



## Knowledge and Perception Regarding Clinical Trials Among Dental Students - A Questionnaire Based Study

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### ABSTRACT



Clinical trials play an important role in improvement of quality on healthcare practice. Good clinical practice is a backbone of conductance of trials. A lack of knowledge may translate to a negative perception towards clinical trials. The study aims to evaluate the awareness of clinical trials among undergraduate dental students in a private dental institute. We have quantified the knowledge and perception of clinical trials by a structured validated questionnaire. The questionnaire was administered to dental students from first year undergraduate to third year Postgraduate. The percentage of questions answered were calculated and tabulated in the excel sheet. Data were analysed using SPSS statistical software and the chi-square test was done. P value was set as 0.05 as a level of significance. From statistical analysis, postgraduate students (59.2%) had better knowledge than undergraduate students (40.8%). Around (46.7%) had been involved in clinical trial training. Within the limitations of current study, students pursuing postgraduate had a better knowledge of clinical trial methodology than compared to undergraduate students.

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### INTRODUCTION

Clinical trials play a very important role in the quality of healthcare practice (Ohmann and Deimling, 2004). Clinical trials help in safe and effective treat-

ment (Maiti and Raghavendra, 2007). Good clinical practice guidelines are the backbone for conductance of these types of clinical trials, helping in ensuring safety of the patients (Yanagawa et al., 2014).

Several studies have identified factors such as academic success, gender, intending to join a competitive speciality and financial worries as key plays in defining the probability of students, engagement in clinical research activities (Galletly et al., 2009; Khan et al., 2006). Most of the teaching medical institutions are involved in clinical trials. Undergraduate dental students are also taught in the pharmacology curriculum about the different phases of clinical trials in brief and the process of conducting a trial. The staff and students are hardly exposed to the concept and modern technologies

which can be utilised for a research purpose (Kumar *et al.*, 2009; Packiri, 2017). The postgraduate students in India undergo both clinical training and research (Richardson, 2009). However undergraduate curriculum does not include the concept of clinical trial. There is a need for these future investigators to be trained in the basic research methodology and the ethics involving clinical trials and medical research (Kumar *et al.*, 2009).

The science of clinical development of chemical entities into a drug is important for progression of healthcare. Regulatory approval for marketing a new molecule subject to production of data from clinical trials compared with standard comparators. The perception of clinical trials inside the medical community has not remained untarnished (Imran *et al.*, 2013). Data regarding knowledge and perception of clinical trials among Indian doctors are scanty (Govindaraju, 2017). Negative perception within the medical community may result in lack of clear knowledge regarding scientific, logistics and procedural intricacies in clinical trials (Nundy and Gulhati, 2005). While the conduct of clinical trial is permitted only when there is enough evidence suggest that the anticipated benefits of the intervention will supersede the associated risks (Jeevanandan and Govindaraju, 2018; Ravikumar *et al.*, 2017), that doesn't happen in reality (Shah, 2012; Nair *et al.*, 2018) the situation has been complicated by the recent incidents of conduct of several studies with questionable integrity and ethics, thus casting a shadow of doubt on a scientific community (Fowler, 2013; Sarojini and Deepa, 2013). A lack of knowledge may result in negative perception toward clinical trials (Somasundaram *et al.*, 2015; Panchal *et al.*, 2019; Govindaraju *et al.*, 2017a; Gurunathan and Shanmugaavel, 2016; Govindaraju *et al.*, 2017c). So to know the importance of clinical trials, there are a lot of clinical trial articles published in many journals (Subramanyam *et al.*, 2018; Jeevanandan, 2017; Ramakrishnan and Bhukri, 2018; Lakshmanan *et al.*, 2020; Govindaraju *et al.*, 2017b). This study aims to evaluate the awareness of clinical trials among undergraduate dental students in a private dental institute.

## MATERIALS AND METHODS

This was a questionnaire based study after obtaining university ethics committee approval. The questionnaire was administered to dental students from first year undergraduate to third year postgraduate through google forms.

