

Developing and Validating an Instrument for Evaluating Research Protocols

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Abstract

Background: Academic agencies are increasingly looking for good protocols that require interdisciplinary and collaborative teams for a scientific issue. Design of research protocols is challenging and often difficult because of the difficulty involved in integrating the differing characteristics of many corrections to develop a single, consistent document. **So, the aim of this study is to Develop and Validate an Instrument to Evaluate Research Protocols. Subjects and Methods:** This study followed the process for instrument development outlined by Polit & Beck (2012). **Results;** the findings of this study showed high internal consistency since the Cronbach alpha coefficient reached the 0.82, also agreed responses of face and content validity of experts opinions.

Conclusion: The scale has acceptable score of the reliability in all dimensions. Additional saturations of each item with their respective factors have high values. So we can say that this study has generated a valid measure that can evaluate research proposals instrument, since the results presented, as a whole, confirm the high reliability, also appropriate face validity and content.

Keywords: research protocols, validity & reliability.

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I. Introduction

Dissertation or Research Project is now a part and parcel of every under-graduate or postgraduate degree. In following their Bachelor's program, quite often students seem confused about their research projects. Initially, they find it difficult to understand what is expected and what they need to do Cook, Beckman (2006). Although most of the time, they receive strong obvious guiding principle and instructions from the university, still they have many questions confusing their minds. At the first, they fight in picking up a right idea related to a research problem and then they get stuck with primary idea for enrolling their protocol. They are expected to develop and present this initial protocol to their supervisors or the evaluation experts before they start working on the research protocol (Gehlbach, Artino & Durning, 2010).

A research protocol is summarizing and comprehensible explanation of a planned research project. It should contain all of the information; the evaluators will need, such as the background information about the topic, the project's significance and objectives, and the methods you will employ to achieve the objectives and budgetary details (Estep, 2017). The components of research proposals are similar worldwide, with small differences that depends on the funder's requirements (Magee, Byars, Rickards & Artino, 2013).

The process of proposing a research protocols helps junior researchers to intellectualize their research project, crystallize their own opinions about their proposal, and provide evidence of some objectivity, ability (resource) and competence (readiness) to do their tasks. Research proposal may be described as an executive summary of your project endeavor without which a research may not start. Indeed, no proposal no project. The research proposal document should be produced in a hardcopy (Kane, 2006).

There are five basic principles for writing a research protocols; clearness, precision, parsimony, coherence, and consideration to arrangement. Each of this should guide how you write, regardless of the specific purpose of the proposal. By "clarity", the proposal needs to be easily understood. By "precision", each thinking and action plan should be explicated. Parsimony which meant that the proposal ought to be pithy and kept to the point. Coherence, the fourth principle, refers to the consistency among and within section of the proposal. The fifth principle involves the need for "attention to structure", such as ensuring that all references are correctly cited (Artino et al., 2014) & (Jain, Dubey, Jain, 2016).

Significant of the study:

Health research, medical education and clinical practice form the three pillars of modern day medical practice. As one authority rightly put it: 'Health research is not a luxury, but an essential need that no nation can afford to ignore'. Health research can and should be pursued by a broad range of people. Even if they do not conduct research themselves, they need to grasp the principles of the scientific method to understand the value

and limitations of science and to be able to assess and evaluate results of research before applying them (Aguilar, Cortés, Guerrero, Herrera & Orozco, 2011).

In the same vein, receiving approval to conduct research has become more complicated because of the increasing complexity of nursing studies, the difficulty involved in recruiting study participants, and increasing concerns over legal and ethical issues (Gray, Grove, & Burns, 2013).

Furthermore, writing a research proposal is a source of anxiety for most students who may feel lost in face of the novelty of the process, pressured by time restrictions and stressed by the forthcoming evaluation of their work. However, it is a crucial step in the development of a research project since the success of such a task is largely dependent on the quality of the original proposal (Alvarado, Leon & Colon, 2016). Hence, the researcher decided to shed the light on such a topic because it is of great importance in facilitating the educational process for postgraduate students as well as reducing the pressures that may face when writing the research plan.

