Original Article

Randomized Controlled Trial of Advance Care Planning Video Decision Aid for the General Population

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Abstract

Context. Advance care planning (ACP) in a healthy general population could improve the quality of care when a health problem arises.

Objectives. The purpose of this study was to evaluate the efficacy of video decision support aid in increasing the intention to document ACP in the general healthy population.

Methods. In this randomized controlled trial, we enrolled 250 members of the general population (aged 20 years and older and determined to be healthy), stratified by age and sex. The intervention was a video that provided information about ACP and end-of-life care options such as cardiopulmonary resuscitation (CPR) and palliative care. An attention-control arm was given a booklet about advance directives. Primary outcome was a change in intention to document ACP. Secondary outcomes included the intention to refuse CPR at terminal status, CPR and palliative care knowledge score, and the Hospital Anxiety and Depression Scale.

Results. About 250 participants were randomly assigned, half to the video-assisted intervention group and half to the attention-control group. Within one week postintervention, the intention to document ACP was significantly higher in the video-assisted intervention arm (68.0% vs. 39.2%; P < 0.001), and changes in the intention to document ACP were significantly greater in the video group than in the brochure group (P = 0.008; $\Delta = 14.4\%$). Palliative care knowledge score was also significantly increased in the video group (P = 0.036).

Conclusion. A well-constructed video decision support intervention can increase the intention to document ACP in the general population that presumably had little opportunity to discuss ACP with physicians. J Pain Symptom Manage 2020; ■:■─■. © 2019 American Academy of Hospice and Palliative Medicine. Published by Elsevier Inc. All rights reserved.

Key Words

Advance care planning, decision aid, palliative care, self-management, terminal care

Key Message

This article describes a randomized controlled trial that describes the efficacy of video decision support aid for advance care planning (ACP). This study shows that ACP video decision aid could enhance the intention to document ACP and awareness of palliative care in the general population.

Introduction

Concern for a patient's end-of-life (EOL) care preferences is an important component of the medical services that improve quality of care and quality of life. If a patient suddenly worsens, however, or if a lifethreatening situation occurs unexpectedly, it might be difficult to determine such preferences. In addition,

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even after hospital admission, a patient's desire for cardiopulmonary resuscitation (CPR) or an EOL care plan is frequently determined too late, ^{2–4} sometimes after the patient has lost decision-making ability.⁵ Advance care planning (ACP), which patients prepare on their own, reflects the patient's intentions and helps providers deliver goal-directed care. Especially in Korea, although 46.2% of the public hoped for a documentation of ACP, only about 1% of the adult population have a written ACP.⁶ Documentation of ACP is currently inexpensive, as it is supported by the government, and Korea has a low patient burden on EOL costs.

ACP decision support tools generally focus on patients with an advanced or terminal illness^{7,8} and are often inadequately explained by medical staff. These traditional approaches for ACP have various limitations, including inadequate explanations of specific disease courses, literacy barriers, and insufficient understanding on the part of the medical staff communicating with the patient. 10 Previous studies showed that providing ACP information and decision-making support to be effective. 11-13 Thus, a decision-making support video could help overcome those limitations. Presentation of an ACP video decision support tool to nursing home residents with advanced dementia increased directives to withhold tube feeding, 14 and a randomized controlled trial (RCT) of seriously ill patients who viewed a video about CPR and intubation were more likely to not want those treatments and to want to have more discussions with their medical providers. 15 A systematic review and meta-analysis concluded that video decision aids could improve some ACP-related outcomes, 12 but the covered studies focused mainly on patient populations. The general population, however, might differ in its understanding of disease, health care services, or ACP. Thus, it is not known whether an ACP educational support tool, such as those used in clinical studies, would encourage a nonpatient population to document ACP.

