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Knowledge, attitude & perceptions of 3rd term medical students towards clinical trials in a medical college in southern India

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Abstract

Aim of the study: The present Study was performed to know the awareness of clinical trials and to assess the effectiveness of an educational intervention.

Materials and Method: This was a questionnaire-based pre- and post-test educational interventional study. Handouts which contain information about clinical trials were given one week before the study. A pre-validated 20-point questionnaire comprising of Knowledge, attitude, perceptions about clinical trials was given to 3rd term medical students (n=115). With the help of Power point presentation the educational intervention was done. For statistical calculation, chi-square test and unpaired paired t-test were performed.

Results: are tabulated as percentages, Mean±SD. The scores pertaining to knowledge, attitude and perceptions of clinical trials were found to be statistically significant (P<0.001) when before (pre-KAP) and after (post-KAP) the educational intervention, was assessed.

Conclusion: The feedback from the students was encouraging, handouts supplied before the class made them to understand the subject better during lectures.

Keywords: Clinical trials, Continuous medical education, KAP questionnaire

Introduction

Over the past 25 years there has been serious decrease in medical graduates choosing clinician scientist careers.[1-5] Encouraging research integrated analytical skills among medical students is now needs to be addressed.[6,7] Together with the development of transferable skills, such as communication, teamwork, and critical thinking, integrating the research-specific skills among undergraduate medical students has been strongly recommended by tomorrows Doctors, the Scottish Deans Curriculum group and by the guide to Good Medical Practice USA.[8-10] A recent review of scholarly activity programmes has shown that completion of such programmes can influence students' choice of clinical speciality or interest in research.[11] However, little is known about how students perceive research.[12] Fostering a supportive undergraduate research environment is recommended.[13,14] Physician participation in research is essential to increase the number of clinical and research studies performed.[15] The review of literature suggests that in India, there is paucity of information examining the awareness, perceptions and practices of medical students towards research.[16] A good training is known to improve the awareness and skill of medical students and help them develop a positive attitude towards research.[17] It has been found that good financial support systems and exclusive support programs for research could increase chances of students taking up research as their career choice or make sure they associated with research irrespective of their future careers.[20] An intensive training or exposure of UG medical students to research will increase their chances of pursuing a research career.[21]

Efforts are needed to create a more widespread awareness of clinical research amongst the general public, patients and medical community, especially doctors and pharmacists to boost the self-confidence and shift from the old concept and renaissance the ideology of clinical trials if India is to take the fair share in the clinical outsourcing business.[20]

The last five years have also witnessed a tremendous interest and activity in the area of clinical research services in India; it is mainly due to a huge medical infrastructure, the availability of large banks of treatment-naive patients with a variety of diseases, increasing (GCP) Good clinical practices awareness among the clinical investigators and the cost effectiveness of Indian operations. So, while India builds up on the potential of being an attractive clinical research destination, it is important that the emerging professional contract research organizations (CROs) maintain high standards of ethics and Good clinical practices compliance to support this endeavor. There is great boom in clinical research in India, since it is a home to a wide variety of diseases ranging from tropical infections to degenerative diseases; it offers the opportunity for pharma companies to develop drugs for a wide spectrum of diseases; to name a few multidrug resistant ones, pneumonia, hepatitis B, diabetes and cancers.[21] In this study, we had chosen sensitive, easily understandable and the most prolific areas of clinical trials and research which were at par with the student's knowledge.

Hence, the present study was designed to assess the knowledge, attitude and the perceptions about clinical trials among medical students at medical college by hand outs and lecture intervention.

Materials and Method

The present study was done at Gulbarga Institute of medical college and research hospital, Kalaburagi. This was an interventional (KAP-Knowledge, Attitude, Perceptions) questionnaire designed study. Third term (n=115) medical students, were enrolled. Handouts informing about the clinical trials were distributed to students one week before the intervention. The questionnaire was designed after the minor modifications of the questionnaires gathered from previous similar studies.[22-24] The questionnaire were analyzed and validated by experts who are currently involved in many clinical trials. The study protocol was examined and validated by conducting pilot study for its readability, aspects of understanding, reliability and comprehensiveness.

