

Analysis of the Development Trend of Clinical Research Nurses in China Based On CiteSpace

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Research Article

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Abstract

Objective

To reveal the development characteristics and trends of clinical research nurses in China and provide a reference for the training and employment of nursing talents.

Methods

Literature about clinical research nurses published from the year of database construction to 2020 were searched through the CNKI, Wanfang, Chinese Biomedical Literature (CBM) and Weipu (VIP) databases, and CiteSpace software was used to conduct a multidimensional analysis of the included literature.

Results

A total of 3,735 pieces of literature were retrieved, and after deduplication and screening, 199 pieces of literature were finally retained for this study. The practice and exploration of CRNs were regionalised, with varying degrees of development, and CRNs were at the forefront of development in oncology specialties.

Conclusion

It is important to continue to expand the breadth and depth of research to promote the continuous development of China's medical and health care to align with international standards.

Introduction

In recent years, as the national pharmaceutical innovation development strategy and reform of the drug review and approval system progresses, China's requirements for the quality of drug clinical trial research implementation are increasing. At the same time, a new type of nursing professional has emerged in the field, namely the clinical research nurse (CRN), also known as the clinical research coordinator, who is authorized by the principal investigator and trained to coordinate the non-medical judgment of the investigator in a clinical study ^[1]. Clinical research nurses are defined by the British Clinical Research Association as nurses who are mainly engaged in clinical research [2]. Nih clearly stated that clinical research nurses should not only provide continuous clinical care to subjects, but also protect subjects' safety and right to information, ensuring comprehensive implementation of protocols, accurate data collection and follow-up [3]. McCabe and other scholars [4] also hold the same view. Korean scholar Jeong et al. believe that clinical research nurses are professional nurses who carry out clinical research according to the instructions of the main researchers. Gibbs et al. [5], a British scholar, proposed that clinical research nurses must be registered nurses with at least 12 months clinical work experience. Chen Sichao et al. [6] believe that clinical research nurses refer to registered nurses who play the role of CRC in

drug clinical trials. To sum up, although different researchers have different definitions of CRN, it is generally believed that the definition of CRN includes three elements: clinical experience, special training and registered nurse.

CRNs play an essential role in clinical research and have attracted widespread attention from relevant organisations. In fact, CRNs first appeared internationally in the United States more than 40 years ago [7] and have developed to occupy an indispensable central and coordinating position in clinical trials, playing a pivotal role in ensuring high quality and subject safety in clinical research [8].

CRNs are an emerging profession in China, and their recruitment and competency are not yet supported by standardised regulations. Although the history of CRN development in China is not long, many questions still need to be answered due to the dramatic increase of drug clinical trial research in China [9]. Is the development of China's CRN workforce commensurate with it? What are the hotspots of CRN-related research in China? What are the current problems of the CRN workforce? What are the trends of future development? Therefore, this paper aims to use CiteSpace bibliometric software to conduct a systematic and comprehensive review of the published literature to answer the above questions, reveal the development trend and provide a reference for professional training and employment on CRNs in China.

1. Data And Methods

1.1 Source

The CNKI, Wanfang, Chinese Biomedical Literature (CBM) and Weipu (VIP) databases were used as literature sources. The search strategy was finalised and constructed after several pre-searches (subject = nurse) AND (title, keyword and abstract = clinical trial OR clinical study OR drug trial OR new drug), the matching method was an exact search and the time range was from the database construction to December 2020. All searches were completed on 30 June 2021. A total of 3,735 documents were retrieved, and after deduplication and screening, 199 documents were finally retained as the research objects of this paper.

Inclusion criteria: the content of the literature was relevant to CRNs, and the type of study was not limited.

Exclusion criteria: newsletters, notices, announcements, call for papers, conference papers; the same study or duplicate publications, literature with incomplete data and unavailable full-text.

1.2 Research methods

In this paper, we used CiteSpace software to conduct bibliometric analysis in terms of literature quantity, annual distribution, literature journals and regional distribution, literature authors, subject funding status, literature type and keywords.

The specific parameters of the CiteSpace software were set as follows: time-slicing was the year of database construction to 2020; years per slice was one; node types were keywords; the threshold was set to Top50; pathfinder was applied to the results to show the important features more intuitively.

