Asia-Pacific Journal of Oncology Nursing 10 (2023) 100265

Contents lists available at ScienceDirect

Asia-Pacific Journal of Oncology Nursing

journal homepage: www.apjon.org

Original Article

The mediating effect of shared decision-making in enhancing patient satisfaction with participation in cancer clinical trials

Wen-Wen Chang [a], Ming-Tzu Wu [b], Yun-Chen Chang [c,d], Wen-Yu Hu [a,e,*]

[a] School of Nursing, College of Medicine, National Taiwan University, Taipei, Taiwan
[b] PAREXEL International, Taipei, Taiwan
[c] School of Nursing and Graduate Institute of Nursing, China Medical University, Taichung, Taiwan
[d] Department of Nursing, China Medical University Hospital, Taichung, Taiwan
[e] Department of Nursing, National Taiwan University Hospital, College of Medicine, National Taiwan University, Taipei, Taiwan

ARTICLE INFO

Keywords:
Shared decision-making
Informed consent forms
Satisfaction with the decision
Cancer
Mediation model

ABSTRACT

Objective: The participation of patients with advanced cancer(s) in clinical trials is vital for new drug development. We aimed to investigate patients' decision-making processes and satisfaction with their decision (SWD) to participate; the study's purpose was to provide results that can help support high-quality research in clinical trials. In addition, we explored how shared decision-making (SDM) mediates the relationship between understanding informed consent forms and SWD to participate in a clinical trial.

Methods: A cross-sectional study was conducted. A purposive sample of 111 cancer patients was recruited, and they completed a questionnaire on demographic characteristics, SDM, and decision-making satisfaction to participate in a clinical trial. Correlation and mediation analyses were used.

Results: Participants aged under 65 years and with higher education reported high SWDs, and SDM significantly mediated the relationship between self-assessed understanding of informed consent forms and SWDs related to clinical trials.

Conclusions: SDM in patients with lung or liver cancer was a significant mediator between understanding the informed consent form and the patient's SWD. The higher the SWD level of participating in clinical trials, the better study team members' SDM involvement and the better the comprehension of informed consent forms. In addition, patients' age and education level should also be considered as influencing factors in SWD. This survey is the first in Taiwan to examine SDM in drug-related clinical trials. The study results provide evidence to support SDM in a clinical trial model and develop informed consent process policies in research facilities.

Introduction

Cancer is the leading cause of death in Taiwan, with lung and liver cell cancers ranked first and second, respectively.[1] According to the 2018 Taiwan Cancer Data Registry, the number of deaths from lung and liver cancers increased by 1.40% and 1.76%, respectively, compared to the previous year.[2] Undoubtedly, patients with advanced cancer encounter many third- or fourth-line drugs and clinical trial-drug treatments. Standard care may have limited efficacy in patients with metastasis or advanced cancer. Instead, new drug trials have been considered most frequently for patients with advanced cancer. On one hand, the drug's effectiveness could be satisfactory for the participants.[3] In addition, an increased trend in the probability of success of drug trials indicated the efficacy of oncology treatment.[4] However, the adverse events or risks associated with randomized clinical trials may cause hesitation or fear in the participants before they sign an informed consent form. Most patients' perspective on participating in a clinical trial was to contribute, but they also worried about the unexpected adverse outcome and the personal data disclosed.[5] Thus, the decision-making process in trials is complicated compared to the usual clinical setting. For example, the fixed schedule of visits written in the informed consent form and trial-related tests or images in cancer trials may be more complex than in a usual clinical setting. A clinical research nurse's job is to assist in explaining the procedure, which usually includes managing tests of blood or images or administering strictly new drugs followed by a protocol schedule.

