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Original Article

Impact of informed consent quality on illness uncertainty among patients with cancer in clinical trials: A cross-sectional study

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ABSTRACT

Objective: This study aimed to examine the level of illness uncertainty and the quality of informed consent among patients with cancer participating in clinical trials and explore their interrelationship.
Methods: A cross-sectional study was conducted with 265 patients with cancer recruited from a tertiary hospital in Beijing, China, from April to November 2023. Participants completed a questionnaire encompassing demographic details, the Mishel Uncertainty in Illness Scale, and the Quality of Informed Consent Questionnaire. Descriptive statistics, correlation analyses, and multiple regression analyses were performed to assess the data.
Results: The mean illness uncertainty score was 40.63 ± 10.12, reflecting a moderately low level of uncertainty, with "Ambiguity" scoring the highest among its dimensions. The mean score for informed consent quality was 3.30 ± 1.20, indicating a moderate level of understanding, with notable gaps in elements such as alternatives and confidentiality. A significant negative correlation was found between the "Foreseeable risks or discomforts" element of informed consent and overall illness uncertainty ($P < 0.05$). Regression analysis revealed that factors such as clinical trial phase, primary caregiver relationship, and health insurance model significantly influenced illness uncertainty and its dimensions.
Conclusions: Enhancing the quality of informed consent can effectively reduce illness uncertainty among patients with cancer in clinical trials. Greater emphasis should be placed on clear communication of risks and discomforts and patient-centered interventions to mitigate psychological stress.

Introduction

Cancer is a significant public health issue that poses a threat to human life and well-being. In 2022, approximately 20 million new cancer cases were diagnosed globally, with nearly 9.7 million deaths reported in the same year.[1] In China, there were 4.82 million new cases and 2.57 million deaths.[2] To enhance the survival rate of patients with cancer, the development of anti-cancer drugs has progressed rapidly. Clinical trials, which are crucial for translating drug development into clinical application, play a critical role. Cancer Clinical Trials (CCT) are a form of clinical research, defined by the National Institutes of Health as "research studies that test a medical, surgical, or behavioral intervention in humans, and are the primary method by which researchers assess the safety and effectiveness of new treatments or prevention measures."[3] Over the past decade, clinical trials have advanced rapidly, with an average annual growth rate of 33%.[4]

The unique diagnostic and treatment procedures and the use of new drugs in CCT can introduce illness uncertainty for patients. Clinical trials offer an alternative for patients when standard treatments such as surgery or chemotherapy are ineffective, or when the disease recurs or metastasizes.[5] Current research tends to focus on patient recruitment and evaluating drug efficacy, often overlooking the psychological impacts on

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this unique group of clinical trial participants. Due to the risks associated with clinical trials, potential drug side effects, and uncertainty of prognosis, clinical trial participants may experience a sense of illness uncertainty. Illness uncertainty is a cognitive state that arises when an individual faces a disease and is unable to assign clear meaning to critical information such as diagnosis, treatment options, and prognosis, or to accurately predict the future progression of the disease.[6] Illness uncertainty can have a dual impact on the psychological state of a patient. It may have a positive effect if assessed as an opportunity; however, it can have a negative impact if evaluated as a threat.[7]

Numerous studies have been conducted on illness uncertainty in the field of oncology. Researchers both domestically and internationally have examined the level of illness uncertainty and its influencing factors in patients with breast cancer,[8–10] prostatic cancer,[11,12] cervical cancer,[13] esophagus cancer,[14] and nasopharynx cancer.[15,16] The results indicated that patients with cervical cancer,[13] those with early esophageal cancer undergoing Endoscopic Submucosal Dissection,[14] and patients with prostatic patients[11,12] all experienced a moderate level of illness uncertainty. Patients with head and neck cancer undergoing radiation therapy,[15,16] breast cancer during the perioperative period[9] and those 1–6 years after surgery[8] exhibited high levels of illness uncertainty. Common factors influencing illness uncertainty include demographic and disease-related factors. Demographic factors influencing illness uncertainty include age, ethnicity, residence, occupation, education level, income, and economic burden. Disease-related factors include neoplasm staging, course of the disease, type of surgery, times of hospitalization, treatment satisfaction, feeling of severity of the illness, and the presence of comorbidities[13,14,17,18] However, there is a gap in research regarding illness uncertainty in patients with cancer participating in clinical trials and the impact of clinical trial quality on this uncertainty. Only a limited number of studies have examined the psychological changes in this particular group. In 2013, Kim et al. from Korea conducted a study on 106 patients with cancer involved in clinical trials, investigating their levels of anxiety, depression, and uncertainty and the factors influencing these conditions.[19] Although this study focused on patients with cancer, it primarily explored the relationship between various emotional states and potential demographic factors. This study did not address the impact of the clinical trial process quality on patients' feelings of illness uncertainty.

Informed consent is crucial in ensuring the autonomy of participants and their right to be informed.[20] Informed consent is a process in which researchers must provide subjects with comprehensive information about the clinical trials, including their purpose, methods, potential risks, and expected benefits, ensuring that participants can make voluntary decisions based on a thorough understanding.[21,22] Clinical trials for new drugs typically involve four stages, from initial testing to approval for market listing.[23] After the initiation of each clinical trial, researchers must recruit participants and provide them with the necessary information to help them make informed decisions and sign the consent form.[24] In recent years, there has been increasing attention to the quality of informed consent in CCT. International studies have revealed that although informed consent should include numerous essential elements, there are still notable shortcomings in its quality, with significant differences in the understanding of informed consent among subjects.[25,26] The quality of informed consent in CCT is influenced by various factors. However, research on the quality of informed consent for patients with cancer participating in clinical trials remains limited in China.[27,28] Existing studies have several limitations, including small sample sizes, a lack of standardized scientific evaluation tools, and limited comparability with similar studies. Informed consent is a critical component of clinical trials, and the potential impact of its quality on the illness uncertainty of patients must be further verified.

This study aimed to thoroughly examine the quality of informed consent and illness uncertainty of patients with cancer participating in clinical trials, explore their relationship, and provide a foundation for developing effective clinical interventions and ensuring the successful progression of clinical trials.

Methods

Participants

This cross-sectional descriptive study was performed between April 2023 and November 2023, with a convenience sample selected from an academic cancer hospital in Beijing, China. The inclusion criteria were as follows: (1) age $\geq$ 18 years, (2) signed informed consent to participate in the clinical trial, (3) voluntary participation in the study with signed informed consent, and (4) ability to communicate, read, and understand Chinese. Participants who were unable to complete the questionnaire due to cognitive or communication disorders, or physical weakness, were excluded from the study.

