Original Article

Culturally Adapted RN-MD Collaborative SICP-Based ACP: Feasibility RCT in Advanced Cancer Patients

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Abstract

Context. Cultural adaptation is essential for optimizing programs centered around autonomy, such as the Serious Illness Care Program (SICP), especially for populations valuing family-involved decision-making.

Objectives. We aimed to evaluate the feasibility and efficacy of a culturally adapted SICP-based nurse-physician collaborative Advance Care Planning (ACP) intervention tailored for patients with advanced cancer who prefer family-involved decision-making.

Methods. Oncology nurses, extensively trained and closely collaborating with physicians, conducted structured discussions with patients in the intervention group. The culturally adapted SICP-based ACP intervention was supplemented with trust-building, family involvement, and understanding of patient values. Primary inclusion criteria included patients within six weeks of initiating first-line palliative chemotherapy. Primary endpoints were achieving a 70% completion rate and assessing spiritual well-being (FACIT-Sp) at six months. Secondary endpoints included anxiety (GAD-7), depression (PHQ-9), quality of life (QOL) (CoQoLo), and ACP progress (ACP Engagement Scale) at the same interval.

Results. Forty-one patients (67.2%) completed the six-month follow-up, falling short of the targeted completion rate. The least-squares mean change from baseline in spiritual well-being at six months was 3.00 in the intervention group and -2.22 in the standard care group (difference, 5.22 points; 95% confidence interval, 1.38-9.06; $P = 0.009$). Similar superiority of the intervention was observed in QOL and ACP progress.

Conclusion. Despite not meeting the targeted completion rate, the intervention group demonstrated enhanced spiritual well-being, QOL, and ACP progress. Our findings suggest revisions to the intervention manual to improve feasibility and to progress to an efficacy-focused randomized controlled trial. J Pain Symptom Manage 2024;68:548−560. © *2024 The Authors.*

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Key Words
Advance care planning, nurse-physician collaboration, cultural adaptation, shared decision-making, advanced cancer

Key Message

Our study highlights promising outcomes of a culturally adapted nurse-physician collaborative SICP-based ACP intervention for patients with advanced cancer who prefer family-involved decision-making. Despite not achieving the targeted completion rate, notable improvements in spiritual well-being, QOL, and ACP progress suggest potential benefits of culturally tailored ACP strategies.

Introduction

Despite advancements in evidence-based advance care planning (ACP),[1,2] demonstrating the efficacy and benefits to patients of ACP interventions remains complex.[3,4] Challenges include cultural adaptation, gaps in healthcare professionals' (HCPs) knowledge, psychological burden, and insufficient interdisciplinary collaboration.[5–7] Among the various ACP programs,[8–12] the Serious Illness Conversation Program (SICP) is notable for training interdisciplinary teams and providing essential tools for these conversations.[13–15] Patients have reported positively on the meaningfulness of SICP-based discussions.[16]

However, most ACP programs, including the SICP, are developed within frameworks emphasizing patient self-determination. While valuable, this approach may not fully align with East Asian cultural norms, particularly in Japan, where patients often prioritize family harmony over autonomy and defer decision-making to families and HCPs.[17–19] In Japan and other Asian countries where legal support for patient self-determination is limited or newly implemented, end-of-life discussions often exclude the patient, even when they have decision-making capacity, allowing family members' preferences to override the patient's wishes.[19,20] In this context, shared decision-making requires HCPs to navigate a process that centers the patient while coordinating family involvement.[21] There is a critical need for culturally sensitive ACP models that equip HCPs with the skills to balance patient autonomy and family involvement effectively.[19]

To ensure that patient values guide all clinical decisions, spiritual care, a fundamental component of person-centered care, should be prioritized.[22] Although ACP definitions highlight spirituality,[23] there is a gap in measuring ACP outcomes from this perspective. Integrating these dimensions into ACP is particularly vital in Eastern Asia, where spiritual beliefs and family dynamics strongly influence healthcare decisions.[17,19,24]

Our previous study identified the Lifeline Interview Method (LIM) as effective in eliciting values and goals from patients with advanced cancer, helping them articulate what matters to them based on their life stories.[25] Building on these findings, we developed a culturally adapted, SICP-based ACP model for nurse-physician collaboration. Through structured LIM and SICP-based conversations, we aimed to help patients explore and express their values, beliefs, and source of meaning. We expected this engagement would enable patients to reflect on their life's purpose and find a sense of peace with their circumstances, allowing HCPs to align care with patients' values.

This study aimed to evaluate the feasibility and effectiveness of this culturally adapted, SICP-based, nurse-physician collaborative ACP intervention for advanced cancer patients who prefer family-involved decision-making.

Methods

Subsequent to Kyoto University Institutional Review Board approval (C1456), a single-blind, two-arm feasibility randomized controlled trial (RCT) adhering to the Consolidated Standards of Reporting Trials (CONSORT) reporting guidelines was conducted from October 26, 2020 to December 20, 2022.[26] The trial was registered at the University Hospital Medical Information Network Clinical Trials Registry (UMIN-CTR 000038522).

Setting

The trial took place at the outpatient clinic of the Department of Clinical Oncology, Kyoto University Hospital, a government-certified cancer hospital,[27] managing approximately 14,000 outpatient chemotherapy cases annually.

Participants

Eligibility criteria included people aged ≥20 years with metastatic tumors of specific types (stomach, esophagus, biliary tract, pancreas, or colon cancer), initiating palliative chemotherapy within six weeks, and having regular visits to the oncology outpatient clinic. We limited the primary cancer site to ensure patient

safety, enabling co-investigators to enroll patients adherently to the protocol and monitor adverse events of the study interventions while closely collaborating with attending oncologists. Additionally, we included patients receiving outpatient palliative chemotherapy, given that the intervention should target individuals with incurable cancer who were independent in daily life and could travel to the clinics. Patients who could bring a caregiver to at least one ACP discussion were also included, aligning with cultural preferences for family-involved decision-making.[28]

We excluded patients with an Eastern Cooperative Oncology Group Performance Status score ≥3 (being in a bed or chair >50% of their waking hours), with a distress score ≥4 and impact score ≥3 as measured by the Distress and Impact Thermometer,[29] with a cognitive impairment, who were unable to consent to treatment, or who had prior ACP discussions with HCPs. All patients provided written informed consent for participation, without monetary compensation.

