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Construction of clinical research nurse training program based on position competence

Sun J *et al.* Construction of clinical nurse training program

Abstract

BACKGROUND

As one of the most important members in clinical trials, the number of clinical research nurses can't keep up with the growth of experimental projects, so it is urgent to build a training program for clinical research nurses and strengthen the construction of nurses.

AIM

To construct clinical research Nurse (CRN) training program based on position competence, accelerate the construction of CRN talent pool and provide scientific guidance significance for CRN training.

METHODS

Based on the position competence model, combined with literature research and qualitative interview results, the first draft of the CRN training program was prepared. 2 rounds of correspondence with 16 experts were conducted using the Delphi method to determine the training program.

RESULTS

The effective recovery rate of the expert correspondence questionnaire was 100% and the authority coefficients of the 2 rounds of experts were 0.826 and 0.895. Finally, 4 first-level indicators and 15 s-level indicators of training objectives were determined. The training

program included 4 first-level indicators, including training requirements, training content, training methods, assessment and evaluation, 15 s-level indicators and 74 third-level indicators.

CONCLUSION

The CRN training program based on position competence is scientific and extendable, providing a basis for participation in CRN training.

Key Words: Research nurses; Position competence; Training program; Delphi method

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Core Tip: With the development of clinical trials, there is a big gap in the number of clinical research nurses. Therefore, the purpose of this study is to build a nurse training program that meets the needs of clinical trials. Based on the results of literature research and interviews, this study compiled a training plan with the post competency model, and finally determined the training plan through two rounds of expert communication review. Multi-dimensional statistical results show that the training program is scientific.

INTRODUCTION

In recent years, clinical trials are in the stage of rapid development and clinical trial projects are increasing year by year. The overall number of clinical trial registrations in China exceeded 3,000 for the first time in 2021, an increase of 29.1% year over year ^[1]. The number of clinical research nurses is far from keeping up with the growth of trial programs. As crucial and indispensable members of clinical trials ^[2], clinical research nurses work throughout the clinical trial process to ensure the quality and efficiency of clinical trial implementation ^[3-4]. However, the training mode for research nursing is still

in the exploration stage with problems like that research nurses doing multiple jobs, inadequate training systems and single training mode^[5]. There is an urgent need to construct a set of training programs for clinical research nurses. Position competence refers to the sum of knowledge, skills, abilities and characteristics that are competent for the job and capable of producing excellent work performance^[6-7]. 《The National Nursing Career Development Plan (2021-2025)》^[8] proposed to strengthen nurse training and establish a nurse training system oriented by job requirements and centered on position competence to strengthen the nurse workforce. Therefore, our study uses CRN position competence as a guide to construct a training program by combining literature search and qualitative interview to provide a reference for training CRN.

MATERIALS AND METHODS

Establish a research group

The research team consisted of six members, including a chief pharmacist, an associate chief nurse practitioner and four charge nurses (all clinical research nurses). The team members were mainly responsible for reviewing and analyzing literature, conducting qualitative interviews, preparing and distributing expert correspondence questionnaires and organizing and analyzing the opinions of experts.

Constructing the first draft of the research nurse training program

1.2.1 Literature research

Databases such as Web of Science, MEDLINE, EMBASE, CINAHL, EBM, PubMed, China Knowledge Network, Wan fang and Wipu.com were searched by computer with a search time frame until June 2022. Chinese search terms are research nurse, position competence, core competency, training model and curriculum system. English search terms are clinical research nurse, post competency, core competency, curriculum system. These were cross-checked by 2 researchers who independently screened the literature and extracted information before.

1.2.2 Qualitative Interviews

An interview outline was developed in conjunction with the literature study and 10 people were interviewed, including clinical research center managers and nursing department managers, research nurses, investigators and clinical research centers. The outline of the interviews with the research nurse and researcher is as follows: ①What does CRN actually do? ②Which aspects of your work do you excel at? Which areas still need improvement? ③What obstacles have you encountered in your work? How did you solve them? ④What core competency do you think CRN should have? ⑤Do you think training for CRN is necessary? What training should be received? Why? The outline of the interview with the managers of the Clinical Research Center and the Nursing Department is as follows: ①All questions in the previous interview outline. ②What do you think are the key points that need quality control in the CRN work content of clinical trials? ③Have you encountered any CRN jobs that you are very satisfied with? If so, could you please recall specific incidents or behaviors? ④What would you recommend for existing CRN training? Interviews were conducted until data saturation was reached and no new information emerged and the data were analyzed using the Colaizzi phenomenological data analysis method [9-10]. The interviewees all agreed that CRN should have a competency system of professional practice, management skills, communication and coordination skills and critical thinking skills, which training objectives should be based on and they proposed the content of training and training methods, *etc.* The assessment and evaluation should be multi-dimensional for a comprehensive assessment of the CRN competency system.