Sample size calculation was based on the estimation method proposed by M. Kendall for analyzing influencing factors, which is as follows: sample size (N) = independent variable (a) $\times$ 5–10/(1-Sample loss rate). The independent variable, $a = 26$ (17 items of general information + 9 elements from the informed consent quality evaluation questionnaire), considering 10% of the invalid questionnaires, the minimum sample size of this study was calculated to be 145 cases.

Measure

General information questionnaire

The patient general information questionnaire, designed by the investigator, consisted of two parts: demographic details and information related to the disease and treatment. The demographic information section consisted of 11 items, including participants' age, gender, education, employment status, occupation, marital status, monthly household income, health insurance payment models, long-term residence, primary caregiver, and main source of information. The disease and treatment information section comprised six items, including the primary tumor site, disease stage, tumor metastasis, whether the patients' first treatment was at our hospital, prior participation in clinical trials, and the phase of the current clinical trial.

Mishel Uncertainty in Illness Scale

The Mishel Uncertainty in Illness Scale (MUIS), developed by Professor Mishel in 1981, was designed to assess uncertainty related to symptoms, diagnosis, treatment, caregiver relationships, and prognosis in adult hospitalized patients.[29] This study used the Chinese version of the Mishel Uncertainty in Illness Scale, which was revised by Zengjie Ye et al., in 2018. The scale includes the dimensions of lack of clarity, ambiguity, and unpredictability, comprising 20 items.[30] The “Lack of clarity” dimension reflects the insufficiency of disease-related information provided or explained by medical staff. Higher scores in this dimension indicate that patients receive less information and fewer explanations from health care professionals. The “Ambiguity” dimension pertains to patients' lack of clarity in understanding their disease. Higher scores indicate greater ambiguity regarding the cause, nature, and treatment of their condition. The “Unpredictable” dimension highlights the uncertainty surrounding the patient’s disease progression and prognosis. Higher scores reflect greater unpredictability regarding the course of the illness and treatment outcome. The scale uses a Likert 5-level scoring system, ranging from “strongly disagree” to “strongly agree,” with scores assigned from 1 to 5, respectively. The total score ranges from 20 to 100 points. A higher score reflects a higher level of experienced uncertainty. The reliability and validity assessment of the scale in Chinese patients with cancer demonstrated a Cronbach’s α of 0.825 and a retest reliability coefficient of 0.836, confirming its suitability as a tool for evaluating illness uncertainty in this population.

Quality of Informed Consent Questionnaire

The Quality of Informed Consent Questionnaire (QuIC), first developed by Joffe et al., in 2001, serves as a specialized tool for assessing the quality of informed consent in clinical trials.[31] This questionnaire was

developed based on eight fundamental elements of informed consent outlined in U.S. federal regulations for the protection of human trial subjects. It includes the following components: key elements of clinical trials, foreseeable risks or discomforts, benefits of clinical trials, alternatives, confidentiality, compensation, contacts information, and voluntary of participation. The tool assesses participants' objective and subjective understanding of informed consent in clinical trials. QuIC questionnaire is divided into two parts: A and B. Part A includes 20 objective items, each divided into three options: "disagree," "uncertain," and "agree." This part quantitatively evaluates the participants' level of agreement with the information provided in the informed consent process. Part B comprises 14 items (including one overall evaluation item) and uses the Likert five-point scale, ranging from "completely unaware" to "completely aware." This part is designed to provide a comprehensive assessment of participants' subjective perception of their understanding. With authorization from Professor Joffe, the questionnaire was translated into Chinese for this study. To ensure accuracy and relevance, an expert panel comprising professionals in medicine, nursing, clinical research, and bioethics reviewed the translation. The Chinese version of the QuIC questionnaire exhibited strong internal consistency, with Cronbach's α values of 0.611 for part A and 0.955 for part B, which can be used as an effective assessment tool for evaluating informed consent in CCT participants in China. In this study, the key elements from Part B of the QuIC questionnaire were used to assess the quality of informed consent during the clinical trial process based on the subjective understanding of the informed consent content of the clinical trial in which the patients with tumors participated.

Data collection

The investigators conducted a survey in the relevant departments of CCT at a tertiary cancer hospital in Beijing and reviewed the medical records to identify eligible participants. The research nurse and Clinical Research Coordinator (CRC) conducted a final verification to ensure that the participants met the inclusion criteria. Following the recommendation of the research nurse, CRC, or ward supervisor, the investigator conducted face-to-face meetings with the participants, providing a detailed explanation of the purpose of this study and the rights and interests of the participants, and obtained their written informed consent. The participants completed the demographic information, illness uncertainty scale, and QuIC questionnaire independently. For participants who had difficulty filling out the questionnaire on their own, the investigator dictated the contents or provided neutral explanations to assist them. After the participants made their selections independently, the investigator verified their choices and recorded the information. Details about the participants' diseases were gathered by reviewing their medical records. If more than 10% of the questionnaire content is missing, or if there are significant errors or logical inconsistencies in the responses, the questionnaire is considered invalid.

Data analysis

Data analysis was conducted using EXCEL and IBM SPSS Statistics 27.0. Descriptive statistics were applied to variables such as gender, age, education level, marital status, and scores from each scale. Categorical data were presented using frequencies and percentages. If the measurement data follows a normal distribution, it is expressed as means and standard deviations. Otherwise, it is presented as the median and interquartile range. The independent sample t test and one-way analysis of variance were used to assess differences in the characteristics of patients with cancer participating in clinical trials. Pearson correlation analysis was used for normal distribution data, while Spearman correlation analysis was applied for non-normal distribution data to examine the relationship between illness uncertainty and quality of informed consent in clinical trials.

Results

Demographic characteristics

Between April and November 2023, 265 eligible participants were included in this study, resulting in the collection of 265 valid questionnaires, achieving a recovery rate of 100.00%. The mean age of the participants was 52.88 years (SD = 13.06) and ranged from 18 to 82 years. The primary caregivers for most patients were their spouses (53.96%). Clinical trial information was primarily obtained from doctors (52.45%), followed by family members (28.30%). A significant proportion of patients (73.21%) were at stage IV of their disease, and most participants (222, 83.77%) had not previously participated in clinical trials. Table 1 presents the detailed information.

Illness uncertainty in patients with cancer participating in clinical trials

Patients with cancer participating in clinical trials reported an overall illness uncertainty score of (40.63 ± 10.12), indicating a moderately low level of uncertainty. The mean scores for the dimensions of Lack of clarity, Ambiguity, and Unpredictability ranged from 1.26 to 3.94. The five highest-scoring items for uncertainty were primarily within the Unpredictability and Ambiguity dimensions. Table 2 presents the detailed information.

