



## A survey on awareness of clinical trials among the people of Chersy Village, Greater Noida

SN Gimba<sup>1\*</sup>, Dr. Anshu Nanda<sup>2</sup>

<sup>1</sup> Department of Chemistry, Shehu Sule College of Nursing and Midwifery Damaturu, Yobe State, Nigeria

<sup>2</sup> School of Allied Health science, Sharda University, Greater Noida, Uttar Pradesh, India

### Abstract

**Background of the study:** Despite the efforts by Government of India and Clinical Research Associations towards enlightening people on clinical trial conduct in order to provide safe and effective medicines for people, a Research needs to be carried out to ascertain their level of awareness. It is in light of this we decide to conduct this survey to ascertain the level of Awareness of people living in Chersy village in Greater Noida.

**Materials and Method:** forty five (45) participants were sampled for the study, in which opinion survey design was used while questionnaire was dispensed as an instrument for data collection. The data generated from this research was analyzed using percentages. Quantitative analysis was used to report the findings of the research.

**Result:** The result of the findings showed that 85% of the people are not aware of clinical trials; however 75% of the participants are willing to participate as study subjects. No correlation was found between their lack of awareness with Age and Gender, but there is a correlation between the lack of awareness with educational background as 36% of the respondents are illiterate and 42% were opportune to attend 12<sup>th</sup> class below only.

**Conclusion:** The people of chersy village are not aware of clinical trials, lack of awareness campaign and illiteracy are the major factors which lead to their un-awareness. Strong measures should be taken by the authorities to educate and enlighten the people in Villages, in order for them to understand the benefits participation in clinical trials comes with.

**Keywords:** participants, villages, despite, clinical, Chersy

### Introduction

Clinical research is a branch of healthcare science that determines the safety and effectiveness (efficacy) of medications, devices, diagnostic products and treatment regimens intended for human use. These may be used for prevention, treatment, diagnosis or for relieving symptoms of a disease. Clinical research is different from clinical practice; in clinical practice established treatments are used, while in clinical research evidence is collected to establish a treatment [3].

Clinical trials are integral to the drug development process, however not all clinical trials are aimed to evaluate the safety and efficacy of new drugs or provide evidence for obtaining market authorization. The extent to which clinical trials are conducted is a reflection of the level of advancement that exists within a health care system [1].

Clinical trial Awareness seeks to educate the public about clinical research and encourage conversations about clinical trials between volunteers/patients and their health care providers. India has the largest number of patients suffering from different type of disease ailments and metabolic syndrome today. And due to the low cost, medical expertise and good hospital facilities, many multinational companies are conducting clinical trials in India, recruiting thousands of Indians [4].

Providing resources to help individuals understand and make

informed decisions about research involvement promotes understanding of the true benefits and risks of participation in clinical trials. It also increases awareness about the importance of clinical trials [2].

### Statement of the Problem

Lack of awareness of clinical trials among people living in villages of India can cause serious health setback. It is in the light of the above therefore the research is design to determine whether or not the people of Chersy village are aware of clinical trials and their willingness to participate. Under enrollment is a significant problem facing clinical trial today. Without participation in research, medical breakthroughs cannot happen and new therapies cannot be approved for patient use around the world.

### Objectives of the Study

Due to the fact that very few people are participating, the objectives of the study are:

1. To ascertain the level of awareness about clinical trials among the people living in Chersy village, greater Noida.
2. To determine their willingness to participate in clinical trials.
3. To recommend to the government and associations of clinical research to embark on massive awareness on clinical trials to villages of Northern India.

**Scope of the study**

This research work covers Chersy village, and includes both Male and Female of different age in order to find out the level of their awareness on clinical trial and their interest to participate.

**Research Questions**

This research work is aimed at answering the following questions

1. Have you heard of “clinical trial”?
2. Do you know what clinical trial is?
3. Do you know why clinical trials are being conducted?
4. Is a clinical trial, an experiment in humans?
5. Do you think clinical trials benefit the community or 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?
11. Will you offer yourself to be a trial subject/volunteer?
12. Describe clinical trial in your own words?

