



## **Awareness On Clinical Trial Among Dental Students-A Survey Study**

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### **ABSTRACT**

**Introduction:** India has the largest population suffering from metabolic syndrome, diabetes, cancer, and other maladies. Due to low costs, good hospital facilities, medical expertise, many companies are conducting several trials in India recruiting several thousands of people. Clinical trials are very useful to generate the highest levels of evidence utilized to inform medical practice and easier to share medical decisions. Objective of the present study evaluates the knowledge and awareness about clinical trials among dental students.

**Materials And Method:** An online survey was conducted with a self-structured questionnaire among dental students with a sample size of 100. The questionnaire was designed using the online survey platform and circulated through “google forms”. Responses from google excel sheets are analysed statistically through Chi-square test.

**Results:** The present study reveals the awareness of the study participants on clinical trials. The participants who had participated in the survey with 55.56% interns, 44.44% final year undergraduate dental students. 78.79% of the participants were aware of clinical trials while the remaining 21.21% were not aware. The results were statistically significant according to the Chi square test, where  $p < 0.05$ .

**Conclusion:** The study is evident that the majority of participants reported positively. The study concluded that most of them are aware of the clinical trials. Dental students need to be trained in their study period about basic clinical research trial principles, regulatory needs and about the clinical trial practices.

**Keywords:** Awareness, clinical trial, phases, Novel method, types of clinical trials

### **INTRODUCTION**

India has the largest population suffering from metabolic syndrome, diabetes, cancer, and other maladies. Due to low costs, good hospital facilities, medical expertise, many companies are conducting several trials in India recruiting several thousands of people. (1) Clinical trials are very useful to generate the highest levels of evidence utilized to inform medical practice and easier to share medical decisions. But, a very small population only enrolls in clinical trials, which has markable implications regarding the progress, the generalizability of trial results, and the cost of clinical therapeutic development.(2)(2,3) Many articles talk about an increase in the number of clinical trials (CTs) and revenues but few only talk about “Amount of Participants ” who contribute to the clinical trials for the advancement of medicine. Few researchers have looked at whether the participants getting recruited in clinical trials know what clinical trials are and if participation is purely their conscious decision. Studies have made known that distrust or suspicion of research, apprehension, and awareness about the clinical trial, especially among participants from rural areas. (4)

In India, it is tough to find literature on topics like to find public awareness on clinical trials. A previous study conducted within Britain had reported that motivators for participating in the trials to improve their own as well as family and help the society.(5) A similar study by Hussan concluded that trial burden, mistrust with health workers, and language barriers to people who are participating in clinical trials. (6,7) Another survey of almost 6,000 people with cancer reported that 85 percent of people with cancer were unaware of participation in clinical trials. (8)The use of qualitative research is more common and popular in clinical trials. These methods involve an in-depth exploration. Qualitative research is concerned with the experiences, opinions, and feelings of individuals producing subjective data collected through direct encounters with individuals or observation or individual interviews or group interviews.

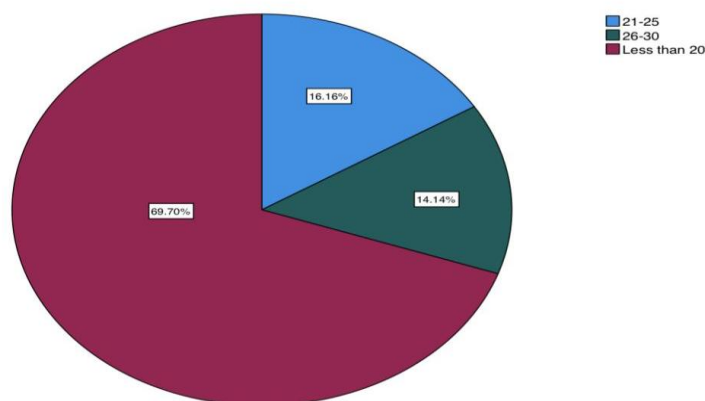
Group methodologies are very essential when there are differences in views and perspectives between researchers and the communities they are targeting. Allison Tong has made a checklist for comprehensive reporting of qualitative studies, which is very useful. If a participant is aware of the concept of conduct of a clinical trial he/she would participate with an informed decision, recruitment will be easy and the retention rate will be high. When participants are aware, compliance will increase with efficient trial results. This would help for the smooth conduct of a clinical trial. Clinical trials generate the highest evidence among medical practice, decisions, and knowledge about the clinical trials among the physicians followed by the awareness and participation of individuals in clinical trials(9,10).Our team has extensive research experience that has translated into high quality publications(11–24) ,(25–29). The Aim of the study is to evaluate the knowledge and awareness about clinical trials among dental students.(30).

