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Clinical Research and GCP Training Perspective with Newly Developed Attitude Scale for Medical Students

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Abstract

Background: The authors discuss the components of clinical research and GCP training programs in successful medical education curricula and introduce a development of clinical research scale first time for evaluation in medical and clinical pharmacology clinical research practices.

Methods: "Retrospective descriptive research" method was preferred for data collection and classification. The study group consists of third grade medical students who volunteered to be evaluated. These students were asked to fill in the form, and the pool of statements was compiled. Literature screening and expression pools selected words, were converted into sentences with attitude expression. A 5-point Likert-type scale consisting of 12 items was prepared through the questionnaire study. The scale study with 150 students was included. Sample size was calculated in order to evaluate the correlation of item total score.

Results: The sample size was "very good" (KMO=0.864). Barlett's test of shericity ($p<0.001$) was significant. Cronbach's alpha value of the scale was 0.91. This value indicates that the scale degree is in "very good" for reliability, validity and sample size. This scale is suitable for correlation matrix factor analysis; the sample adequacy degree is "very good". The reliability coefficient of Guttman (rt=0.830) and Spearman-Brown (rsb=0.831), which represent the scale divided into two, were found.

Conclusion: These GCP trainings can be included in the curricula and newly developed scale was able to evaluate students' attitudes towards clinical research and can be used in future education.

Research registration: "Retrospective descriptive research"

Keywords: Clinical research education • GCP • Clinical pharmacology • Medical education • Measurement technique • Development scale

Introduction

This article provides an explanation of the development and innovation of education opportunities in medical education curriculum in clinical research and Good Clinical Practice (GCP), along with the development of a new education assessment scale. In this article, the authors discuss the components of clinical research and GCP training programs in successful medical education curricula and explain the factors that led to the successful outcome of this training. The medical education sector in Turkey is in a state of significant change and transformation with its recovery policies, which include structured strategies for integration and competition at international level. It is seen that the current medical education and training practices are tried to be progressed with solutions that will be integrated with the requirements of health, economy and social life. The right to education within the perspective of lifelong learning requires that the individual has access to education, that there are educational programs and institutions that meet the educational needs of the individual and society, and that the offered education-research has the flexibility, and adaptability to meet the needs. The governments are expected to produce and implement policies to eliminate obstacles, difficulties and disadvantages in providing the right to education-research by ensuring social participation. This understanding explains the concept of education-research right for the need that education-research is integrated beyond traditional medical education and has a further meaning. The number of clinical studies, which are vital in the development of scientific and technological research, has been increasing gradually in order to solve the problems in Turkish society. Turkish researchers are trying