Randomization and Enrollment

Eligible patients were identified from upcoming appointment lists for patients with specified metastatic gastrointestinal tumors. Co-investigators and participating oncologists verified eligibility among 1100 patients treated in the outpatient oncology department (Fig. 1). Among them, 61 were enrolled, 14 declined, 991 were ineligible, and 34 were not approached due to the infeasibility of contacting them (e.g., canceled appointments or patients leaving the clinic before contact).

Participants were randomized at a 1:1 ratio into intervention or control groups using permuted blocks with a block size of four and stratified by[1] upper gastrointestinal tract,[2] lower gastrointestinal tract, and[3] biliary tract and pancreatic cancer. HCPs and researchers were unaware of the block size. The computer-generated allocation sequence was prepared by an external statistician not involved in this study. This sequence was maintained on a centralized secured server managed by an external research organization, the Institute for Advancement of Clinical and Translational Science at Kyoto University Hospital. To maintain the integrity of the blinding process, participants were informed about the two study arms yet without detailed descriptions of the differences between them. Owing to the nature of the intervention, HCPs and researchers were unblinded.

Intervention Arm

Aligned with the definitions of ACP from the European Association for Palliative Care,[23] our intervention employed a holistic approach with a nurse−physician collaborative ACP to improve ACP delivery within an outpatient oncology clinic. In our intervention, we embraced the key elements of the above definition and utilized LIM[25] to facilitate patients' identification of values and consideration of the meaning and consequences of serious illness scenarios. Additionally, the Serious Illness Conversation Guide (SICG)[8] was incorporated to define goals and wishes regarding future medical treatment and care and discuss these with family members and HCPs (Table 1).

Communication Skills Education

Y.K., M.M., and S.T. worked closely with the SICP developers and led the translation and revision processes, ensuring the program was culturally and linguistically adapted to the Japanese healthcare context. The adapted SICP comprised several key components: SICG, a preparatory letter for patients and caregivers for the conversation, a clinician's guide for serious illness conversations, specialized clinician training, and an electronic health record (EHR) documentation template.

Four oncology nurses, selected for their expertise in oncology care, were designated to implement the interventions and were not involved in routine clinical care for the participants. These nurses underwent specialized training to provide ACP support in collaboration with oncologists. Training included viewing a 15-min video example conversation based on SICG and participating in approximately 2.5 hours of structured communication skills education. While the original SICP training procedures were adapted for efficient and quick learning, the core content and educational objectives were preserved.

The training emphasized guiding participants in reflecting on significant life events, articulating their meaning, identifying their strengths, and facilitating discussions based on the SICG to help participants find purpose and meaning, set priorities, and live peacefully. Detailed training goals and schedules for this study are provided in Supplements 1 and 2.

Additionally, the nurses received extensive training on the research protocols to ensure adherence to study procedures and roles, and thus maintaining fidelity and effectiveness.

Intervention Delivery

The nurse−physician collaborative ACP was implemented within 28 days of enrollment, involving two in-person and two telephone discussions. Trust-building was established according to ACP best practices,[30] with nurses utilizing the LIM to elicit patients' values and wishes. In-person discussions lasted ≤30 minutes and occurred on scheduled clinic visit days. Caregivers were required to participate in one discussion but were also welcomed to join the other conversations. Each patient was consistently assigned to the same nurse for all interactions.

The oncologist explained the purpose of the ACP and introduced the nurse who would intervene. After