Quality of informed consent in cancer clinical trials

The mean score of the overall understanding of informed consent content in clinical trials involving patients with cancer was (3.30 ± 1.20), indicating that the quality of informed consent was at a moderate level. Patients scored above four points on the items "The fact that participation in the clinical trial is voluntary." and "Which of these treatments and procedures are experimental." reflecting a strong understanding of the voluntary and experimental nature of the trial. However, patients demonstrated limited understanding of informed consent content, including Alternatives, Confidentiality, Compensation, trial purpose, and trial procedures. The entry scores for these items were lower than three points. Table 3 presents the detailed information.

Association between the quality of informed consent and illness uncertainty in patients with cancer participating in clinical trials

Pearson correlation analysis revealed a negative correlation between patients' understanding of the "Foreseeable risks or discomforts" element of informed consent content and the total illness uncertainty score ($P < 0.05$). A negative correlation was observed between Patients' understanding of all elements of informed consent and the "Lack of clarity" dimension of illness uncertainty ($P < 0.05$). Table 4 presents the details.

Analysis of the factors influencing illness uncertainty in cancer clinical trials

Univariate analysis of factors influencing illness uncertainty in cancer clinical trial participants

One-way analysis of variance and t test were used to examine the potential factors influencing illness uncertainty and its dimension. The results indicated that factors such as health insurance payment models, long-term residence, whether patients were treated for the first time at our hospital, the phase of the clinical trial, and the relationship between primary caregivers and patients significantly influenced the overall level of illness uncertainty, with statistically significant ($P < 0.05$). Above influencing factors, except for long-term residence on the "Ambiguity" dimension of illness uncertainty were statistically significant ($P < 0.05$). The "Lack of clarity" dimension of illness uncertainty was significantly influenced by participants' age, education, occupational status, health insurance payment models, long-term residence, main caregiver, main information source, and the phase of the clinical trial ($P < 0.05$). The

Table 1
General information of participants and univariate analysis of the level of illness uncertainty and dimensions ($N = 265$).