2. Results

2.1 Spatio-temporal knowledge mapping of research areas

2.1.1 Time distribution mapping

The number of annual publications is an important indicator of the hotness and development trend of related research. The literature varying with chronology can reflect the overall development of CRNs in China to some extent. The statistical results showed that there were 199 publications about CRNs in China between 1992–2020. The regression analysis with publication time as the independent variable X and annual literature volume as the dependent variable y showed $R^2 = 0.707$, indicating that the model fit the data well. The linear regression equation was $y = 0.7244x - 1446.5$ ($F = 48.369$, $P < 0.01$), and the literature volume showed an overall increasing trend with the year (Figure 1). Further analysis revealed that the earliest literature that met the criteria appeared in 1992 with only one publication. Since then, the volume of literature has gradually increased, showing a growing trend. Among them, the number of publications was higher from 2011 to 2020, with 149 publications accounting for 75% of the total literature. According to Price's 4-stage theory of scientific and technical literature growth, the absolute number of papers about CRN research in China was small, and the growth was unstable, which belongs to the first stage, i.e. the development stage. The current year's papers are in the process of being published (five have already been published), so the literature in 2021 is not included in the yearly analysis.

2.1.2 Spatial distribution map

2.1.2.1 Author distribution

The 199 papers included in this study involved 539 authors, and Table 1 lists the 26 scholars with more than three publications, among which Chunmei Yang had eight publications and ranked first. In terms of cross-institutional research, the authors and institutions in each study area showed a fragmented distribution, no obvious clustering, very few collaborations and the sharing and mobility of knowledge and research results were not strong.

2.1.2.2 Regional distribution

Among the institutions occupying the top 10 positions in terms of number of publications (Table 2), seven were general hospitals and three were specialised oncology hospitals. The 199 included papers were counted according to the region of the first author and were completed by authors from 180

provinces, cities and autonomous regions. According to the number of publications by area, the top 10 regions published 138 papers, accounting for 69.3% of the literature volume (Table 2).

2.1.2.3 Published journals

The 199 papers included in this study were derived from 86 journals and the top 10 in terms of publication volume accumulated a total of 63 publications (38%). Most of the journals with high publication volume were special journals with great influence in the field of nursing and pharmacology, including *Chinese Nursing Research*, *Chinese Journal of Clinical Pharmacology*, *Chinese Journal of New Drugs* and *Chinese Journal of New Drugs and Clinical Remedies*, all of which belong to the core journals of Peking University [10].

2.1.2.4 Funding support

Scientific research funding is an important indicator to evaluate the academic quality and level of journals [11]. The financial support of CRN research in China: among the included literature, there were 42 funded papers, and the ratio of funded papers was 21.1% (funded papers ratio = number of funded papers/total papers x 100%), among which 10 papers were at the national level (5.02%), 23 at the provincial level (11.56%) and seven at the institutional level (3.52%), which showed the lack of financial support for CRN research in China.

2.1.2.5 Type of literature

Types of literature on CRN research in China: see Table 4.

2.2 Hotspots in the research field

2.2.1 Research hotspots based on keyword frequency and mediated centrality display

Authors use keywords to favourably summarise their core arguments, and their distribution frequency and characteristics can reflect the general characteristics of the research field, the interconnection between research hotspots and the development trend. Keyword co-occurrence analysis was performed by CiteSpace software to generate a knowledge graph in this study (Figure 2). The main idea of the intermediate centrality algorithm is to measure the extent to which a node is located in the middle of the shortest path between two other nodes as a 'traffic hub'. In this paper, the top 20 keywords in terms of frequency and intermediary centrality from 1992 to 2020 were counted, and the keywords with the highest frequency were clinical trials, clinical research, CRNs, etc.

2.2.2 Research hotspots based on keyword clustering analysis

Keyword clustering analysis was performed by CiteSpace software to generate a knowledge map (Figure 3). The keyword clustering knowledge map can classify hot keywords according to their scope and facilitate the identification of hot areas of research. The clustering analysis, combined with the keywords

contained in the clustered content, provides further insight into the specific content of a given topic. There are two important indicators in the clustering view, namely the Q value of modularity and silhouette values, where the Q value of modularity is an indicator of network modularity evaluation, and $Q > 0.3$ is generally considered to mean a significant clustering structure. The silhouette value is used to measure network homogeneity, $S > 0.5$ is generally considered reasonable and $S > 0.7$ is considered convincing [12]. A Q value = 0.791 and an S value = 0.949 of the automatic clustering label view generated by the software indicated that the clustering results were highly credible.