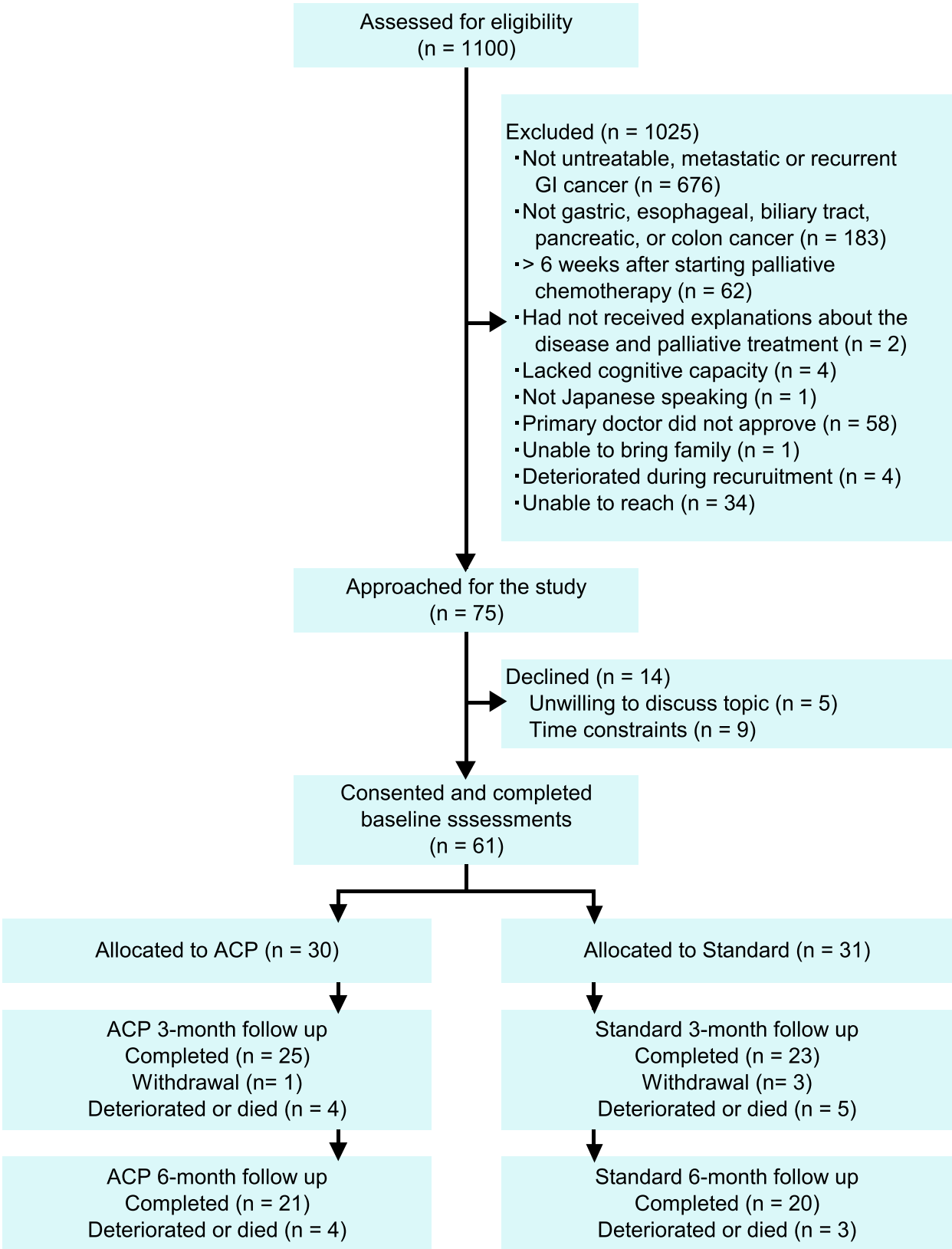

Fig. 1. CONSORT Diagram.Footnote: GI: gastrointestinal; RN: registered nurse; MD: physician; ACP: advanced care planning; ACP: culturally adapted registered nurse-physician collaborative SICP-based ACP intervention; Standard: standard care.

Table 1
Definition of Advance Care Planning (ACP)[23] and Components of the Intervention

Definitions of ACP	Intervention Components			
	LIM	SICP	RN−MD Collaboration	RN−MDT Collaboration
Advanced care planning enables individuals who have decisional capacity to				
identify their values and reflect upon the meanings and consequences of serious illness scenarios	•	•		
define goals and preferences for future medical treatment and care	•	•		
discuss these with family and health-care providers		•	•	
ACP addresses individuals' concerns across the physical, psychological, social, and spiritual domains.	•	•	•	•
ACP encourages individuals to identify a personal representative and record and regularly review any preferences, which can then be taken into account should they, at some point, be unable to make their own decisions.		•	•	•

LIM: Lifeline Interview Method; SICP: Serious Illness Care Program; RN: registered nurse; MD: physician; MDT: Multidisciplinary team.

addressing the patient's symptom-related needs, the nurse focused on establishing trust with the patient and caregivers to best elicit the patient's values and wishes regarding future care based on the LIM. At the end of the first visit, the nurses asked the patients to bring a family member or a caregiver acting as a surrogate decision-maker (SDM) to their next visit; patients also received a letter outlining the topics to be discussed.

At the second visit, in the SDM's presence, the nurse reviewed what was discussed at the initial visit, including the purpose of the ACP and the patient's values, and then facilitated a discussion about future care plans based on the SICG. The nurse worked with the patient and SDM to assist in the shared decision-making process, particularly to agree on the patient's goals of care. Nurses reviewed care plans with the attending oncologist (in person, by phone, or by email) to maintain intervention fidelity after each visit.

Two follow-up phone calls at three and six months postintervention, lasting ≤20-min, addressed physical, psychosocial, and spiritual concerns about daily living and any issues with the care plan. All visits were documented in the EHR. The project manager assessed nurses' fidelity to the rigorous intervention protocol and provided ongoing feedback during site visits and regular meetings.

Standard Care Arm

Participants in this group received a brochure introducing ACP at baseline. Standard care involved ACP discussions tailored to individual preferences, incorporating supportive measures deemed appropriate by the oncology/palliative care team without communication skills training.

Data Collection and Participant Self-Reported Outcomes

Participants' demographic data were collected from patient reports and the EHR, with oncologists assessing patient performance status. Y.U. and A.C. then confirmed the diagnoses and cancer staging. After baseline data collection, participants completed questionnaires at the first visit and the one, two, three, and six-month follow-ups through mailed questionnaires. If participants did not return the questionnaires by mail after reminders, a research assistant, blinded to the group allocation, collected the outcome data via telephone.

The primary outcome was spiritual well-being, measured using the Japanese version of the questionnaire Functional Assessment of Chronic Illness Therapy-Spirituality Well-being (FACIT-Sp).[31] The FACIT-Sp has been widely utilized in palliative intervention trials and has demonstrated responsiveness to change.[32] Scores on this tool range from 0 to 60; higher scores indicate higher levels of spiritual well-being.[33] Given the context of our study involving terminal cancer patients, we determined that spiritual well-being was the most appropriate primary outcome measure to evaluate our intervention's impact on helping participants reaffirm life's meaning, identify priorities, and live peacefully.[22,34,35]

Secondary outcomes included anxiety and depression, measured using the Japanese versions of the Generalized Anxiety Disorder-7 (GAD-7) (score range, 0−21; scores ≧15 indicate severe anxiety)[36−38] and the Patient Health Questionnaire-9 (PHQ-9) (score range, 0−27; ≧20 indicate severe depression),[39,40] respectively. Comprehensive QOL was assessed with the 14-item supplement of the Comprehensive Quality of Life Outcome Inventory (CoQoLo), designed to measure comprehensive QOL outcomes in patients with advanced cancer (score range, 10−70; higher scores indicate better QOL).[41] ACP progress was evaluated using the nine-item version of the ACP Engagement Survey, Japanese version (readiness subscale score range, 6−30; self-efficacy subscale score range, 3−15; higher scores indicate higher levels of engagement).[42,43]

