Original Article

Public awareness of clinical trials: A qualitative pilot study in Pune

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Abstract

Context: Medical expertise combined with availability of patients with varied diseases have resulted in rapid increase in number of clinical trials (*CTs*) recruiting millions of patients in India. Yet, few researchers have tried to understand if the *public* in India is *aware* of *CTs*. **Aims**: To explore the *awareness, perceptions of and attitude* towards participating in *CTs* among *general public* in Pune. **Materials and Methods**: *Focus group discussions (FGDs)* and interviews were conducted by contacting people in the community of various age groups and socio economic status with 7 *Trial participants (TPs*) and 17 *Non Trial Participants (NTPs*). The survey tool consisted of open-ended questions that assessed the *awareness and attitudes* of the individuals regarding the *CTs*. Interview were recorded on paper and translated from (Marathi) local language to English for analysis. Qualitative analysis was used to report the findings. **Results**: Most participants could associate *CTs* with medicine or development of new medicine; however they did not have a good understanding of the manner and safeguards with which *CTs* are conducted. Participants were not aware about different types of *CTs* and phases of the *CTs*. *CTs* were felt to be of benefit to the community and advancement of science. However, due to fear of adverse effe*cts*, 80% of the respondents were not ready to participate in the *CTs*. **Conclusions**: The Indian Pharmaceutical company is the world's 3rd largest by volume as per Dr. Shivathanu Pillai's report 17th March 2010, in spite of that it has been noticed that the *awareness* about *CTs* is very low; therefore there is a need to create *awareness* about *CTs* which helps the participants to participate in *CTs* based on their own decision. These *FGD* findings require validation in a larger sample.

Key words: Attitude, awareness, clinical trial, focus group discussions, public, perceptions

INTRODUCTION

India has the largest pool of patients suffering from cancer, diabetes, metabolic syndrome, and other maladies. Furthermore, due to low costs, medical expertise and good hospital facilities, many Multinational Companies are conducting several trials in India recruiting several thousands of Indians.[1] Several articles talk about increase in number of clinical trials (*CTs*) and revenues but few talks about *"Trial Participants (TPs)"* who contribute to the advancement of science and to the revenue. Few researchers have looked at whether the TPs who get recruited in *CTs* are *aware* of what *CTs* are and if participation agreement is purely their conscious decision. Studies have made known that fear, distrust or suspicion of research, apprehension and scepticism could hinder *awareness* about the *CTs*, especially among minorities.[2] Language and literacy barriers may make it difficult for some people to understand which may be the main barrier for *awareness*.

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In the west, studies have been carried out with cancer patients about their *awareness* of *CTs* mainly because of recruitment difficulties but few researchers have tried to find out general *public awareness* of *CTs*. In India, it is hard to find literature on such topics. Thus, this study has used references from the west. A study conducted with South Asian Patients in Briton had identified motivators for participating in the trials as, improve own as well as family and friend's health, help to the society and increase in scientific knowledge.[3] The same study had reported the deterrents as concerns of drug side effe*cts*, language barriers, previous bad experiences, mistrust and feeling of not belonging to British society.[3] Another study by Hussan-Gambles reported barriers to participate in CT were trial burden, mistrust with health workers and language barriers.[4] Catanica in his study with Italian patients reported the deterrents as prejudices, and fear that doctors were interested in advancing their own research, even though there were more efficient drugs available.[5] All these instances point out that *awareness* of clinical trial may increase conscious motivation to participate.

According to New Mexico Cancer Care Alliance, lack of *awareness* of *CTs* hinders patients' participation in cancer trials.[6] A survey of almost 6,000 people with cancer showed that 85 percent of people with cancer were either unaware or unsure that participation in *CTs* was an option, though 75 % of these people said they would have been willing to participate.[7]

Many times researchers do not try to make the *public aware* by not displaying the relevant information about their study. Giuliano's study on participation of minorities in cancer research found that while some minority women were reluctant to join research studies, the others lacked the information necessary to explore these options.[8] Some are never offered the information, while others lack the scientific framework needed to make an informed decision.[6] Providing resources to help individuals make informed decisions about research involvement promotes understanding of the true benefits and risks of participation in *CTs*. It also increases *awareness* about the importance of *CTs*.[9]