Items	Grouping	*n* (%)	Total score of MUIS			Lack of clarity dimension			Ambiguity dimension			Unpredictable dimension		
			Mean ± SD	*t/F*	*P*	Mean ± SD	*t/F*	*P*	Mean ± SD	*t/F*	*P*	Mean ± SD	*t/F*	*P*
Age, years	< 45	73 (27.55)	39.48 ± 8.81	1.018	0.363	10.48 ± 2.95	4.778	0.009	14.21 ± 4.13	1.491	0.227	14.79 ± 3.35	0.941	0.392
	45–65	151 (56.98)	40.74 ± 10.04			11.26 ± 3.46			15.33 ± 5.05			14.15 ± 3.45		
	> 65	41 (15.47)	42.27 ± 12.37			12.59 ± 4.39			15.54 ± 5.97			14.15 ± 3.39		
Gender	Male	140 (52.83)	40.28 ± 10.54	0.357	0.550	11.09 ± 3.52	0.631	0.428	15.04 ± 5.29	0.003	0.953	14.16 ± 3.51	0.746	0.388
	Female	125 (47.17)	41.02 ± 9.65			11.43 ± 3.57			15.07 ± 4.63			14.52 ± 3.30		
Education	Primary school or less	26 (9.81)	42.38 ± 12.19	0.500	0.776	12.81 ± 4.57	2.720	0.020	15.23 ± 5.67	0.294	0.916	14.35 ± 3.14	0.921	0.468
	Junior high school	65 (24.53)	39.82 ± 10.16			11.35 ± 3.64			14.74 ± 4.99			13.72 ± 3.43		
	Senior high school/ Technical secondary school	65 (24.53)	41.49 ± 10.86			11.88 ± 3.70			15.46 ± 5.34			14.15 ± 3.55		
	Junior college	40 (15.09)	39.17 ± 9.14			10.23 ± 2.71			14.43 ± 4.57			14.53 ± 3.70		
	Undergraduate college	62 (23.40)	40.81 ± 9.27			10.61 ± 3.08			15.27 ± 4.68			14.92 ± 3.15		
	Postgraduate or more	7 (2.64)	40.43 ± 8.34			10.14 ± 2.41			15.14 ± 4.81			15.14 ± 3.58		
Employment status	Full-time job	67 (25.28)	38.72 ± 8.34	1.296	0.276	10.10 ± 2.79	3.799	0.011	14.19 ± 4.19	1.151	0.329	14.42 ± 3.12	0.288	0.834
	Retire/take time off	96 (36.23)	40.69 ± 10.37			11.30 ± 3.61			15.26 ± 5.13			14.13 ± 3.44		
	Sick leave/retirement	25 (9.43)	42.16 ± 11.96			11.88 ± 3.84			16.16 ± 5.60			14.12 ± 4.23		
	No fixed job	77 (29.06)	41.73 ± 10.51			11.97 ± 3.74			15.18 ± 5.19			14.57 ± 3.37		
Marital status	Unmarried	26 (9.81)	41.19 ± 9.65	0.082	0.970	10.88 ± 3.15	0.244	0.866	14.96 ± 4.25	0.005	1.000	15.35 ± 3.91	2.049	0.107
	Married	228 (86.04)	40.61 ± 10.07			11.28 ± 3.55			15.06 ± 5.04			14.27 ± 3.30		
	Divorced	6 (2.26)	40.33 ± 10.39			10.83 ± 3.06			15.00 ± 4.98			14.50 ± 3.67		
	Bereft of one's spouse	5 (1.89)	38.80 ± 16.65			12.20 ± 5.98			15.20 ± 7.33			11.40 ± 4.51		
Monthly household income, RMB	< 2000	43 (16.23)	41.98 ± 9.36	0.642	0.588	11.79 ± 3.67	2.021	0.111	15.51 ± 4.51	0.379	0.768	14.67 ± 3.17	0.176	0.913
	2001–5000	108 (40.75)	40.80 ± 10.19			11.60 ± 3.68			14.92 ± 4.92			14.28 ± 3.54		
	5001–10,000	85 (32.08)	40.41 ± 10.71			10.93 ± 3.33			15.24 ± 5.42			14.25 ± 3.49		
	> 10,000	29 (10.94)	38.66 ± 9.26			10.07 ± 3.22			14.34 ± 4.65			14.24 ± 3.17		
Models of health insurance payment	Self-paying	20 (7.55)	35.65 ± 7.07	4.558	0.001	9.45 ± 2.33	4.666	< 0.001	12.55 ± 3.58	3.514	0.004	13.65 ± 3.22	2.274	0.048
	Non-local insurance	145 (54.72)	42.97 ± 10.31			11.96 ± 3.73			16.06 ± 5.20			14.94 ± 3.34		
	Beijing Medical insurance	56 (21.13)	37.07 ± 8.56			9.91 ± 2.78			13.68 ± 4.14			13.48 ± 3.37		
	Free medical service	6 (2.26)	36.50 ± 5.51			9.33 ± 1.75			13.67 ± 3.72			13.50 ± 3.15		
	New rural cooperative medical insurance	36 (13.58)	40.58 ± 11.23			11.83 ± 3.75			14.94 ± 5.29			13.81 ± 3.64		
	Other	2 (0.75)	34.00 ± 1.41			10.50 ± 0.71			11.50 ± 0.71			12.00 ± 1.41		
Long-term residence	In Beijing	75 (28.30)	38.21 ± 8.93	6.081	0.014	10.32 ± 2.97	7.376	0.007	14.20 ± 4.42	3.092	0.080	13.69 ± 3.17	3.660	0.057
	Out of Beijing	190 (71.70)	41.58 ± 10.42			11.62 ± 3.68			15.39 ± 5.16			14.58 ± 3.48		
Primary caregiver	Spouse	143 (53.96)	39.85 ± 9.89	3.954	0.009	10.92 ± 3.37	8.795	< 0.001	14.81 ± 4.93	4.190	0.006	14.11 ± 3.36	0.530	0.662
	Parents	23 (8.68)	39.74 ± 8.28			10.3 ± 2.79			14.57 ± 4.04			14.87 ± 3.40		
	Children	59 (22.26)	44.44 ± 12.00			13.17 ± 4.13			16.86 ± 5.88			14.41 ± 3.59		
	Other	40 (15.09)	38.33 ± 7.36			10.13 ± 2.46			13.53 ± 3.31			14.68 ± 3.39		
Main information source	Family member	75 (28.30)	42.61 ± 11.55	1.599	0.190	12.48 ± 4.19	4.381	0.005	15.75 ± 5.50	0.852	0.467	14.39 ± 3.44	0.937	0.423
	Doctors	139 (52.45)	40.12 ± 9.68			10.76 ± 3.19			14.91 ± 4.79			14.45 ± 3.53		
	CRC	48 (18.11)	39.31 ± 8.92			10.77 ± 3.06			14.48 ± 4.74			14.06 ± 3.01		
	Other	3 (1.13)	35.67 ± 1.53			11.00 ± 1.73			13.33 ± 3.22			11.33 ± 2.89		
Disease diagnosis stage	I	8 (3.02)	38.50 ± 8.78	1.272	0.284	10.88 ± 1.36	0.177	0.912	13.38 ± 3.82	1.655	0.177	14.25 ± 4.27	1.573	0.196
	II	25 (9.43)	42.16 ± 9.47			11.20 ± 3.34			15.64 ± 4.46			15.32 ± 3.07		
	III	38 (14.34)	38.00 ± 7.94			10.92 ± 2.78			13.63 ± 3.74			13.45 ± 3.19		
	IV	194 (73.21)	41.04 ± 10.59			11.34 ± 3.77			15.32 ± 5.25			14.38 ± 3.44		
Whether first treatment at our hospital	Yes	26 (9.81)	44.92 ± 11.20	5.272	0.022	12.46 ± 4.13	3.412	0.066	17.50 ± 5.09	7.123	0.008	14.96 ± 3.57	0.993	0.320
	No	239 (90.19)	40.16 ± 9.91			11.12 ± 3.46			14.79 ± 4.91			14.26 ± 3.39		
Whether previous participated in clinical trials	Yes	43 (16.23)	40.67 ± 10.27	0.018	0.894	11.38 ± 3.63	1.962	0.163	15.10 ± 5.07	0.142	0.707	14.18 ± 3.36	2.595	0.108
	No	222 (83.77)	40.44 ± 9.44			10.56 ± 2.96			14.79 ± 4.54			15.09 ± 3.60		
Phase of clinical trials	I	58 (21.89)	45.98 ± 10.27	12.651	< 0.001	12.86 ± 4.02	8.608	< 0.001	17.48 ± 5.28	11.616	< 0.001	15.64 ± 3.21	6.053	0.003
	II	97 (36.60)	40.31 ± 9.43			11.04 ± 2.92			15.09 ± 4.65			14.18 ± 3.62		
	III	110 (41.51)	38.09 ± 9.63			10.58 ± 3.54			13.74 ± 4.64			13.77 ± 3.17		

MUIS, Mishel Uncertainty in Illness Scale; CRC, Clinical Research Coordinator.

Table 2
Illness uncertainty in patients with cancer participating in clinical trials ($N = 265$).

Dimension	Scoring range	Total score (Mean ± SD)	Mean score (Mean ± SD)
Lack of clarity	7–35	11.25 ± 3.54	1.61 ± 0.51
Ambiguity	8–40	15.05 ± 4.98	1.88 ± 0.62
I do not know whether my current treatment is working for me*	1–5	–	2.60 ± 1.26
I have been getting better and worse than I expected*	1–5	–	2.52 ± 1.20
Unpredictability	5–25	14.33 ± 3.41	2.87 ± 0.68
I do not know how long the disease (or treatment) will last*	1–5	–	3.94 ± 1.04
I am not sure how my disease is going to progress*	1–5	–	3.86 ± 1.09
I do not know what kind of pain I am going to suffer*	1–5	–	2.65 ± 1.21
MUIS	20–100	40.63 ± 10.12	2.03 ± 0.51

Only the top five entries in the disease uncertainty score are presented in the table (*).
MUIS, Mishel Uncertainty in Illness Scale.

"Unpredictability" dimension of illness uncertainty was significantly influenced by health insurance payment models and the phase of the clinical trial ($P < 0.05$). Table 1 presents the detailed information.

Multivariate regression analysis of factors influencing illness uncertainty in cancer clinical trial participants

The total score of illness uncertainty and its dimension scores in the cancer clinical trial participants were used as dependent variables, combined with a one-way analysis of variance and correlation analysis. We selected patients' age, education, employment status, health insurance payment models, main information source, long-term residence, whether the treatment was the first at our hospital, phase of the clinical trial, relationship with the primary caregiver, and the eight elements of QuIC as independent variables to develop a multiple linear regression model. Table 5 shows the assignment of categorical variables and the setting of dummy variables.