**MATERIALS AND METHOD**

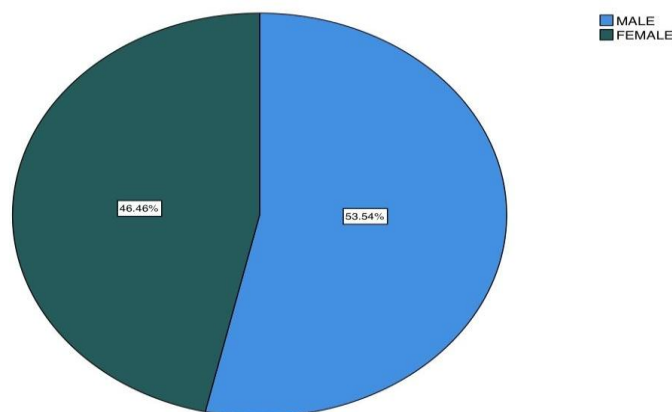
This is a prospective observational survey-based study. A self-designed questionnaire of 10 questions was framed about clinical trials experiments done in a research laboratory. The numbers who participated in the study are 100 dental college students from Saveetha Dental College Chennai by volunteer participation in the study. The volunteers were given one week for survey completion.

Clinical trial questionnaire output result variables are the demographic details about the knowledge and awareness of clinical trials among the population of dental students. The questionnaire was prepared from clinical trial study articles. It was approved by the Scientific Review Board of Saveetha dental college, Chennai. Participation in the study was voluntary and was circulated online using google forms. Before proceeding to start the survey, a detailed explanation was shared with all participants. Once the survey was completed, data were collected and analyzed with statistics. A Chi-square test was done with SPSS software and values were analyzed. Bar diagrams and Pie charts were used for output variable representation.

**RESULT AND DISCUSSION**



**Figure 1.** The pie chart depicts the age of the participants. 69.70%(red) belonged to the age group of less than 20 years, 16.16% (blue) belonged to the age group of 21-25years and remaining 14.14% (green) belonged to the age group of 26-30 years.



**Figure 2:** Pie chart depicts the gender of the participants. 53.54%(blue) are males and remaining 46.46%(green) are females.

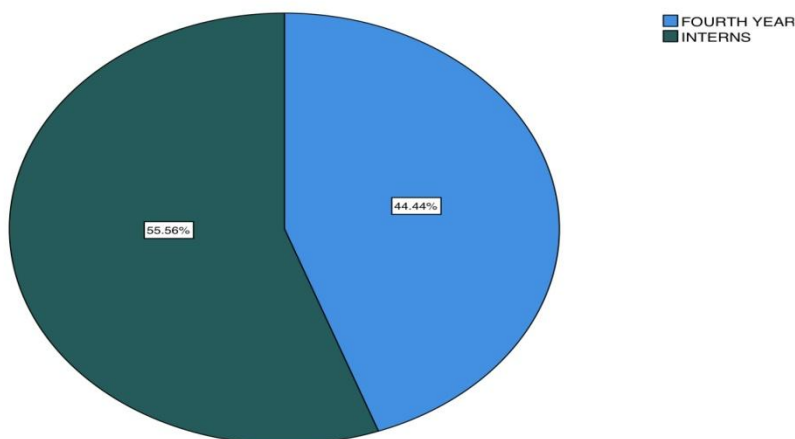


Figure 3: Pie chart depicts the years of study of the participants who had participated in the survey. 55.56% (green) of the participants were interns, 44.44% (blue) were the fourth year. BDS.