1.2.3 Develop first draft

Analyze the current situation of the CRN position competence system and training at home and abroad through literature research, understand the training needs and suggestions through qualitative interviews and combine with Good clinical practice (GCP) for clinical trial quality management [11]. After the research team deliberated, the preliminary draft of the CRN training program was prepared, including four parts: training objectives, training content, training methods and assessment and evaluation.

1.3 Expert correspondence

1.3.1 Preparation of expert correspondence questionnaire

It consists of 3 parts: ①Research-related information and instructions for filling out the project; ②Expert-related information, including general information questionnaires, expert familiarity questionnaires and judgment basis questionnaires; ③The evaluation of the importance of the indicators of the training program (preliminary draft) is based on the Likert 5-point scale, with "very important" to "unimportant" being assigned a score of 5-1 in that order and experts can make comments in the revision column.

1.3.2 Selection of experts for correspondence

Inclusion Criteria: ①Bachelor's degree or above, intermediate title or above, 10 years or above working experience; ②Participation as a key participant in clinical trials, clinical trials or care management and 10 years or more of teaching experience in their field; ③Active participation in research.

1.3.3 Implementation of expert correspondence

Email and on-site questionnaires were used and experts were asked to respond within 2 wk. After collecting the data, members of the research team analyzed and organized the data, adjusted the items according to the screening criteria (importance value > 3.5 , coefficient of variation < 0.25 , or expert agreement $\geq 75\%$) and expert opinions. Then they formed the next round of expert consultation questionnaires and distributed the questionnaires again until the experts' opinions were in agreement. Two rounds of correspondence were conducted in this study to make the results scientific and convergent.

1.3.4 Statistical methods

Excel 2019 and SPSS 25.0 software were used to analyze the data. The questionnaire return rate indicated the positivity of experts, the authority coefficient indicated the degree of authority of experts, the mean, standard deviation and full score ratio of importance scores of indicators indicated the degree of concentration of experts' opinions and the coefficient of variation and Kendall's coordination coefficient indicated the degree of coordination of experts' opinions.

RESULTS

2.1 General information about the experts

Sixteen experts from seven tertiary hospitals with clinical trial qualifications completed the correspondence, involving clinical trials, clinical research centers and professional fields of nursing management and nursing education. Age ranged from 38 to 55 (43.56 ± 5.34) and working years were 20 to 36 (26.72 ± 7.41). There were 2 bachelor's degrees, 12 master's degrees and 2 doctoral degrees among them.

2.2 Expert activism and authority

The effective recall rate was 100% after 2 rounds of expert correspondence, indicating that experts were highly motivated to participate in this study [12]. The authority coefficients (Cr) for the corresponding experts were 0.854 and 0.887.

2.3 Degree of coordination of expert opinions

The coefficients of variation of the indicators were 0-0.1247 and 0-0.2290 after 2 rounds of correspondence. The Kendall coordination coefficients of the 2 rounds of expert correspondence were 0.212 and 0.332 ($p < 0.001$), as shown in Table 1.

2.4 Results of expert correspondence

The first round of expert consultation added 3 training objectives, 3 sary indicators, 8 tertiary indicators, deleted 2 tertiary indicators and merged 5 tertiary indicators into 2 tertiary indicators. The second round of expert correspondence modified 5 tertiary indicators. According to the opinions and suggestions of experts, 4 primary indicators and 15 sary indicators of training objectives and 4 primary indicators, 15 sary indicators and 74 tertiary indicators of training programs were finally formed, which are shown in Table 2 and Table 3.

