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

Ahmad H. Al-Badr1,2, Nahid K. El-Bakri1, Amani K. Abu-Shaheen1 and Mohamad A. Al-Tannir1*

1Research Center, King Fahad Medical City, Riyadh P.O. Box 59046, Riyadh 11525, Saudi Arabia
2Department 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 enrollment of 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.

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 successful completion of the project [3]. Even though PIs 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 indispensable for dealing with various intricacies in the research conduct and ensuring safety and efficiency.

Although research in the healthcare delivery system has 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 and perception of researchers in research conduct remains widely unexplored. Previous studies have dwelt on the various aspects of CRCs, their tasks, their work attitudes and their perception and experiences at work [2,5,6].

Keywords:
Clinical Research Coordinators, Research conduct promptness, Research, Saudi Arabia

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

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

Citation: Al-Badr AH, El-Bakri NK, Abu-Shaheen AK, Al-Tannir MA (2017) Satisfaction and Perception of Researchers towards the Enrollment of Clinical Research Coordinators on Research Conduct and Promptness: A Cross-Sectional Study. Int J Clin Res Trials 2: 117. doi: https://doi.org/10.15344/2456-8007/2017/117

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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 search who did not carry out any research related activity in 2014. Participants who met the inclusion criteria were invited to 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 time constraints.

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 test to 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

Forty-nine participants were entered into final data analysis. Respondents' demographic characteristics are presented in Table 1.

| 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 imply that 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 any patient 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 procedures besides ensuring that protected health information will not be disclosed under any 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

The enrollment of CRCs achieved significant promptness of research work plan management as reported by 81.6% of researchers compared to 46.9% who had previously delayed 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).

The Cronbach’s alpha was >0.70.

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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 wide variety of tasks 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.

| 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 due to lack of clinical research Coordinators |
| Yes                                                  | 23 (46.9) |
| No                                                   | 26 (53.1) |
| Responsibility of CRCs involved in the research study |
| Reviewing the research proposal                      | 23 (16.3) |
| Submitting research proposal / Amendment to IRB      | 35 (24.9) |
| Data Collection/CRF filling                         | 34 (24.5) |
| Data Entry                                          | 22 (15.8) |
| Obtaining Informed Consent                          | 11 (7.9)  |
| Arranging Activities                                | 13 (9.4)  |
| Others                                              | 1 (0.7)   |

**Services provided by the CRC**

| Services provided by the CRC | n (%)     |
|------------------------------|-----------|
| Very satisfied               | 29 (59.2) |
| Satisfied                    | 11 (22.4) |
| Somehow Satisfied            | 9 (18.4)  |
| Dissatisfied                 | 0 (00)    |
| Very dissatisfied            | 0 (00)    |

**Promptness of the research services provided after enrollment of clinical research Coordinators**

| Promptness of the research services provided after enrollment of clinical research Coordinators | n (%)     |
|--------------------------------------------------------------------------------------------------|-----------|
| 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?**

| Do you believe that adding a CRC in your department will help you to perform your research more efficiently? | n (%)     |
|--------------------------------------------------------------------------------------------------------|-----------|
| Agree                                                                                                                                                  | 49 (100)  |
| Disagree                                                                                                                                               | 0 (00)    |

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

| Variables                                           | n (%)     |
|-----------------------------------------------------|-----------|
| Satisfaction of service provided by the CRCs         |           |
| Very satisfied                                      |           |
| n (%)                                               |           |
| Satisfied                                          |           |
| n (%)                                               |           |
| Somehow satisfied                                   |           |
| n (%)                                               |           |

| Sex                                                 | n (%)     |
|-----------------------------------------------------|-----------|
| Male                                                | 22 (75.9) |
| Female                                              | 7 (24.1)  |

| Age (years)                                         | n (%)     |
|-----------------------------------------------------|-----------|
| < 35                                                | 9 (31.0)  |
| 35 - 45                                             | 12 (41.4) |
| > 45                                                | 8 (27.6)  |

| Job title                                           | n (%)     |
|-----------------------------------------------------|-----------|
| Consultant                                          | 15 (51.7) |
| Assistant Consultant                                | 4 (13.8)  |
| Resident                                            | 7 (24.1)  |
| Others                                              | 3 (10.3)  |

| Years of experience at KMFC                         | n (%)     |
|-----------------------------------------------------|-----------|
| ≤10                                                 | 14 (56.0) |
| > 10                                                | 15 (51.7) |

| Total years of experience                           | n (%)     |
|-----------------------------------------------------|-----------|
| ≤10                                                  | 26 (66.7) |
| > 10                                                 | 3 (10.3)  |

| Number of research studies per PI                    | n (%)     |
|-----------------------------------------------------|-----------|
| 1 - 5                                               | 14 (48.3) |
| 6 - 10                                              | 7 (24.1)  |
| > 10                                                | 8 (27.6)  |

### Table 3: Association between satisfaction of services provided by CRCs with the respondent characteristics. |

**p- value**

|                                 | p- value |
|---------------------------------|----------|
| Sex                             | 0.460    |
| Age (years)                     | 0.238    |
| Job title                       | 0.152    |
| Years of experience at KMFC     | *0.018   |
| Total years of experience       | *0.003   |
| Number of research studies per PI| 0.970    |

*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.

Acknowledgements

The authors gratefully acknowledge King Fahad Medical City, Riyadh, Saudi Arabia and Research Center for their support and fund. Also, the authors gratefully acknowledge the contribution of Dr. Humariya Heena for scientific editing of the manuscript.

Funding

The work was supported by Intramural Research Fund at KFMC, Riyadh (IRF No: 015-009).

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