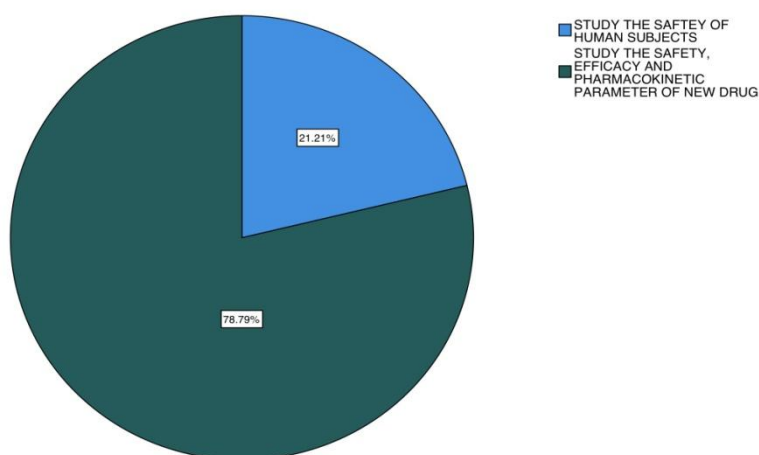


Figure 4: Pie chart depicts the awareness of the study participants on clinical study. 78.79% (green) of the participants were answered that the safety, efficacy and pharmacokinetic parameter or new drug, and remaining % 21.21% (blue) agreed with Study the safety of human subjects

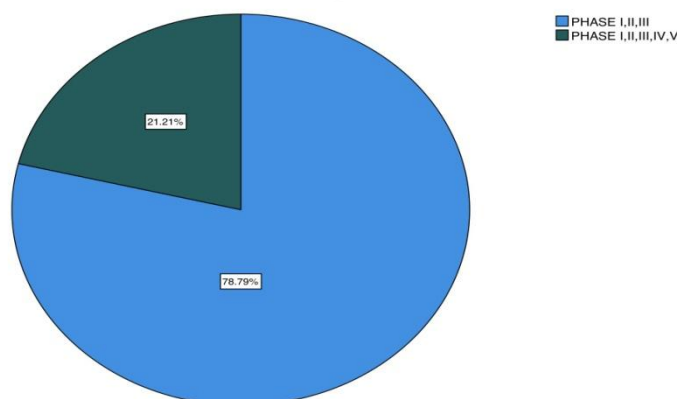
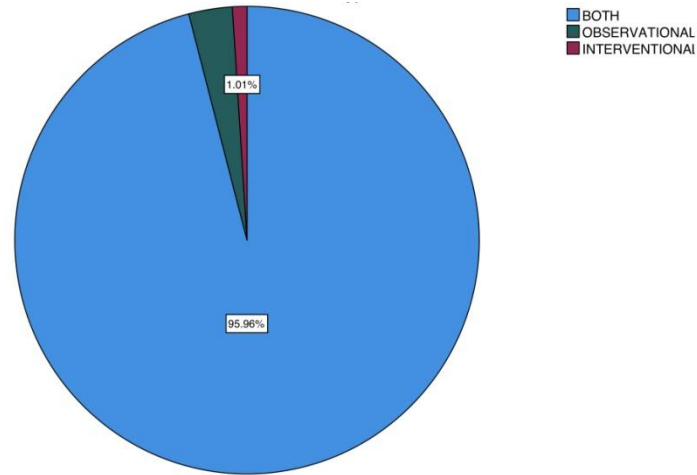
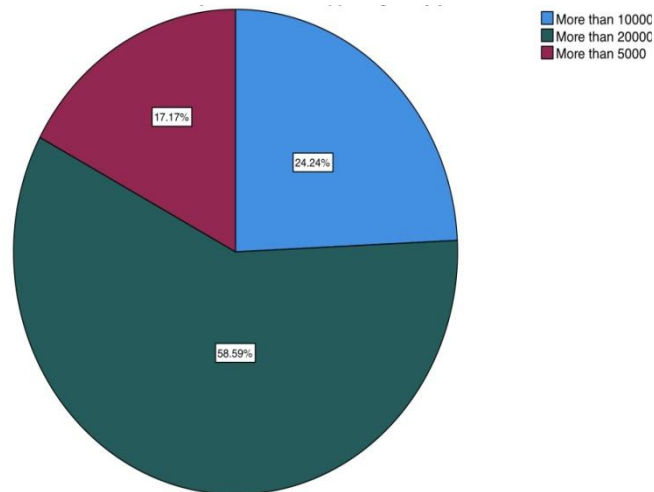


