

Original Article

Efficacy of a Decision Aid Consisting of a Video and Booklet on Advance Care Planning for Advanced Cancer Patients: Randomized Controlled Trial

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Abstract

Context. Few randomized controlled trials of advance care planning (ACP) with a decision aid (DA) show an effect on patient preferences for end-of-life (EOL) care over time, especially in racial/ethnic settings outside the U.S.

Objectives. The objective of this study was to examine the effect of a decision aid consisting of a video and an ACP booklet for EOL care preferences among patients with advanced cancer.

Methods. Using a computer-generated sequence, we randomly assigned (1:1) patients with advanced cancer to a group that received a video and workbook that both discussed either ACP (intervention group) or cancer pain control (control group). At baseline, immediately after intervention, and at 7 weeks, we evaluated the subjects' preferences. The primary outcome was preference for EOL care (active treatment, life-prolonging treatment, or hospice care) on the assumption of a fatal disease diagnosis and the expectation of death 1) within 1 year, 2) within several months, and 3) within a few weeks. We used Bonferroni correction methods for multiple comparisons with an adjusted *P* level of 0.005.

Results. From August 2017 to February 2018, we screened 287 eligible patients, of whom 204 were enrolled to the intervention (104 patients) or the control (100 patients). At postintervention, the intervention group showed a significant increase in preference for active treatment, life-prolonging treatment, and hospice care on the assumption of a fatal disease diagnosis and the expectation of death within 1 year ($P < 0.005$). Assuming a life expectancy of several months, the change in preferences was significant for active treatment and hospice care ($P < 0.005$) but not for life-prolonging treatment. The intervention group showed a significant increase in preference for active treatment, life-prolonging treatment, and hospice care on the assumption of a fatal disease diagnosis and the expectation of death within a few weeks ($P < 0.005$). From baseline to 7 weeks, the decrease in preference in the intervention group was not significant for active treatment, life-prolonging treatment, and hospice care in the intervention group in the subset expecting to die within 1 year, compared with the control group. Assuming a life expectancy of several months and a few weeks, the change in preferences was not significant for active

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treatment and for life-prolonging treatment but was significantly greater for hospice care in the intervention group ($P < 0.005$).

Conclusion. ACP interventions that included a video and an accompanying book improved preferences for EOL care. *J Pain Symptom Manage* 2019;■:■–■. © 2019 American Academy of Hospice and Palliative Medicine. Published by Elsevier Inc. All rights reserved.

Key Words

Advance care planning, decision aid, advanced cancer patients

Introduction

Most patients, caregivers, and health care practitioners believe that patients want to share decision-making regarding their end-of-life (EOL) care.^{1,2} Although patients' wishes to discuss their preferences regarding aggressive care, life-prolonging treatments, and hospice care should be respected,^{3,4} most patients do not have the opportunity to express them.⁵ Recent studies suggest that inadequate information, poor communication with practitioners, and being unprepared for EOL decision-making lead to patients receiving unwanted aggressive care,^{1,2,6,7} which is associated with poor caregiver bereavement adjustment.⁸

In February 2016, the Act on Decisions on Life-Prolonging Treatment for Patients at the End of Life was enacted in South Korea. After February 2018, Korean physicians could withhold or withdraw chemotherapy, ventilators, cardiopulmonary resuscitation (CPR), and hemodialysis from dying patients. The Act introduced advance care planning (ACP), such as advance directives (ADs) and physicians' orders for life-sustaining treatment (POLSTs).

ACP consists of voluntary discussions concerning EOL care options, including hospice care, life-prolonging treatments, and surrogate decision-making through an AD or documentation of patient preferences in the medical record, such as a POLST.^{3,7,9–11} Some ACP randomized controlled trials (RCTs) that included a decision aid (DA) such as a short video or a Web site describing CPR were associated with an increase in the completion of ADs or written legal documentation and EOL discussions.^{4,6,12–15}

Few tools met all the International Patient Decision Aid Standards (IPDAS)¹⁶ for judging the quality and efficacy of DAs for ACP, and some did not include a self-management strategy for developing a decision support tool for ACP.¹³ Moreover, despite well-documented racial and ethnic differences in ACP,¹⁷ few ACP trials have been evaluated in racial/ethnic settings outside the United States.^{1,17} Furthermore, no RCT of an ACP decision support tool has evaluated the efficacy of a DA with a video and a booklet providing ACP information compared with a tool consisting of a video and a control booklet containing

different content. More studies are needed with different experimental designs, settings, populations, and outcome measures.

Therefore, using the IPDAS¹⁶ criteria and strategy for self-management, we aimed to develop a complex DA consisting of an ACP video and a booklet explaining active treatment, life-prolonging treatments, and hospice care, as well as DA and POLST, to help patients understand their EOL care options. Here, we describe a multisite RCT designed to test whether the DA explaining ACP is more likely than the control DA to help patients with advanced cancer understand ACP and select a preference for their eventual EOL care.

Methods

Design and Participants

In this RCT, we examined the efficacy of an educational DA explaining ACP versus a control DA. The trial was conducted in Seoul National University Hospital and seven general hospitals in Korea from August 2017 to February 2018. Patients with advanced cancer were identified as potential participants by the investigators at outpatient clinics and hospital wards of eight participating South Korean hospitals and were provided with information pamphlets about this study. If patients expressed an interest in participating, the research staff provided them with details about the study's purpose and procedures. Participants provided written informed consent and were subjected to a baseline survey. The institutional review boards in Seoul National University Hospital Clinical Research Institute approved the protocol (IRB No. 1706-026-857), and this study is also registered with [ClinicalTrials.gov](https://www.clinicaltrials.gov), number NCT03252678.