In this study, we constructed ACP video decision support materials for the general population and compared their effects on the intention to document ACP to a brochure on advance directives (ADs). The purpose of our study was to determine whether ACP educational materials are effective in a healthy general population who were not continuously admitted to hospital or hospitalized and did not have a chance to discuss ACP with medical staff. Our primary hypothesis was that participants in the video-assisted intervention arm would be more likely to change to intend to document ACP than those who received only the brochures on AD. Our secondary hypothesis was that the video-assisted arm would be more knowledgeable about CPR and ACP/palliative care and more likely to against CPR at terminal status.

Methods

Participants

We enrolled participants from April 27 to May 25, 2018. Of those who agreed to participate, eligibility criteria included aged at least 20 years, an understanding of the study intention, ability to speak or read Korean, and healthy people who have never been diagnosed with cancer or severe disease. The participants were recruited in accordance with the 2017 Korean census, using age and sex strata, in each of 17 major cities and local districts. We applied probability proportion-to-size sampling, ¹⁶ a technique that selects a representative national sample, adjusting the difference in probability between larger and smaller sampled groups.

Subjects were recruited through direct in-home visitations. Before study enrollment, an interviewer met potential participants, explained the aim of the study, obtained written informed consent, and then administered a baseline questionnaire. The interviewer visited the interviewees' home and helped them respond to the questionnaire.

Study Design and Randomization

This open-label, parallel-group, and RCT evaluated the efficacy of a video decision support tool for ACP compared with that of a brochure on AD. We used computer-generated simple randomization to create a 1:1 randomization list and used an Internet-based clinical research and trial management system (iCreat; Centers for Disease Control and Prevention, Korea) for allocation concealment. Participants were assigned equally to either the video-intervention arm or the booklet attention-control arm. Because this was done face to face, subjects and research assistants could not be blinded, so research assistants did not participate in the intervention or the evaluation of the results. This trial was registered, and the protocol was approved by the institutional review board (IRB) in Seoul National University Hospital Clinical Research Institute (IRB no. 1804-083-937 and clinicaltrials.gov identifier: NCT03638934).

Intervention

Participants assigned to the intervention arm viewed the 20-minute educational decision support video entitled *Advance Care Planning*, and this video was modified for the general population. These educational videos were previously tested and used in studies of patients with advanced cancer. ¹⁷ The video provided information about ACP and EOL care options such as CPR. It also included appropriate CPR information. The video was designed to enhance knowledge of ACP and motivate the general population to discuss their values and EOL care preferences

with their family, friends, and physicians. To develop the video, we reviewed studies and literature about ACP, 5,18,19 hospice palliative care, and EOL care. 18–20 We developed a video support decision aid based on the Smart Management Strategy for Health 11 to encourage participants in self-directed learning. We evaluated the educational video using International Patient Decision Aid Standards criteria to maintain the quality of available decision support devices. This video was designed for persons at all levels of health literacy comprehension, and the script was reviewed by experts in health literacy. Furthermore, a professional announcer read the script for clear distinct word enunciation and pronunciation.

Participants randomized to the attention-control arm received and read a 13-page brochure entitled, *Understanding the Life-Sustaining Treatment Act*, which was developed by the Korean Ministry of Health and Welfare. ²³ Participants completed the baseline questionnaire, were randomly assigned to either the group that watched the video or the group that read the brochure for 20 minutes, and then completed the postintervention questionnaire. Subjects provided postintervention responses within one week of receiving the education materials.

