

Characteristics of Nursing Related Clinical Trials Registered on the Chinese Clinical Trial Registry (ChiCTR) from 2009 to 2023

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Abstract: Background: The retrieval and analysis of nursing-related clinical trials registered in the Chinese Clinical Trial Registry (Chi CTR) database are conducive to understanding the registration characteristics and development trends of such trials in China and can offer guidance for nursing researchers to standardize their clinical research. **Objectives:** This research aims to explore the registration characteristics and development trend of nursing-related clinical trials in the Chi CTR. **Methods:** This is a retrospective observational study. The Chi CTR database was searched for nursing-related clinical trials from its establishment until December 31, 2023. The retrieved clinical trials were re-checked and extract relevant data from retrieved clinical trials. Excel software was utilized to analyze the data of the included studies and summarize the characteristics of the clinical trials. **Results:** A total of 1,314 nursing-related trials were included, of which 1,102 trials were registered as prospective registration. The registered trials were distributed across 33 regional areas and 498 clinical registration institutions, The top 1 registered clinical trials regions, organization and sources of funds were Guangdong province(138, 10.50%), School of Nursing, Jilin University(73, 5.56%) and local finance (312, 23.75%) respectively. The main types of studies were intervention studies(1031, 78.46%), and randomized parallel controlled trials were the main study design(773, 58.83%) . A total of 812 studies (61.80%) used the simple randomized method, and 243 studies (18.49%) used the blind method. **Discussion:** The number of nurse-related clinical trial registrations in China present a tendency of increasing overall, but the experimental design, methodology and reporting quality were poor, and the regional distribution of trial registration was unbalanced, Chi CTR should strengthen the control of registration, standardize clinical trial registration, and improve the level and quality of clinical trial registration reports.

Keywords: Nursing; Clinical Trials; Chinese Clinical Trial Registry

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1. Introduction

In the context of the robust development of nursing education, the continuous expansion of the nursing workforce, and the ongoing improvement of nursing capabilities, the nursing profession has achieved remarkable accomplishments on a global scale^[1]. Nevertheless, nursing is a discipline that requires the support of scientific research, with the progress of evidence-based nursing, there has been an increasing emphasis on the transparency and standardization of clinical research^[2].

Notably, the registration of clinical trials constitutes a crucial step in promoting the standardization and transparency of research efforts. Clinical trial registration refers to the process in which investigators complete of registration and disclosure of information about their upcoming clinical trials within a specified clinical trial registry^[3]. The primary aim of such registration is to ensure the transparency of clinical trial and maintain the validity and integrity of the resulting data.

The International Committee of Medical Journal Editors (ICMJE) requires that all clinical trials be registered internationally prior to publication. The Chinese Clinical Trial Register (Chi CTR) is designated by the National Health Commission of China and has been approved by the World Health Organization International Clinical Trial Registry Platform (WHO ICTRP). As a certified clinical trial registry, the Chi CTR contains comprehensive registration entries. This characteristic is beneficial for ensuring the transparency of registered trials, promoting the improvement of the quality of clinical research, and facilitating the effective dissemination of research results^[4]. The retrieval and analysis of nursing-related clinical trials registered in the Chi CTR database are conducive to understanding the registration characteristics and development trends of such trials in China and can offer guidance for nursing researchers to standardize their clinical research^[5].