Semi-structured interviews on patient satisfaction with the interventions were conducted after the six-month follow-up by a researcher not involved in the intervention. Intervention group participants were asked to discuss their experiences, satisfaction with or burdens related to the intervention. A qualitative descriptive exploratory design was employed to capture participants' perspectives. The interviews were audio-recorded, and transcribed verbatim, and a thematic content analysis was performed.[44]

Statistical Analysis

Based on previous trials,[45] we anticipated a mean difference (two weeks after intervention) of 6.63 in the FACIT-Sp score and a standard deviation of 6.55. A sample size of 44 participants was required to satisfy 90% power with a two-sided significance level of 0.05. Therefore, we recruited the target sample size of 30 participants per group after accounting for 25% attrition. To evaluate feasibility, we set the target completion rate of data collection six months after the initial visit at 70%.[13,45]

All analyses were performed with an intention-to-treat principle. No interim analyses were conducted. Under the assumption that data were missing at random, we used a linear mixed-effects model with repeated measures to estimate the least-squares mean group difference in continuous outcome scores (FACIT-Sp, GAD-7, PHQ-9, CoQoLo, ACP Engagement Scale) from baseline at one, two, three, and six months. This model included the study group, time points, baseline scores, and interactions between the study group members and the time points. The primary time point was set to six months for the primary analysis. No adjustment for multiplicity was included.

At the six-month follow-up, feasibility benchmarks included retention >70% and data completeness >90%. The predetermined hypothesis for intervention group outcomes specified that they would[1] maintain or improve spiritual well-being and QOL,[2] experience reduced anxiety and depressive symptoms, and[3] demonstrate increased ACP engagement compared to standard care. All statistical analyses were performed using SAS version 9.4 (SAS Institute, Cary, NC).

Results

Among the 61 enrolled patients, the mean age was 67.2 years, and 21 (34.4%) participants were female (Table 2). Predominant primary cancer sites were the pancreas (29, [47.5%]), esophagus (9, [14.8%]), and colon (9, [14.8%]). All in-person visits coincided with scheduled oncology clinic visits, and 30 (96.8%) intervention group patients had caregivers present for all second visits to discuss SICG. All telephone follow-ups were conducted on separate days by oncology nurses.

Table 2
Patients' Baseline Clinical Characteristics

Characteristics	Intervention Group N = 30	Standard Care Group N = 31
Age in years, mean (SD)	67.3 (12.3)	67.2 (10.7)
Sex, female	10 (33.3)	11 (35.5)
Race/Ethnicity		
Japanese	30 (100)	31 (100)
ECOG performance status[a]		
0	28 (93.3)	28 (90.3)
1	2 (6.7)	2 (6.5)
2	0 (0)	1 (3.2)
Primary cancer site		
Upper gastrointestinal tract	7 (23.3)	7 (22.6)
Stomach	5	2
Esophagus	2	5
Lower gastrointestinal tract: Colon	4 (13.3)	5 (16.1)
Biliary tract and pancreatic cancer	19 (63.3)	19 (61.3)
Biliary tract	4	5
Pancreas	15	14
Current marital status, married	28 (93.3)	25 (80.6)
Current employment status, employed	13 (43.3)	13 (41.9)
Living status, alone	4 (13.3)	4 (12.9)
Spiritual well-being		
FACIT-Sp, mean (SD)[d]		
Peace/meaning subscale score	23.0 (6.26)	20.2 (5.16)
Faith subscale score	8.83 (4.24)	7.35 (2.55)
Anxiety		
GAD-7 total score, mean (SD)[c]	3.90 (4.28)	4.35 (3.87)
Depression		
PHQ-9 total score, mean (SD)[d]	5.10 (4.04)	6.19 (4.24)
Quality of life		
CoQoLo total score, mean (SD)[e]	69.8 (6.58)	69.2 (7.54)
ACP progress		
ACP Engagement Survey, mean (SD)[f]	24.9 (8.17)	23.2 (5.16)

Categorical data presented as No. (%).
ECOG: Eastern Cooperative Oncology Group; FACIT-Sp: Functional Assessment of Chronic Illness Therapy-Spirituality Well-being Japanese version; GAD-7: Generalized Anxiety Disorder-7 Japanese version; PHQ-9: Patient Health Questionnaire-9 Japanese version; CoQoLo: Comprehensive Quality of Life Outcome Inventory; ACP: advance care planning.
[a]ECOG Performance Status 0: Fully active; 1: Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature; 2: Ambulatory and capable of all self-care but unable to carry out any work activities, up and about more than 50% of waking hours.
[b]FACIT-Sp: Peace/meaning subscale score range 0–32; and Faith subscale score range 0–16; higher scores indicate higher levels of spiritual well-being.
[c]GAD-7: score range, 0–21; 0–4: indicates minimal anxiety, 5–9: mild anxiety, 10–14: moderate anxiety, 15–21: severe anxiety.
[d]PHQ-9: score range, 0–27; 0–4: indicates minimal depression, 5–9: mild depression, 10–14: moderate depression, 15–19: moderately severe depression, 20–27: severe depression.
[e]CoQoLo: score range, 7–84; higher scores indicate better quality of life.
[f]ACP Engagement Survey: Readiness subscale score range, 5–45; higher scores indicate higher levels of engagement.

The qualitative content analysis of the patient satisfaction interviews (n = 14) revealed that participants generally described engaging in ACP discussions as a positive experience that brought them a sense of relief and peace. The detailed qualitative analysis results will be reported in a separate paper.

Feasibility Evaluation

Fig. 1 outlines patients' reasons for declining participation. At three months, 48 (78.7%) patients completed measures (25 intervention; 23 control), and at six months, 41 (67.2%) completed follow-up (21 intervention; 20 control). Baseline demographic or medical data showed no substantive differences between groups. More withdrawals in the standard care group were due to the psychological burden of the questionnaires (1 [3.2%] vs. 3 [10%]). They reported feeling distressed from being reminded of their serious illnesses when answering questionnaires. Mortality rates were 26.7% and 25.8% in the intervention and standard care groups, respectively. No complaints were reported by oncologists regarding referred patients to this trial and collaborating closely with nurses in interventions.

