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Contents

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Contents

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Contents

ABOUT COVER

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SCIENTOMETRICS

Construction of clinical research nurse training program based on position competence

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Abstract

BACKGROUND

As one of the most important members in clinical trials, the number of clinical research nurses (CRN) can't keep up with the growth of experimental projects, so it is urgent to build clinical research training and strengthen the background knowledge of nurses.

AIM

To construct 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 was prepared of the CRN training program. Two 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 determine 15 s-level indicators of training objectives. The training program included 4 first-level indicators, training requirements, content, 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

Core Tip: With the development of clinical trials, there is a big gap in the number of clinical research nurses. Therefore, this study aims 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.

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INTRODUCTION

In recent years, clinical trials are in the stage of rapid development and the projects are increasing every year. However, the overall number of clinical trial registrations in China exceeded 3000 for the first time in 2021, an increase of 29.1% yearly[1]. The number of clinical research nurses (CRN) is far from keeping up with the growth of trial programs. As crucial and indispensable members of clinical trials[2], CRN work throughout the clinical trial process to ensure the quality and efficiency of implementation[3,4]. However, the training mode for clinical 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 a demanding need to construct a set of training programs for CRN. 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 improve the strengthen of nurse training and establish a training system oriented by job requirements and centered on position competence to strengthen the nurse workforce. Therefore, our study uses clinical research nurse (CRN) position competence as a guide to construct a training program by combining literature search and qualitative interview to provide a reference for CRN.

MATERIALS AND METHODS

Establish a research group

The research team consisted of 6 members, including a chief pharmacist, an associate chief nurse practitioner and four charge nurses (all CRN). The team members were mainly responsible for reviewing and analyzing literature, conducting qualitative interviews, preparing and distributing expert correspondence questionnaires, organizing and analyzing the expert's opinions, and constructing the first draft of the research nurse training program.

Literature research

Databases such as Web of Science, MEDLINE, EMBASE, CINAHL, EBM, PubMed, China Knowledge Network, Wan fang, and Wipu were searched 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, and curriculum system. These were cross-checked by 2 researchers who independently screened the literature and extracted information before.

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: (1) What does CRN actually

do? (2) Which aspects of your work do you excel at? Which areas still need improvement? (3) What obstacles have you encountered in your work? How did you solve them? (4) What core competency do you think CRN should have? (5) Do you think training for CRN is necessary? (6) What training should be received? and (7) Why training should be done? The outline of the interview with the managers of the Clinical Research Center and the Nursing Department is as follows: (1) All questions in the previous interview outline; (2) What do you think are the key points that need quality control in the CRN work content of clinical trials? (3) Have you encountered any CRN jobs that you are very satisfied with? If so, could you please recall specific incidents or behaviors? and (4) What would you recommend for existing CRN? Interviews were conducted until data was reached and no new information emerged and the data were analyzed using the Colaizzi phenomenological data analysis[9,10]. The interviewees all agreed that CRN should have a competency system of professional practice, management skills, communication and coordination skills, critical thinking skills, and 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.

Develop first draft

Analyze the current situation of the CRN position competence system with home and abroad training through literature research, understand the training needs and suggestions through qualitative interviews, and combine with Good clinical practice 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.

Expert correspondence

Preparation of expert correspondence questionnaire: It consists of 3 parts: (1) Research-related information and instructions for filling out the project; (2) Expert-related information, including general information questionnaires, expert familiarity questionnaires, and judgment basis questionnaires; and (3) The importance evaluation of the training program indicators (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.

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

Implementation of expert correspondence: Email and on-site questionnaires were used and experts were asked to respond within 2 wk. After collecting the data, 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 ≥ 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.

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 showed the degree of concentration of experts' opinions and the coefficient of variation and Kendall's coordination coefficient which indicated the degree of coordination of experts' opinions.

RESULTS

General information about the experts

Sixteen experts from seven different 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 experience was 20 to 36 (26.72 ± 7.41). There were 2 bachelor's degrees, 12 master's degrees, and 2 doctoral degrees.