On the other hand, the success rate of cancer drug development trials is less than 5%, according to one biostatistics report;[4] therefore, some individuals participate in trials for diverse reasons.[6–8] One study[9] indicated

* Corresponding author.
E-mail address: weyuhu@ntu.edu.tw (W.-Y. Hu).

https://doi.org/10.1016/j.apjon.2023.100265
Received 9 February 2023; Accepted 16 June 2023

that personal benefits, altruism, obtaining insights into new medical treatment developments, and trust in the clinical teams were among the factors that motivated participation in clinical trials. Participants were also more likely to collaborate with the physician conducting the research. Typically, participant recruitment for a clinical trial involves a physician's verbal invitation, and a clinical research nurse assists the participants in signing an informed consent form. However, the quality of the information process for patients participating in clinical trials is important and must be measured for patients' understanding; they must truly believe that they have been well-informed.[10] One study showed that even for patients who were satisfied overall with their participation in clinical trials, some were dissatisfied with certain aspects of trial participation after comparing prior expectations with subsequent evaluations.[11] Conversely, those who were less satisfied expressed regret after the trial.[12]

Literature review

One study indicated that tailored materials were helpful for participants to understand the clinical trials and had higher satisfaction scores with the decision to participate.[13] Tailored materials nowadays could be a written informed consent form. Therefore, ensuring that participants fully understand the content of the informed consent form during the consent process is essential as it may be associated with their satisfaction with trial participation.[14]

Nevertheless, to protect human rights, the entire process should be governed by the *Good Clinical Practice* rule,[15] which includes several steps. First, the physician provides patients with brief information about clinical trials. Second, the clinical research nurse must give the patient sufficient time and fully explain the risks and benefits of the trial in a patient-friendly language. Third, the investigator should thoroughly answer the patient's questions during the consent process. Finally, the study team must respect the patient's decision to either agree to sign a consent document or refuse to participate. Therefore, this recruitment process comprises 3 essential elements: forming an understanding based on adequate information provided by the investigator, having the ability to freely make decisions, and ensuring the voluntariness of consent or refusal.[16,17]

Shared decision-making (SDM), which involves collaboration between patients and their physicians to make treatment decisions that improve patient compliance, has been recommended in medical settings for decades.[18,19] However, previous studies[4,20,21] have mainly focused on the relationship between SDM and the treatment consent process in the clinical, non–informed consent SDM in the clinical trials context. One recommendation is to apply SDM in oncology settings, including explicit discussions of standard-of-care options or clinical trials for patients.[20] The researchers analyzed all providers' conversations with explicit patient recommendations for the Phase I trial. They found that most conversations followed the structure of the SDM process. Moreover, understanding the informed consent form was strongly associated with SDM when the oncologists communicated with the patients to enter the clinical trials.[22]

The number of clinical trials in different phases has been increasing in Taiwan. However, little research has examined the relationship between cancer patients, their SDM, satisfaction after deciding to participate in clinical trials, and their self-assessed understanding of consent documents in this process. Thus, this study explored the relationship between understanding informed consent forms, satisfaction with decisions (SWDs), and SDM in clinical trials of patients with lung or liver cancer in Taiwan. We hypothesized that SDM mediates the relationship between understanding informed consent and satisfaction with clinical trial participation.

Methods

Study design

For this cross-sectional study, we followed the Strengthening the Reporting of Observational Studies in Epidemiology reporting guidelines statement.

Study participants

Purposive sampling was used to recruit patients from the oncology outpatient department of a medical center in Northern Taiwan. We initially screened eligible patients with lung or liver cancer who had signed up for a drug treatment clinical trial 6 months prior. The inclusion criteria were as follows: (1) being aged $>$ 20 years and willing to participate in this study; (2) having a diagnosis of lung or liver cancer; and (3) having participated in a treatable clinical trial at least once, including a new drug(s). Those who refused to sign a consent form, had an acute infectious disease or mental disorder, or were restricted from another trial, were excluded.

The oncologists and clinical research nurses were invited to collaborate daily with a researcher to identify eligible patients in their outpatient visits for both lung and liver cancer clinical trials. A total of 125 patients were invited to participate in our survey. Each patient sat in a quiet room for about 15–20 min. We performed a power analysis for sample size based on regression using the online software G*Power 3, a flexible and widely used tool in social and behavioral studies.[23] The significance level of α was set at 0.05, the power was set at 0.8, and the effect size was considered medium at 0.3.

Research framework

We first reviewed recent literature to develop our conceptual framework (Fig. 1). One article stated that patients' higher SWD positively correlated with understanding the content of informed consent in the process.[24] Understanding the informed consent form was associated with SDM.[22] Other variables reported as potentially having a relationship with SWD were several patient demographic characteristics (sex, age, marital status, education, clinical trial experience, and SDM).[25,26]

Therefore, we examined participants' SWD based on the outcome variable, their understanding of the informed consent content. The participants rated their understanding of informed consent on a 5-point Likert scale (1, *no understanding* [understood 0%]; 2, *very little understanding* [$<$ 30%]; 3, *partial understanding* [30%–50%]; 4, *some understanding* [$>$ 50%]; and 5, *complete understanding* [90%–100%]).