The keywords appearing in the literature on CRNs published in China from 1992 to 2020 could be roughly clustered into 10 major categories (Figure 3). These keywords were not completely independent of each other, and there were overlaps and crossovers. Therefore, the analysis results based on the clustering were summarised, and the specific research issues under different keywords were discussed in the following four aspects.

The keywords in the first category were summarised as clinical research, including drug clinical trials, GCP, clinical trials and new drugs, and the literature under this cluster primarily focused on the exploration and analysis of the roles, responsibilities and functions of CRNs in different stages and types of clinical trials. Keywords in the second category were summarised as CRNs, including research nurses and clinical research coordinators. The literature under this cluster was mostly a reflection on the current status of CRN development in China and a discussion of the construction and practice aspects of CRN training models. Keywords in the third category are summarised as influencing factors. The literature under this cluster focused on the factors affecting the trial quality, effectiveness and level of CRNs in clinical trial implementation from different perspectives. Keywords in the fourth category were summarised as management, and the literature under this cluster included studies on CRN management, focusing on training, assessment and promotion of CRNs. There were also analyses of CRNs management of trial quality, ward standardisation, practice and effectiveness in clinical trials. Most of the literature under this cluster has been published in the last five years.

2.3 Trends based on keyword emergence

Identifying and tracking research frontiers can provide researchers with the latest evolutionary developments in disciplinary research, predict trends in research areas and identify issues that need further exploration. In CiteSpace, research frontiers are rising theoretical trends and emergent new topics that should be synthesised and judged based on the analysis of growing literature and terms [13]. The 25 nodal emergent words with highly developing values were obtained by running the CiteSpace software (Figure 4), and the top five keywords in terms of the strength of keyword emergence were new drugs (3.44), clinical research assistants (2.78), nursing staff (2.10), bioequivalence (2.06) and nurses (1.88).

From the time of the emergence of each keyword, the literature published in China about CRNs in the early stage was mostly about practical experience in clinical/new drug research, and the middle stage was mainly for the discussion of CRNs capabilities in various aspects of clinical trials, such as the

management of adverse reactions, drugs and SOPs, which indicates that CRNs were becoming more involved in clinical trials and playing an increasing function and role. The later published literature focused more on drug clinical trials as well as bioequivalence studies and therefore paid more attention to the quality and level of trials, which is related to the fact that the level of clinical trials in China has reached a new high standard. In general, the keywords that emerge to date can be regarded as the current research frontier in this field^[14]. The emergence of 'clinical research nurse', 'bioequivalence' and 'clinical research coordinator' in this study continues today. This indicates that the cutting-edge topics in the CRN field in China are more concerned with the development of CRNs and clinical research coordinators themselves.

3. Discussion

3.1 The development of CRNs in China is in its infancy and is receiving increasing attention

Internationally, CRNs first appeared in the United States in the 1970s, It first appeared in university affiliated hospitals, large public hospitals and large research institutions. It is mainly served by research doctors, pharmacists, testers, nurses and other personnel with biomedical professional background. Nurses are the best choice for this role^[15],and were widely accepted and developed in Europe, the United States and Japan because of their great contribution to the quality and efficiency of clinical trials^[16]. Since the 1990s, there has been a global boom in clinical research, and the development of multinational, multicentre collaborative clinical studies has led to prosperous growth in CRNs. In 2007, the United States began to build a conceptual model of clinical research nursing practice areas, standardised and described the work of CRNs, the education and training concept and management decision-making mechanism of CRNs have been relatively mature^[17]. In addition, the definition, job content, inclusion and training standards of CRNs have been practiced and explored to varying degrees in the United Kingdom, Japan, New Zealand and Italy^[16,18,19].

CRNs in China emerged around the 1990s, with a late start and slow development^[20]. This can also be seen from the content of the published literature between 1992 and 2003, which mainly introduced the basic information and working experience of foreign CRNs in the medical nursing branch. The earliest report of CRN practice in China was published during the clinical trial of a new class I drug invented in China in 1999, which suggests that nurses played an essential role in ensuring the smooth conduct of the trial from the nursing perspective^[21]. In 2005, at the National Oncology Nursing Academic Exchange Meeting of the Chinese Nursing Association, the term CRN was used for the first time, and the role and professional characteristics of CRNs in drug clinical trials were standardised^[22]. Since then, the exploration and practice of CRNs in China have entered a new stage. Since 2005, the number of articles on CRNs has increased significantly, and the issues of concern include the problems of CRNs in clinical trials, the role played at various key points in the trials, the introduction and reflection of domestic and foreign experiences and the in-depth discussion on the cultivation and management of CRNs in China.

