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Current status and influencing factors of nurses' knowledge and attitudes towards clinical research ethical in China: a provincewide cross-sectional survey

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Abstract

Background Nurses' competence in clinical research is a key element in promoting high quality in the discipline of nursing, and the ethical aspects of research are of paramount importance. Therefore, nurses need to have a comprehensive understanding of the ethics associated with clinical research, which is an integral part of safeguarding the safety of subjects, ensuring the quality of nursing clinical research, and improving the ethical standardization of clinical research.

Methods A cross-sectional survey was conducted on 304 nurses in a province of China between April 2023 and September 2023, utilizing convenience sampling. The survey questionnaire comprised two sections: a general information form and a questionnaire focusing on nurses' knowledge and attitudes towards clinical research ethics. Data analysis encompassed descriptive statistics, t-tests, one-way ANOVA, and multiple linear regression.

Results A total of 320 questionnaires were distributed, of which 304 were valid. The ethical attitude of nurses in clinical research was better (91.17±15.96), while the cognitive score was lower (63.08±12.30). The results of multiple linear regression analysis showed that degree, grade of hospital (I, II or III), technical title, number of clinical projects chaired in one year and whether the respondent has ever participated in an ethics training were the five factors influencing the knowledge of clinical research ethics (F=9.341, P < 0.001, R2=18.0%); degree, grade of hospital (I, II or III), technical title, number of clinical research ethics chaired in one year, whether the hospital has an ethics committee and whether the respondent has ever participated in an ethics training were the six factors affecting ethical attitudes towards clinical research (F=8.919, P < 0.001, R2=17.3%).

Conclusions Nurses in a Chinese province scored low on the cognitive dimension of clinical research ethics, but their attitudes were at a relative high level, with many influencing factors. Degree, technical title, and grade of hospital, all affect cognitive and attitude scores. It is also worth noting that whether the hospital has an ethics committee affects the attitude scores, but has no effect on the cognitive scores. Nursing administrators and educators should consider

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providing effective and targeted strategies (e.g., ongoing training, scholarly seminars, and scholarly exchanges) to enhance nurses' knowledge and competence in clinical research ethics to protect subject rights as well as to ensure the quality of clinical research.

Keywords Nurses, Clinical research, Ethics, Ethical review, Cross-sectional survey

Background

Clinical research refers to scientific research in the field of medicine to study the physiology, pathology, pharmacology and other aspects of humans, patients or volunteers through observation and experiments. Its purpose is to improve medical practice, optimize treatment options, improve the quality of care, and promote the development of medical science [1]. Clinical research plays a vital role in disease prevention and treatment and in maintaining the health of the population. Nurses can better carry out clinical research, which is the basis for promoting the development of nursing disciplines and an important means of improving the quality of clinical care [2, 3]. Nursing personnel can disseminate new methods, theories, concepts, and new standards of nursing practice through research. With the rapid development of clinical research in recent years, clinical research is now gradually exploring towards the experimental stage. At this stage, the main research object is the patient, and taking the patient as the research object involves many complex ethical issues, such as how to respect the patient's rights and protect the patient's interests in clinical research [3]. Therefore, the benchmark issue of ethics will be an important issue facing the clinical research process in the future.

Medical and nursing journals are probably the most important way for nursing staff to disseminate their new ideas, methods, etc. These journals can play an important role in promoting compliance with ethical principles in clinical research among caregivers [4, 5]. A growing number of medical and nursing journals require physicians or nurses to publish studies that have addressed ethical issues and have been approved by Institutional Review Boards (IRBs) [6, 7]. However, not every journal emphasizes the requirement to address ethical issues. An online review of 767 articles from leading European otolaryngology journals by an academic [8] found that 49.9% of the articles lacked an ethics committee approval statement and 42.9% lacked informed consent disclosure. Another researcher [9] conducted an ethical review of 32 stepped wedge clustered randomized trials and found that only 24 trials (75%) passed the research ethics committee review and only 16 (50%) reported informed consent of the study participants, with only one-third of the studies overall complying with the requirements. A number of studies by Chinese scholars have shown [10, 11] that nursing staff research capacity is poor in mainland China and publish articles of lower quality, which is reflected in their impact factors and citation reports, and that one possible reason for the lower quality of articles is the lack of ethical concerns of nursing staff during the research process. These nursing research findings from the East and West suggest that clinical research ethics should receive widespread attention and focus from nursing workers. Although countries have actively explored ethical issues in clinical research and have published guidelines and management norms related to clinical research ethics [12], ethical awareness during the implementation of the study has not really penetrated into the research work of nursing workers, and therefore may still not be able to adequately protect the subjects.