Aim of this study:-

Developing and Validating an Instrument to Evaluate Research Protocols

Theoretical framework of this study designed to support nursing educational & clinical practice with knowledge development related to research.

The specific objectives were to:

1. Examine face & content validity through a panel of experts.
2. Evaluate internal consistency and test-retest reliability of the developed questionnaire evaluating research proposals and protocols.
3. Evaluate quality of research protocols using the validated scale.

Research questions of the study were:

1. What characteristics of good - approved research protocols and proposals?
2. What are the weight and contribution of each dimension?

Process for Instrument Development

This study followed the process for instrument development outlined by Polit & Beck (2012), Polit & Yang (2016). The following sections describe the steps that were taken in developing and validating the Instrument that evaluate research proposals.

Conceptualizing the construct. The first step in the instrument development was to thoroughly understand the definition of the concept and its underlying construct to be measured.

The conceptual definition and attributes of research proposals are based on an extensive review of relevant research studies, comprehensive literature review conducted by consultation of the numerous publications related to the theories and existing instruments. There are six parts of the research proposal or protocols that can be noticed in the most recent research protocols:-

- 1- Title
- 2- Introduction & research problem
- 3- Aim of the Study & Objectives
- 4- Research Question & Hypothesis
- 5- Research Methodology
- 6- References.

Developing an item pool. Items in an instrument collectively contribute to the operational definition of the concept to be measured. According to Polit and Beck (2012), the initial item pool should comprise at least 50% of items from the final scale. The item pool was generated based on a literature review (Sidik, 2005, Mekelle University, 2016 & Committee for the Evaluation of Research, 2017), existing questionnaires, and the conceptual definition and attributes of approved research protocols. The first draft of the item pool consisted of 54 items with 6 dimensions that mentioned previously with different items per each subscale.

Deciding on the type of scale. Rating scales are most commonly used within nursing research. An ordinal scale of measurement was selected for this instrument because the measurement is regarded as the rank and ordering of research protocol attributes into quantitative categories according to the relative amount of the specified attribute. A choice of two responses was developed for each item: Achieved= (1) & Not Achieved= (0).

Scoring. The next step in the scale (instrument) development was to decide how to express the final score in a meaningful way. There are two commonly used methods to calculate the final score of an instrument. One is to simply add or average the responses on individual items. The other way is to give weights to each item or subscale if the contribution of each item or subscale to the total score is different.

The final scoring system that achieved by the researcher after the finalization of modifications of the jury comment and data analysis was:-

(A) Good quality that can be accepted at 75% of the total score and more which equals score ranges from 44 to 58.

(B) Moderate quality and need some modifications ranges from 50% to less than 75% of the total score which equals score ranges from 29 to 43.

(C) Very Low quality that must be not accepted less than 50% of the total score which equals score less than 29.

Wording items. Items were worded to enhance the likelihood that respondents would answer all of the questions in the same manner. Questions were written in a simple, concise, and comprehensible format. The items were worded to ensure clarity, avoid use of medical terminology, and prevent question bias. In addition, questions were worded to avoid double negatives and double barreled items (Polit & Yang, 2016).

Internal review: readability. Since there are various accepted and approved levels of research protocols for master and doctoral dissertation in our country and national universities. Therefore, the research protocols level with higher values are indicating greater ease. Reading ease scores that are considered acceptable should be in the range of 65, 70 and the scale's readability to be on a sixth or seventh grade level or lower (Polit & Yang, 2016).

Deciding item features. A set of items that represented the key characteristics of each attribute (subscale) in slightly different ways was developed to cancel out the irrelevant idiosyncrasies of individual items. This was supported by the Cronbach's alpha values.

Expert review for content validity. The revised 54 items created for each subscale were subjected to an external review by a group of experts to assess the instrument's content validity. The aim of the expert panel review was to eliminate ambiguous, irrelevant, and inappropriate items from the instrument. The inclusion criteria for the expert panel was to consist of academic professors in nursing and medical fields, male and female, who have a great experience in research proposals and editing who are knowledgeable in statics & research and also reviewers in an international research journals.