The CRNs in China has gradually developed from part-time to full-time staff ^[2] and work in hospitals at all levels with national clinical trial qualifications.

An overview of the development of CRNs in China reveals that the number and quality of studies conducted on them have increased significantly, reflecting that the status and role of CRNs in clinical trials are more recognised, valued and play an important role in guiding the summary of the initial exploration work and the direction of future development. However, it is clear from the characteristics of the authors and institutions that the practice and exploration of CRNs in China are regionalised and unevenly influenced by various factors, such as the level of urban development and health policy orientation, and the overall level of research still needs to be improved, with more exploratory and empirical articles published, and less empirical research in line with China's national conditions. Therefore, in general, the development of CRNs in China is still in its initial stage, but the attention and importance are increasing.

3.2 Clarifying the role and scope of work is a central theme in the development of CRNs

Whether by the statistics of keyword frequency and mediated centrality or by the interpretation of keyword clustering analysis and emergence, 'clinical research', 'research nurse', 'drug clinical trial' and 'management' were all hot words in the literature published in China about CRNs. Through the analysis of these hot terms and combined with the literature where the keywords were found, it was discovered that most of them were discussions on the professional orientation and job responsibilities of CRNs, including both the reference to the advanced experience of foreign developed countries and the practical summary of localisation in China.

In fact, at the early stage of drug clinical trial development in China, CRNs and clinical research coordinators (CRCs) were not distinguished and were defined in general terms as staff members authorised by the principal investigator and trained to coordinate investigators in clinical research for non-medical judgemental matters ^[6,23]. However, this definition does not reflect the importance of CRNs in ensuring the quality of clinical research and the safety of subjects, and therefore the perception of the role of CRNs is ambiguous and not conducive to their development ^[24]. A clear professional orientation is essential for nurses to actively participate in clinical practice, establish positive self-understanding and improve professional identity, further enhancing the quality of care and professional satisfaction ^[3,25-28]. Clarifying the role and scope of work of CRNs is of great significance to the development of this professional field. The role orientation, role functions and practice areas of CRNs were all explored and studied in developed Western countries in the early 1990s ^[29].

With the introduction and implementation of CRC industry guidelines in China, the occupational scope of CRNs and CRCs has been further defined, and the occupational scope of CRNs is more inclined to protect subjects and nursing operations related to clinical trials. Some domestic scholars ^[3,30-33] have already investigated and practiced CRN job categories that meet China's national conditions and hospital development needs and have initially constructed a framework for CRN core job competencies. In

addition, 'Consensus of Experts on Clinical Research Nurse Management in China' released in June 2021 is a detailed description of the definition, job settings and qualifications, duties and tasks, training and assessments, job quantifications and manpower allocation performance assessments and promotion of CRNs. This is a milestone on the road to the standardised development of CRNs in China and lays the foundation for its future standardised management and employment.

3.3 Specialisation is the future direction of CRN development

The keywords related to CRNs in China with high emergence intensity found in this study were 'new drug', 'nursing staff', 'clinical research assistant', 'bioequivalence' and 'clinical research nurse', and 'bioequivalence' and 'clinical research coordinator' continued to emerge so far, which indicates that nurses play an essential role throughout China's drug clinical trials. This puts forward higher requirements for the practice and exploration of the professional development of CRN positions, including position management, performance appraisal, promotion, etc. The exploration in this field will be the future research direction for the development of CRNs in China.

The CRNs nursing practice is focused on maintaining a balance between trial subject care and compliance with the study protocol ^[34]. The CRN also plays the role of educator, advocate, partner, data collector, direct caregiver, liaison, interpreter and observer in clinical trials, which is very challenging and complex, requiring leadership and organisational skills ^[35]. However, these skills are beyond the scope of traditional specialty nursing, and there are no teaching arrangements to match them in our current nursing education system. Throughout the development of research nurses in Europe, the United Kingdom, Japan and other developed countries, they have continuously established and improved their education and training systems ^[36], not only by increasing the number of research practical training courses and providing internship opportunities in universities and colleges to develop practical nursing skills but also by providing online training and continuing education courses in various institutions to improve their critical thinking skills, making them better adapt to their roles and career development. Therefore, there is an urgent need for nursing institutions to construct relevant education and training programs and courses based on the core competencies and developmental needs of CRNs.