Nurses, as the main body of conducting nursing clinical research, are the actual operators of the research and the close contacts of the subjects [13], and their comprehensive ethical level of ethical knowledge, ethical attitudes and ethical implementation have a direct impact on the quality of clinical research and the safety of the subjects. The theory of knowledge, attitude and practice believes that individuals can eventually develop healthy behaviors by acquiring health knowledge and building positive attitudes [14]. Therefore, attention must be paid to cultivating and improving cognitive awareness and attitudes. At present, developed countries such as the United States, the United Kingdom and France have constructed a systematic and comprehensive medical ethics education and training model, and the form of education is appropriate, but the medical workers' medical ethics knowledge and practice still need to be improved. Surveys show that medical interns, medical officers, residents and consultants in Nigeria generally have inadequate knowledge of medical ethics; truthfully obtaining informed consent has become a major medical ethical challenge for medical workers in Europe [15, 16]. However, at this stage, there are fewer investigations related to ethical perceptions of nursing workers during clinical research. In China, research on research ethics is underdeveloped, and the cities with more ethical studies are mainly Beijing, Shanghai, Zhejiang and Jiangsu. The studies mainly focused on clinical researchers and medical staff in a certain province or hospital with regard to the ethical review of clinical research, ethical knowledge and training needs [17, 18]. The investigation of nursing staff's ethical knowledge and attitude towards clinical research is still insufficiently concerned. As an important member of the nursing staff to promote the high quality development of hospital research, only by mastering the knowledge

related to clinical research ethics and correctly understanding the connotation, can they better practice ethical behavior. Therefore, this study aims to understand the level of nurses' clinical research ethics knowledge and attitudes through a cross-sectional survey, analyze the factors affecting nurses' clinical research knowledge and attitudes, and provide precise suggestions for nurses to carry out targeted training related to clinical research ethics.

Methods

Design

The study used a cross-sectional design and convenience sampling approach.

Participant selection and setting

From April 2023 to September 2023, we conducted a cross-sectional survey involving 304 participants recruited from registered nurses in Hunan Province, China. The inclusion criteria consisted of the following: (1) being a registered nurse and (2) proficiency in the Chinese language. Exclusion criteria included: (1) nurses undergoing training, internships, or further education, and (2) nurses on maternity leave, sick leave, or engaged in further training during the survey period. Hunan Province comprises 14 prefecture-level cities. The research sample was selected through convenience sampling from 20 hospitals across 8 cities in Hunan Province, namely Changsha, Zhuzhou, Chenzhou, Changde, Zhangjiajie, Hengyang, and Shaoyang. The sample size was calculated using G-Power with a confidence interval of 95% and an alpha of 0.05. The estimated target sample size was 138.

Data collection

Convenience sampling method was used to recruit the sample for this study. The formal questionnaire was edited to form an electronic questionnaire, a link was generated and posted on social media, and the team members or the head of the hospital Ethics committee office sent invitation messages to different hospitals in various cities in Hunan Province. Nurses in these hospitals can scan the QR code on social media to fill in the questionnaire, and sign the informed consent before filling in the questionnaire. Whether to fill in the questionnaire is completely voluntary. The survey link was available for one week (15 September 2023 to 21 September 2023). In total, 320 nurses completed the survey. Based on the total number of survey items, we estimated that it would take approximately 10 min to complete all items. To ensure the quality of the data, we decided to exclude questionnaires with very short (3 min) or long (20 min) completion duration, leaving 304 valid questionnaires. All questionnaires were completed through an online survey and an electronic data collection tool, Questionnaire Star (www.wjx.cn).