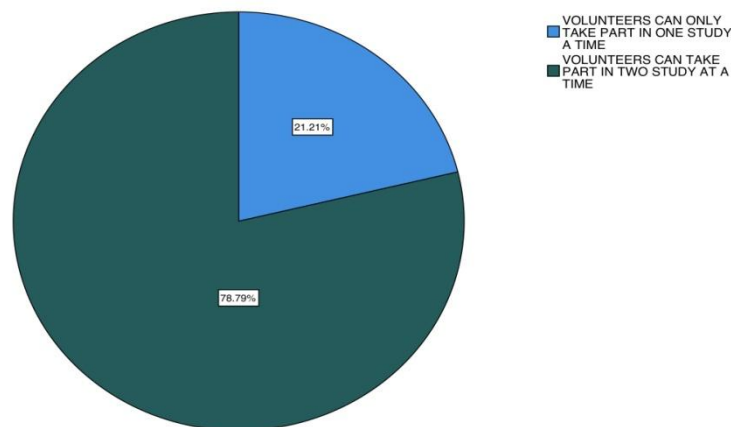
Figure 5: Pie chart depicts the awareness of the study participants on phases of the clinical trial. 78.8% (blue) of the participants were not aware of phases and the remaining 21.21%(green) were answered positively.



**Figure 6: Pie chart depicts the awareness of the study participants on types of clinical trial.95.96% (blue) of the participants were answered that interventional and remaining 3% (green ) were answered as observational and 1.01%were answered interventional.**



**Figure 7: Pie chart depicts the awareness of the study participants in clinical trials happening every year in India.58.58% (green ) of the participants were answered more than 10000 and 24.24%(blue) were answered more than 20000 and the remaining 17.17%(red ) were answered more than 5000.**



**Figure 8: Pie chart depicts the awareness of the study participants on the participation in clinical trials. 78.58% (green ) of the participants were not aware of participation and the remaining 21.21%(blue) were answered positivel**

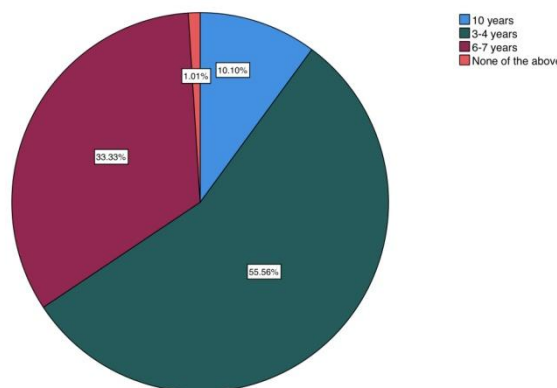


Figure 9: Pie chart depicts the awareness of the study participants on how long it takes to develop a new drug. 55.56%(green)of the participants were answered as 3-4years and 33.33%(red)of the participants were answered as 6-7years, 10.10%(blue) of the participants were answered as 10 years, and the remaining 1.01% (orange) answered as none of the above.

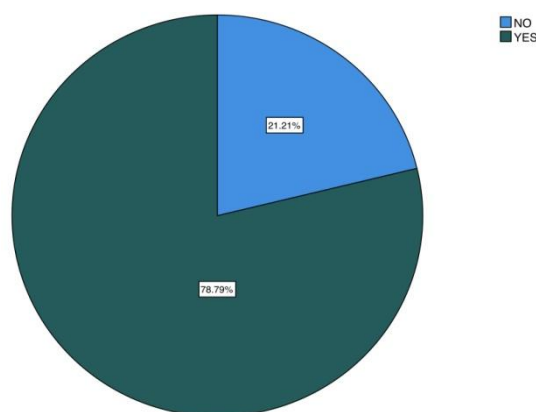


Figure 10: Pie chart depicts the awareness of the study participants on clinical trials. 78.79% (green) of the participants answered yes and the remaining 21.21%(blue) answered no.

