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Satisfaction and Perception of Researchers towards the Enrollment of Clinical Research Coordinators on Research Conduct and Promptness: A Cross-Sectional Study

Ahmad H. Al-Badr[1,2], Nahid K. El-Bakri[1], Amani K. Abu-Shaheen[1] and Mohamad A. Al-Tannir[1*]

[1]*Research Center, King Fahad Medical City, Riyadh P.O. Box 59046, Riyadh 11525, Saudi Arabia*

[2]*Department of Urogynecology and Pelvic Reconstructive Surgery, Women's Specialized Hospital, King Fahad Medical City, Riyadh P.O. Box 59046, Riyadh 11525, Saudi Arabia*

Abstract

Background: Although there is a growing presence of research in the healthcare delivery system, little information is available about the perception of researchers towards the enrollment of Clinical Research Coordinators (CRCs) on improving research conduct promptness.

Objective: To assess the satisfaction and perception of researchers towards the enrollmentof CRCs on promptness of research conduct.

Design: A cross-sectional study.

Setting: The study was conducted at King Fahad Medical City, Riyadh, Saudi Arabia. Participants: Researchers from different hospitals and centers.

Main outcome measure: Data was collected by using a self-administered questionnaire. The questionnaire consisted of four sections; the first one consists of data on respondents' demographics, and the other three sections explore the respondents' satisfaction and perception towards the enrollment of CRCs in enhancing research conduct promptness.

Results: The enrollment of CRCs achieved significant promptness of research work plan management (P< 0.0001) as reported by 81.6% of researchers compared to 46.9% previously. All respondents (100%) believed that enrolling CRCs helped them to perform research tasks more efficiently.

Conclusion: Although this study was only one part of a far-reaching project, it has divulged a promising level of researchers' satisfaction and perception towards the enrollment of CRCs in enhancing research conduct promptness.

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Abbreviations:

CRCs: Clinical Research Coordinators
KFMC: King Fahad Medical City
PI: Principal Investigator
IRB: Institutional Review Board
RC: Research Center

Introduction

Clinical research has a substantial impact on the improvement of medical care [1]. The principal investigator (PI) is in-charge of overseeing a research project and commonly delegates responsibilities of conducting it to CRCs [2]. The CRCs, in turn, play a vital role in achieving the highest research ethical standards,by ensuring data integrity and accuracy, protection of human subjects and, the successfulcompletion of the project [3]. Even though PI's have historically assumed a leadership role in the research settings, CRCs contribute more in these areas and are commonly considered as the "glue" that holds the studies together [4]. Industry professionals have noted that a CRCs perform almost 50 different tasks a day such as assisting with protocol development, recruitment, patient education, informed consent and enrollment of eligible subjects, coordinating visits, and collecting and maintaining clinical data as well as serving as the main liaison between the subject and the PI. These tasks extend beyond data collection and administrative support and contribute significantly to the accuracy and quality of data. Thus, involving skilled CRCs in research projects is indispensablefor dealing with various intricacies in the research conduct and ensuresafety and efficiency.

Although research in the healthcare delivery systemhas registered a phenomenal growth in the past few years and has a substantial impact through implementation of the better health policies, the arena for exploring the needs andperception of researchers in research conduct remains widely unexplored.Previous studies have dwelt on the various aspectsof CRCs, their tasks, their work attitudesand their perception and experiences at work [2,5,6].

Unfortunately, in such a high competency busy tertiary care center clinicians are heavily involved in clinical duties fuelling the need for trained CRCs to assist with research conduct.

The Research Center (RC) at KFMC seeks to achieve thisobjective and fulfill this genuine need by enrolling CRCs. The main aim of this study was to assess the satisfaction and perception of researchers towards the enrollment of CRCson research conduct promptness at KFMC.

Materials and Methods

Study design

A cross-sectional study was conducted at KFMC during 2015, after obtaining the Institutional Review Board (IRB) approval (IRB015-170).

***Corresponding Author:** Dr. Mohamad AlTannir, Chairperson of Clinical and Translational Research Department, Research Center, King Fahad Medical City, P.O. Box 59046, Riyadh 11525, Saudi Arabia; E-mail: maltannir@kfmc.med.sa

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Study design

Participants were researchers from different hospitals and centers at KFMC who submitted a proposal for IRB approval throughout 2015 or published an article in 2014. Exclusion criteria included are searcher who did not carryout any research related activity in 2014. Participants who met the inclusion criteria were invitedto participate in this study; those who agreed to take part gave written informed consent.