This RCT had an open-label, parallel-group, and comparative efficacy design. We used an Internet-based clinical research and trial management system (iCreat) for subject randomization. Based on a computer-generated random scheme, patients were assigned equally to either the intervention group (video and book about ACP) or the control group (video and book about controlling cancer pain). Participants had two visits but completed the

questionnaire at all three time points. At the baseline visit, they were asked to complete the questionnaire before the randomization. They received and viewed either video and book about ACP (the intervention group) or video and book about controlling cancer pain (the control group). They were asked to respond to the second questionnaire immediately after intervention and to the third questionnaire was during the second visit seven weeks after intervention. Owing to the nature of the study, research assistants had to perform face-to-face procedures and so could not be blinded when assigning participants and collecting data seven weeks after intervention.

Participants randomized to the intervention group received and viewed a 20-minute decision-support video on a notebook computer and a companion 43-page book developed by the research team entitled *Advance Care Planning*. Participants randomized to the control group received and viewed a 23-minute video on cancer pain control on a notebook computer and a 26-page companion book developed by the National Cancer Center—Korea entitled *Controlling Cancer Pain*. It was not developed using IPDAS. The video and book about controlling cancer pain were not provided as a standard of care but as an attention control.

Participants were given enough time to view the books and videos, which took, on average, about an hour. Researchers helped the patient finish the books and videos. Participants filled out a questionnaire and received a take-home compact disc containing the watched video and the companion book. All the video materials were provided in compact disc format, and quick response codes were generated to be available for home use. After seven weeks, patients returned to the hospital where they had answered the baseline questionnaire and, with the help of the research assistant (RA), answered a third questionnaire. The RA was blinded to the random assignment scheme when collecting data at Week 7.

We invited patients with advanced cancer who were over 20 years of age, understood the intention of the study, and agreed to participate to enroll in the study. We defined cancer as advanced if it had metastasized and could no longer be cured or controlled. Patients who were unable to speak or read Korean, had trouble understanding the contents of videos because of vision or hearing defects, or were in poor health (e.g., had symptoms of dyspnea, severe depression, or other psychological problems) were excluded. Physicians confirmed inclusion and exclusion criteria before patient enrollment.

Development of Decision Aid

We reviewed the literature on ACP,^{18–21} hospice care, early palliative care,^{22,23} and EOL care²⁴ and

developed book and video drafts that were reviewed by a group of oncologists. In addition, we held structured discussions of ACP and hospice care with 10 patients and included that content in the books and videos as appropriate. As recommended by the Smart Management Strategy for Health Assessment Tool,²⁵ we provided information in the two-part DA (video and companion book) about ACP, including its planning and preparation, life-prolonging treatment, hospice care, the need for patient participation in decision-making, the necessity to prepare for death, perceptions of death, and the requirement, methods, and barriers of communication with medical staff, friends, and family. Using IPDAS criteria,¹⁶ we evaluated the decision-support tools to establish consensus on the quality of available patient decision-support devices.

Measurements

The primary outcome was the change in EOL care preferences from baseline to immediately after intervention and seven weeks. The questionnaire asked the following at all three time points: What would be your care preference when you are diagnosed with a fatal disease and are facing death 1) within one year, 2) within several months, and 3) within a few weeks? The response options for care preference were 1) active treatment, including clinical trials, 2) life-prolonging treatment, such as admission to an intensive care unit, mechanical ventilation, and CPR, and 3) hospice care. The score for each the response options ranged from 1 (strongly agree) to 4 (strongly disagree) (online [Appendix Table 1](#)).

We assessed knowledge of ACP and CPR with six questions¹⁵ with scores ranging from 0 to 6 and higher scores indicating greater knowledge. The questionnaire examined the patients' intention to develop an ACP, their completion of an ACP discussion, or their obtaining assistance in preparing an advanced care document. For participating in decision preferences, we used the Control Preferences Scale,²⁶ which measures "the degree of control an individual wants to assume when decisions are being made about medical treatment."

To measure psychological distress, we used the Hospital Anxiety and Depression Scale,²⁷ which consists of 14 items—seven for anxiety and seven for depression. In addition, we investigated the decisional conflict of participants with the Decisional Conflict Scale.²⁸ Decision conflict occurred when a patient was diagnosed with a fatal disease and had to decide on care preferences. Those participants randomized to the intervention arm were asked how comfortable they were watching the images (very, somewhat, a little, or not), how clear the decision support tool was (very, somewhat, a little, or not), and whether they would