Use of qualitative research is popular in *CTs*. Qualitative methods involve an in-depth exploration of a phenomenon. Qualitative research is concerned with the opinions, experiences and feelings of individuals producing subjective data collected through direct encounters with individuals, through one on one interviews or group interviews or by observation[10] and facilitate research focusing on cultural issues and diverse ethnic populations like India. Thus, the use of focus group methodology was anticipated to allow the research team to gain insight into participants' beliefs and attitudes about *CTs* and a medium for their voices to be heard. Since the discussions are in respondents' own verbatim, FGD and interviews generate information that helps to tailor health educational tools with appropriate cultural content and language. Focus group methodologies are essential when there are differences in perspectives or views between researchers and the communities they are targeting.[11] Allison Tong[12] has developed a check list for comprehensive reporting of qualitative studies. We tried to follow this consolidate criteria for our study.

The Need for *Awareness* of *CT*: National Institute of Health in the US (NIH) website has mentioned that people need to consider how they can help advance the prevention, diagnosis, and treatment of disease. It is never too early to consider participation whether or not someone ultimately chooses to join a study[13] making *public aware* about *CTs* is advantage for the participant as well as for the investigator. Participant's *awareness* is necessary to know the availability of *CTs* so that those who cannot afford the treatment or when there is no alternate treatment available for the disease, one can get benefited by participating in a *CTs*. Harris Interactive Survey, 2001 had indicated that *awareness* changes attitudes toward *CTs*, enrollment, and the benefits of participation.[14]

If participant is *aware* of the manner of conduct of a *CT* he/she would participate with an informed decision, recruitment will be easy and retention rate will be high. When participants are aware, compliance will increase giving better trial results. This would help the investigator for smooth conduct of a *CT*. Although there is an extensive literature[15-17] evaluating the factors promoting and precluding participation in *CTs* among various populations, there are a limited number of studies that focus on understanding the *awareness, perceptions* and *attitudes* to participate in *CTs*. The aim of this study is to explore the *awareness*, *perception* and *attitude* towards participating in *CTs* among the general *public* in Pune. There is an urgent need to find the *public* level of *awareness* about *CTs*, which will help in planning and conducting, targeted population specific education programs.

MATERIALS AND METHODS

Convenience sampling was used to recruit participants. None of the participants refused to participate. Participants who were friends or relatives of patients at outpatient department at a tertiary Hospital in Pune were approached face to face or by telephone. Participants were asked about their age, level of education and occupation in addition to questions about *CT* such as what was the source of information about *CT*, what did they know about *CT*,

were they aware that participant's consent is taken before participation and what is consent and when to give consent and if they are willing to participate. *Trial Participants* were asked how was the participant's experience with the *CT*, why did they participate, would he/she participate again in *CT* etc. Graduate and above level of education was treated as higher level of education. The interviews and *FGD's* were conducted at Department of Research office during Nov and Dec 2011 by contacting people of various age group and socio economic status from Erandawane area in Pune. The interviews were conducted with *Trial participants (TPs)* and *FGD's* and interviews were conducted with *Non Trial Participants (NTPs)*.

Individual interviews

One-on-one interviews were conducted where discussion between one interviewer and one TP took place.

Focus group discussions (FGD)

Were conducted with small group gatherings (8-10 people per session) where the materials and messages were discussed in a group setting. The authors approached individuals and briefly informed them about the study, which was to assess individual's knowledge, *attitudes* and behaviour regarding *CTs*. All interviews were conducted in English and Marathi language. The interviewers were authors, who had no prior relationship with the individuals participated in this study. Interview lasted approximately 30-45 min and were recorded on paper and translated into English for analysis.

The survey tool consisted of open ended questions that assessed the *awareness* and attitudes of the individuals regarding the *CTs*, their perceptions about *CTs* and their willingness to participate in different types of *CTs*, (e.g. Drug trial, device trial etc. if they would participate in *CT*), and informed consent document.

NTP: One *FGD* was conducted with six people and 11 people were interviewed (nine women and seven men; age ranged from 27 to 71 years). Education level was graduate and above graduate.

TP: Seven people (four men and three women) who had completed the trial were interviewed (age ranged from 50 to 70 years). Education level was graduate and above graduate.

