

Development of Evaluation Scale for Clinical Research Education

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Research Article

Keywords: Clinical Research, GCP, Clinical Pharmacology, Medical Education Evaluation

Posted Date: August 3rd, 2021

DOI: <https://doi.org/10.21203/rs.3.rs-754366/v1>

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Abstract

Background: There is no scale developed to evaluate clinical research education. The aim of the study is to 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 of the research consists of students who volunteered to be evaluated in the third grade medical students. The students were asked to fill the *form* and the pool of statements was compiled. Literature screening and expression pools selected words, has been 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 Sphericity [$p<0.001$] 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 in 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: This newly developed scale has been shown to be able to evaluate students' attitudes towards clinical research and can be used in future education periods.

Trial registration: "Retrospective descriptive research"

Background

In Turkey, according to the design clinical research\trials are carried out with the approval and permission of the related ethic committee institutions and organizations. It is sufficient that the approval only from "Non-invasive Clinical Research Ethics Committee" for non-interventional clinical research. While, it needs to be taken that both the approval from "Invasive Clinical Research Ethics Committee" [1], and also it needs to be permits of health authority [TMMDA, our country Medicines and Medical Devices Agency allowed [2] for interventional clinical trials. In Europe, according to the European Commission Directives clinical trials/research are carried out with the approvals and / or permits received from the local and central Institutional Review Boards / Independent Ethics Committees [IRB] [3]. And also, in USA, clinical trials are carried out with the approvals and / or permits received from FDA [Food and Drug Administration] [4–6]. While clinical research are carrying out with must be complied with Good Clinical Practices [GCP] standards in the actual ICH-GCP guidelines [7].

GCP is an international ethical and scientific quality standard for clinical trials and clinical research. About the accuracy and reliability of clinical trial and clinical research results assures the society. It is a single standard regulating the design, conduct, recording and reporting of clinical trials and clinical research on the participation of patient volunteers in the study. It includes the necessary arrangements to facilitate the international mutual acceptance of clinical data [7]. 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 [8].

For this reason, it has been necessary 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, is 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 trials and clinical research [9–14]. In clinical research practices, is related to drug problems, also unwanted reactions, events etc. in volunteers in clinical trials and research and constitutes the subfield of the multidisciplinary area of Medical and Clinical Pharmacology [9–11]. Detailed experiences, including safety issues in the clinical trials/research, have been shared in practice. E-books, books, academic, and regular documents related to GCP [7, 12–15], and drug databases are widely used as facilitators in the practices [16].

In recent years, the studies that included of the "GCP Lesson" related to clinical research [8] 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.

The aim of the study is to introduce a development of scale for evaluation in Medical and Clinical Pharmacology practices in order to clearly learn the current interests, 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.

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 students who volunteered to be evaluated in the third grade students for two academic year in clinical research practices. The scale was developed using the data of the questionnaire (14).

This clinical research practices that 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 this 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 presentations and evaluations, the students were asked to fill 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 were 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, with consisted of closed-ended three questions; **feedback**, with consisted of closed-ended two, opened-ended one and Likert-type five questions; and **evaluation of the groupwork**, with consisted of Likert-type eight and opened-ended ne 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, has been converted into sentences with attitude expression. Draft scale items, intelligibility, competence, easy applicability, etc. 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, since it cannot 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. 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 do not agree, I do not agree completely" 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; will give an idea about 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 high 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. How many sizes of substances are collected under the scale and the relationship between them was shown. The rule of "taking part an item in only one factor" was considered. Since the high variance explained 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 [Appendix e-1].

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. 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 to be 0.90 [Cronbach's alpha based on standardized items Cronbach's alpha value was found to be 0.91]. This value indicates that the scale degree is in "very good" for reliability [Table 1]. 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 continue the scale with 12 items and then

factor analysis was performed. When looking at the anti-image table, there was no item that disrupted the factor analysis of this 12-item 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. All two factors account for 63.82% of the total variance [Table 1]. This variance value can be considered degree in "good" for a 2-factor 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 2].

In addition, the KMO coefficient value was 0.864 and Barlett's Test of Sphericity [$p<0.001$] was significant. Since Barlett's chi-square value [$\chi^2=1070.35$] 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 0.68 - 0.94 [Table 2].

The reliability coefficient of Guttman [$\alpha = 0.830$] and Spearman-Brown [$\alpha_{SB}=0.831$], which represent the scale divided into two, were found. It was shown that the scale developed is reproducible with these coefficients greater than 0.80 with the rule that the test is reproducible. In addition, the scale items was shown to be reproducible [F values Table 1].

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, it is seen from the correlation table that there is a significant relationship between the total score of the scale and the factors [Table 3]. When the correlation coefficients are examined; 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 3]. This shows the power of factor analysis of the scale.

Discussion

Experience based learning [ExBL] and Team-based learning [TBL] is an effective training method among health professionals. It should be more widely used in medical education and medical course programs [17–20]. Thus, this is reflected in the groupwork 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 successful model with students' demand the "Scientific Activity/Festival" in the future for students' evaluation.

These practices are very important education model, which are models for educating physician researchers in medical departments that it was suggested that the more medical students were exposed to research experiences, the more self-sufficiency they demonstrated [21, 22]. Improving the clinical research skills of students can be linked to enhancing research motivation and so, it is necessary to evaluate students' attitudes towards clinical research with this scale such as this practices.

