

# Effect of a planned training session on good clinical practice knowledge in research professionals: A pilot study

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## Abstract

**Context:** Adherence to good clinical practice (GCP) guidelines by the researcher provides public confidence that the rights, safety and well-being of human participants involved in research are protected. It has been observed that researchers require basic GCP training. Considering this, we had decided to conduct a training session on overview of GCP.

**Aims:** To strengthen the knowledge and awareness regarding GCP.

**Settings and Design:** The design of the study was quasi-experimental one group, pre-test and post-test design and the study was conducted at ACTREC among healthcare professionals at Tata Memorial Centre.

**Methods and Material:** A semi-structured questionnaire was used to collect the data in pre and post-test. A total of 138 participants were participated in the study. The training session was pre-planned which included a lecture followed by the question-answer session.

**Statistical Analysis Used:** Wilcoxon Signed Rank test was used to assess the effect of the planned teaching programme. Macnemar test was used for item wise comparison of pre and post-test scores. Mann Whitney test was used to determine the significant difference between knowledge scores and selected demographic variables.

**Results:** This study has resulted in overall improvement of knowledge with a median difference of 5 with *P*-value <0.001. There was a statistically significant improvement of knowledge between pre and post-test of those having GCP training in the past, working group and education.

**Conclusions:** The exercise of holding training program was found to be significant in improving the knowledge base of participants, especially investigators and study coordinators.

**Keywords:** Advanced Centre for Training, Research and Education in Cancer, good clinical practice, health professional, pre- and post-design

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## INTRODUCTION

Good clinical practice (GCP) is an international ethical and scientific guidelines for clinical research which includes

designing, planning, conducting, monitoring, recording, and reporting of biomedical studies or trials that involve human

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participants.<sup>[1,2]</sup> GCP ensures that the studies are carried out in a scientific and ethical manner. These guidelines have two important principles, namely, protection of rights of human participants and credibility of data generated.<sup>[3]</sup> The central objective of GCP in human studies is to give priority to the well-being of the human participants. The interest of science and society should not be above the wellbeing of the participants.<sup>[2,4]</sup> Adherence to GCP guidelines by the researcher provides public confidence that the rights, safety, and well-being of human participants involved in research are protected. WHO, ICH, USFDA, and European GCP are taken into consideration while formulating Indian GCP. In India, researcher is required to comply with the ethical guidelines for biomedical research involving a human participant laid down by the Indian Council for Medical Research and ICH-GCP guidelines.<sup>[1,5]</sup> An expert committee set up by Central Drugs Standard Control Organization has formulated these GCP guidelines in consultation with clinical research specialists. The Drug Technical Advisory Board, the specialized body under Drug and Cosmetic Act, has endorsed adoption of these GCP guidelines for streamlining the clinical research in India.<sup>[6]</sup>

The unique opportunities that India provides for conducting clinical trials due to a large number of patients and qualified and trained medical professionals have been widely appreciated. The presence of premiere medical institutes in the country has benefitted both researchers and the patients.<sup>[7]</sup>

As per the GCP guidelines, everyone involved in the conduct of clinical research must be competent to perform their tasks, qualified, trained, and experienced to ensure that they are prepared to undertake their responsibilities. It is mandatory for the investigators to undergo GCP training before undertaking any project which involves human participants. At the Tata Memorial Centre (TMC), clinicians, and basic scientists; principal investigators submit their proposals to the Institutional Ethics Committee (IEC) for scientific and ethical approval.

IEC members of Advanced Centre for Training, Research, and Education in Cancer (ACTREC), TMC identified the need to conduct a GCP training session for researchers. It was also a requirement for certification by the Association for Accreditation of Human Research Protection Programme. For this purpose, a training session was planned with an additional objective of ascertaining the effectiveness of this training session by undertaking a pretest and posttest.

### Aim

The aim of the training was to strengthen the knowledge and awareness regarding GCP among healthcare professionals

at TMC. The objective of this study was to assess basic knowledge about GCP before training program, to assess the effect of a training session on knowledge related to the GCP and to evaluate the relation between knowledge score and selected demographic variables among research professionals at TMC.