Findings generated from these interviews can be used to develop the questionnaire for evaluating *public* and the patient's *perception, awareness, attitudes* and behaviour regarding *CTs* participation in the next project.

We did not apply for approval from Institutional Ethics Committee, as we conducted qualitative study with public with the intension of designing a questionnaire for quantitative study based on FGDs and interviews only. No personal identifiers, clinical information or sensitive questions were asked to the participants. However, this manuscript was reviewed and approved by Deenanath Mangeshkar Hospital and Research Centre (IEC_DMHRC).

RESULTS

After each *FGD* and *interviews*, the researchers reviewed their field notes from the discussion and highlighted comments that were offered, and then clustered the comments into themes.

Themes for each of the FGD and *interviews* were collated. The results are shown in Tables 1 and 2.

The first theme focused on respondents' *awareness* of *CTs* and source of information of *CTs*.

For the second theme were reasons for participation in the *CTs*.

For the third theme was their knowledge of Informed consent form (ICF).

The fourth theme was their overall experience with the *CTs*.

For the fifth theme was respondents informed their attitude towards participation in a *CTs*.

Sixth theme discribed the risks and benefits of *CTs* as perceived by the respondents.

The seventh theme was advise others to participate in a *CTs*

The eighth theme was Necessary to create *awareness* about *CTs*.

The Ninth theme was how to create *awareness* of *CTs* among general *public*.

- *Awareness* of CT: About 90% of *NTP* agreed that they knew nothing about *CTs* and they were not inquisitive to find out about *CTs*. Among *NTP*, the *awareness* about *CTs* was very low only 18% people knew the term *CTs* and 82% of the respondents were unaware about *CTs*. Two out of 17 *NTPs* said that *CTs* should be conducted only on terminally ill patient and one *NTP* said *CTs* should be conducted only on healthy people. 16 out 17 *NTPs* were not familiar with device trial; also they were not aware of types and phases of *CTs*. While our *FGD* showed that 86% of *TPs* were aware about *CT* and 14 % of them were unaware about

Table 1: Content analysis of *FGD* with 20 *NTPs*

Theme	Verbatim Quote
Awareness of CT and Source of information about CT	• Do not know anything about *CTs*…. • Rejected information because anyway we are not going to be guinea pigs therefore did not bother to read it" • "Had heard of *CTs* before but I do not know how it is conducted" • in general public it may be less than 5% • Not aware about phases in CT. • Not aware about device trials. • CT should be conducted only on healthy people. • *CTs* should be conducted only on terminally ill patients when no other treatment is available for them.
Informed consent Form (ICF)	• None of the NTP knew about ICF
Theme	**Verbatim Quote**
Attitude towards participation Positive attitude	• I will participate after discussing the risks involved with my family members. • I will be doing a favour to the doctor by participating in the CT. • I will think after discussing with a participant who had already participated in the same trial. • If I participate in CT, my family will not face financial burden about my disease. • Compensation must be assured. • Willing to participate for noble cause.
Negative attitude	• Useful for science but why should someone volunteers for society? • I will not participate. Scared of adverse events • Companies are playing with human life for their own interest. • *"Ekache balidan lakhona jivan dan".* (Marathi language)
Risks	• It is risky to participate in a trial because drug is on trial and no one knows the side effe*cts*. • Participation in Phase I and II trials is risky. • Drug can give negative effe*cts*. • Trials should not be conducted on small children. • *CTs* are conducted for health improvements.
Benefits	• Beneficial to science and community. • CT is the only way to evaluate the side effe*cts* of the drug.
Theme	**Verbatim Quote**
Would you advice your close friends and relatives to participate?	• Always (30%) • May think if doctor is very sure and there are previous known results. • Must give whole picture to participants and then let them weigh the options. • No. Never. (60%)
How *awareness* should be created?	• *Awareness* through mouth publicity. • Conducting lectures in colleges • Putting posters, Banners, • TV/ Radio • Conducting camps • Putting proper information with flow of events during the trial on notice boards in Hospitals. • Completed trial results must be communicated. • Print media are the best. • Above 20 years. • Should be created among all the students from 12th grade. • *Awareness* must be created in such a way that fear must be removed from everybody's mind.