Efficacy Outcome Measures

Fig 2 shows the least-squares mean changes from baseline at each time point for the primary outcome of spiritual well-being based on FACIT-Sp scores. At six months, the least-squares mean change was 3.00 in the intervention group and -2.22 in the standard care group. The difference between the two groups was 5.22 points higher (95% confidence interval [CI], 1.38 −9.06; $P = 0.009$) in the intervention group. Up to six months, the difference was maintained at one month (difference [95% CI], 6.21 [3.05−9.37]; $P < 0.001$), two months (difference [95% CI], 4.93 [1.58−8.28]; $P = 0.005$), and three months (difference [95% CI], 6.80 [3.54−10.07]; $P < 0.001$). For the secondary outcomes, QOL and ACP progress suggested that the intervention was superior to standard care at six months (Table 3).

Discussion

This trial introduces a pioneering approach to promoting culturally adapted ACP in outpatient oncology clinics by integrating life review with LIM and SICG discussions, facilitated collaboratively by nurses and physicians. Primarily, we demonstrate the feasibility of our culturally adapted nurse-physician collaborative SICP-based ACP approach for patients with advanced cancer who prefer family-involved decision-making. Although we did not achieve the anticipated 70% completion rate at six months due to a higher-than-expected number of participants experiencing deterioration or death (26.2%), our findings confirm the feasibility of retention at the 12-week mark. The majority of surviving patients, with only four declining, consistently engaged in all visits and measurements, highlighting patients' positive receptivity toward the interventions and willingness of oncologists to refer advanced cancer patients, further validating our approach.

The second significant finding is that our ACP approach improved spiritual well-being, QOL, and ACP progress, suggesting that the benefits to the participants likely outweighed the burdens of the

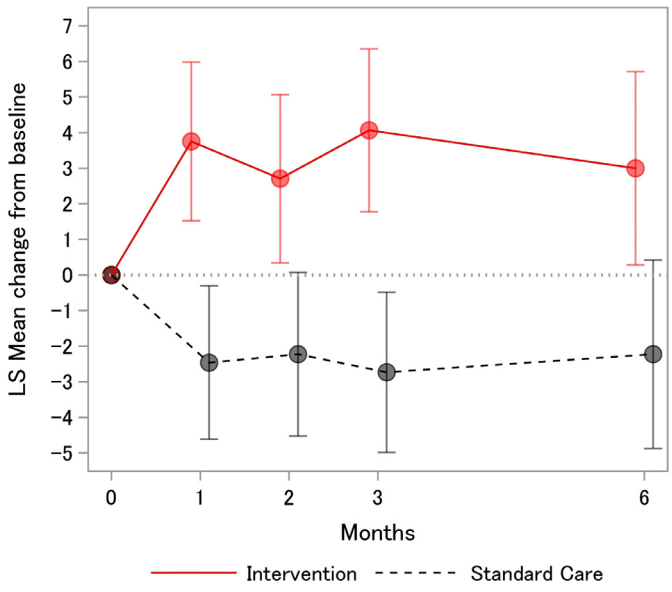

Fig. 2. Change from baseline for the spiritual well-being score for the FACIT-Sp.Footnote: LS: least squares; FACIT-Sp: Functional Assessment of Cancer Therapy-Spirituality Well-being Japanese version.

Table 3

Mean Scores and Adjusted Mean Differences in Patient Outcomes Between Groups Up to Six Months