## MATERIALS AND METHODS

### Study design

The design of the study was quasi-experimental, one group, pretest and posttest design. A convenient sampling technique (a type of nonprobability) was adopted to select the samples ( $n = 138$ ), and the study was conducted at the ACTREC.<sup>[8]</sup>

### Development of the instrument

The study instrument comprised a questionnaire. The questionnaire included questions based on the knowledge about GCP as per guidelines. Manuscripts and published articles describing similar research and methodological issues were studied.<sup>[8,9]</sup> In this study, a semi-structured questionnaire (34 items) was used to collect the data. The initial section consisted of nine questions on demographic data which included age, gender, qualification, years of experience, primary work groups such as consultant, scientist, researcher, project staff, student, resident doctors, and objective behind attending this course and history of previous GCP training. Section II had questions to assess knowledge. Out of the 34 knowledge questions, 14 questions were on GCP principles, 8 were related to investigator's responsibilities, 6 pertaining to the ethics committee, and 6 regarding essential documents. Out of 34 questions, 25 questions were multiple choice questions, 8 were of true or false, and only one item was open-ended related to the definition of GCP. Each item had only one correct answer. The respondents were requested to select the best possible options. Pretest and posttest consisted of same questions, but the sequence was changed.

### Pretesting the questionnaire

The questionnaire was tested for readability and ease of understanding by giving it to departmental colleagues for their inputs and feedback. The questionnaire was then sent to experts of TMC Research Administrative Council for validation and editing of contents. Content validity was obtained by sending the questionnaire to content experts of IEC for review and subsequent approval. Internal consistency was computed using Cronbach's alpha, which was  $r = 0.753$  indicating its reliability.

### Conduct of the study

The participants were given a pretest, which required approximately 10–15 min to complete. The pretest was followed by training session and clarification of participants'

questions. The duration of the training session was 4 h. At the end of the teaching session, a posttest was administered.

### Educational intervention

The investigators had planned to conduct a training session on “Overview of GCP” The training session was to inform participants about the principles of GCP (Overview of GCP, the role of an investigator, ethics committee, essential documents,) in clinical research. The training session was preplanned which included a lecture followed by a question-answer session. Subject experts were invited as faculty to conduct the training.

### Data analysis and statistical consideration

The study questionnaire consisted of 34 questions for assessing knowledge. Each item had a score of one for the correct answer and zero for the wrong answer. The total score ranged between 0 and 34. The percentage of preintervention and postintervention knowledge scores were categorized into two groups as follows: <71% as an average category and ≥71% (median of pre-intervention was 71%) as a good category. The knowledge scores were tested for normality of distribution using Shapiro–Wilk test. The knowledge scores were not normally distributed. Hence, Median, inter-quartile range and Wilcoxon Signed Rank test were used for comparing pre- and post-test scores (continuous variables). The analysis is performed on each section of training and overall as well. All categorical data were presented as number and percentage. Item-wise comparison of pretest and posttest knowledge scores of answering correctly was analyzed using Macnemar’s test for individual items (34 questions). The significance of difference for nominal variables was analyzed using Chi-square test. The relation test between knowledge scores (Post–Pre) and selected demographic variables were analyzed using Mann–Whitney test. The value of  $P < 0.05$  was considered as statistically significant. Statistical analysis was performed using Statistical Package for the Social Sciences version 21.0 (SPSS, Inc.; Chicago, IL, USA) for Windows.

### Ethical consideration

The study was approved by the IEC of ACTREC, TMC, Navi Mumbai. All participants were informed and explained about the objectives of the study and invited to participate. All participants voluntarily participated after signing an informed consent form.

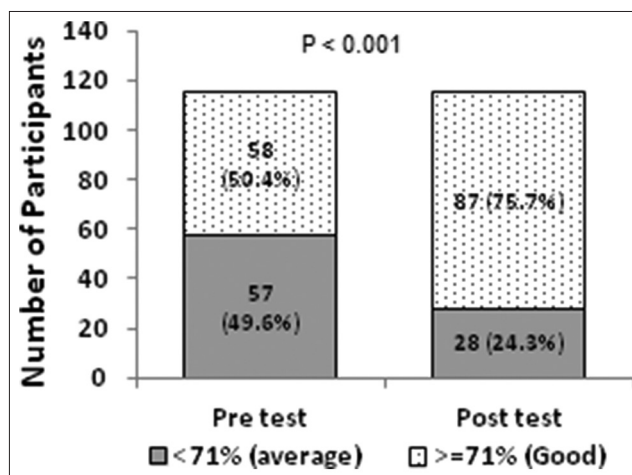
## RESULTS

A total of 138 participants were present and consented for the study, of which 115 (83%) participants completed both pretest and posttest. The overall response rate was 83%.