The questionnaire was divided into three parts- part one demographic profiles, part two questions about

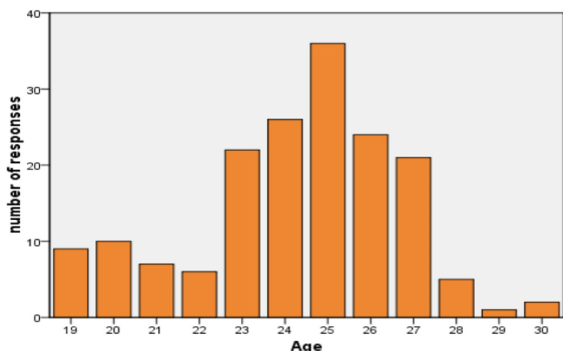
knowledge of clinical trials, part three questions about perception of clinical trials. The answered questions assessed as a five point agreement scale which includes strongly agree, agree, neither agree nor disagree, strongly disagree and disagree. Tabulation was done in excel sheet. Data were analysed using SPSS software. Descriptive statistics test was done.

## RESULTS AND DISCUSSION

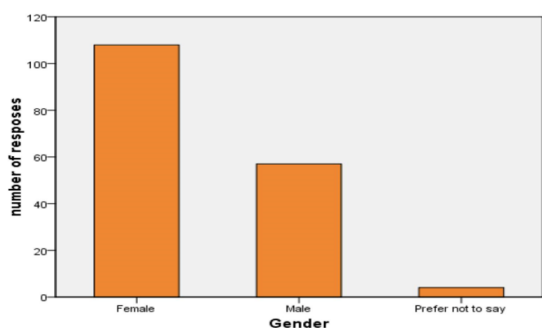
A total of 169 students had participated in the study. The most common age group of respondents is above 25 years [Graph 1]. Around 33.7% of them were male and 63.9% were female [Graph 2]. Proportion of females was more than the male respondents. Among the respondents, 59.2% were Postgraduate students and 40.8% were undergraduate students [Graph 3]. The frequency distribution of responses to assess the knowledge and perception regarding the clinical trials were given in Table 1. Of all students, 59.2% were not involved in clinical trials and 40.8% were involved in clinical trials. Majority of students agree with clinical trials done in healthy volunteers, not only the patients (56.3%). Among the respondents, 52% of students agree with the statement that clinical trials is a research study with human volunteers to answer health education. 45.6% of students agree with the ideal idea of a placebo. A placebo looks like a real drug but has no effect for this statement, which was agreed by 45.6% of students. Among 169 students, 55.6% students showed a good response on consent form which explains the known dangers of being in the clinical trials. 52.1% of students agree with a question that once a patient enrolled in clinical trials cannot withdraw until the study completion and 50.7% disagree with this question. 42.2% agrees that sometimes a patient is prevented from joining clinical trials because they were too sick. 51.8% of students agree that registration of clinical trials is not necessary.

Among 169 students who participated, 45.3% agreed for the statement that clinical trials of experimental drugs were monitored for safety by the government. Majority of students (54.5%) agree that patients' identity and address were kept protected. 47% of students agree with the statement that patients continue to receive study medications free of cost after completion of clinical trials and 55.5% disagree with this statement. The responses for the statement on the need for clinical trial was agreed by 50.2% of respondents. There is a good response for the statement of the experimental drug and 45% of respondents agreed with this statement.

53.9% of patients agree with the statement that clinical trial patients can be conducted without any animal toxicity study reports of the drug. Clinical protocols should be approved by higher authority before initiation was agreed by 52% of students and disagreed by 47.9% of students.