The pre-validated, questionnaire was used to know the student's scores. The questionnaire enlisted of 20 questions regarding clinical trials. Out of them, 11 questions on knowledge, 05 questions on attitude, and 04 questions on perception were prepared. The scoring was designed such that the correct answer was allotted 1 point and wrong answer was given zero point for all questions. Likert scale was used to assess the attitude based questions to know the student degree of agreement. The score was assigned as per below. "0"– strongly disagree, "1" – disagree, "2"- uncertain, "3"- agree and "4"-strongly agree. To avoid the bias, mentioning of the student name was not made compulsory.

To begin with the study, all the students were explained regarding the nature, pros and cons of the study, student's consent was obtained; after that, pre-KAP questionnaire was given to answer the questions. An intervention in the form of lecture using power point presentation for one hour was used by well-deserved staff to all the students in view of disseminating the concepts about clinical trials. After the lecture, all the students were given Post-KAP questionnaire to answer the questions and answers were assessed. The gathered information was recorded obtained were entered in Microsoft excel spread sheet and evaluated. The chi-square test and unpaired t test were used to assess the scores. Graph Pad Instat was used to do the statistical analysis. The p value ($p<0.05$) was considered to be statistically significant.

Results

All the responses are tabulated as per percentages and Mean±SD and are depicted in Table 1, 2, 3, 4 and Fig. 1. In many of the student's answers it was evident that after the educational interventional program their scores were drastically increased implying the effectiveness of the interventional program. Enhanced Students knowledge, attitude, regarding the various aspects like importance of Clinical trials, understanding about the permission required by the Drug Controller General of India (DCGI) for the conduct of clinical trials, regarding the different phases of clinical trials and perceptions of benefits of participating in clinical trial were noted. This data suggests that continuing educational intervention is pivotal step for increasing all health care professionals' awareness to clinical trials.

Question 05 from Table 1, was framed to obtain the information about Phase III clinical trials, we could see drastic increased score of 20.9% before to 86.9% after the lecture. The study was focused on assessing the perception of benefits of participating in clinical trial in question 17 Table 3, which revealed to be 26.1% before pre-KAP to 83.5% post-KAP, which also points to the importance of impact of educational interventions on clinical trials. In question 14 and 15 Table 2, the attitude of medical students- on why clinical trials conducted due to insufficient data, requirement of man power changed from 40% to 88.7%, and 21.7% to 90.4% respectively, in which strongly suggests that students need to undergo educational sessions on clinical trials.

Question 20 from Table 3, to clinical trials may help others by contributing to medical research in near future revealed to be 34.8% to 95.7%, this type of enthusiasm, motivation attained by students after the lecture session is overwhelming and to be acknowledged.