Questionnaire development, SDM, SWD

We found that SDM and SWD questionnaires had been modified and used in clinical trials in the early 2000s. Thus, we obtained permission from the original authors for initial translation work for the SDM and SWD questionnaires into Chinese (Mandarin) to use as survey tools.

Shared decision-making

In the late 1990s, the SDM model gained increasing popularity in the medical context between physicians and oncology patients[27] to make behavior change decisions for treatment preference.[28] Thus, SDM was considered a process concept and a measurable outcome. In 2006, German scholars developed an initial SDM questionnaire to measure the

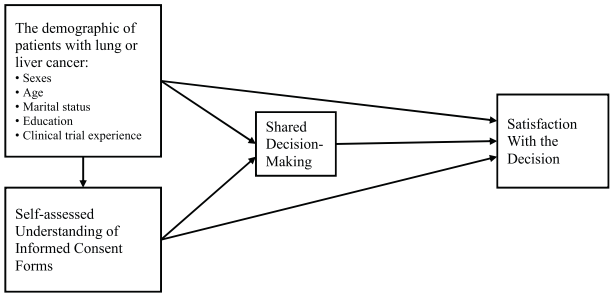

Fig. 1. A conceptual framework for patient satisfaction with clinical trial decision-making among patients with cancer and the factors influencing it.

process of SDM.[29] It was used in a few oncology studies,[30] mainly in breast cancer care. Good reliability and validity were indicated by the research outcome. In addition, it was a feasible and acceptable tool. Subsequently, the instrument was modified by incorporating new items and changing the scaling format to create a reliable and highly acceptable 9-item questionnaire (SDM-Q-9) with a Cronbach's alpha of 0.938.[31] The study used it for its high reliability and validity.

Satisfaction with decision

Research measuring patient satisfaction has become increasingly valuable over the past few decades.[11,12] The measurement of patient satisfaction with healthcare decisions was first proposed in 1996 when Holmes-Rovner et al. developed a 6-item scale to measure patient satisfaction regarding healthcare decisions, which they used first used in an intervention trial.[32] We translated the scale from English into Chinese (Mandarin), with adjustments for better semantics in the translated version. We deleted the words "treatment" and "possibility" in the second question and the word "belief" in the fourth. In addition, the scale items are rated on a 5-point scale instead of yes or no questions. Subsequently, the psychometric results demonstrated that patients with much stronger decision-making ability certainty had higher SWDs.

The translation process featured 3 steps: first, we obtained both authors' permissions; second, the author and one of the team members worked on the forward translation. Then, the original bilingual-language Chinese professionals translated it back into German and English; and finally, we asked the original authors to validate our back-translated version and finalize the Chinese (Mandarin) version. We retained the same number of questions on SDM and SWD and performed a content validity test on the Chinese (Mandarin) version. Similarly, we adopted the 9-item "Shared Decision-Making Questionnaire"[31] (Appendix A) and the 6-item "Patient Satisfaction with Clinical Trial Decisions"[32] (Appendix B) in the Chinese (Mandarin) version. The questionnaire had high internal consistency, with Cronbach's values ranging from 0.85 to 0.88.

Data analysis

To describe and test the variables that affect SWD, statistical analyses were conducted using SPSS® for Windows (Version 26) and the SPSS® PROCESS macro (Version 3.5). First, an independent-samples *t*-test was performed to identify differences among the subgroups of sex, age, marital status, education, clinical trial experience, and self-assessed understanding of informed consent forms, according to the dependent variables of "Comprehension of informed consent forms" and SWD scales. We then performed a multiple linear regression to examine the factors correlated with the dependent variable of the SWD scale. Subsequently, a bootstrap method (1000 samples) with 95% confidence intervals was applied. The mediation test was based on the simple Hayes model.[33]