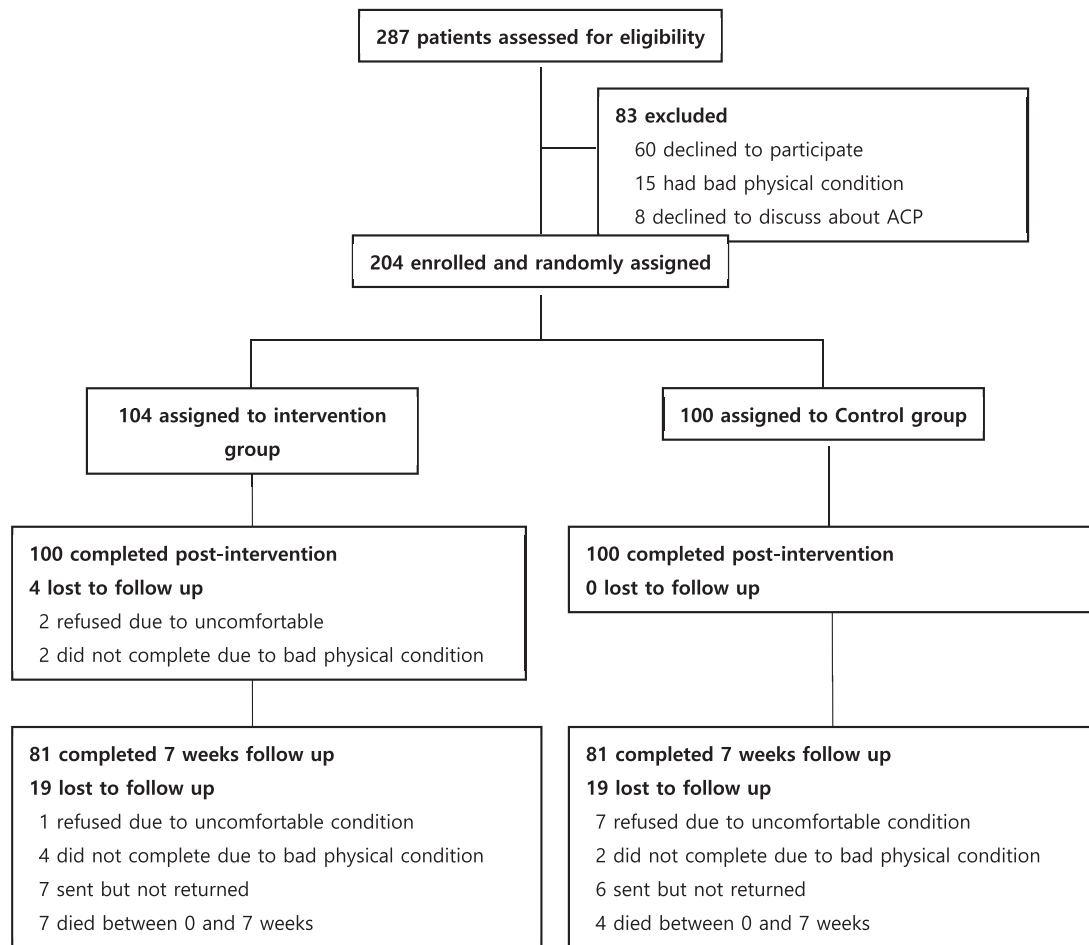


Fig. 1. Flow diagram of participants: recruitment and eligibility screening, randomization, follow-up, and analysis.

recommend the tool to other patients (definitely, probably, probably not, or definitely not).

Secondary outcomes, which were also assessed at baseline and seven weeks, included intention to develop an ACP document, knowledge about ACP and CPR, a decision to participate in EOL care discussions and prepare required documents, knowledge of ADs, anxiety, depression, and decisional conflict.

Statistical Analyses

The primary outcome was the difference between the intervention and control groups in change of preference for EOL care under the three life expectancy assumptions from baseline to seven weeks. Needing a sample size of 164, we calculated the size by the Chi-square test, assuming that the proportion change of the two groups' preferences would not be unequal, a 15% proportion difference (20% and 5%), 5% type I error rate, and greater than 80% power to detect a between-group difference. We analyzed the 204 participants assigned to both the intervention and the control group using incidence and percentage for categorical variables and mean \pm SD for continuous

variables. We used the Chi-square test to compare baseline EOL care preferences for the two groups and the Chi-square test or Fisher's exact test for change of primary outcomes from baseline to postintervention and at seven weeks. We also examined secondary outcomes between the two groups from baseline to seven weeks with the Chi-square test or Fisher's exact test for categorical variables and the two-sample *t*-test or Mann-Whitney test for continuous variables. Although we measured the change rates of preference for hospice care, we measured change rates of nonpreference for active treatment, including clinical trials and life-prolonging treatment that would be excessively aggressive at the end of life.

We also used Bonferroni correction methods to adjust for multiple comparisons and to maintain a family-wise error rate of less than 0.05. For nine primary outcomes (preference of active treatment, life-prolonging treatment, and hospice care if the expected life expectancy was within one year, several months, or a few weeks from baseline to seven weeks), the cutoff α level was 0.005 ($\alpha' = 0.05/9$). For eight secondary outcomes, the cutoff α level was 0.006

Table 1
Demographic and Clinical Characteristics of Participants

	Intervention Group (<i>n</i> = 104)		Attention-Control Group (<i>n</i> = 100)	
	No. of Patients	%	No. of Patients	%
Age, yrs				
Mean ± SD	58.1 ± 11.9		57.1 ± 11.0	
Sex				
Male	41	39.4	38	38.0
Female	63	60.6	62	62.0
Education				
≤ Middle school graduate	40	38.5	27	27.0
High school	43	41.3	41	41.0
≥ College or University	21	20.2	32	32.0
Marital status				
Married or with partner	78	75.0	76	76.0
Single	7	6.7	10	10.0
Widowed	11	10.6	6	6.0
Divorced or separated	8	7.7	8	8.0
Tumor site				
Breast	35	33.7	40	40.0
Lung	8	7.7	10	10.0
Colon	14	13.5	14	14.0
Stomach	3	2.9	4	4.0
Pancreas/bile duct/gall bladder	3	2.9	3	3.0
Other	41	39.4	29	29.0
ECOG status				
0–1	80	76.9	82	82.0
2	15	14.4	13	13.0
3–4	9	8.7	5	5.0

ECOG = Eastern Cooperative Oncology Group.

($\alpha' = 0.05/8$). We used STATA software, version 14.1, and SPSS software, version 23.0, for all analyses, and considered $P < 0.05$ to be statistically significant.

