



Research Article

Perceptions, Understandings, and Practices in Clinical Research Ethics among Medical Postgraduates in India: A Cross-Sectional Study

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Received: 16 September 2023; Revised: 31 October 2023; Accepted: 18 November 2023

Abstract

Background: Research methodology is now part of the MBBS curriculum, which is a substantial adjustment to MCI standards. **Objective:** To assess the student's comprehension of the subject, level of interest and how it is used in clinical studies. **Methods:** We created a standard set of 25 questionnaires to assess postgraduate and PhD students' attitudes, awareness, and knowledge about research ethics and committees. Statistical analysis was used to compare the mean knowledge scores of several groups (age, gender, education, past research experience, etc.). **Results:** Students had a good attitude and understanding of research ethics and research ethics committees. We observed that past research experience and training are critical in predicting knowledge ratings. The study findings indicated a significant difference in the mean knowledge score depending on past research experience. Similarly, we observed that prior research ethics training had a significant impact on mean scores. **Conclusions:** A functioning research ethics committee should be present in every hospital. Students should be informed of the role and responsibilities of the ethics committee. Students must be informed of research ethics before undertaking any human subjects research. To broaden student comprehension, the ethics committee must offer seminars, workshops, and conferences on a regular basis.

Keywords: Awareness, Attitudes, Ethics committee, Knowledge, Private medical college.

التصورات والفهم والممارسات في أخلاقيات البحوث السريرية بين طلاب الدراسات العليا الطبية في الهند: دراسة مقطعية

الخلاصة

الخلفية: أصبحت منهجية البحث الآن جزءاً من منهج MBBS، وهو تعديل جوهري لمعايير البحوث السريرية الطبية. **الهدف:** تقييم فهم الطالب للموضوع ومستوى الاهتمام وكيفية استخدامه في الدراسات السريرية. **الطريقة:** أنشأنا مجموعة قياسية من 25 استبياناً لتقييم مواقف طلاب الدراسات العليا والدكتوراه ووعيهم ومعرفتهم بأخلاقيات البحث واللجان. تم استخدام التحليل الإحصائي لمقارنة متوسط درجات المعرفة لعدة مجموعات (العمر، الجنس، التعليم، الخبرة البحثية السابقة، إلخ). **النتائج:** كان لدى الطلاب موقف وفهم جيدين لأخلاقيات البحث ولجانها. لاحظنا أن الخبرة البحثية السابقة والتدريب أمران حاسمان في التنبؤ بتصنيفات المعرفة. أشارت نتائج الدراسة إلى اختلاف كبير في متوسط درجة المعرفة اعتماداً على الخبرة البحثية السابقة. وبالمثل، لاحظنا أن التدريب السابق على أخلاقيات البحث كان له تأثير كبير على متوسط الدرجات. **الاستنتاجات:** يجب أن تكون هناك لجنة أخلاقيات بحثية عاملة في كل مستشفى. يجب إبلاغ الطلاب بدور ومسؤوليات لجنة الأخلاقيات وأخلاقيات البحث قبل إجراء أي بحث على البشر. لتوسيع فهم الطلاب، يجب على لجنة الأخلاقيات تقديم ندوات وورش عمل ومؤتمرات على أساس منتظم.

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Article citation: Panda NR, Samantasinghar P, Bhuyan SK, Bhuyan R. Perceptions, Understandings, and Practices in Clinical Research Ethics among Medical Postgraduates in India: A Cross-Sectional Study. *Al-Rafidain J Med Sci.* 2023;5(Suppl 1):S147-150. doi: <https://doi.org/10.54133/ajms.v5i1S.303>

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INTRODUCTION

The primary goal of ethics education is to inspire students to be familiar with challenging situations from both a logical and ethical perspective. This allows medical students to develop their self-esteem and confidence [1]. Numerous examples of misconduct by medical students and healthcare workers exist in the literature [2]. Students should adhere to four medical ethics principles: beneficence, non-maleficence, autonomy, and justice. In today's world, almost all countries are focusing on human subjects research to provide high-quality healthcare [3,4]. To ensure the safety of participants' rights, this type of research should be guided by all ethical principles [5,6]. To participate in various national and international projects, researchers must be aware of research ethics and participate in research training programs. Currently, developing countries are conducting many clinical trials with pharmaceutical companies. They are working to improve healthcare and the global drug market [4–8]. Nowadays, all developing countries contribute significantly to medical research. Moreover, it has been rapidly growing over the last few decades. An institutional review board (IRB) is present in many healthcare research projects to provide judgment on all ethical research aspects. Junior and senior resident doctors are now involved in medical research in almost every aspect of healthcare. This study aims to learn about our hospital's postgraduate students' knowledge, awareness, and attitudes.