Measures

Demographic questionnaire

We used a self-designed questionnaire to collect nurses' individual and unit characteristics. Nurses' individual characteristics including gender, age, degree,, technical title, working years, number of clinical research projects participated in one year, number of clinical research projects chaired in one year, whether you have attended any training on ethics knowledge. Unit characteristics including grade of hospital(China's hospital level refers to the hospital level according to the "hospital grading management standards". It is divided into one, two and three levels; each level is further divided into A, B and C, of which three levels of hospitals are added to the special level, with a total of three levels and ten levels. Hospital grade is based on hospital functions, facilities, technical strength and other indicators of hospital qualification assessment) and whether the hospital has an ethics committee.

Clinical research ethics knowledge, attitude questionnaire

According to the references [18–20] and combining the opinions of clinical professionals and researchers, the questionnaire on ethical knowledge and attitude of clinical research was prepared by ourselves after group discussion. The questionnaire was also administered to 30 nurses in Hunan to test the reliability and validity of the questionnaire, which was finally formed into a questionnaire containing a total of 19 items in 2 dimensions: knowledge (13 items) and attitude (6 entries). The Cronbach's alpha coefficient for the total dimension of the questionnaire was 0.835, and the Cronbach's alpha coefficients for the knowledge dimension and attitude dimension were 0.922 and 0.812, respectively. The knowledge dimension included contents related to ethical concepts, the basic principles of medical ethics, the contents of the Declaration of Helsinki of the World Medical Assembly and the Measures for Ethical Review of Biomedical Research Involving Human Beings (2016), and the setup of ethics committees, Knowledge of Good Clinical Practice (GCP) for Drug Clinical Trials, and cases of ethical problems in clinical research projects, etc. The Clinical Research Ethics Questionnaire has a total score of 100 points, with questions 1-8 being single choice questions worth 7 points each, questions 9–11 being multiple choice questions worth 10 points each, and questions 12–13 being situational judgment single choice questions worth 7 points each. Higher scores indicate better knowledge of clinical research ethics. The attitude dimension includes the attitude towards the fulfilment of the duties of the ethics committee, the importance of ethical review and the need for GCP certificate for clinical research,

Table 1 Nurses' clinical research ethics knowledge and attitude scores (*n* = 304)

Dimension	score(⁻ x±s)	standard scores(_x±s)
Total knowledge score	63.08 ± 12.30	63.08
Total attitude score	27.35 ± 1.88	91.17

 $\it Note$ The total score of the questionnaire and of each dimension was interpreted as: < 60 poor, 60 to 85 medium, > 85 good 45

etc. Each item is scored on a Likert 5-point scale, with "strongly disagree, basically disagree, not sure, relatively agree, strongly agree" scoring from 1 to 5. The higher the score, the better the subject's attitude towards the ethics of clinical research is. The standard score was used to calculate knowledge and attitude of the questionnaire, which was average score/total score×100% [22].

Data analysis

The data collected was transferred to the statistic software SPSS for analysis. All data were analysed by SPSS 26.0. Categorical variable data (demographic and other characteristics of nurse) were presented as numbers and percentages, while continuous variables (knowledge, attitude total score) were expressed as means and standard deviation (SD). Multiple linear regression analysis was used to determine the relevant factors affecting nurses' knowledge and attitude towards clinical research ethics. The total score of knowledge and attitude for each factor was set as the dependent variables, while univariate analysis found that statistically significant variables were used as independent variables.When processing multiple regression analysis, the nominal variables were set as dummy variables, such as whether the hospital has an ethics committee(yes=(0, 0), no=(1, 0), unclear=(0, 1)). A *p* value of <0.05 was considered statistically significant.

Ethical considerations

The study was approved by the Hunan Children's Hospital Research Ethics (Reference number: HCHLL-2024-09).

Results

Sample characteristics

Among 304 participants, 92.4% (n=281) were female. The majority were under 39 years of age. The mean age was (34±8.56) years. Most (60.4%) of the participants (n=225) had a bachelor's degree or higher. The majority were of intermediate title. Regarding unit characteristics, half (67.4%) of the participants' hospitals belonged to tertiary Grade 3B and above. Nearly half of the participants' hospitals (49.7%) had an ethics committee. Other general information characteristics are shown in Table 1.