Results

Of the 287 eligible patients we contacted, 60 refused to participate, the most common reason being that they felt uncomfortable with the questionnaire. In addition, 15 people were excluded because they were not in good enough physical condition to watch videos or read educational materials, and eight refused to discuss ACP. [Figure 1](#) shows the patient flow chart, and [Table 1](#) shows their baseline characteristics. At seven weeks, compliance was 78% (81 patients) in the intervention group and 81% (81) in the control group.

Outcomes

[Table 2](#) shows the changes in preference for active treatment, life-prolonging treatment, and hospice care according to life expectancy (a few weeks, a few months, or a year) at postintervention and at seven weeks. At postintervention, the intervention group showed a significant change in all EOL care except

for life-prolonging treatment when life expectancy was assumed to be several months. From baseline to seven weeks, the decrease in preference was not significant for active treatment (group difference, 7.3%), life-prolonging treatment (9.9%), and hospice care (11.1%) in the intervention group in the subset expecting to die within one year, compared with control group. Assuming life expectancy to be several months, the change in preferences was not significant for active treatment (3.5%) or for life-prolonging treatment (2.5%) but was significantly greater for hospice care (16.0%) ($P = 0.001$). In the subset expecting to die within a few weeks, the intervention group showed a significant change in hospice care preference (16.0%) ($P = 0.003$). There were no significant change differences for active treatment, life-prolonging treatment, and hospice care from postintervention to seven weeks for each scenario.

We added a table for the result with the change pattern for each group (online [Appendix Table 2](#)).

[Table 3](#) shows that, compared with the control group, the intervention group did not significantly decrease its intention to document its advance care preferences. At baseline, the intervention and control groups did not differ significantly in CPR knowledge scores (4.18 vs 4.38), but at seven weeks, the score significantly increased in the intervention group, but not in the control group ($P = 0.005$). At baseline, 22 respondents in the intervention group and 14 in the control group reported discussing EOL care with their families, friends, or physicians. After seven weeks, 27 in the intervention group and 18 in the control group reported such discussions, but the difference was not significant ($P = 0.127$). And at seven weeks, only seven subjects in the intervention group and five in the control group reported documenting their advance care preferences ($P = 0.577$). At seven weeks after the intervention, we found no significant disparity between the intervention group and the control group in changes of decisional role preference ($P = 0.583$), in decisional conflict ($P = 0.681$), or in anxiety ($P = 0.917$) and depression ($P = 0.321$).

Of the 100 respondents who participated in the intervention, 96 reported that they were very comfortable or moderately comfortable with the material, and 98 reported that the training materials were helpful. In addition, 88 of the subjects noted that they would recommend this decision support tool to other patients.

Discussion

Main Findings of the Study

The DA intervention for ACP reduced the preference for active and life-prolonging treatment and

Table 2
Group Differences in the Proportion of the Patients Whose End-of-Life Care Preference Change

	Intervention Group (<i>n</i> = 104)	Attention-Control Group (<i>n</i> = 100)	Group Difference (95% CI, %) ^{<i>a</i>}	Adjusted <i>P</i> -value ^{<i>b</i>}
	No./Total No. (%)	No./Total No. (%)		
Expected to die within one year				
Active treatment ^{<i>c</i>}				
Baseline to postintervention	16/100 (16.0)	1/100 (1.0)	15.0 (7.5 to 22.5)	<0.001
Baseline to seven weeks' f/u	15/81 (18.3)	9/81 (11.1)	7.3 (−3.8 to 18.1)	N/S
Postintervention to seven weeks' f/u	10/81 (12.3)	9/81 (11.1)	1.1 (−7.2 to 9.9)	N/S
Life-prolonging treatment				
Baseline to postintervention	11/100 (11.0)	1/100 (1.0)	10.0 (3.5 to 16.5)	0.003
Baseline to seven weeks' f/u	16/81 (19.8)	8/81 (9.9)	9.9 (−1.1 to 20.9)	N/S
Postintervention to seven weeks' f/u	13/81 (16.0)	9/81 (11.1)	4.7 (−3.5 to 12.8)	N/S
Hospice care ^{<i>d</i>}				
Baseline to postintervention	18/100 (18.0)	3/100 (3.0)	15.0 (6.7 to 23.3)	0.001
Baseline to seven weeks' f/u	14/81 (17.3)	5/81 (6.2)	11.1 (1.2 to 21.0)	N/S
Postintervention to seven weeks' f/u	7/81 (8.5)	6/81 (7.4)	1.1 (−7.0 to 9.4)	N/S
Expected to die within several months				
Active treatment				
Baseline to postintervention	19/100 (19.0)	2/100 (2.0)	17.0 (8.7 to 25.3)	<0.001
Baseline to seven weeks' f/u	16/81 (19.5)	13/81 (16.0)	3.5 (−8.4 to 15.4)	N/S
Postintervention to seven weeks' f/u	7/81 (8.5)	15/81 (18.3)	−9.9 (−18.2 to 1.7)	N/S
Life-prolonging treatment				
Baseline to postintervention	13/100 (13.0)	3/100 (3.0)	10.0 (2.5 to 17.5)	N/S
Baseline to seven weeks' f/u	12/81 (14.8)	10/81 (12.3)	2.5 (−8.2 to 13.2)	N/S
Postintervention to seven weeks' f/u	5/81 (6.2)	10/81 (12.3)	−6.0 (−14.2 to 2.4)	N/S
Hospice care				
Baseline to postintervention	21/100 (21.0)	5/100 (5.0)	16.0 (7.6 to 23.2)	0.001
Baseline to seven weeks' f/u	15/81 (18.5)	2/81 (2.5)	16.0 (6.8 to 25.3)	0.001
Postintervention to seven weeks' f/u	7/81 (8.5)	3/81 (3.7)	4.8 (−11.2 to 20.2)	N/S
Expected to die within a few weeks				
Active treatment				
Baseline to postintervention	11/100 (11.0)	1/100 (1.0)	10.0 (3.5 to 16.5)	0.003
Baseline to seven weeks' f/u	7/81 (8.5)	6/81 (7.4)	1.1 (−7.3 to 9.6)	N/S
Postintervention to seven weeks' f/u	3/81 (3.7)	8/81 (9.9)	−6.2 (−14.2 to 1.7)	N/S
Life-prolonging treatment				
Baseline to postintervention	8/100 (8.0)	0/100 (0.0)	8.0 (2.6 to 13.4)	0.004
Baseline to seven weeks' f/u	10/81 (12.3)	6/81 (7.4)	4.9 (−4.3 to 14.2)	N/S
Postintervention to seven weeks' f/u	5/81 (6.2)	8/81 (9.9)	−3.4 (−9.4 to 2.9)	N/S
Hospice care				
Baseline to postintervention	24/100 (24.0)	4/100 (4.0)	20.0 (10.7 to 29.3)	<0.001
Baseline to seven weeks' f/u	18/81 (22.2)	5/81 (6.2)	16.0 (5.4 to 26.7)	0.003
Postintervention to seven weeks' f/u	10/81 (12.3)	7/81 (8.5)	3.7 (−5.5 to 12.8)	N/S