METHODS

We conducted a cross-sectional study at our institution to evaluate the knowledge, cognizance, and attitudes of postgraduate and doctoral students regarding research ethics and the research ethics committee. On the basis of the survey results, online-based inquiries were formulated. Each and every pupil volunteered to participate. With the students, we discussed the purpose and objectives of the study. Every single student maintained the confidentiality of the study. The present study was conducted in March 2022. Following the institutional review board's approval, we developed Google form-based inquiries and disseminated them to students through the messaging platforms WhatsApp and Telegram. Incorporating all four categories (demographic, awareness, attitude, and knowledge) was the total quantity of 25 inquiries. We downloaded the spreadsheet containing the student responses and imported the data into SPSS version 25 in preparation for further analysis. The survey was partitioned into four distinct sections. We requested demographic information including name, age, gender, and level of education in the initial section. In the second section of the survey, institutions' knowledge of research ethics and research ethics committees was inquired about. In this segment, the participant was presented with five

inquiries. An inquiry was made into perspectives regarding research ethics in the subsequent segment. We asked the participant six queries in this section to ascertain their attitude. Ten questions, each with a value of two points, were then administered to evaluate our understanding of research ethics.

RESULTS

Among the 103 students who participated in the study, 57 (55.3 percent) were female and 46 (44.7%) were male. Nine students (8.7%) were discovered to be under the age of 25, while 94 students (91.3%) were over the age of 25. The participants comprised an average age of 26.9 years. The participants consisted of the following: 25 (24.3%) PhD students, 35 (34%) DM students, and 43 (41.7%) MD students (Table 1).

Table 1: The participant's demographic characteristics

Variables	n(%)
Age (year)	
<25	9(8.7)
≥25	94(91.3)
Gender	
Male	46(44.7)
Female	57(55.3)
Educational level	
MD	43(41.7)
DM	35(34)
PhD	25(24.3)

A total of 57 (55.34 percent) of the 103 participants lacked prior research experience, whereas 46 (44.66 percent) did. Similarly, our findings revealed that out of the 85 participants (82.53%), 18 (17.47%) had successfully completed a research ethics training course. Conversely, the remaining 85 had not engaged in any form of training research. In Table 2, we utilized a *t*-test or ANOVA to determine the knowledge of the participants across categories.

Table 2: Association between mean knowledge score and independent variables using *t*-test and ANOVA test

Groups	Students	Mean score	p-value
Gender			
Male	46	14.91	0.547
Female	57	15.19	
AGE (year)			
<25	9	14.89	0.534
≥25	94	15.09	
Qualification			
MD	43	15.07	0.222
DM	35	14.57	
PHD	25	15.76	
Research experience			
Yes	46	17.51	0.022
No	57	14.02	
training on ethics			
Yes	18	16.36	0.043
No	85	14.02	

All other demographic parameters were regarded as independent variables, while knowledge was regarded as the dependent variable in this instance. There was no statistically significant disparity observed between the sexes in terms of the average level of knowledge regarding research ethics. A similar pattern was observed in the mean scores when age was accounted for; no significant difference. We determined the mean knowledge across educational levels by employing ANOVA testing (Table 2). Moreover, it was determined that there is an absence of substantial variation in knowledge scores. Nonetheless, we discovered that research experience has a substantial impact on knowledge scores. With a *p*-value of 0.022,

our analysis revealed a significant difference in the mean knowledge scores of individuals with prior research experience. There is statistical significance in this difference. Similarly, we discovered that knowledge scores are impacted by ethics training courses. With a *p*-value of 0.043, we identified a significant difference in the mean knowledge scores of the two groups (those who received training on research ethics versus those who did not). Additionally, the response of participants to the questions related to the attitude towards research ethics were detailed in Table 3. While the responses toward their awareness about ethics committee were detailed in Table 4.