**Table 1: Demographic data (n=138)**

Variable	Sub variables	Frequency (%)
Gender	Male	46 (33)
	Female	92 (67)
Age	Mean	33.00
	Median	30.00
	≤30	75 (54)
Education	>30	63 (46)
	UG	31 (23)
Years of experience	PG	107 (77)
	Mean	6.24
	Median	3.00
Primary work	≤3	71 (51)
	>3	67 (49)
	Scientist/consultant	22 (16)
Objective behind attending this course	Hospital staff	40 (29)
	PhD student/trainees	19 (14)
	Research co-coordinators	28 (20)
	Resident doctors	3 (2)
	Nursing staff	4 (3)
	Gain knowledge	99 (72)
Training in GCP	As a PI to update recent information	4 (3)
	Intend to undertake study and working with human samples	9 (6)
	Not answered	26 (19)
Training in GCP	Yes	58 (42)
	No	75 (54)
	Not answered	5 (2)

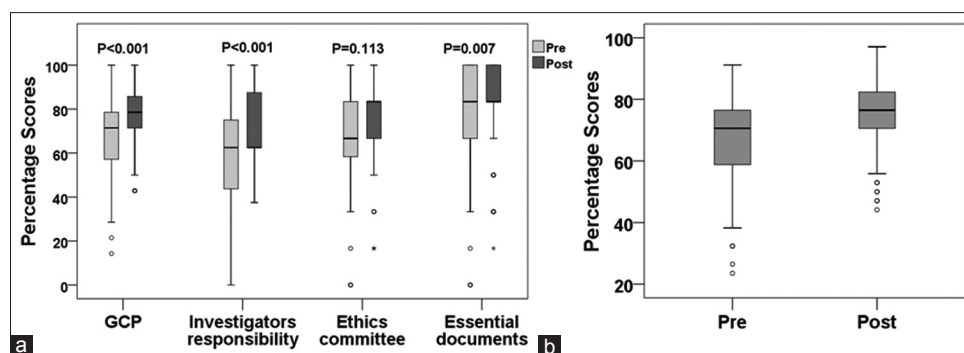
GCP=Good clinical practice, PI=Principal investigator



**Figure 1:** Distribution of participant with respect to pretest and posttest scores (n = 115)

Table 1 shows the demographic details of participants. Out of 138 participants, 92 (67%) were females. Seventy-five (54%) participants were below 30 years of age, 107 (77%) were post graduates, and 104 (75%) were working as research coordinators, research fellows or nurses. Majority of participants (72%) mentioned that objective behind attending the course was to gain knowledge. Out of 138 participants, only 58 (42%) had undergone formal training in GCP.

Figure 1 shows the distribution of participants related to knowledge scores in pre- and post-test. In the pretest,



**Figure 2:** Differences in knowledge scores and effectiveness of training session among study participants in pretest and posttest. (a) represents the section-wise differences in knowledge scores and effectiveness of training session among the study participants in pretest and posttest (b) represents the overall differences in knowledge scores and effectiveness of training session among the study participants in pretest and posttest

57 (49.6%) participants had a below <71% median (average) category which decreased to 28 (24.3%) in the posttest. In the pretest, 58 (50.4%) were in  $\geq 71\%$  median (good) category which was significantly increased to 87 (75.7%) in the posttest ( $P < 0.001$ ).

Figure 2a and b show differences in knowledge scores and effectiveness of training session among participants in pretest and posttest. The result showed the knowledge in the area of GCP ( $P < 0.001$ ), investigators' responsibilities ( $P < 0.001$ ). Essential documents (records and reports) ( $P = 0.007$ ) significantly improved after the training session except for ethics committee (EC) ( $P = 0.113$ ), which was not statistically significant). Overall the median knowledge percentage scores of pretest 71 increased to 76 after the intervention with  $P < 0.001$ .

The item (question)-wise comparison of pretest and posttest was analyzed for individual items (34 questions). There was a significant difference ( $P < 0.05$ ) among 13 items in being answering correctly in preintervention and postintervention. The highest increase in knowledge (31% improvement was seen with a question). "The person responsible for the conduct of the clinical trial at a trial site?".