Recruitment

We approached 65 active researchers from different hospitals and centers at KFMC over a one-month period. Of whom, 16 declined to participate due to timeconstraints.

Recruitment

Data was collected using a self-administered questionnaire to assessthe satisfaction and perception of researchers towards the enrollmentof CRCson promptness of research conduct at KFMC. To ensure the clarity of the questionnaire a pilot study was conducted on 10participants. The Cronbach's alpha was >0.70.

The questionnaire consisted of four sections. The first section gathered the data on demographics (age, gender, job title, country of academic qualification, total years of experience and years of experience at KFMC). The second section explored the respondent's role in conducting research. The third and fourth sections explored the various CRC responsibilities, previous delay in research study due to lack of CRCs and respondents' satisfaction and perception towards the enrollment of CRCs in research conduct promptness at KFMC. A 5-point Likert scale was used to assess the satisfaction level (very satisfied, satisfied, somewhat satisfied, dissatisfied, very dissatisfied) and their perception was graded as strongly agree, agree, uncertain, disagree and strongly disagree, and binary questions were also used to assess the promptness/delay of research conduct.

Ethics approval and consent to participate

Ethics approval was obtained from KFMC IRB (IRB015- 170). All participants consented to participate.

Statistical analysis

Data analysis was carried out using SPSS 22.0 software (SPSS Inc., Chicago, IL, USA). Categorical variables were presented as frequencies with corresponding percentages. We used descriptive and Fisher's exact testto determine the impact of CRCs enrollment on research conduct promptness. The Likert scale responses were collapsed into combinations of (1) "strongly agree" and "agree" and (2) "uncertain," "disagree," and "strongly disagree." A p-value of ≤0.05 was considered as statistically significant.

Results

Fortynine participants were entered into final data analysis. Respondents' demographic characteristics are presented in Table 1. Thirty-four (69.4%) respondents were male.

The enrollment of CRCs achieved significant promptness of research work plan management (p< 0.0001) as reported by 81.6% of researchers compared to 46.9% who had previously delay in research study due to lack of CRCs. All respondents (100%) believed that enrolling CRCs to their projects helped them to perform research tasks more efficiently (Table 2).

The satisfaction of the services provided by CRCs was significantly associated with years of experience at KFMC (p=0.018), as well as with the total years of experience (p=0.003). Participants with >10 years of experience at KFMC were more satisfied than other participants (Table 3).

Variables	Number of participants (%)
Gender	
Male	34 (69.4)
Female	15 (30.6)
Age Group (Years)	
<35	13 (26.5)
35 – 45	21 (42.9)
>45	15 (30.6)
Job title	
Consultant	24 (49.0)
Assistant Consultant	12 (24.5)
Resident	10 (20.4)
Others	3 (6.1)
Country of Academic Qualification	
Middle East and North Africa	26 (53.1)
Europe and the USA	18 (36.7)
Other Countries	5 (10.2%)
Total Years of experience	
≤10 years	39 (79.6)
>10 years	10 (20.4)
Years of experience at KFMC	
≤10 years	25 (51.0)
>10 years	24 (49.0)

Table 1: Demographic characteristics of the respondents.

Discussion

The results of this study implythat the majority of respondents expressed a positive level of satisfaction with the research conduct promptness as a consequence of the enrollment of CRCs capped by a significant improvement in research work plan management. One of the main responsibilities of the CRCs is to protect the rights and welfare of the human research participants in the studies. To do so, the CRCs must understand regulatory, institutional, sponsor and protocol requirements for the study and comply with all IRB decisions and requirements. They should also ensure that all studies have current IRB approval before anypatient enrollments or data collection.They need to coordinate with the PI and other key research members to assure that clinical research activities are performed in compliance with institutional regulations, policies, and proceduresbesides ensuring that protected health information will not be disclosed underany circumstances except to those mentioned in the IRB-approval or if required by law [7]. The PIs' evaluation of CRCs performance is pivotal as it provides an insight into the measure to be taken in further enhancing the research conduct and productivity of an institution. Appraisal sessions help to make corrective action plans and pinpoint performance problems. Moreover, all participants acknowledged that CRCs have a positive effect on research conduct and promptness. Previous studies have also highlighted the significance of involving CRCs in clinical research as they are more adept in applying ethical standards and guarding the safety of the subjects which is in