Data Collection and Other Variables

Baseline participant data included demographics (age, sex, educational status, marital status, and monthly income). We assumed that information exchange would occur through educational materials, and that could lead to changes in participants' priorities or preferences. We therefore set the primary outcomes confirming the effect of this study as healthy subjects' changes in intention to document ACP.²⁴ We explained the definition of ACP to the subjects and assessed their intention to document ACP with the question, "Are you willing to write an Advance Care Plan?" The scores for that intention ranged from one to four (one meaning strong rejection and four meaning strong intention). Intention to document ACP was determined to be present for response options three and four, whereas it was determined to be absent for response options one and two.¹⁷ We measured knowledge of CPR with four questions and knowledge of palliative care with two questions.8 Knowledge scores of CPR ranged from zero to four and scores of palliative care from zero to two, with higher scores representing more knowledgeable. The willingness to CPR in terminal status was categorized as 1) yes, attempt CPR, 2) no, do not attempt CPR, and 3) not sure. To measure psychological distress, we evaluated the Hospital Anxiety and Depression Scale, which consists of seven items for anxiety and seven items for depression. 25-28 To assess the acceptability of the educational materials, participants were asked to evaluate whether the decision support materials were comfortable to watch, helpful, and good enough to recommend to acquaintances.

Statistical Analyses

The primary outcome of our study was the change of the percentage in participants with a positive intention to document ACP. We calculated that a sample size of 220 patients per group had >80% power to detect a 15% difference at the 5% significance level, using the two-sample t-test for the difference between groups. We expected that the proportion of respondents with intentions for ACP documentation would differ between the two groups and further assumed that the difference would be at least 15%. We ascertained the percentage of the intention to document ACP at postintervention of the intervention arm and the attention-control arm initially and then examined the changes from baseline to postintervention between the two groups using Pearson's χ^2 test. One of the secondary outcomes was the willingness for the performance of CPR. We compared the change of the percentage of participants with CPR willingness between participants in the intervention arm and individuals in the attention-control arm using Pearson's χ^2 test with P-values. We also analyzed the changes from baseline to postintervention in secondary outcomes (CPR knowledge score, palliative care knowledge score, anxiety, and depression) between the intervention and attention-control arms using the two-sample

We performed univariate analyses to determine the relationship between characteristics of respondents (age, sex, educational status, marital status, monthly income, baseline knowledge of ACP, and random group assignment) and the intention to document ACP using Pearson's χ^2 test. The threshold for monthly household income was based on the median income for a family of four in Korea in 2018 (approximately \$4000), and the age of 50 years was based on the median age of Korean adults. We used multivariable logistic regression analysis to identify factors independently associated with the intention to document ACP, obtaining odds ratios (ORs) and 95% CIs. We described all participant characteristics as incidence percentage for categorical variables mean \pm SD for continuous variables. We also analyzed satisfaction with the educational materials in both postintervention groups. We used STATA software, Version 14.1 (StataCorp, College Station, TX) for all analyses.

Results

Recruitment and Follow-Up

During the study period, we contacted 832 eligible participants, of whom 272 (32.7%) agreed to

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participate and were enrolled. Eleven subjects in each group were lost after random assignment (Fig. 1). In the intervention group, nine patients refused to participate because of discomfort and two refused to discuss ACP. In the attention-control group, seven patients refused to participate because of discomfort and four refused to discuss ACP. Thus, 250 (30.0%) patients were assigned and completed the study. Participants did not differ significantly from nonparticipants in sex or mean age distribution. Subjects provided postintervention responses within one week of receiving the education materials. About 90.0% of the participants conducted postintervention surveys immediately after the intervention. If not, the research assistant visited the participants after adjusting the schedule to conduct the questionnaire. None of the participants was lost in follow-up (Fig. 1). At baseline, participants in the video and attentioncontrol group did not differ significantly in age, sex, educational level, marital status, monthly income, or knowledge of ACP (Table 1).

Intention to Document ACP

At postintervention, we found significant differences in the intention to document ACP between intervention and attention-control groups (Fig. 2). Although the intention to document ACP in the baseline was higher in the intervention group, group differences of the change of the intention to document ACP showed that the intention in the intervention

group increased significantly (group difference = 14.4%; P = 0.008).

Against CPR at Terminal Status

The opposition to CPR at terminal status did not differ significantly between the video group and the brochure group after intervention (Fig. 2). Compared with baseline, however, the intervention group significantly increased its opposition to EOL CPR, whereas the attention-control group showed a significant decrease. Thus, change of opposition to CPR differed significantly between the two arms (group difference = 10.4%; P = 0.024).