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to put forward some solutions and suggestions with their clinical studies that will help the advancement of scientific research in terms of quantity and quality. It also provides assurance to the society by complying with good practice examples and the GCP standard. Many researchers believe that clinical research is indispensable to obtain maximum benefit from the current situation in order to achieve development goals, thus keeping up with the maximum scientific progress in well-being and patient care. The fact that should be taken into account in today's world is that clinical research is included in the strategies of the modern state structure and has become a necessity in all plans of developed nations and even developing countries. In order to meet the demands of globalization for the next century, to find solutions to the economic crises around the world, to develop human capacity, for the stability of communities, we should make maximum use of scientific research such as clinical research and its outputs, incorporating scientific technologies into daily life, and by incorporating clinical research and GCP training into medical education curricula. The opinion that it should be brought to a more effective point in the field of health is presented by the authors. Well-trained and skilled health professionals contribute more to health system by improving health outcomes through clinical care and community interventions, and by raising standards of practice, quality, and control. It is a great advantage for educational institutions to have experienced faculty members who design and implement education in order to prepare these individuals. The authors quantitatively demonstrate research intensive by measuring the attitudes of medical students, as well as the experience of Istanbul University in promoting improvements triggered by the transition to institutional research university status with a large research capacity. Then it responded by introducing long-term continuous improvement strategies. This study demonstrates that faculty members are keen on institutional support to enable medical students to develop good practice skills and are able to pursue a program of clinical research and GCP education development in a faculty curriculum for their peers. And also, giving clinical research and GCP trainings in medical education to early years means that the expected improvement from the field of health will be brought to an early time. GCP is an international ethical and scientific quality standard for clinical research. The accuracy and reliability of clinical research results assure the society. It is a single standard regulating the design, conduct, recording and reporting of clinical research in the participation of patient volunteers in the study. It includes the necessary arrangements to facilitate the international mutual acceptance of clinical data [1]. In clinical research, it has become a necessity to integrate the GCP Education, which consists of information transfer of the whole process and interactive practical teachings into the pre-graduate medical education curriculum [2]. Each country has procedures for conducting clinical trials and there are differences in the process at the time of application apart from the international GCP standards that must be followed. For example, in Turkey, according to the design the clinical research are carried out with the approval and permission of the related ethic committee institutions, and organizations. The approval only from "Non-invasive Clinical Research Ethics Committee" is sufficient for non-interventional clinical research. However, both the approval of "Invasive Clinical Research Ethics Committee" [3], and the permits of health authority (TMMDA), Turkey Medicines and Medical Devices Agency allowed [4] are required for interventional clinical research. In Europe, clinical research is carried out with the approvals and/or permits received from the local and central Institutional Review Boards/Independent Ethics Committees (IRB) according to the European Commission Directives [5]. The clinical research in the USA is carried out with the approvals and/or permits received from Food and Drug Administration (FDA) [6-8]. While the carried out clinical research must comply with Good Clinical Practices (GCP) standards in the actual ICH-GCP guidelines in the world. Therefore, it is required to provide an important education-research flow and to create a rational model that will provide good practice strategies of research universities by withdrawing the GCP trainings to be given in the early years with an understanding of ethics, and quality. In this respect, it is important to evaluate the medical and clinical pharmacology practices conducted in two separate periods between 2015-2016, and 2016-2017 for curriculum integration in order to improve the students' GCP skills. It was aimed at improving GCP skills enriched with clinical experience. The content of these applications has been designed from the initiation of clinical trials to safety declarations in pharmacovigilance. Pharmacovigilance that due to legal regulations, safety of ongoing clinical trials and clinical research is a widely agreed topic in pre and post-licensing is important area in clinical research [9,10]. In clinical research practices, related to drug problems, also unwanted reactions, events etc. in volunteers in clinical research constitute the subfield of the multidisciplinary area of medical and clinical pharmacology. The detailed experiences, including safety issues in the clinical research, have been shared in practice. E-books, books, academic, and regular documents related to GCP, and drug databases are widely used as facilitators in practices. In recent years, the studies that included the “GCP Lesson” related to clinical research in the curriculum of pre-graduate medical education are continuing. The first studies on this GCP educational model and long-term educational programs were prepared at the department of medical and clinical pharmacology. To improve the model, it is beneficial to measure student satisfaction desire and response to the model, as well as to measure their skills in critical thinking, academic understanding, comprehensive clinical research methods and raise awareness in this field. There is currently no valid and reliable scale developed to determine student attitudes in this area. An attitude study in this field would increase research incentives through increasing self-confidence, facilitation of new research ideas, and scientific thinking. Thus, developing an evaluation criterion is a need. In this study, it was aimed to develop a scale to evaluate these trainings. For this reason, the other aim of the present study is to introduce the development of a scale for evaluation in medical and clinical pharmacology practices in order to clearly understand the current intensive, behaviors, and attitudes of students, in which the students would constitute the sample in the educational model. The article discusses the outcomes of the two-term practices within the framework of teaching and learning targets.

Materials and Methods

Working group selection, data collection and classification “retrospective descriptive research” method was preferred for data collection, and classification. The study group of the research consists of third grader students who volunteered to be evaluated for two academic years in clinical research practices. The scale was developed using the data of the questionnaire.

This clinical research practices in order to develop medical students' professional skills, and to be able to take part to in the research network; was designed as a new clinical research course evaluated with development of the Likert-type scale. In this article, the scale was developed with the evaluation of two-semester practices. Feedback form results and questionnaire data were used at the end of each group application in this study. Among the measurement and evaluation techniques based on different methods, attitude scale development and evaluation study were discussed.

At the end of the first academic year, in presentations and evaluations, the students were asked to fill in the form. The form has three open-ended questions on describing emotions, thoughts and behaviors. At the end of the lesson, according to the results of these evaluations, a questionnaire study for the academic year second was prepared. The questionnaire study was planned in order to obtain feedback from the students to evaluate these practices, create positive outcomes in the future, and ensure development. The questionnaire study had three parts in total: preliminary evaluation of the scientific activities, consisted of three closed-ended questions; feedback, consisting of closed-ended two, open-ended one and Likert-type five questions; and evaluation of the group work, consisted of Likert-type eight, and open-ended one questions. A 5-point Likert-type scale consisting of 12 items was prepared through the questionnaire study for trial application in the second semester. The pool of statements was compiled by compiling a large number of expressions and feedback received during the first training period. Literature screening and expression pools selected words, were converted into sentences with attitude expression. Draft scale items, intelligibility, competence, easy applicability, and the opinions of the specialist educators were taken. At the end of the opinions, necessary arrangements were made and a 5-point Likert-type scale consisting of 13 items was prepared for trial application. Each item contained a single attitude. After the trial study, the scale; item, validity and reliability analyzes were performed. Since it is a post-training scale, and it could not be applied to the same group twice, Guttman (rt) and Spearman-Brown (rsb) reliability coefficient reliability coefficients were calculated by using split-half reliability method.