Variables	Time	Intervention Group (n = 30)			Standard Care Group (n = 31)			Comparison Between Groups		
		N	Mean (SD)	LSM Changes [95% CI]	N	Mean (SD)	LSM Changes [95% CI]	Difference in LSM Changes [95% CI]	p-value	Effect Size[a,48]
Spiritual well-being: FACIT-Sp	Baseline	27	32.81 (9.30)		30	27.93 (6.44)				
	1 Month	26	35.92 (8.82)	3.75 [1.52, 5.99]	27	26.15 (6.50)	−2.46 [−4.61, 0.31]	6.21 [3.05, 9.37]	<0.001	1.08
	2 Month	26	34.88 (8.85)	2.70 [0.34, 5.07]	26	26.35 (7.16)	−2.23 [−4.53, 0.07]	4.93 [1.58, 8.28]	0.005	0.82
	3 Month	25	36.64 (8.54)	4.07 [1.78, 6.35]	23	26.30 (7.14)	−2.74 [4.98, 0.49]	6.80 [3.54, 10.07]	<0.001	1.21
	6 Month	20	34.65 (8.30)	3.00 [0.28, 5.72]	21	27.10 (7.92)	−2.22 [−4.87, 0.42]	5.22 [1.38, 9.06]	0.009	0.85
Anxiety: GAD-7	Baseline	30	3.90 (4.28)		31	4.35 (3.87)				
	1 Month	26	2.50 (3.68)	−1.01 [−2.14, 0.12]	27	4.33 (4.89)	0.25 [−0.84, 1.34]	−1.26 [−2.83, 0.31]	0.112	−0.44
	2 Month	26	2.77 (3.83)	−0.74 [−1.82, 0.33]	26	3.88 (4.18)	−0.32[−1.36, 0.73]	−0.43 [−1.93, 1.07]	0.572	−0.16
	3 Month	25	2.36 (3.01)	−1.18 [−2.23, −0.14]	23	4.13 (3.76)	0.27 [−0.76, 1.31]	−1.46 [−2.93, 0.01]	0.051	−0.58
	6 Month	20	3.35 (4.20)	−0.52 [−2.32, 1.28]	21	4.52 (4.06)	0.58 [−1.18, 2.35]	−1.10 [−3.62, 1.42]	0.381	−0.28
Depression: PHQ-9	Baseline	30	5.10 (4.04)		31	6.19 (4.24)				
	1 Month	26	4.00 (3.74)	−0.87 [−2.00, 0.26]	26	5.85 (5.24)	−0.02 [−1.13, 1.09]	−0.85 [−2.44, 0.74]	0.287	−0.30
	2 Month	26	4.42 (4.05)	−0.40 [−1.68, 0.88]	26	6.19 (4.76)	0.24 [−1.00, 1.48]	−0.64 [−2.43, 1.15]	0.477	−0.20
	3 Month	25	3.80 (3.35)	−0.93 [−2.12, 0.26]	23	6.00 (4.52)	0.50 [−0.68, 1.67]	−1.43 [−3.11, 0.26]	0.094	−0.49
	6 Month	19	4.32 (4.30)	−0.59 [−2.62, 1.44]	21	6.57 (4.35)	0.86 [−1.09, 2.81]	−1.45 [−4.27, 1.37]	0.304	−0.33
Quality of life: CoQoLo	Baseline	30	69.83 (6.58)		31	69.23 (7.54)				
	1 Month	25	69.60 (6.95)	−0.11 [−2.42, 2.21]	25	65.40 (7.71)	−3.84 [−6.09, −1.60]	3.74 [0.51, 6.96]	0.024	0.66
	2 Month	25	68.04 (7.55)	−1.69 [−3.81, 0.44]	25	64.92 (8.96)	−4.58 [−6.68, −2.49]	2.90 [−0.09, 5.88]	0.057	0.55
	3 Month	24	70.67 (6.79)	0.52 [−1.56, 2.59]	22	65.36 (8.41)	−4.60 [−6.65, −2.55]	5.11 [2.19, 8.04]	0.001	1.04
	6 Month	20	70.05 (6.98)	0.28 [−2.44, 3.00]	19	65.74 (7.31)	−5.10 [−7.86, −2.34]	5.38 [1.50, 9.25]	0.008	0.90
ACP progress: ACP Engagement Survey	Baseline	30	24.93 (8.17)		31	23.23 (5.16)				
	1 Month	26	32.62 (10.53)	7.07 [4.58, 9.56]	27	24.19 (6.64)	1.35 [−1.02, 3.72]	5.72 [2.26, 9.18]	0.002	0.91
	2 Month	26	31.88 (10.66)	6.31 [3.59, 9.03]	26	25.65 (8.09)	2.75 [0.15, 5.34]	3.57 [−0.21, 7.35]	0.064	0.52
	3 Month	24	32.46 (10.78)	6.92 [4.33, 9.51]	22	26.05 (8.07)	2.94 [0.44, 5.44]	3.98 [0.35, 7.60]	0.032	0.65
	6 Month	20	31.50 (10.63)	6.75[3.73, 9.78]	20	25.25 (8.89)	2.24 [−0.70, 5.18]	4.52 [0.28, 8.76]	0.037	0.67

LSM: Least-squares mean; FACIT-Sp: Functional Assessment of Cancer Therapy-Spirituality Well-being Japanese version; GAD-7: Generalized Anxiety Disorder-7 Japanese version; PHQ-9: Patient Health Questionnaire-9 Japanese version; CoQoLo: Comprehensive Quality of Life Outcome Inventory; ACP: advance care planning.

[a]Effect sizes are Cohen's d: an effect size of 0.20 is small, 0.50 is moderate, and 0.80 is large.