^aGroup difference in the percentage of people whose preferences have changed.

^bSignificant after Bonferroni correction for multiple comparisons with an adjusted *P* level of 0.005 (*P*' = 0.05/9).

^cPatients with a change in preference for active treatment or life-prolonging treatment were defined as persons who preferred these treatments at baseline and changed to not prefer them after intervention. Those who had no preference but changed to preferred and those who had no change in preference were considered to be in the unchanged group.

^dPatients with a change in preference for hospice care were defined as persons who did not prefer hospice care at baseline and changed to prefer hospice care after intervention. Those who had a preference for hospice care but changed to not prefer hospice care and those who had no change in preference were considered to be in the unchanged group.

increased the preference for hospice care as a primary outcome in all three life expectancy subgroups. The effect of the DA intervention for ACP continued over seven weeks in all three subgroups only for hospice care. Our finding that a cancer patient DA intervention that consisted of a video plus a booklet explaining ACP increased the preference for EOL care as a primary outcome was consistent with an

earlier study of that reported the efficacy of a DA for ACP along with a video.⁴ Although at postintervention, the intervention was significantly associated with a change in all EOL care except for life-prolonging treatment assuming a life expectancy of several months, it was associated only with a change in preference for hospice care at seven weeks. This intervention needs further development to improve EOL care

Table 3

Secondary Outcomes Between Intervention Group and Attention-Control Group at Baseline and Seven Weeks' Follow-Up

	Intervention Group	Attention-Control Group	Adjusted <i>P</i> value ^a
Intention to document ACP—No. of participants/Total no. (%)			
Baseline ^b	74/104 (71.1)	64/100 (64.0)	0.007
Seven weeks' f/u ^c	60/81 (74.1)	44/81 (54.3)	
CPR Knowledge score			
Baseline	4.18 ± 1.51	4.38 ± 1.37	0.005
Seven weeks' f/u	5.12 ± 0.97	4.66 ± 1.11	
Decisional role preference (active roles)			
Baseline	77/104 (74.0)	75/100 (75.0)	0.583
Seven weeks' f/u	68/81 (84.0)	69/81 (85.2)	
EOL care discussion and documentation			
Having EOL care discussion (Yes)			
Baseline	22/104 (21.2)	14/100 (14.0)	0.127
Seven weeks' f/u	27/81 (33.3)	18/81 (22.2)	
Having documentation of their own preference of EOL care (Yes)			
Baseline	6/104 (5.8)	3/100 (3.0)	0.577
Seven weeks' f/u	7/81 (8.6)	5/81 (6.2)	
HADS ^d			
Anxiety score			
Baseline	6.14 ± 4.00	5.98 ± 3.96	0.917
Seven weeks' f/u	6.18 ± 4.17	6.23 ± 3.73	
Depression score			
Baseline	6.87 ± 3.87	7.02 ± 3.83	0.321
Seven weeks' f/u	6.71 ± 4.13	7.30 ± 3.57	
Decisional Conflict Scale (Total) score ^e			
Baseline	31.60 ± 13.88	32.34 ± 12.36	0.681
Seven weeks' f/u	31.21 ± 11.78	34.36 ± 12.81	

ACP = advance care preference; CPR = cardiopulmonary resuscitation; EOL = end of life; f/u = follow-up; HADS = Hospital Anxiety and Depression Scale.

^aSignificant after Bonferroni correction for multiple comparisons with an adjusted *P* level of 0.006 (*p*' = 0.05/8).

^bAt baseline, intervention group *N* = 104 and attention-control group *N* = 100.

^cAt seven weeks' follow-up, intervention group *N* = 81 and attention-control group *N* = 81.

^dHADS anxiety and depression scores are based on a scale of 0 to 21 separately, with lower scores indicating better anxiety or depression ("± values" are means ± SD).

^e*P* values are based on a two-sided score test of the intervention effect using seven-week data estimated from a linear regression model controlling for baseline value.