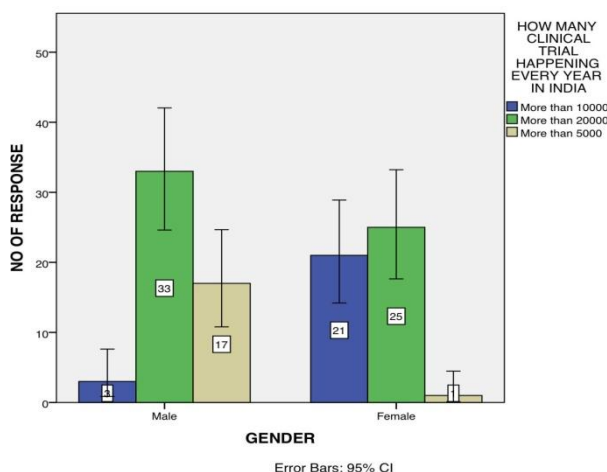
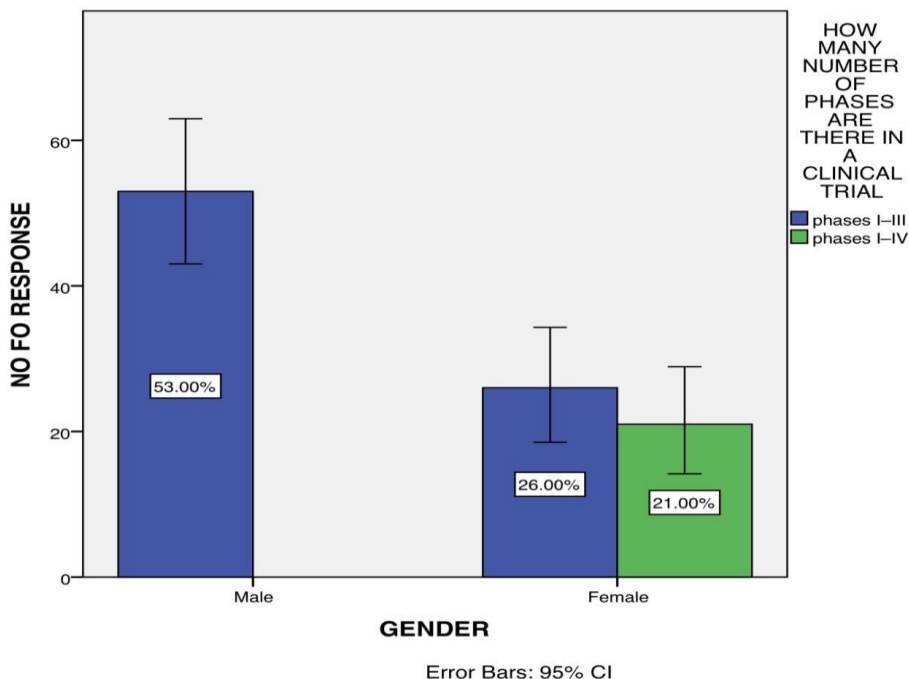
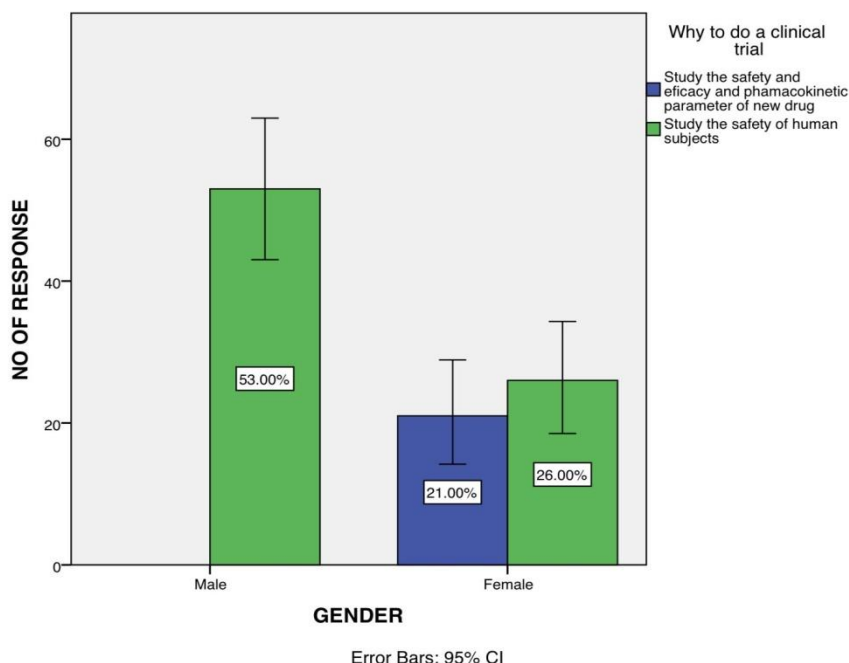