The results indicated that all four regression models assessing the level of illness uncertainty and its three dimensions were statistically significant ($P < 0.05$). The health insurance payment models and the phase of the clinical trial affected the overall level of illness uncertainty. The phase of the clinical trial in which patients participated, the correlation between primary caregivers and patients, and the "Foreseeable risks or discomforts" element in the QuIC affected the score of the "Lack of clarity" dimension of illness uncertainty. The "Ambiguity" dimension score of illness uncertainty was influenced by whether it was the patient's first treatment at our hospital and the phase of the clinical trial. In addition, the phase of the clinical trial affected the score of the "Unpredictability" dimension of illness uncertainty. The "Foreseeable risks or discomforts" element of informed consent exhibited a negative correlation with the "Lack of clarity" dimension of illness uncertainty ($\beta = -0.152$, $P < 0.05$). As patients receive more information about the risks and discomforts associated with clinical trials, their need for clarification decreases, thereby reducing the level of illness uncertainty related to lack of clarity. Table 6 presents the details.

Discussion

Cancer clinical trial participants have a moderately low level of illness uncertainty

The total illness uncertainty score for patients with cancer participating in clinical trials was (40.63 ± 10.12), indicating a moderately low level of uncertainty. The scores were comparable to those reported by Kim et al. for patients with cancer participating in clinical trials in Korea (41.70 ± 10.00),[19] and were lower than the scores of patients with cancer who were not involved in clinical trials.[32] Given that 90.19% of the patients in this group had previously received treatment at the hospital, they were more familiar with the hospital environment, medical staff, and standard procedures. In addition, participation in clinical trials is often chosen after conventional cancer treatments have shown poor results or failed, which means patients are typically psychologically prepared for this option. Furthermore, during the survey, patients involved in the clinical trial reported that communication and interaction with other participants enrolled in the same clinical trial allowed them to share experiences, which helped alleviate their sense of uncertainty. However, patients continue to experience significant uncertainty in some aspects of the clinical trial process. Among the three dimensions of illness uncertainty, the severity in descending order was "Ambiguity" (15.05 ± 4.98), "Unpredictability" (14.33 ± 3.41), and "Lack of clarity" (11.25 ± 3.54). The top five items contributing to illness uncertainty are primarily derived from the Ambiguity and Unpredictability dimension. The Ambiguity dimension primarily reflects patients' perception of their disease and

Table 3
Scores for all elements of QuIC in patients with cancer participating in clinical trials ($N = 265$).

Items	Mean ± SD
Alternatives	2.61 ± 1.59
The alternatives to participation in the clinical trial.	
Confidentiality	2.78 ± 1.58
The effect of the clinical trial on the confidentiality of your medical records.	
Compensation	2.96 ± 1.61
Who will pay for treatment if you are injured or become ill because of participation in this clinical trial.	
Key elements of clinical trials	3.29 ± 1.27
The fact that your treatment involves research.	2.97 ± 1.57
How long you will be in the clinical trial.	2.99 ± 1.59
The treatments and procedures you will undergo.	3.16 ± 1.58
What the researchers are trying to find out in the clinical trial.	3.29 ± 1.56
Which of these treatments and procedures are experimental.	4.00 ± 1.28
Benefits of clinical trials	3.40 ± 1.39
The possible benefits to you of participating in the clinical trial.	3.21 ± 1.56
How your participation in this clinical trial may benefit future patients.	3.59 ± 1.44
Foreseeable risks or discomforts	3.41 ± 1.51
The possible risks and discomforts of participating in the clinical trial.	
Contacts	3.66 ± 1.52
Whom you should contact if you have questions or concerns about the clinical trial.	
Voluntary of participation	4.25 ± 1.17
The fact that participation in the clinical trial is voluntary.	
Average score of items (except self-evaluation)	3.30 ± 1.20

Table 4
Association between the quality of informed consent and illness uncertainty in patients with cancer participating in clinical trials (*r*).

Items	Total score of MUIS	Dimension 1: Lack of clarity	Dimension 2: Ambiguity	Dimension 3: Unpredictability
Key elements of clinical trials	−0.103	−0.216[a]	−0.039	−0.024
Foreseeable risks or discomforts	−0.136[b]	−0.255[a]	−0.076	−0.029
Benefits of clinical trials	−0.066	−0.193[a]	0.013	−0.015
Alternatives	−0.090	−0.175[a]	−0.056	−0.005
Confidentiality	−0.100	−0.213[a]	−0.053	0.002
Compensation	−0.043	−0.155[b]	0.024	−0.003
Contacts	−0.039	−0.149[b]	0.018	0.012
Voluntary of participation	−0.066	−0.169[a]	−0.034	0.030
Self-evaluation	0.065	0.053	0.071	0.035
Average score of items (except self-evaluation)	−0.102	−0.232[a]	−0.034	−0.102

[a] $P < 0.01$, [b] $P < 0.05$. MUIS, Mishel Uncertainty in Illness Scale.

health status, whereas the Unpredictability dimension captures patients' uncertainty regarding treatment and prognosis. Most patients participating in the new drug clinical trials had advanced-stage tumors, with disease progression and poor health. In addition, since the clinical trial drugs had not yet been widely used in clinical practice and their efficacy was uncertain, patients experienced a stronger sense of uncertainty.

Cancer clinical trial participants have a moderate level of informed consent quality

The average understanding of the informed consent content by patients with cancer participating in the clinical trial was (3.30 ± 1.20), indicating that the quality of informed consent was moderate. Although patients demonstrated a clear understanding of the voluntary nature and therapeutic purpose of clinical trials (average score above 4), there was a notable lack of understanding regarding key elements such as trial alternatives, confidentiality, compensation mechanism, and other essential elements of clinical trials (average score below 3). This lack of understanding may be attributed to several factors. First, there may be flaws in the design or expression of informed consent. A survey on the quality of informed consent in China found that in clinical practice, alternative treatment options are often not adequately disclosed to clinical trial participants.[33] Therefore, many patients believe that the current trial protocol is the only effective treatment for their condition. Second, insufficient informed consent contributes significantly to patients' lack of understanding.[33] Researchers frequently avoid discussing complex or sensitive topics, such as compensation mechanisms and specific trial procedures, often providing limited explanations. This leads to patients having an incomplete understanding of these crucial aspects of the trial. Furthermore, patients with cancer focus more on the potential treatment outcomes during the trial, often paying less attention to the confidentiality of the trial and its purpose, leading to a lack of understanding of these key elements of clinical trials. During the informed consent process, medical staff should provide a thorough and detailed explanation of essential information, such as the nature, significance, and process of the clinical trial. Furthermore, medical staff should address sensitive topics such as trial efficacy and compensation mechanisms, with objectivity and honesty. This approach will enhance the quality of informed consent and

Table 5
Assignment of categorical variables and the setting of dummy variables.