Expert activism and authority

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

Degree of coordination of expert opinions

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

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, and the second round of expert correspondence modified 5 tertiary indicators. According to the opinions and suggestions of experts, finally formed a 4 primary indicators

Table 1 Degree of coordination of expert opinions in two rounds

Items	First round of consultation			Second round of consultation		
	Coordination factors	χ^2	*P* value	Coordination factors	χ^2	*P* value
Primary indicators	0.250	13.230	< 0.001	0.246	12.533	< 0.001
Secondary indicators	0.302	77.263	< 0.001	0.341	96.354	< 0.001
Tertiary indicators	0.284	332.587	< 0.001	0.286	335.624	< 0.001

Table 2 Training objectives for research nurses based on position competence

Items	Importance score (mean ± SD, score)	Variance coefficient	Full score ratio (%)
Knowledge objectives	4.538 ± 0.247	0.0544	90.76
Acquire specialist knowledge related to clinical research	4.535 ± 0.264	0.0582	90.70
Acquire pharmacological knowledge related to drug testing	4.535 ± 0.317	0.0699	90.70
Familiar with the fundamentals of medicine and nursing in clinical research specialties	4.548 ± 0.244	0.0536	90.96
Familiar with laws and regulations related to clinical research	4.875 ± 0.101	0.0207	97.50
Skill objectives	4.868 ± 0.059	0.0121	97.36
Acquire basic nursing skills	4.855 ± 0.082	0.0169	97.10
Acquire practical skills during the project implementation	4.881 ± 0.032	0.0066	97.62
Acquire emergency handling skills for emergencies	4.878 ± 0.043	0.0088	97.56
Competency objectives	4.378 ± 0.049	0.0112	87.56
Ability to manage projects	4.564 ± 0.505	0.1110	91.28
Ability to communicate and coordinate	4.574 ± 0.204	0.0446	91.48
Ability to think critically	4.591 ± 0.224	0.0488	91.82
Ability to research and innovate	4.581 ± 0.210	0.0458	91.62
Ability to provide health education	4.525 ± 0.206	0.0455	90.50
Professionalism objectives	4.640 ± 0.579	0.1247	92.80
Comply with GCP regulations and safeguard the rights of subjects	4.578 ± 0.549	0.1199	92.56
Discretion spirit	4.564 ± 0.405	0.0887	93.28
Teamwork spirit	5.574 ± 0.604	0.1083	92.48

GCP: Good clinical practice.

and 15 sary indicators of training objectives and 4 primary indicators, 15 sary indicators and 74 tertiary indicators of training programs, which are shown in Tables 2 and 3.

DISCUSSION

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 also have a profound impact on the promotion and development of clinical trials. The oncology nursing society (ONS) emphasizes the training of research nurses and builds a 9-part core competency system[14]. The United Kingdom now has over 20000 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 compet-

Table 3 Research nurse training program consulting results based on position competence