We performed mediation analysis using SPSS® PROCESS mediation Model 1, and the SDM score was considered a mediator. Four steps were followed in this analysis: Step (1) "Self-assessed understanding of informed consent forms," which significantly predicted SWD in a regression equation (estimation and test path c); Step (2) "self-assessed understanding of informed consent forms," which significantly predicted SDM in a regression equation (estimation and test path a); Step (3) SDM, which significantly predicted SWD in the regression equation (estimation and test path b); and Step (4) The Sobel test evaluates the effect of the indirect path (from X through M to Y) to determine if it is statistically significant. The null hypothesis is H_0, stating that the indirect effect is 0, in which $a \times b = 0$. The coefficient c' represents the direct effect of "self-assessed understanding of informed consent forms" on SWD when controlling for the effect of SDM on SWD coefficient c denotes the total effect of "Understanding of the informed consent form" and SDM on SWD. Accordingly, the coefficients a, b, c, and c' were used to formulate the equation (Fig. 2) based on the approach proposed by Baron and Kenny.[23]

Ethical considerations

This study was approved by the Research Ethics Committee of the National Taiwan University Hospital (IRB No. 201101071RC). All participants provided written informed consent.

Results

Of the 125 eligible patients invited to respond to the face-to-face survey, data from 111 who fully completed the questionnaires were included for analysis (restriction rate = 6.4%).

Participant characteristics

Table 1 shows the participants' demographic information. The average age of the 111 participants was 60.1 years (range: 30–86 years; standard deviation: 12.54). Furthermore, 51.4% of the participants were women, and 78.4% were married. Notably, most participants had an educational level of above junior high school (68.4%). Two-thirds had participated in a clinical trial once. Only 4 participants reported having participated in more than 4 clinical trials. Most "Self-assessed Comprehension of Informed Consent Forms" scores indicated that patients had partial to complete understanding (Mean: 4.23, SD: 0.51).

SDM and SWD

Tables 1 and 2 display the mean scores of the independent coefficient *t*-test for SDM and SWD. The subgroups for scales of SDM and SWD scores showed significant differences in age, education, and "Self-assessed Understanding of Informed Consent Forms." For patients with lung and liver cancers, the average score of SDM was 4.14 points (SD: 0.56), and the degree of SDM reached 86.5% after percentage conversion (SD: 11.97). The results indicated that most patients perceived the quality of SDM as "good" in the clinical trials, for which the research team invited their participation. In other words, the treatment-related information instructions were also fully explained and communicated. The 3 highest-scoring topics were: (1) "My attending physician/professional care team informed me that there is an important decision that needs to be made by me" (Mean: 4.58 points; SD: 0.74); (2) "My attending physician/professional care team will try to determine how I want to be involved in this decision based on what I say exactly" (Mean: 4.46 points; SD: 0.69); and (3) "My attending physician/professional care team talked to me about future treatment processes so we could reach a mutually acceptable and agreeable consensus" (Mean: 4.44 points; SD: 0.73). Compared to the average scores of the other items, only the average of Item 7 is slightly lower than 4 points: "My attending physician/professional care team and I have worked together to make a complete assessment of different treatment options" (Mean: 3.77 points; SD: 1.16). Overall, the SWD scores of patients with lung and liver cancers indicated relative satisfaction with participation in decision-making in the clinical trial experience. The average value of each question subitem was over 4 points.

Table 3 presents the correlation between independent and dependent variables of "self-assessed comprehension of informed consent forms," SDM, and SWD. The results indicated significant correlations between these variables. Table 4 presents the results of the regression models. A multiple linear stepwise regression model was performed to examine the predictors of the dependent variables. In this model, the independent variables explained 24.8% of the total variance.

Mediation of SDM

We performed a PROCESS-mediating variable analysis for "self-assessed understanding of informed consent forms," SDM, and SWD (Fig. 2). The result revealed that the relationship between "self-assessed comprehension of informed consent forms" and SWD was mediated by