Independent variables	Static single assignment form
Education	Education (1-Junior high school): Primary school or less = 0, Junior high school = 1, Senior high school/Technical secondary school = 0, Junior college = 0, Undergraduate college = 0, Postgraduate or more = 0 Education (2-Senior high school/Technical secondary school): Primary school or less = 0, Junior high school = 0, Senior high school/Technical secondary school = 1, Junior college = 0, Undergraduate college = 0, Postgraduate or more = 0 Education (3-Junior college): Primary school or less = 0, Junior high school = 0, Senior high school/Technical secondary school = 0, Junior college = 1, Undergraduate college = 0, Postgraduate or more = 0 Education (4-Undergraduate college): Primary school or less = 0, Junior high school = 0, Senior high school/Technical secondary school = 0, Junior college = 0, Undergraduate college = 1, Postgraduate or more = 0 Education (5-Postgraduate or more): Primary school or less = 0, Junior high school = 0, Senior high school/Technical secondary school = 0, Junior college = 0, Undergraduate college = 0, Postgraduate or more = 1
Employment status	Employment status (1-Retire/take time off): Full-time job = 0, Retire/take time off = 1, Sick leave/retirement = 0, No fixed job = 0 Employment status (2-Sick leave/retirement): Full-time job = 0, Retire/take time off = 0, Sick leave/retirement = 1, No fixed job = 0 Employment status (3-No fixed job): Full-time job = 0, Retire/take time off = 0, Sick leave/retirement = 0, No fixed job = 1
Long-term residence	In Beijing = 0, out of Beijing = 1
Health insurance payment models	Health insurance payment models: (1-Non-local insurance): Beijing Medical insurance = 0, Self-paying = 0, Non-local insurance = 1, Free medical service = 0, New rural cooperative medical insurance = 0, Other = 0 Health insurance payment models: (2-Beijing medical Insurance): Beijing Medical insurance = 1, Self-paying = 0, Non-local insurance = 0, Free medical service = 0, New rural cooperative medical insurance = 0, Other = 0 Health insurance payment models: (3-Free medical service): Beijing Medical insurance = 0, Self-paying = 0, Non-local insurance = 0, Free medical service = 1, New rural cooperative medical insurance = 0, Other = 0 Health insurance payment models: (4-New rural cooperative medical insurance): Beijing Medical insurance = 0, Self-paying = 0, Non-local insurance = 1, Free medical service = 0, New rural cooperative medical insurance = 1, Other = 0 Health insurance payment models: (5-Other): Beijing Medical Insurance = 0, Self-paying = 0, Non-local insurance = 0, Free medical service = 0, New rural cooperative medical insurance = 0, Other = 1
Primary caregiver	Primary caregiver (1-Parents): Spouse = 0, Parents = 1, Children = 0, Other = 0 Primary caregiver (2-children): Spouse = 0, Parents = 0, Children = 1, Other = 0 Primary caregiver (3-other): Spouse = 0, Parents = 0, Children = 0, Other = 1
Main information source	Main information source (1-doctor): Doctor = 1, Family member = 0, CRC = 0, Other = 0 Main information source (2-CRC): Doctor = 0, Family member = 0, CRC = 1, Other = 0 Main information source (3-other): Doctor = 0, Family member = 0, CRC = 0, Other = 1
Whether first treatment at our hospital	No = 0, Yes = 1

CRC, Clinical Research Coordinator.

Table 6
Multiple regression analysis of illness uncertainty in cancer clinical trial participants.

Items	Grouping	Total score of MUIS			Lack of clarity			Ambiguity			Unpredictability		
		β	*t*	*P*	*β*	*t*	*P*	*β*	*t*	*P*	*β*	*t*	*P*
Age	–	–	–	–	−0.083	−1.039	0.300	–	–	–	–	–	–
Education	Primary school or less	–	–	–	1.000			–	–	–	–	–	–
	Junior high school	–	–	–	−0.033	−0.328	0.743	–	–	–	–	–	–
	Senior high school/ Technical secondary school	–	–	–	0.134	1.206	0.229	–	–	–	–	–	–
	Junior college	–	–	–	−0.021	−0.196	0.845	–	–	–	–	–	–
	Undergraduate college	–	–	–	−0.022	−0.182	0.856	–	–	–	–	–	–
	Postgraduate or more	–	–	–	−0.067	−0.966	0.335	–	–	–	–	–	–
Employment status	Full-time job	–	–	–	1.000			–	–	–	–	–	–
	Retire/take time off	–	–	–	−0.048	−0.617	0.538	–	–	–	–	–	–
	Sick leave/retirement	–	–	–	0.070	1.128	0.260	–	–	–	–	–	–
	No fixed job	–	–	–	0.025	0.298	0.766	–	–	–	–	–	–
Health insurance payment models	Self-paying	1.000	–	–	1.000	–	–	1.000	–	–	1.000	–	–
	Non-local insurance	0.231	2.068	0.040	0.204	1.816	0.071	0.200	1.810	0.072	0.217	1.878	0.062
	Beijing Medical insurance	−0.023	−0.229	0.819	−0.005	−0.050	0.960	−0.015	−0.154	0.878	0.006	0.063	0.950
	Free medical service	−0.038	−0.597	0.551	−0.047	−0.714	0.476	−0.033	−0.515	0.607	−0.007	−0.097	0.922
	New rural cooperative medical insurance	0.102	1.156	0.249	0.116	1.259	0.209	0.102	1.167	0.244	0.031	0.329	0.743
	Other	−0.003	−0.061	0.952	0.019	0.331	0.741	−0.008	−0.145	0.885	−0.031	−0.491	0.624
Long-term residence	In Beijing	1.000			1.000	–	–	–	–	–	–	–	–
	Out of Beijing	0.021	0.238	0.812	0.015	0.164	0.870	–	–	–	–	–	–
Primary caregiver	Spouse	1.000	–	–	1.000	–	–	1.000			–	–	–
	Parents	0.045	0.716	0.475	0.022	0.338	0.735	0.051	0.810	0.419	–	–	–
	Children	0.116	1.966	0.050	0.152	2.366	0.019	0.097	1.653	0.100	–	–	–
	Other	0.036	0.604	0.546	0.032	0.537	0.592	−0.005	−0.092	0.927	–	–	–
Main information source	Family member	–	–	–	1.000	–	–	–	–	–	–	–	–
	Doctor	–	–	–	−0.058	−0.725	0.469	–	–	–	–	–	–
	CRC	–	–	–	−0.056	−0.757	0.450	–	–	–	–	–	–
	Other	–	–	–	−0.081	−1.457	0.146	–	–	–	–	–	–
Whether first treatment at our hospital	–	−0.093	−1.685	0.093	–	–	–	−0.113	−2.041	0.042	–	–	–
Phase of clinical trial	–	−0.242	−4.069	< 0.001	−0.202	−3.332	0.001	−0.205	−3.463	0.001	−0.201	−3.359	0.001
Foreseeable risks or discomforts	–	−0.075	−1.256	0.210	−0.152	−2.355	0.019	–	–	–	–	–	–
R^2		0.268			0.342			0.285			0.082		
ΔR^2		0.224			0.267			0.239			0.061		
F		6.086			4.566			6.171			3.851		
P		< 0.001			< 0.001			< 0.001			0.001		

