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Running heading:

Knowledge and Attitudes toward Clinical Trials

Title:

Ward-Based Nurses' Knowledge and Attitudes Toward Clinical Trials: A Survey Study in Taiwan

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Heading level 2:

Abstract

Purposes: Clinical trial education has not been extensively integrated into nursing education systems. Acute care nurses may lack sufficient knowledge when caring for admitted trial patients, which may negatively influence their attitudes toward clinical trials. The aim of this study was to explore ward-based nurses' knowledge and attitudes toward clinical trials.

Design and Methods: Ward-based nurses working in medical, surgical, and intensive care units in a medical center in Taiwan were approached to complete a questionnaire. The questionnaire was developed by the research team and included four parts: demographics, experience with clinical trials, clinical trial knowledge, and attitudes toward clinical trials.

Findings: A total of 161 nurses responded. Nearly 90% of the nurses accessed trial information in their workplace. Nearly 80% of the respondents had experience with caring for trial patients, but the mean score of clinical trial knowledge was 4.5 out of a possible score of 10. For attitudes toward clinical trials, the mean score for positive beliefs was 39.7, and the mean score for negative expectations was 42.5, both out of a possible score of 55. The results indicated that respondents typically tended to hold a negative attitude toward clinical trials, especially in regard to the side effects of study drugs and communication with investigators.

Conclusions: Knowledge deficits of ward-based nurses concerning trial participation is apparent. Continuing education for ward-based nurses is necessary to promote implementation of clinical trials and reduce negative expectations related to clinical trials.

Clinical Relevance: One way to improve nurses' knowledge is to integrate

clinical trial education into nursing education systems, which will provide more channels through which nurses can understand how a trial works, including the risks, benefits, and participant protection. Through such educational initiatives, ward-based nurses may develop more positive beliefs regarding clinical trials and provide higher quality clinical trial care to participants.

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Body of article:

The number of clinical trials and the number of patients involved in clinical trials are both steadily increasing worldwide. While there is a clear and growing role for specially trained clinical research nurses (CRNs), there is also a requirement for nurses based in inpatient medical surgical units to understand the purpose of clinical trials and to assist with conducting them in order to work effectively with patients who are admitted while participating in a clinical trial (American Nurses Association and International Association for Clinical Research Nursing, 2016; Hastings, Fisher, & McCabe, 2012; Jones, 2015). Here we report on a study of knowledge and attitudes among nurses (designated "ward-based nurse" in this study) in inpatient units regarding clinical trials.

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Background

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Clinical Trials

A clinical trial is a specific type of clinical research intended to increase health care knowledge, frequently focusing on laboratory discoveries, clinical innovation, and the testing and application of promising findings. After 2000, the clinical trials method emerged as an important, cutting edge priority for research enterprises at the international level (American Nurses Association and International

Association for Clinical Research Nursing, 2016; Hastings et al., 2012; Lubejko et al., 2011). Phase I trials test a new drug or treatment for the first time in humans to evaluate its safety, determine a safe dosage range, and identify unwanted effects in a small group of trial participants. Intervention, usually in a larger group of people from the target population. Depending on the results from the phase I and II trials, randomized controlled trials (RCTs) are the gold standard for phase III trials. They are conducted to compare the efficacy and adverse effects of a new intervention with other standard or experimental treatments, or against a placebo. The results from phase III trials become source data to determine approval of drugs or treatments by the Food and Drug Administration in the United States or other relevant authorities in other countries (U.S. National Institutes of Health [NIH], 2017; Yang, Huang, Chen, Chiang, & Tzou, 2016). Thus, clinical trials are fundamentally about obtaining supporting evidence related to experimental treatments rather than standard treatments (Kao, Hu, Yang, Wang, & Yu, 2015; Yanagawa et al., 2014).

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Clinical Research Nurses in Clinical Trials

As the number of clinical trials increases internationally, the CRN has become an essential member of the clinical research team to help facilitate and conduct any phase of a clinical trial, to manage the project, and to communicate about the trial with clinical staff and participants (American Nurses Association and International Association for Clinical Research Nursing, 2016; Spilsbury et al., 2008). The CRN roles and responsibilities often include protocol assessment and review, a site qualification visit, regulatory submissions, investigator meetings, budget management, clinical trial document preparation, a site initiation visit, ancillary staff education, participant recruitment and retention, informed consent seeking, research coordination and management, data collection and management, ongoing site monitoring, sponsor communication, and study close out or reconciliation (Poston & Buescher, 2010; Spilsbury et al., 2008). Under the framework of the U.S. NIH Clinical Center, nurses with advanced education and experience can be

trained as CRNs, focusing on research participant care. They can also extend their roles to be nurse scientists or principal investigators after further training, usually via a research degree (Hastings et al., 2012; Jones, 2015; Lubejko et al., 2011). CRNs have the potential to make significant contributions to clinical trial efficiency and quality and to improve participants' healthcare knowledge (Coulson & Grange, 2012; Gibbs & Lowton, 2012; Nagel, Gender, & Bonner, 2010).