Table 2 Nurses scores for each entry of knowledge and attitudes in clinical research ethics (n = 304)

Item	Mini- mum value	Maxi- mum value	Average score
Knowledge			
The following is a correct statement of "ethics"	0	7	6.54±1.74
The Declaration of Helsinki of the World Medical Assembly refers to	0	7	4.44±1.19
During what period of time do ethics committees review clinical research?	0	7	3.73±1.20
The contents of the ethics committee review are	0	7	5.67 ± 2.76
The central role of ethical review for clini- cal research is to	0	7	5.27±2.17
In your opinion, the most important part of a clinical study is	0	7	5.34±2.98
The Chinese name of GCP is	0	7	6.19±2.24
Do all research subjects need to sign an informed consent form before clinical research	0	7	5.80±2.64
Basic Principles of Medical Ethics	0	10	4.74±1.29
Informed consent involves	0	10	8.13±3.91
Requirements for research subjects to sign the informed consent form	0	10	2.66 ± 0.25
Situation judgement 1	0	7	2.39±0.19
Situation judgement 2	0	7	2.16±0.18
Attitude			
Do you think that ethical committee review is required to conduct clinical research?	3	5	4.69±0.53
Do you think the ethics committee has the right to question or modify the research protocol	2	5	4.62±0.65
Do you think that any changes in the clinical research protocol during the study need to be reported to the ethics committee?	2	5	4.36±0.73
The ethics committee has the right to order suspension/stoppage of the trial in case of adverse events during the clinical study?	2	5	4.63±0.65
Do you think that ethical review is needed before clinical research	1	5	4.49 ± 0.60
Do you think GCP certificate is needed to conduct clinical research?	1	5	4.56±0.76

Nurses' clinical research ethics knowledge and attitude score

In this study, 304 nurses had total scores of 63.08 and 27.35 for clinical research ethics knowledge and attitude, with standard scores of 63.08 and 91.17, respectively, with moderate knowledge scores and good attitude scores. The scores of each dimension and each entry are shown in Tables 1 and 2.

One-way analysis of nurses' clinical research ethics knowledge and attitude scores

Table 3 presented clinical research ethics knowledge and attitude for different general characteristics.Clinical research ethics knowledge and attitude in participants with a PhD/Postdoctoral degree were significantly higher than in those below this level (p < 0.001, p = 0.001). The level of clinical research ethics knowledge and attitude was significantly higher working in Grade 2 A or above hospitals compared to those working in hospitals below Grade 2 A(p<0.001, p<0.001). The clinical research ethics knowledge and attitude of the participants with senior titles were significantly higher than those of the participants with junior and intermediate titles (P=0.001, P < 0.001). The higher the number of participants who presided over the number of clinical research projects in one year, the higher the scores of clinical research ethics knowledge and attitude (P<0.001, P<0.001).Clinical research ethics knowledge and attitude showed a significant difference with whether the hospital has an ethics committee (p < 0.001, p < 0.001), and whether to participate in training related to ethical knowledge (p < 0.001, p=0.008). However, other characteristics of nurses had no obvious impact (p > 0.05).

Multiple regression analysis of nurses' clinical research ethics knowledge and attitude scores

The results of multiple linear regression analysis, as shown in Table 4, showed that degree, grade of hospital (I, II or III), technical title, number of clinical research projects chaired in one year and whether to participated in training related to ethical knowledge were the five factors influencing the knowledge of clinical research ethics (F=9.341, P<0.001), which explained 18% of the variance. Degree, grade of hospital (I, II or III), technical title, number of clinical research projects chaired in one year, whether the hospital has an ethics committee and whether to articipate in training related to ethical knowledge were the six factors affecting ethical attitudes towards clinical research (F=8.919, P<0.001), which explained 17.3% of the variance.

Discussion

To the best of our knowledge, This is the first study to examine the current status of nurses' ethical knowledge and attitudes toward clinical research and their associated factors in different levels of hospitals in China. The results of this study not only help nursing managers to understand the ethical knowledge and attitudes of nurses in clinical research, but also lay the foundation for further research.