Items	Importance score (mean ± SD, score)	Variance coefficient	Full score ratio (%)
I-1 Training requirements	4.649 ± 0.292	0.0628	92.98
II-1 Requirements for training teachers	4.584 ± 0.359	0.0783	91.68
III-1 Theoretical teaching experts: with a bachelor's degree or above, associate senior title or above, presiding over and participating in 20 clinical trials or above	4.686 ± 0.195	0.0416	93.72
III-2 Practice leading teachers: with bachelor degree or above, intermediate title or above, presiding over and participating in 20 clinical trials or above, participating in 10 clinical trials or above	4.445 ± 0.340	0.0765	88.90
III-3 Scientific research ability guidance experts: with a master's degree or above, associate senior title or above, strong scientific research ability, published ≥ 10 relevant articles in core journals as first author or correspondence author, or ≥ 2 SCI articles	4.487 ± 0.305	0.0680	89.74
II-2 CARGO REGISTRATION NOTE access conditions	4.457 ± 0.374	0.0839	89.14
III-4 Bachelor's degree or above in nursing	4.615 ± 0.277	0.0600	92.30
III-5 5 yr or more of clinical nursing experience	4.701 ± 0.237	0.0504	94.02
I-2 Training contents	4.607 ± 0.192	0.0417	92.14
II-3 Research nurses development status and prospects	4.638 ± 0.273	0.0589	92.76
III-6 Research nurse development and credentialing	4.590 ± 0.238	0.0519	91.80
III-7 Research nurse development prospects	4.607 ± 0.136	0.0295	92.14
III-8 Current status and prospects of research nurses at home and abroad	4.732 ± 0.211	0.0445	94.64
III-9 Research on nursing industry trends and career planning	4.682 ± 0.070	0.0150	93.64
II-4 Theoretical knowledge	4.665 ± 0.544	0.1166	93.30
III-10 ICH GCP thirteen basic principles	4.719 ± 0.475	0.1007	94.38
III-11 Interpretation of the new version of drug clinical trial quality management specification in 2020	4.677 ± 0.232	0.0496	93.54
III-12 Basic pharmacological knowledge related to clinical trials	4.534 ± 0.165	0.0364	90.68
III-13 Fundamentals of medicine and nursing for clinical research specialties	4.765 ± 0.116	0.0243	95.30
III-14 Basic process of clinical trials	4.565 ± 0.371	0.0813	91.30
III-15 Clinical study design and methods in Biostatistics	4.625 ± 0.169	0.0365	91.50
III-16 Role responsibilities of the researcher and research team	4.363 ± 0.449	0.1029	87.26
III-17 Role responsibilities of the sponsor/CRO	4.284 ± 0.428	0.0999	85.68
III-18 Key points of ethical review in clinical trials	4.646 ± 0.629	0.1353	78.92
III-19 Interpretation of ethics and laws and regulations related to clinical research	4.713 ± 0.158	0.0335	94.26
III-20 Introduction to the main contents of the trial protocol and investigator's manual	4.767 ± 0.748	0.1569	95.34
III-21 Partner information protection	4.755 ± 0.496	0.1043	95.10
III-22 Subject rights protection	4.625 ± 0.428	0.0925	96.50
III-23 Clinical trial necessary documents interpretation	4.757 ± 0.324	0.0681	95.14
III-24 Key points of informed consent for subjects	4.775 ± 0.340	0.0712	95.50
III-25 Difference and treatment of AE, SAE, SUSAR	4.445 ± 0.526	0.1183	88.90
III-26 Common quality issues in clinical trials	4.672 ± 0.207	0.0443	93.44
III-27 Compliance in clinical research	4.566 ± 0.165	0.0361	91.32
III-28 Audit verification case sharing	4.751 ± 0.341	0.0717	95.02
II-5 Practical skills	4.753 ± 0.216	0.0454	95.06
III-28 Pre-launch preparation	4.513 ± 0.345	0.0764	90.26
III-29 Application and follow-up of various project reviews	4.692 ± 0.199	0.0424	93.84

III-30 Project launch	4.701 ± 0.231	0.0491	94.02
III-31 Subject recruitment	4.636 ± 0.168	0.0362	92.72
III-32 Subjects screening and enrollment	4.642 ± 0.223	0.0362	92.84
III-33 Informed consent of the subject	4.638 ± 0.225	0.0485	92.76
III-34 Subject entry visit	4.607 ± 0.210	0.0455	92.14
III-35 Subject visit management	4.528 ± 0.177	0.0391	90.56
III-36 CRF entry	4.570 ± 0.182	0.0398	91.40
III-37 Project closure management	4.601 ± 0.169	0.0367	92.02
III-38 Nursing skills related to clinical research	4.788 ± 0.191	0.0399	95.76
III-39 Emergency treatment of emergencies	4.757 ± 0.178	0.0374	95.14
II-6 Competency development	4.765 ± 0.157	0.0329	95.30
III-40 Planning and implementation	4.676 ± 0.118	0.0252	93.52
III-41 Equipment management	4.661 ± 0.147	0.0315	93.22
III-42 Subjects management	4.507 ± 0.158	0.0351	90.14
III-43 Trial drug administration	4.528 ± 0.103	0.0227	90.56
III-44 Test equipment and reagent management	4.586 ± 0.202	0.0440	91.72
III-45 Security management	4.563 ± 0.684	0.1499	91.26
III-46 Sample collection and management	4.695 ± 0.572	0.1218	91.90
III-47 Clinical study data management	4.614 ± 0.412	0.0892	91.28
III-48 Contract and funding management	4.131 ± 0.441	0.1068	82.62
III-49 File management	4.351 ± 0.251	0.0577	87.02
III-50 Material management	4.621 ± 0.194	0.0420	92.42
II-7 Professionalism	4.131 ± 0.471	0.1140	82.62
III-51 Clinical research nurse communication methods and techniques	4.341 ± 0.256	0.0590	86.82
III-52 Teamwork for clinical research nurses	4.591 ± 0.155	0.0338	91.82
II-8 Research capacity expansion	4.695 ± 0.482	0.1026	92.90
III-53 Method of selecting topics for scientific research	4.622 ± 0.341	0.0727	88.44
III-54 Knowledge of literature search	4.112 ± 0.251	0.0610	82.24
III-55 Statistical analysis methods	4.242 ± 0.142	0.0335	84.84
III-56 Research paper writing	4.343 ± 0.351	0.0808	86.86
I-3 Training methods	4.156 ± 0.336	0.0808	83.12
II-9 Training location	4.691 ± 0.891	0.2290	77.82
III-57 Clinical research center conference room	4.012 ± 0.721	0.1797	80.24
III-58 Phase I clinical trial ward	4.336 ± 0.432	0.0996	86.72
III-59 Clinical skills training center	4.521 ± 0.234	0.0518	90.42
III-60 Specialty group clinical trials office	4.142 ± 0.312	0.0753	82.84
II-10 Training format	4.356 ± 0.366	0.0840	87.12
III-61 Theoretical lectures (combination of online and offline)	4.369 ± 0.459	0.1051	87.38
III-62 Clinical practice leaders	4.121 ± 0.462	0.1121	82.42
III-63 Scenario-based teaching	4.353 ± 0.228	0.0524	87.06
III-64 Case study	4.367 ± 0.234	0.0536	87.34
III-65 Group study and discussion	4.199 ± 0.785	0.1869	77.98
II-11 Duration of training	4.690 ± 0.679	0.1447	79.80