However, in mainstream nursing education, little explicit attention has been given to this emerging advanced practice role and the associated knowledge at the international level (American Nurses Association and International Association for Clinical Research Nursing, 2016; Kao, Huang, Dai, Pai, & Hu, 2015). Consequently, nursing knowledge and skills regarding clinical trial support are unfamiliar to most nurses, and the scope and practice of CRNs has not been well defined (Hastings et al., 2012; Lubejko et al., 2011; Yanagawa et al., 2014). In 2016, the American Nurses Association and International Association of Clinical Research Nurses published *Clinical Research Nursing: Scope and Standards of Practice*. This was the first time national organizations supported efforts to describe the competence level for clinical research in nursing as demonstrated by a critical thinking model known as the nursing process (American Nurses Association and International Association for Clinical Research Nursing, 2016).

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Care of Clinical Trial Participants

While more participants are receiving clinical trial treatments, many of these participants may need to be hospitalized for the safe conduct of the trial. Ward-based nurses provide direct care based on patients' clinical needs and the clinical needs that emerge in the context of trial participation, such as administering an investigational drug. Ideally, there should be effective communication and interaction between CRNs and ward-based nurses to share and evaluate patient responses (American Nurses Association and International Association for Clinical Research Nursing, 2016). Throughout an inpatient stay, CRNs commonly rely on ward-based nurses to report patient symptoms and collect

data in order to meet the protocol requirements. It is necessary that ward-based nurses in such situations have adequate knowledge of clinical trials and a positive engagement with the trial objectives and process (Grady & Edgerly, 2009; Yanagawa et al., 2014). Results of a focus group with nine CRNs indicated that there was a lack of understanding of clinical trials among ward-based nurses (Spilsbury et al., 2008). Ward-based nurses sometimes were unable to follow the protocol requirements or misunderstood the randomization process, which resulted in patients having to be excluded from the trial. A survey of 254 nurses in cancer-related units including outpatient clinics and inpatient units in Taiwan also reported that most nurses had insufficient knowledge of cancer clinical trials, especially the purposes of clinical trial and the purposes of informed consent (Chang et al., 2009).

A poor understanding of the nature of clinical trials on the part of nurses and other health professionals may influence their attitudes toward clinical trials and may be a barrier to discussing clinical trials with patients (Chang et al., 2009; Ulrich et al., 2012). Ulrich et al. (2012) investigated the attitudes of 455 primary care nurse practitioners toward a cancer clinical trial and their willingness to recommend trial participation. The results showed that nurse practitioners who believed in the importance of clinical trials in improving the future standards of care were more willing to recommend clinical trials when asked about such trials by patients ($p < .001$); nurse practitioners who were comfortable discussing cancer clinical trials were almost five times more likely to think clinical trials were useful (odds ratio [*OR*] = 4.70; $p = .001$) (Ulrich et al., 2012). Chang et al. (2009) indicated that nurses who were more senior and who worked at cancer outpatient clinics in Taiwan had a more positive attitude toward cancer clinical trials, while nurses from cancer inpatient units had the lowest positive attitude scores. The researchers proposed that senior nurses and nurses working at cancer outpatient clinics may have more experience in caring for trial patients, resulting in a better understanding and more positive attitudes toward clinical trials. Conversely, nurses from cancer inpatient units may have less experience caring for clinical trial patients and may not have received relevant clinical trial training, thus resulting in negative attitudes (Chang et al., 2009).

As hospital admissions for patients in clinical trials increase, ward-based nurses will have more opportunities to provide care. Ward-based nurses with insufficient understanding or negative attitudes toward clinical trials may influence patients' decisions to participate in clinical trials (Grady & Edgerly, 2009; Yanagawa et al., 2014). As in other countries, Taiwanese cancer settings are engaged in an increasing number of clinical trials. Optimal care for participants will depend on the skills, knowledge, and cooperation between CRNs and unit-based nurses. Previous research has shown efforts toward examining nurses' attitudes toward cancer clinical trials, but no research has explored nurses' knowledge and attitudes toward general clinical trials. Therefore, the purpose of this study was to explore ward-based nurses' knowledge of and attitudes toward clinical trials.