Clinical trial transparency is one of the core strategies of the international medical community to ensure the quality of clinical trials^[6]. The Declaration of Helsinki indicates that “Every clinical trial must be registered in a publicly accessible database before recruitment of the first subject, and researchers have a duty to make publicly available the results of their research on human subjects”^[7]. Researchers register in the clinical trial registry before the start of the trial, and disclose the relevant information of their upcoming clinical trials, which is conducive to ensuring the transparency of clinical trial information and the authenticity and integrity of the results^[8]. At present, ICMJE, FDA US, World Medical Association (WMA) and International Society of Physical Therapy Journal Editors (ISPJE) have mandatory prospective clinical trial registration^[9]. many countries have following unified standards developed a country-based registration platforms to ensuring all registered trials receive a unique identification number for global searching^[10]. Chi CTR is a nonprofit organization which is hosted by the Chinese Evidence-Based Medicine Centre, West China Hospital, Sichuan University, It was established in 2005 according to both the Standard of the World Health Organization International Clinical Trial Registration Platform and Ottawa Group^[11]. Based on the registration guideline, all of study design such as randomized controlled trial or case-control study, or cohort study, or non controlled study or other any observational studies of prevention and treatment studies, prognosis studies, cause studies and diagnostic tests should be registered^[12]. Chi CTR accepts registration of clinical trials conducted in China and around the world, and makes the general characteristic of clinical trials transparent to the public, which is great significance to promote the quality of healthcare studies in China^[13].

Many researchers have analyzed the current status of disease or medicine registered in the Chi CTR. Fan^[14] based on the all clinical trial records registered on the Chi CTR from 2007 to 2020 executed in China, analyzed the geographical distribution, year of implementation, disease type, resource and funding type, trial duration, trial phase, and the type of experimental approach. Xu^[15] made a comprehensive analysis of the characteristics of COVID-19 clinical trials registered in the Chi CTR. Zhou et al^[16-18] reported the application and characteristics of patient-reported outcomes measurements as outcomes in clinical trials in China. But few studies have examined the registration status of nursing-related clinical trials.

Nursing research has developed rapidly across the globe over the years, but there is a lack of comprehensive understanding regarding its overall progress. the profile of nursing related clinical trials registered in Chi CTR might reflect the current situation of clinical studies in China, which has not been reported until now. In this study, the records of all the registered trials from 2009 to 2023 were retrieved from Chi CTR. By leveraging the retrieved data, we aimed to identify and analyze the key trial characteristics of the currently registered clinical trials related to nursing, including critical design elements, sponsorship and regional distribution, our data analysis provides insights into the state of nursing related clinical trials from Chi CTR for nurses, the geographical distribution of trial registration, the registered duration of trials, the research phase, the type of experimental approach, and the funding types reported in a 14-year duration (2009–2023).

2. Method

2.1 Study Design

In this retrospective observational study, a multi-dimensional grouping analysis was conducted to estimate trends in the

annual trial registration, geographical distribution, sources of funding, targeted diseases, and trial subtypes.

2.2 Source of the Database

All nursing related clinical trials were collected from the database of the Chi CTR (URL: <http://www.chictr.org.cn/index.aspx>). A downloadable CSV-type file from the Chi CTR is available, which includes medical research conducted in China and is updated on a daily basis. The data collection process was carried out as follows. First, The key words (“nursing” and “nurse”) were used to identify search in “Public title”, “Scientific title”, “Primary sponsor”, “Secondary sponsor” and “interventions”, Second, all registration information of the studies that met the requirements from construction to December 31, 2023 was downloaded manually from the Chi CTR. Third, Each record of nursing related clinical trials such as the registration number, date of registration, registration status, public title, scientific title, approved by ethic committee, primary sponsor, secondary sponsor, source(s) of funding, target disease, study type, study phase, objectives of study, study design, interventions, countries of recruitment and research settings, multi-centre study, participant number, collecting samples from participants, randomization procedure, blinding, key inclusion criteria and key exclusion criteria were transferred into an Excel software document by two reviewers. Trials with 2 registration identification numbers were considered duplicate and were counted only once (in the Chinese Clinical Trial Registry) to avoid deviations caused by repeated statistics.

2.3 Data Extraction

Two investigators used predesigned data extraction tables extracted the data of nursing-related clinical trials and entered them into Microsoft Excel 2010 software independently, Each record of nursing-related clinical trials contains several mandatory elements, including general characteristics (ethics approval, clinical trial phase, facilities, enrolment, lead sponsor, overall status), and the design data (the primary purpose, type of intervention allocation, blinding, type of participants, primary outcomes), Any discrepancies were resolved by consensus among a panel of investigators within the review team. The authors intended to invite a third data reviewer to scrutinize the data if consensus could not be reached during data extraction.