Sample size was calculated in order to evaluate the correlation of item total score. In order to obtain 90% power (beta type 2), a sample size of at least 145 was taken as a rule. A comparison was made between the groups. The Statistical Package for the Social Sciences (SPSS) 21.0 Package program was used for all statistical analysis.

Scale of item scores, reliability and validity analysis likert -type questions; “i fully agree, i agree, i am undecided, i disagree, i completely disagree” 5,4,3,2,1 respectively. The score to be obtained by dividing the sum of the item scores of the sentences marked by a medical student by the number of sentences marked; would give an idea about the attitudes of medical students such as gain, interest and satisfaction towards this practice. The highest score from the scale was 60 and the lowest was 12. Students who scored 4 or more in each item stated that they had positive attitudes. The higher scale score showed a high positive attitude. In addition, item averages were calculated.

For content validity, Content Validity Ratio (CVR) and Content Validity Index (CVI) values were calculated by applying specialist opinion according to Lawshe technique. Since this scale was developed for the first time and there was no similar scale made before, no comparison was made for criterion validity. Anti-image correlation table was used to exclude variables that may have a distorting effect on factor analysis in the sample item. In addition, the suitability of this scale for the analysis of the principal components was examined by the Kaiser-Meyer-Olkin (KMO) coefficient and the Barlett’s test of shericity. Factor loads and summability were evaluated by factor analysis for the construct validity. The number of the sizes of collected substances under the scale and the relationship between them were shown. The rule of "taking part an item in only one factor" was considered. Since the high variance was an indication that the related concept or structure was measured so well, the variance percentages of the factors forming the scale were examined. Cronbach's alpha coefficients were calculated for reliability. Guttman and Spearman-Brown reliability coefficients, which represent the scale divided into two, were calculated because it was a post-training scale and could not be repeated after a certain period of time. Whether test items are collectable the test items were evaluated by adding additivity test. In addition, the correlation coefficients were calculated to determine the relationship between the total scores of the scale and the scores of the two sub-dimensions. Finally; a check-list was created for scale development and the analysis was completed (Table 1).

A. Likert-type scale
Defining the attitude to be measured
Writing a large number of positive or negative attitude statements that are considered to be related to the determined attitude
Arranging the trial scale and performing the trial application
Analysis of data obtained from trial scale
B. Determination of the attitude to be measured
Literature research
Collecting information from a similar group representing the audience to be measured
Gathering oral expressions through focus group discussions

Table 1. Check list for development of scale.

Results

According to Lawshe technique, although it is expected to be at least 0.56 for 12 specialist opinions, since the CVR and CVI values are 1.00, this scale which is formed from the questionnaire has coverage (content) validity. Item averages of the scale that created Likert-type were given in Figure 1.

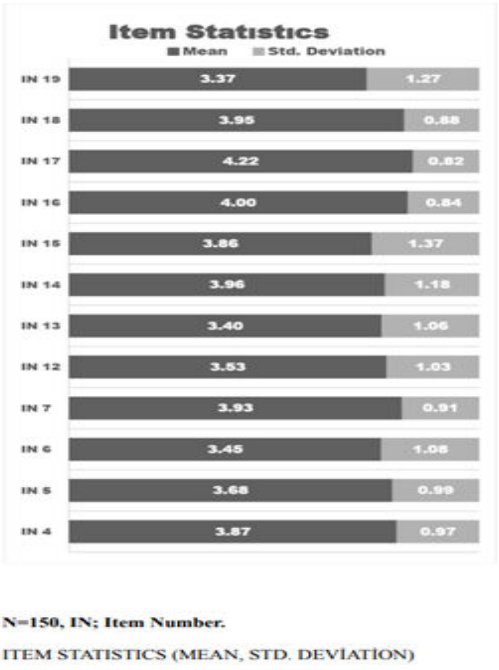

Figure 1. Means with standard devaluations of items.

As a result of the validity study of 156 students, the scale was reduced from 13 items to 12 items and its internal consistency (Cronbach's alpha) reliability coefficient was found as 0.90 (Cronbach's alpha based on standardized items Cronbach's alpha value was found as 0.91).

This value indicates that the scale degree is in "very good" for reliability (Table 2).