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Methods

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Design, Setting, Sample, and Procedure

A descriptive correlational design was used to obtain data from medical-surgical nurses in northern Taiwan. A representative sample of 10 units was randomly selected by a computer program among 43 adult medical, surgical, and intensive care units of a large teaching medical center. A total of 245 nurses were eligible to participate. During the shift report, the purpose of the study was announced, and all registered nurses were invited to participate. Questionnaires were distributed to the nurses' stations of the selected units. There were no exclusion criteria. Human subject approval was obtained from the institutional review board (IRB) of the participating institution. Written consent was obtained from each nurse prior to completing the anonymous survey. No identifying information was requested on the questionnaire.

The study was completed with 161 nurses. In order to determine the adequacy of the sample size upon completion of the study, post hoc power analysis was performed, with alpha of 0.05 and the mean difference in clinical trial knowledge scores of 1.1 (knowing the function of the IRB:

5.02; not knowing the function of the IRB: 3.92), revealing 0.95 power using G*Power version 3.1.9.2.

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Instruments

The questionnaire was developed by the research team based on a literature review and consultation with a panel of experts. It included demographics, experience with clinical trials, clinical trial knowledge, and attitude toward clinical trials. The content validity index ranged from 0.85 to 0.91 across experience, knowledge, and attitude sections. The survey took approximately 15 min to complete.

Experience with clinical trials included clinical trial experience, the IRB, and the role of CRNs was determined by five questions, providing a list of multiple choices, and generating categorical data. Clinical trial knowledge included 10 statements. Participants were required to indicate if they agreed, were unsure, or disagreed. A correct answer received 1 point. A pilot test of discrimination and the difficulty of the 17 original items was conducted using 21 students who had completed a clinical research nurse program. Based on the findings, seven items were deleted. The clinical trial knowledge total possible score ranges from 0 to 10 (discrimination > 0.4, with a difficulty percentage between 40% and 70%).

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The attitude toward clinical trials section of the questionnaire included 22 items scored on a 5-point Likert scale ranging from 1 to 5, where 1 represented "*strongly disagree*" and 5 represented "*strongly agree*." The exploratory factor analysis identified two factors: positive beliefs (11 items) and negative expectations (11 items). The factor loading of each item was between 0.45 and 0.80, and these two factors explained 41.47% of the total variance. For the positive beliefs subscale, the total score ranges from 11 to 55, where a higher score indicated a more positive attitude toward clinical trials. For the negative expectation subscale, the total score ranged from 11 to 55, where a higher score indicated a more negative attitude toward clinical trials. In this study, Cronbach's alpha was 0.87, and the positive beliefs and negative expectation subscales also had good internal

consistency (Cronbach's alpha 0.83 and 0.85, respectively).

Heading level 2:

Data Analysis

Descriptive statistics were computed for each item and total score. A Pearson correlation and one-way analysis of variance were used to analyze the correlation between the demographic variables and the research variables. SPSS for Windows version 18 (IBM Corp., Armonk, NY, USA) was used for the statistical analyses.

Heading level 1:

Results

Heading level 2:

Demographics

A total of 161 nurses returned questionnaires, for a response rate of 65.7%. The nurses reported a mean age of 30.6 years (*SD* = 6.7), and 91.3% had a minimum of an undergraduate education (Table 1). The majority (56.5%) reported over 5 years of nursing experience. Thirty percent of the nurses practiced in surgical units, 42.9% practiced in medical units, and 27.1% practiced in intensive care units.

Insert Table 1 about here

Heading level 2:

Experience With Clinical Trials

The majority (*n* = 155, 96.7%) of nurses had heard about clinical trials (*n* = 144, 89.4% from working experience; Table 2). Over three fourths of the nurses (*n* = 24, 77%) had experience working with CRNs. More than half of the nurses (*n* = 87, 54%) knew the function of the IRB. Nearly 80% of the nurses (*n* = 128) had experience in providing nursing care for clinical trial patients. Experience included specimen collection

(*n* = 84, 52.2%) and administering an investigational drug (*n* = 71, 44.1%). Over a quarter of the nurses reported that their practice involved the provision of emotional support during the trial process (*n* = 44, 27.3%), communicating with other ancillary departments to arrange relevant treatments and examinations (e.g., tests and scans; *n* = 43, 26.7%), and the assessment and management of side effects (*n* = 39, 24.2%). A few nurses reported that their work involved screening for eligible trial patients (*n* = 30, 18.6%), obtaining informed consent (*n* = 25, 15.5%), contacting subjects for follow-up (*n* = 22, 13.7%), or arranging clinic visits, treatments, or examinations for protocols (*n* = 20, 12.4%).

