prospective participants. Informed consent is an ongoing process that starts before any forms are signed and continues through the completion of the study. The consent document is only a confirmation of the consent process.

Patient recruitment in clinical trials is recognized as one of the most difficult tasks. (2) Recruitment processes include recruitment in the hospital, recruitment through telephonic contact, advertisement like flyers and educational program.

Patients are generally interested in participating in clinical trials but due to lack of adequate information about clinical trials, they expect their treating physicians to provide detailed information. If patients receive such information through their treating physicians, enrollment might improve (3).

METHODOLOGY

The relatives of the patients who attended Chettinad hospital & Research institute, Kelambakkam, Chennai were randomly selected.

The demographic data such as name, age, sex, address, educational qualification and income were recorded. Then they were enquired about their awareness about clinical trial, previous participation and their willingness to participate in clinical trials. The participants who responded negatively to all the above three questions were selected and asked for their willingness to participate in the present study.

Those who volunteered to participate in the present study as well as who knew the local language were invited to the department of pharmacology and given a leaflet containing information about clinical trial in the local language. Sufficient time was given for them to go through the leaflet and clarify doubts. After that, their willingness to participate in clinical trial was recorded. Then they were requested to report the next day. Those who were not willing were individually met outside the department in the institutional visitors' lounge and informally enquired about their day to day activities, the nature of their job, the number of children they have, their awareness about clinical trials and then discussed with them the benefit, risk, the importance of conducting clinical trials, its relevance to human health and how the trial volunteers contribute to new drug development which would help the society. Subsequent to the discussion, the willingness to participate in clinical trials was recorded again from the participants. The difference in the number of participants willing to participate in clinical trials before and after personal interaction was statistically analyzed.

RESULTS

516 subjects were contacted to determine their willingness to participate in clinical trial.

316 subjects rejected participation in the interview.

200 showed willingness to participate in the study.

Among the 200, 99 were males and 101 females.

The response obtained from the 200 people was classified on the basis of age, sex, income, educational qualification and awareness of clinical trials.

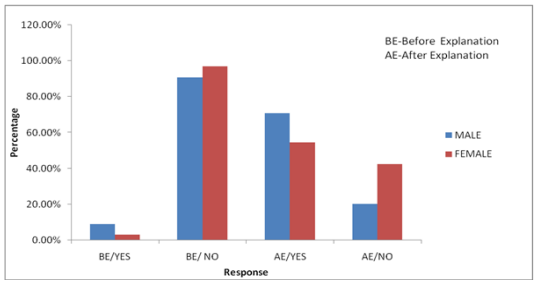

Fig.1: Willingness between male and female

Fig.1: Before the explanation was given, 9.09% male offered willingness and 90.9% was not willing to take part in trials. Among the females, 2.97% offered willingness and 97.02% was not willing to participate in the trials. After giving explanation about clinical trial process, 70.7% males gave positive reply and 20.2% gave negative response to take part in trials, among the females 54.45% were willing and 42.57% were not willing to participate in trials. We observed that males are willing to participate more than the females.

Based on the age of the participants they were classified into 5 groups and the response obtained from each age group was segregated.

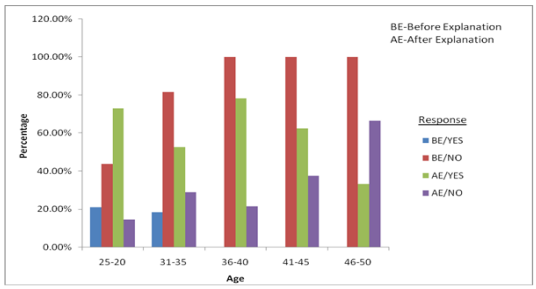

Fig.2: Willingness among different age groups

Fig.2: Before explanation, the participants in the age group 25-30 and 31-35 years expressed willingness to participate in the trial while the other age groups expressed unwillingness to participate in the study. After personal dialogue 78.43% in 36-40 age group, 73.17% in 25-30 group, above 50% in the age group 31-35 and 41-45 and below 50% in group 46-50 were willing to participate in the study. It can be inferred that age group 36- 40 (78.43%) showed more willingness.

Based on the educational qualification the participants were divided into 6 groups and their responses recorded.