**Material and Method**

A total of forty five (45) participants were sampled for the

study, in which opinion survey design was used while questionnaire was dispensed as an instrument for data collection. Ethics Committee Approval was not taken because it was observational study, however informed consent was taken before respondents were questioned/interviewed whether they want to take part in it or not. Data generated from this research was analyzed using percentages. Some of the Responses were recorded on paper and translated from local language (Hindi) to English language due to language barrier. Quantitative analysis was used to report the findings of the research.

The questionnaire was assembled using information from the literature. It was then reviewed and validated by an experienced professional involved in clinical trials. The questionnaire was administered to people of Chersy village. The questionnaire was divided into two parts; part one contains personal information, while the second part is a set of questions regarding the Awareness of Clinical Trials among the People of Chersy Village, Greater Noida

**Results**

**Table 1: Gender Distribution**

Gender	Number	%
Male	26	58
Female	19	42
Total	45	100

**Table 2: Age Distribution**

Age	Number	%
10-25	9	20
26-35	11	24
36-45	14	31
46-55	7	16
56-65	4	9
Total	45	100

**Table 3: Educational Qualification**

Categories	Number	%
12 <sup>th</sup> class below	19	42
Graduate	9	20
Postgraduate	1	2
Illiterates	16	36
Total	45	100

**Table 4**

S/N	Questions	Yes (%)	No (%)
1	Have you heard of “clinical trial”?	15	85
2	Do you know what clinical trial is?	25	75
3	Do you know why clinical trials are being conducted?	40	60

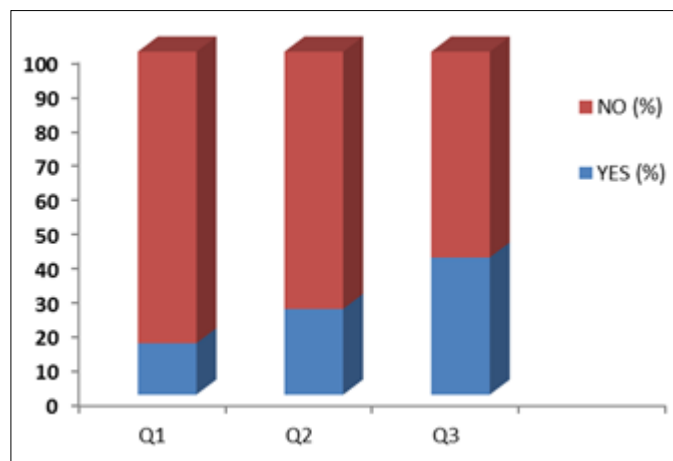


Fig 1: Diagrammatical representation of question 1-3

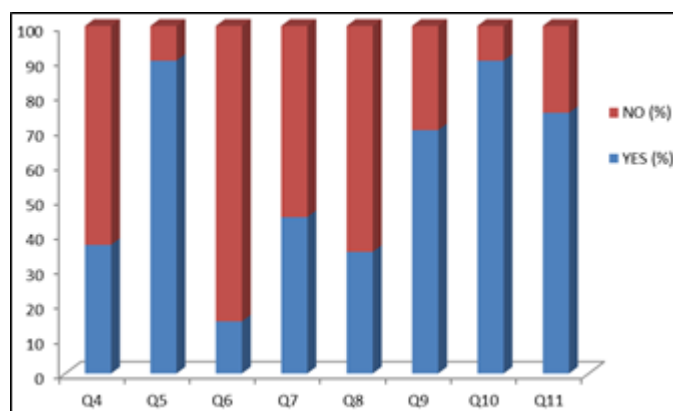


Fig 2: Diagrammatical representation of question 4-11

## Discussion

Among the forty five participants who responded to the survey questions, 26 were males (58 %) and the remaining 19 are females (42 %) (Figure 1); their Age distribution, Educational qualification and responses to the research questions are attached in table 1-12.

44% of the respondents were between the ages of 10 – 35 years while 56 % are between the ages of 36 – 65 years. Table 3 shows that 64% of the respondents are educated while 36 % were illiterates.

Of the total respondents only 15 % of them heard of clinical trials, while the remaining 85% have never had of Clinical trial. Similarly only 25% knew what clinical trial is (Tables 4), 40 % of the respondents knew why clinical trials are being conducted while 60% of the respondents responded that they don't know why clinical trials are being conducted (table 4).