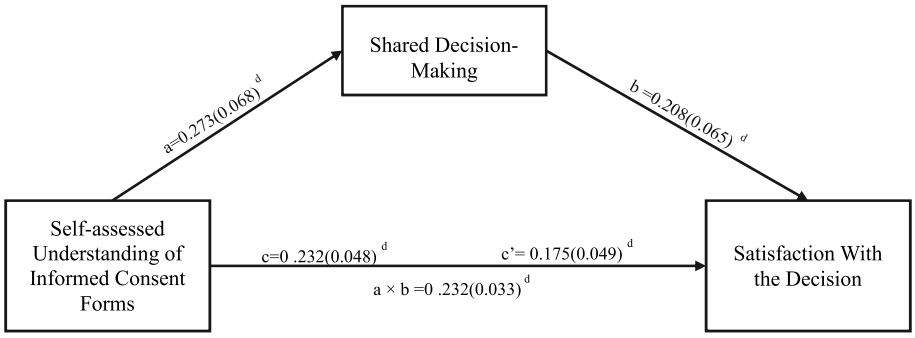

Fig. 2. The Hayes PROCESS macro (version 3.5) was used to analyze the mediating role of shared decision-making in the relationship between self-assessed understanding of informed consent forms and satisfaction with the decision.

Table 1
Demographic and mean scores of SWD ($N = 111$).

Characteristics	*n* (%)	Mean	SD	Significant
Gender				1.496*
Male	54 (48.6)	4.28	0.55	
Female	57 (51.4)	4.02	0.50	
Age, years				1.572*
< 65	74 (66.7)	4.25	0.53	
≥ 65	37 (33.3)	3.95	0.50	
Marital status				0.992
Single (included divorce and widowed)	24 (21.6)	4.17	0.60	
Married	87 (78.4)	4.14	0.52	
Education				0.091*
Under junior high school	35 (31.5)	3.98	0.53	
Junior high school	38 (34.2)	4.23	0.54	
Above University/college	38 (34.2)			
Clinical trial experience				3.022
1	70 (63.1)	4.21	0.57	
≥ 2	41 (36.9)	4.05	0.46	
Self-assessed understanding of informed consent forms				1.417**
No understanding	5 (4.5)	3.71	0.46	
Very little understanding	13 (11.7)			
Partial understanding	39 (35.1)	4.23	0.51	
Understanding	43 (38.7)			
Complete understanding	11 (9.9)			

*$P < 0.05$, **$P < 0.01$.
SD, standard deviation.

Table 2
Differences in terms of "Shared decision-making" ($N = 111$).

Variables	Mean	SD	Significant
Gender			0.294
Male	4.49	0.82	
Female	4.28	0.64	
Age, years			1.150*
< 65	4.54	0.73	
≥ 65	4.06	0.64	
Marital status			0.013
Single	4.39	0.71	
Married	4.38	0.75	
Education			0.052*
Under junior high school	4.16	0.65	
Above junior high school	4.48	0.75	
Clinical trial experience			
No			0.585
Yes	4.48	0.81	
Self-assessed understanding of informed consent forms	4.21	0.57	
No understanding to very little understanding	3.83	0.78	1.300**
Partial understanding to complete understanding	4.49	0.68	

*$P < 0.05$, **$P < 0.01$.
SD, standard deviation.

the indirect effect of SDM, and the direct effect remained significant (c' = 0.175; $P = 0.049$).

Discussion

Principal findings

For this study, we recruited a small but adequate sample of patients with lung and liver cancers in Taiwan to examine the factors affecting SWD. In addition, the study explored the mediation of SDM in the relationship between understanding informed consent forms and patient SWD to participate in a clinical trial.

"Self-assessed understanding of informed consent forms" had a significant positive relationship with both SDM and SWD. The results indicated that patients with lung and liver cancer had high SWD regarding clinical trial participation, which may also reflect that those patients had an acceptable degree of understanding of the informed consent form. Similarly, a previous study[12] demonstrated the strong relationship between SWD and understanding informed consent. Additionally, the informed consent form is a tailored document that increasingly seems to help patients by providing them with a useful reference upon which they can base a decision.[13]

The study aimed to test the mediation factor of SDM, and the results indicated that the patient understood the consent form. As a usual trial condition, the study team members thoroughly explained the informed consent form for clinical trials at the time of consent. However, they might not have formally implemented the assumed SDM. In other words, the study results indicated that the recruited patients with lung and liver cancer understood the trial, although SDM was not directly explained or observable. Unlike previous researchers who focused on the relationship between SDM and the treatment consent process in clinical trials,[20] we did not compare 2 situations where a healthcare provider should recommend a trial to the patient regardless the SDM process. The study did not indicate the SDM process' objective aspect, whereas we assessed patient-reported SDM. A future study design should investigate the specific steps of SDM for the clinical trial consent process in greater detail. An objective SDM evaluation tool to improve SWDs made by patients with cancer in clinical trials should be developed.