DISCUSSION

3.1 The necessity of constructing a training program for research nurses based on position competence

There is a great demand for CRN across many nations due to the sharp rise in clinical trials, institutions implementing clinical trials on file and the development of clinical trial wards in research hospitals [13]. The core competency of CRN, as key participants in clinical trials, is not only related to the quality of clinical trial projects, but can also have a profound impact on the promotion and development of clinical trials. The American Society of Oncology Nursing emphasizes the training of research nurses and builds a 9-part core competency system [14]. The UK now has over 20,000 CRN, with a more established system for the inclusion, training and job functions of research nurses [15]. However, research nurses in many national medical institutions are undertaken part-time by nurses in clinical positions, who lack specialized training and education [16]. There is also a large gap between countries and no unified training system. Position competence [17] serves as a crucial foundation for competence in all clinical trial processes and CRN training, as well as a crucial indicator of CRN's real capacity to take part in clinical trials. Therefore, it is necessary to construct a training program for research nurses based on position competence.

3.2 A research nurse training program based on position competence has good scientific validity and reliability

The 2 rounds of expert consultation in strict accordance with the Delphi method played an important role in the study results [18]. The experts involved in the consultation in this study were involved in several professional fields and experienced in clinical trial project management, including 7 with senior titles and 9 with associate titles, indicating that the experts had good representation and authority. The reliability of the study was reflected according to the positivity and expert authority. The return rate of the consultation questionnaires was all higher than the statistical requirement of 70%, indicating that the experts were highly motivated. Correspondence expert judgment coefficient, expert familiarity coefficient and authority coefficient are all greater than 0.80, indicating a high level of an expert authority. At the end of the second round of consultation, the coefficient of variation of each indicator is less than 0.25, which indicates

that the experts' opinions are more convergent and the importance and operability of the entries at all levels are recognized.

3.3 Characterization of a research nurse training program study based on position competence

Based on extensive literature review and questionnaire survey, this program follows the principles of scientific, systematic and feasible, including all processes required for the successful implementation of the training program in clinical trials. The training program includes training objectives, training contents, training methods and assessment and evaluation four primary indicators, 16 sary indicators and 62 tertiary indicators, which comprehensively enumerates the elements of research nurse training and has good practicality. The content covers core courses such as project plan implementation and follow-up, ethical application, management of each process, document management, subject management, safety management, drug management, *etc.* Flexible and diverse learning and teaching formats are used for different courses. As a key link in the education and training process, assessment and evaluation is an important means of testing the quality of education and training ^[19]. This program determines the specific assessment methods, forms, evaluation criteria and proposes specific passing standards, which have a certain reference value. After the training, follow up the implementation every year to supervise the continuous improvement of competency and complete clinical trial projects with high quality.

CONCLUSION

Based on the theoretical basis of position competence, this study constructed a training program for research nurses through literature study, qualitative interview and the Delphi method, which can provide a reference basis for research nurse training.

However, this study also has certain limitations. The training system constructed in this study has basically covered the knowledge and skills of clinical research nurses, but there is still a lack of detailed training knowledge systems for different departments. Therefore, its training methods need to be further optimized and refined. In addition, this study

aims to scientifically develop training methods for clinical research nurses, but there is a lack of empirical research, so corresponding validation experiments are needed in the future.

ARTICLE HIGHLIGHTS

Research background

Based on the background of the rapid development of existing clinical trials, a scientific nurse training scheme is constructed to train professional clinical research nurses.

Research motivation

Based on the existing talent gap of clinical research nurses, the training scheme of nurses should be scientifically customized to promote the development of clinical trials.

Research objectives

To construct a scientific and systematic training scheme for clinical research nurses to serve the current construction of nurses.

Research methods

Construct a scientific and effective training plan for clinical research nurses by combining literature research and expert targeted interviews.

Research results

Determine four dimensions (training requirements, training content, training methods, assessment and evaluation) as first level indicators, 15 s level indicators, and 74 third level indicators.

Research conclusions

Based on the job competency model, a four dimensional and 15 sary indicator nurse training plan has been constructed, which is scientific and practical.

Research perspectives

Formulate, construct and evaluate all processes of clinical nurse training program to serve the efficient development of clinical trial projects.

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ORIGINALITY REPORT

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SIMILARITY INDEX

PRIMARY SOURCES

1

Yu Liu, Lingli Fu, Xinglin Fu. "Exploration of experimental teaching mode based on immunology combined with the medical laboratory profession", 2021 4th International Conference on Information Systems and Computer Aided Education, 2021

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