Figure 11: The chart depicts the chi-square correlation between gender and the awareness regarding the number of clinical trials happening every year in India. X axis represents the gender and the Y axis represents the frequency of response. Blue represents more than 10000 in which 21% of the participants were female and 3% of the participants were male. Green represents more than 20000 in which 25% of the participants were female and 32% of the participants were male. Beige colour depicts more than 5000 in which 17% of the participants were male and 1% were female. This difference was statistically significant (Chi-Square test; p-value=0.000-significant)



**Figure 12:** The chart depicts the chi-square correlation between gender and the awareness regarding how many phases are there in a clinical trial. The x-axis represents the gender and the y-axis represents the frequency of response. Blue colour represents Phases 1,2 and 3 in which 26% of the participants were female and 53% participants were male. Green colour represent Phases 1,2,3,4 and 5 in which 21% of the participants are female. This difference was statistically significant (Chi-Square test; p-value=0.000- significant)



**Figure 13:** The chart depicts the chi-square correlation between gender and the awareness regarding why to do a clinical trial. The x-axis represents the gender and the y-axis represents the frequency of response. Blue represents a study of the safety of human subjects in which 21% of participants are female and 53% of the participants are male. Green colour represents study of the safety, efficacy of the new drug in which 26% were female. This difference was statistically significant (Chi-Square test; p-value=0.000- significant)

Figure 1 reveals the ratio of age of the participants. 69.70% were in the age group of less than 20 years, 16.16% belonged to the age group of 21-25 years and the remaining 14.14% belonged to the age group of 26-30 years. Figure 2 reveals the distribution of gender of the participants 53.54% were male and the remaining were 46.46% female. Figure 3 reveals the ratio of participants from different years of study, 56.7% of the participants were from the 4th year and 43.3% were interns. Figure 4 in the current study depicts the need to perform a clinical response, 78.9% have answered that clinical study is done to understand the safety of human subjects. Safety, efficacy about 21.21% have given positive responses regarding the pharmacokinetic parameter of new drugs. Figure 5 reveals the number of phases, 78.8% of the population has answered that there are 3 phases and around 21.21% have answered that there are around five phases.

In the current study Figure 6 depicts the main types of the clinical trial, 95.9% considered the main type of clinical trial as interventional, observational. Figure 7 depicts the total number of clinical trials taking place in India every year, 58.6% has answered as more than 2000 studies are occurring, 24.2% as more than 1000, and around 17.2% as more than 500 studies are occurring in India. Figure 8 depicts the awareness of the study participants on participation in clinical trials. 78.58% of the participants were not aware of participation and the remaining 21.21% were answered as volunteers can take part in one study at a time. Figure 9 depicts the awareness of the participants on the period to develop a new drug, 55.56% of the participants answered as 3-4 years and 33.33% of the participants answered as 6-7 years, 10.10% of the participants answered as 10 years. Figure 10 reveals the awareness of the study participants on clinical trials. 78.79% of the participants answered yes and the remaining 21.21% answered no. Figure 11 reveals a chi-square correlation between gender and the awareness regarding how many clinical trials happening every year in India. Figure 12 depicts the chi-square correlation between gender and the awareness regarding how many phases are there in a clinical trial. And figure 13 depicts the chi-square correlation between gender and the awareness regarding why to do a clinical trial.