MUIS, Mishel Uncertainty in Illness Scale.

ensure that patients can make informed based on a full understanding of the clinical trial.

Association between quality of informed consent and illness uncertainty in cancer clinical trial participants

The results of this study indicated that the understanding of the "Foreseeable risks or discomforts" in the elements of informed consent of patients with cancer participating in clinical trials was negatively associated with the total score of illness uncertainty ($P < 0.05$). When patients did not clearly understand the risks and discomforts associated with clinical trials, their experience of illness uncertainty increased. Most patients were enrolled in phase II and phase III clinical trials (78.11%). The primary aim of clinical trials is to evaluate the effectiveness and safety of new drugs. However, the potential risks and discomforts associated with these trials were somewhat unpredictable, including treatment-related side effects, complications, and even life-threatening disease progression resulting from treatment failure. These potential immediate health risks undoubtedly contribute to patients' sense of uncertainty.[33] Therefore, when providing informed consent, medical staff should thoroughly research the potential risks of new drugs and provide patients with clear, detailed information, avoiding vague or generalized statements. In addition, it is crucial not only to provide comprehensive information about the risks but also to reassure patients that medical staff are well-prepared with effective strategies to manage these risks and discomforts. This approach helps foster patient understanding and provides them with a sense of reassurance and security.

Correlation analysis revealed a negative relationship between the "Lack of clarity" dimension of illness uncertainty and patients' understanding of all elements of the QuIC, including Key elements of clinical trials, Foreseeable risks or discomforts, Benefits of clinical trials, Alternatives, Confidentiality, Compensation, Contacts, and Voluntary of Participation ($P < 0.05$). "Lack of clarity" is the uncertainty participants experience about their illness due to insufficient information and explanations provided by health care professionals. In the context of CCT, patients' information needs are primarily focused on the relevant information of clinical trials, and the quality of informed consent reflects their level of understanding of this information.[34,35] These findings highlight the reciprocal relationship between these factors. Limited information and ambiguous explanations from health care providers contribute to patients' inadequate understanding of clinical trials, and their poor understanding of informed consent content increases their sense of illness uncertainty, exacerbating psychological stress and emotional distress. Therefore, effective strategies to enhance the quality of informed consent are essential to alleviate patient illness uncertainty. However, this task can be particularly challenging for patients with cancer participating in

new drug clinical trials. In the unique context of CCT, patients' cognitive abilities may be compromised due to disease progression, adverse side effects, and accompanying psychological stress. These complex factors could influence the potential correlation between quality of informed consent and illness uncertainty.[36] There may be limitations in the informed consent process, such as excessive terminology or insufficient communication between participants and researchers. These issues may lead participants to sign the informed consent form based on trust or the desire for treatment, making it difficult to establish a direct relationship between informed consent and illness uncertainty in practice.[37] Therefore, enhancing quality of informed consent is essential for effectively reducing the illness uncertainty of patients.

Numerous studies have investigated strategies to enhance the quality of informed consent. Some studies have proposed that informed consent documents should be simplified and made more accessible to present research objectives, procedures, and risks in a clear and concise manner.[38,39] This approach helps prevent information overload and ensures that patients with varying levels of literacy and comprehension can fully grasp the content. Other studies have implemented training programs for medical staff based on ethics, language, psychological principles, and communication techniques.[38,40,41] These initiatives aim to enhance the understanding of informed consent, improve their awareness of effective medical disclosure, and refine their communication skills, thereby fostering stronger interactions during the informed consent process. It is important to thoroughly assess patients' communication skills, cultural backgrounds, and capacity for understanding while avoiding professional terms and using simple, clear language during interactions with them. Furthermore, it is important to emphasize that during the informed consent process, patients should be encouraged to participate in shared decision-making and given ample time to consider their options. A dynamic assessment should be conducted to evaluate the participants' cognition and understanding of the informed consent content, ensuring that any psychological discomfort, such as feelings of rush, pressure, disrespect, or exploitation, is avoided.[38,39] Furthermore, some researchers have investigated the use of assistive technologies in interpreting informed consent. Multimedia information delivery formats can ensure consistent presentation of information while providing a more personalized experience for patients.[39,42] For instance, using visuals such as pictures, flowcharts, videos, short messages, recordings, and electronic resources that allow patients to ask questions and access relevant information, can provide continuous support and enhance the clarity of the research content. In 2017, the European Commission addressed the need to enhance the informed consent process and its readability by launching the "i-CONSENT" project, aimed at improving informed consent guidelines, with a focus on vulnerable populations and a gender perspective.[43] The publication "Guidelines for Tailoring the Informed Consent Process in Clinical Studies" was subsequently updated based on the i-CONSENT, incorporating more detailed guidelines for creating evidence-based patient information materials.[44,45] The guidelines also offer a set of user-friendly instructions and tools designed to highlight the significance of all elements of the informed consent process and provide recommendations for its effective implementation. The above measures are valuable and should be adapted and implemented in clinical practice, considering specific clinical situations, to enhance the quality of informed consent of patients. These approaches aim to reduce the illness uncertainty of patients during clinical trials and help them better manage the challenges associated with new drug clinical trials.