The opinion of the respondents indicated that 37% belief that clinical trials are an experiment on human, while only 63% responded that it is not (figure 2). 90% of the respondents were of the view that clinical trials do benefit the community or the society while 10% are of the view that clinical trials do not benefit the community or the society as they don't receive free medications from government (figure 2).

A good number of respondents (85%) believe that clinical trial is ethical while 15% were of the opinion that it is unethical (figure 2). 45% of the respondents think there is risk in participating in clinical trial while 55% do not believe there is

a risk in participating as patients receive promising medication compared to standard treatment (figure 2). In table 8, the question; is it necessary for a company to get approval from the government before conducting a clinical trial? Was responded yes by 35% while 65% answered no, because they believe it's not necessary for a company to request for governments approval. About 70% of the respondents believed that clinical trial participants are paid money because of the high risk involved, while 30% were of the view that there is no need of paying a trial participant (figure 2). Should India allow pharmaceutical companies to conduct clinical trial in India was responded yes by 90% respondents while only 10% believed that the government of India should not permit pharmaceutical companies to conduct trial in India (figure 2). Due to the fact that people in the rural area did not properly understood clinical trials, Most of the respondents could associate clinical trial with medicine or development of medicine; however they did not have the good understanding of the way in which clinical trials are conducted. About 75% of the respondents are willing to offer themselves for clinical trials but have never been contacted while 25% of them said they can't offer to be a trial subject because of the risk involved in it (figure 2).

Most of the respondents were of the view that clinical trials only benefit the researcher and not the community. Considering the fact that India today is among the first three world largest pharmaceutical industries, its level of awareness on clinical trial is very low. This is attributed to the language barrier, ethical issues and fear of drug side effect as 45% of the respondents have had drug side effect on a standard treatment (figure 2).

This study tries to access the level of awareness on clinical trials among the people of Chersy village, greater Noida. Most of the responses show a negative outcome as many of the people of the village are unaware of what clinical trial is, this can also be attributed to illiteracy, hence education is a major contributor for perception of clinical trials.

There is a need for the Indian society for Clinical research (ISCR) to step up to its objectives not only in building awareness of clinical research as a specialty but also dissemination of information on clinical trial participation to the people living in rural areas.

One of the important players of clinical trials is the volunteer. Volunteer, either patient or one who is healthy, are recruited from the people around the community were clinical trial is going to be conducted. Hence awareness of clinical trial among the people especially its importance in new drug development would help them take part in clinical trials. But it is not known to what extent the villagers are aware of clinical trials. Hence this study was undertaken to find out whether the people of Chersy know about clinical trials. It was observed that majority of the participants have not heard of 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 a clinical trial is not an ethical one but it benefits the society.

## Conclusion

Based on the result of this study it can be concluded that

illiteracy and language barrier are the major problem leading to inadequate awareness on clinical trials which subsequently leads to non-participation in clinical trials by the people living in Chersy village greater Noida, UP India. This finding is in conformity with the findings of (4) which also recommend that there is an urgent need to increase public awareness and understanding of clinical research in India. Television and Newspaper advertisement should explain to the public the importance of Clinical Trials, importance of informed consent document, understanding the pre requisites of conducting a trial and participants' rights. The media campaigns should also include results of some if not all completed successful trials. Rigors of research should be adopted so as to maximize the benefits of clinical trials to human at minimum costs and risks.

### References

1. Ali S, Egunsola O, Babar ZU, Hasan SS. Clinical trials in Asia: world Health Organization database study. *Perspect Clin Res.* 2019; 10:121-4.
2. Alvins A, Goldberg H. creating a culture of research. *Contemp clin Trials.* 2007; 4:557-62.
3. Balasubramanian J, *et al.* Awareness of clinical trials among general population. *Int. j. of allied med. Sci. and clin. Research.* 2013; 1(1):8-17.
4. Joshi VD, Oka GA, Kulkarni AA, Bivalkar VV. Public awareness and perception of clinical trials: quantitative study in pune. *Perspect Clin Res.* 2013; 4:169-74. <http://www.picronline.org>