This study shows that the standardized total score of nurses' knowledge of clinical research ethics was 63.08, which was in the middle level. It is related to the overall low educational level of the Chinese nurse population, the low number of clinical research projects carried out, and the serious lack of continuing education and training.In 2010, the state promulgated the Guiding Principles for Ethical Review of Drug Clinical Trials [23], and major hospitals across the country constructed and perfected the ethical review procedures for drug clinical trials based on this principle and the Code for Quality Management of Drug Clinical Trials [24]. In contrast, clinical research involving human beings has only gradually begun to regulate the ethical review of scientific research since the promulgation of the Measures for Ethical Review of Biomedical Research Involving Human Beings in 2016, but the needs and development paths of hospitals of different regions and grades are different, leading to differences in the importance attached to ethical review of scientific research. Clinical research programs in nursing primarily focus on nurses with postgraduate backgrounds. Over the past three years, there has been a gradual increase in the number of nurses in this group. Typically engaged in clinical nursing duties, they often have limited participation in conferences and studies concerning research ethics, leading to a lack of knowledge in this area. Therefore, in this group, there are still cases in which the papers published by nursing research are reviewed as research proposals, and the research proposals tend to emphasize science rather than ethics [25], and thus lack the knowledge related to research ethics. knowledge of ethics-related aspects. The cognitive dimension scores were consistent with the results of most scholars' [26, 27] studies.

In the cognitive dimensions, the situational judgement questions based on ethical controversies that often arise in the course of clinical research had the lowest scores. The score of the first situational judgment question was 2.39 ± 0.19 , and the score of the second was 2.16 ± 0.18 . These results indicate that nurses have insufficient thinking and experience about possible ethical disputes in clinical research practice, which may be related to the few clinical studies carried out by hospitals or the lack of attention to relevant research ethical issues in the process of carrying out clinical research. While entries such as the definition of ethics, the Chinese name of GCP, and the content involved in an informed consent form had higher scores. This may be related to the gradual emphasis on nursing scientific research and the more basic scientific research ethics education and knowledge training carried out by hospitals. Therefore, we need to further strengthen the training of research ethics for nursing staff. In particular, hospitals or schools should increase the content of research ethics when setting up basic nursing education training courses, so as to improve the operation level of clinical research ethics of nursing staff, so that they can correctly analyze and deal with various ethical conflicts

Variable	Numbers of people	Constituent ratio(%)	knowledge	Attituda
Gondors	Numbers of people	Constituent ratio(70)	Kilowiedge	Attitude
Male	23	76	6787+1564	26.83 + 1.02
Female	23	7.0 02.4	67.68 ± 11.04	20.03 ± 1.92 27.39 ± 1.87
t	201	72.4	1 954	-1 380
p			0.052	0.169
			0.052	0.105
	60	10.7	65 10 + 15 60	26.09 ± 1.05
20 38	1/13	19.7	60.95 ± 0.00	20.98 ± 1.95
29-50	63	47.0	63.70 ± 12.38	27.40 ± 1.94 27.63 ± 1.57
40 58	22	20.7 7 0	65.73 ± 12.30	27.03 ± 1.37 26.55 ± 1.02
-59 -58	16	5.2	67.25 ± 10.47	20.33 ± 1.32
E	10	J.J	07.23±14.09	27.44 ± 1.79
			2.307	2.130
P			0.055	0.074
Deglees	70	21.2	FO 47 + 10 FC	26761226
Specialist and below	172	21.2	59.47 ± 10.50	20.70 ± 2.20
Bachelor's Degree	173	40.5	62.08 ± 12.18	27.42 ± 1.03
Master	4/	12.6	68.40±13.56	27.85 ± 1.81
	5	1.3	70.02 ± 12.70	29.40±0.89
F			8.178	6.053
			<0.001**	0.001**
Grade of hospital	495		<5.00 AD 05	
Grade 3 A hospital	125	41.1	65.90±13.85	27.76±1.41
Grade 3B hospital	80	26.3	63.56±6./2	$2/.54 \pm 1.86$
Grade 2 A hospital	58	19.1	60.16±10.76	26.93 ± 1.96
Grade 2B hospital	41	13.5	57.63±15.11	26.29 ± 2.52
F			6.329	8.057
P			<0.001**	<0.001**
Technical Title				
Junior	66	21.7	60.45 ± 14.01	26.56 ± 2.32
Intermediate	174	57.2	62.19±10.70	27.46 ± 1.62
Senior	64	21.1	68.19±13.22	27.84 ± 1.81
F			7.817	8.748
Р			0.001**	<0.001**
Working years				
0–5	61	20.1	66.03 ± 13.94	27.56 ± 1.82
6–10	103	33.9	61.68 ± 11.84	27.41 ± 1.95
11–15	89	29.3	61.97±10.90	27.28 ± 1.88
16–20	29	9.5	64.10 ± 14.37	26.97 ± 1.88
>20	22	7.2	64.55 ± 11.40	27.23 ± 1.77
F			1.535	0.563
Ρ			0.192	0.690
Number of clinical research projects participated in one year (items)				
0	152	50.0	62.14±13.31	27.44 ± 1.79
1–3	118	38.8	63.69 ± 10.64	27.42 ± 1.81
4–10	28	9.2	63.14±12.14	26.64 ± 2.30
>10	6	2.0	74.33 ± 13.59	26.83 ± 2.99
F			2.093	1.647
Р			0.101	0.179
Number of clinical research projects chaired in one year (items)				
0	181	59.5	60.31±11.46	26.93±2.10
1–3	112	36.8	66.83±12.03	27.94±1.32
4–10	8	2.6	68.88±17.18	28.00 ± 0.53