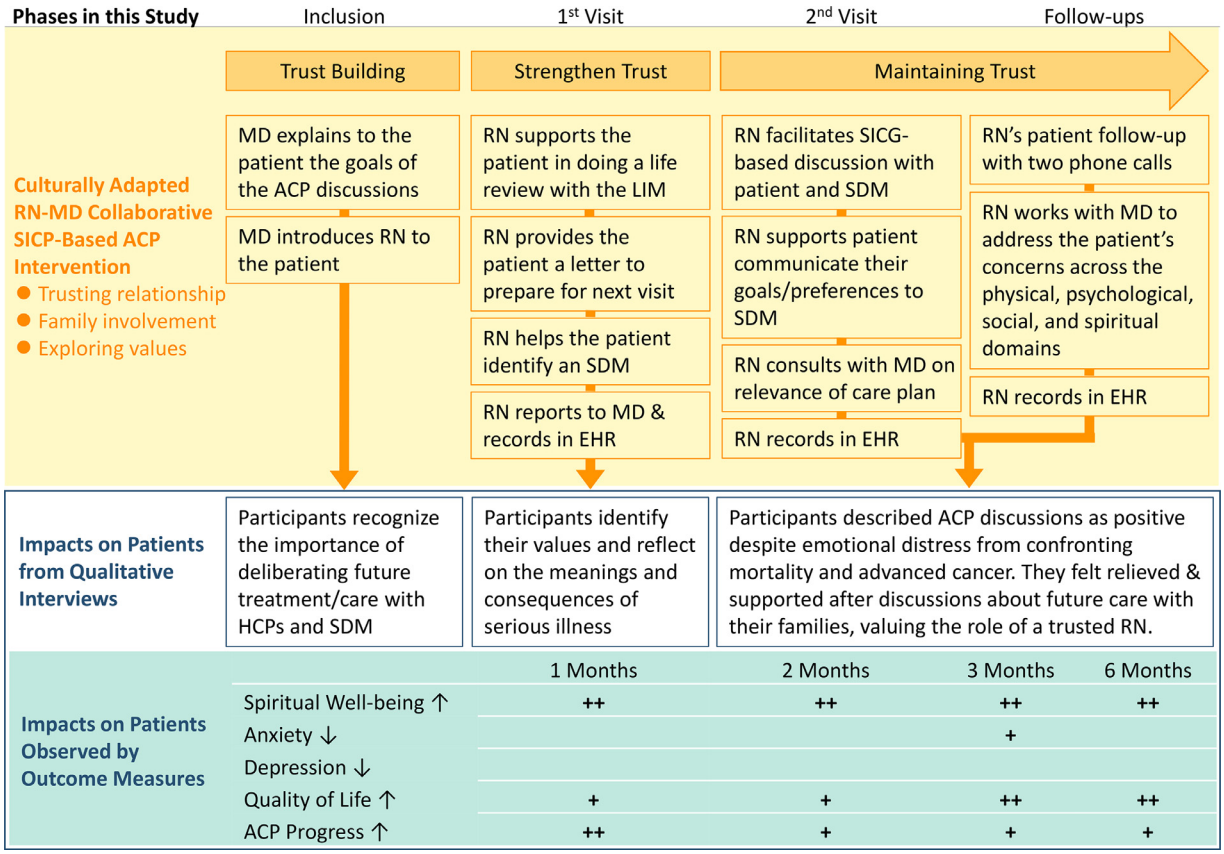

Fig. 3. Structural model of culturally adapted nurse-physician collaborative serious illness care program-based advance care planning intervention and its impacts. Footnote: RN: registered nurse; MD: physician; ACP: advanced care planning; HCPs: health care professionals; SDM: surrogate decision-maker; LIM: Lifeline Interview Method; EHR: electric health record; SICG: Serious Illness Conversation Guide.

intervention. We attribute this improvement to four key innovations aimed at overcoming previously identified barriers/facilitators of ACP[6,46,47] (Fig. 3,4):

(1) Trust Building and Value Exploration: Given the hierarchical nature of Japanese medical practice, patients tend to place their trust in physicians.[18] Consequently, attending physicians played a pivotal role in introducing the oncology nurses responsible for ACP discussions, thereby fostering trust and facilitating the process. LIM facilitated respectful communication to establish trust and explore patient values, supporting a smooth transition into the ACP discussions.
(2) Culturally-Tailored Communication Training: Short SICP training, optimized for cultures that prefer family-involved decision-making, was provided to bridge HCPs' knowledge and skills gaps, address concerns leading to emotional distress, and ensure effective SICG utilization.
(3) Interdisciplinary Collaboration in Shared Decision-Making: Physicians worked closely with oncology nurses to address needs identified during the ACP discussions. This collaborative approach ensured that medical queries and concerns raised by the patients were promptly addressed, enhancing intervention efficacy. This collaboration enabled a flexible care plan adaptable to changes in the patients' feelings and circumstances, potentially contributing to improved outcomes.
(4) Family Involvement: Nurses consistently facilitated patient-centered, family-involved shared decision-making processes. They coordinated the entire process, from identifying and delegating SDMs to actively engaging in discussions. Given the importance of family involvement in ACP outcomes,[21] the interventions of trusted nurses contributed to participants feeling relieved and at peace, positively influencing outcomes.

Our approach aligns with the recommended ACP building block approach[15] by culturally optimizing ACP measures and promoting a comprehensive approach. Although no substantial improvements in anxiety and depressive symptoms were observed, the

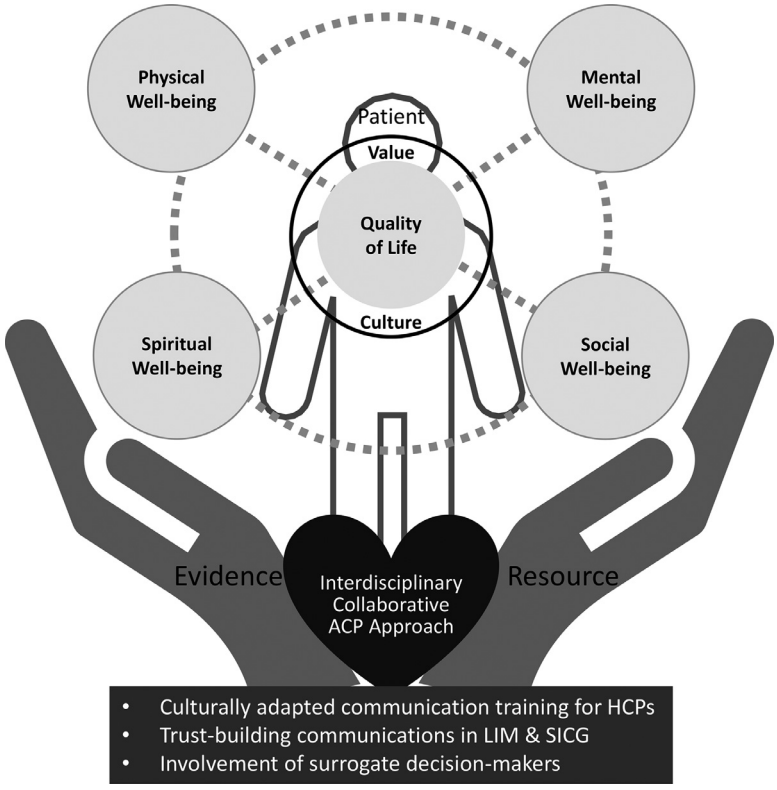

Fig. 4. Conceptual model of culturally adapted nurse-physician collaborative serious illness care program-based advance care planning approach.Footnote: ACP: advanced care planning; HCPs: health care professionals; LIM: Lifeline Interview Method; SICG: Serious Illness Conversation Guide.

absence of worsening trends with minimal mean values for anxiety and depression at all measurement points indicates the intervention's safety. Several factors, including the low proportion of participants with moderate to severe anxiety or depression and potential floor effects, may explain the lack of significant differences. Maintenance of mental health stability in this vulnerable population is a positive achievement.

Strategies to improve outcomes for patients with advanced cancer through ACP are not well-supported by sufficient evidence,[2] and the true outcomes of ACP for patients and HCPs are still being investigated. Further development of this trial for the quantitative and qualitative assessment of the ACP approach could enrich the existing body of knowledge on its effectiveness.