Graph 1: Bar graph shows an age wise distribution of respondents

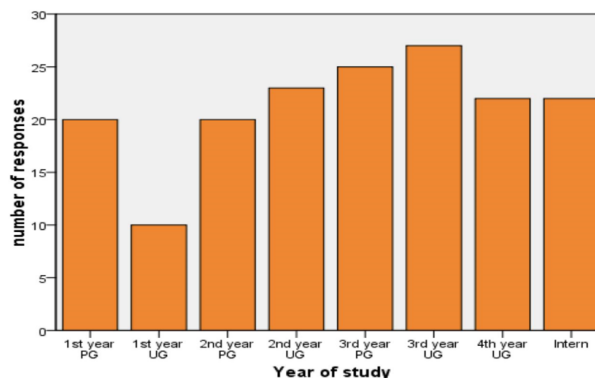


Graph 2: Bar graph shows gender wise distribution of respondents

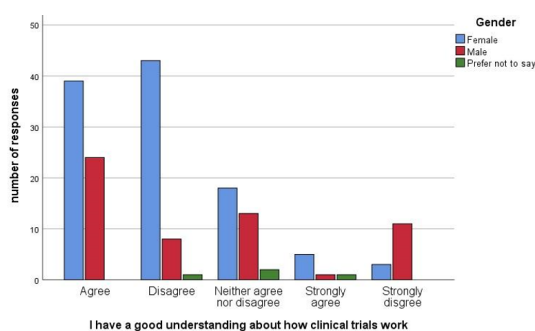
45.6% of the students agree with the statement that all clinical trials should be approved by the institutional ethics committee before starting. There is a good response for the proper standard treatment is done in clinical trials(56.2%). Regarding the statement of participation, the majority of students(48.8%) agree and 50.7% of students disagree. 60.1% of students agree with the statements where patients were exploited in industry sponsored clinical trials. Majority of students agree with a statement that patients were exploited in industry sponsored clinical trials (60.1%). Majority of students (51.8%) agree that television and audio communication helps to create awareness on clinical trials among the people.

For the statement, compensation for study related injuries were not reimbursed to patients was agreed by 50.3% of students. About 58% of students agreed for the statement, the primary objective for conducting clinical trials is for science for commerce. From

169 responses, 50.9% agreed for the statement, reason for participating in clinical trials for treatment benefits. 54.4% of the students agree that age wise no difference was observed in terms of perception and 46.6% disagree with this statement. Majority of students (51.8%) agree that television and audio communications are the best way to create awareness about clinical trials. Regarding the statement of informed content, 48.8% agree and 50.9% disagree. 70.1% of students agree with the statement that the primary objective of conducting sponsored clinical trials is commerce not science. Comparison of responses based on gender, showed statistically significant differences with higher number of females students agreeing to the statements on clinical trials (Chi-square test; p-value < 0.05) (Graphs 4, 5 and 6).



Graph 3: Bar graph shows frequency distribution of samples based on year of study



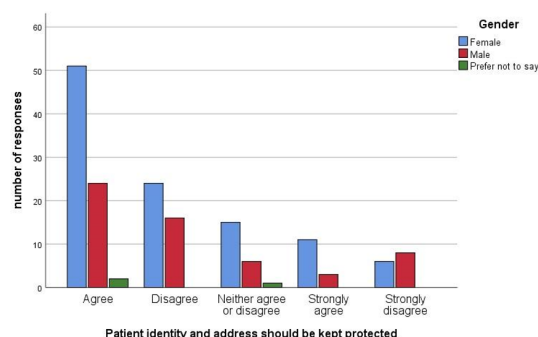
Graph 4: Bar graph describing the comparison of responses for the statement “I have a good understanding about how clinical trials work” based on gender

The science of clinical trials may not be well understood by dental students, who were not specifically trained in it. A lack of knowledge may result in negative perception toward clinical trials. Negative perception within the medical community is caused due to lack of clear knowledge regarding the scientific, logistic and procedural intricacies of clinical

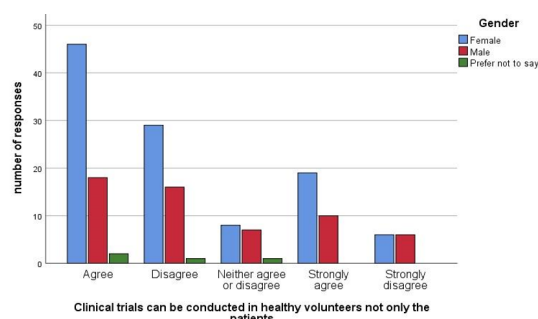
trials. In medical education, there is no organized structure regarding the student's participation in clinical research. The early involvement of undergraduate students in clinical trials will help them to make evidence-based decisions for their future clinical practices. One of the reasons for less involvement of dental students in clinical trials could be poor clinical knowledge and clinical interest. Information and educational material related to clinical trials should be provided through seminars, audio-visual communications, lectures, classes as well as educational websites. The low rates of participation in clinical trials suggests that more attention should be given to enhance clinical trials experience of medical students, dental students and interns to increase their involvement in clinical trials.