CTs and 28.57% *TPs* were not aware who will sign for child who participated in *CTs*. This shows that overall public *awareness* about *CTs* was poor.

- Source of information about *CTs***:** TPs got the information about *CTs* mainly from their physician (72%) and the other sources were friends and relatives (14% each).
- The main reason of participation in *CTs:* It was doctor's advice (70%). The other reasons were the drug may be useful for curing their disease and just wanted to try it out (15% each).
- *Attitude* towards participation in *CTs*: 15% of TPs were not willing to participate in any study in future but thought that people should volunteer for the benefits of others while 15 % said they will participate even if their family member and close friends object. The same percentage of people (15%) said that they will participate only if their family members have no objection. These participants pointed out that "their family member's opinion was valuable for them". Remaining 55% said they will participate and they perceived that "people should participate in CT". 20% of *NTPs* stated that they will participate after discussing the risks involved with their family members. One *NTP* declared that he will decide to participate after discussing with others who had already participated in the study. 9% of *NTPs* thought that they will be doing favour to the doctor by participating in

Table 2: Content analysis of Interview with *TPs*

Theme	Verbatim Quote
Awareness of CT and source of information	• Most of them were aware (85%) however some were not aware who will sign for child if a child had to participate in a trial. • According to two respondents, in the past also drugs were developed but there were no trials on humans. • Did not know what phase was the trial when he participated. • Friend • Family Physician (82%) • Relatives
Reason for participation	• Wanted to try out copper T. • Thought drug was useful for curing his disease • Doctor suggested trial drug is suitable for his disease condition.
Informed consent form (ICF)	• There must be transparency in the ICF and signing it should be a must for all kind of studies.
Trial experience	• Very bad. Very time consuming, far away distance.
Bad experience	• Very painful. Withdraw from the trial. • "Okay", not very good. Lengthy procedures and long term follow up. Too frequent visits and time consuming
Good experience	• Good experience- free medicines, free check up. Health status improved. • Health readings like blood pressure etc were taken regularly. • Doctors gave more attention. Free transport. • Good experience. All study team members were co-operative and helpful.
Idea about risks	• "The side effe*cts* are scary. I do not want to be a sample for them. I do not want to risk my life. I love my life and my opinion is fair". • The risk depends on study drug and the doctor. • All drugs have side effe*cts*. But the respondent was not told about the side effe*cts* of the trial drug. • I had no idea about the risks when I participated. • People should participate. There is no risk involved. Participants are not treated as Guinea pigs. Every medicine has some side effe*cts* either it is study drug or marketed drug. Everyone must have his own thinking power to decide about participation.
Benefits	
Trial participants' suggestions	• Doctors should give proper attention to participants. • CT is not beneficial to patient but is beneficial to the Pharma Company. It is only money making business. • All trial participants' information should be kept confidential. • When the drug comes into market, it should be given free or at least at reasonable cost to participants.
Would you advice your close friends and relatives to participate?	• Those who want to participate should know the implications of the trial. • Let them decide on their own
Is it necessary to create *awareness* about *CTs*? Yes	• Yes. It is necessary. • *Awareness* should be created but it should not be irritating. People should not get bored and confused. • Doctors must take initiative in *awareness* program. • *Awareness* must be created among young people.
No	• No need. It is waste of time. • No need. Public gets bored due to these *awareness* programs. One can become aware from own experience.
How to create *awareness* about *CTs*	• Mouth publicity, TV is the best media that is watched regularly and in urban and rural areas as well. Documentary and short films. • Conducting lectures in colleges, presentation for community. • Radio

CTs. 80% of the *NTPs* were worried about the adverse events and therefore they had made a decision of not participating in a CT. 91% TPs were concerned about the compensation. They would participate only after getting assurance from the investigator. Only 9% each said that they will participate for a noble cause and advancement of science.

- Knowledge of Informed Consent Form: All the NTPs had no knowledge of Informed Consent Form (ICF).
- Among TPs, 85% of participant had signed the ICF while 15% were not aware of the term ICF and were unaware of what document they had signed. All of them said there must be transparency in the ICF and signing should be a must for all kind of studies.
- *CTs* experience: 15 % of *TPs* revealed that the overall *CT* experience was not very good. It was very time consuming and they had to travel far away distance. For 15 % of the participants, the experience was very painful and they had to withdraw from the trial. While for (70%) of the respondents, the *CTs* experience was good. They got free medicine, free check up and free transportation, their health status improved, they received more attention from the doctors, and furthermore they were satisfied with all study team

members and said study team was co operative and helpful.