CPR and Palliative Care Knowledge Scores, Anxiety, and Depression

The CPR knowledge questionnaire consisted of four questions with one point for each. The intervention group and attention-control group did not differ significantly in CPR knowledge score. The palliative care questionnaire contained two 1-point questions; its knowledge score was significantly higher in the intervention group (P = 0.036). The change in anxiety and depression did not differ significantly between the intervention group (P = 0.363) and the attention-control group (P = 0.933) (Table 2).

Predictors of the Intention to Document ACP

In the multivariable logistic regression model (Table 3), female participants' intention to document

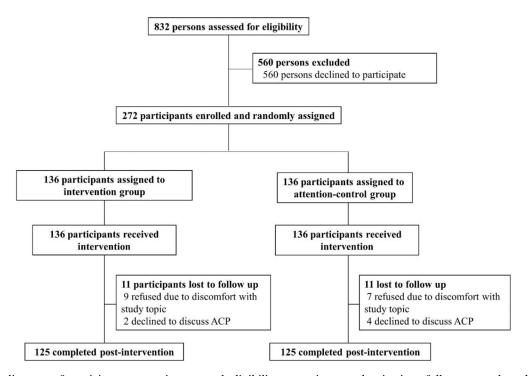


Fig. 1. Flow diagram of participants: recruitment and eligibility screening, randomization, follow-up, and analysis. ACP = advance care planning.

 $Table\ 1$ Demographic and Clinical Characteristics of Participants

	Intervention Group $(n = 125)$	Attention- Control Group (n = 125)
Age, Mean (SD), yrs	45.58 (13.43)	45.76 (12.85)
Sex, n (%)		
Male	62 (49.6)	62 (49.6)
Female	63 (50.4)	63 (50.4)
Education, n (%)		
Middle school or less	3 (2.4)	4 (3.2)
High school	50 (40.0)	53 (42.4)
College or university or higher	72 (57.6)	68 (54.4)
Marital status, n (%)		
Married or with partner	88 (70.4)	95 (76.0)
Single	32 (25.6)	29 (23.2)
Widowed, divorced, or separated	5 (4.0)	1 (0.8)
Monthly income, n (%)		
<4000 USD	37 (29.6)	39 (31.2)
≥4000 USD	88 (70.4)	86 (68.8)
Knowledge of ACP, n (%)		
Yes	110 (88.0)	97 (77.6)
No	15 (12.0)	28 (22.4)

USD = U.S. dollars; ACP = advance care planning.

the ACP were significantly higher (adjusted OR 1.62; 95% CI 1.18–2.39; P=0.019). In addition, people who were married or living with their partners were significantly intented to document the ACP compared with those who were not married or were with partner (adjusted OR 1.59; 95% CI 1.21–1.96; P=0.009). Age, educational status, household income, and knowledge of ACP were not significantly associated with the intention of ACP documentation.

Opinion of the Video

One hundred thirteen participants (90.4%) in the intervention arm and 118 subjects (94.4%) in the attention-control arm responded that they were very comfortable or comfortable with the use of the educational materials. Most respondents in the intervention arm (93.6%) and the attention-control arm (90.4%) answered that the decision support material was helpful, whereas 105 subjects (84.0%) of the attention-control arm and 100 subjects (80.0%) of the intervention arm responded that they would recommend this educational material to their acquaintances.