In the present study, we estimated the knowledge and perception regarding clinical trials. Most of the questions have shown a good response. Most of the students were involved in clinical trial training. The results of our study shows (46.7%) had clinical trials training and (53.3%) did not receive clinical trial training. This study coincided with Dhodiet et al., he stated doctors who received clinical trials training were (36.3%), the proportion of not received higher than the received (Dhodi et al., 2013). About (55.6%) students believed informed consent is mandatory, this coincided with the study provided by Bhowmick et al., he stated that majority of the doctors believed that the informed consent procedure followed in our country and it is mandatory (Sikdar et al., 2014). About (53.9%) of the students thought patients were at risk by participating in clinical trials. Similar to our observation. Study provided by Jadhav and Behati reported that half of the clinical trials professionals from India believe in the risk of participating in clinical trials (Jadhav and Bhatt, 2013; Christabel, 2015; Ravikumar et al., 2017). In our study (40.8%) of students involved in clinical trials. Similar to our findings, study conducted by a Koyto et al. believed most of the postgraduate students involved in clinical trials (Chatterjee et al., 2016) and according to supro Chaudhary et al-she observed 90% of doctors wanted clinical trials training to be incorporated in the undergraduate curriculum. The results of our study shows postgraduates have a better knowledge about clinical trials than the undergraduate. It was observed that clinical trial training is emphasized and incorporated in postgraduate curricula. In our study, analysis showed students having clinical trials training and involvement in trial fared better in areas of knowledge. Almost (51.8%) of students believe that television and audio communication is the best way to create awareness on clinical trials. The results

were similar to a study provided by Vittal et al. in 2018, he also believed awareness can be done either in television and audio communication (Vittalrao et al., 2018). In our study maximum preference is seen in willingness to participate (60.7%), free medications (55%), informed consent (55.6%), registrations of clinical trials (51.8%) and proper standard treatment (56.2%) This study is not concordant with a study provided by Vittal Rao et al. in 2018-he stated that no organised structure seen in education for a students knowledge regarding clinical trials. As some percent of medical/dental undergraduates may be future investigators. Hence they needed to be trained in their study period about clinical research and medical ethics. Limitations of the study include smaller sample size and does not respond to all the ethics groups or populations around the world. Future scope of this study is to increase the awareness of clinical trials among the undergraduate students and to ascertain their interest in being involved in clinical trial and research studies.



Graph 5: Bar graph describing the comparison of responses for the statement "patient identity and address should be kept protected" based on gender



Graph 6: Bar graph describing the comparison of responses for the statement "Clinical trials can be conducted in healthy volunteers not only the patients" based on gender

In Graph 1, X-axis shows the age of the respondents and Y-axis shows the number of responses. Higher

**Table 1: Frequency distribution of responses obtained from the questionnaire regarding clinical trials**

Sl no.	Questionnaires	Strongly agree	dis-disagree	neither agree nor disagree	agree	strongly agree
1	Clinical trials can be conducted in healthy volunteers Not only the patients.	7.1%	27.2%	9.5%	39.1%	17.2%
2	A Clinical trial is a research study with human volunteers to answer a health education	8.3%	33.7%	7.7%	45%	7%
3	I have Good understanding about how clinical trials work	8.3%	30.8%	19.5%	37.3%	7.1%
4	A placebo looks like a real drug but has no effect	7.1%	29%	19.5%	39.6%	6%
5	The standard treatment will be withheld if a placebo is given	7.1%	28.4%	14.2%	44.4%	8%
6	The consent form explains the known dangers of being in the clinical trial. Informed consent is mandatory in clinical trials	9.5%	26.6%	24%	47.3%	8.3%
7	In clinical trial, once patient enrolled cannot withdraw till study completion	9.2%	27.8%	13.7%	42%	10.1%
8	Sometimes a patient is prevented from joining clinical trial because they are too sick	7.7%	36.7%	13.6%	36.1%	6.1%
9	In academic clinical trials- registration of clinical trials is not necessary	8.3%	31.5%	8.3%	35.7%	16.1%
10	Clinical trials of experimental drugs are monitored for safety by the government	11.3%	35.2%	10.7%	36.3%	9%
11	Patient identity and address should be kept protected	8.4%	24%	13.3%	46.1%	8.4%
12	Patients continue to receive study medications free of cost after completion of clinical trials	9%	11.3%	35.2%	10.7%	36.3%
13	Clinical trials may be conducted to evaluate the effectiveness and safety of the patients	8.9%	32.5%	10.1%	43.2%	7%
14	A clinical trial can be test of an experimental drug to see if it is safe	7.7%	27.2%	15.4%	44.4%	6%