Factors affecting SWD

Differences in SWD among age groups

In this study, patients aged over 65 years had significantly lower SWD and SDM scores than those under 65. The result was similar to a study in which the mean age was more than 65 years, indicating that only a small number of older adults would strongly agree with SDM in the trial for treatment decisions.[34] In several prior investigations in a clinical trial setting, age may have been a factor in SWD and SDM.[35,36] However, according to the regression model results, the age subgroup in this study was controlled to show a significant SWD effect size. However, it might

Table 3
Correlations between "self-assessed understanding of informed consent forms," "shared decision-making," and "satisfaction with the decision" ($N = 111$).

Variables	Mean (SD)	Self-assessed understanding of informed consent forms	Shared decision-making	Satisfaction with the decision
Self-assessed understanding of informed consent forms	2.62 (0.97)	1	0.387 (< 0.001)**	0.435 (< 0.001)*
Shared decision-making	4.14 (0.56)		1	0.400 (< 0.001)**
Satisfaction with the decision	4.15 (0.54)			1

*$P < 0.05$, **$P < 0.01$.
SD, standard deviation.

Table 4
Multiple linear regression stepwise model of "satisfaction with the decision" ($N = 111$).

	F	*B*	*SE*	β	*P*
Constant	17.829*	2.645	0.278		
Self-assessed understanding of informed consent forms		0.175	0.049	0.318	0.001*
Shared decision-making		0.208	0.065	0.286	0.002*

*$P < 0.05$, **$P < 0.01$.
Dependent variable: Satisfaction with the decision.
R: 0.498, R2: 0 0.248 Adjusted R2: 0.234 (SE: 0.47).

be an interesting question to determine the factors contributing to lower scores of understanding informed consent forms and the SDM and SWD outcomes among older patients. Moreover, in an aging society in Taiwan, older adults might have a higher chance of getting cancer than the young. Further studies on designs of increasing understanding of informed consent forms of clinical trials for older adults with cancer are promising.

Differences in the SWD outcome among different education groups

Among patients with cancer in Taiwan, a higher education level was associated with higher scores for SDM and SWD. The results suggested that higher education levels may improve patients' understanding and knowledge of the informed consent form, leading to more informed decisions regarding participation in clinical trials. Thus, when study team members approach or recommend patients for clinical trials, the informed consent process should consider the patients' education levels. As noted in previous studies,[37,38] patients with limited health literacy (HL) might have fewer opportunities to participate in clinical trials. Those studies suggest that the low HL might have a negative effect or impact on being comprehensive in understanding the informed consent form. Additionally, older adults are considered to have "low HL" generally. Future research is needed to improve the straightforward and scientific content of the informed consent form.

Strengths and limitations

The strengths of this study lie in its elucidating the relationship between understanding informed consent forms and SWD to participate in clinical trials among patients with cancer. Furthermore, the study highlights the importance of comprehension among older adults and patients with lower education levels when recruiting for clinical trials and implementing SDM skills to provide valuable informed consent information. This study contributes to clinical trial practice in developing training programs and materials for facilities to train newcomers in clinical trials.

However, this study had some limitations. First, we enrolled only patients with cancer from a single medical center, and the results may not apply to other groups in different clinical trial settings. Second, the sample size was small, which further limited the generalizability of the results. Oncology-related clinical trials in future studies should involve more patients with a broader range of cancer diagnoses to ameliorate these limitations.

Conclusions

In this study, SDM in patients with lung or liver cancers was a significant mediator in the relationship between understanding informed consent forms and SWD. In addition, having an educational level below college adversely affected older patients' SWD. Notably, this is the first survey conducted in Taiwan to test the application of SDM in drug-related clinical trials. The study findings supported the SDM model's importance in clinical trial settings. Furthermore, it highlights the need for research facilities to prioritize and develop training programs for SDM.

Acknowledgments

The authors would like to thank the clinical trial and research teams for their support and thank all the participants in this study.