Heading level 2:

Clinical Trial Knowledge

The mean score of clinical trial knowledge was 4.5 (*SD* = 1.9) and ranged from 0 to 9 (Table 3). Nurses knowing the function of the IRB had significantly higher knowledge scores overall (mean = 5.02, *SD* = 2.0) than those not knowing the function of the IRB (mean = 3.92, *SD* = 1.7; *t* = -3.727; *p* < .001). Nurses with higher academic preparation had better knowledge scores (*r* = 0.176; *p* = .025).

Insert Table 3 about here

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Attitude Toward Clinical Trials

The positive belief subscale total mean score was 39.7 (*SD* = 4.7) and ranged from 29 to 55 (Table 4). The nurses strongly agreed that clinical trials provide an alternative treatment option, increase medical knowledge, and develop new treatments. The negative expectation subscale total mean score was 42.5 (*SD* = 4.8) and ranged from 32 to 55 (see Table 4). The nurses had a negative attitude toward the side effects of study drugs and communication with investigators, and they also feared the physicians would be unable to manage the side effects of the study drugs. Nurses with experience working with CRNs had higher positive belief

scores toward clinical trials than those not having any experience (t = -2.276; p = .024). There was no significant difference in attitude scores between nurses with or without experience providing nursing care for clinical trial patients. Nurses with higher positive beliefs scores had higher negative expectation scores toward clinical trials (r = 0.356; p < .001).

Heading level 1:

Discussion

In Taiwan, 221 clinical trial protocol reviews were approved in 2016 (Center for Drug Evaluation, 2017). Because clinical trials are becoming more common in Taiwan, more medical centers are participating in clinical trials, presenting more opportunities for ward-based nurses to become involved. The level of clinical trial knowledge was low among the practicing nurses under consideration in this study. For the ward-based nurses, the main source of information regarding clinical trials was previous work experience; information was infrequently obtained from continuing education or the nursing school curriculum. Clinical trial education programs have not been extensively integrated into Taiwan's nursing education system, potentially contributing to a knowledge deficit when caring for clinical trial patients (Kao, Hu, et al., 2015).

The study results indicated that nurses who were aware of the purpose of the IRB have a better understanding of clinical trials. The IRB was established to ensure the protection of human beings involved in research by reviewing protocols and relevant documents. Nurses who know about the IRB may be versed in trial processes and patient protection. In addition, the study findings support the view that nurses with advanced education better understand the fundamentals of research, which contributes to a better understanding of clinical trials (Hastings et al., 2012; Jones, 2015).

Because most clinical trial patients are outpatients, CRNs usually provide direct care, consultation, and communication with ancillary departments during clinic visits. However, clinical team members fail to understand the contribution of CRNs to health care, resulting in a distance between clinical staff and CRNs and less than optimal

collaboration (American Nurses Association and International Association for Clinical Research Nursing, 2016). These findings suggest that when trial patients are admitted to the hospital, ward-based nurses are unlikely to be familiar with clinical trial procedures. The lack of familiarity requires the CRNs to provide care to hospitalized patients (Coulson & Grange, 2012; Gibbs & Lowton, 2012; Nagel et al., 2010). This may explain the finding that nearly 80% of nurses in this study reported experience in caring for clinical trial patients, but their roles may have been narrowly defined, focusing on routine tasks, such as specimen collection and providing clinical trial medications. A smaller number of these nurses provided emotional support and consultation, assessment and management of side effects, and informed consent.