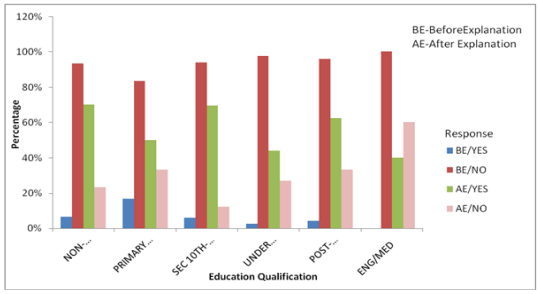

Fig.3: Educational qualification and willingness

Fig.3: Before explanation, less than 10% of all the categories other than those with primary education and 16.66% with primary education have given willingness to participate in the trial. After explanation, 70% of uneducated people, 69.5% with secondary education, 62.5% post graduates, 50% with primary qualification and less than 50% of under graduates and professionals have shown willingness.

Based on the income, the participants were divided into 2 groups with income above Rs. 10,000 and below Rs. 10,000 and responses were recorded.

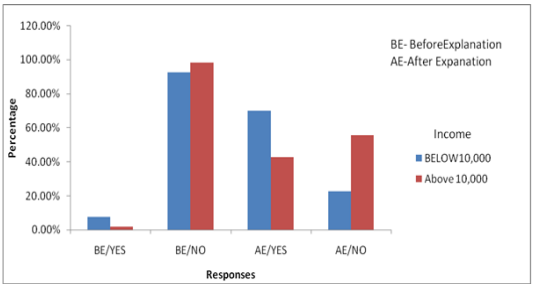

Fig.4: Willingness among different socio-economic groups

Fig.4 shows that the subjects earning below Rs. 10,000 per month showed more willingness (77.3%) to participate. Participants earning above Rs. 10,000 showed less willingness (27.7%). This suggests that the socio-economic status of the participant plays an important role in their decision to participate.

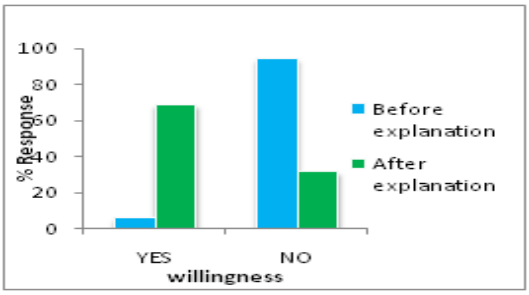

Fig.5 Willingness to participate before and after explanation

Fig.5: Overall only 6% of the participants were willing to participate in the trial before personal dialogue and after explanation 68.5% expressed willingness. More number of males showed willingness compared to females.

The percentage of willing subjects was analysed using Fisher's exact test and the P value was < 0.01 indicating statistically significant difefrence in the results between before explanation and after explanation.

DISCUSSION

Among the causes for delay in completion of clinical trial, more than 25% delay is due to failure of subject recruitment (4). "In the UK, only 31% of CTs sponsored by the Medical Research Council and the Health Technology Assessment Programme achieved their original recruitment target; furthermore, 55% did not reach the revised target (5). In 333 concluded UK public and charity sponsored cancer trials that were started between 1971 and 2000, only 48% reached the planned sample size, whereas 20% of the CTs recruited less than 25% of the planned sample size" (6).

"Recent US data showed that among 180 National Cancer Institute (NCI) Cancer Evaluation Program-sponsored CTs, activated between 2000 to 2004 and closed to accrual, 36% and 62% of phase 2 and 3 trials, respectively, did not attain their recruitment goals" (7). Similar data are not found regarding clinical trials conducted in India.

Poor recruitment will result in failure to conduct clinical trials and it may lead to delay in introducing new drugs in to the market which in turn may have an impact on patient's treatment and health. Participating in clinical trials may provide timely intervention by the administration of the prospective new drug to potential study

subjects and result in therapeutic benefit and the delay may deprive this benefit to the patients of especially incurable diseases.

Hence successful recruitment of the target number of participants within the stipulated time period is one of the key factors for the completion of clinical trials. The reasons for incomplete recruitment include subjects' unawareness about clinical trials, failure to get informed consent, stringent inclusion criteria, the time subjects have to spend in CRO, the frequency of visits, the distance to CRO and the adverse effects of drugs. These causes have to be handled individually and strategies have to be evolved to overcome these barriers.