2.4 Data Synthesis and Analysis

Two investigators used predesigned data extraction tables extracted the data of nursing-related clinical trials and entered them into Microsoft Excel 2010 software independently, Each record of nursing-related clinical trials contains several mandatory elements, including general characteristics (ethics approval, clinical trial phase, facilities, enrolment, lead sponsor, overall status), and the design data (the primary purpose, type of intervention allocation, blinding, type of participants, primary outcomes), Any discrepancies were resolved by consensus among a panel of investigators within the review team. The authors intended to invite a third data reviewer to scrutinize the data if consensus could not be reached during data extraction.

3. Results

3.1 Search Process and Results

Using “nursing” as the search term in “Public title”, “Scientific title”, “Primary sponsor”, “Secondary sponsor” and “interventions”, Chinese search obtains 419, 421, 424, 325 and 952 studies respectively. Using “nurse” as the search term, 114, 115, 0, 1 and 106 studies were obtained in “Public title”, “Scientific title”, “Primary sponsor”, “Secondary sponsor” and “interventions”, respectively. A total of 2,877 studies were initially retrieved, of which 1,514 were excluded because of duplicate records. After reading the registration details (Research Objectives, inclusion criteria, exclusion criteria and interventions), we excluded 49 trials, because the respondents of these trials were nurse or nursing students or infants and young children, However, we would include them if the intervention object both infants and their parents. Finally, a total of 1314 eligible trials were identified for analysis.

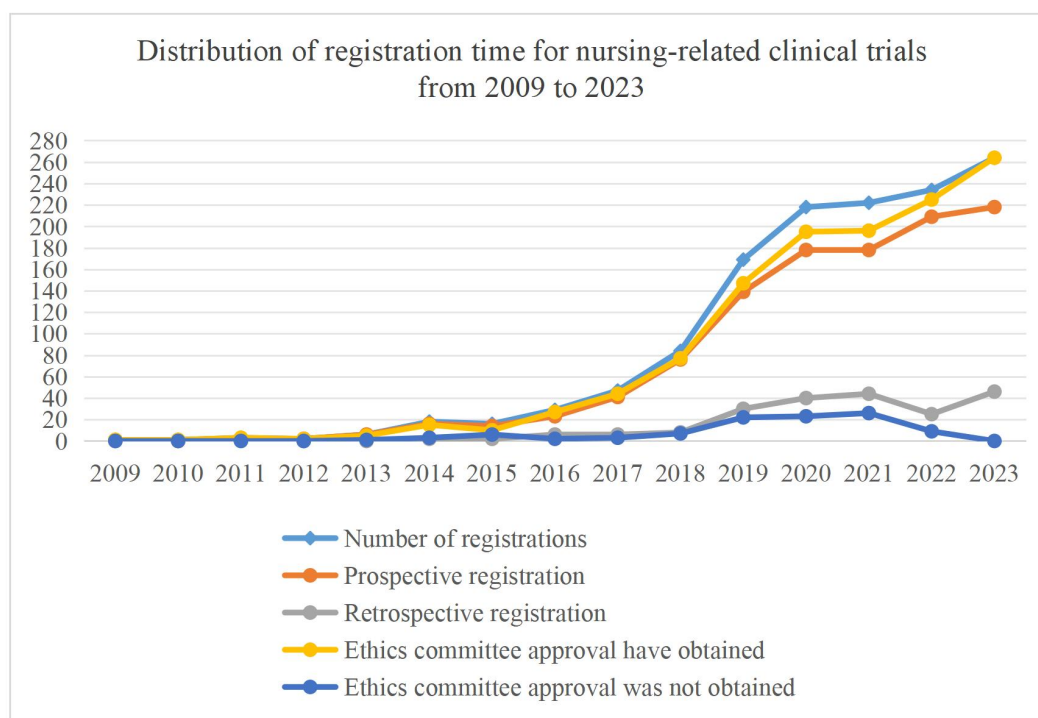
3.2 Number of Nursing Related Clinical Trials Registered in Chi CTR over the Years