- Risk and Benefits of *CTs:* Among NTP 80 % felt that it is risky to participate in trial because drug is still in trial phase and at this stage, no one knows the side effe*cts*. 20% thought participation in phase 1 and phase 2 *CTs* is risky while 30% of them believed that *CTs* is beneficial to science. 9% assured that one can get more accurate results by conducting *CTs*. 20% were convinced that *CTs* is the only way to evaluate side effe*cts* of the drug. Remaining *NTPs* were neutral as they were totally unaware about *CTs*. Among *TPs,* 15 % of them were scared of the side effe*cts*. One of the female participants expressed her feelings by saying "I do not want to be a sample for them; I don't want to risk my life. I love my life and my opinion is fair." 15% *TP* did not know of any risk that is caused by participating in *CTs* as they had never experienced or have heard about the risk of *CTs* while 15% said that there is no risk involved in *CTs* and trial participants were not treated as guinea pigs. These *TPs* felt that every medicine has side effe*cts* whether it is study drug or a marketed drug. Remaining 55% *TPs* voiced their opinion by saying that risk depends on study drug as well as on the treating doctor. There were mixed reactions about the benefits of *CTs*. 65% of *TPs* felt that *CTs* are beneficial because doctor gives more attention to the trial participants, and participants get free medication, treatment and transportation. However 15% of the respondents said *CTs* is not beneficial to the participants but beneficial to the Pharma Company; and, one male *TP* perceived it as money making business. According to 15 % participants, giving free treatment and medication is bribing. 15% of the participants demanded that when the drug comes into the market, it should be given free or at least at reasonable cost to the *TP.*
- Would you advise others to participate in *CTs?* 40% of *TPs* stated that those who want to participate should know the implications of the trial. 40% felt that let people decide on their own if they want to participate or not. 20% of *TPs* were ready to be an advocate for other participants so that they can participate in *CTs*.
- 75% of *NTPs* said that they always advice their close friends and relatives to participate in *CTs*, if doctor is very sure and previous trial results are available. 9% said that they will reveal the complete picture to the participants and then let them weigh the options. 18% of participants did not want to advice any one to participate in *CTs*.
- Necessary to create *awareness* about *CTs:* 90% *NTPs* said that *awareness* should be created among all, at least from 12th standard of education onwards. 80% of the participants suggested that *awareness* must be created in such way that fear must be removed from everybody's mind.
- 70% of *TPs* said *awareness* is necessary while 30% did not feel that there is a need to create *awareness* among public. According to these 30% respondents, public gets bored due to this *awareness* programs and felt that one can become aware from their own experience of participation in a *CT*.
- How to create *CTs awareness:* Mouth publicity (70%), TV and Radio (95%), documentary and short films (35%), print media publicity (20%) conducting lecture in colleges, presentation for community (15%) were some of the ideas to create *awareness*.

The main themes generated from the qualitative research were, importance of first contact point i.e. principal investigator (P.I) / person in *CTs* recruitment, and most (90%) participants believed on their P.I.'s decision.

DISCUSSION

As seen in this study, focus groups and interviews have generated information that helped us to understand the beliefs and views of the general *public* as well as the *TPs* regarding *CTs* and the related issues. The results of our study indicated that there is low *awareness* about *CTs* among the general public. It was noticed that despite the high education level of our sample, many still had difficulty understanding basic concept of *CTs*. Few *TPs* were unsure about what documents they had signed. Although CT aims to provide a high standard of care and help contribute to increased scientific knowledge only a relatively small proportion of patients received treatment as a part of formal *CTs*. From our study it is seen that selection of *TPs* was often based on level of patient – doctor-patient's relative relationship and trust. Our study showed that the patients entered the *CTs* because of their primary care physician. When the trial's principal investigator is also the patient's primary physician, there is scope for a direct conflict of interest, especially if physicians are paid recruitment fees to recruit their patients into trials.[18] Results from Breast Cancer study showed that a recommendation by their physician was the primary factor influencing patients' decision to enrol in a trial. If the patient must be referred elsewhere to participate in a trial, doctors fear they may lose control over the patient's care.[19] For the same reason, doctors are reluctant to refer their patients to a trial conducted by another doctor.[19] This keeps the patients away from the trial information. *FGD* conducted in North Carolina with cancer patients reported that personal relationship of the patients with the staff influenced their decision to volunteer and their willingness to participate. Participant's decision was also based on cues