Table 1: Knowledge of clinical trials before & after educational intervention

Q. no	K A P - Items	Pre–KAP Score n(%)	Post-KAP score n(%)	p- value
1.	Clinical trials are conducted to determine whether newer drugs/ treatments are both safe & effective.	52 (45.2)	110 (95.6)	p<0.0001
2.	In India, no newer drugs shall be manufactured for sale or imported unless it is approved by the Drug Controller General of India (DCGI).	28 (24.3)	104 (90)	p<0.0001
3.	Informed consent for a participant before joining clinical trial includes details about the study purpose, how long it lasts, required procedures, and benefits but not the potential true risks by participating in the study.	38 (33)	96 (83.5)	p<0.0001
4.	Phase I clinical trials are conducted in healthy volunteers, cancer and HIV patients.	32 (27.8)	90 (78.2)	p<0.0001
5.	Most of the phase III clinical trials are designed as randomized, double blind, controlled trials.	24 (20.9)	100 (86.9)	p<0.0001
6.	To see if a new drug works, researchers must compare a group of subjects who took with a group of people who did not take the drug. This comparator group is called as control group.	32 (27.8)	94 (81.7)	p<0.0001
7.	It is also important to conduct clinical trial in a variety of people, because different people may respond differently to treatments.	56 (48.7)	106 (92.2)	p<0.0001
8.	The purpose of blinding in the clinical trials is to avoid the bias.	37 (32.2)	92 (80)	p<0.0001
9.	The following are categorized as serious adverse event- Death, life-threatening events, illness requiring hospitalization, permanent damage or congenital anomalies	30 (26.1)	102 (88.7)	p<0.0001
10.	All serious adverse events occurring in patients who are participating in the clinical trial should be reported to DCGI within 14 calendar days.	20 (17.4)	88 (76.5)	p<0.0001
11.	Post marketing surveillance of drug usage is important to detect how fast the drug is sold.	30 (26.1)	100 (86.9)	p<0.0001
12.	The average time period required for the drug development starting from human testing till it gets approval is 8-12 years.	25 (21.7)	74 (64.3)	p<0.0001

Table 2: Attitude on clinical trials before & after educational intervention

Q. No	K A P Items	Pre–KAP Score n(%)	Post–KAP Score n(%)	p- value
13.	The potential benefit of clinical trials is to deliver the basic need for betterment of mankind and health status**.** -Strongly agree*	58 (50.4)	100 (86.9)	p<0.0001
14.	The clinical trials are unethical, incorrect and purely inhuman –Strongly disagree*	36 (31.3)	110 (95.6)	p<0.0001
15.	Clinical trials are conducted because of insufficient research data available from previous study. -Strongly agree*	46 (40)	102 (88.7)	p<0.0001
16.	Conducting clinical trials is waste of time, man power and money. -Strongly disagree*	25 (21.7)	104 (90.4)	p<0.0001

Table 3: Perception of clinical trials before & after educational intervention

Q. No	K A P Items	Pre–KAP Scores n(%)	Pre–KAP Scores n(%)	p- value
17.	Do you think that the potential benefit of participating in well-designed & executed clinical trials for eligible patients is to procure medicine free of cost and minimal health risk? -Yes*	30 (26.1)	96 (83.5)	p<0.0001
18.	Clinical trials compare new drugs or device with the existing treatments/placebos to determine which is better? -Yes*	42 (36.5)	88 (76.5)	p<0.0001
19.	Do you think that exit from the clinical trial before it is over will result in huge penalty to the participant? -No*	38 (33)	100 (86.9)	p<0.0001
20.	Do you think that clinical trials may help others by contributing to medical research? -Yes*	40 (34.8)	110 (95.7)	p<0.0001

Correct Response*, P<0.001 (comparison between the pre- KAP and Post- KAP responses).