The development of the profession cannot be separated from a sound management system of inclusion, training and assessment. A sound management system can include more excellent talents for the CRN team and bring ongoing vitality to the profession. With the flourishing development of clinical trials in China and the emergence of more full-time CRNs as an extension of the field of nursing specialties, questions arise as to how to select, train, employ and evaluate the management of CRNs, and how to adopt a reasonable incentive mechanism to bring the role of CRNs in nursing work and research into play. The field of practice for CRNs is unlike that of clinical wards, and there are differences between various specialties, so the requirements for their core and job competencies are different, which urgently requires health administration departments as well as medical institutions to establish sound job inclusion criteria, evaluation of work, continuing education and performance appraisals. Improving the appraisals plays a crucial role in the career development of this profession ^[37,38].

As an emerging nursing professional role, the development of CRNs also requires the establishment of an academic community to promote the sharing of research results and practical experience among peers at home and abroad so that the training, employment and management of CRNs can gradually embark on a scientific and standardised path and contribute nursing power to the high-level development of clinical research in China.

In summary, the CRN is currently in a period of rapid development, and a single-core research pattern has been formed, which has played a strong leading role in the development of CRNs. In the future, cross-regional authors and inter-institutional cooperation need to be strengthened to narrow the regional development gap and to promote and popularise rigorous and standardised clinical nursing methods nationwide to improve the quality of clinical nursing research results. In recent years, clinical nursing research has focused on clinical trials, and the scope of research needs to be expanded. It can be started from education and management to change the concept of clinical nurses' experience-based care, strengthen continuing education about clinical nursing courses and effectively improve the practical ability of CRNs to provide more scientific and high-quality nursing services to patients.

Declarations

Ethics approval and consent to participate

This study was conducted in accordance with the Declaration of Helsinki, any relevant ethical issues are not involved.

Consent for publication

Not applicable.

Availability of data and materials

All data generated or analyzed during this study are included in this published article

Competing interests

All of the authors had no any personal, financial, commercial, or academic conflicts of interest separately.

Authors' contributions

W.N., L.M. conceived of the study, participated in its design and coordination, draft the manuscript together. All authors read and approved the final manuscript.

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Tables

Table 1
Core authors and number of articles published in China on CRN

Rank	Scholars	Number of articles issued
1	Yang Chunmei	8
2	Minghuang Hong	6
3	Ge Jieying/Li Yanyan/Liu Xiaohong	5
4	Jian Jiang / Xiuli Wang / Dan Li / Cao Ye / Huafang Cen / Yali Zhang / Jieyu Zhang / Yuping Tang	4
5	Wang Xinghe / Wang Xiaoxia / Yang Quan / Deng Rong / Geng Yan / Zhao Tongfang / Wang Zejuan / Zhu Leilei / Zhang Guimin / Zhang Donglin / Lu Jiaxiu / Yuan Wei'an / He Lianzhu	3

Table 2
Top 10 institutions (regional distribution) in terms of the number of publications on CRN

Rank	Province and City	Number of literature (articles)	Percentage (%)
1	Beijing	31	15.6
2	Shanghai	22	11.1
3	Guangdong	20	10.1
4	Jiangsu	15	7.5
5	Hubei	14	7.0
6	Sichuan	8	4.0
6	Zhejiang	8	4.0
8	Shanxi	7	3.5
8	Tianjin	7	3.5
10	Hebei / Jilin	6	3.0