Expert panel participants were solicited through faculty of nursing and faculty of medicine in some universities in Egypt. Thirty nine eligible participants of jury were provided the instrument for face and content validity. Only thirty three participants from the total participants consented and completed the face and content validity assessment, the intent was to recruit both male and female participants.

The expert panel reviewers were given an operational definition of a research protocols. In addition, the reviewers were given identified attributes and characteristics of research protocols and six described subscales. The experts were directed to rate the 54-item subscales for clarity, relevance, and centrality. Reviewers were instructed to determine each item for relevance and determine its congruency with the construct and significance for the research problem. Clarity was rated by the degree in which the item was clear in perception and/or understanding and free from ambiguity. Centrality was rated by the degree and quality of the match between the content addressed in each item and the objective it was assigned to measure.

Finally after the editing and modification that done by the expert jury, the researcher modified the instrument that become 58 item included into six dimensions namely Title that contain 7 items, Introduction & research problem that contain 19 item, Aim of the Study & Objectives that contain 8 items, Research Question & Hypothesis that contain 3 items, Research Methodology that contain 14 item, & References that contain 7 items.

Pilot testing. After expert evaluation, a convenient sample of research protocols chosen for a period of 6 months. The total sample determined 30 nursing research protocols for both master and doctorate degree with internal and external researchers and higher degree students from the period time of November -2018 until April -2019. The researchers who accept to participate in the study with their protocols are from different faculties in all of Egyptian universities were solicited to participate in the pilot study through evaluation and measuring by the instrument. The inclusion criterion for these protocols was the same as those in the full scale study used to test the reliability and validity of the instrument. The questionnaire package is described in the "tool of data collection design". The data collection process was the same as the "Full Scale Study".

The primary purpose of the pilot study was to examine the feasibility of data collection tools. This included average time to complete the entire survey, the number of questions to be shown on each page, the order of item arrangement, potential causes for missing responses (Paganucci, 2016), response rate and responding time to study invitation, and clarity of instructions and items, or any other survey concern identified by the participants. Feedback was elicited through debriefing questions. The final instrument was revised according to the pilot testing results which are presented in the following section.

Data collection. Data was collected through self-administered questionnaire done by the assessors of experts for evaluating the 30 research protocols. Then the evaluative score are recorded and enumerated within the tables of results.

Ethical Considerations

The research was designed to ensure sound ethical principles and protect human rights. The aim of the research is to contribute to the body of research, specifically for the practice of nursing research protocols. All eligible and interested participants were advised of the purpose of the study, and how the information will be used,

through a cover letter and informed consent form. The informed consent form was prepared according to research requirements. In support of the principle of autonomy, the participant's whether jury or young researchers who have scientific research protocols were informed regarding their voluntary participation and withdrawal from the study at any time without negative outcomes.

Participants were assured that their confidentiality will be upheld. The questionnaires were coded, and their names were linked to their questionnaire answers. Their contact information and the collected data will be kept in secret place. The computer used to analyze the data is password-secured and will be kept in a protected place for five (5) years, after such time all data will be disposed of properly. Only the researcher will have access to this secret place and password-secured data.

II. Data Analysis

Data collected through e-mail was downloaded and converted into SPSS 22 data analysis. Descriptive statistics, including frequency distributions, central tendency (mean, median), and variability (range and Standard Deviation) was calculated to describe demographic characteristics, quality of scientific research protocols for validity (face & content), The test content analysis was conducted through evaluation of its items in order to judge their relevance for the construct in question, Cronbach's alpha was analyzed for reliability, and evaluation of the protocols.

Test-retest reliability was examined, items with 0.7 or greater will be kept in the scale without revision or changes while those 0.7 will be revised or discarded based on the expert panel's suggestion. Reliability using Cronbach's Alpha if Item Deleted is computed by average and a value of 0.7 as the standard of excellent for content validity (Nikolai, 2018). Therefore, a total of four questions were added and the instrument was further revised to a final item pool of 58 items, with different items per each subscale. A detailed description of the expert panel review and opinions will be discussed in results. Exploratory factor analysis and confirmatory factor analysis was conducted to examine the structure of the developed instrument as well as a reliability analysis was conducted to answer research question 2.