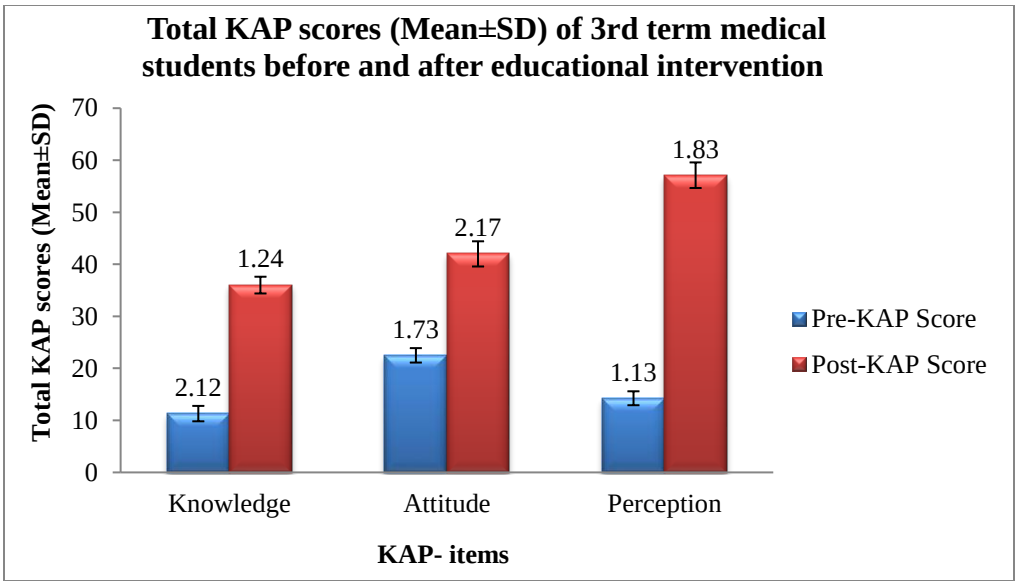

Fig. 1: Mean KAP scores of responders-Overall level of knowledge and attitude among the participants (n=115)

Table 4: Student Feedback regarding Educational intervention on clinical trials

Students opinions:	Response	n (%)
I would like to participate in clinical trials as researcher if I get opportunities in future-	Yes*	104 (90.4)
I would like to visit a clinical research organization (CRO) to know how the clinical trials are conducted.	Yes*	98 (85.2)
I would like to take part to raise the awareness of clinical trials among community to encourage their participation.	Yes*	100 (86.9)
I would willingly take part in clinical trials as a trial participant/subject in future.	Yes*	94 (81.7)
In depth knowledge about clinical trials should be imparted to students, interns, physicians which prepare them to become future efficient clinical trial researchers.	Yes*	110 (95.7)

n- Number of Yes*responses, (%) - percentage of responses

Discussion

The study showed that medical students who attended the lecture session on clinical trials were much satisfied, and considered more effective. This was demonstrated by an increase in the scores in pre and post-KAP questions (1 to 20) on clinical trials with statistical significance ($p<0.0001$), after the lecture session highlighting the impact on its effectiveness.

Questions 08 and 09 from Table 1 were framed to obtain the knowledge about the purpose of blinding in the clinical trials is to avoid the bias and which medical conditions are categorized as serious adverse events. The score was from 32.2% to 80% and from 26.1% to 88.7% respectively. The result strongly suggests that students were greatly influenced by the educational session regarding the clinical trials which is in accordance with earlier study by Vodopivec I et al. [23]

Question 10 from Table 1, shows the scores from 17.4% to 76.5% which strongly suggests the information about when and where to report all serious adverse events occurring in patients who are participating in the clinical trial. Question 12 from table 02, showed that from 21.7% to 64.3%, and Question 13 from table 02 showed that from 50.4% to 86.9% post-KAP strongly suggests the improved scores among students about potential benefits of clinical trials. Based on our study results and the finding of Makoul G et al. It is recommend that the medical students should be assessed on performance based key ethics skills as early as in the first year of training[23,25] to enhance their skills.

There is a felt need to generate awareness on attitude perceptive of clinical trials among medical students can be fulfilled by continuous medical education programs. In Fig. 1, the total Pre-KAP scores on knowledge (14.3 ±2.12), attitude (26.5±1.73), perception (17.25 ±1.13) when compared to total post- KAP scores on knowledge (42 ±1.24), attitude (47±2.17), perception (59.12 ±1.83) respectively, the overall increase in correct answers with statistical significance ($p<0.0001$) was observed after the session.

The study period was too short. And the study findings could not be applied to the wider community medical students and other health care professionals as the study was restricted to 3rd term medical students in department of Pharmacology, Gulbarga institute of

medical sciences, Kalaburagi were the two of our study limitations.

Conclusion

The results of the present study depict the intervention has greatly enhanced awareness of clinical trials among the medical students. The feedback from the students was encouraging and positive.

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