Table 3 Results of one-way analysis of general information and nurses' clinical research ethics knowledge and attitude scores ($x \pm s$, n = 304)

Table 3 (continued)

Variable	Numbers of people	Constituent ratio(%)	knowledge	Attitude
>10	3	1.0	74.00 ± 15.52	28.00 ± 1.73
F			8.489	7.624
Р			<0.001**	<0.001**
Whether the hospital has an ethics committee				
Yes	151	49.7	65.85 ± 12.38	27.60 ± 1.51
No	83	27.3	61.92 ± 12.93	27.57 ± 1.96
Not clear	70	23.0	58.46 ± 9.58	26.53 ± 1.88
F			9.686	9.052
Р			<0.001**	<0.001**
Whether the respondent has ever participated in an ethics training				
Yes	130	42.8	64.28 ± 12.24	27.72 ± 1.70
No	147	48.4	63.86±12.32	27.12 ± 1.90
Not clear	27	8.9	53.00 ± 7.10	26.78 ± 2.28
F			10.622	4.906
<u>P</u>			<0.001**	0.008**

Note *P<0.05, **P<0.01

Table 4	Multiple linear r	egression anal	vses of nurses	knowledge, a	attitudes about	clinical research	ethics $(n = 304)$)
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Dependent variable	Independent variable	b	95%CI	Sb	b′	t	Р
knowledge1	Constant	53.110	46.269–59.952	3.476	-	15.278	< 0.001
	Degree	2.496	0.519-4.472	1.004	0.140	2.485	0.014
	Grade of hospital	-1.412	-2.770-0.054	0.690	-0.123	-2.046	0.042
	Technical title	2.102	0.081-4.123	1.027	0.112	2.047	0.042
	Number of clinical research projects chaired in one year	3.501	1.226-5.775	1.156	0.171	3.028	0.003
	Whether to participate in training related to ethical knowledge (yes=reference group)						
	No	-7.459	-4.641-1.945	2.503	-0.173	-2.980	0.003
	Not clear	0.778	-6.089-1.181	1.376	0.032	0.565	0.572
Attitude2	Constant	26.276	25.225–27.326	0.534	-	49.219	< 0.001
	Degree	0.348	0.044-0.651	0.154	0.128	2.256	0.025
	Grade of hospital	-0.390	-0.598-0.181	0.106	-0.222	-3.678	< 0.001
	Technical title	0.392	0.081-0.702	0.158	0.136	2.483	0.014
	Number of clinical research projects chaired in one year	0.402	0.053-0.752	0.178	0.129	2.267	0.024
	Whether there is an ethics committee in our hospital (Yes = reference group)						
	No	-0.518	0.013-1.024	0.257	-0.123	-2.017	0.045
	Not clear	-0.360	-0.918-0.198	0.284	-0.081	-1.269	0.206
	Whether the respondent has ever participated in an eth- ics training (Yes = reference group)						
	No	-0.425	-0.841-0.009	0.211	-0.113	-2.011	0.045
	Not clear	-0.220	-0.977-0.536	0.384	-0.033	-0.573	0.567

Note 1: R2=0.202, adjusted R2=0.180, F=9.341, *p*<0.001; 2: R2=0.195, adjusted R2=0.173, F=8.919, *p*<0.001

they may face, so that nursing scientific research and ethics can promote each other and coordinate development.