III. Results

Table (1) Total Scale Reliability for the Instrument

Dimensions	No of items	Cronbach's Alpha Reliability
1- Title	7	0.89
2- Introduction & research problem	19	0.78
3- Aim of the Study & Objectives	8	0.79
4- Research Question & Hypothesis	3	0.85
5- Research Methodology	14	0.80
6- References.	7	0.83
Total	58	0.82

Table (2) Responses of Jury Sheet Face Validity

Overall opinions	Agree		Disagree	
1- The preliminary tool looks like a tool for evaluating research proposal.	32	97.0	1	3.0
2- The wording of the tool are:-				
- Clear	30	90.9	3	9.1
- Correct	32	97.0	1	3.0
- Scientific	31	93.9	2	6.1
- Understandable	32	97.0	1	3.0
- Realistic	31	93.9	2	6.1
3- The form covers all aspects of the research proposal:-				
- Title	33	100	0	0
- Introduction	32	97.0	1	3.0
- Aim of the study& Objectives	31	93.9	2	6.1
- Research Question & Hypothesis	30	90.9	3	9.1
- Methodology	32	97.0	1	3.0
- References	32	97.0	1	3.0
4- The form is free from any duplication.	32	97.0	1	3.0
5- The form is free from redundant items.	32	97.0	1	3.0
6- There is a balance among various sections of the form				

- Title (7 items)	31	93.9	2	6.1
- Introduction (16 items)	31	93.9	2	6.1
- Aim of the study& Objectives (8 items)	30	90.9	3	9.1
- Research Question & Hypothesis (3 items)	32	97.0	1	3.0
- Methodology (13 items)	32	97.0	1	3.0
- References (7 items)	32	97.0	1	3.0
7- The form is in logical sequence.	31	93.9	2	6.1
8- The dimensions of the form are:-				
- Clear.	31	93.9	2	6.1
- Enough to measure evaluating research proposal.	31	93.9	2	6.1
9- The scale used in the evaluation is appropriate.	33	100	0	0
10- The scoring used is clear.	31	93.9	2	6.1

Table (3) Total Score of Each Dimension for Jury Sheet Content Validity

Dimensions	Agree		Disagree	
	No	%	No	%
1- Title	32	97.0	1	3.0
2- Introduction	32	97.0	1	3.0
3- Aim of the Study & Objective	32	97.0	1	3.0
4- Research Question & Hypothesis	31	93.9	2	6.1
5-Research Methodology	33	100	0	0
6- References	32	97.0	1	3.0
Total	32	97.0	1	3.0

Table (4) Personal Data for Experts (n=33)

Variable	Experts (n=33)	
	N	%
Age in Years 30 :40 year	5	15.2
41 :50 year	13	39.4
51 : 60 year	11	33.3
61 and more	4	12.1
Academic Years of Experience		
1:10 year	7	21.2
11: 20year	11	33.3
21: 30year	9	27.3
31: 40 year	5	15.2
More than 40 year	1	3.0
Job Title Lecturer	5	15.2
Assistant Professor	19	57.5
Professor	9	27.3
Specialty Nursing Administration	7	21.2
Medical Surgical Nursing	5	15.2
Pediatric Nursing	3	9.1
Community Nursing	4	12.1
Psychiatric Nursing	4	12.1
Obstetrics Nursing	3	9.1
Critical and Emergency Nursing	4	12.1
Medicine	3	9.1
University Port-Said University	9	27.2
Mansoura University	6	18.2
Cairo University	4	12.1
Alexandria University	4	12.1
Beni-Suef University	5	15.2

Kafr-Elsheikh University	3	9.1
Fayoum University	2	6.1
Gender Male	4	12.1
Female	29	87.9

Table (5) Evaluation Scores of all Dimensions in all Protocols for the Pilot Study (N=30)

Dimensions	Good quality		Moderate quality		Low quality	
	N	%	N	%	N	%
1- Title	8	26.6	17	56.7	5	16.7
2- Introduction	10	33.3	15	50	5	16.7
3- Aim of the Study & Objective	12	40	14	46.7	4	13.3
4- Research Question & Hypothesis	9	30	18	60	3	10
5- Research Methodology	11	36.7	16	53.3	3	10
6- Reference	12	40	13	43.3	5	16.7
Total score	10	33.3	16	53.3	4	13.3

Table (6) Relation between quality of protocols and Personal Data for Pilot Sample (N=30).