that caught their eyes (after reading news paper ads), ears (recommendations by someone), and attention (personal or family health issues).[18] The same results are seen in our *FGD*. One of the study conducted by SM Madsen in year 2002 suggested that trial participants as compared with non participating respondents were, more positive towards both participation of self and others,[20] our evaluation about *TPs'* attitude showed similar results. Study conducted by Barrie R showed that most respondents (71%) believed that patient should serve as research subjects.[21] In support of this belief, the majority of the respondents from our study cited potential benefit to others and the opportunity to increase scientific knowledge, but the difference bias emerged when we asked them about their own potential participation. Altruistic attitude was observed among participants of this study which is consistent with other ethnic groups from Briton[22] and Rheumatoid Arthritis patients in California.[22] Participants of this study depended on their family members or friends to guide the decision of their own participation which is consistent with the dependency issues mentioned by Shah in his Meta-analysis of Qualitative studies.[1]

In our study, all NTPs and few TPs were unaware of the term inform consent. Similar result was reported by the focus groups conducted with 33 African American adult patients where the results revealed that few participants had understood concept of informed consent.[23]

In the same study[23] and the studies reported in Briton[3,4] the patients had expressed distrust with the medical community. Also participants expressed fear that the doctors could and would make statements to persuade people to participate in the research.[2,3] In our study distrust was expressed only with the Pharma companies.

The results of our study offered us a chance to compare the levels of awareness of trial and non-trial participants using trial participants as a control. Our findings require validation in a larger sample that includes other geographical areas in the country. The findings generated from these interviews will then be used to develop the questionnaire for evaluating public and the patient's perception, Knowledge, attitudes and behaviour regarding *CT* participation in the next project. Also the study would help in modelling culture specific education programs for the masses regarding phases and types of *CTs*, conduct of *CTs*, risks and benefits involved in the trials, and participant's rights while participating in *CTs* by understanding the importance of informed consent form. This education would in turn help people make better informed decisions and choices regarding participation in trials (it would be a self-initiated participation rather than an "influenced" participation). *Awareness* about *CTs* should reduce exploitation of *TPs* by Multinational Companies (MNCs).

There were a number of limitations to this study. This study was not conducted on a random sample. This study was conducted in a particular location (Our sample was limited to one geographic area of the city) leading to a biased sample. Data was collected from few individuals so findings cannot be generalized to a larger population. The education level of the respondents was higher as compared to the general public. Despite these weaknesses, there are some strengths. The response rate for the study was 100% offering opinions about clinical trials. This is one of the few studies in India, where information has been gathered to understand *awareness*, perceptions and attitudes about clinical trials.

The *awareness* of *CTs* was low even among fairly well educated respondents of our study. Considering that 70% of India's population is rural, there is an urgent need to look at *awareness* of *CTs*.

CONCLUSION

From focus group discussions and interviews participants revealed that the *awareness* of *CTs* is low. Participation was highly based on physician's trust. Willingness to participate in *CTs* was not very high among the *public*. It was more among *TPs* as compared to *NTPs* and those who are willing, wanted to participate for noble cause. Conducting a quantitative study with a large sample should validate the results of this study.