The results supported previous studies that found that exposure to patients in trials was not associated with positive attitude toward trials (Yanagawa et al., 2014). In line with our characterization of ward-based nurses as having limited knowledge and roles with patients in trials, their experiences in providing nursing care for clinical trial patients did not influence their attitudes. Rather, it was nurses with experience working with CRNs who tended to have positive beliefs toward clinical trials in this study. These findings demonstrate the importance of identifying and formalizing the emerging advanced practice CRN role across healthcare services. Work is needed to integrate the CRN into the clinical team and build cooperation between ward-based nurses and CRNs (American Nurses Association and International Association for Clinical Research Nursing, 2016; Coulson & Grange, 2012; Gibbs & Lowton, 2012; Nagel et al., 2010; Thiel et al., 2012). Evidence suggests that a clinical trial education curriculum is needed to ensure that nurses have more opportunities for formal professional trial training, to consolidate the CRN's advanced practice contribution in research, to increase its recognition in mainstream nursing, and thereby to improve quality of care in clinical trials overall (Gibbs & Lowton, 2012; Kao, Hu, et al., 2015; Kao, Huang, et al., 2015; Lubejko et al., 2011). In Taiwan, the first clinical research nurse program was established in the Department of Nursing, National Taiwan University in 2005, providing a formal educational path for nurses who are interested or work in the area of clinical research or trials (Kao, Huang, et al., 2015). In line with

this, the first master's program for clinical research nurses in Taiwan was established in 2009 to further expand the CRN profession in order to promote quality of care during clinical trials (Kao, Huang, et al., 2015; Yeh, 2017).

Reinforcing findings from a previous survey, these nurses were positive about the way clinical trials can provide alternative treatment options for patients and the way in which they increase medical knowledge (Ulrich et al., 2012). The study results also highlight nurses' concerns regarding safety issues for the patients in clinical trials; they were not knowledgeable about or reassured by the rigorous research design or the governance of clinical trials. Ward-based nurses' negative expectations may improve if they are better informed about participant protections in clinical trials. They may currently lack information about governance arrangements, for example, that biomedical and behavioral research with humans can only be conducted after receiving approval from a health authority or an ethics committee in the country where approval of the therapy is sought, and only if risks to patients have been minimized and are reasonable in relation to the anticipated benefits, or that the importance of the knowledge that may reasonably be expected to result from trials is clearly stipulated (U.S. National Cancer Institute, 2016).

Ward-based nurses may also be more confident about the way risks to patients are minimized if they better understand the role of CRNs and if nurses communicate more readily with CRNs. When conducting a clinical trial, CRNs must record relevant data, manage adverse effects by following strict protocols, and provide relevant documents for monitoring, auditing, and inspection to ensure the trial quality (Catania, 2012; Poston & Buescher, 2010). Therefore, even though the clinical trial is an experimental treatment, many mechanisms are set to protect the safety of the participants. The study findings reinforce the importance of integrating clinical trial education programs into nursing curricula or providing continuing education programs intended to help nurses gain an understanding of clinical trials that may in turn reduce their concerns regarding negative expectations of trials.

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Limitations

The findings of this study are based on the experience of nurses practicing in a major medical center. Nurses at regional or local hospitals may have different experiences. The sections of clinical trial knowledge and attitudes toward clinical trials in the study questionnaire require further psychometric testing for validity and reliability. Applicability to nurses outside Taiwan requires further testing.

Heading level 1:

Implications

Clinical trials are important to advance healthcare knowledge. However, clinical trial education has not been integrated into the nursing education system, either for the broader nursing workforce, or for advanced practice CRNs. The current study indicates that inpatient nurses may have experience caring for trial patients, but their understanding of clinical trials is marginal, and their attitude generally negative. Academic and continuing education providers must include clinical trial education into curricula to assist nurses with gaining an understanding of the contribution of clinical trials in research and inpatient care. Reducing negative expectations of trials will enable quality care of trial patients.

Heading level 1:

Conclusions

A knowledge deficit of ward-based nurses concerning trial participation is apparent in this setting. The generalizability of the results may be a concern. Continuing education for ward-based nurses is necessary to promote implementation of clinical trials and reduce negative expectation of clinical trials. Through this education, ward-based nurses may have more positive beliefs in clinical trials and, together with the CRNs, may thus provide high-quality care to patients

participating in clinical trials.

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Acknowledgments

The authors would like to thank all participants in this study.