The attitude dimension scores in this study were good and consistent with the findings of scholars from Ghana and Ethiopia [28, 29]. China's National Health Commission, in order to further regulate clinical research, issued the Guidelines for the Construction of Ethical Review Committees for Clinical Research Involving Human Beings in October 2019 [4] and required that clinical research involving human beings be comprehensively filed in the Medical Research Registration and Filing Information System from September 2020, and the Opinions on Strengthening the Ethical Governance of Science and Technology issued by the Central Committee of the Communist Party of China (CPC) and the State Council of China in April 2023 [29] proposing that emphasis be placed on education and training in science and technology ethics, and that not only are universities encouraged

to offer ethics-related courses, but that ethics training should also be actively carried out after entry into the workforce, thereby enhancing the ethical awareness of research-related personnel. A series of documents have been issued to encourage hospital ethics committees to rigorously review the ethical issues in the whole process of clinical research, and to require hospitals and universities to strengthen ethical training in clinical research. In addition, in recent years, more and more high-quality nursing journals require contributors to provide ethical approval numbers and informed consent, etc [30, 31]., which is also an important basis for reflecting academic standards. With the support of the national policy, the gatekeeping of the hospital ethics committee and the personal experience of contributing to make research ethics in the spotlight, so the nurses have a more positive attitude towards the ethical issues of clinical research. Therefore, the nursing management department needs to pay attention to this issue, to actively improve and standardise the ethical system of clinical research, to strengthen the relevant knowledge and skills training and inspection, and to promote the standardised development of nursing clinical research ethics in mainland China.

In this study, we found that the level of nurses' knowledge and attitude towards clinical research ethics were related to their degree, grade of hospital, technical title, number of clinical research projects chaired in one year, and whether the respondent has ever participated in an ethics training. The higher the degree, the better the knowledge and attitude of the nurses, which is consistent with the results of previous studies [32]. Nurses with a master's degree have a systematic background of clinical research knowledge, and they have learnt a more scientific research design method, and they pay attention to randomised, blinded and other research methods in nursing research. Both research knowledge and research practice are richer than those of other academic groups. They are also strict with themselves and can take the initiative to participate in research-related training and learning according to their research direction to expand their knowledge field, so they have a more solid grasp of research ethics knowledge and a more positive attitude towards ethical work in clinical research. Nurses with a bachelor's degree or lower accounted for 67.7% of the nurses in this study, accounting for a larger proportion. This phenomenon should attract the attention of the nursing management department, which should further cultivate highly educated nursing talents, encourage nurses to participate in continuing education to improve their own ability and professionalism, and also suggest that targeted training in ethics courses should be conducted at different levels according to different educational backgrounds.

The higher the hospital ranking, the higher the level of clinical research ethics knowledge and attitudes, which is consistent with the results of many similar studies [33, 34]. The higher the hospital ranking, the more importance was given to the ranking of hospitals and disciplines in terms of scientific and technological(S&T) impact. S&T impact is determined by the total ranking of S&T inputs, S&T outputs, and academic impact. Therefore, the higher the hospital ranking, the more importance the nursing discipline places on clinical research outputs and the more resources and platforms available to the nursing discipline, so the clinical research is also very important. The higher the level of the hospital, the more resources and platforms nursing can use, so the experience of clinical research is richer, and the knowledge of research ethics is better mastered, which leads to a more positive attitude towards the ethical work in clinical research.

The higher the technical title, the better the knowledge and attitude, which is consistent with the findings of Famuyide M, Ayoub NM [26, 35]and others, who found that the ethical knowledge, belief and behaviour of the researchers tended to increase as the title increased. At present, more and more nurses in hospitals need scientific research achievements to promote their titles, and nurses with higher technical titles have more research outputs, more experience in clinical research, more opportunities to participate in research ethics training, and more systematic and comprehensive reserves of ethical knowledge in clinical research, and thus their ethical awareness has become stronger, and they pay more attention to ethical issues in clinical research.