Discussion

This study evaluated the efficacy of educational materials that provide ACP information and decision-making support to a sample of the general population. This investigation is a step forward because it confirms the efficacy of such materials, going beyond the limitations of prior research for ACP educational materials that mainly targeted severely ill patients. ^{7,8,29–31}

This study also corroborates previous studies showing that ACP educational intervention is effective

for supporting ACP decision making in nonseverely ill populations, such as primary care clinic patients and veterans. 32,33 Also, although various decision support materials for ACP were developed for healthy populations, including Go Wish Cards, MyDirectives, and Stanford Letter Writing Project, we know of no studies evaluating the effects of ACP educational materials in a general population.³⁴ A previous study involving a small number of patients aged 55 years or older who visited a primary care clinic showed that a video intervention group demonstrated significantly increased ACP knowledge, and more participants completed ADs.³³ In another RCT that included primary care clinic elderly patients,³² the group using a Web sitebased decision support intervention increased its ACP compared with the AD-only group. Sudore et al., 35 who recruited primary care patients, found an online ACP program to be more effective than an easy-to-read AD in educating severely ill patients. These findings with our results suggest the possibility that decision support of ACP can be extended to other populations, particularly healthy populations.

ACP conversations can be difficult when healthy persons, or those with relatively minor illnesses, suddenly find themselves seriously ill and decision making becomes difficult. In addition, ACP discussions after a diagnosis are sometimes delayed. 36-38 Patients and their families, however, can learn about treatment goal options and make decisions while they are still healthy so that their values will be respected under more difficult circumstances. Our approach to using video decision support tools should aid conversations about ACP considerably. Through visual imagery, video-assisted intervention promotes an enhanced understanding of potential loss of health and significantly affects the intention to document ACP by providing applicable information, even if not for a specific disease. An additional finding of our study was the association of gender and marital status with the intention to document ACP. In our study, men and unmarried people had a significantly lower intention to document ACP. Thus, there is a need to consider providing additional information about the ACP for those groups.

Discussing ACP in the general population can be burdensome, but in the long run, ACP and chosen EOL care reduces stress, anxiety, and depression in patients' families and relatives.³⁹ Similar to previous findings that ACP conversations did not increase symptoms of depression and/or anxiety,^{40,41} we did not find any increase in anxiety in the video-assisted intervention group compared with the attention-control group.

In a previous study, young adults recognized ACP as a rewarding health behavior, but they found discussion difficult because of their lack of information.⁴²

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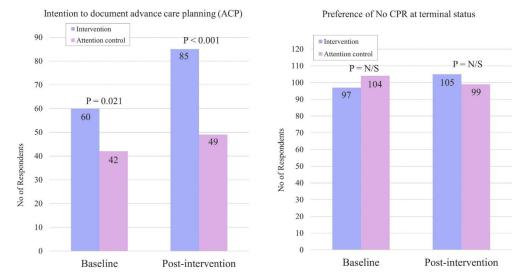


Fig. 2. Intention to document ACP and refuse to CPR at baseline and postintervention. ACP = advance care planning; CPR = cardiopulmonary resuscitation.

Furthermore, although awareness of ACP is low, the general population is reportedly willing to discuss it. ⁴³ Decision support tools, such as the video used in this study, have made a positive change in the understanding and documentation of ACP in the general population, and that could lead to greater and more practical discussions. Increasing changes in the understanding and documentation of ACP, the video will be released and freely available to the general public via media outlets such as Internet (Web pages) and YouTube after publication of this study.

Our research has several limitations. First, the study included only Koreans, which limits generalizability across people from other cultures. Similar studies need to be conducted in other cultures. Second, our research assistants were not blinded during the random group assignments, and this study was

conducted via research assistant home visits to healthy individuals. However, the same preintervention and postintervention questionnaires were used, all answers to the questionnaires were self-reported, and the research assistants did not help the participants with the postintervention survey. For data analysis, we stratified the participants by sex, age, and region of the country to obtain various subsample information. Third, the primary outcome in our study was the postintervention difference in intention to document ACP between the video group and the brochure group, but the intervention group's intention to document ACP was significantly higher at baseline. We believe this limitation was compensated for by the finding that the difference between the groups preintervention and postintervention was significantly higher in the intervention group. Finally, we measured the effect