Table 3: Attitudes towards research ethics among the participants

Questions	Strongly agree n(%)	Agree n(%)	Disagree n(%)
Weather Should ethics be taught as a mandatory module in postgraduate studies?	68(66)	34(33)	1(1)
Training in research ethics at the postgraduate level should be mandatory.	63(61.2)	39(37.9)	1(1.0)
Whether Should patients be informed about the compensation policy?	52(50.5)	47(45.6)	4(3.9)
All patients should be informed about the risk factor involved in the study.	74(71.8)	28(27.2)	1(1.0)
There must be a research ethics committee for each research conducting the university.	70(68)	33(32)	0(0)
All research proposals (Retrospective, observational, interventional) involving human subjects must be submitted to the ethical and scientific committees for review.	60(58.3)	39(37.9)	4(3.9)

Table 4: Awareness of research ethics and research ethics committees among the participants

questions	Yes n(%)	No n(%)
Are you aware of the roles of the Ethical committee of your institute?	88(85.4)	15(14.6)
Are you familiar with Ethical principles that govern conducting research involving human subjects?	84(81.6%)	19(18.4)
Medical ethics teaching will influence the attitude and behavior of doctors and improve doctor-patient relationships.	102(99)	1(1)
The doctor's decision should be considered as a final decision, in case there is a disagreement between patients' families and healthcare professionals about treatment decisions.	60(58.3)	43(41)
A participant has the right to withdraw from clinical research even if he signed an informed consent form.	96(93.2)	7(6.8)

DISCUSSION

This research investigates the knowledge, cognizance, and attitudes of postgraduate and PhD students with regard to research ethics committees. Research preparation is a requirement of the curriculum at a number of medical institutions in India [9]. This study revealed that doctoral students exhibited a marginally superior average knowledge score in comparison to postgraduate students. This discrepancy may be ascribed to the latter group's research ethics instruction. [11,12,15]. Insofar as ethics policy is an issue, both theories and practices of healthcare should adhere to the principle of healthcare ethics [13]. The results of the analyses indicated that an overwhelming majority (99%) of the study participants concurred that postsecondary research training and a course on research ethics were essential. Before beginning any research, appropriate consent should be obtained from the patient, and they should be fully informed of the

risks associated with the study, according to the majority of students. In conclusion, all participants reached a consensus that it is imperative for each medical institute to have a research ethics committee. Furthermore, they concurred that the committee should conduct ethical clearance reviews on all research proposals involving human subjects, whether they be retrospective, observational, or interventional. 85.4% of the participants were aware of the functions of the institute's Ethical Committee. Comparable to the inquiry, "Do you possess knowledge regarding the ethical principles that regulate research that involves human subjects?" A total of 81.6% of the respondents indicated their knowledge of ethical principles, whereas 18.4% expressed disapproval of the data derived from the study conducted by Singh *et al.* [14]. The results of the analysis indicate that medical students have a profound understanding of research ethics and research ethics committees. Furthermore, the present investigation provided significant findings

regarding the attitudes, awareness, and knowledge of society regarding crucial ethical concerns. Notwithstanding the absence of prior research experience and lack of participation in a research ethics training course, all participants reached a consensus regarding the necessity of a postgraduate-level research ethics course. It is mandatory for every medical institute to offer a postgraduate foundation course on research ethics [10].

Conclusion

Each medical institution ought to have a completely operational research ethics committee that is actively engaged in its duties. Students ought to be apprised of the functions and protocols of the ethical committee. It is imperative that students possess a comprehensive understanding of research ethics prior to conducting any investigation involving human subjects. In order to enhance students' comprehension, institutes ought to regularly coordinate seminars, workshops, and conferences pertaining to randomized clinical trials and excellent clinical practice.

Conflict of interests

No conflict of interest was declared by the authors

Funding source

The authors did not receive any source of fund.

Data sharing statement

Supplementary data can be shared with the corresponding author upon reasonable request.

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