Figures

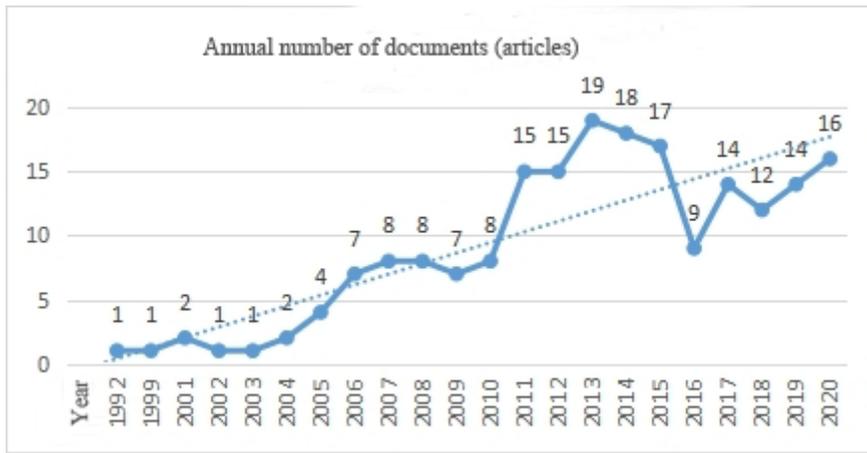


Figure 1

Trend of annual number of documents on CrN in China from 1992 to 2020

CiteSpace, v. 5.8.R2 (64-bit)
 November 17, 2021 2:04:08 PM GMT+08:00
 WOS: C:\Users\admin\Desktop\wos\data
 Timespan: 1992-2021 (Slice Length=1)
 Selection Criteria: g-index (k=25), LRF=3.0, L/N=5, LBY=8, e=2.0
 Network: N=205, E=318 (Density=0.0152)
 Largest CC: 179 (87%)
 Nodes Labeled: 1.0%
 Pruning: Pathfinder
 Modularity Q=0.8253
 Weighted Mean Silhouette S=0.9589
 Harmonic Mean(Q, S)=0.8871

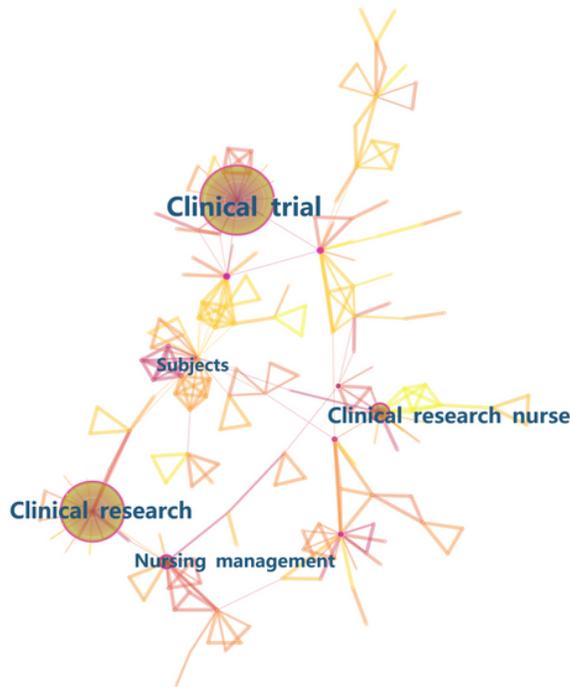


Figure 2

Knowledge map of keyword co-occurrence in CrN research field in China

netSpace, v. 5.0.R2 (64-bit)
November 17, 2021 2:04:08 PM GMT+08:00
filePath: C:\Users\admin\Desktop\pws\data
timeSpan: 1992-2021 (Slice Length=1)
selection Criteria: g-index (k=25), LRF=3.0, L/N=5, LBY=8, e=2.0
network: N=205, E=318 (Density=0.0152)
largest CC: 179 (87%)
nodes Labeled: 1.0%
running: Pathfinder
modularity Q=0.8253
weighted Mean Silhouette S=0.9589
armonic Mean(Q, S)=0.8871