Component	Cronbach's Alpha	Cronbach's Alpha Standardized Items	N of Items	Eigenvalues	% of Variance	Cumulative %	Value*	Value
Total	0.899	0.908	12				F=14.121	p<0.001
Factor 1	0.909	0.914	10	6.088	50.734	50.734	F=7.622	p=0.006
Factor 2	0.88	0.884	2	1.57	13,083	63.817	F=7.468	p=0.006

Table 2. Realibility analysis for scale with Cronbach alpha, Eigenvalue and variance percentage of the factors that create the scale.

Additivity values of the scale ad its sub-dimentions (Tukey's test of additivity test) case processing summary; Cases Valid 150 (96.2%), Excluded 6 (3.8%), total 156 (100.0%) Listwise deletion based on all variables in the procedure (Table 3).

Grand mean=3,77
Tukey's estimate of power to which observations must be raised to achieve additivity=2,019.

Table 3. ANOVA test result.

Therefore, it can be said that the items that created the scale are consistent with each other and reflect the attitude they want to measure. Subtracting the 10th item from the scale, it was seen that the Cronbach's alpha coefficient reached above 0.90, it was decided

to pursue the scale with 12 items and then factor analysis was performed. The examination of the anti-image table showed no item that disrupted the factor analysis of this 12 items scale. Therefore, no rotated component matrix was required. All values were above 0.50 (Table 2). As shown in the Scree test (Figure 2), which expresses eigenvalues in factor analysis, two factors with an eigenvalue greater than 1.00 were found.

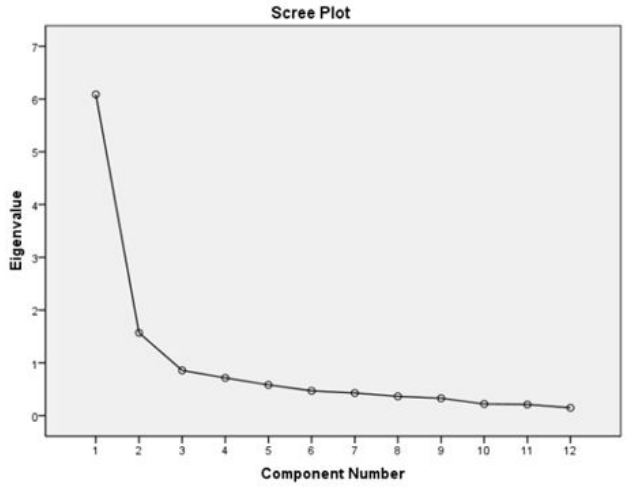

Figure 2. Scree Plot.

Item number (N=150)	Anti-image values of items	Component	
		1	2
IN 4	0.874[a]	0.812	
IN 5	0.909[a]	0.812	
IN 6	0.886[a]	0.787	
IN 7	0.911[a]	0.683	
IN 12	0.875[a]	0.679	
IN 13	0.909[a]	0.711	
IN 14	0.678[a]		0.778
IN 15	0.705[a]		0.718
IN 16	0.878[a]	0.808	
IN 17	0.833[a]	0.744	
IN 18	0.940[a]	0.787	
IN 19	0.892[a]	0.592	
IN: Item Number.			

Table 4. Anti-image values of items, component matrixa.

In addition, the KMO coofficient value was 0.864 and Barlett's Test of Shericity ($p<0.001$) was significant. Since Barlett's *chi-square* value (X_2=1070.35) has a degree of freedom (df=66), this scale is suitable for correlation matrix factor analysis and the sample adequacy degree is "very good". In this study, the diagonal values of anti-image correlation matrix ranged from 0 to 68-0.94 (Table 2).

The reliability coefficient of Guttman (rt=0.830) and Spearman-Brown (rsb=0.831), which represent the scale divided into two, were found. It was shown that the developed scale is reproducible with these coefficients greater than 0.80 with the rule that the test is reproducible. In addition, the scale items were shown to be reproducible (F values Table 1).

All two factors accounted for 63.82% of the total variance (Table 1). This variance value can be considered a degree in "good" for a 2 factors scale.

The number of items of the two factors in which the items were collected is 10 and 2, respectively.

Factor loads of the items ranged from 0.81 to 0.59 (Table 4).

Content dimensions of scale items collected in factor is expressed as

Factor 1: Acquisition, gain and satisfaction=Interest and satisfaction towards this practice, the contribution of this practice to the students and their earnings, **Factor 2:** Behavior and compliance

=Assessment of team, teamwork and friends' compliance while working in this practice and preparing for schoolwork presentation. In the analysis, the correlation table shows that there is a significant relationship between the total score of the scale, and the factors (Table 3). The examination of the correlation coefficients showed; a degree in "high" positive correlation was identified between factor 1 and total item scores, and a "middle" correlation between factor 2 and total item scores (Table 5). This shows the power of factor analysis of the scale.