Decisional Conflict Scale scores are based on a scale of 0 to 100, with higher scores indicating more severe conflict status ("± values" are means ± SD). *P* values are based on a two-sided score test of the intervention effect using seven-week data estimated from a linear regression model controlling for baseline value.

preferences. The efficacy of the DA for preference for hospice care at seven weeks was probably enhanced by patients taking the video and book home, where they could review them repeatedly at their leisure.

In addition, patients who viewed the DA for ACP were more knowledgeable about CPR, whereas there seemed to be no detrimental effect on decisional conflict, anxiety, or depression. These findings suggest that patients' decisional conflict, anxiety, or depression might not increase with a greater understanding of ACP, which is consistent with another RCT that used video tools.¹⁰ With further development, the DA for ACP could be made effective enough to lessen such distress.²⁹ The total Decisional Conflict Scale score was higher in this study than in others.^{29,30} That result is understandable considering that although >72% of the patients were willing to conduct ACP when their disease was aggressive or terminal, only one in three patients in Korea knew about ADs. Furthermore, the most common reason for not wanting to write an AD was the possibility of patients changing their mind when faced with the reality of the situation. In addition, the utilization of hospice care was low: 22.0% among patients with cancer and 6.1% of deaths nationwide in 2017, in contrast with the high use of aggressive EOL care in Korea.

In Korea in 2012, over 90% of patients, family caregivers, the general public, and oncologists agreed with the need for DAs.³¹ In February 2016, the National Assembly of Korea ruled that patients could make their own life-prolonging treatment decisions, and after February 2018, dying patients with a DA or POLST could withhold or withdraw life-prolonging treatments such as chemotherapy, ventilators, CPR, and hemodialysis. Thus, physicians need to discuss their patients' EOL preference via the DA, and involving patients with cancer in ACP empowers them by respecting their autonomy.⁷ A DA with video and booklet could play a significant role in helping patients make more informed decisions and communicate with health professional about their EOL care.¹³

Strengths and Limitations of the Study

To the best of our knowledge, this study represents the only RCT that compares a decision support tool with both a video and book for ACP using the IPDAS criteria and strategy for self-management to a similar tool consisting of a video and booklet but with different contents (serving as an attention control) among non-U.S. patients with advanced cancer.

Our findings have several limitations. First, the RAs were not blinded to the random group assignments or

while collecting primary outcome data, although they were blinded when we measured primary and secondary outcomes at seven weeks. Second, the study focused only on understanding ACP to help patients decide on their EOL care goals. A long-term study is needed to evaluate the efficacy of our DA on the completion of an ACP document and its effect on EOL care decisions. Third, the question used to measure the primary outcomes was generated by the authors for the purpose of this investigation and was not validated. Fourth, the difference between “active treatment, including clinical trials” and “life-prolonging treatment” such as admission to an intensive care unit, mechanical ventilation, and CPR is weak and vague. Therefore, there were some outcome measurement errors. Fifth, the primary outcome used to investigate care preference with the hypothetical scenarios was validated. This primary outcome was used to investigate care preference with the same hypothetical scenarios among the general population, patients with cancer, their family members, and physicians. We did not publish these data yet, however, and did not evaluate psychometric properties. Finally, the generalizability of our study is limited because all the participants were Korean patients with cancer. Further study is needed to evaluate the usefulness of our DA in more diverse populations, including the general population and patients with other severe illnesses, and in other cultures.

Conclusion

This study provides evidence that a decision support tool with a video and an ACP booklet using the IPDAS criteria and strategy for self-management can improve understanding of ACP and attitudes toward EOL care. Further long-term study is needed to evaluate the usefulness of the DA in more diverse populations, including the general population and patients with other illnesses.

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References

1. Austin CA, Mohottige D, Sudore RL, Smith AK, Hanson LC. Tools to promote shared decision making in serious illness: a systematic review. *JAMA Intern Med* 2015; 175:1213–1221.
2. Walling A, Lorenz KA, Dy SM, et al. Evidence-based recommendations for information and care planning in cancer care. *J Clin Oncol* 2008;26:3896–3902.
3. Houben CH, Spruit MA, Groenen MT, Wouters EF, Janssen DJ. Efficacy of advance care planning: a systematic review and meta-analysis. *J Am Med Directors Assoc* 2014; 15:477–489.
4. Volandes AE, Paasche-Orlow MK, Barry MJ, et al. Video decision support tool for advance care planning in dementia: randomised controlled trial. *BMJ* 2009;338:b2159.
5. Korfage IJ, Rietjens JA, Overbeek A, et al. A cluster randomized controlled trial on the effects and costs of advance care planning in elderly care: study protocol. *BMC Geriatr* 2015;15:87.
6. El-Jawahri A, Mitchell SL, Paasche-Orlow MK, et al. A randomized controlled trial of a CPR and intubation video decision support tool for hospitalized patients. *J Gen Intern Med* 2015;30:1071–1080.
7. El-Jawahri A, Podgurski LM, Eichler AF, et al. Use of video to facilitate end-of-life discussions with patients with cancer: a randomized controlled trial. *J Clin Oncol* 2010; 28:305.
8. Park SM, Kim YJ, Kim S, et al. Impact of caregivers' unmet needs for supportive care on quality of terminal cancer care delivered and caregiver's workforce performance. *Support Care Cancer* 2010;18:699–706.
9. Dixon J, Matosevic T, Knapp M. The economic evidence for advance care planning: systematic review of evidence. *Palliat Med* 2015;29:869–884.
10. Green MJ, Schubart JR, Whitehead MM, et al. Advance care planning does not adversely affect hope or anxiety among patients with advanced cancer. *J pain symptom Manag* 2015;49:1088–1096.
11. Volandes AE, Levin TT, Slovin S, et al. Augmenting advance care planning in poor prognosis cancer with a video decision aid. *Cancer* 2012;118:4331–4338.
12. Vogel RI, Petzel SV, Cragg J, et al. Development and pilot of an advance care planning website for women with ovarian cancer: a randomized controlled trial. *Gynecol Oncol* 2013;131:430–436.
13. Volandes AE, Paasche-Orlow MK, Mitchell SL, et al. Randomized controlled trial of a video decision support tool for cardiopulmonary resuscitation decision making in advanced cancer. *J Clin Oncol* 2013;31:380.
14. Volandes AE, Mitchell SL, Gillick MR, Chang Y, Paasche-Orlow MK. Using video images to improve the accuracy of surrogate decision-making: a randomized controlled trial. *J Am Med Directors Assoc* 2009;10:575–580.