Figure 3a-c depicts the relation between the knowledge scores (post-pre) and selected demographic variables of research professionals ( $n = 115$ ). There was the statistical significant difference between (post-pre) knowledge scores and those having GCP training in the past ( $P = 0.003$ ) working group ( $P = 0.018$ ) and education ( $P = 0.028$ ). There was no statistically significant relation between knowledge scores and age of the participants, years of experience, gender, and year of GCP training

## DISCUSSION

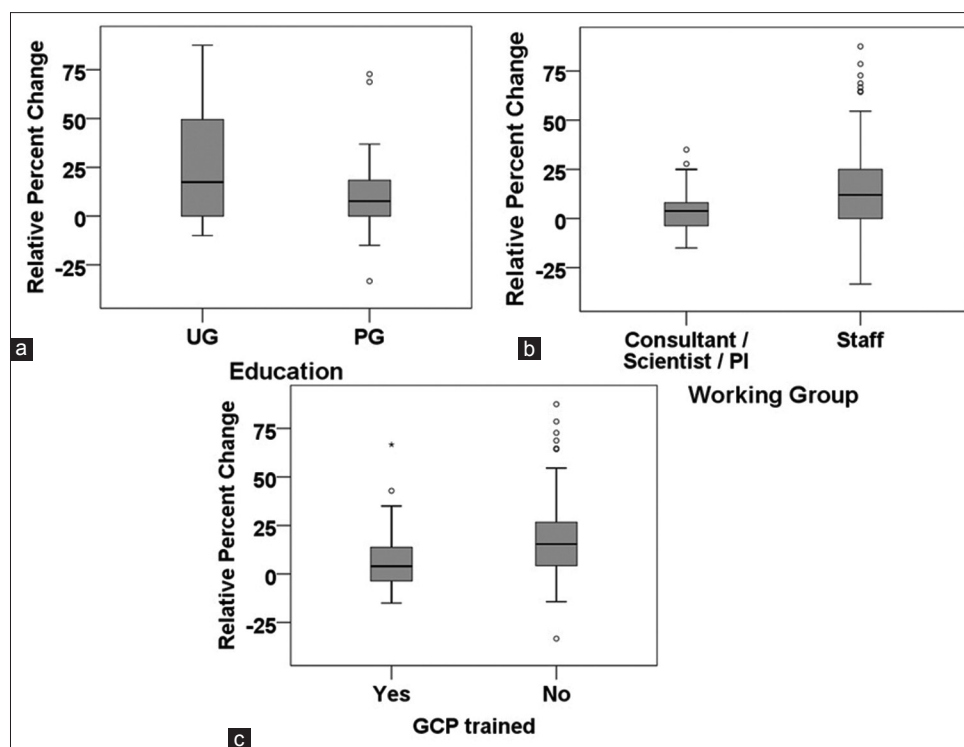
In-service professional education has proved to be a challenge as it requires efficient training strategies at a

clinical research site in which research professionals are actively or indirectly involved in the trial related activities.<sup>[10]</sup> In the present study, out of 138 participants (consented), 115 (83%) attended both (pre-test and post-test), while 19 (14%) participants did not attend post-test as they left training session halfway due to paucity of staff in their respective department and only four participants (3%) did not attend the pretest since they joined the training midway and were keen to participate in the training session. We have included their data in the demographic section. The overall response rate is 83%. This response rate coincides with a study conducted Dhodi *et al.* vis a vis 87.8% (395/450).<sup>[11]</sup>

The study questionnaire was valid and reliable ( $r = 0.753$ ) and was free of bias for the assessment of the pretest and posttest.<sup>[12]</sup> The knowledge questionnaire was given to experts for content validity, and their suggestions were incorporated before finalizing the questionnaire. Objective assessment of the effect of training using standard (validated) questionnaire is essential to assess the effectiveness of the training program. The lucidity of the questionnaire had the direct impact on data collected by researchers and responses given by the participants.<sup>[13]</sup>

In this study, we tried to find out the objectives behind attending the training. Around 75% (103/138) mentioned that they wanted to enhance knowledge of GCP and update themselves with recent information and a few 6% (9/138) intended to undertake a study using human samples in the future.