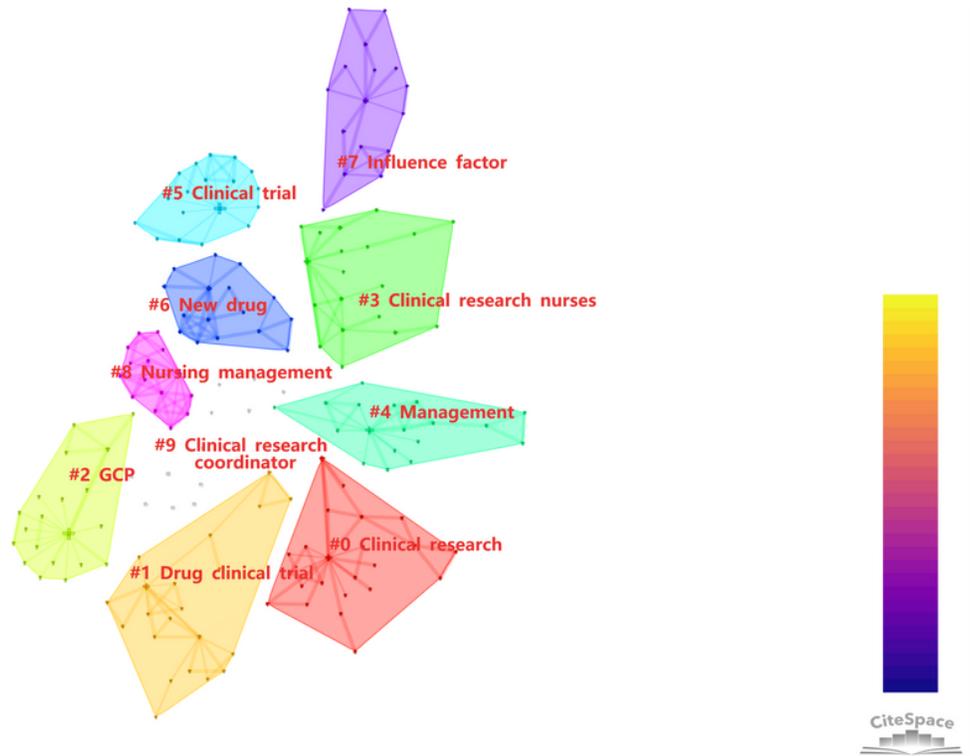


Figure 3

Keyword clustering knowledge map in the literature on CrN published in China

Top 25 Keywords with the Strongest Citation Bursts

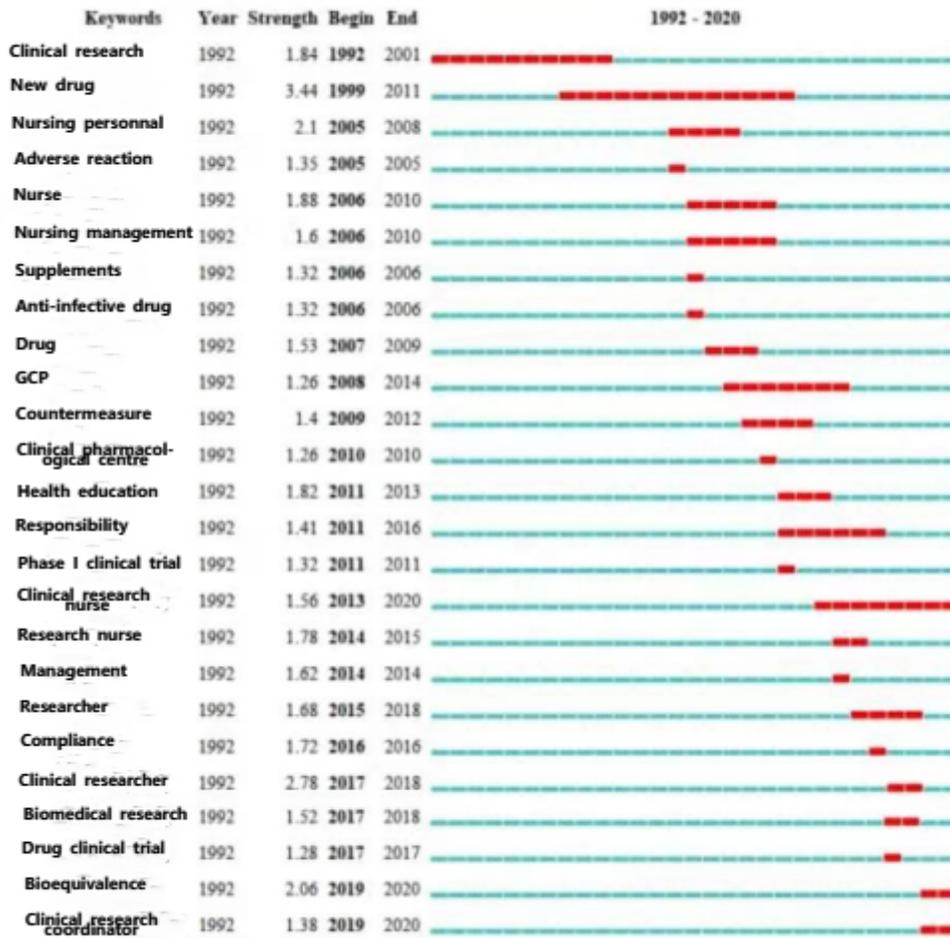


Figure 4

Keyword emergence rate in CrN literature published in China (top 25)