15. El-Jawahri A, Paasche-Orlow MK, Matlock D, et al. Randomized, controlled trial of an advance care planning video decision support tool for patients with advanced heart failure: clinical perspective. *Circulation* 2016;134:52–60.
16. Holmes-Rovner M. International Patient Decision Aid Standards (IPDAS): beyond decision aids to usual design of patient education materials. *Health Expect* 2007;10:103–107.
17. Smith AK, McCarthy EP, Paulk E, et al. Racial and ethnic differences in advance care planning among patients with cancer: impact of terminal illness acknowledgment, religiousness, and treatment preferences. *J Clin Oncol* 2008;26:4131.
18. Mullick A, Martin J, Sallnow L. Advance care planning. *BMJ* 2013;347:28–32.
19. Henry C, Seymour J, Ryder S. Advance care planning: a guide for health and social care staff. London: National End of Life Care Programme, Department of Health, 2007.
20. Butler M, Ratner E, McCreedy E, Shippee N, Kane RL. Decision aids for advance care planning. Rockville, MD: Agency for Healthcare Research and Quality Publications, 2012.
21. Oncology ASOC. Advanced cancer care planning: a decision-making guide for patients and families facing serious illness. In: Oncology ASOC, ed. Alexandria, VA: American Society of Clinical Oncology, 2013:4–29.
22. Zimmermann C, Swami N, Krzyzanowska M, et al. Early palliative care for patients with advanced cancer: a cluster-randomised controlled trial. *Lancet* 2014;383:1721–1730.
23. Bakitas MA, Tosteson TD, Li Z, et al. Early versus delayed initiation of concurrent palliative oncology care: patient outcomes in the ENABLE III randomized controlled trial. *J Clin Oncol* 2015;33:1438–1445.
24. Balboni TA, Balboni M, Enzinger AC, et al. Provision of spiritual support to patients with advanced cancer by religious communities and associations with medical care at the end of life. *JAMA Intern Med* 2013;173:1109–1117.
25. Yun YH, Jung JY, Sim JA, et al. Patient-reported assessment of self-management strategies of health in cancer patients: development and validation of the Smart Management Strategy for Health Assessment Tool (SAT). *Psycho-Oncology* 2015;24:1723–1730.
26. Degner LF, Sloan JA, Venkatesh P. The control preferences scale. *Can J Nurs Res* 1997;29:21–43.
27. Zigmond AS, Snaith RP. The hospital anxiety and depression scale. *Acta Psychiatr Scand* 1983;67:361–370.
28. O'Connor AM. Validation of a decisional conflict scale. *Med Decis making* 1995;15:25–30.
29. Yun YH, Lee MK, Park S, et al. Use of a decision aid to help caregivers discuss terminal disease status with a family member with cancer: a randomized controlled trial. *J Clin Oncol* 2011;29:4811–4819.
30. Miller SM, Hudson SV, Eggleston BL, et al. The relationships among knowledge, self-efficacy, preparedness, decisional conflict, and decisions to participate in a cancer clinical trial. *Psychooncology* 2013;22:481–489.
31. Hong JH, Kwon JH, Kim IK, et al. Adopting advance directives reinforces patient participation in end-of-life care discussion. *Cancer Res Treat* 2016;48:753.

Appendix

Appendix Table 1
End-of-Life Care Preferences of Participants

	Strongly Agree	Agree	Disagree	Strongly Disagree
What would be your care preference when you are diagnosed with a fatal disease and are facing death 1) within one year, 2) within several months, and 3) within a few weeks? Please respond to the Following steps to indicate your preference for the following options:				
Expected to die within one year				
Active treatment including clinical trials	①	②	③	④
Life-prolonging treatment such as admission to an intensive care unit, mechanical ventilation, and CPR	①	②	③	④
Hospice care	①	②	③	④
Expected to die within several months				
Active treatment including clinical trials	①	②	③	④
Life-prolonging treatment such as admission to an intensive care unit, mechanical ventilation, and CPR	①	②	③	④
Hospice care	①	②	③	④
Expected to die within a few weeks				
Active treatment including clinical trials	①	②	③	④
Life-prolonging treatment such as admission to an intensive care unit, mechanical ventilation, and CPR	①	②	③	④
Hospice care	①	②	③	④

Appendix Table 2
End-of-Life Care Preferences^a: For Aggressive Care, Life-Sustaining Treatment, and Hospice Care at Baseline and After Intervention