CRediT author statement

Wen-Wen Chang: Data curation, Data analysis and Writing - Original draft preparation.

Ming-Tzu Wu: Research conceptualization, Methodology, Data curation.

Yun-Chen Chang: Supervision.

Wen-Yu Hu: Research conceptualization, Writing- Reviewing.

Declaration of competing interest

The authors declare no conflict of interest.

Funding

This study received no external funding.

Ethics statement

This study was approved by the Research Ethics Committee of the National Taiwan University Hospital (IRB No. 201101071RC). All participants provided written informed consent.

Data availability statement

Data available on request from the authors.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.apjon.2023.100265.

References

1. Ministry of Health and Welfare. *Cause of Death Statistics*; 2020. https://www.mohw.gov.tw/lp-5256-2.html. Accessed April 16, 2023.
2. Health Promotion Administration, Ministry of Health and Welfare. *Cancer Registry Annual Report, 2020 Taiwan*; 2020, 578–600. Available at: https://www.hpa.gov.tw/Pages/List.aspx?nodeid=269. Accessed April 16, 2023.
3. Gregersen TA, Birkelund R, Wolderslund M, Steffensen KD, Ammentorp J. When life gives you no choice: context of decision-making when offered an oncology clinical trial. *Scand J Caring Sci*. 2021:9.
4. Wong CH, Siah KW, Lo AW. Estimation of clinical trial success rates and related parameters. *Biostatistics*. 2019;20(2):273–286.
5. Mello MM, Lieou V, Goodman SN. Clinical trial participants' views of the risks and benefits of data sharing. *N Engl J Med*. 2018;378(23):2202–2211.