Taking informed consent is a difficult task at times for the investigator. Informed consent is a two edged weapon which may facilitate or prevent the subjects' participation. Detailed description of the entire process of clinical trial including the probable adverse effects is both an ethical and regulatory requirement. Detailed information about the clinical trials may adversely affect subjects' decision to participate. Adams et al have reported from a two-year study conducted in Tibet that the presentation of informed consent protocols will be more effective if it is more flexible and focuses on the intent rather than the specific information of the informed consent process(8). Innovation in informed consent taking is essential to improve subject recruitment.

Usually the volunteers are interviewed in a CRO, an official organization with specific rules and regulations like specific entry, exit points and other restrictions. In this official setup even if the investigators explain without any bias all the details of clinical trials, it may not be possible for the subjects to freely ask questions and clarify doubts. Most of these subjects are uneducated and naïve. The cultural barriers may also prevent them from freely conversing with the new person in an unfamiliar setting. A friendly chat in an informal setting may help the subjects to talk freely and take the right decision.

Hence this study was undertaken and the subjects who took part in this survey belong to different socio economic and educational status. Men predominantly participated in this study. We have observed that before personal dialogue the percentage of subjects willing to participate in clinical trial was only 6 %(12 among the 200 subjects).

After personal interaction clearly explaining the benefits and the risks and how they would be taken care of if any adverse event occurs and how they could contribute to the health of the society by taking part in clinical trials, the number of subjects who were willing improved significantly (137 out of 200 subjects).

The present study has shown that mostly males and subjects in the age group of 36 – 40 yrs, uneducated and who belong to lower income group(below Rs 10000 per month) were ready to participate in clinical trials. This observation is in line with earlier views regarding subject's enrollments in clinical trials.

The probable reasons could be the patriarchal society to which they belong, the faith they have in the medical personnel and the social responsibility they have as a citizen to contribute to the health of the society.

The percentage of subjects who offered willingness after detailed informal chat improved from 6% to 68.5%. (P value < 0.01) Such a marked increase in the percentage of willing subjects could be due to the environment they had to intervene, ask questions and clarify. Though they might have the same opportunity in an official environment, the confidence and the closeness created by the informal setting, the lack of hierarchy and the concern and interest shown by the investigator in their personal life could have contributed to the change in the decision making.

CONCLUSION

The results of the present study thus have shown that informal chat with the subject outside the official setting has significantly improved the decision making to participate in clinical trials.

Such an informal dialogue can be used as tool to improve informed consent without compromising the ethical principles of voluntariness, information and comprehension.

CONFLICT OF INTEREST

Nil

REFERENCES

1. Glossary 1.28, ICH -GCP, www.ICH- org.com
2. Prout TE. Patient recruitment techniques in clinical trials. Control Clin
3. Trials. 1981 May;1(4):313-8
4. Sood A, Prasad K, Chhatwani L, Shinozaki E, Cha SS, Loehrer LL, Wahner-Roedler DL. Patients' attitudes and preferences about participation and recruitment strategies in clinical trials. Mayo Clin Proc. 2009 Mar; 84(3):243-7.
5. Janice Cruz Rowe, Martin E. Elling, Judith G. Hazlewood, and Randa Zakhary A cure for clinical trials. P 137 -38, The Mckinsey Quarterly 2002: 2
6. McDonald AM, Knight RC, Campbell MK, Entwistle VA, Grant AM, Cook JA, Elbourne DR, Francis D, Garcia J, Roberts I, Snowdon C. What influences recruitment to randomised controlled trials? A review of trials funded by two UK funding agencies. Trials. 2006 Apr 7;7:9.
7. Vale C, Stewart L, Tierney J; UK Coordinating Committee for Cancer Research National Register of Cancer. Trends in UK cancer trials: results from the UK Coordinating Committee for Cancer Research National Register of Cancer Trials. Br J Cancer. 2005 Mar 14;92(5):811-4
8. Cheng SK, Dietrich MS, Dilts DM. A sense of urgency: Evaluating the link between clinical trial development time and the accrual performance of cancer therapy evaluation program (NCI-CTEP) sponsored studies. Clin Cancer Res. 2010 Nov 15;16(22):5557-63.
9. Adams V, Miller S, Craig S, Sonam, Nyima, Droyoung, Le PV, Varner M. Informed Consent in cross-cultural perspective: clinical research in the Tibetan Autonomous Region, PRC. Cult Med Psychiatry. 2007 Dec; 31(4):445-72.