Nurses who chaired more clinical research projects had better ethical knowledge and attitudes, consistent with the results of previous studies [36]. When hosting clinical research projects, nurses must have really experienced various ethical reviews in the whole process from project declaration, project implementation and project completion, and the ethical materials required for the research projects have been examined and approved by the research department and the ethics committee, so that nurses' ethical knowledge has been strengthened and their ethical thinking and awareness have been improved when they hosted the clinical research projects over and over again. The results of this study show that nurses who has ever participated in an ethics training have higher scores of ethical knowledge and attitude consistent with the results of many studies [37, 38]. Medical ethics training is a key aspect of improving medical staff's cognitive level, analysing and dealing with ethical dilemmas [39], and clinical research ethics training can be taught from various aspects such as the basis of ethical review, procedures, and how to apply for ethical review of scientific research, etc., so the more training you participate in, the more comprehensive the knowledge you acquire, and the more positive the ethical attitudes are. Therefore, nursing managers should pay attention to the ethical atmosphere and education to improve the enthusiasm of nurses to participate in ethical training, and then translate the value theory of research ethics into clinical ethical norms, and play a guiding and warning role in clinical practice [40].

The most important finding in the present study was that the cognitive score was not related to whether the hospital had an ethics committee, but the attitude score was. The reason for this may be that hospitals with ethics committees have more comprehensive ethical review systems and can regularly conduct publicity and ethical lectures for the entire medical staff, thus improving their attitudes towards clinical research ethics, but the improvement of ethical knowledge requires one's own proactive understanding and study. However, a survey of 73 hospitals in China on the implementation of ethical review systems and review programmes found that most of the hospitals had problems such as irrational structure of the ethics committee members, imperfect ethical review process and lack of consistency in the review contents [41]. Therefore, we need to strengthen the construction of ethics committees in Chinese hospitals and develop a more standardised review mechanism [42], so as to ensure the quality of clinical research projects and better protect the rights and interests of subjects.

Limitations

There are some limitations that must be considered: (1) the cross-sectional survey makes it difficult to identify the causal relationships between the variables; (2) the N was not large enough to detect significant differences; (3)the participants were all nurses from one province and (4) the content of questionnaire items is not wide enough. Therefore, the differences in clinical research ethics knowledge and attitudes of nurses in hospitals in different provinces and regions of China need to be explored. It is recommended that a more scientific and comprehensive questionnaire should be set up next, and a larger sample and multi-center investigation and research should be conducted in each province. In the future, the level of nurses' knowledge, attitude and practice towards clinical research ethics can also be explored from the theory of knowledge, attitude and practice(KAP) the facilitating and inhibiting factors affecting knowledge, attitude and practice can be analysed. This will provide a reference for nurses to carry out personalized training on clinical research ethics, and suggest precise countermeasures to improve the level of knowledge and attitude of all Chinese nurses towards clinical research ethics.

Conclusion

Nurses in one province in China scored low on the cognitive dimension of clinical research ethics but high on the attitudinal dimension. Nurses scored highest on the "content of informed consent" and lowest on the two "situational judgement questions". In addition to degree, technical title, grade of hospital, number of clinical research projects chaired in one year and whether to participate in training related to ethical knowledge. Whether the hospital has an ethics committee was associated with the nurses' attitude towards clinical research ethics .

Therefore, nursing managers know which aspects of nurses' knowledge need to be strengthened in terms of clinical research ethics knowledge. In order to improve nurses' knowledge of clinical research ethics, nursing managers need to give full consideration to these lowscoring entries and the influencing factors when setting up training courses on clinical research ethics, and explore effective training modes and targeted strategies according to different situations in order to ensure the effectiveness of training implementation. It is hoped that in the future, nursing managers in different levels of hospitals can set up specialized, systematic, standardized and procedural clinical research ethics training courses according to their own weaknesses and needs, and evaluate the effectiveness of the training afterwards. We still need to conduct deeper research in this area.

Supplementary Information

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Supplementary Material 1

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Author contributions

H Q, L Zand N Z conducted research design, Q Cand L W conducted data collection, S J, Z Z, T L Luo conducted cleaning and analysis. N Z conducted the write-up of this research article. All authors reviewed the manuscript.

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Data availability

Data is provided within the manuscript or supplementary information files.

Declarations

Ethics approval and consent to participate

The study was approved by the Hunan Children's Hospital Research Ethics (Reference number: HCHLL-2024-09).Informed consent forms, were signed by participants, and they were ensured about the confidentiality of information.

Consent for publication

Not applicable.

Competing interests

The authors declare no competing interests.

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