Variables	n (%)
Number of research studies participated in	
1 – 5	23 (47.0)
6 – 10	13 (26.5)
>10	13 (26.5)
Previous delay in research study due to lack of clinical research Coordinators	
Yes	23 (46.9)
No	26 (53.1)
Responsibility of CRCs involved in the research study	23 (16.5)
Reviewing the research proposal	35 (24.9)
Submitting research proposal / Amendment to IRB	34 (24.5)
Data Collection/CRF filling	22 (15.8)
Data Entry	11 (7.9)
Obtaining Informed Consent	13 (9.4)
Arranging Activities	1 (0.7)
Others	
Services provided by the CRC	29 (59.2)
Very satisfied	11 (22.4)
Satisfied	9 (18.4)
Somehow Satisfied	0 (00)
Dissatisfied	0 (00)
Very dissatisfied	
Promptness of the research services provided after enrollment of clinical research Coordinators	
Yes	40(81.6)
No	9 (18.4)
Do you believe that adding a CRC in your department will help you to perform your research more efficiently?	49 (100)
Agree	0 (00)
Disagree	

Table 2: Satisfaction and perception towards the enrollment of the CRCs on the research activities.

conformity with our study [8, 9]. The most important finding was the decrease in the reported delay from 46.9% to 18.4% due to the enrollment of CRCs in their teams and overall the researchers were satisfied and perceived that CRCs help to perform research related tasks in a more organized manner. The CRCs assisting the PI with a wid variaty of taskes including protocol development, enrollment of eligible subjects, collecting and keeping clinical data and maintaining the communication between the subject and the PI. The absence or inadequacy of CRCs negatively affects undergraduate medical students towards research and also results in decreased if not absent research output [7, 10]. Studies have also attributed the subject recruitment and retention in clinical trials to the structure within a clinical research team [11].

The current results highlighted the importance of the support and management provided by the CRCs, who handle the day-to-day work of the study, channel the resources, constantly check for any protocol deviations. Our results will serve as the basis for future research in this area which will help to contribute to developing and optimize strategies for initiating training and educational programs through advanced knowledge and skills to come up with qualified CRCs. Consequently, the research outcomes will be enhanced. This study has two main limitations including the fact that the data was obtained by self-administered questionnaire and the small sample size.

Conclusion

Although this study is only one part of a far-reaching project, it has divulged a promising level of researchers' satisfaction and perception towards the enrollment of CRCs in enhancing research conduct quality and promptness.

Competing interests

The authors declare that they have no conflict and no competing of interests.

		Satisfaction of service provided by the CRCs			p- value
		Very satisfied n (%)	Satisfied n (%)	Somehow satisfied n (%)	
Sex	Male	22 (75.9)	7 (63.6)	5 (55.6)	0.460
	Female	7 (24.1)	4 (36.4)	4 (44.4)	
Age (years)	< 35	9 (31.0)	4 (36.4)	0 (0.0)	0.238
	35 - 45	12 (41.4)	5 (45.5)	4 (44.4)	
	> 45	8 (27.6)	2 (18.2)	5 (55.6)	
Job title	Consultant	15 (51.7)	5 (45.5)	4 (44.4)	0.152
	Assistant Consultant	4 (13.8)	3 (27.3)	5 (55.6)	
	Resident	7 (24.1)	3 (27.3)	0 (0.0)	
	Others	3 (10.3)	0 (0.0)	0 (0.0)	
Years of experience at KMFC	≤10	14 (56.0)	7 (28.0)	4 (16.0)	*0.018
	> 10	15 (51.7)	4 (36.4)	5 (55.6)	
Total years of experience	≤10	26 (66.7)	10 (25.6)	3 (7.7)	*0.003
	> 10	3 (10.3)	1 (9.1)	6 (66.7)	
Number of research studies per PI	1 - 5	14 (48.3)	4 (36.4)	5 (55.6)	0.970
	6 - 10	7 (24.1)	4 (36.4)	2 (22.2)	
	> 10	8 (27.6)	3 (27.3)	2 (22.2)	

Table 3: Association between satisfaction of services provided by CRCs with the respondent characteristics.
* P – value ≤ 0.05.

Author Contributions

AAB undertook the initial literature review and reviewed the final write up, MAT and AA contributed to data collection, data analysis, and write-up. NEB added further literature and supported MAT with the final write-up. All authors read and approved the final manuscript.

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