Correlations					
Component			Factor 1	Factor 2	Total
Spearman's rho	Factor 1	Correlation coefficient	1.000	0.330**	0.923**
		Sig. (2-tailed)	.	0	0
		N	150	150	150
	Factor 2	Correlation coefficient	0.330**	1.000	0.602**
		Sig. (2-tailed)	000	.	0
		N	150	152	150
	Total	Correlation coefficient	0.923**	0.602**	1.000
		Sig. (2-tailed)	0	0	.
		N	150	150	150

Table 5. Result of correlation analysis between scale scores and sub-dimentions.

Discussion

Experience Based Learning (ExBL) and Team-Based Learning (TBL) is the effective training methods for health professionals. It should be used more widely in medical education and medical course programs. Thus, this is reflected in the group work success and attitude of the students. It is also shown that group discussions can be a useful educational method in this study. It was shown this succesfull model with students' demand the “scientific activity/festival” in the future for students' evaluation.

These practices are very important education model, which are the models for educating physician researchers in medical departments that it was suggested that the more number of medical students were exposed to research experiences, the more self-sufficiency they demonstrated. Improving the clinical research skills of students can be linked to enhancing research motivation and therefore it is necessary to evaluate students' attitudes towards clinical research with this scale in such practices.

The educators reported to reach the objectives and goals of the scale. Also, the development scale within the questionnaire study is an example model. This developed scale has been shown to be able to evaluate students' attitudes towards clinical research and can be used in future education periods. With the attitudes measured in such practices, it is possible to draw attention to more research curiosity, critical approach to research, to raise awareness of the need for clinical research, to create new research ideas, where to start the research, and to take part in group work, and to share responsibility. Since it is considered in clinical research, positive attitude and behavior and presentation technique skills can also be developed at international level for the practices handled in multicentre clinical research. Within the framework of ethical approach, teaching the steps of conducting research with such practices in the early years and developing their skills will lead them to transfer results of their research to the clinic more effectively, safely and quickly and will ensure the continuity of lifelong learning in their professional lives. At the same time, it can be stated that there may be partial or full time career choices in both academic and industrial in these fields. Through this scale, it was shown to be able to evaluate students' attitudes towards clinical research. Measurement with this scale is therefore useful in the process of education and training because it was valid and reliable.

In a study, the aim was to develop a blueprint for education in ambulatory and synthesized a theory of how students learn. They said that it has been provided a blueprint for designing and evaluating clerkship curricula as well as helping patients, students, and practitioners collaborate in educating tomorrow’s doctors. Therefore this scale study, within the framework of the collaboration among patients, students, educator and institutions and organizations young researchers are provided opportunities and all parties are facilitated and provided an advantage in the university.

In a different study, the authors looked for an answer to "How can good educational practice move beyond of excellence?" and also it is considered that many studies are needed along with these studies.

Conclusion

This clinical researcher, IRB/IEC, Ethics Committee members should be collectively qualified to review the scientific, medical and ethical aspects of the research. So, it is important to develop a scale for the evaluation of clinical research practices. Thus, the students’ clinical research skills can be improved by increasing research motivation by measuring the attitude, harmony and interests area according to the orientation in the results. It can be shown where to start the research, to develop a new approach to research, and to take part in group work, and to share responsibility. Through the scale, it has been shown to be able to evaluate students' attitudes

towards clinical research. The scale that had high validity and reliability can be used in future education periods by all educators.

Declaration, ethics approval and consent to participate

The study was based on volunteer participation, the details of the study were explained to the participants and their verbal informed consent was taken prior to the assessment. As this study was outside the mandate of the Turkish Medicines and Medical Devices Agency (TMMDA), the clinica research ethics committee of Istanbul medical faculty determined in a written statement that no ethical approval was required for this study (Number:1383).

Consent for publication

Not applicable.

Availability of data and materials

These data and materials used and/or analyzed during the final of the practices (schoolwork presentations) are available from the corresponding author and evaluated the total data at the end of the semesters. No personal information was provided in this study.

Competing interests

The author (s) declared no conflict of interest with respect to the research, authorship and/or publication of this manuscript.

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Authors' contributions

MD all contributed to conception and the design of the study. MD was responsible for the data acquisition. MD analyzed the data and drafted the manuscript. MD was an educator and a researcher in these practices. All authors selected schoolworks and evaluated the presentations. MD read and controlled the manuscript critically and then approved of the final version for publication.

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