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Clinical Resources

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- Clinical Research Nurse Program at National Taiwan University. http://nursing.mc.ntu.edu.tw/en/news/Program/Pages/Clinical-research-nurse-program.aspx
- ClinicalTrial.gov. https://clinicaltrials.gov/
- International Association of Clinical Research Nurses. https://iacrn.org/
- U.S. Food and Drug Administration. Clinical trials—What patients need to know: https://www.fda.gov/ForPatients/ClinicalTrials/ucm20041753.htm

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Table 1. Demographic Characteristics of Ward-Based Nurses

Characteristic	n	%
Age, years (range 22–58; mean 30.6; SD = 6.7)		
21–30	95	60.1
31–40	49	31.0
41+	14	8.9
Highest education level		
Diploma	14	8.7
Associate's degree	59	36.6
Bachelor's degree	78	48.4
Master's degree	10	6.2
Years of nursing experience		
<2	33	20.5
2–5	37	23.0
5–10	42	26.1
10–15	25	15.5
>15	24	14.9
Current unit		
Intensive care unit	38	27.1
Medical unit	60	42.9
Surgical unit	42	30.0

Table 2. Nurses' Source of Information Regarding Clinical Trials

Source	n	%
Work experience	144	89.4
Continuing education	51	31.7
School nursing curriculum	48	29.8
Media	18	11.2
Newspaper/magazine	10	6.2
Internet	5	3.1
Never heard of clinical trials	5	3.1

Table 3. Clinical Trial Knowledge of Ward-Based Nurses

Item	Answered correctly	
	n	%
1. When the investigator informs you that a patient has agreed to participate in a trial, you can ask the patient to sign the consent form without further explanation.	143	88.8
2. If participants have signed the consent form, they cannot withdraw from the clinical trial without the investigator's approval.	124	77.0
3. Research science should be put first when conflicts of interest exist between research science and patients' health needs during a clinical trial.	116	72.0
4. The purposes of phase I studies are mainly to investigate the safety, PK, and PD of investigational drugs in humans.	102	63.4
5. The sponsor is responsible for performing inspections.	97	60.2
6. Most participants in phase I studies are patients.	49	30.4
7. The trial always includes a control group with a placebo in order to assess the efficacy of the drug.	35	21.7
8. When trial participants are admitted, nurses should follow the normal daily routine to provide the study drug rather than following the protocol.	30	18.6
9. The best way to reduce reporting bias is to conduct an open-label, active controlled clinical trial.	24	14.9
10. Phase III studies are done after the drug or treatment has been marketed to gather information on the drug's effect in various populations and any side effects associated with long-term use.	9	5.6

Table 4. Attitudes Toward Clinical Trials of Ward-Based Nurses

Item	Mean (SD)
Positive Belief subscale	
1. Clinical trials provide patients with another treatment option.	4.1 (0.5)
2. Clinical trials are intended to add to medical knowledge and potentially help improve patient care.	3.9 (0.6)
3. Clinical trials are used to develop new treatments from which patients may benefit.	3.9 (0.7)
4. Clinical trials provide patients having no other treatment options with a last resort.	3.8 (0.6)
5. I can work with clinical research nurses to complete clinical trials.	3.7 (0.7)
6. Patients do not need to pay the huge medical fees because trial sponsors pay the fees of the study drug and tests for the trial.	3.6 (0.8)
7. Patients in trials usually have more frequent contact with the research team than they might normally have with their physician.	3.5 (0.8)
8. Clinical trials could improve the nursing profession.	3.5 (0.8)
9. Patients in trials may receive better treatment than the standard treatment.	3.4 (0.8)
10. Patients in trials may receive better care than other patients.	3.3 (0.8)
11. I help physicians to conduct the research.	3.1 (0.9)
Total mean score	39.7 (4.6)
Negative Expectation subscale	
12. The trials have unknown side effects which may hurt or harm patients.	4.1 (0.5)
13. I cannot assist with conducting clinical trials because the investigator did not introduce the trial, including purposes and trial-related procedures.	4.0 (0.6)
14. I am worried that physicians may be unable to deal with side effects of the trial drug.	4.0 (0.6)
15. I am worried that the effects of the trial drug may be worse than the standard treatment.	3.9 (0.6)
16. Patients in trials might need extra biopsies, scans, and blood samples as part of the trial process, which may affect their daily routine and quality of life.	3.9 (0.7)

17. Patient disease status may be worse in the placebo group.	3.8 (0.8)
18. Patients in trials may be treated as guinea pigs.	3.8 (0.7)
19. When patients are in double-blind trials, I may feel anxious because I do not know the drug patients receive.	3.8 (0.7)
20. Clinical trials are experimental treatments which may result in patient harm.	3.8 (0.7)
21. I feel uncertain because patients are randomized to receive treatments.	3.7 (0.7)
22. Clinical trials will affect my routine care and increase my workload.	3.7 (0.8)
Total mean score	42.5 (4.8)