From our study, The results (fig 10) indicated that there is high awareness about CTs among dental students. Studies have reported unethical conduct of trials. (31,32) Awareness will help the participant to decide about who should participate in the trial and the participant's rights, safety, duration, and compensation. From (fig5). It was reported that despite the high education level of our sample, many still had difficulty understanding basic concepts of CTs. This is strengthened by the previous study, in most countries, recruitment for CTs is not easy. In India, it was observed that participants participated without knowing the basic concept about the trial and it was noticed that participants' participation was only based on trust in the physician.

The authors get this result to be consistent with results from a meta-analysis study that showed that a physician's recommendation was the primary factor influencing patients' decision to enroll in a trial. Even Though 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 a previous study, it is seen that selection of TPs was often based on the level of patient-doctor patient's relative relationship and trust (33). The study showed that the primary care physician plays a vital role in patients entering the CTs. This is strengthened by our result that from (Figure7) depicts the total number of clinical trials taking place in India every year, 58.6% has answered as more than 2000 studies are occurring in India, When the patient's primary physician is the trial's principal investigator, there is scope for a direct conflict of interest, especially if physicians are paid recruitment fees to recruit their patients into trials. (34) Results from a Breast Cancer Study showed that a recommendation by their physician was one of the primary factors which influenced patients' decision to enroll in a trial.

In the current study, Figure 6 depicts the main types of clinical trial, 95.9% considered the main type of clinical trial as interventional, observational which was supported by the previous study(35), In an observational type of study, the subjects and their outcomes are measured by the investigators. In this type, researchers do not manage the study actively. Like that in an interventional study, the investigators assess how the subject's health changes by giving the subjects experimental drugs, use of a medical device, and other intervention or diagnostic to compare the trial participants with people receiving standard treatment or no treatment. Results from Figure 8 correlated with the previous study (36) that all the trial participants are informed to undertake a medical checkup. The requirements depend on the trial needs, but moreover, participants would be screened in a medical laboratory. Results from figure 4 were supported by the previous study (37); clinical trials are observations or experiments done in clinical research to generate data on safety and efficacy. After receiving health authority/ethics committee approval only they conduct the clinical trial in that country. These people are responsible for the risk/benefit ratio. But mainly their approval is only for the trial to conduct, which does not mean the therapy is effective or safe.

From the previous studies (38), clinical trials are commonly classified into five phases. Every phase of the drug approval procedure is treated as a separate clinical trial. Normally the drug development process proceeds through I-IV phases over several years mostly involving a decade or longer. If the drug successfully progresses through phases I, II, and III, it commonly is approved by the national regulatory authority for use in the general public. Phase IV trials are conducted after the newly approved drug or the device is marketed, to assess the



risks, benefits, or best uses. which was correlated with our results from figure 5, which depicts awareness of the study participants on phases of the clinical trial.

As some percent of dental undergraduates may be future investigators. Hence they should be trained in their study period about clinical research and its ethics. But the limitation of this study is only 100 participants were included, in the future more populations will be included.

## CONCLUSION

From this study, it is evident that the majority of the dental students reported positively. The study concluded that most of the dental students are aware of the clinical trials. As some percent of dental undergraduates may be future investigators. Dental students need to be trained in their study period about basic clinical research trial principles, regulatory needs and about the clinical trial practices. As UM Thatte has suggested conducting clinical trials one needs to have sound knowledge about basic principles of clinical research, ethical and regulatory requirements, and good clinical practices.

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## Conflict Of Interest

The authors declare that there is no conflict of interest in the present study.

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