Our study also revealed a higher-than-expected disease progression. Although patients with an estimated life expectancy of six months or longer were selected, 20 participants unexpectedly became critically ill or passed away during the observation period, five of whom died within two months of the initial visit. Contrary to concerns, during the satisfaction interviews, no patient complained of starting too early. Rather, participants stated that early discussion helped them feel prepared and at peace, suggesting the need for earlier identification and inclusion of patients in future trials.

Limitations

Limitations of this study include the intervention being administered by oncology nurses not responsible for participants' care in a clinical setting. While this approach was necessary to ensure intervention fidelity, challenges remain regarding the timeliness of ACP discussions relative to daily nursing practices and the feasibility of implementation in clinical practice. To navigate these challenges, the interventionist nurses first focused on building cooperative relationships with the nurses working in the outpatient clinic. Additionally, our trial's external validity may be limited, as it was conducted in a tertiary university hospital and limited to patients with advanced gastrointestinal and biliary pancreatic cancer. Although the participants were blinded, patients in the intervention group were more frequently approached by nurses for discussion, which might have caused a participant bias.

Participants who withdrew due to the questionnaire burden were interviewed to understand their reasons. They expressed that the questions were mentally distressing, prompting them to confront their inevitable death and condition decline, rather than the number of questions being burdensome. Based on this feedback, we received advice to reduce the frequency of the questionnaires. For future confirmatory trials, careful procedure modifications that consider appropriate

timing of recruitment, intervention initiation, and data collection will be paramount, especially when expanding to different institutions and cancer types.

Conclusion

Despite not meeting the targeted completion rate, the intervention group showed significant improvements in spiritual well-being, QOL, and ACP progress. Our findings suggest revisions to the intervention manual to improve feasibility, with the aim of progressing to an efficacy-focused RCT. To implement this approach into routine practice, clinic nurses who already have a trusting relationship with the patients and work closely with oncologists could collaboratively administer the intervention. Interdisciplinary collaboration, provision of communication training, supportive institutional policies, and adequate time allocation for ACP discussions are critical elements that need to be implemented to ensure success of this approach in real-world settings.

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Supplement 1

Training Program Goals and Expected Outcomes for Oncology Nurses

Program Objectives/Goals for Nurses	Corresponding Criteria/Outcomes
1. Communication Skills	
1) Using silence, facilitating patient talk	• Allows silence before responding when patient is taking in information or expressing emotions • **Ensure the** patient **speaks** >50% of the time, **rather than family or clinicians**
2) Acknowledging and responding to patient/family emotion	• **Prioritizes** acknowledging difficult emotions during discussion • Responds to emotions with empathic comments or further exploration • Avoids using information or premature assurance to respond to emotion • **Prioritizes responding to the patient's emotions over the family's emotions**
3) Eliciting **and addressing** patient concerns	• Encourages patients to express fears, worries, other concerns **(e.g., use of future line drawings in LIM)** • **Coordinates with interdisciplinary team members to address physical, psychosocial, or spiritual concerns promptly**
4) Assessing patient/**family** receptivity	• Accurately assesses patient's receptivity to receiving new information and considering other options for treatment/care • **Assesses the family's receptivity to new information and understanding the patient's reactions and thoughts**
5) Recognizing appropriate time for exploration and for making a recommendation	• Initiates conversation **in consultation with the attending physician** early in the course of illness, and when prompted by disease progression or other clinical changes • Makes a recommendation based on an accurate assessment of patient receptivity **and caregiver feasibility** • **Provides specific recommendations based on discussions about the kind of life the patient wants to lead and how this can be achieved**
6) Identifying key challenging scenarios in using the SICG, and strategies for addressing them	• Describes concrete strategies for dealing with crying, anger, denial, and avoidance • **Utilizes information gathered in the LIM to assist patients who find it difficult to express their values and thoughts**
7) Using follow-up questions to further explore unclear or limited patient responses	• Asks follow-up questions when patient does not provide a full or complete answer to an SICG question • **Always verifies the validity of a response when a family member responds on the patient's behalf**
2. Mastery of LIM	
1) Guiding participants through life reflection using LIM	• **Facilitates participants in reflecting on significant life events and articulate their meaning** • **Encourages participants to identify their strengths and recognize achievements**
2) Exploring emotional trajectories and concerns	• **Explores the reasons behind participants' emotional ups and downs and addresses any identified concerns or anxieties** • **Collaborates with interdisciplinary team members to address concerns promptly**
3) Facilitating expression of values and future expectations	• **Supports participants in expressing their values and future expectations based on their life reflections** • **Encourages participants to articulate their priorities and propose specific measures for achieving their goals**
3. Mastery of SICG	
1) Effectively using SICG	• Completes all elements of the SICG **at the patient's pace**
2) Sharing prognosis (upon patient's wishes)	• **Requests the attending physician to** provide a prognosis using a range (days to weeks, weeks to months, etc.), acknowledging uncertainty
3) Recording what was discussed about ACP	• Documents critical information for colleagues in the electronic health record

LIM: Life-line Interview Method; SICG: Serious Illness Conversation Guide; ACP: advance care planning.
Items in **boldface type** are new additions to this trial.

Supplement 2

Time Schedule of the Training Program

Start Time	Duration (Min)	Content
[Day 1] 17:30−18:30 Lecture on SICP		
17:30-	00:10	Welcome, Introduction of participants
17:40-	00:10	Video reflection of serious illness discussion utilizing SICG
17:50-	00:30	Lecture: Overview of ACP; Evidence and Serious Illness Care Program
18:20-	00:10	Reflection, questions and answers
[Day 2] 17:30−19:00 Small group exercises using SICG		
17:30-	00:15	Welcome, Drills
17:45-	00:60	Discussion exercises utilizing LIM and SICG (10 min. introduction [7 min. for reading scenario, 10 min. for role-play, 8 min. for feedback] x 2 times)
18:45-	00:15	Reflection, questions and answers

SICP: Serious Illness Care Program; SICG: Serious Illness Conversation Guide; ACP: advance care planning; LIM: Life-line Interview Method.