Baseline	Intervention Group (<i>n</i> = 104) No./Total No. (%)				Attention-Control Group (<i>n</i> = 100) No./Total No. (%)			
	Preferred on Baseline		Not Preferred on Baseline		Preferred on Baseline		Not Preferred on Baseline	
After intervention	Preferred	Not Preferred	Preferred	Not preferred	Preferred	Not Preferred	Preferred	Not Preferred
Expected to die within one year								
Active treatment								
Baseline	78/104 (75.0)		26/104 (25.0)		71/100 (71.0)		29/100 (29.0)	
Postintervention	58/74 (78.4)	16/74 (21.6)	4/26 (15.4)	22/26 (84.6)	70/71 (98.6)	1/71 (1.4)	6/29 (20.7)	23/29 (79.3)
Seven weeks' f/u	42/57 (73.7)	15/57 (26.3)	8/24 (33.3)	16/24 (66.7)	46/55 (83.6)	9/55 (16.4)	7/26 (26.9)	19/26 (73.1)
Life-prolonging treatment								
Baseline	34/104 (32.7)		70/104 (67.3)		27/100 (27.0)		73/100 (73.0)	
Postintervention	23/34 (67.6)	11/34 (32.4)	5/66 (7.6)	61/66 (92.4)	26/27 (96.3)	1/27 (3.7)	5/73 (6.8)	68/73 (93.2)
Seven weeks' f/u	11/27 (40.7)	16/27 (59.3)	5/54 (9.3)	49/54 (90.7)	14/22 (63.6)	8/22 (36.4)	14/59 (23.7)	45/59 (76.3)
Hospice care								
Baseline	81/104 (77.9)		23/104 (22.1)		76/100 (76.0)		24/100 (24.0)	
Postintervention	72/77 (93.5)	5/77 (6.5)	18/23 (78.3)	5/23 (21.7)	74/76 (97.4)	2/76 (2.6)	3/24 (12.5)	21/24 (87.5)
Seven weeks' f/u	60/63 (95.2)	3/63 (4.8)	14/18 (77.8)	4/18 (22.2)	47/61 (77.1)	14/61 (22.9)	5/20 (25.0)	15/20 (75.0)
Expected to die within several months								
Active treatment								
Baseline	62/104 (59.6)		42/104 (40.4)		57/100 (57.0)		43/100 (43.0)	
Postintervention	39/58 (67.2)	19/58 (32.8)	3/42 (7.1)	39/42 (92.9)	55/57 (96.5)	2/57 (3.5)	5/43 (11.6)	38/43 (88.4)
Seven weeks' f/u	29/45 (64.4)	16/45 (35.6)	10/36 (27.8)	26/36 (72.2)	29/42 (69.1)	13/42 (30.9)	6/39 (15.4)	33/39 (84.6)
Life-prolonging treatment								
Baseline	30/104 (28.8)		74/104 (71.2)		26/100 (26.0)		74/100 (74.0)	
Postintervention	17/30 (56.7)	13/30 (43.3)	2/70 (2.9)	68/70 (97.1)	23/26 (88.5)	3/26 (11.5)	2/74 (2.7)	72/74 (97.3)
Seven weeks' f/u	11/23 (47.8)	12/23 (52.2)	4/58 (6.9)	54/58 (93.1)	10/20 (50.0)	10/20 (50.0)	9/61 (14.8)	52/61 (85.2)
Hospice care								
Baseline	78/104 (75.0)		26/104 (25.0)		77/100 (77.0)		23/100 (23.0)	
Postintervention	69/74 (93.2)	5/74 (6.8)	21/26 (80.8)	5/26 (19.2)	74/77 (96.1)	3/77 (3.9)	5/23 (21.7)	18/23 (78.3)
Seven weeks' f/u	61/61 (100.0)	0/61 (0.0)	15/20 (75.0)	5/20 (25.0)	49/63 (77.8)	14/63 (22.2)	2/18 (11.1)	16/18 (88.9)
Expected to die within a few weeks								
Active treatment								
Baseline	30/104 (28.8)		74/104 (71.2)		25/100 (25.0)		75/100 (75.0)	
Postintervention	16/27 (59.3)	11/27 (40.7)	1/73 (1.4)	72/73 (98.6)	24/25 (96.0)	1/25 (4.0)	6/75 (8.0)	69/75 (92.0)
Seven weeks' f/u	10/17 (58.8)	7/17 (41.2)	6/64 (9.4)	58/64 (90.6)	11/17 (64.7)	6/17 (35.3)	7/64 (10.9)	57/64 (89.1)
Life-prolonging treatment								
Baseline	21/104 (20.2)		83/104 (79.8)		13/100 (13.0)		87/100 (87.0)	
Postintervention	12/20 (60.0)	8/20 (40.0)	1/80 (1.3)	79/80 (98.7)	13/13 (100.0)	0/13 (0.0)	4/87 (4.6)	83/87 (95.4)
Seven weeks' f/u	4/14 (28.6)	10/14 (71.4)	3/67 (4.5)	64/67 (95.5)	5/11 (45.5)	6/11 (54.5)	7/70 (10.0)	63/70 (90.0)
Hospice care								
Baseline	73/104 (70.2)		31/104 (29.8)		65/100 (65.0)		35/100 (35.0)	
Postintervention	61/69 (88.4)	8/69 (11.6)	24/31 (77.4)	7/31 (22.6)	60/65 (92.3)	5/65 (7.7)	4/35 (11.4)	31/35 (88.6)
Seven weeks' f/u	53/56 (94.6)	3/56 (5.4)	18/25 (72.0)	7/25 (28.0)	40/53 (75.5)	13/53 (24.5)	5/28 (17.9)	23/28 (82.1)

^aThe number of people who responded with "strongly agree" or "agree" for each preference.