Variable	Sample (n=30)		Test of sig. χ^2
	N	%	
Age in Years			$\chi^2 = -8.4$ P = 0.041*
20 :30 year	13	43.3	
31 :40 year	15	50.0	
41 :50 year	2	6.7	
Years of Experience			$\chi^2 = 3.1$ P = 0.121
1:10 year	2	6.7	
11: 20year	9	30.0	
21: 30year	8	26.7	
31: 40 year	8	26.7	
More than 40 year	3	10.0	
Wanted degree Master	20	66.7	$\chi^2 = 9.21$ P = 0.01*
PhD	10	33.3	
Gender Male	10	33.3	$\chi^2 = 1.098$ P = 0.562
Female	20	66.7	

(*) statistically significant at $p < 0.05$.

Table (1); this table shows the reliability of all dimensions of the instrument with total reliability of the scale. This table shows accepted score of the reliability in all dimensions and total score.

Table (2); this table shows the Face Validity of expert evaluation's. This table show accepted and agreed responses in all items of the scale according to the audit of jury.

Table (3); this table shows the evaluation of content validity according to the jury opinions. This table shows highly percent of agreement and approval regarding the dimensions of the scale.

Table (4); this table shows the general characteristics of the experts. 39.4% from the experts within the age group between 41 to50 years old, the majority of them were female and assistant professor category. Approximately one quarter of them belong to port-said university and nursing administration department.

Table (5); this table shows the evaluation of the sample proposals of the pilot study. This evaluation presents the most percent and score are for the moderate quality category for all dimensions of the scale and the total score of the scale. Also the good quality percent was more than the poor quality percent.

Table (6); this table shows the relation between quality of protocols and Personal Data for Pilot Sample. According to the table there was a statistical significant difference in age and the wanted degree.

IV. Discussion

The integrity of any research depends on the accuracy of the measures used, especially when exploring complex phenomena such as designing scale measuring the quality of research protocols. The results of the validity and reliability testing on this scale (instrument) indicated it is an accurate measure of research protocols.

The processes used to validate this scale were difficult and appropriate (Parsian, Dunning, 2009). While face validity is the lowest form of validity, it was useful in that provided important information about the operationalization of the questionnaire by jury of experts with great experiences in research and publications. Content validity helped assess whether the content was relevant to the concept of evaluating quality of research protocols that defined for the study. Factor analysis assessed the construct of the scale. The internal reliability

(alpha) reached the recommended level for clinical use; and test-retest indicated stability of the responses to the items on the instrument over time.

Therefore, the scale could be used in education and management and mainly for research fields, for example, assessors of protocols could use it confidently in evaluating the quality of the new examined research protocols for both master and doctoral degrees. While the research protocols has been recently recognized as an important aspect of research, both professors and postgraduate students find it difficult to measure when they assess their initial work; largely because it is sometimes highly subjective and often confused with other factors. This paper reported the psychometric validation of the research protocols (Jayasinghe, 2003).

However, to strengthen the rigor of the questionnaire for further research, the researchers recommend undertaking convergent and discriminant validity to examine the similarity and differences of the research protocols with other tools. It is also recommended that structured equation modeling (SEM) and confirmatory factor analysis be undertaken in a larger sample to support the generalizability of the questionnaire (Donohue, 2018).

The factors that form the questionnaire, "Process scientific information", "Managing scientific information" and "Develop scientific information" could evaluate proposals like Bastidas (2013), who mentions that based teaching research students act as researchers learn related skills and teaching aims to help students understand the phenomena of how the experts do it, plus it could assess the methodological proposals.

V. Conclusion

The scale has high internal consistency since the Cronbach alpha coefficient reached the 0.82. Additional saturations of each item with their respective factors have high values. On the other hand, correlations between factors indicate a good relationship and dependence between them, so we can say that this study has generated a valid measure that can evaluate research proposals instrument, since the results presented, as a whole, confirm the high reliability, also appropriate face validity and content.

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