REFERENCES

1. Shah JY, Rajgor D, Vaghasia M, Pradhan S, Zelko H, Pietrobon R. What leads indians to participate in clinical trials? A meta-analysis of qualitative studies. PloS One 2010;5:1-9.
2. Gonzalez LE, Gwendolyn PQ, McIntyre J. Barriers to participation in clinical trials among Hispanic cancer patients. Undergrad Res J Hum Sci 2010;9.
3. Hussan-Gambles M, Leese B, Atkin K, Brown J, Mason S, Tovey P. Involving South Asian patients in clinical trials. Health Technol Assess 2004;2:1-109.
4. Hussan-Gambles M. South Asian Patients' views and experiences of clinical trial participation. Fam Pract 2004;21:636-42.
5. Catania C, De Pas T, Goldhirsch A, Radice D, Adamoli L, Medici M, *et al*. Participation in clinical trials as viewed by the patient: Understanding cultural and emotional aspects which influence choice. Oncology 2008;74:177-87.
6. Clinical trial awareness month March 2011. New Mexico clinical trial alliance. Available from: http://www.nmcca.org/whatsnew/whatsnew.htm [Last accessed on 2011].
7. Linden HM, Reisch LM, Hart A Jr, Harrington MA, Nakano C, Jackson JC, *et al*. Attitudes toward participation in breast cancer randomized clinical trials in the African American community: A focus group study. Cancer Nurs 2007;30:261-9.
8. Giuliano AR, Mokuau N, Hughes C, Tortolero-Luna G, Risendal B, Ho RC, *et al*. Participation of minorities in cancer research: The influence of structural, cultural, and linguistic factors. Ann Epidemiol 2000;10(8 Suppl):S22-34.
9. Alvins A, Goldberg H. Creating a culture of research. Contemp Clin

Trials 2007;4:557-62.
10. Hancock B. An introduction to qualitative research. In: Honcock B, editor, Trent Focus for Research and Development in Primary Health Care. 1st ed. Nottingham: Trent focus group; 1998. p. 1-27. Available from: http://books.google.co.in/books?id=xokwPwAACAAJ [Last accessed on 2012 Mar 25].
11. Morgan DL. Focus groups. Ann Rev Sociol 1996;22:129-52.
12. Tong A, Sainsbury P, Craig J. Consolidated Criteria for reporting qualitative research (COREQ): A 32 item checklist for interviews and focus groups. Int J Qual Health Care 2007;19:349-57.
13. The need for awareness of clinical research. NIH clinical research trials and you. Available from: http://www.nih.gov/health/clinicaltrials/providers/awareness.htm [Last accessed on 2012].
14. Taylor H. Misconceptions and lack of awareness greatly reduce recruitment for cancer, Clinical trials. Healthcare news 2001;1-3. Available from http://www.harrisinteractive.com/news/newsletters/healthnews/HI_HealthCareNews2001Vol1_iss3.pdf [Last accessed on 2012 Mar 25].
15. Catania C, De Pas T, Goldhirsch A, Radice D, Adamoli L, Medici M, *et al*. Participation in clinical trials as viewed by the patient: Understanding cultural and emotional aspe*cts* which influence choice. Oncology (Williston Park) 2008;74:177-87.
16. Lavallie DL, Wolf FM, Jacobsen C, Buchwald D. Barriers to cancer clinical trial participation among native elders. Ethn Dis 2008;18:210- 7.
17. Jones JM, Nyhof-young J, Moric J, Friedman A, Wells W, Catton P. Identifying motivations and barriers to patient participation in clinical trials. J Cancer Educ 2006;21:237-42.
18. Kinney AY, Richards C, Vernon SW, Vogel VG. The effect of physician recommendation on enrolment in the breast cancer chemoprevention trial. Prev Med 1998;27:713-9.
19. Mcdonald D. Meeting of the institute of clinical research (India), Mumbai. Available from: www.icri**india**.com/newsandevents.htm [Last accessed on 2008].
20. Madsen SM, Mirza MR, Holm S, Hilsted KL, Kampmann K, Riis P. Attitudes towards clinical research amongst participants and non participants. J Intern Med 2002;251:156-68.
21. Cassileth BR, Lusk EJ, Miller DS, Hurwitz S. Attitudes toward clinical trials among patients and the public. JAMA 1982;248:968-70.
22. Lee SJ, Lenert L, Weisman S, Kavanaugh A., Factors affecting rheumatoid arthritis patients' decisions to participate in clinical trials. J Rheumatol 2005;32:2317-25.
23. Corbie-Smith G, Thomas SB, Williams MV, Moody-Ayers S. Attitudes and beliefs of African Americans Toward participation in medical research. J Gen Intern Med 1999;14:537-46.

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