Since Chi CTR was established in 2005, the first nursing clinical trial registration appeared in 2009. As of December 31, 2023, a total of 1314 trials were included, the number of Prospective registration of nursing related clinical trials in Chi CTR was 1102, and the number of Retrospective registration was 212. most trials (1,212, 92.24%) provided their ethic approvals to the registration system, while 102 trials (7.76%) did not obtain ethics approvals. Table 1 summarizes the general characteristics of nursing related clinical trials from Chi CTR and Figure 1 shows the time trend.

Table1 Distribution of registration time for nursing-related clinical trials from 2009 to 2023

Year	Number of registrations	Prospective registration	Retrospective registration	Ethics committee approval have obtained	Ethics committee approval was not obtained
2009	1	1	0	1	0
2010	1	0	1	1	0
2011	3	1	2	3	0
2012	2	2	0	2	0
2013	6	6	0	5	1
2014	18	16	2	15	3
2015	16	14	2	10	6
2016	29	23	6	27	2
2017	47	41	6	44	3
2018	84	76	8	77	7
2019	169	139	30	147	22
2020	218	178	40	195	23
2021	222	178	44	196	26
2022	234	209	25	225	9
2023	264	218	46	264	0

Figure 1. The number of registered nursing related clinical trials, ranging from September 2009 to July 31, 2023 in China. The X-axis is the trend of the registration date. The Y-axis is the number of nursing related clinical trials.



3.3 The Primary Sponsor, Registration Regions and Funding Sources of Nursing Related Clinical Trials in Chi CTR

Among the 1,314 nursing-related clinical trials registered in Chi CTR, 7 were located in Hong Kong Special Administrative

Region of China, 1 was from New Zealand and the remaining 1,306 studies are located in 33 provinces, municipalities or autonomous regions of China except for Macau Special Administrative Region and Taiwan Province. The top three registration regions of nursing related clinical trials were Guangdong (138, 10.50%), Shanghai (130, 9.89%) and Sichuan province (128, 9.74%), accounting for 30.13% of clinical trial registration. Among the 498 Primary sponsors, the Nursing School of Jilin University had the largest number of registrations, accounting for 5.56% of the total number of registered trials. Table 2 shows the distribution results of the top 10 nurse-related clinical trial primary sponsor. Among the 1,314 studies were included, 922 of which were funded, accounting for 70.17% of the total number of registered clinical trials. The most common sponsor of nursing related clinical trials were local finance (207, 15.75%), and followed by hospitals (153, 11.64%) and national finance (132, 10.05%), Table 3 shows the funding sources of nursing-related clinical trials.

Table 2 Distribution of nursing-related clinical trials primary sponsor (Top 10)

Primary sponsor	No (%) (n = 1314)
School of Nursing in Jilin University	73 (5.56)
West China Hospital, Sichuan University	61 (4.64)
Xiangya School of Nursing, Central South University	50 (3.81)
School of Nursing, Sun Yat-sen University	28 (2.13)
School of Nursing, Fujian Medical University	26 (1.98)
School of Nursing and Rehabilitation, Shandong University	25 (1.90)
School of Nursing Fudan University	24 (1.83)
School of Nursing, Peking University	23 (1.75)
College of nursing and health, Zhengzhou University	15 (1.14)
The First Affiliated Hospital College of Medicine Zhejiang University	14 (1.07)

Table 3 Funding sources of nursing-related clinical trials

Source(s) of funding	No (%) (n = 1314)
Self-funded/None	392 (29.83)
Local finance	312 (23.75)
Universities	207 (15.75)
Hospitals	153 (11.64)
National finance	132 (10.05)
Not stated	64 (4.87)
Social welfare fund	36 (2.74)
Business support	18 (1.37)