6. Hwangbo Y, Son GM, Kim KH, Kwon MS, Kim KH. Colorectal cancer survivors' willingness to participate in a hypothetical clinical trial of Korean medicine: a cross-sectional study. *Eur J Integr Med*. 2020;33:7.
7. Schapira MM, Mackenzie ER, Lam R, et al. Breast cancer survivors willingness to participate in an acupuncture clinical trial: a qualitative study. *Support Care Cancer*. 2014;22(5):1207–1215.
8. Midgley N, Isaacs D, Weitkamp K, Target M. The experience of adolescents participating in a randomised clinical trial in the field of mental health: a qualitative study. *Trials*. 2016;17:12.
9. Drury NE, Menzies JC, Taylor CJ, Jones TJ, Lavis AC. Understanding parents' decision-making on participation in clinical trials in children's heart surgery: a qualitative study. *BMJ Open*. 2021;11(2):8.
10. Joffe S, Cook EF, Cleary PD, Clark JW, Weeks JC. Quality of informed consent: a new measure of understanding among research subjects. *J Natl Cancer Inst*. 2001;93(2):139–147.
11. Verheggen FW, Nieman FH, Reerink E, Kok GJ. Patient satisfaction with clinical trial participation. *Int J Qual Health Care*. 1998;10(4):319–330.
12. Stryker JE, Wray RJ, Emmons KM, Winer E, Demetri G. Understanding the decisions of cancer clinical trial participants to enter research studies: factors associated with informed consent, patient satisfaction, and decisional regret. *Patient Educ Counsel*. 2006;63(1–2):104–109.
13. Wray RJ, Stryker JE, Winer E, Emmons KM, Demetri G. Do cancer patients fully understand clinical trial participation? A pilot study to assess informed consent and patient expectations. *J Cancer Educ*. 2007;22(1):21–24.
14. Jefford M, Mileshkin L, Matthews J, et al. Satisfaction with the decision to participate in cancer clinical trials is high, but understanding is a problem. *Support Care Cancer*. 2011;19(3):371–379.
15. Taylor BP, Rebok GW, Marsiske M. Good clinical practice improves rigor and transparency: lessons from the ACTIVE trial. *Psychol Aging*. 2022;37(1):43–50.
16. Cheng CT, Lin CC. The use of informed consent in clinical nursing practice. *J Nurs*. 2017;64(1):98–104.
17. Feehan AK, Garcia-Diaz J. Investigator responsibilities in clinical research. *Ochsner J*. 2020;20(1):44–49.
18. Deniz S, Akbolat M, Cimen M, Unal O. The mediating role of shared decision-making in the effect of the patient-physician relationship on compliance with treatment. *J Patient Experience*. 2021;8:5.
19. Oerlemans AJM, Knippenberg ML, Olthuis GJ. Learning shared decision-making in clinical practice. *Patient Educ Counsel*. 2021;104(5):1206–1212.
20. Hianik RS, Campbell GP, Abernethy E, et al. Provider recommendations for phase I clinical trials within a shared decision-making model in phase I cancer clinical trial discussions. *JCO Oncol Pract*. 2020;16(9):e859–e867.
21. Bernat JL, McQuillen MP. On shared decision-making and informed consent. *Neurol Clin Pract*. 2021;11(2):93–94.
22. Brown RF, Butow PN, Ellis P, Boyle F, Tattersall MHN. Seeking informed consent to cancer clinical trials: describing current practice. *Soc Sci Med*. 2004;58(12):2445–2457.
23. Baron RM, Kenny DA. The moderator-mediator variable distinction in social psychological research: conceptual, strategic, and statistical considerations. *J Pers Soc Psychol*. 1986;51(6):1173–1182.
24. Hallock JL, Rios R, Handa VL. Patient satisfaction and informed consent for surgery. *Am J Obstet Gynecol*. 2017;217(2):7.
25. Rencz F, Tamasi B, Brodszky V, Ruzsa G, Gulacsi L, Pentek M. Did you get what you wanted? Patient satisfaction and congruence between preferred and perceived roles in medical decision making in a Hungarian national survey. *Value Health Reg Iss*. 2020;22:61–67.
26. Weiss SM, Wengert PA, Martinez EM, Sewall W, Kopp E. Patient satisfaction with decision-making for breast cancer therapy. *Ann Surg Oncol*. 1996;3(3):285–289.
27. Charles C, Gafni A, Whelan T. Shared decision-making in the medical encounter: what does it mean? (Or it takes at least two to tango). *Soc Sci Med*. 1997;44(5):681–692.
28. Rostoft S, van den Bos F, Pedersen R, Hamaker ME. Shared decision-making in older patients with cancer - what does the patient want? *J Geriatr Oncol*. 2021;12(3):339–342.
29. Simon D, Schorr G, Wirtz M, et al. Development and first validation of the shared decision-making questionnaire (SDM-Q). *Patient Educ Counsel*. 2006;63(3):319–327.
30. Doherr H, Christalle E, Kriston L, Harter M, Scholl I. Use of the 9-item shared decision making questionnaire (SDM-Q-9 and SDM-Q-Doc) in intervention studies-A systematic review. *PLoS One*. 2017;12(3):16.
31. Kriston L, Scholl I, Holzel L, Simon D, Loh A, Harter M. The 9-item Shared Decision Making Questionnaire (SDM-Q-9). Development and psychometric properties in a primary care sample. *Patient Educ Counsel*. 2010;80(1):94–99.
32. Holmes-Rovner M, Kroll J, Schmitt N, et al. Patient satisfaction with health care decisions: the satisfaction with decision scale. *Med Decis Making*. 1996;16(1):58–64.
33. Hayes AF. *Introduction to Mediation, Moderation, and Conditional Process Analysis: A Regression-Based Approach*. New York, NY: Guilford Publications; 2017.
34. Frazier R, Levine S, Porteny T, et al. Shared decision-making among older adults with advanced CKD. *Am J Kidney Dis*. 2022;80(5):599–609.
35. Henselmans I, van Laarhoven HWM, van Maarschalkerweerd P, et al. Effect of a skills training for oncologists and a patient communication aid on shared decision making about palliative systemic treatment: a randomized clinical trial. *Oncologist*. 2020;25(3):E578–E588.
36. Bieber C, Nicolai J, Gschwendtner K, et al. How does a shared decision-making (SDM) intervention for oncologists affect participation style and preference matching in patients with breast and colon cancer? *J Cancer Educ*. 2018;33(3):708–715.
37. Ousseine YM, Bouhnik AD, Mancini J. Health literacy and clinical trial participation in French cancer patients: a national survey. *Curr Oncol*. 2022;29(5):3118–3129.
38. Burks AC, K-M J. Health literacy and informed consent for clinical trials: a systematic review and implications for nurses. *Nurs Res Rev*. 2019;9:31–40.