Factors affecting illness uncertainty in cancer clinical trial participants

The results indicated that patients with medical insurance in other places who participated in CCT experienced higher levels of illness uncertainty. This may be due to different medical insurance policies across provinces, which result in different reimbursement ratios and can create increased financial pressure for patients. Furthermore, patients seeking medical treatment in different locations may not be familiar with the local medical treatment process. The costs associated with CCT can involve various factors, such as sponsors, which may lead to uncertainties regarding payment and reimbursement for treatment. The accumulation of doubts further intensified the illness uncertainty of the participants.[28,46] Consequently, when patients with non-local medical insurance seek treatment, the relevant hospital departments should enhance the communication and clarification of the non-local medical treatment policy and improve the participants' understanding of the medical insurance policy and the local medical treatment process. This can help reduce the illness uncertainty caused by gaps in medical insurance information. Patients who participated in earlier phases of clinical trials experienced higher levels of illness uncertainty. Phase I clinical trials are the first step in the new drug clinical trials, which aim to assess the safety and tolerability of the drugs. These trials involve more uncertainties regarding the efficacy and potential side effects of the drugs compared to Phase II and III clinical trials.[24] Thus, for Phase I clinical trial participants, researchers and medical staff should prioritize addressing their psychological and information needs through personalized psychological and detailed information support to help them navigate the uncertainty associated with their illness more effectively.

The results indicated a negative correlation between the "Foreseeable risks or discomforts" element of informed consent and the "Lack of clarity" dimension of illness uncertainty. The results of the correlation analysis further demonstrate that among the eight elements of informed consent, "Foreseeable risks or discomforts" was the primary factor influencing the illness uncertainty of patients, particularly in the "Lack of clarity" dimension. The more patients are informed about the risks and discomforts associated with clinical trials, the less clarification they require, which may further reduce their illness uncertainty. Thus, during the informed consent process, researchers and medical staff should focus on providing clear and thorough explanations to patients about the potential risks and discomforts of participating in clinical trials. This can help reduce the illness uncertainty caused by insufficient information. In addition, patients whose primary caregiver is a child tend to have higher scores on the "Lack of clarity" dimension than those whose main caregiver is a spouse. Due to filial piety, children often take on the role of communicating with doctors about their disease and making treatment decisions, fearing that discussing the patient's health or the impact of the disease might cause undue distress. In their interactions with patients, caregivers may downplay or oversimplify the patient's condition and treatment. Thus, patients receive incomplete information, which requires further clarification to reduce the illness uncertainty caused by insufficient information. Consequently, while respecting the family dynamics of patients, researchers and medical staff should emphasize the importance of shared decision-making, address the essential information needs of patients, and promptly resolve any uncertainties they may have.

The results of this study indicated that patients participating in the cancer clinical trial treated at our hospital for the first time had higher "Ambiguity" dimension scores. Patients may be diagnosed for the first time, transitioning from healthy individuals to patients with cancer, possibly experiencing denial or anger. In addition, their first visit to our hospital may lead to a mistrust of the medical quality. Therefore, patients develop a vague understanding of the causes, nature, and treatment of their diseases, which contributes to an increased sense of illness uncertainty. Thus, researchers and medical staff should focus on patients seeking treatment for the first time, paying attention to their psychological state and understanding of the diseases. They should provide personalized psychological support, offer life advice, and educate patients about their conditions and treatments to clarify misconceptions, helping them better cope with the uncertainty of their illness.

Implications for nursing practice and research

This study focused on a unique group of patients with cancer participating in new drug clinical trials and examined the correlation between

the quality of informed consent and their level of illness uncertainty. The illness uncertainty among patients with cancer participating in clinical trials was slightly low, and the quality of informed consent was at a moderate level. A negative correlation was observed between the two factors. These results contribute to filling the gap in quality of informed consent research on clinical trials and illness uncertainty. In clinical practice, health care professionals should conduct a thorough assessment of the factors affecting quality of informed consent and develop targeted interventions, including the enhancement of medical staff's understanding and communication skills regarding informed consent, optimization of informed consent documents and processes, ensuring comprehensive disclosure of key information, employing suitable communication methods and interpretations, and providing continuous information support. Enhancing the quality of informed consent of patients with cancer participating in clinical trials can reduce their illness uncertainty and the psychological distress associated with the clinical trials. This improvement can also boost patient compliance and confidence, ultimately ensuring the successful progression of clinical trials.

Limitations

This study has several limitations. The cross-sectional design restricted our ability to monitor and fully understand the levels of illness uncertainty and the dynamic changes in influencing factors among patients with cancer participating in clinical trials at different stages. Due to limited information screening and tracking of outpatient patients with cancer participating in clinical trials, a convenient sampling approach was used with independent access to medical records to select inpatient participants. However, outpatients and patients who failed screening were excluded, potentially introducing selection bias. In addition, the sample was drawn from a single medical institution, which limits the generalizability of the findings. In the future, a multi-center longitudinal cohort study will be conducted with parallel control and self-before-after control to further investigate the factors influencing psychological distress, its trajectory, and care strategies for this unique population.

Conclusions

This study highlighted the importance of addressing illness uncertainty in patients with cancer participating in new drug clinical trials and emphasized the need to enhance the quality of informed consent in these trials. The understanding of some elements of informed consent by patients is associated with their feelings of illness uncertainty. The lower the perceived quality of informed consent , the more intense the feelings of illness uncertainty. Medical staff should be attentive to the illness uncertainty experienced by patients with cancer participating in clinical trials and acknowledge the current inadequacies in the quality of informed consent and its effect on the illness uncertainty of patients. Research nurses should leverage their expertise in health education and decision-making support to enhance the psychological well-being of cancer clinical trial participants and facilitate the implementation of effective management strategies.

CRediT authorship contribution statement

Sihan Kang: Conceptualization, Data curation, Writing – Original draft preparation. Jie Zhang: Data curation, Formal analysis, Data curation, Writing – Original draft preparation. Dong Pang: Conceptualization, Supervision. Hong Yang: Methodology, Data curation. Xiaohong Liu: Resources, Investigation, Data curation. Renxiu Guo: Resources, Investigation, Data curation. Yuhan Lu: Conceptualization, Formal analysis, Supervision, Writing – Reviewing and Editing. All authors had full access to all the data in the study, and the corresponding author had final responsibility for the decision to submit for publication. The corresponding author attests that all listed authors meet authorship criteria and that no others meeting the criteria have been omitted.

Ethics statement

This study was approved by the ethical review committee of Beijing Cancer Hospital (IRB No. 2023YJZ24) and was conducted in accordance with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards. All participants provided written informed consent.

Data availability statement

The data that support the findings of this study are available from the corresponding author, Prof. Yuhan Lu, upon reasonable request.

Declaration of generative AI and AI-assisted technologies in the writing process

No AI tools/services were used during the preparation of this work.

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