 ${\it Table~2}$ Changes in Knowledge of CPR and Palliative Care, and in Anxiety and Depression

	Intervention Group $(n = 125)$		Attention-Control Group $(n = 125)$			
	Mean (SD)	Change	Mean (SD)	Change	Group Difference (95% CI)	P^a
CPR knowledge score						
Baseline	3.58 (0.67)	0.06	3.26 (0.95)	-0.02	$0.08 \ (-0.09 \ \text{to} \ 0.25)$	N/S
Postintervention	3.64 (0.71)		3.24 (1.03)			
Palliative care knowledge	e score					
Baseline	1.27(0.74)	0.12	1.21 (0.63)	-0.06	0.18 (0.02-0.35)	0.036
Postintervention	1.39(0.72)		1.15 (0.64)			
$HADS^b$						
Anxiety						
Baseline	4.45(2.94)	-0.10	4.42 (3.10)	0.08	$0.18 \ (-0.20 \ \text{to} \ 0.55)$	N/S
Postintervention	4.35 (2.91)		4.50 (3.04)			
Depression						
Baseline	5.66 (3.20)	0.07	5.88 (3.17)	0.09	$0.02 \ (-0.35 \ \text{to} \ 0.39)$	N/S
Postintervention	5.73 (3.35)		5.97 (3.29)			

CPR = cardiopulmonary resuscitation; N/S = not significant; HADS = Hospital Anxiety and Depression Scale.

all reported P-values are two-sided, with P < 0.05 considered statistically significant.

 $^{^{}b}$ HADS anxiety and depression scores are based separately on a scale of 0-21, with lower scores indicating better condition.

Table 3

Predictors of the Intention to Document ACP in Baseline

	Participants With the Intention to Document ACP n (%)			Adjusted P^{b}
Characteristics			Adjusted OR ^a (95% CI)	
Age, yrs				
Younger than 50	58	40.3	1 (Reference)	N/S
50 and older	44	41.5	0.99 (0.52-1.89)	
Sex				
Male	43	34.7	1 (Reference)	0.019
Female	59	46.8	1.62 (1.18-2.39)	
Educational status				
High school graduate and less	47	42.7	1 (Reference)	N/S
College or university or higher	55	39.3	$0.90 \ (0.47 - 1.72)$	
Marital status				
Married or with partner	81	44.3	1 (Reference)	0.009
Not married or with partner	21	31.3	1.59 (1.21-1.96)	
Monthly income				
<4000 USD	30	39.5	1 (Reference)	N/S
≥4000 USD	72	41.4	1.15 (0.64-2.07)	
Knowledge of ACP				
Yes	53	40.5	1 (Reference)	N/S
No	49	41.2	1.07 (0.63-1.81)	

ACP = advance care planning; OR = odds ratio; N/S = not significant; USD = U.S. dollars.

only immediately after the intervention. Considering the time difference between the documentation of an AD and the recognition and discussion of ACP, more research might be needed to evaluate the long-term effects of the ACP decision support intervention in general populations.

An ACP video decision aid based on International Patient Decision Aid Standards and self-management strategies could enhance the intention to document ACP and awareness of palliative care in the general population. On the basis of this evidence, video intervention could be used as a tool to improve the perception of ACP in the general population who were healthy and with less opportunity to discuss ACPs with physicians. Because video intervention can be operated without special education sites or educators, it could be used as a tool to improve the ACP awareness of the general public using tools such as those found online. Video, however, is not an effective method of education for all populations, so future studies may require the development of more diverse forms of educational material. Also, long-term followup studies are needed to evaluate whether these ACP decision support materials actually increase ACP documentation.

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Data management and sharing: Data available only if requested to author.

The authors declare no conflicts of interest.

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[&]quot;For the multivariable analysis, all characteristics (age, sex, education, marital status, monthly income, and knowledge of ACP) were included.

^bAll reported *P*-values are two-sided, with P < 0.05 considered as statistically significant.

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