III-66 Not less than 40 h of theoretical training	4.593 ± 0.221	0.0481	91.86
III-67 Not less than 160 h of Practical skills training	4.644 ± 0.168	0.0362	92.88
II-12 Training cycle	4.352 ± 0.225	0.0517	87.04
III-68 Organize a training once a year	4.675 ± 0.122	0.0261	93.50
I-4 Appraisal and evaluation	4.675 ± 0.245	0.0524	93.50
II-13 Theoretical examination (30%)	4.567 ± 0.332	0.0727	91.34
III-69 Closed-book written examination, ≥ 80 points to pass (percentage system)	4.669 ± 0.156	0.0334	93.38
II-14 Practical examination (50%)	4.564 ± 0.268	0.0587	91.28
III-70 First aid nursing skills assessment, ≥ 80 points to pass (percentage system)	4.559 ± 0.156	0.0342	91.18
III-71 Participate in project reporting in clinical trial projects and assessment of contingency plans	4.342 ± 0.355	0.0818	86.84
III-72 Participate in multicenter clinical research projects with a 90% compliance rate and less than 10% shedding rate	4.352 ± 0.395	0.0908	87.04
II-15 Research capability examination (20%)	4.253 ± 0.423	0.0995	85.06
III-73 Literature reporting in small groups, ≥ 40 points to pass (out of 50 points)	4.012 ± 0.701	0.1747	80.24
III-74 Each person formed a clinical trial-related scientific research paper, ≥ 40 points to pass (out of 50 points)	4.553 ± 0.254	0.0558	91.06

AE: Adverse event; CRF: Case report form; CRO: Contract research organization; GCP: Good clinical practice; ICH: International conference on harmonization; SAE: Serious adverse event; SUSAR: Suspected unexpected serious adverse reaction.

enceserves 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[17]. Therefore, it is necessary to construct a training program for research nurses based on position competence.

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]. In this study, the experts involved in the consultation 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 study reliability 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 consultation round, 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.

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, and 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. 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. However, this study also has certain limitations. The training system constructed in this study has basically covered the knowledge and skills of CRN, but there is still a lack of detailed training knowledge systems for different departments. Therefore, the training methods need to be further optimized and refined. In addition, this study aims to scientifically develop training methods for CRN, but there is a lack of empirical research, so corresponding validation experiments are needed in the future.

CONCLUSION

Based on the theoretical basis of position competence, this study constructed a training program for research nurses

through literature study, qualitative interview, and Delphi method, which can provide a reference basis for research nurse training. The nurses training program should be scientifically customized to improve the clinical trials. This study found a 4 dimensional and 15 sary scientific and practical indicator for nurse training, which is essential to improve nurses' clinical trial.

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 (CRN).

Research motivation

Based on the existing talent gap of CRN, 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 CRN to serve the current construction of nurses.

Research methods

Construct a scientific and effective training plan for CRN 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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FOOTNOTES

Author contributions: Sun J, Shan WC and Liu J contribute equally to this work. Sun J conceived and designed the experiments; Shan WC, Liu JM, Liu J, Xu L, Zhang QQ, Lu XY selected the literature; Zhong K extracted data and analyzed it; Sun J wrote the manuscript.

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