It was reported to reach the objectives and goals of the scale by the educators. 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 groupwork, 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 are handled in multicentre clinical trials [23]. 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 has been 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 finds valid and reliable.

In a study, their aim was to develop a blueprint for education in ambulatory and synthesised a theory of how students learn. They said that it has been provides a blueprint for designing and evaluating clerkship curricula as well as helping patients, students, and practitioners collaborate in educating tomorrow's doctors [24]. 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 at the university.

A different study, the authors are seeking an answer to "How can good educational practice move beyond pockets of excellence?" and the authors are seeking an answer to "How can good educational practice move beyond pockets of excellence?" [25] and also It is considered that many studies are needed along with this studies.

In Conclusion

these clinical researcher, IRB/IEC, Ethics Committee members etc. should be collectively qualified to review the scientific, medical and ethical aspects of the trial/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 with increasing research motivation by measured 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 groupwork, and to share responsibility. Through the scale has been shown to be able to evaluate students' attitudes towards clinical research. The scale that had high validity and realibility can be used in future education periods by the all educators.

Declarations

Declaration, Ethics approval and consent to participate

The study was based in 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 Clinical 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 analysed during final of the practices (schoolwork presentations) are available from the corresponding author and evaluated the total data at the end of the semesters. It hasn't personal information in 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.

Funding

The author(s) received no financial support for the research.

Authors' contributions

MD all contributed to conception and the design of the study. MD was responsible for the data acquisition. MD analysed the data and drafted the manuscript. MD were an educator and a researcher in this 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.

Acknowledgements

We would like to thank these medical students and medical lecturer and webmaster and measurement and evaluation unit (from Istanbul University, Istanbul Faculty of Medicine) for their contributions in these practices and for their contributions when preparing questionnaire study.

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Tables

Table 1 Reliability 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-dimensions (Tukey's test of additivity test)

Component	Cronbach's Alpha	Cronbach's Alpha Based on 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	0.880	0.884	2	1.570	13.083	63.817	F=7.468	p=0.006

Case Processing Summary; Cases Valid 150(96.2%), Excluded 6(3.8%), total 156(100.0%)

a. Listwise deletion based on all variables in the procedure.

*ANOVA test result.

Grand Mean = 3,77

a. Tukey's estimate of power to which observations must be raised to achieve additivity = 2,019.

Table 2 Anti-image values of items, Component Matrix^a

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 3 Result of correlation analysis between scale scores and sub-dimensions

Correlations					
	Component		Factor 1	Factor 2	TOTAL
Spearman's rho	Factor 1	Correlation Coefficient	1.000	0.330**	0.923**
		Sig. (2-tailed)	.	0.000	0.000
		N	150	150	150
	Factor 2	Correlation Coefficient	0.330**	1.000	0.602**
		Sig. (2-tailed)	,000	.	0.000
		N	150	152	150
	Total	Correlation Coefficient	0.923**	0.602**	1.000
		Sig. (2-tailed)	0.000	0.000	.
		N	150	150	150

Figures



N=150, IN; Item Number.

ITEM STATISTICS (MEAN, STD. DEVIATION)

Figure 1

Means with standart devaluations of items

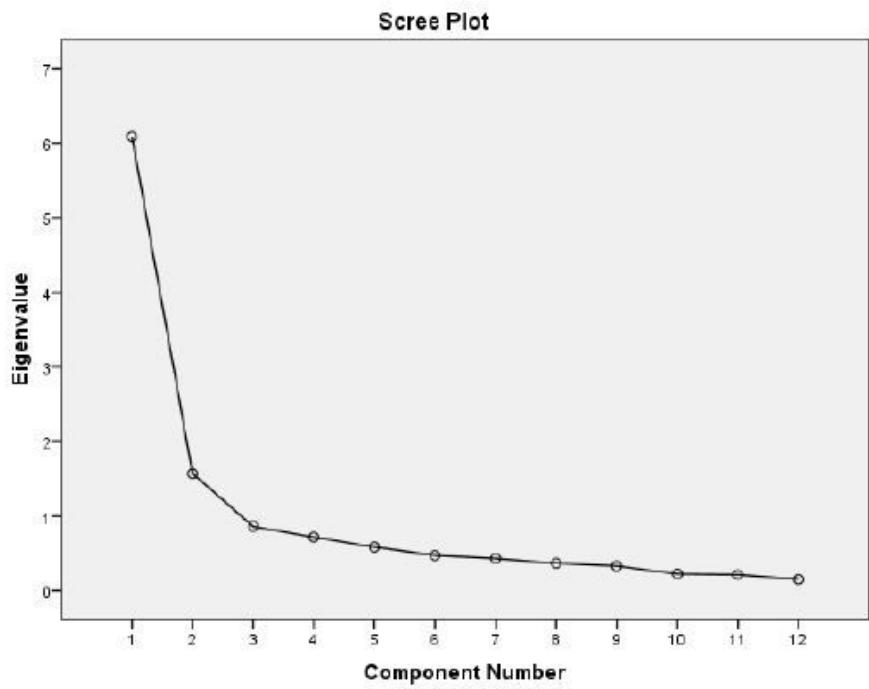


Figure 2

Scree Plot

Supplementary Files

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- [Appendix1ze.Checklist.docx](#)