*Continued on next page*

Table 1 continued

Sl no.	Questionnaires	Strongly agree	dis-	disagree	neither agree nor disagree	agree	strongly agree
15	Clinical trials can be conducted without any animal toxicity study reports of the drug	7.2%		26.3%	12.6%	39.5%	14.4%
16	In clinical trial patient will always get the experimental drug	7.7%		32.1%	14.9%	41.1%	3.9%
17	Clinical trial protocols should be approved by higher authority before initiation	12.6%		26.9%	8.4%	28.0%	24%
18	Proper standard treatment is always done in a clinical trial	9.5%		20.7%	13.6%	47.9%	8.3%
19	All clinical trials should be approved by the institutional ethics committee before starting.	8.9%		36.7%	8.9%	36.7%	8.9%
20	Patients are not supposed to receive any sharing profits for participating in a clinical trials	10.1%		29.6%	11.2%	41.2%	7.6%
21	Patients are exploited in industry sponsored clinical trials	0		39.9%	0	60.1%	0
22	Compensation for study related injury are not reimbursed to the patients	0		49.7%	0	50.3%	0%
23	Primary objective for conducting clinical trials is for science not commerce	0		42%	0	58%	0
24	Reason for participation in clinical trials is for treatment benefits	0		49.1%	0	50.9%	0
25	Age wise no difference was observed in term of perception	0		45.6%	0	54.4%	0
26	Television and audio communications are the best way to create awareness about clinical trials	0		48.2%	0	51.8%	0
27	Informed consent process in clinical trial is not informed at all	10.1%		29.6%	11.2%	41.2%	7.6%
28	Primary objective of conducting sponsored clinical trial is commerce not science	13.2%		8.4%	8.4%	46.1%	24%



number of responses was obtained from students between 24-26 years of age. In Graph 2, X-axis shows the gender of the respondent and Y-axis showing the number of responses. Higher number of responses was obtained from students who were females. In Graph 3, X-axis showing the year of study of the students and Y-axis showing number of responses. Higher number of responses was obtained from 3rd year undergraduate students. In Graph 4, X-axis shows the Five point agreement scale and Y-axis shows the number of responses. Blue color represents females, red color represents males and green color represents respondents who preferred not to say. This statement was disagreed by a higher number of students who were females when compared to males. This difference was statistically significant. (Chi-square test;  $p = 0.000$  - statistically significant). In Graph 5, X-axis shows the Five point agreement scale and Y-axis shows the number of responses. Blue color represents females, red color represents males and green color represents respondents who preferred not to say. This statement was agreed by a higher number of students who were females when compared to males. This difference was statistically significant (Chi-square test;  $p = 0.002$  - statistically significant). In Graph 6, X-axis shows the Five point agreement scale and Y-axis shows the number of responses. Blue color represents females, red color represents males and green color represents respondents who preferred not to say. This statement was agreed by a higher number of students who were females when compared to males. This difference was statistically significant (Chi-square test;  $p$ -value = 0.000 - statistically significant).

## CONCLUSION

Within the limitations of current study, a decrease in awareness about clinical trials was noticed among dental students. Females showed better knowledge when compared to males and postgraduate students had better knowledge when compared to undergraduate students.

## Conflict of Interest

The authors declare that there is no conflict of interest for this study.

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The authors declare that they have no funding support for this study.

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