In the present study, item-wise comparison of pretest and posttest knowledge scores was analyzed, and there was a significant difference ( $P < 0.05$ ) among 13 items of pre and post GCP workshop in answering questions correctly. The highest increase in knowledge improvement (31%) was seen with question involving "The person responsible for the conduct of the clinical trial at a trial site." This indicates



**Figure 3:** The correlation between the knowledge scores (post-pre) and selected demographic variables of research professionals ( $n = 115$ ). (a) Represents the correlation between the knowledge scores (post-pre) and those having previous good clinical practice training versus having good clinical practice training in the past. (b) Represents the correlation between the knowledge scores (post-pre) and working group such as staff versus consultants/principal investigators/scientists. (c) Represents the correlation between the knowledge scores (post-pre) and education among undergraduate and post-graduates

that out of 268 projects, which were reviewed by IEC, ACTREC, TMC in the past 8 years (2010–2017), 261 were basic research and investigator-initiated studies and a few 7 (3%) studies were initiated by Pharma. This study was beneficial for those participants who were working as basic science researchers or scientists and research staff. Furthermore, this finding could be because GCP training session was interactive which included powerpoint slides presentation followed by discussion.<sup>[14]</sup>

While conducting a clinical trial, it is important that clinical investigators successfully meet all research expectations, including regulatory requirements and the requirements of GCP guidelines to ensure the safety and to protect the rights and welfare of human participants.<sup>[15]</sup> The training should begin before participation of the investigator in clinical research. All people involved in biomedical research, need to understand their roles and responsibilities as defined by GCP principles. This will enable them to understand how to obtain informed consent precisely, completing case record form, documentation, monitoring, and recording of adverse events (AEs) and serious AEs promptly. This should be reflected in improved staff performance which will, in turn, lead to an increase in the patients safety and the protection of their rights which leading to scientific and ethical research.<sup>[14]</sup> In

a current scenario, sometimes, it is possible that there may be only a principal investigator or two individuals (PI or co-investigators) who are adequately trained to lead and guide rest of the team who may not know fully or understand the fundamental concepts of GCP but are there to accomplish work orders in the clinical research studies.<sup>[11]</sup>

This study provides evidence that interaction, in the form of workshop on GCP has resulted in improvement of knowledge of the participants with a median difference of five with  $P < 0.001$  which is clearly reflected in participants' scores of general GCP principles, Investigators' Responsibilities, Essential Documents ( $P < 0.001$ ) except the EC responsibilities ( $P = 0.113$ , which was not statistically significant). This finding could be because half of the participants were clinical research coordinators ( $n = 52$ , 45%), a few were IEC members ( $n = 5$ , 4%). These coordinators are used to communicating with EC secretariat on day-to-day basis for their work purpose, and EC members are already well-versed with EC principles. We assume this could be the reason, EC section did not show improvement in knowledge ( $P = 0.113$ ).

We analyzed the relation between knowledge scores and selected demographic variables, as we felt there could be

a relation between the two and because there was enough number of participants in each subgroup. The results showed that there was a significant relation between pretest and posttest scores of those having GCP training in the past, working group (professional background), and Education [Figure 3]. A study by Dhodi *et al.* mentioned that the current practice of conducting clinical research is dependent more on experience rather than knowledge.<sup>[11]</sup> However, we have noted that there was no statistical significant change in score with respect to age, years of experience, gender, and year of GCP training.

### Limitations

In this study, the effect of the training was immediately assessed, and we did not attempt to study the reasons for not undertaking training in the past. The practice regarding the implementation of knowledge was not assessed. We used convenient sampling leading to the inadequate representation of the population. One group pretest and posttest design was used which may affect the external validity of findings.

### Recommendation

In the current scenario, no formal training regarding clinical research is incorporated into the syllabus of medical and para-medical courses. The researchers or research staffs have to learn or undertake GCP training by other means. In addition, GCP guidelines recommended that the investigators undergo GCP training before undertaking any project which involves human subjects.<sup>[4]</sup> Considering this, the following is recommended

- Clinical research education should be a part of medical and paramedical courses in India
- The clinical trial site or clinical research secretariat should ensure that research professionals are adequately trained and retrained on an annual basis especially. Those who are involved in a clinical trial such as trial investigators and coordinators, which may contribute to scientific and ethical research.

### CONCLUSION

The exercise of holding training program was found to be significant in improving the knowledge base of participants, especially investigators and study coordinators suggesting that structured and interactive teaching and practical training session were effective ways of learning. This study also shows that training in the form of formal lectures is beneficial in improving the knowledge of the researchers.

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### Conflicts of interest

There are no conflicts of interest.

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