3.4 Design Characteristics of Nursing-Related Clinical Trials in Chi CTR

In the 1,314 trials, the most common research type was interventional study (1031, 78.46%). There were 20 types of research designs, of which 773 were randomized parallel controlled trials, accounting for 58.83%. Among those using randomization, the majority was computer-generated random number list design (812, 61.80%), followed by block randomization (53, 4.03%), and a total of 391 (29.76%) were not randomized or not stated. Among those using blinding, the majority used open-label design (216, 16.44%), followed by single-blinded (201, 15.30%), and double-blinded (42, 3.20%) studies, Table 4 shows the design characteristics of nursing-related clinical trials. Within all registered 1,314 trials, a more significant percentage of trials focused explicitly on cardiovascular disease (83, 6.32%). The top 3 diseases of 1,314 trials were the cardiovascular disease (83, 6.32%), stroke (75, 5.71%), and diabetes (66, 5.02%)(Supplementary Digital Content).

Table 4 Design characteristics of of nursing-related clinical trials

Research type	No (%) (n = 1314)
Interventional study	1032 (78.54)
Observational study	221 (16.82)
Cause/Relative factors study	21 (1.60)
Health services reaserch	17 (1.29)
Diagnostic test	9 (0.68)
Epidemilological research	6 (0.46)
Prevention	3 (0.23)
Basic Science	2 (0.15)
Screening	2(0.15)
Prognosis study	1(0.08)
Research design	
Randomized parallel control	773 (58.83)
Non randomized control	152 (11.57)
Sequential	94 (7.15)
Cross-sectional	87 (6.62)
Cluster randomly sampling	42 (3.20)
Single arm	39 (2.97)
Cohort study	30 (2.28)
Quasi-randomized controlled	27 (2.05)
Factorial	20(1.52)
Case-Control study	17(1.29)
Randomly Sampling	13(0.99)
Historical control	8(0.61)
Cross-over	5(0.38)
N of 1 Trial	4(0.30)
Case study	2(0.15)
Nested case-control study	1(0.08)
Randomization Procedure	
computer generated random number list	812(61.80)
Non-randomized	366(27.85)
Block randomization	53(4.03)
Cluster sampling	36(2.74)
Not stated	25(1.90)
Stratified block randomization	10(0.76)
Stratified randomization	10(0.76)
Dynamic randomization	1(0.08)
stepped-wedge cluster randomized	1(0.08)
Blinding	

Research type	No (%) (n = 1314)
Not stated	855(65.07)
Open	216(16.44)
Single-blind	201(15.30)
Double-blind	42(3.20)
Multicentre study	
Yes	192(14.61)
No	1122(85.39)

4. Discussion

As more and more institutions require registration, and as more and more researchers become aware of the value of registration, the number of CTRs is steadily increasing^[19]. Nursing has been shown to be a highly specialized subject, and a multitude of highly educated and qualified individuals are now engaged in nursing research activities, the number of findings in nursing research has increased year by year^[20]. In this study, we retrieved all registered trials of nursing-related clinical trials from the ChiCTR database during 2009-2023 and assessed the registration characteristics, development trend. Our results indicate that the number of nursing-related clinical trials trial registrations has continuously increased since 2009, especially from 2018, the registered trials has increased rapidly. However, there is still a large gap between the numbers of registered clinical trials and published studies. Giménez-Espert^[21] performed a bibliometric analysis of the six most important nursing journals according to the impact factor of the Science Citation Index through Web of Science, showing that 3,937 articles were written by 1,1371 authors from 2,980 institutions and 84 countries from 2012 - 2017. Wang^[22] conducted bibliometric analyses of global nursing-related research activity from 2009 to 2020, finding 109,782 papers, and Publication numbers were increasing. In this study, only 594 studies were registered in CTRs from 2009 to 2020, indicating that the registration rate of nursing clinical research is still low, and the registration awareness needs to be further improved. Ndwandwe^[23] report that the number of trials registered has increased continuously, more than half of the trials in the registry were prospectively registered. Ethical approval was received by 90% of the registered trials. Among the registered trials, 102 (7.76%) have not obtained the ethics committee approval, and 212 (16.13%) were retrospective registration, which also reflected that the knowledge of standardized scientific research procedures (such as ethical approval and clinical registration) still needs to be further promoted.

A global analysis overview for nursing research shows that the global paper output varies in different countries/regions with the USA being far ahead of the others. The paper output and cross-border collaboration are mainly distributed in several developed countries such as the USA, the UK, Australia, and Canada. The University of Pennsylvania, Harvard University, University of Toronto, and University of North Carolina at Chapel Hill have high academic influence in the field of nursing^[24]. the registration regions of nursing-related clinical trials involved 33 provinces/municipalities/autonomous regions, which involved a wide range of regions but the distribution was uneven, mainly concentrated in economically developed areas. Most of registration institutions were colleges and universities, and the registration institutions were relatively consistent with the regional distribution, indicating that nursing staff in colleges and universities have a high awareness of clinical trial registration and attach great importance to the standardization of clinical research methods. The possible reason is that high-level nursing personnel are more inclined to enter colleges and universities to engage in education and research after graduation^[25]. Colleges and universities can provide more theoretical and technical support for clinical research. In nursing research, financial support plays a key supporting role^[26]. In this study, a total of 858 studies (65.30%) were funded by the country and government, indicating that the country and government gave a high level of attention and support to nursing related clinical trials.

Among the nursing-related clinical trials registered in the Chi CTR, 1031 (78.46%) were Interventional studies, Randomized parallel control was the main research method. The possible reason is that nursing researchers have realized the importance

of clinical research randomization and they researchers pay more attention to the acquisition of reliable clinical evidence-based medicine evidence and actively carry out randomized controlled trials. The implementation of blinding is an important way to reduce the interference of subjective factors to the trial and ensure the preciseness of the trial conclusions. In this study, Only 243 (18.49%) of the included clinical trials used blinding, 65.07% of the studies did not mention whether blinding was used, suggesting that researchers did not pay enough attention to blinding, which may be related to the non-standard and imperfect data filling in during registration. With the increasing number of randomized controlled studies in the field of nursing, some researchers have found that the reporting and methodological quality of studies was deficient^[27-28], The quality of the results was relatively low^[29]. In future, researchers of nursing randomized controlled trials should attach more importance to experimental design and methodological quality, receive relevant training, and improve reporting quality using the Consolidated Standards of Reporting Trials (CONSORT) statement, so as to improve the quality of nursing clinical research and ensure truth and reliability of conclusions^[30]. Among the 1314 clinical trials included, 1122 were single-center trials, accounting for 85.39%, which may be related to the higher close collaboration ability of multi-center clinical trials, higher technical requirements of fund and the lack of popularization of center review system^[31].

5. Limitations

Although the World Health Organization has mandated the registration for all clinical trials, we are concerned that there were omissions in some cases. In addition, the data of this study was just from the Chi CTR, Some nursing-related clinical trials might have been registered on other clinical trial registration platforms, Therefore, it cannot truly reflect the real data and level of nursing-related clinical trials in China. In the future, researchers can analyze the primary registration institutions of each clinical trial registration platform, explore the current status and development trend of nursing-related clinical trials, to provide reference for nursing-related clinical trials.

Conclusion

This cross-sectional descriptive study found that the number of nurse-related clinical trial registrations in China present a tendency of increasing overall, and the researchers' awareness of clinical registration has been significantly improved. However, the experimental design, methodology and reporting quality were poor, and the regional distribution of trial registration was unbalanced. Therefore, universities and hospitals can set up scientific research courses for different levels of nursing staff to improve the scientific research abilities of nursing staff. At the same time, Chi CTR should strengthen the control of registration, standardize clinical trial registration, and improve the level and quality of clinical trial registration reports.

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No

Conflict of Interests

The authors declare that there is no conflict of interest regarding the publication of this paper.

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